

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 August 2001 (30.08.2001)

PCT

(10) International Publication Number
WO 01/62172 A1

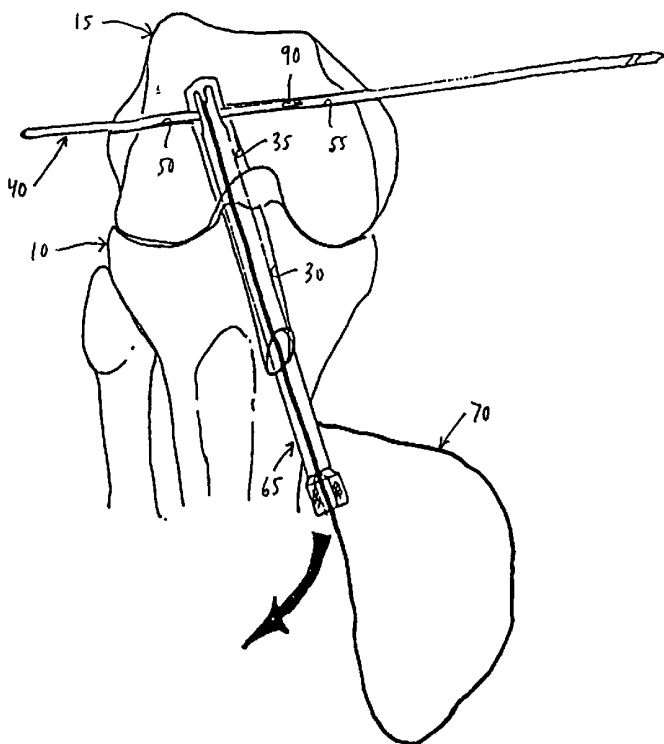
- (51) International Patent Classification⁷: A61B 19/00 (74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).
- (21) International Application Number: PCT/US01/40175 (81) Designated States (*national*): AU, CA, JP.
- (22) International Filing Date: 22 February 2001 (22.02.2001) (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/184,292 23 February 2000 (23.02.2000) US
- (71) Applicant: ETHICON, INC. [US/US]; Route 22 West, Somerville, NJ 08824 (US).
- (72) Inventor: JUSTIN, Daniel, F.; 185 North Winding Way, Logan, UT 84321 (US).

Published:

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

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHOD FOR RECONSTRUCTING A LIGAMENT



(57) Abstract: Apparatus and method for securing a graft ligament in a bone tunnel. In one form of the invention, the method comprises the steps of forming a first bone tunnel (20) in a bone; forming a second bone tunnel (35) in the same bone, the second bone tunnel being transverse to, and intersecting, the first bone tunnel; positioning a closed loop of a flexible member (70) within the first bone tunnel and out through a first portion of the second bone tunnel; parting the closed loop outside the first portion of the second bone tunnel so as to create a first free end (95) and a second free end (105); passing the second free end through the second bone tunnel so that the second free end extends out of a second portion of the second bone tunnel; positioning the graft ligament (25) over a portion of the flexible member; and pulling the first and second free ends of the flexible member so as to draw the graft ligament into the first bone tunnel.



WO 01/62172 A1

APPARATUS AND METHOD FOR RECONSTRUCTING A LIGAMENTReference To Pending Prior Patent Application

5 This patent application claims benefit of pending
prior U.S. Provisional Patent Application Serial No.
60/184,292, filed February 23, 2000 by Daniel F. Justin
for METHOD OF DELIVERING AN ACL GRAFT, which patent
application is hereby incorporated herein by reference.

10 Field Of The Invention

This invention relates to medical devices and
procedures in general, and more particularly to medical
devices and procedures for reconstructing a ligament.

15 Background Of The Invention

A ligament is a piece of fibrous tissue which
connects one bone to another.

20 Ligaments are frequently damaged (e.g., detached
or torn or ruptured, etc.) as the result of injury
and/or accident. A damaged ligament can impede proper
motion of a joint and cause significant pain.

Various procedures have been developed to repair
or replace a damaged ligament. The specific procedures

- 2 -

used depend on the particular ligament which is to be restored and on the extent of the damage.

One ligament which is frequently damaged as the result of injury and/or accident is the anterior cruciate ligament (ACL). Looking now at Fig. 1, the ACL 5 extends between the top of the tibia 10 and the bottom of the femur 15. A damaged ACL can cause instability of the knee joint and cause substantial pain and arthritis.

Numerous procedures have been developed to restore the ACL through a graft ligament replacement. In general, and looking now at Fig. 2, these ACL replacement procedures involve drilling a bone tunnel 20 through tibia 10 and up into femur 15. Then a graft ligament 25, consisting of a harvested or artificial ligament or tendon(s), is passed through the tibial portion 30 of tunnel 20 (sometimes referred to as "the tibial tunnel"), across the interior of the joint, and up into the femoral portion 35 of tunnel 20 (sometimes referred to as "the femoral tunnel"). Then a distal portion of graft ligament 25 is secured in femoral tunnel 35, and a proximal portion of graft ligament 25 is secured in tibial tunnel 30.

There are numerous ways in which graft ligament 25 may be positioned in tunnel 20 and secured in position. However, none of the prior art apparatus and methods has proven to be entirely satisfactory, for a variety of reasons.

Summary Of The Invention

As a result, one object of the present invention is to provide improved apparatus for reconstructing a ligament.

And another object of the present invention is to provide an improved method for reconstructing a ligament.

These and other objects of the present invention are addressed by a novel apparatus and method for reconstructing a ligament.

In one preferred form of the invention, the invention comprises a method for securing a graft ligament in a bone tunnel, the method comprising the steps of: (1) forming a first bone tunnel in a bone, the first bone tunnel having a first opening at one end thereof, and forming a second bone tunnel in the same bone, the second bone tunnel being transverse to, and

- 4 -

intersecting, the first bone tunnel, the second bone tunnel having first and second portions extending from the first bone tunnel, the first portion of the second bone tunnel having a second opening at one end thereof, and the second portion of the second bone tunnel having a third opening at one end thereof; (2) positioning a closed loop of a flexible member within the first bone tunnel and the first portion of the second bone tunnel such that a first portion of the closed loop extends out of the first opening and a second portion of the closed loop extends out of the second opening, parting the closed loop outside the second opening so as to create a first free end and a second free end, and passing the second free end through the second bone tunnel so that the second free end extends out of the third opening, and positioning the graft ligament over a portion of the flexible member extending out of the first opening; and (3) pulling the first and second free ends of the flexible member so as to draw the graft ligament into the first bone tunnel.

In another form of the invention, the invention comprises a system for securing a graft ligament in a bone tunnel, the system comprising a flexible member

- 5 -

for positioning the graft ligament in the bone tunnel,
the flexible member comprising a closed loop; an
inserter for positioning a first portion of the closed
loop in the bone tunnel; and a passing pin for
5 withdrawing the first portion of the closed loop from
the inserter positioned in the bone tunnel and pulling
that portion of the closed loop through a portion of a
second bone tunnel which intersects, and extends
traverse to, the first-mentioned bone tunnel.

10 An in another form of the invention, the invention
comprises a system for securing a graft ligament in a
bone tunnel, the system comprising a flexible member
extending through a second bone tunnel which
intersects, and extends traverse to, the bone tunnel,
15 the second bone tunnel having a first opening and a
second opening, the flexible member having a first free
end extending out of the first opening and a second
free end extending out of the second opening, and
wherein the graft ligament is looped over the flexible
20 member; a cannulated crosspin mounted on the flexible
member external to the first opening; a cannulated
driver mounted on the flexible member outboard of the
cannulated crosspin; and a cannulated bead mounted on

- 6 -

the flexible member outboard of the cannulated driver,
the cannulated bead having a larger outside diameter
than the inside lumen of the cannulated driver;
whereby, when tension is applied to the second end of
5 the flexible member, the cannulated driver may be used
to pass the cannulated crosspin beneath the graft
ligament.

Brief Description Of The Drawings

10 These and other objects and features of the
present invention will be more fully disclosed or
rendered obvious by the following detailed description
of the preferred embodiments of the invention, which is
to be considered together with the accompanying
15 drawings wherein like numbers refer to like parts, and
further wherein:

Fig..1 is a schematic side view of a knee joint,
showing an ACL extending between the top of the tibia
and the bottom of the femur;

20 Fig. 2 is a schematic side view of the same knee
joint, except showing portions of an ACL
reconstruction;

- 7 -

Figs. 3, 5, 6 and 8-21 are schematic front views of a knee joint, illustrating a novel procedure for positioning a graft ligament in a bone tunnel and securing it in position;

5 Fig. 4 is a schematic side view of a passing pin used in a preferred form of the invention;

Fig. 7 is a schematic perspective view of an inserter used in a preferred form of the invention; and

10 Fig. 22 is a schematic side view of another form of passing pin used in a preferred form of the invention.

Detailed Description Of The Invention

15 The present invention comprises a novel apparatus and method for reconstructing a ligament.

More particularly, and looking now at Fig. 3, the bone tunnel 20 is first formed by drilling through tibia 10 and up into femur 15, whereby to form tibial tunnel 30 and femoral tunnel 35. This is done with
20 conventional ACL drilling apparatus of the sort well known in the art.

Next, a transverse bone tunnel is formed in femur 15 so that the transverse bone tunnel intersects

- 8 -

femoral tunnel 35. This is preferably done using a passing pin 40 such as that shown in Fig. 4. Passing pin 40 is drilled transversely across femoral bone tunnel 35 (Fig. 5) so as to produce the transverse bone tunnel 45. Bone tunnel 20 effectively bifurcates transverse bone tunnel 45 into two tunnel portions, a first transverse bone tunnel portion 50 and a second transverse bone tunnel portion 55. After transverse bone tunnel 45 has been formed, passing pin 40 is retracted within transverse bone tunnel 45 so that the leading tip 60 of passing pin 40 is located in first transverse bone tunnel portion 50 (Fig. 6).

Once transverse bone tunnel 45 has been formed and passing pin 40 has been backed off so that its leading tip 60 is in first transverse bone tunnel portion 50, a flexible member is passed up bone tunnel 20. This is preferably done using an inserter 65 such as that shown in Fig. 7. More particularly, the flexible member 70 (Fig. 8) is initially in the form of a closed loop. This closed loop is slipped into a pair of diametrically-opposed grooves 75 (Fig. 7) located at the distal end of inserter 65. As a result, a segment 80 (Fig. 8) of flexible member 70 is suspended across a

- 9 -

diametrically-extending channel 85 (Figs. 7 and 8) formed in the distal end of inserter 65. Then the distal end of inserter 65 is passed up tibial tunnel 30, across the interior of the knee joint, and then up femoral tunnel 35 (Fig. 9). Inserter 65 is pushed far enough up femoral tunnel 35 so that the aforementioned segment 80 of flexible member 70 is positioned on the distal side of transverse bone tunnel 45, with channel 85 of inserter 65 being aligned with transverse bone tunnel 45.

Next, passing pin 40 is advanced in transverse bone tunnel 45 so that the passing pin passes through channel 85 in inserter 65 and beneath segment 80 of flexible member 70 (Fig. 10). Passing pin 40 is advanced far enough so that its notch 90 (Fig. 4) is on the distal side of inserter 65 (Fig. 10). Then inserter 65 is retracted proximally so that segment 80 of flexible member 70 is brought into engagement with, and is supported by, the top of passing pin 40 (Fig. 11). Inserter 65 is preferably fully withdrawn from bone tunnel 20 at this point (Fig. 12).

Next, as slight downward pressure is applied to flexible member 70, passing pin 40 is retracted until

- 10 -

flexible member 70 slips into, and is captured by,
notch 90 of passing pin 40 (Fig. 13). Then passing pin
40 is retracted further out of transverse bone tunnel
45, until its notch 90 (and hence flexible member 70)
5 is free of transverse bone tunnel 45 (Fig. 14).

At this point, the closed loop of flexible member
70 extends into first transverse bone tunnel portion
50, down femoral tunnel 35, across the interior of the
knee joint, down tibial tunnel 30, and out the front of
10 tibia 10.

Next, the closed loop of flexible member 70 is
withdrawn from notch 90 of passing pin 40, and then
flexible member 70 is cut (Fig. 15). Then, one free
end 95 of flexible member 70 is attached to passing pin
15 40 (Fig. 16) by passing that free end 95 through one or
more holes 100 (Fig. 4) formed in the proximal end of
passing pin 40. The other free end 105 (Fig. 16) of
flexible member 70 is left hanging outside the joint.

Next, passing pin 40 is passed completely through
20 femur 15 (Fig. 17), carrying the free end 95 of
flexible member 70 with it. Free end 95 of flexible
member 95 is then dismounted from passing pin 40 (Fig.
18).

- 11 -

At this point flexible member 70 extends into first transverse bone tunnel portion 50, down femoral tunnel 35, across the interior of the knee joint, down tibial tunnel 30, forms a loop 110 outside the front of tibia 10, extends back up tibial tunnel 30, across the interior of the knee joint, back up femoral tunnel 35, and then out second transverse bone tunnel portion 55.

Next, and looking now at Fig. 19, the graft ligament 25 is looped through loop 110 of flexible member 70. First and second ends 95, 105 of flexible member 70 are then pulled outboard, away from femur 15, in the manner shown in Fig. 19, whereby to pull loop 110 of flexible member 70, and hence graft ligament 25, up tibial tunnel 30, across the interior of the knee joint, and up femoral tunnel 35 so as to achieve the position shown in Fig. 20.

Looking next at Fig. 21, flexible member 70 is then used as a guide to pass a cannulated crosspin 115 through transverse bone tunnel 45 and, in the process, beneath looped graft ligament 25, whereby to support graft ligament 25 within bone tunnel 20. A cannulated driver 120 may be used to set cannulated crosspin 115 in transverse bone tunnel 45. It will be appreciated

- 12 -

that flexible member 70 should be held under tension while cannulated crosspin 115 is deployed in femur 15 so as to provide proper guidance for cannulated crosspin 115. This can be achieved by simultaneously pulling on the two free ends, 95 and 105, of flexible member 70 and then turning cannulated driver 120.

However, it will be appreciated that this technique requires three hands: one for pulling on free end 95, one for pulling on free end 105, and one for turning cannulated driver 120. In some instances, it may be

desirable to use only two hands. To this end, in one preferred form of the invention, a cannulated bead 125 may be set on flexible member 70, adjacent free end 105, and then a knot 130 formed in the flexible member proximal to the cannulated bend. This construction

allows a surgeon to maintain tension on flexible member 70 by pulling, with one hand, on the free end 95 while using the other hand to turn cannulated driver 120.

Once cannulated crosspin 115 has been deployed in femur 115, flexible member 70 may be removed from transverse bone tunnel 45, e.g., by pulling proximally on bead 125.

- 13 -

The proximal ends of graft ligament 25 may thereafter be secured to tibia 10 in ways well known in the art so as to complete the ligament repair procedure.

5 It should be appreciated that notch 90 (Fig. 4) of passing pin 40 may have various configurations consistent with the present invention. Thus, for example, in Fig. 4 notch 90 is shown as having a substantially T-shaped configuration. However, other
10 configurations may also be used. Thus, for example, and looking now at Fig. 22, notch 90 may have a substantially straight configuration. Still other configurations will be apparent to those skilled in the art in view of the present disclosure.

15 It is to be understood that the present invention is by no means limited to the particular construction and method steps disclosed above and/or shown in the drawings, but also comprises any modifications or equivalents within the scope of the claims.

20

What Is Claimed Is:

1. A method for securing a graft ligament in a bone tunnel, said method comprising the steps of:

5 (1) forming¹ a first bone tunnel in a bone, said first bone tunnel having a first opening at one end thereof, and forming a second bone tunnel in the same bone, said second bone tunnel being transverse to, and intersecting, said first bone tunnel, said second bone
10 tunnel having first and second portions extending from said first bone tunnel, said first portion of said second bone tunnel having a second opening at one end thereof, and said second portion of said second bone tunnel having a third opening at one end thereof;

15 (2) positioning a closed loop of a flexible member within said first bone tunnel and said first portion of said second bone tunnel such that a first portion of said closed loop extends out of said first opening and a second portion of said closed loop
20 extends out of said second opening, parting said closed loop outside said second opening so as to create a first free end and a second free end, and passing said second free end through said second bone tunnel so that

said second free end extends out of said third opening, and positioning the graft ligament over a portion of said flexible member extending out of said first opening; and

5 . . . (3) pulling said first and second free ends of said flexible member so as to draw said graft ligament into said first bone tunnel.

10 2. A method according to claim 1 wherein said closed loop of said flexible member is positioned in said first bone tunnel and said first portion of said second bone tunnel by mounting said closed loop of said flexible member onto an inserter, passing said inserter into said first opening of said first bone tunnel, up
15 said first bone tunnel until said first portion of the closed loop is located at the intersection of said second bone tunnel with said first bone tunnel, and pulling said first portion of said closed loop through said first portion of said second tunnel and out said
20 second opening.

3. A method according to claim 2 wherein said inserter comprises a shaft having a

- 16 -

diametrically-extending channel formed in the distal end thereof.

5 4. A method according to claim 3 wherein said inserter has a pair of diametrically-opposing grooves on either side of said channel.

10 5. A method according to claim 2 wherein a pulling pin is used to pull said first portion of said closed loop through said first portion of said second bone tunnel and out of said second opening.

15 6. A method according to claim 5 wherein said pulling pin comprises a notch for releasably capturing said flexible member.

7. A system for securing a graft ligament in a bone tunnel, said system comprising:

20 a flexible member for positioning the graft ligament in the bone tunnel, said flexible member comprising a closed loop;

an inserter for positioning a first portion of said closed loop in the bone tunnel; and

- 17 -

a passing pin for withdrawing said first portion of said closed loop from said inserter positioned in the bone tunnel and pulling that portion of said closed loop through a portion of a second bone tunnel which intersects, and extends traverse to, the first-mentioned bone tunnel.

8. A method according to claim 7 wherein said inserter comprises a shaft having a diametrically-extending channel formed in the distal end thereof.

9. A method according to claim 8 wherein said inserter has a pair of diametrically-opposing grooves on either side of said channel.

10. A method according to claim 9 wherein said pulling pin comprises a notch for releasably capturing said flexible member.

11. A system according to claim 7 further comprising an arthroscope to aid in the visualization of positioning said inserter and pulling said first

portion of said closed loop through a portion of said second bone tunnel.

12. A system for securing a graft ligament in a bone tunnel, said system comprising:

a flexible member extending through a second bone tunnel which intersects, and extends traverse to, the bone tunnel, the second bone tunnel having a first opening and a second opening, said flexible member having a first free end extending out of said first opening and a second free end extending out of said second opening, and wherein the graft ligament is looped over said flexible member;

a cannulated crosspin mounted on said flexible member external to said first opening;

a cannulated driver mounted on said flexible member outboard of said cannulated crosspin; and

a cannulated bead mounted on said flexible member outboard of said cannulated driver, said cannulated bead having a larger outside diameter than the inside lumen of said cannulated driver;

whereby, when tension is applied to said second end of said flexible member, said cannulated driver may

- 19 -

be used to pass said cannulated crosspin beneath the graft ligament.

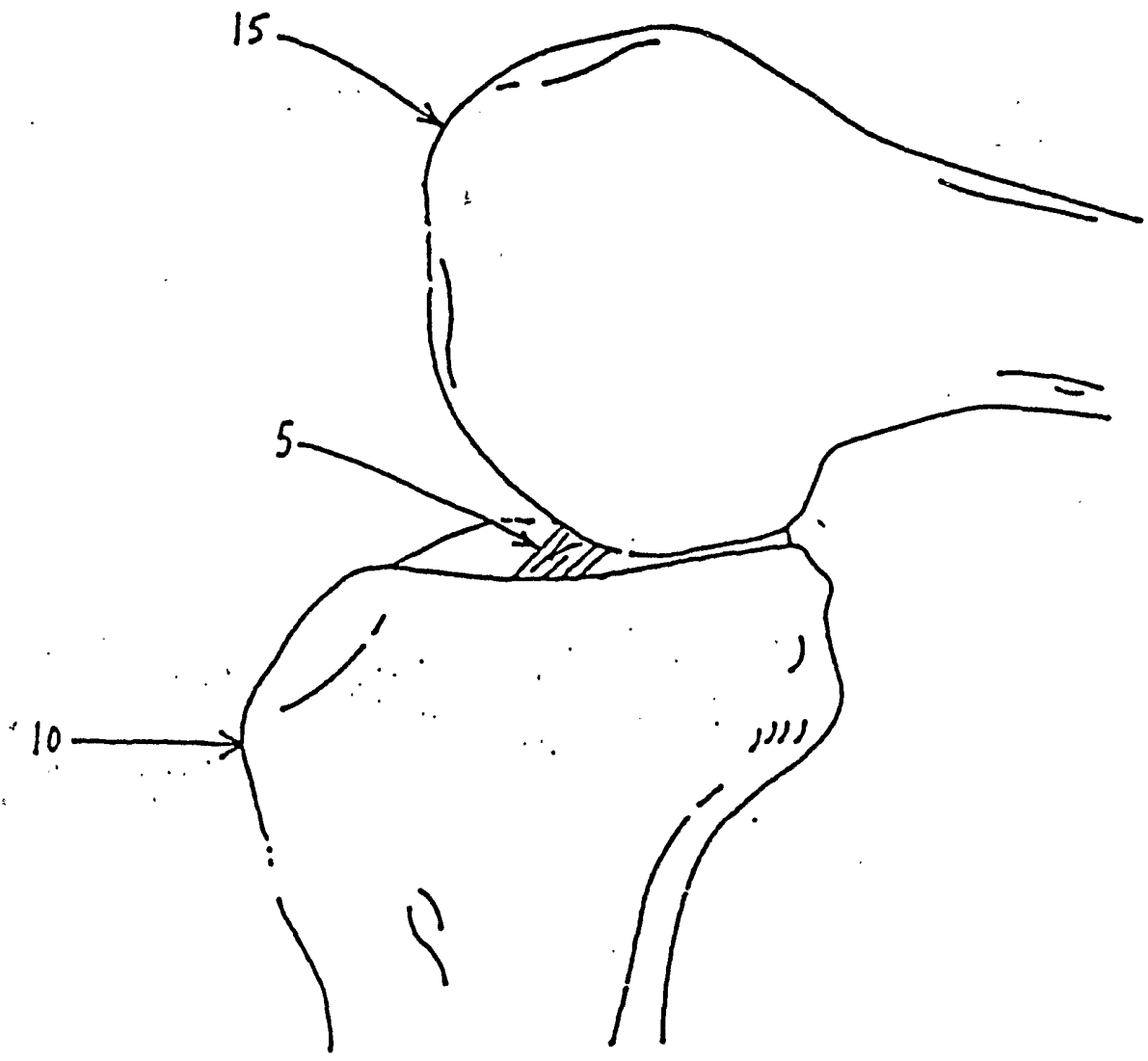


FIG. 1

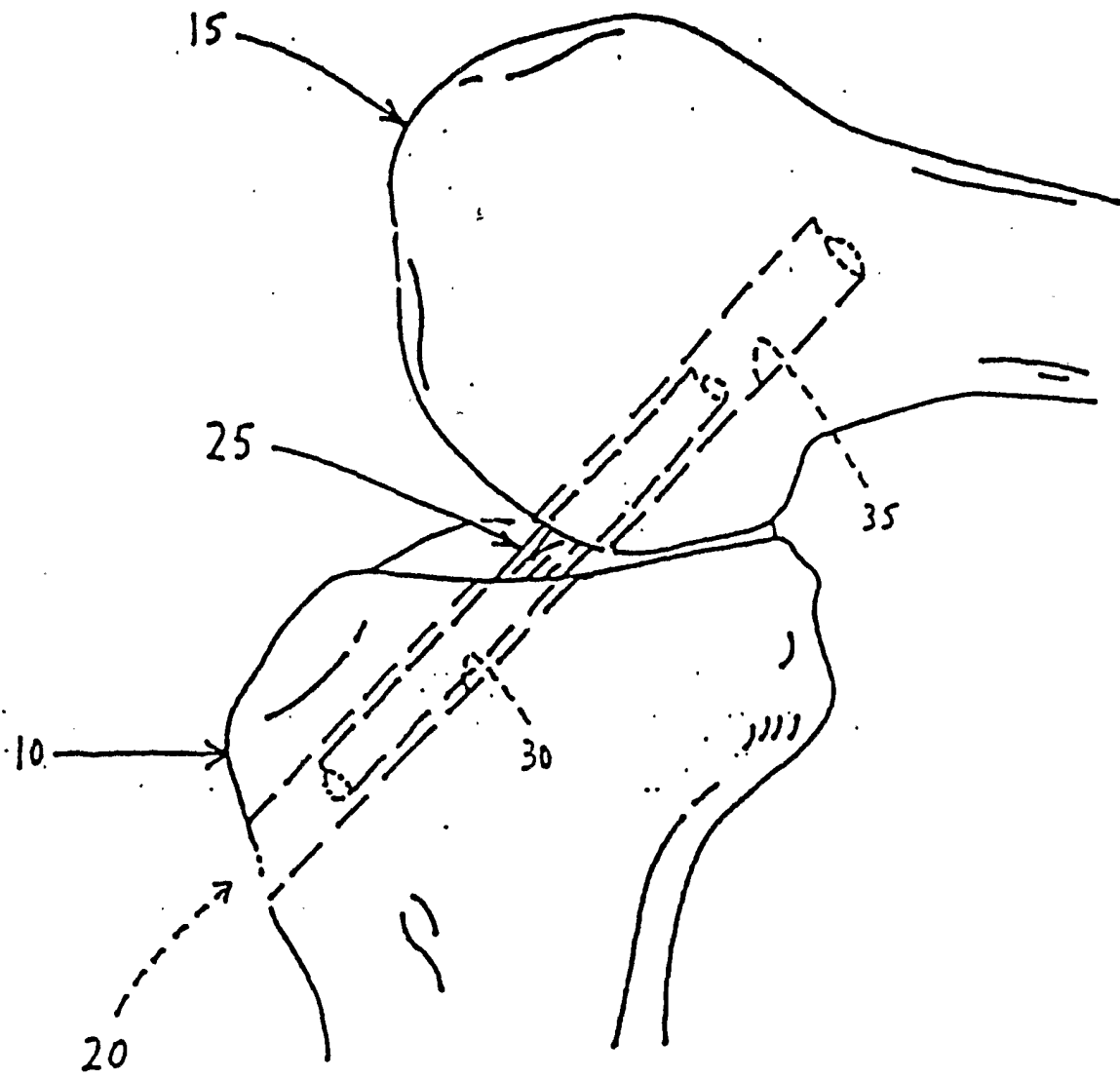


FIG. 2

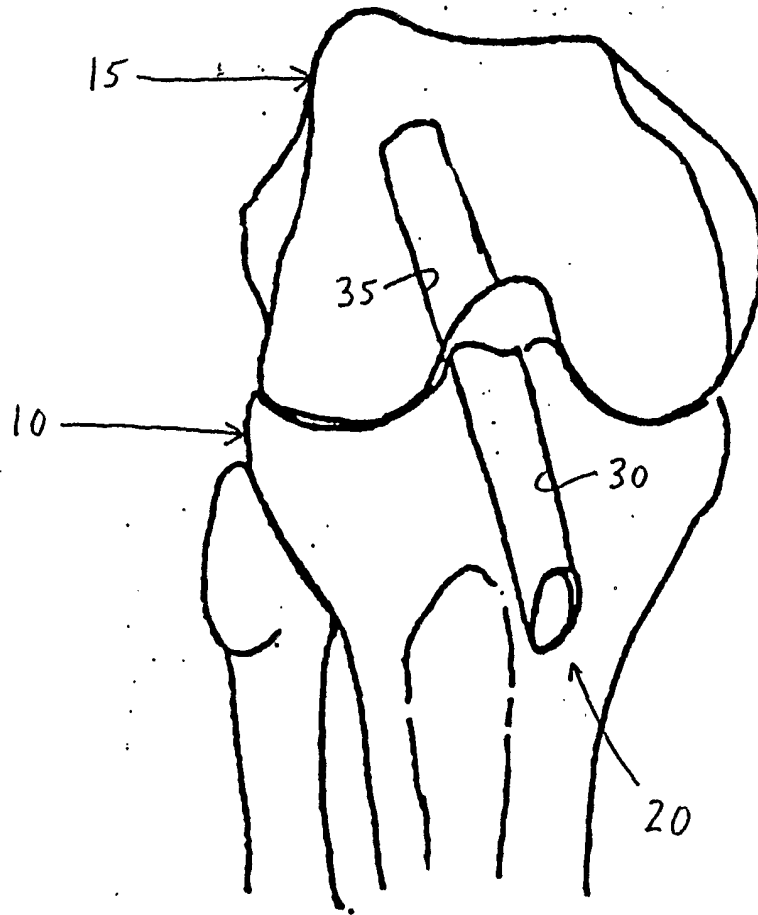


FIG. 3

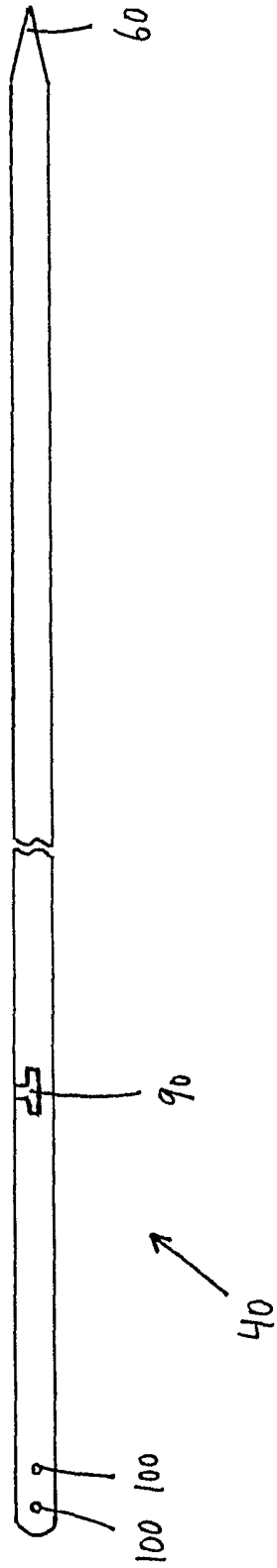


FIG. 4

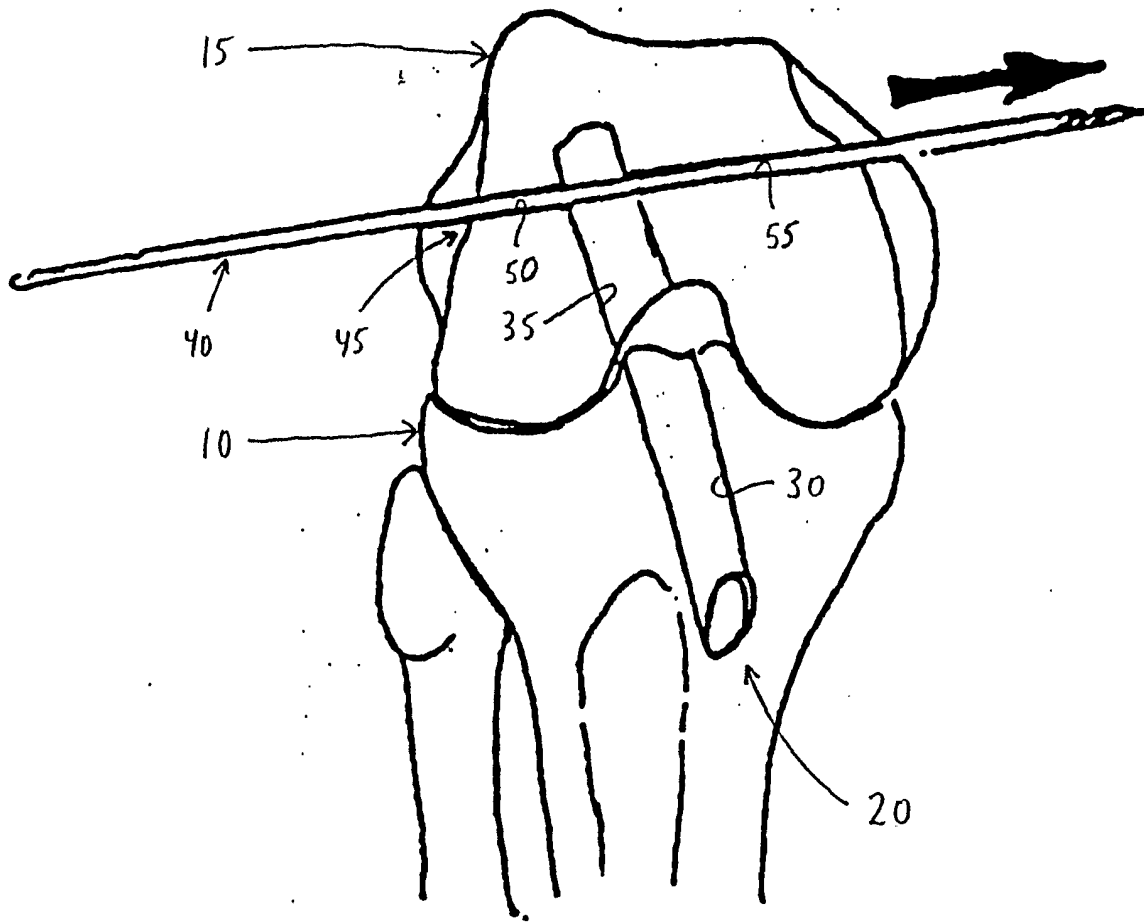


FIG. 5

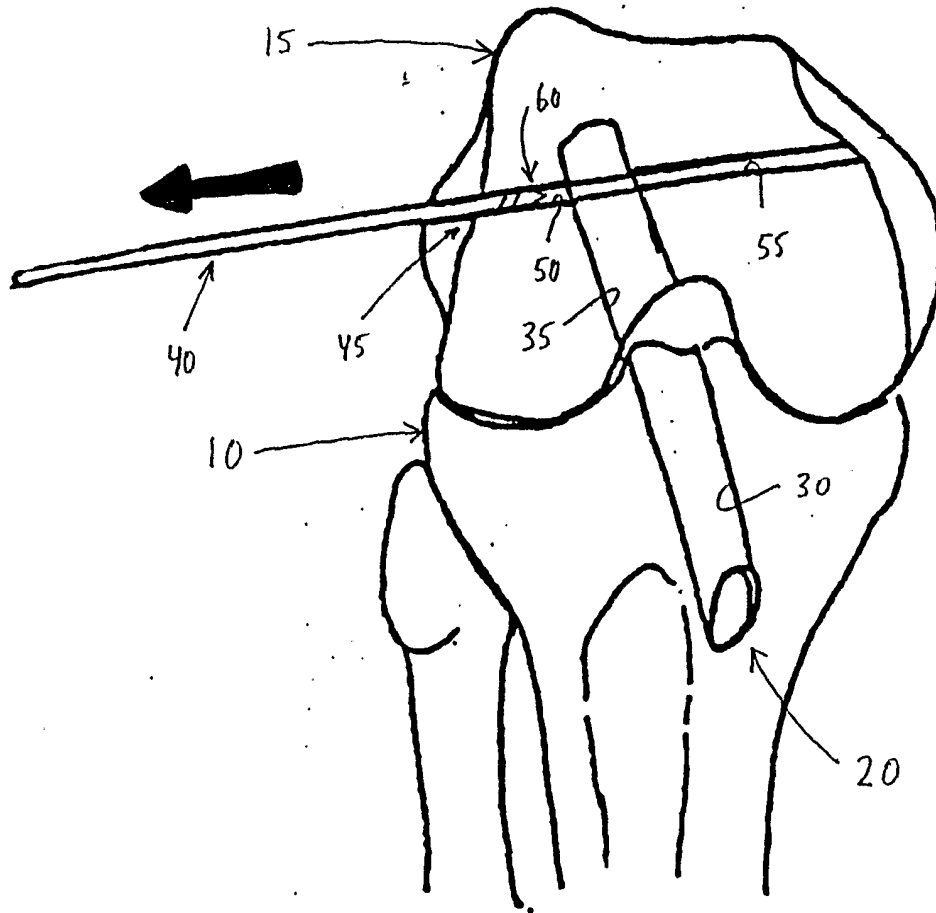


FIG. 6

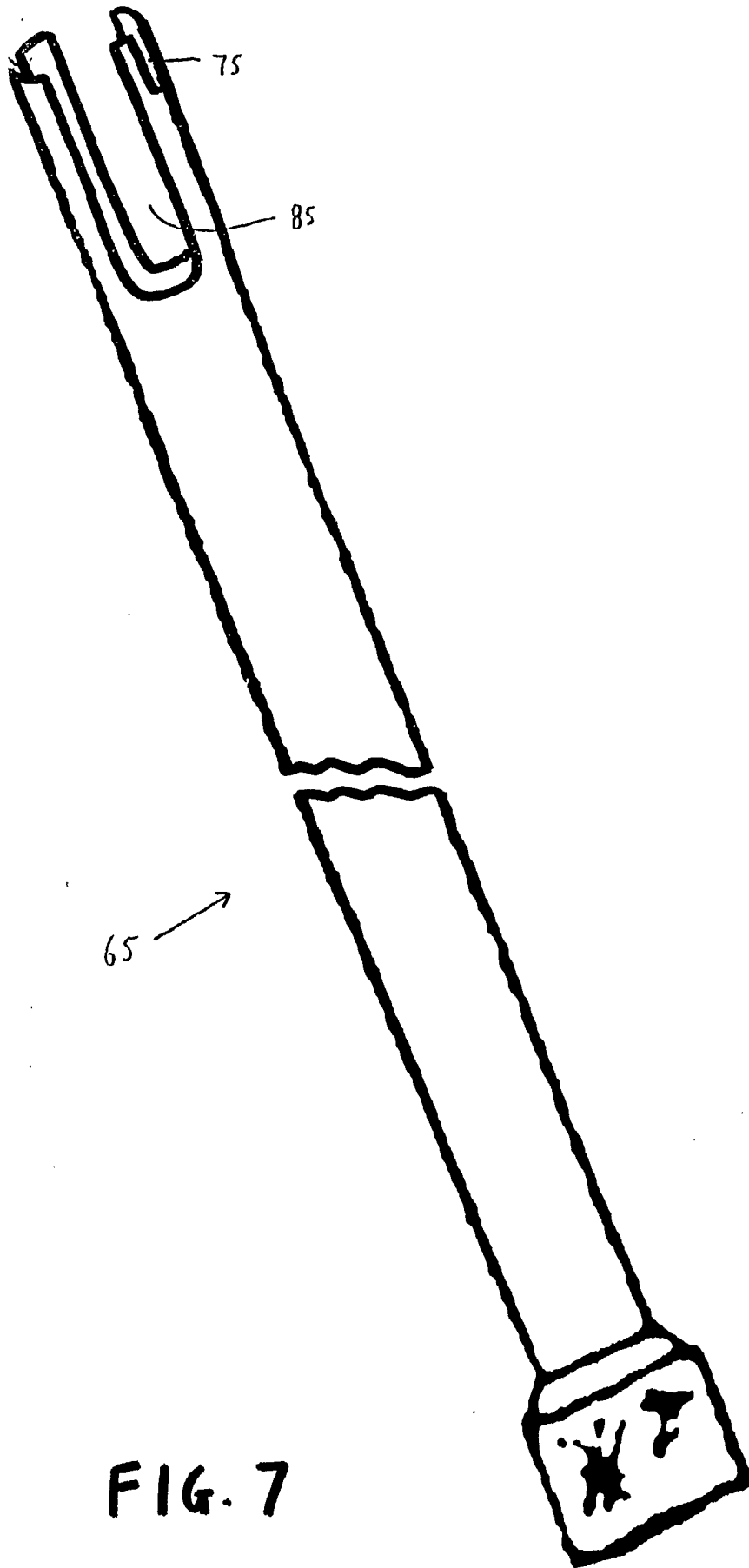


FIG. 7

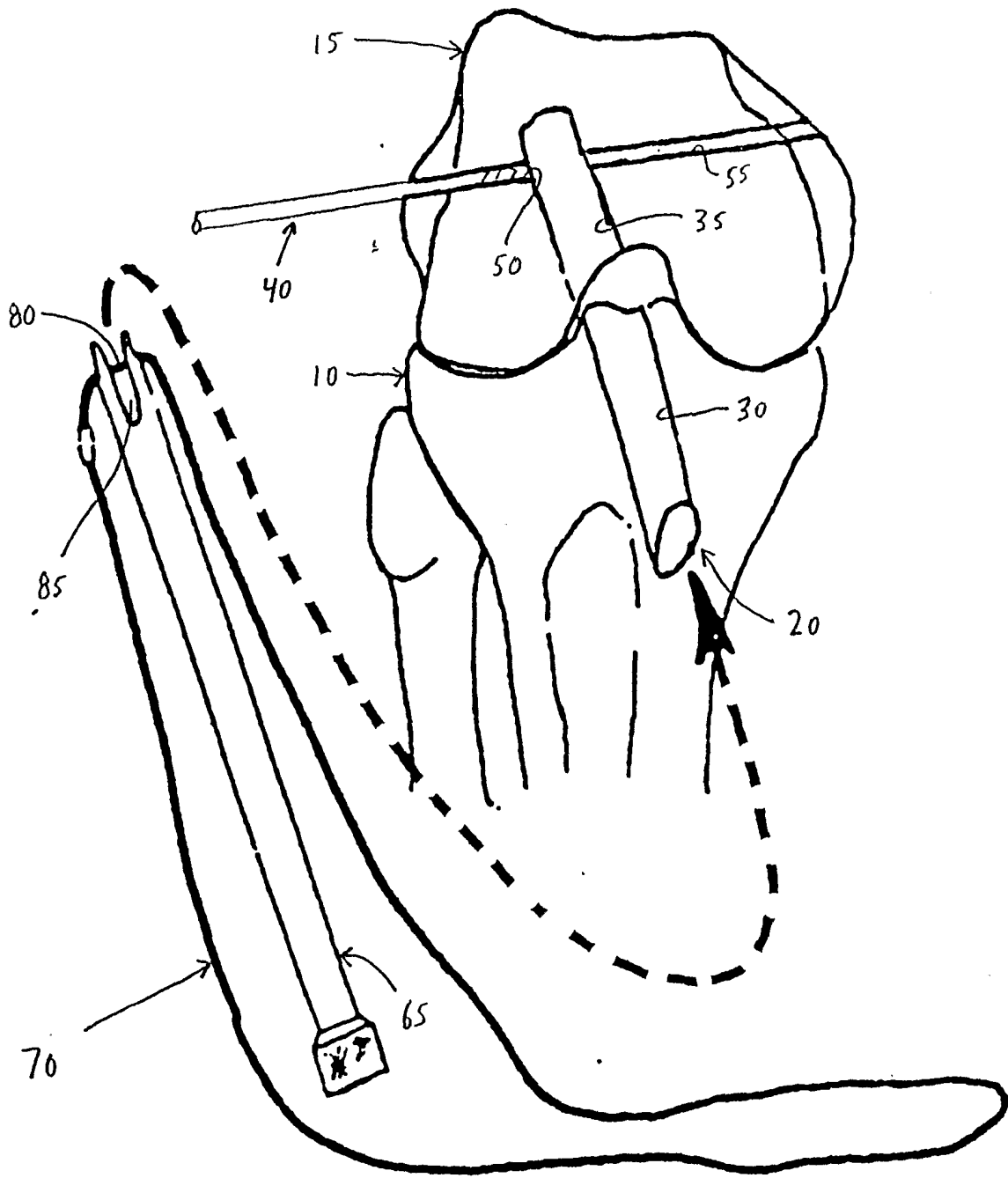


FIG. 8

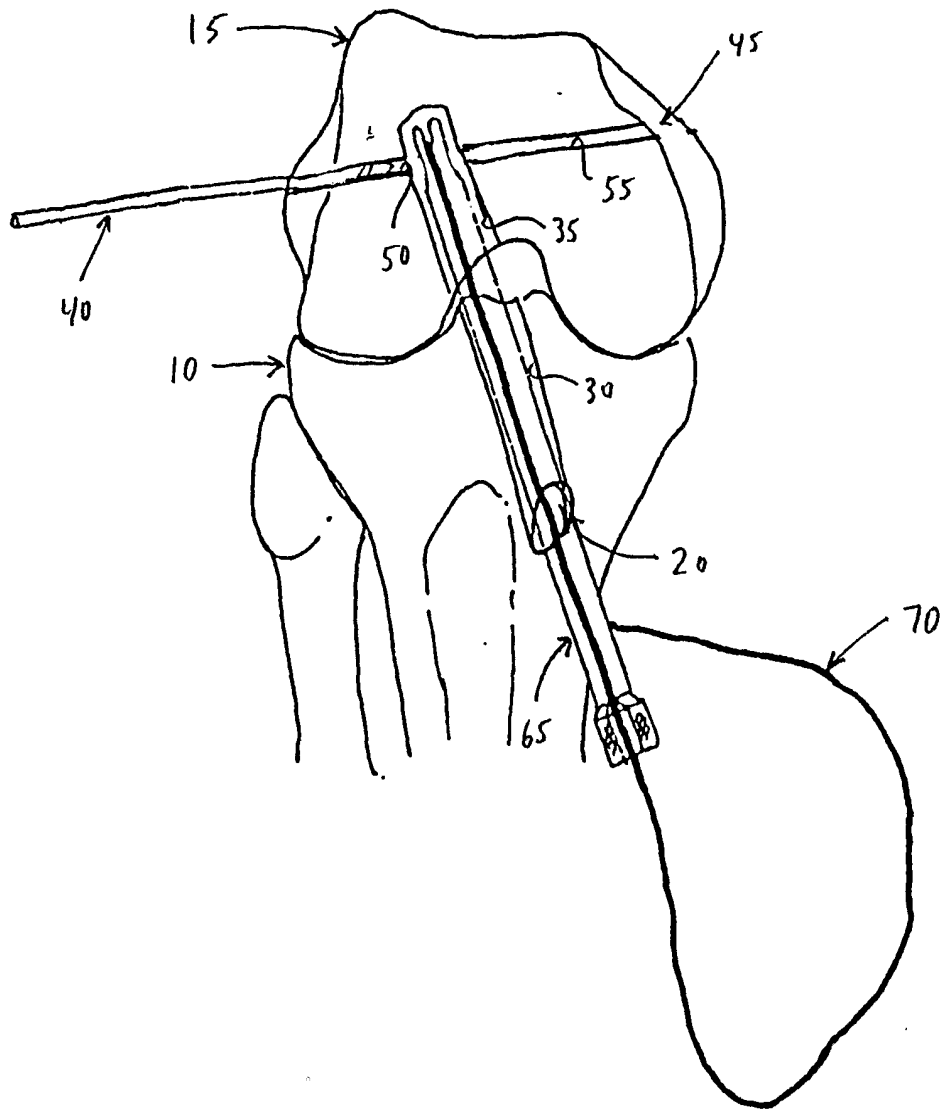


FIG. 9

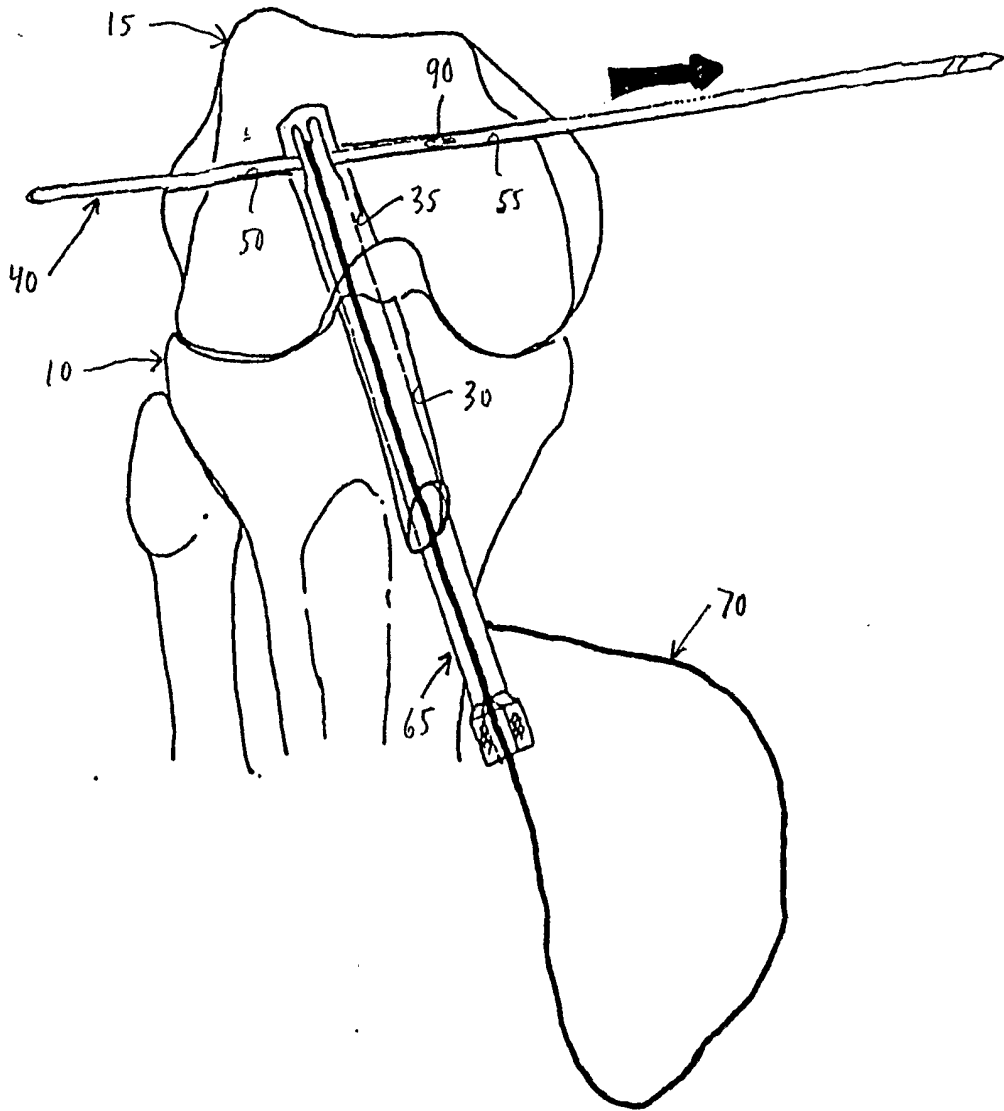


FIG. 10

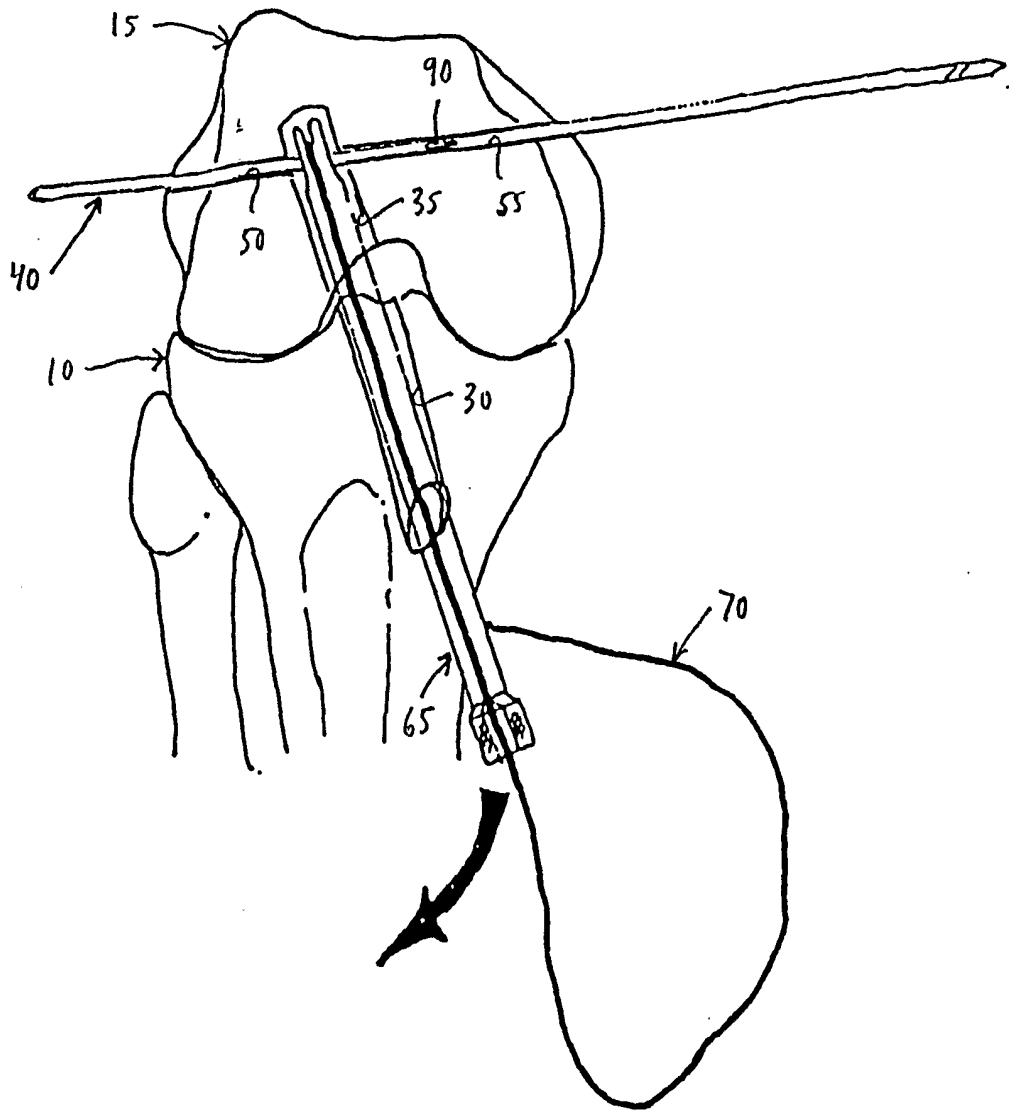


FIG. 11

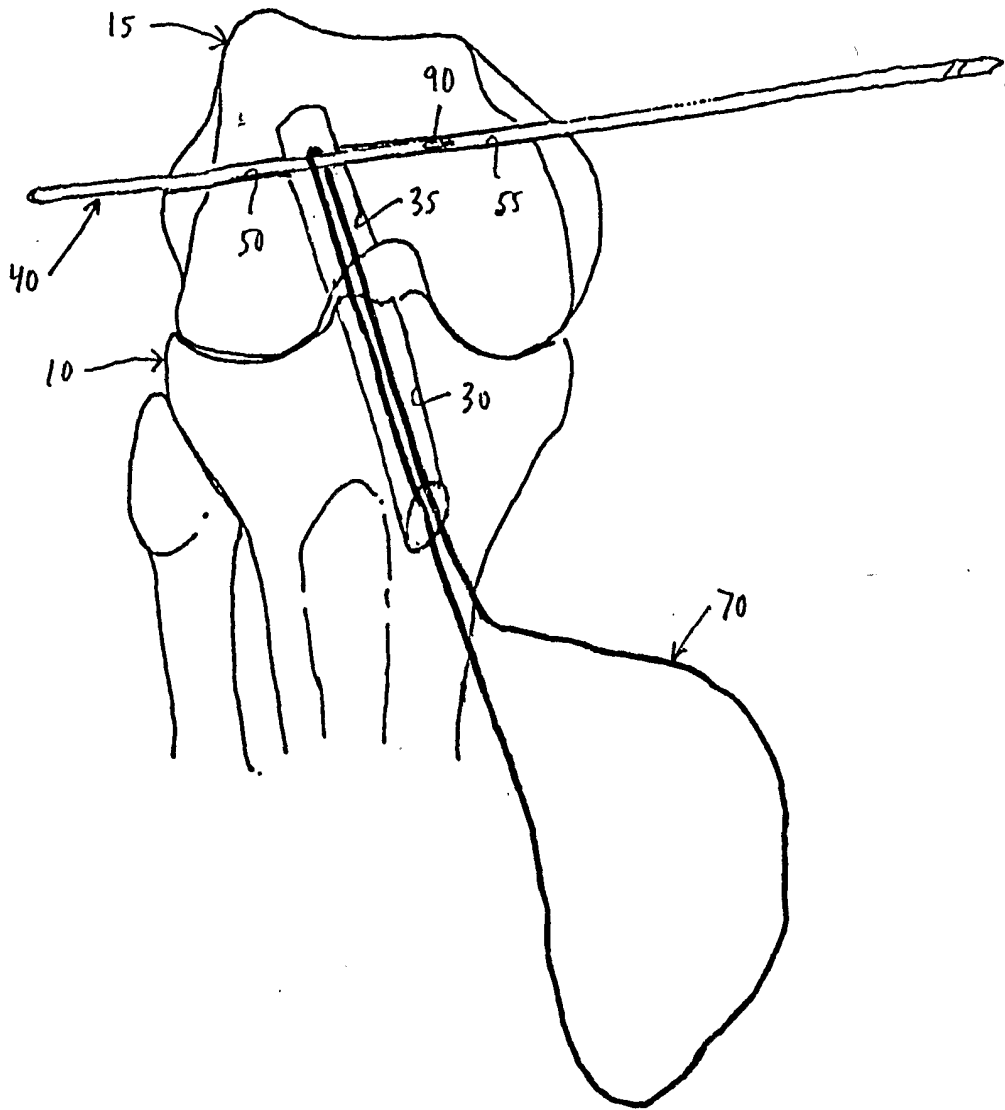


FIG. 12

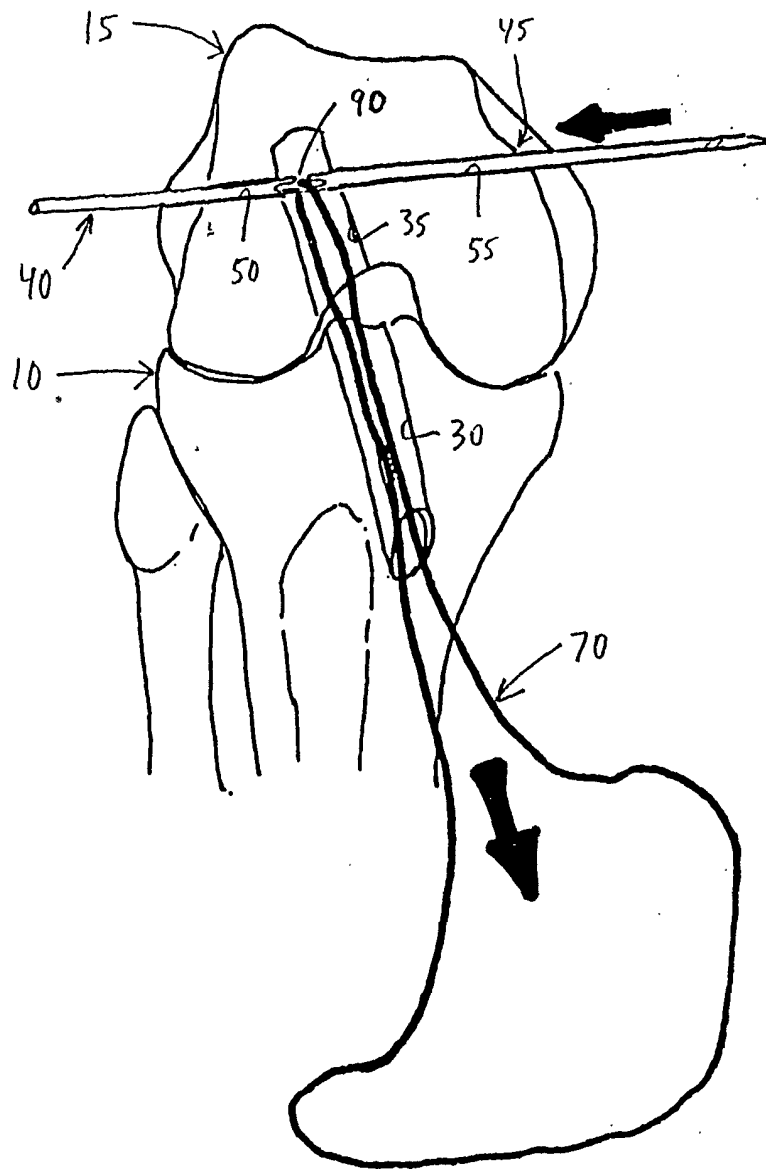


FIG. 13

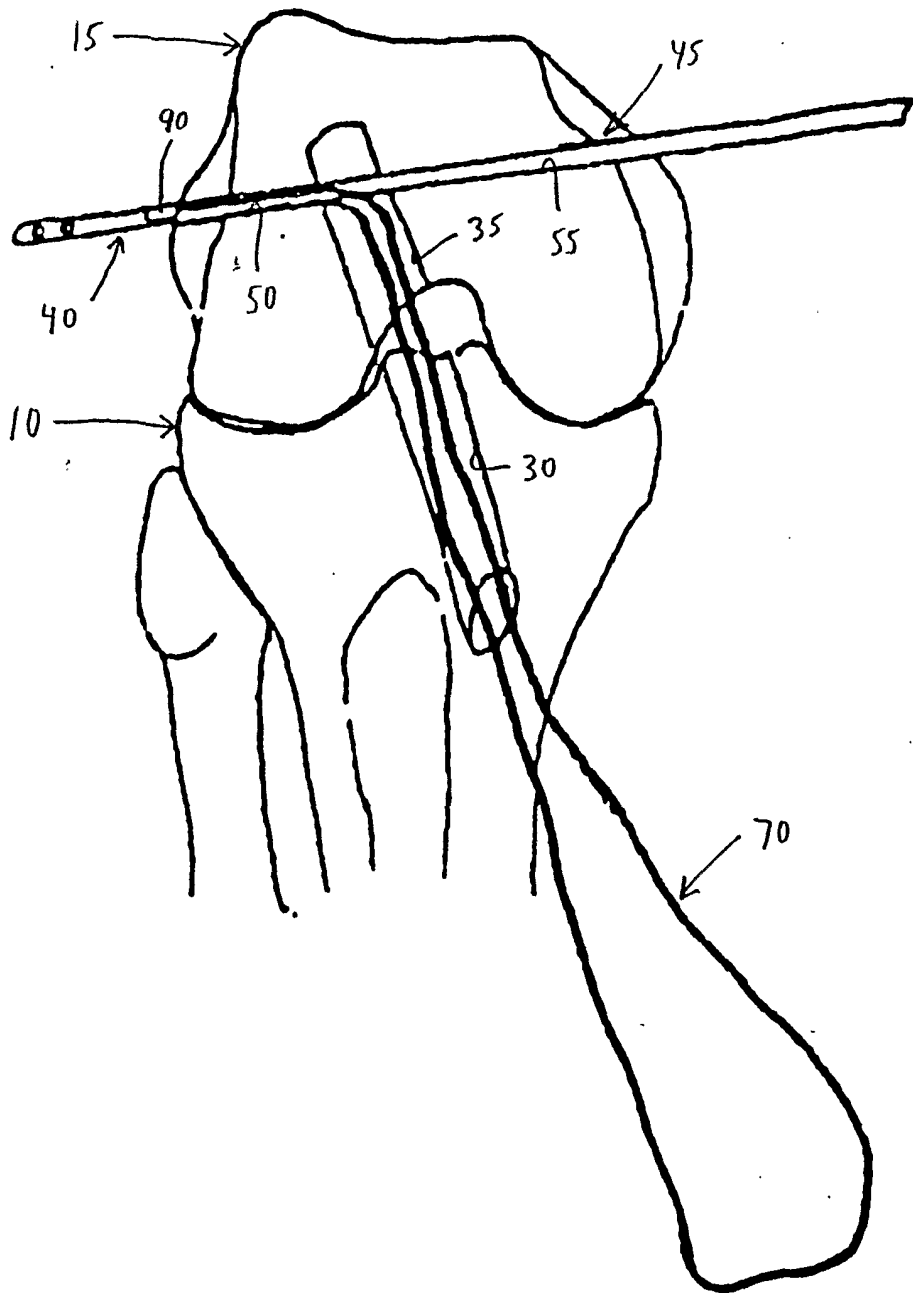


FIG. 14

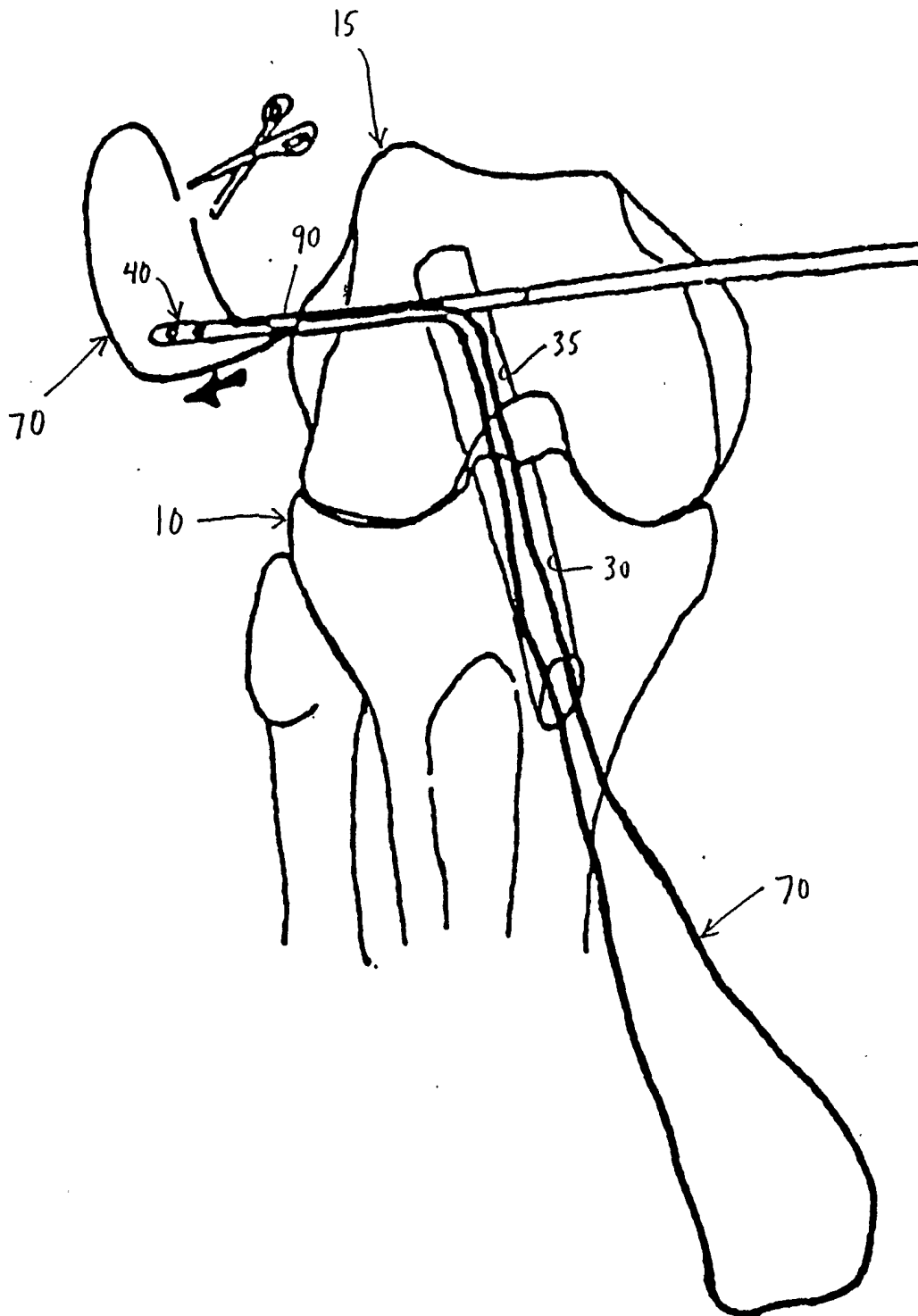


FIG. 15

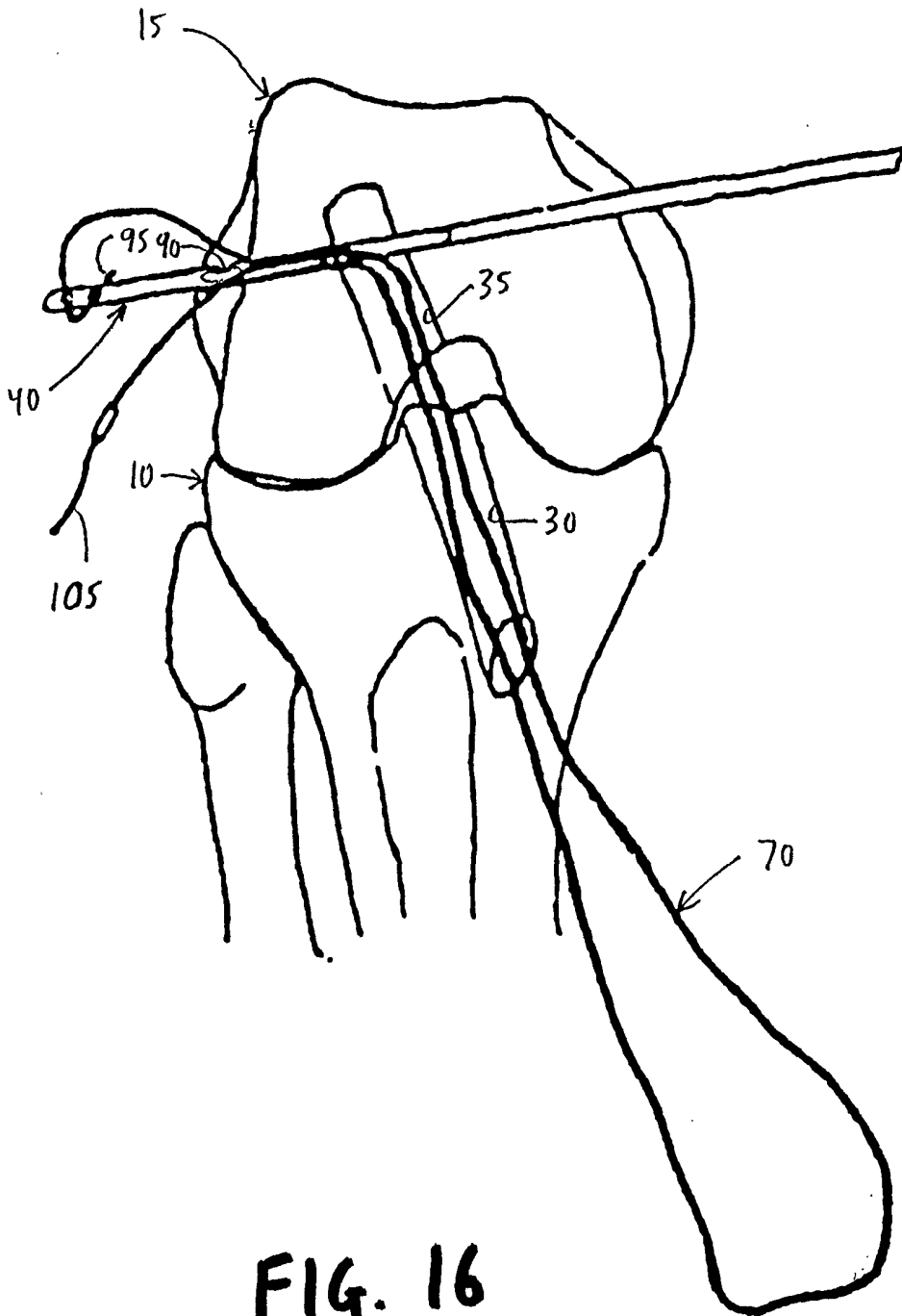


FIG. 16

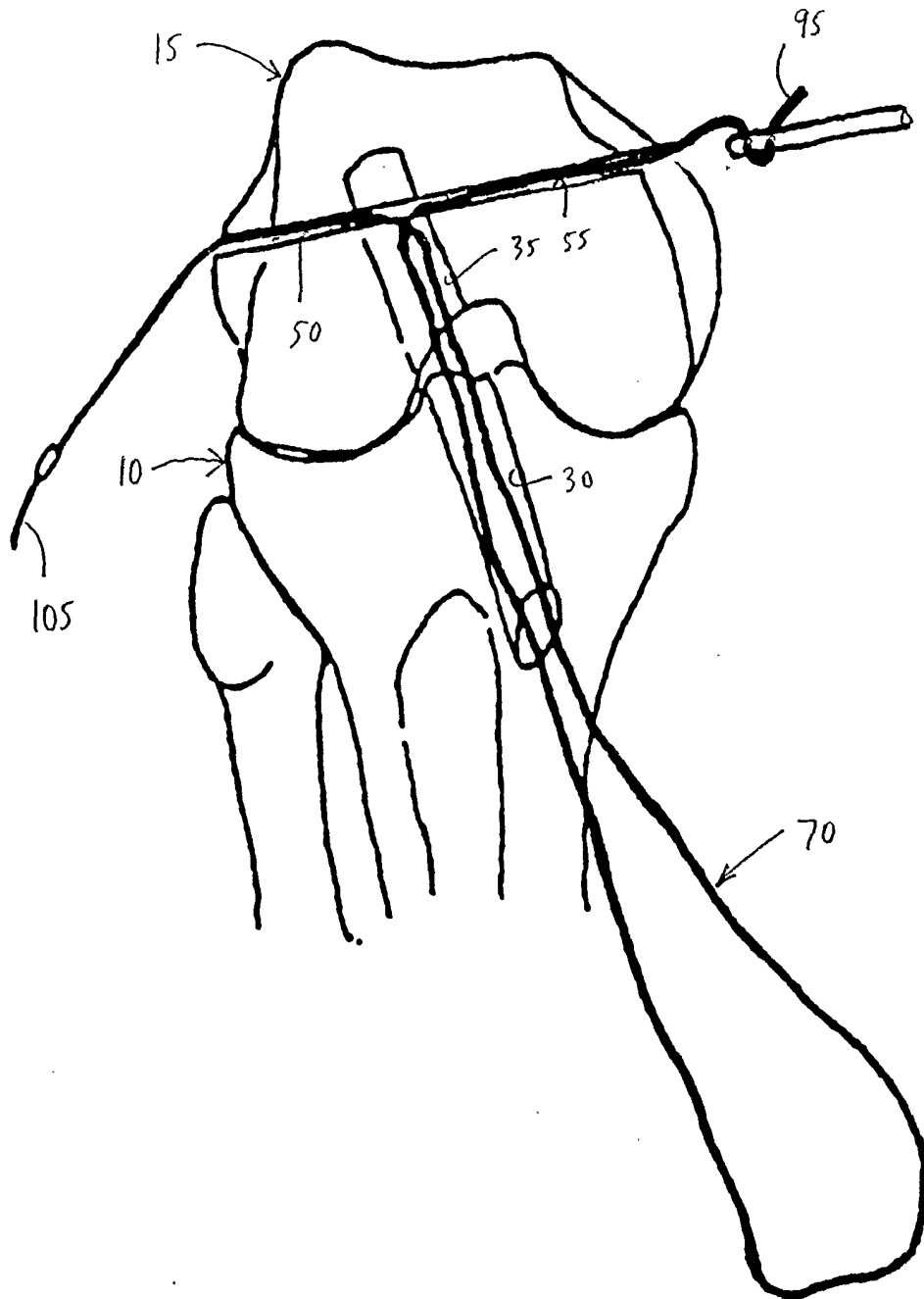


FIG. 17

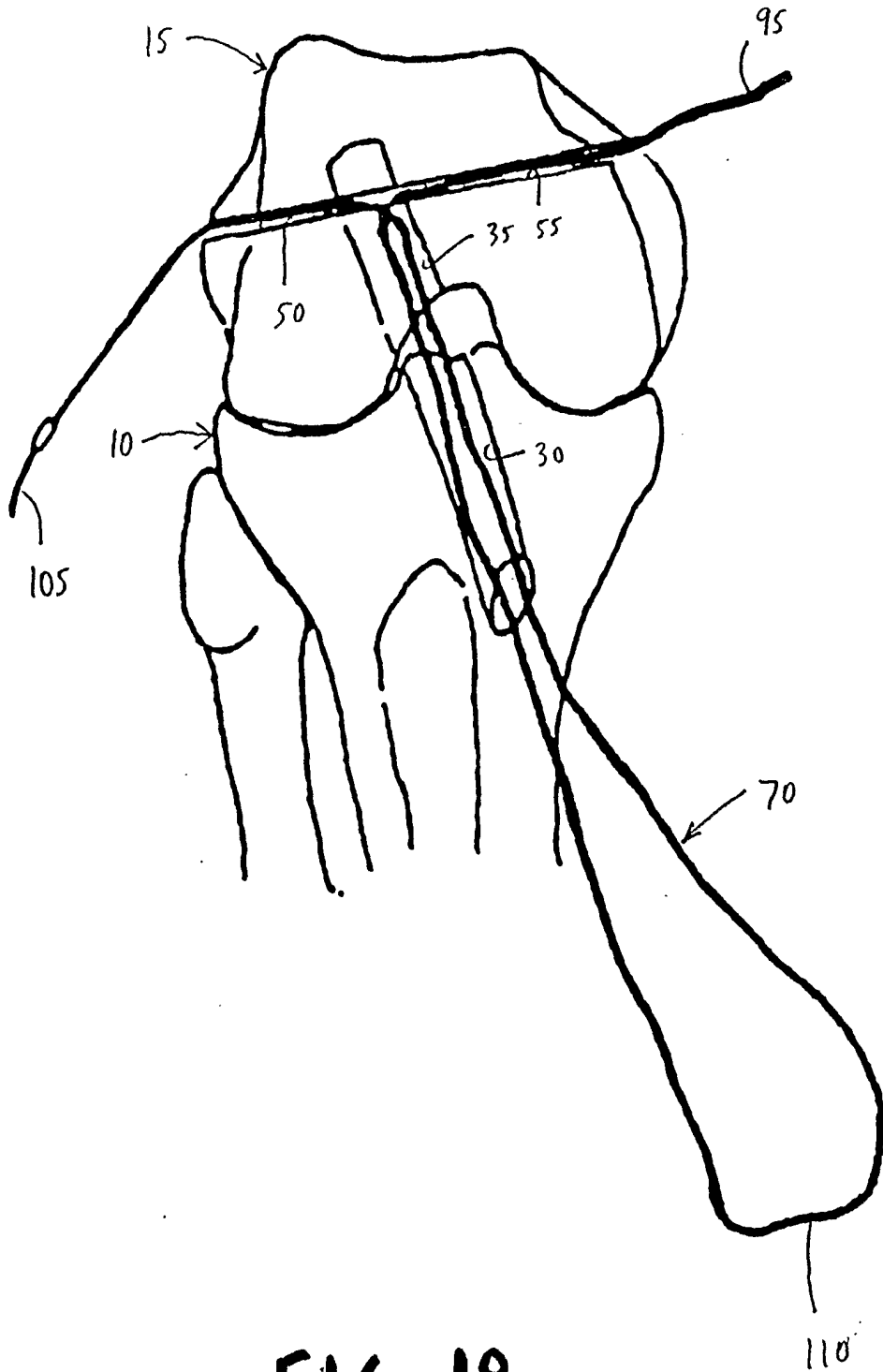


FIG. 18

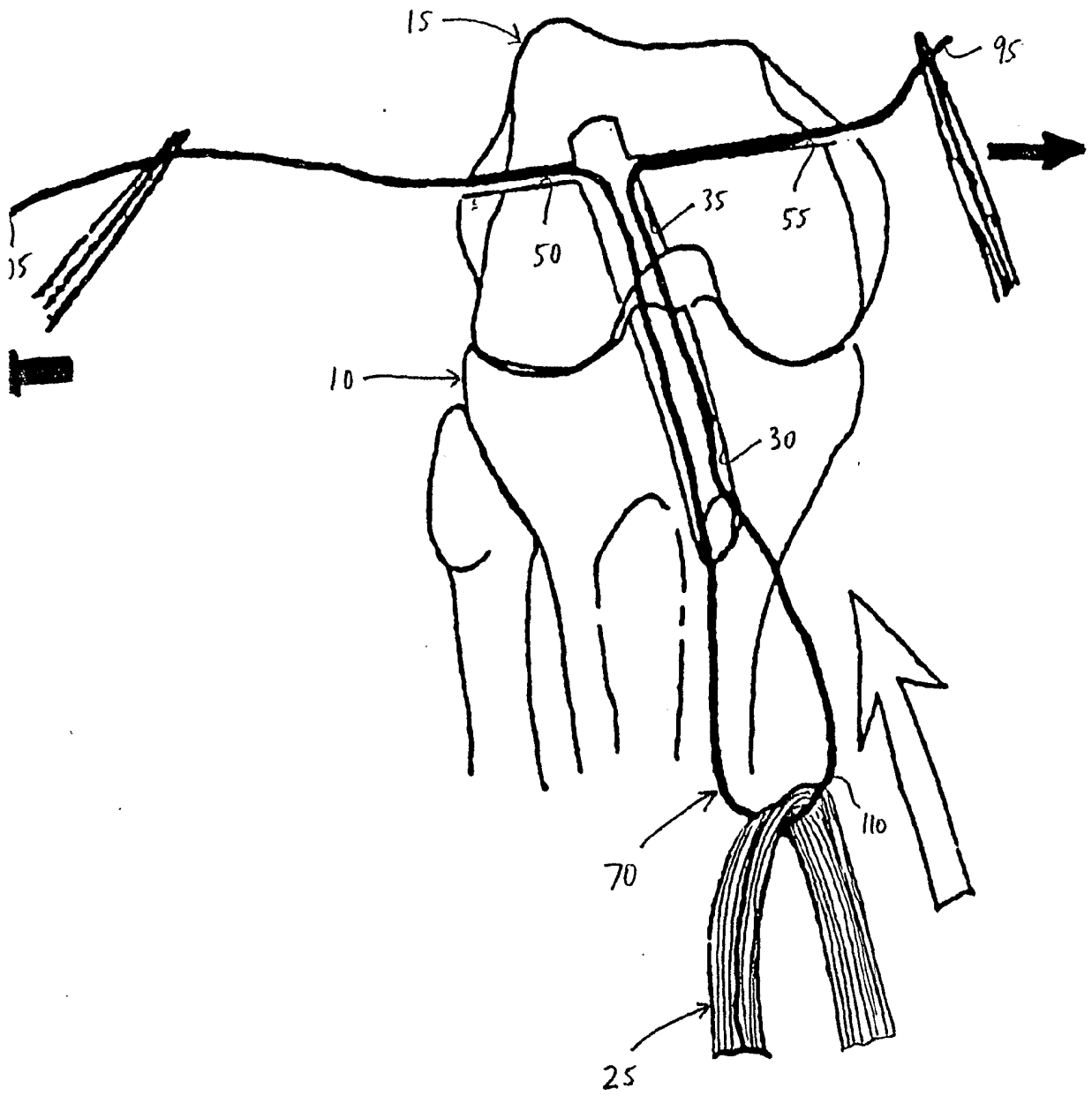


FIG. 19

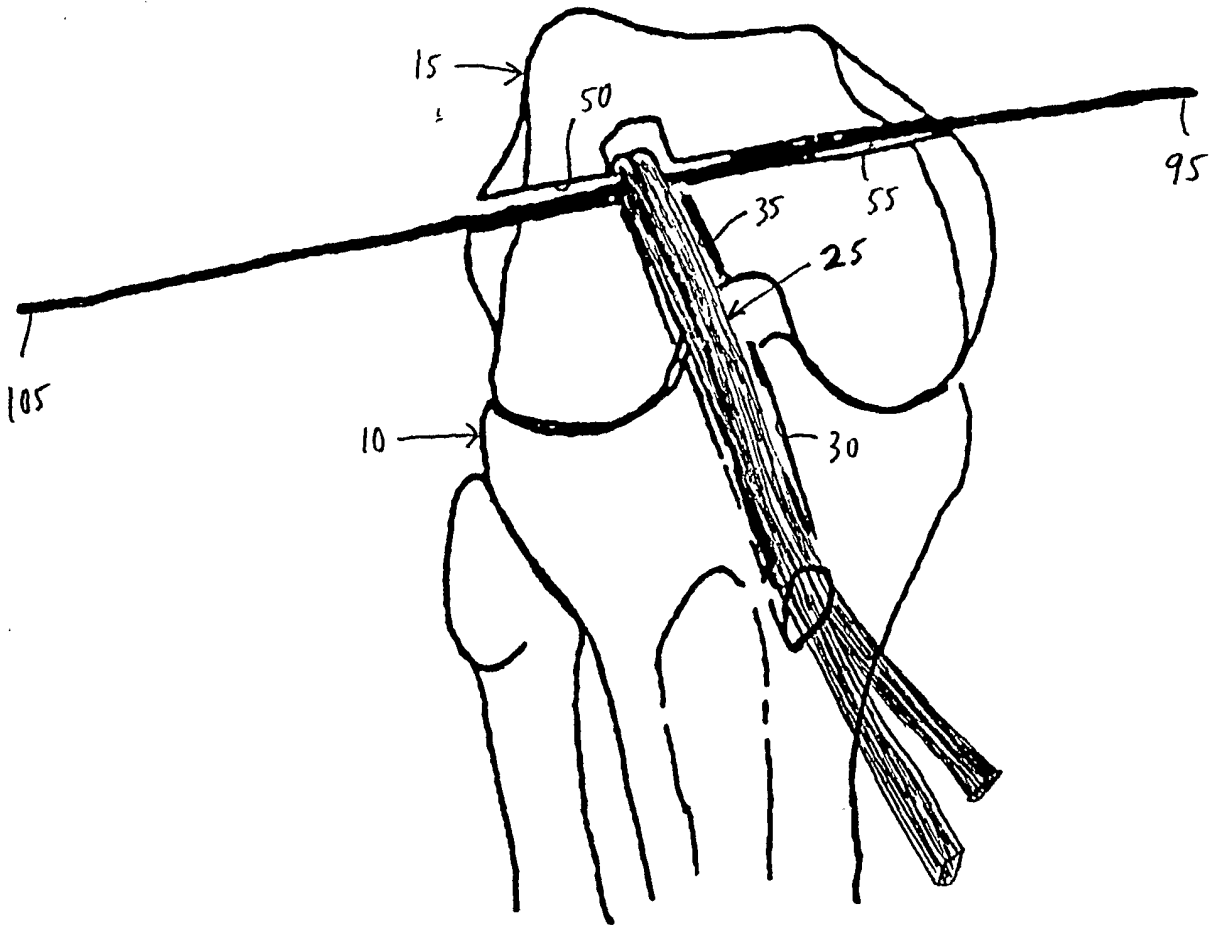


FIG. 20

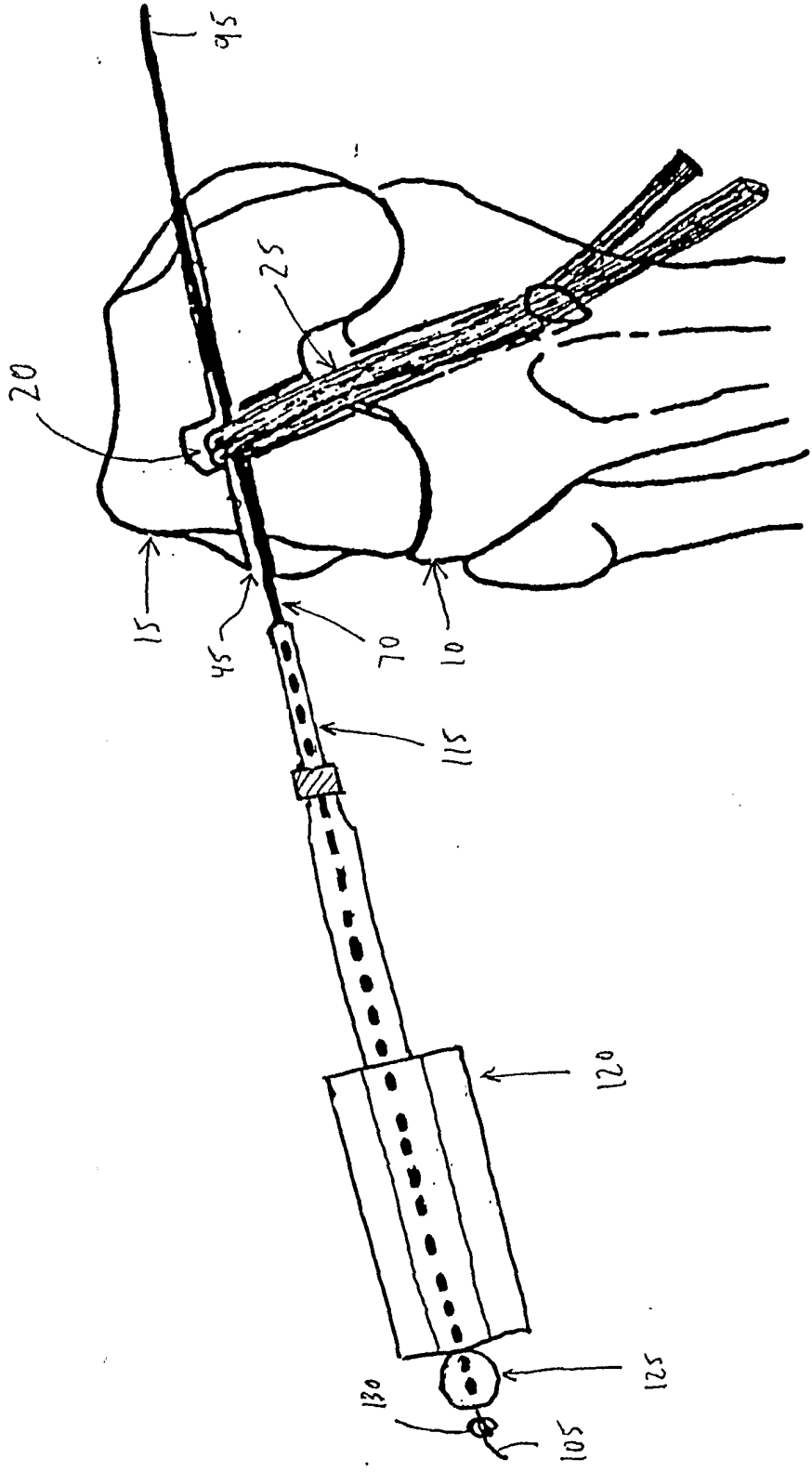


FIG. 21

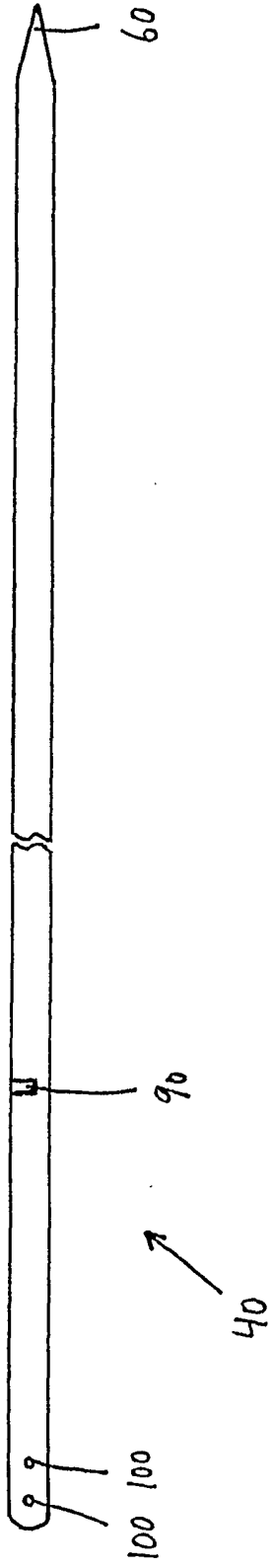
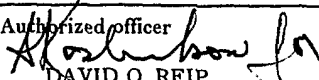


FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/40175

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) :A61B 19/00 US CL : 606/88 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, 86, 88, 96, 98, 99, 103, 104; 623/13.11, 13.12, 13.14 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EAST BRS search terms: acl, ligament, graft, anterior cruciate ligament		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,918,604 A (WHELAN) 06 July 1999, all.	1-12
A	US 5,601,562 A (WOLF et al) 11 February 1997, all.	1-12
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 13 JULY 2001	Date of mailing of the international search report 02 AUG 2001	
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  DAVID O. REIP Telephone No. (703) 308-0858	