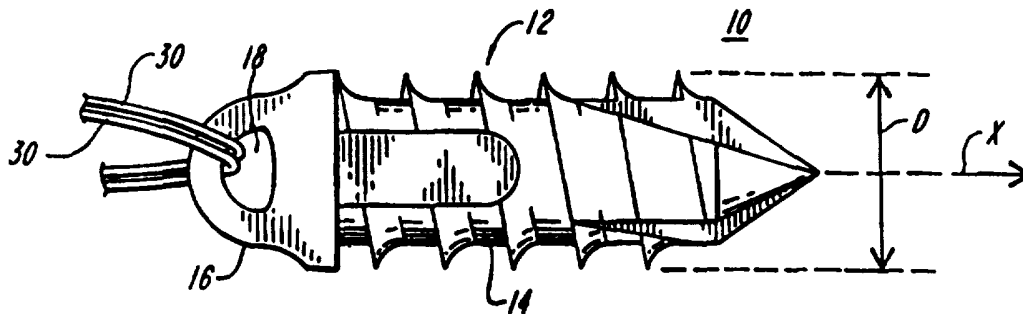




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/00	A1	(11) International Publication Number: WO 96/17551 (43) International Publication Date: 13 June 1996 (13.06.96)
<p>(21) International Application Number: PCT/US94/13897</p> <p>(22) International Filing Date: 5 December 1994 (05.12.94)</p> <p>(71)(72) Applicant and Inventor: STONE, Kevin, R. [US/US]; 3727 Buchanan Street, San Francisco, CA 94123 (US).</p> <p>(72) Inventor: DESATNICK, Allen, H.; 17 McKinley Road, Marblehead, MA 01945 (US).</p> <p>(74) Agents: LEVY, Elizabeth, A. et al.; Lappin & Kusmer, Two Hundred State Street, Boston, MA 02109 (US).</p>	<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report.</i></p>	

(54) Title: SUTURE ANCHOR ASSEMBLY



(57) Abstract

Suture anchor assembly for attaching soft tissue to bone. The assembly (10) includes an elongated member (12) having a self-tapping threaded anchor portion (14) at one proximal end, and an integral eyelet (18) for receiving a suture (30) at its distal end. The distal end further includes a receiver for a rotating driver device (20), such as a cannulated drill. The assembly (10) is designed for endoscopic insertion of the anchor (14), with the suture (30) extending along the central axis (X₁) of the driver (20).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

SUTURE ANCHOR ASSEMBLY

Background of the Invention

5

The present invention generally relates to suture anchors. Specifically, the invention relates to suture anchors used in securing soft tissue to bone.

10

Soft tissues, such as tendons and ligaments generally insert into bone through small collagenous fibers called sharpey's fibers. These connections are strong and permit the muscle which pull on the tendons to effect force on the bones, or the ligaments which stabilize the body's joints, the resist force. When a tissue is torn away from the bone and requires repair, the surgeon is often required to fashion tunnels into the bone through which to pass sutures, which are then threaded through the soft tissues. The bone tunnels are often difficult to make, and generally require large open incisions. Recently, through the advent of endoscopic surgery, where the surgeon looks into a joint cavity with a telescope, there has been a desire to repair soft tissues back to bone without performing a large open incision. The device described herein facilitates that procedure.

15

20

A variety of devices are available for attaching objects to bone, such as screws, staples, cement, and sutures alone. These devices have been used to attach soft tissue, such as ligaments, tendons, muscles, as well as objects such as prostheses, to bone. Screws tend to loosen with time, usually requires a second operation to remove the loosened screw. In addition, conventional screws tend to be time-consuming and difficult to install, especially in a tight space such as that encountered during endoscopic surgery.

25

Installation of presently available bone screws involves several

steps. First, a pilot hole must normally be drilled into the bone. Then, depending on the bone structure, the bone may also have to be tapped to accept to the screw. The screw is next positioned and turned to fasten. Finally, if the suture is not preattached, the suture is threaded into an eyelet
5 contained in the screw. This multi-step process, necessitated by the structure of available bone screw devices, is difficult for the surgeon, especially in confined surgical areas. Often, such accessibility considerations limit the ability of the surgeon to secure sutures at optimal locations, forcing the surgeon to select a less-than-desirable location.
10 Furthermore, the final position of the screw is determined once the hole has been drilled, making it difficult to relocate or position the screw in a different position.

U.S. Patent No. 4,632,100 discloses a cylindrical suture anchor which includes a drill at a first end (for boring a hole in a bone) and a
15 flight of threads on the other end, and distal from the drill, for securing the anchor in a hole established by the drill. Sutures are held in the interior of the anchor by means of an annular disc that is press fit into the interior of the anchor. This two piece assembly is difficult to assemble and, due to the suture-holding disc, is substantially limited in the number of sutures
20 that can be held. Moreover, the discrete drill and thread flights are inefficient in their operation.

Staples are disadvantageous for some of the same reasons as standard screws, plus there are additional set-backs for using staples for attachment. Staples have been known to crack the bone during
25 deployment, or to accidentally transect the object being attached to the bone.

Other devices that currently exist for attaching soft tissue to bone include metal screws with sutures attached, shaped metal anchors through which sutures can be threaded, and plastic tacks with sutures attached.

Each of these devices includes a single suture affixed to the device prior to implantation. These devices are difficult to deploy endoscopically and are limited to single sutures even though multiple sutures are often required for soft tissue repair.

5 Accordingly, it is an object of the invention to provide a device that is designed for endoscopic use and that accommodates multiple suture fixation.

Summary of the Invention

10

The present invention generally relates to suture anchor assemblies of the type used for securing soft tissue to bone. The inventive assembly includes an elongated, generally cylindrical member having an anchor portion at a first end and a suture/driver portion at a second end. An eyelet is positioned at the second end for receiving and securing a suture. The second end also includes a coupler for coupling a cannulated driver to the anchor to enable insertion of the anchor into bone.

15

20

The cylindrical member of the anchor assembly generally extends along a central axis X, and has a maximum outer diameter D. The anchor portion forms a point at its distal tip, and has a self-tapping thread pattern on its outer surface.

25

The eyelet is positioned near the second end such that a suture path is defined from the region adjacent to the second end, through the eyelet and back to the region adjacent to the second end. The endpoints of the suture path are less than $D'/2$ from the central axis. In a preferred form of the invention, D' is less than the maximum outer diameter of the cylindrical member D.

The coupler that forms part of the suture/driver end of the cylindrical member is adapted to mechanically couple a distal tip of a

cannulated driver. The driver may have an inner diameter greater than or equal to diameter D^1 and an outer diameter less than or equal to diameter D . The driver is rotatable about a drive axis and thus rotates the cylindrical member about that drive axis when the distal tip of the driver is
5 mechanically coupled with the coupler.

In one embodiment, the coupler includes at least first and second planar flanges located at opposite sides of the central axis, and extending radially outward from the central axis in opposite directions. The coupler
10 may further include third and fourth planar flanges, also on opposite sides of and extending radially outward from the central axis. The flanges function as stop-points, or form a shoulder, to prevent the cylindrical member from being inserted beyond a predetermined point into the bone.

The coupler may also include one or more pair of grooves in the
15 side of the cylindrical member and extending from the second end to the first end. The grooves extend along groove axes essentially parallel to the central axis. Each groove of each pair of grooves are located on opposite sides of the cylindrical member, and the respective opposing groove axes are essentially coplanar with the central axis.

20

Brief Description of the Figures

The invention is further described by the following description, and
Figures in which:

25

FIGURE 1 shows a side plan view of one embodiment of the suture anchor assembly of the present invention;

FIGURE 2 shows an alternate side plan view of the embodiment of

FIGURE 1 rotated 90° from FIGURE 1;

FIGURE 3 shows a longitudinal cross-section view of a driver assembly engaging the suture anchor assembly of FIGURE 1;

5

FIGURE 4 shows a perspective view of another embodiment of the inventive suture anchor assembly, including the distal portion of a driver assembly,

10

FIGURE 5 shows a perspective view of another embodiment of the inventive suture anchor assembly, including the distal portion of a driver assembly;

15

FIGURE 6 shows a perspective view of another embodiment of the inventive suture anchor assembly, including the distal portion of a driver assembly;

20

FIGURE 6A shows an end view of the suture anchor assembly of FIGURE 6;

FIGURE 7 shows a perspective view of another embodiment of the suture anchor assembly of the present invention, including the distal portion of a driver assembly;

25

FIGURE 7A shows an end view of the suture anchor assembly of FIGURE 7;

FIGURE 8A shows a side plan view of another embodiment at the inventive suture anchor assembly;

FIGURE 8B shows an end view of the suture anchor assembly of
FIGURE 8A from the drive end;

5 FIGURE 8C shows a longitudinal cross-section of the suture anchor
assembly of FIGURE 8A;

FIGURE 8D shows an end view of the suture anchor assembly of
FIGURE 8A from the anchor end;

10 FIGURE 8E shows a cross-section of the anchor of FIGURE 8A
together with a drive assembly;

FIGURE 8F shows an exploded perspective view of the driver of
FIGURE 8E;

15

FIGURE 9A shows a side plan view of another embodiment of the
inventive suture anchor assembly;

20 FIGURE 9B shows a cross-section of the suture anchor assembly of
FIGURE 9A;

FIGURE 9C shows a perspective view of a driver for use with the
anchor of FIGURES 9A and 9B;

25

FIGURE 9D shows a sectional view of the driver of FIGURE 9C;

FIGURE 10A shows a side plan view of another embodiment of the
inventive suture anchor assembly;

FIGURE 10B shows a cross-section of the suture anchor assembly of FIGURE 10A;

5 Like elements in the respective FIGURES have similar reference numbers.

Description of the Preferred Embodiment

10 The suture anchor assembly of the present invention primarily is for use during endoscopic surgery. The anchors are intended for permanent implantation into a patient, however it is possible to remove the anchors if necessary. The use of suture anchors that fix soft tissue to bone is frequent in orthopedic surgery, though such anchors may be used in other fields as
15 appropriate.

 Generally, and as illustrated in Figures 1 and 2, the inventive suture anchor assembly 10 includes an elongated cylindrical member 12. The cylindrical member 12 includes a threaded anchor portion 14 at one end and a suture/drive portion 16 at the opposite end. The suture/drive portion
20 16 is adapted for insertion into the distal end of a driver 20, such as a standard operating room cannulated drill. The inventive assembly 10 is thus adapted for installation into a patient by endoscopic means, or any other appropriate surgical procedure. The inventive assembly 10 may include several different embodiments illustrated and described herein.

25 Preferably, the cylindrical member 12 is manufactured from stainless steel, titanium, or some other durable, non-degradable, biocompatible material. Alternatively, the cylindrical member 12 may be manufactured from a non-biocompatible material, but coated with a biocompatible substance prior to insertion in the patient. The assembly 10

may be manufactured as a single piece, using standard metal-shaping techniques. Alternatively, the top portion 16 may be manufactured separately from the bottom anchor portion 14 and attached by conventional methods and materials. In such an embodiment, the two separate portions
5 may be manufactured using the same or different materials.

In one form, the anchor portion 14 may be metal, forming a permanent element, while the suture/driver portion 16 may be made of a bioresorbable material (which will be resorbed after residing in a patient). The latter form is particularly useful where it is the eventual goal to have
10 no protuberance beyond the bone surface.

The threaded anchor portion 14 of the cylindrical member 12 covers a portion of the surface of that member 12. The actual amount of threaded anchor portion 14 may depend upon several variables, such as the type of tissue, the type of anticipated surgical procedure in which the assembly will
15 be used, manufacturing limitations, materials limitations, and other variables readily determinable by one skilled in the relevant art.

The top suture/driver portion 16 at the distal end of the assembly 10 is designed both to hold a suture material and to fit the head of a driver device. In the illustrated embodiment of Figure 1, the top portion 16
20 includes an eyelet 18 of sufficient size to receive one or more sutures 30. Since sutures are made of different materials and, consequently, are available in a variety of different diameters, the actual size of the eyelet 18 may be of a standard size to accept any suture material or may come in a range of sizes specific to different suture types.

In alternative embodiments, and as exemplified in Figure 5, the top
25 portion 16 may include a plurality of aligned eyelets 18 to enable one or more sutures to pass through two or more such eyelets 18. Alternatively, multiple sutures may pass through any one of the eyelets. The suture 30 is preferably prethreaded in the suture anchor 10, but may be threaded once

the anchor assembly 10 is positioned. Generally, the suture 30 passes through a suture path P through eyelet 18. The outermost boundary of suture path P is less than distance $D'/2$ from the central (X) axis of anchor 10, i.e. within the cylindrical regional diameter (D, where $D' \leq D$) defined by the greatest diameter of the cylindrical member 12. This restriction on the diameter of path P is necessitated by the requirement that the top portion 16 (and suture 30) fit into a distal tip 22 of a cannulated driver assembly 20, as shown in Figure 3.

Figure 3 illustrates the driver assembly 20 interfitted with the anchor assembly 10 of Figures 1 and 2. As shown, the driver assembly 20 includes a distal tip element 22 that extends from a cannulated member 23. The distal tip element 22 interfits with suture/drive portion 16. The outer diameter D_3 of the distal tip 22 preferably is less than or equal to outer diameter D of the cylindrical member. This reduces the amount of trauma to surrounding tissue during insertion of the assembly 10.

As shown in the Figures, the anchor portion 14 of the cylindrical member 12 is preferably self-tapping. The tip of the anchor portion 14 may taper to a point, or may be blunt-ended depending upon the specific environment in which the suture anchor assembly 10 will be used. Other tapered configurations may be used. In a preferred embodiment, and as illustrated, the tip is pointed to facilitate inserting the anchor assembly 10 at an optimal location selected by the user.

The outermost diameter D, as measured at the widest portion of the cylindrical member 12, may vary depending upon such variables as the specific environment for which the assembly 10 will be used, the materials from which the assembly 10 is manufactured, and other variables readily determined by one skilled in the relevant art. In a preferred form of the invention, the cylindrical member 12 of a typical assembly may have D approximately equal to 0.2 inches.

The top portion of the cylindrical member adjacent to the top portion may include a shoulder 17 that extends beyond the diameter D of the cylindrical member 12, as shown in Figure 1. Thus, the shoulder 17 may consist of a set of discrete shoulder flanges, or may be a continuous portion of the top of the cylindrical member that extends beyond diameter D. The shoulder 17, whether in the form of discrete flanges or a continuous extension portion, functions to stop insertion of the anchor assembly 10 into the bone beyond the shoulder 17. Thus, the shoulder 17 prevents a user from inserting the assembly 10 so far into the bone that the suture/driver portion 16 becomes lodged in the bone.

In a preferred form of practicing the present invention, the suture/drive portion 16 is adapted to fit into the chuck of a standard operating room cannulated drill generally commercially available. In other forms of practicing the invention, a driver assembly 20 may be used having a distal tip element 22 adapted to interfit with the suture/drive portion 16 of the inventive assembly. In a preferred form of the invention, and as best shown below in conjunction with Figure 4, the inner diameter D_2 of the driver tip 22 is greater than or equal to the diameter D_1 of suture/drive portion 16.

The distal tip 22 is cannulated to allow the suture/drive portion 16, with sutures in place in the suture path, to extend into the distal tip element 22. In one embodiment, the drive assembly 20 is cannulated, however it may only be necessary for the tip 22 to be cannulated an amount sufficient to receive the suture/drive portion 16, with sutures.

In a preferred form of practicing the present invention, the driver assembly 20 is rotatable about an axis X_1 , which axis X_1 is coaxial with a central axis X_2 along which the cylindrical member 12 extends. Thus, when the anchor assembly 10 is engaged with the drive assembly 20, the drive assembly 20 rotates the anchor assembly 10 in such a manner as to

screw the anchor 10 into the target bone.

In the illustrated embodiment of Figure 4, the suture/drive portion 16 consists of a pair of planar flanges 24, 24' extending radially outward from and on either side of the central axis X_2 . A suture eyelet 18 extends through the flanges 24, 24'. The distal tip element 22 of driver 20 has an inner geometry that is complementary to the outer geometry of flanges 24, 24', so that the distal tip element can engage the flanges for rotational driving.

In an alternative embodiment shown in Figure 5, the suture/drive portion 16 includes four planar flanges, 24a, 24b, 24c, and 24d, each flange positioned about 90° from the other about the central axis. The generally "+"-shaped cross-section formed by the planar flanges then inserts into a complementary pattern in the driver distal tip element 22.

In yet another embodiment, shown at Figure 6, the cylindrical member 12 includes a pair of grooves 26, 26' extending from the suture/drive portion end of the member 12. The grooves 26 may extend either the entire length of the cylindrical member 12, or, as shown in Figure 6, may extend only a portion of the way down the member 12. The exact length and depth of each groove depends on such variables and considerations as manufacturing constraints, the type of driver used, and other variables readily discernible by one skilled in the relevant art. For this form of the invention, the distal tip element 22 of driver 20 includes a pair of ridges 27, 27' that are complementary to grooves 26, 26', so that the driver 20 can engage the end of member 12.

As shown in the top plan view of this embodiment of the assembly 10 in Figure 6A, a structure 28 may be provided solely for the suture eyelet 18. As illustrated, the eyelet structure 28 has a length L less than or equal to the diameter D of the cylindrical member. The structure 28 is positioned at the end of the cylindrical member 12 opposite the anchor

portion 14. The structure may be integral to the cylindrical member 12 or may be mechanically or otherwise attached to the cylindrical member 12.

In another alternative embodiment, and as illustrated in Figure 7, the inventive assembly 10 may include a plurality of grooves 26a, 26b, 26c, and 26d positioned in predetermined locations about the surface of the cylindrical member 12. These grooves 26a, 26b, 26c, and 26d, are structurally similar to the grooves 26 and 26' described in relation to Figure 6. As further illustrated in Figure 7A, this illustrated embodiment includes a suture structure 28 having characteristics to the similar structure 28 described above in conjunction with Figures 6 and 6A. The distal tip element 22 of driver 20 for the anchor of Figures 7 and 7A includes four internal ridges 27a, 27b, 27c, and 27d.

Yet another embodiment of the anchor 10 is shown in Figures 8A, 8B, 8C and 8D. That anchor is generally similar to that of Figure 5, except that the member 12 includes a square cross-section central bore 40 extending along its central axis X_2 , having dimensions $d/\sqrt{2} \times d/\sqrt{2}$. In this element, a flanges 50, 52, 54 and 56 each include a respective one of suture eyelets 50a, 52a, 54a and 56a, and determine suture paths positioned such that all points are separated from the central axis X_2 by a distance greater than $d/2$.

The anchors of FIGURES 8A-8D are particularly adapted for driving with a square cross-section driver positioned in the central bore 40. FIGURES 8E and 8F show a cannulated driver 20 having a tip 22 which supports a drive element 60 extending from an aperture 64 in tip 22. The drive element 60 includes a square cross-section portion 70 (for driving anchor 10) and a cylindrical lead portion 72 (for guiding the lead tip of anchor 10 into a pilot hole in the target bore). In this configuration, the tip 22 also includes apertures 76 and 78 to define a suture path between the eyelets of anchor 10 and the interior of cannulated driver 20.

FIGURES 9A and 9B and FIGURES 10A and 10B show additional embodiments of the invention. The anchors of these figures include shoulders 17, which serve to limit the insertion depth of the anchors. Also these embodiments include different exemplary suture eyelet configuration
5 compared with the configurations of the other figures.

The embodiment of FIGURES 9A and 9B is particularly adapted for use with the driver 80 shown in FIGURES 9C and 9D. That driver 80 includes an elongated tubular member extending along a driver axis 82 between a proximal end 80a and a distal (or driving) end 80b. A pair of
10 resilient, elongated finger members 84 and 86 extend from the distal end along respective finger axes 84a and 86a, respectively; axes 84a and 86a are substantially coplanar with axis 82. The finger members 84, 86 are shaped so that the anchor 10 of FIGURES 9A and 9B may be supported by the finger members 84, 86, with those finger members fitting within the
15 elongate grooves 26 and 26' in the outside of member 14. The separation of fingers is such that upon placement an anchor 10 between finger members 84, 86 in alignment with grooves 26, 26', the separation between finger members is slightly increased, and the resilient fingers effect a bias force, holding the anchor 10 in place. Thus, the fingers 84, 86 act as
20 spring-biased flexures to support an anchor. Preferably the driver 80 has a pair of slots 90, 92 in its distal top, as shown, which are adapted to receive element 16 upon full insertion of finger members 84, 86 into grooves 26, 26'. With this configuration, a controlled, substantial driving torque may be applied to the drive end of the anchor 10 for insertion.

25 One aspect of the present invention, and as shown in the figures, is that the anchor portion 14 may include a self-tapping threaded portion. The self-tapping aspect of the threaded anchor portion facilitates insertion of the anchor assembly 10 into a patient's bone or other anchor base at a location desired by the practitioner. Unlike prior art devices that require

the creation of an initial insertion hole before introduction of a screw-type anchor, the self-tapping aspect of the threaded portion of the inventive suture anchor assembly allows the user to select the optimal location for insertion of the assembly 10.

5 The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments and examples are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by
10 the appended claims rather than by the foregoing description, and all changes that come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

Claims

1. A surgical suture anchor assembly, comprising:

5 an elongated, generally cylindrical member extending along a central axis and having a maximum outer diameter, said member including an anchor portion at a first end thereof rigidly coupled to a suture/drive portion at a second end thereof, said second end being opposite said first end,

10

wherein said anchor portion has a self tapping thread pattern on the outer surface of said anchor portion, said pattern extending from said first end, and

15

wherein said suture/drive portion includes:

20

A. at least one eyelet positioned at or near said second end, said eyelet having a central aperture, whereby a suture path extending between two end points is defined by a region adjacent to said second end, through said aperture of said eyelet and back to said region adjacent to said second end, wherein the end points of said suture path are less than a distance equal to $D'/2$ from said central axis, where D' is less than or equal to said maximum outer diameter; and

25

B. coupling means for receiving a distal tip of a cannulated driver rotatable about a drive axis, whereby said cylindrical member and said distal tip

are mechanically coupled for mutual rotation with said drive axis and said central axis being coaxial when said distal tip of said driver is received by said coupling means.

5

2. A suture anchor assembly according to claim 1 further including a cannulated driver wherein said distal tip of said driver has an inner diameter greater than or equal to D' .

10

3. A suture anchor assembly according to claim 1 wherein said distal tip of said driver has an outer diameter less than or equal to D .

15

4. A suture anchor assembly according to claim 1 wherein said coupling means comprises at least first and second planar flanges at said second end, said first and second flanges being on opposite sides of said central axis and extending radially outward from said central axis in opposite directions.

20

5. A suture anchor assembly according to claim 4 wherein said coupling means further comprises third and fourth planar flanges at said second end, said third and fourth flanges being on opposite sides of said central axis and extending radially outward from said central axis in opposite directions and angularly offset from said first and second flanges.

25

- 5 6. A suture anchor assembly according to claim 1 wherein said coupling means comprises a first pair of grooves in a side of said member extending from said second end along groove axes parallel to said central axis, wherein the groove axes of said first pair are on opposite sides of said central axis and are coplanar therewith.
- 10 7. A suture anchor assembly according to claim 6 where said coupling means further comprises a second pair of grooves in a side of said member extending from said second end along groove axes parallel to said central axis, wherein the groove axes of said second pair are on opposite sides of said central axis and are coplanar therewith, wherein the plane of said grooves of said second pair are angularly offset from the plane of said grooves of said first pair.
- 15 8. A suture anchor assembly according to claim 1 further comprising a central bore extending along said central axis from said first end to said second end and having a cross-section with a greatest dimension d , wherein all points of said suture path are separated from said central axis by a distance greater than equal to a distance $d/2$, and said central bore diameter being less than D .
- 20
- 25

9. A suture anchor assembly according to claim 1 further comprising a plurality of sutures extending along said suture path.
- 5
10. A driver assembly for releasably supporting a suture anchor assembly wherein said driver assembly comprises:
- 10
- A. an elongated tubular member extending along a driver axis and having a proximal end and a distal end.
- 15
- B. a pair of resilient, elongated finger members extending from opposite sides of the end of said distal end of said tubular member and along respective finger axes parallel to said driver axis, said finger axes and said driver axes being substantially coplanar, wherein said finger members are separated by a first distance S1 at said distal end of said tubular member and by lesser distances at other locations along said driver axis.
- 20
11. A driver assembly according to claim 10 wherein said tubular member includes two slots extending from opposing points of said distal end thereof, each of said slots being interspersed between said finger members.
- 25

12. A surgical anchor kit, comprising:

I. an elongated, generally cylindrical member extending
along a central axis and having a maximum outer
5 diameter, said member including an anchor portion at
a first end thereof rigidly coupled to a suture/drive
portion at a second end thereof, said second end
being opposite said first end,

10 wherein said anchor portion has a self tapping
thread pattern the outer surface of said anchor
portion, said pattern extending from said first
end, and

15 wherein said suture/drive portion includes:

A. at least one eyelet positioned at
or near said second end, said
eyelet having a central aperture,
20 whereby a suture path extending
between two end points is
defined by a region adjacent to
said second end, through said
aperture of said eyelet and back
to said region adjacent to said
25 second end, wherein the end
points of said suture path are
less than a distance equal to
 $D'/2$ from said central axis,

where D' is less than or equal to said maximum outer diameter; and

5

- B. coupling means for receiving a distal tip of a cannulated driver rotatable about a drive axis, whereby said cylindrical member and said distal tip are mechanically coupled for mutual rotation with said drive axis and said central axis being coaxial when said distal tip of said driver is received by said coupling means, and

10

15

II. a driver assembly for releasably supporting a suture anchor assembly wherein said driver assembly comprises:

20

- A. an elongated tubular member extending along a driver axis and having a proximal end and a distal end.

25

- B. a pair of resilient, elongated finger members extending from opposite sides of the end of said distal end of said tubular member and along respective finger axes parallel to said

driver axis, said finger axes and said driver axes being substantially coplanar, wherein said finger members are separated by a first distance S1 at said distal end of said tubular member and by lesser distances at other locations along said driver axis.

5

13. A kit according to claim 12 wherein said coupling means comprises a first pair of grooves in a side of said member extending from said second end along groove axes parallel to said central axis, wherein the groove axes of said first pair are on opposite sides of said central axis and are coplanar therewith.

10

15

14. A kit according to claim 12 wherein said coupling means further comprises a second pair of grooves in a side of said member extending from said second end along groove axes parallel to said central axis, wherein the groove axes of said second pair are on opposite sides of said central axis and are coplanar therewith, wherein the plane of said grooves of said second pair are angularly offset from the plane of said grooves of said first pair.

20

25

15. A kit according to claim 12 wherein said tubular member includes two slots extending from opposing points of said distal end thereof, each of said slots being interspersed between said finger members.

5

16. A surgical suture anchor assembly, comprising:

10

an elongated, generally cylindrical member extending along a central axis and having a maximum outer diameter, said member including an anchor portion at a first end thereof rigidly coupled to a suture/drive portion at a second end thereof, said second end being opposite said first end,

15

wherein said anchor portion includes drilling and tapping means for establishing a tapped bore in a bone and for anchoring said anchor portion therein, and wherein said suture/drive portion includes:

20

- A. at least one eyelet positioned at or near said second end, said eyelet having a central aperture, whereby a suture path extending between two end points is defined by a region adjacent to said second end, through said aperture of said eyelet and back to said region adjacent to said second end, wherein the end points of said suture path are less than a distance equal to $D'/2$ from said central axis.

25

where D' is less than or equal to said maximum outer diameter; and

- 5 B. coupling means for receiving a distal tip of a cannulated driver rotatable about a drive axis, whereby said cylindrical member and said distal tip are mechanically coupled for mutual rotation with said drive axis and said central axis being coaxial when said distal tip of said driver is received by said coupling means.
- 10
17. A suture anchor assembly according to claim 16 wherein said drilling and tapping means includes a self-drilling bit at a distal tip of said anchor portion and a self-tapping thread pattern on at least a portion of the outer surface of said anchor portion.
- 15
18. A suture anchor assembly according to claim 17 further including a cannulated driver wherein said distal tip of said driver has an inner diameter greater than or equal to D' .
- 20
19. A suture anchor assembly according to claim 17 wherein said distal tip of said driver has an outer diameter less than or equal to D .
- 25

- 5 20. A suture anchor assembly according to claim 17 wherein said coupling means comprises at least first and second planar flanges at said second end, said first and second flanges being on opposite sides of said central axis and extending radially outward from said central axis in opposite directions.
- 10 21. A suture anchor assembly according to claim 20 wherein said coupling means further comprises third and fourth planar flanges at said second end, said third and fourth flanges being on opposite sides of said central axis and extending radially outward from said central axis in opposite directions and angularly offset from said first and second flanges.
- 15 22. A suture anchor assembly according to claim 17 wherein said coupling means comprises a first pair of grooves in a side of said member extending from said second end along groove axes parallel to said central axis, wherein the groove axes of said first pair are on opposite sides of said central axis and are coplanar therewith.
- 20 23. A suture anchor assembly according to claim 22 where said coupling means further comprises a second pair of grooves in a side of said member extending from said second end along groove axes parallel to said central axis, wherein the groove axes of said second pair are on opposite sides of said central axis and are coplanar therewith, wherein the plane of said grooves of said second pair are angularly offset from the plane of said grooves of said first pair.
- 25

24. A suture anchor assembly according to claim 17 further comprising a central bore extending along said central axis from said first end to said second end and having a cross-section with a greatest dimension d , wherein all points of said suture path are separated from said central axis by a distance greater than equal to a distance $d/2$, and said central bore diameter being less than D .
25. A suture anchor assembly according to claim 17 further comprising a plurality of sutures extending along said suture path.
26. A surgical anchor kit, comprising:
- I. an elongated, generally cylindrical member extending along a central axis and having a maximum outer diameter, said member including an anchor portion at a first end thereof rigidly coupled to a suture/drive portion at a second end thereof, said second end being opposite said first end,
- wherein said anchor portion includes drilling and tapping means for establishing a tapped bore in a bone and for anchoring said anchor portion therein, and
- wherein said suture/drive portion includes:

- 5
- 10
- 15
- 20
- 25
- A. at least one eyelet positioned at or near said second end, said eyelet having a central aperture, whereby a suture path extending between two end points is defined by a region adjacent to said second end, through said aperture of said eyelet and back to said region adjacent to said second end, wherein the end points of said suture path are less than a distance equal to $D'/2$ from said central axis, where D' is less than or equal to said maximum outer diameter; and
- B. coupling means for receiving a distal tip of a cannulated driver rotatable about a drive axis, whereby said cylindrical member and said distal tip are mechanically coupled for mutual rotation with said drive axis and said central axis being coaxial when said distal tip of said driver is received by said coupling means, and

- II. a driver assembly for releasably supporting a suture anchor assembly wherein said driver assembly comprises:
- 5 A. an elongated tubular member extending along a driver axis and having a proximal end and a distal end, and
- 10 B. a pair of resilient, elongated finger members extending from opposite sides of the end of said distal end of said tubular member and along respective finger axes parallel to said driver axis, said finger axes and said driver axes being substantially coplanar, wherein said
- 15 finger members are separated by a first distance S1 at said distal end of said tubular member and by lesser distances at other locations along said driver axis.
- 20 27. A kit according to claim 26 wherein said drilling and tapping means includes a self-drilling bit at a distal tip of said anchor portion and a self-tapping thread pattern on at least a portion of the outer surface of said anchor portion.
- 25 28. A kit according to claim 27 wherein said coupling means comprises a first pair of grooves in a side of said member extending from said second end along groove axes parallel to said central axis, wherein the groove axes of said first pair

are on opposite sides of said central axis and are coplanar therewith.

- 5 29. A kit according to claim 27 wherein said coupling means further comprises a second pair of grooves in a side of said member extending from said second end along groove axes parallel to said central axis, wherein the groove axes of said second pair are on opposite sides of said central axis and are coplanar therewith. wherein the plane of said grooves of said
- 10 second pair are angularly offset from the plane of said grooves of said first pair.
30. A kit according to claim 27 wherein said tubular member includes two slots extending from opposing points of said
- 15 distal end thereof, each of said slots being interspersed between said finger members.

1/6

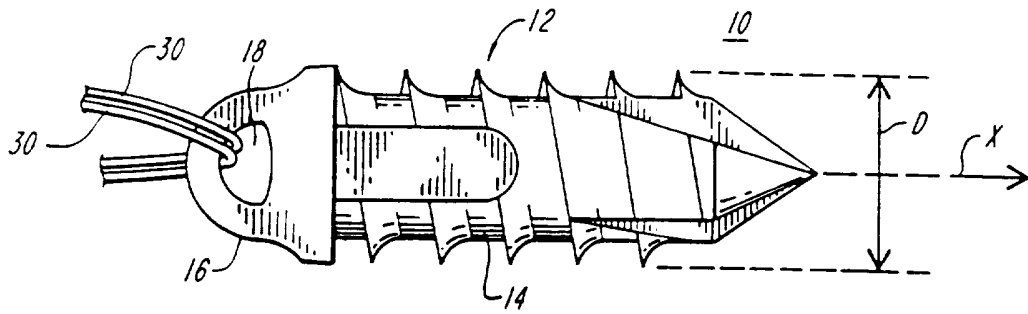


FIG. 1

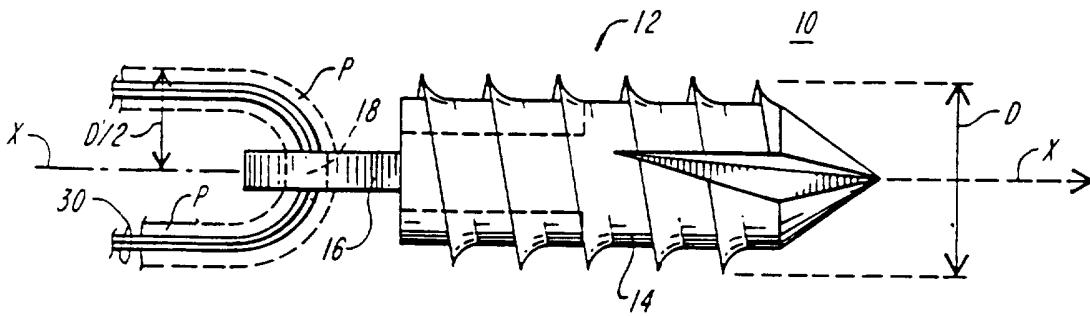


FIG. 2

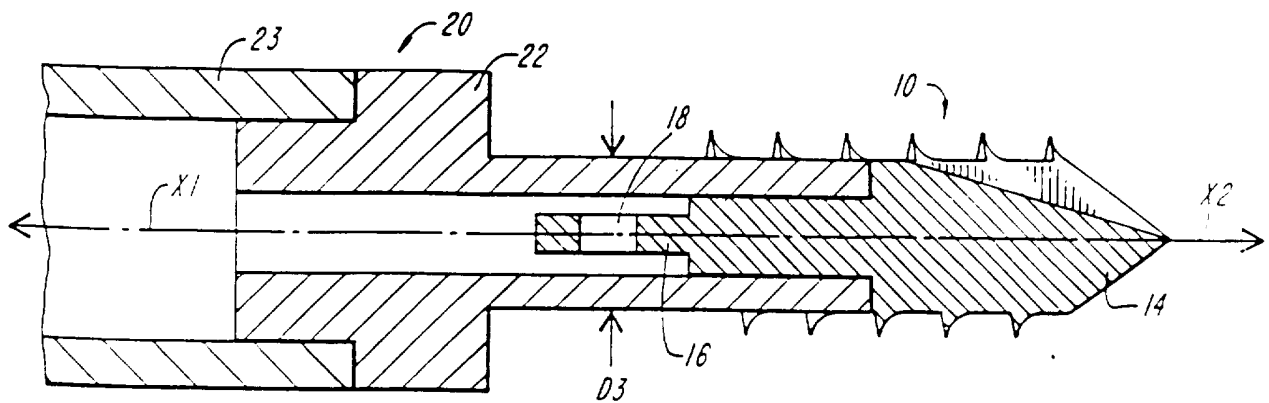


FIG. 3

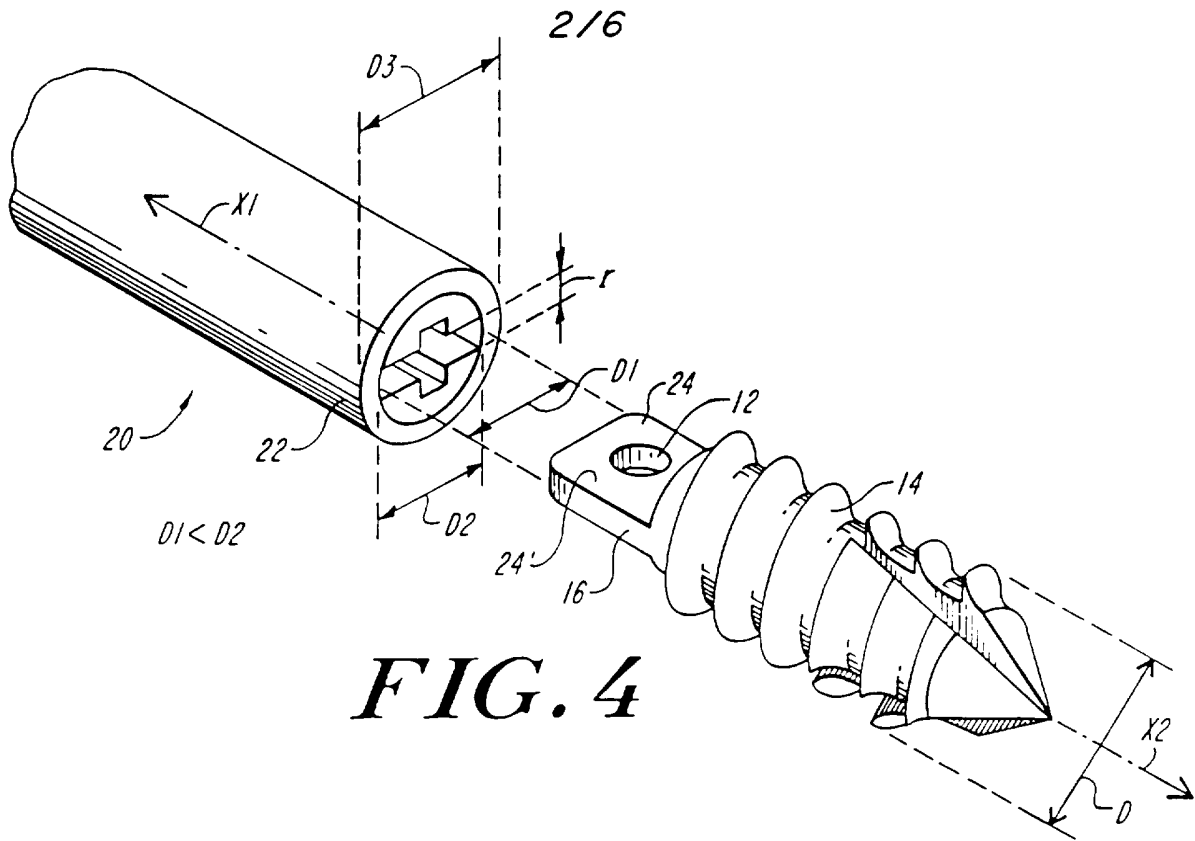


FIG. 4

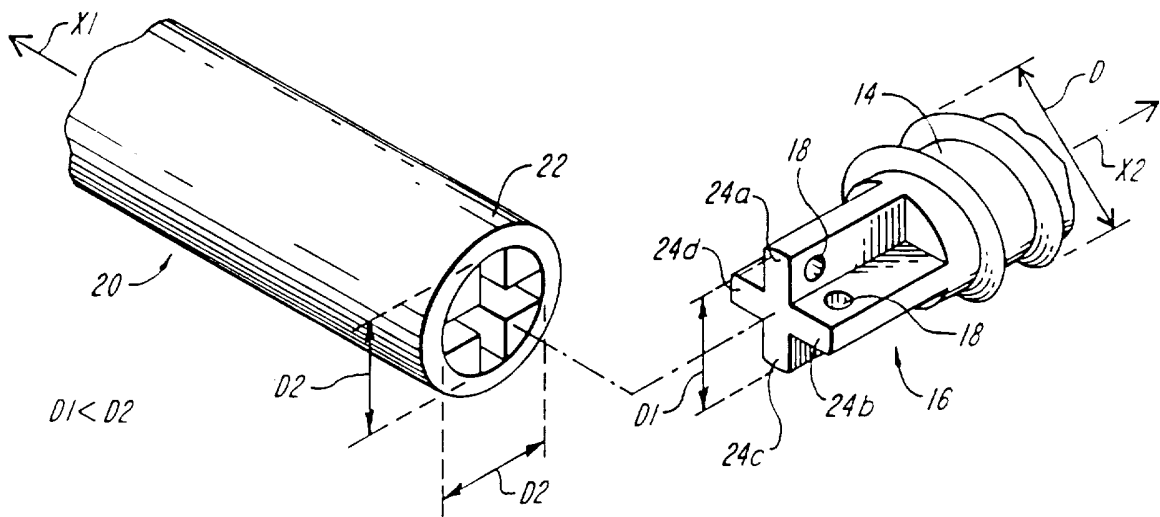


FIG. 5

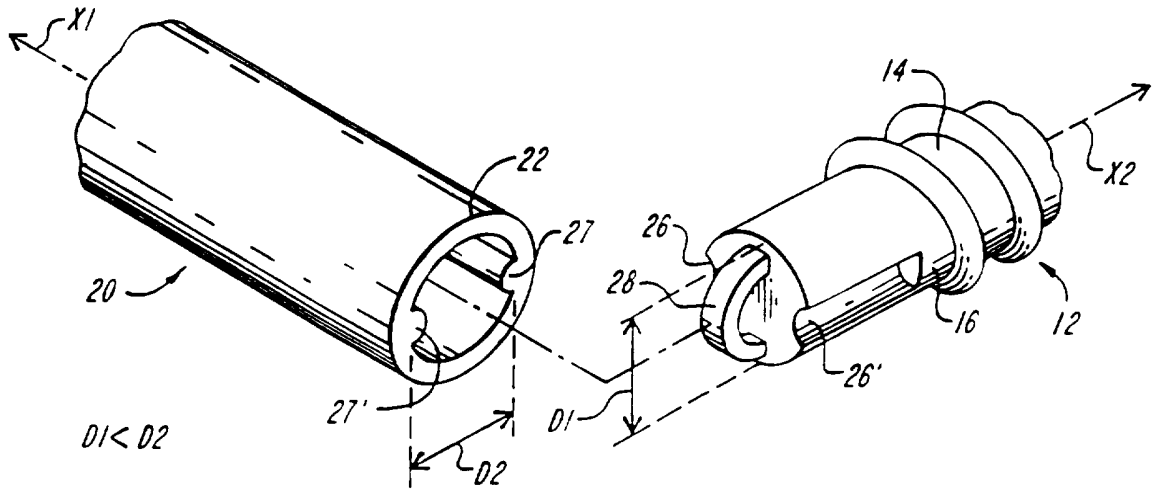


FIG. 6

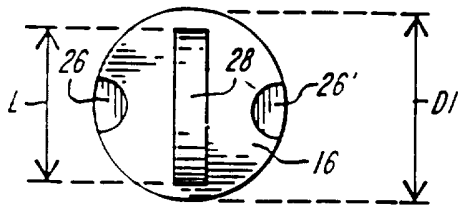


FIG. 6A

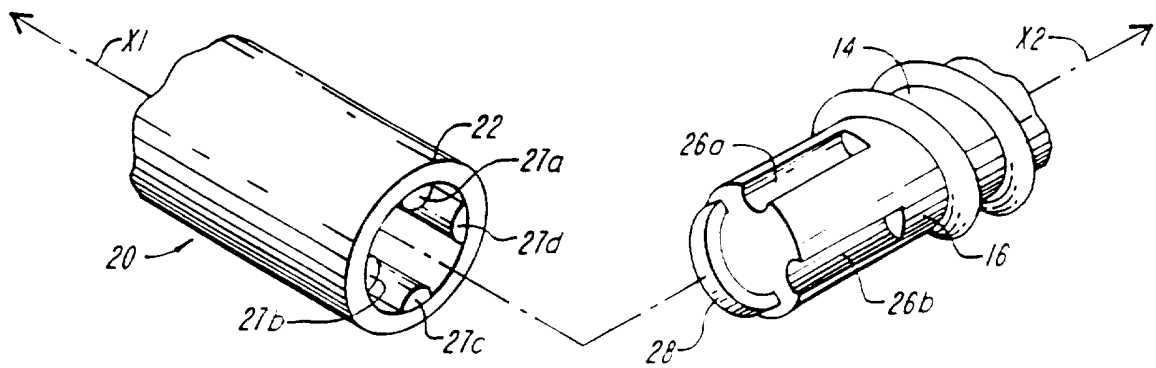


FIG. 7

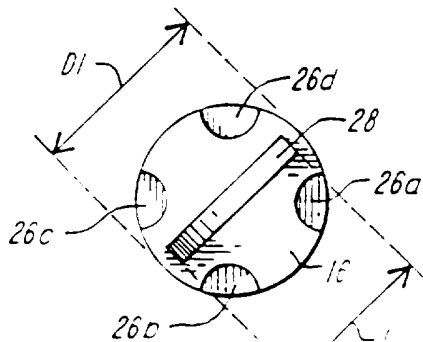


FIG. 7A

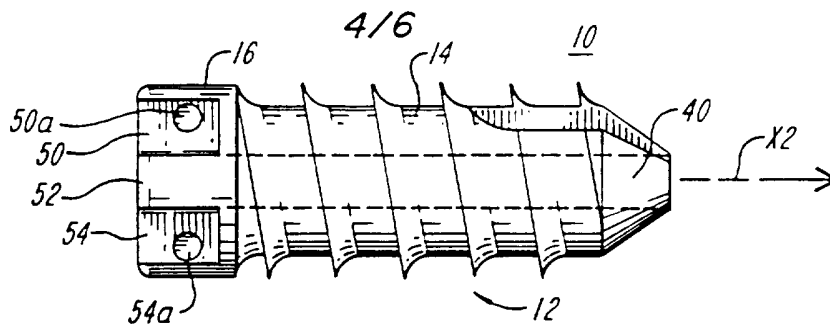


FIG. 8A

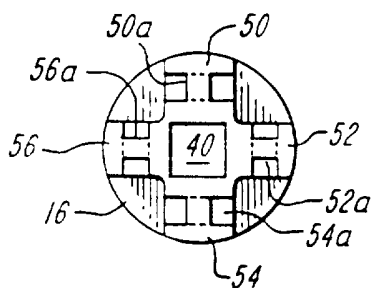


FIG. 8B

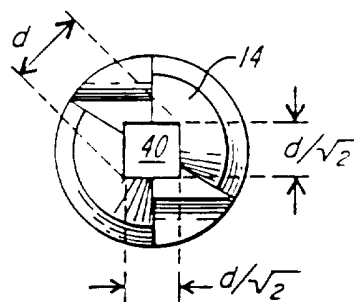


FIG. 8D

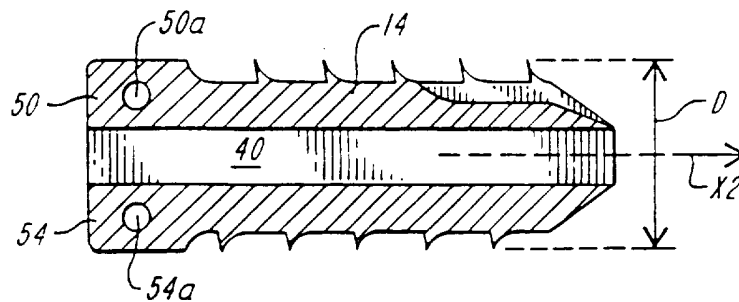


FIG. 8C

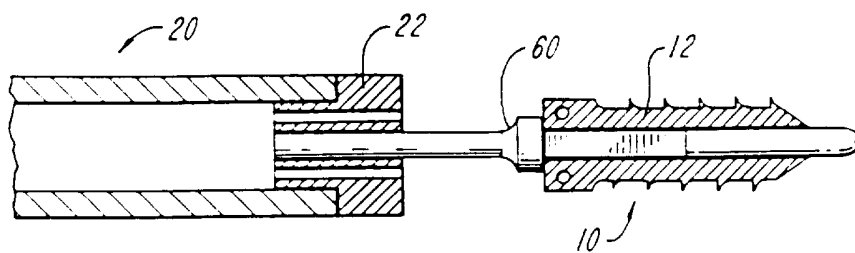


FIG. 8E

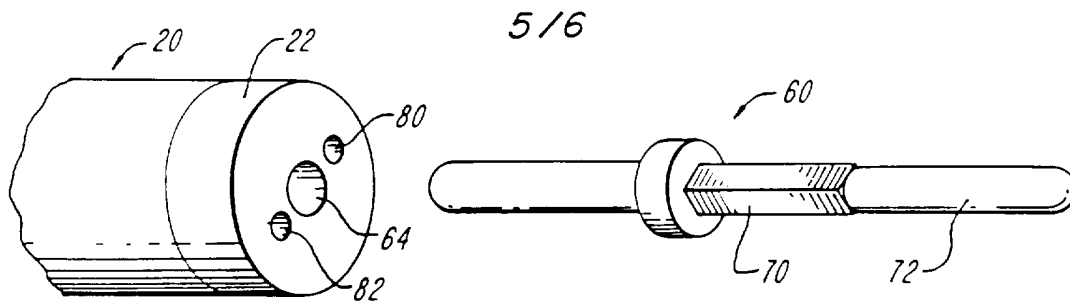


FIG. 8F

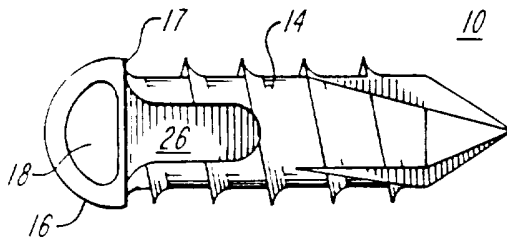


FIG. 9A

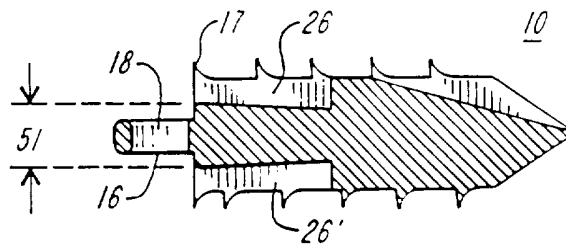


FIG. 9B

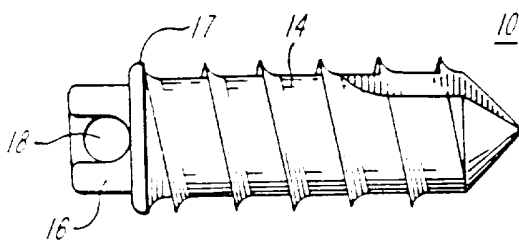


FIG. 10A

6 / 6

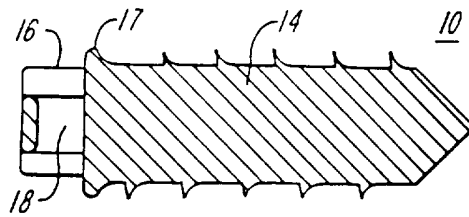


FIG. 10B

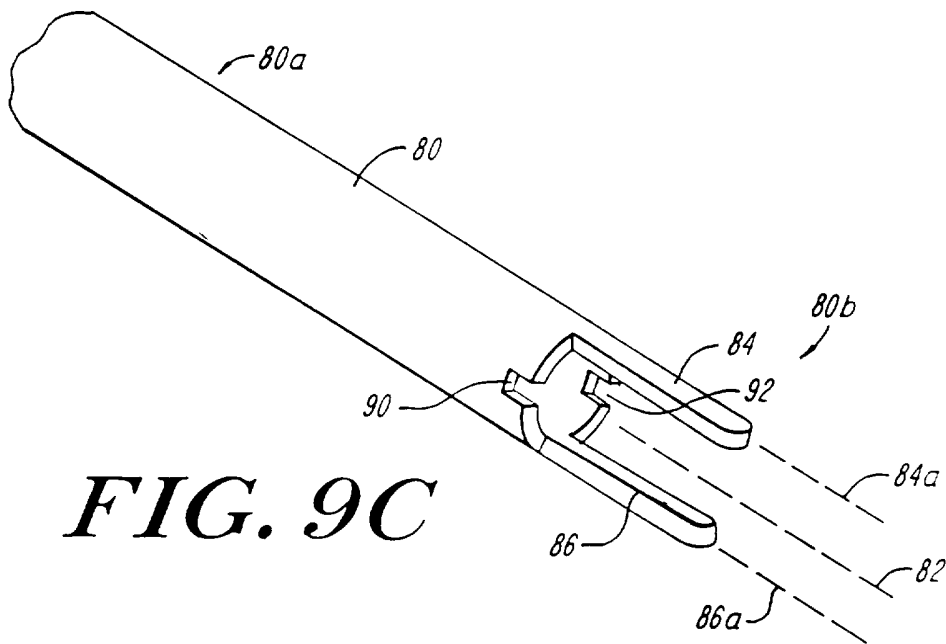


FIG. 9C

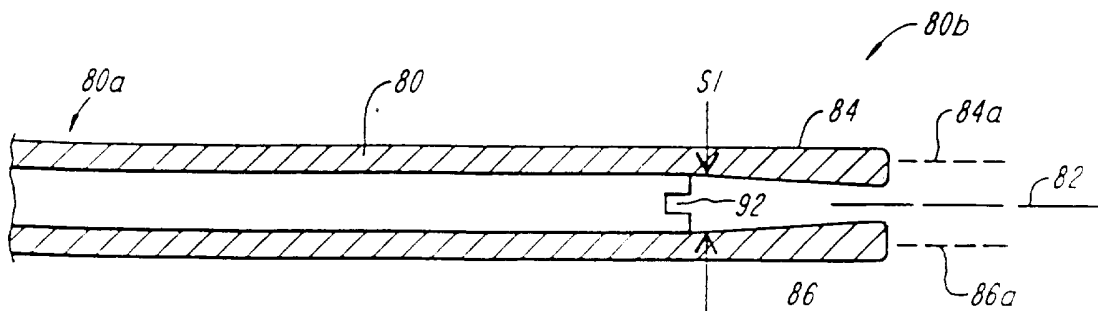


FIG. 9D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13897

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/00

US CL :606/232

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/72-76, 219, 220, 232

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,156,616, (MEADOWS ET AL.), 20 October 1992.	1-30
A	US, A, 5,152,790, (ROSENBERG ET AL.), 06 October 1992.	1-30
A	US, A, 5,102,421, (ANSPACH, JR.), 07 April 1992.	1-30

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:		*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance		*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date		*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)		
O document referring to an oral disclosure, use, exhibition or other means		
P document published prior to the international filing date but later than the priority date claimed	*2*	document member of the same patent family

Date of the actual completion of the international search

29 MARCH 1995

Date of mailing of the international search report

20 APR 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

Jeffrey A. Schmidt
JEFFREY A. SCHMIDT

Telephone No. (703) 308-3141