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(54) Title: PATIENT SPECIFIC KNEE ALIGNMENT GUIDE AND ASSOCIATED METHOD

(57) Abstract: A method of preparing a joint for a prosthesis in a patient. The method includes obtaining scan data associated with the joint of the patient, preparing a three-dimensional image of the joint based on the scan data, preparing an interactive initial surgical plan based on the scan data, sending the surgical plan to a surgeon, receiving a finalized surgical plan from the surgeon, and preparing an image of a patient-specific alignment guide.



WO 2007/145937 A2

## PATIENT SPECIFIC KNEE ALIGNMENT GUIDE AND ASSOCIATED METHOD

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. Utility Application No. 11/756,057, filed May 31, 2007, and U.S. Provisional Application No. 60/812694, filed June 9, 2006. The disclosure of the above applications are incorporated herein by reference.

### INTRODUCTION

**[0002]** Proper alignment of prosthetic components in knee arthroscopy is an important factor in the longevity and function of the implant. Misalignment can cause increased wear of the implant, patient discomfort, and functional limitation.

**[0003]** Although various methods and devices are known for addressing the above problems, patient specific alignment methods and alignment guides are still desirable.

### SUMMARY

**[0004]** The present teachings provide a method of preparing a joint for a prosthesis in a patient. In one aspect, the method includes obtaining scan data associated with the joint of the patient, preparing a three-dimensional image of the joint based on the scan data, preparing an interactive initial surgical plan based on the scan data, sending the surgical plan to a surgeon, receiving a finalized surgical plan from surgeon, and preparing an image of a patient-specific alignment guide.

**[0005]** In another aspect, the method includes securing a patient-specific alignment guide to a joint surface of the patient, attaching a guide element through the alignment guide to the joint surface, removing the alignment guide without removing the guide element, and resecting the joint surface using the guide element.

**[0006]** The present teachings also provide a method of preparing a knee joint for a prosthesis in a patient. The method includes locking a patient-specific femoral alignment guide onto a femoral joint surface of the patient,

inserting at least one first guide element through the femoral alignment guide into the anterior or the anterior-medial side of the femoral joint surface, and drilling resection-locating apertures in the distal side of femoral joint surface. The method further includes removing the femoral alignment guide without  
5 removing the first guide element, supporting a femoral resection device on the first guide element, and resecting the femoral joint surface.

[0007] Further areas of applicability of the present invention will become apparent from the description provided hereinafter. It should be understood that the description and specific examples are intended for purposes  
10 of illustration only and are not intended to limit the scope of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The present invention will become more fully understood from the detailed description and the accompanying drawings, wherein:

15 [0009] FIG. 1 is a flowchart of an exemplary method of preparing patient specific alignment guides according to the present teachings;

[0010] FIG. 2 is a flowchart of an alignment method according to the present teachings;

20 [0011] FIG. 3 is a view illustrating the mechanical axis in a patient's anatomic image;

[0012] FIG. 4 is a view illustrating the transepicondylar and cylindrical axes in a patient's anatomic image;

[0013] FIG. 5 is a view illustrating the mechanical and anatomic axes in a patient's femoral image;

25 [0014] FIG. 6 is a flowchart of an exemplary method of using patient specific alignment guides according to the present teachings;

[0015] FIG. 7 is an exemplary image of a patient's anatomy with implants shown, as viewed in interactive software according to the present teachings;

30 [0016] FIG. 8 is a perspective view of an exemplary femoral alignment guide according to the present teachings, shown next to a corresponding anatomic femur;

**[0017]** FIGS. 9A and 9B are perspective view of the femoral alignment guide of FIG. 8 shown mounted on the femur;

**[0018]** FIGS. 10A and 10B are perspective view of the femoral alignment guide of FIG. 8 shown with spring pins securing the alignment guide to the femur;

**[0019]** FIG. 11A is a perspective view of the femoral alignment guide of FIG. 8 shown with a drill guide;

**[0020]** FIG. 11B is a perspective view of the femoral alignment guide of FIG. 11A shown with two guide pins drilled through the drill guide;

**[0021]** FIGS. 11C is perspective view of the femoral alignment guide of FIG. 11B showing the removal of the drill guide;

**[0022]** FIG. 12A is a perspective view of the femoral alignment guide of FIG. 11C shown after the removal of the drill guide;

**[0023]** FIG. 12B is a perspective view of the femoral alignment guide of FIG. 12A shown after the removal of the spring pins;

**[0024]** FIG. 13A is a perspective view of FIG. 12B illustrating the guide pins after the removal of the femoral alignment guide;

**[0025]** FIG. 13B illustrated a detail of the femoral alignment guide of FIG. 12B;

**[0026]** FIG. 14A is a perspective view of distal femoral cutting block shown over two pins on a patient's femur, according to the present teachings;

**[0027]** FIG. 14B is a perspective view of distal femoral cutting block shown over two guide pins on a patient's femur, according to the present teachings;

**[0028]** FIG. 15A is a perspective view of an exemplary 4-in-1 cutting block positioned on the femur with reference to holes corresponding to the spring pins;

**[0029]** FIG. 15B a perspective view of the cutting block of FIG. 15A shown with a cutting blade;

**[0030]** FIG. 16A is a perspective view of a tibial alignment guide according to the present teachings, shown mounted on the tibia;

**[0031]** FIG. 16B is a perspective view of the tibial alignment guide of

FIG. 16A shown with a drill guide;

[0032] FIG. 16B is a perspective view of the tibial alignment guide of FIG. 16A shown with a drill guide;

[0033] FIG. 16C is a perspective view of FIG. 16B illustrating the guide pins after the removal of the tibial alignment guide; and

[0034] FIG. 16C is a perspective view of FIG. 16C illustrating a tibial cutting guide mounted on the guide pins.

#### DESCRIPTION OF VARIOUS ASPECTS

[0035] The following description is merely exemplary in nature and is in no way intended to limit the scope of the present teachings, applications, or uses. For example, although the present teachings are illustrated for alignment guides in knee surgery, the present teachings can be used for other guides, templates, jigs, drills, rasps or other instruments used in various orthopedic procedures.

[0036] The present teachings provide a method for preparing patient-specific alignment guides for use in orthopedic surgery for a joint, such as, for example, the knee joint. Conventional, not patient-specific, prosthesis components available in different sizes can be used with the alignment guides, although patient-specific femoral and tibial prosthesis components prepared with computer-assisted image methods can also be used. Computer modeling for obtaining three dimensional images of the patient's anatomy, such as a patient's joint, for example, the patient-specific prosthesis components, when used, and the alignment guides and templates can be provided by various CAD programs and/or software available from various vendors or developers, such as, for example, from Materialise USA, Ann Arbor, Michigan.

[0037] Referring to FIG. 1, an MRI scan or a series of CT scans of the entire leg of the joint to be reconstructed, including hip and ankle, as shown in FIG. 3, can be performed at a medical facility or doctor's office, at aspect 10. In some cases, the scan may be performed with the patient wearing an unloader brace to stress the ligaments. The scan data obtained can be sent to a manufacturer, at aspect 20. The scan data can be used to construct a three-

dimensional image of the joint and provide an initial implant fitting and alignment in a computer file form or other computer representation. The initial implant fitting and alignment can be obtained using an alignment method, such as the alignment method illustrated in FIG. 2 and described below. Other alignment  
5 methods can also be used, such as alignment protocols used by individual surgeons.

**[0038]** The outcome of the initial fitting is an initial surgical plan that can be printed or provided in electronic form with corresponding viewing software. The initial surgical plan can be surgeon-specific, when using surgeon-specific alignment protocols. The initial surgical plan, in a computer file form  
10 associated with interactive software, can be sent to the surgeon, or other medical practitioner, for review, at 30. The surgeon can incrementally manipulate the position of images of implant components 502, 504 in an interactive image form 500 of the joint, as illustrated in FIG. 7. After the surgeon  
15 modifies and/or approves the surgical plan, the surgeon can send the final, approved plan to the manufacturer, at 40.

**[0039]** Various methods of sending the initial and final surgeon-approved surgical plans can be used. The surgical plans can be, for example, transferred to an electronic storage medium, such as CD, DVD, flash memory,  
20 which can then be mailed using regular posting methods. Alternatively, the surgical plan can be e-mailed in electronic form or transmitted through the internet or other web-based service, without the use of a storage medium.

**[0040]** After the surgical plan is approved by the surgeon, patient-specific alignment guides for the femur and tibia can be developed using a CAD  
25 program or other imaging software, such as the software provided by Materialise, for example, according to the surgical plan, at 50. Computer instructions of tool paths for machining the patient-specific alignment guides can be generated and stored in a tool path data file, at 60. The tool path can be provided as input to a CNC mill or other automated machining system, and the  
30 alignment guides can be machined from polymer, ceramic, metal or other suitable material, and sterilized, at 70. The sterilized alignment guides can be shipped to the surgeon or medical facility, at 80 for use during the surgical

procedure.

[0041] Referring to FIG. 2, an exemplary method for providing the initial implant fitting and alignment is illustrated. The method can be modified or completely replaced according to a surgeon-specific alignment protocol. After  
5 the scan data is converted to three dimensional images of the patient anatomy from hip to ankle, images of the tibial and femoral components can be manipulated for obtaining patient-specific alignment by making use of the femoral and tibial mechanical axes 402, 404, illustrated in FIG. 3, and the transepicondylar and cylindrical axes 406, 408, illustrated in FIG. 4. Images of  
10 the knee joint anatomy can include images of the joint surfaces of the distal femur and proximal tibial with or without the associated soft tissues, such as articular cartilage, on the respective bone surfaces.

[0042] Generally, the femoral mechanical axis is defined as the line joining the center of the femoral head and the center of the intercondylar notch.  
15 The femoral anatomic axis is defined as the line along the center of the femoral shaft. The tibial mechanical axis is the line joining the center of the tibial plateau to the center of the tibial plafond or the center of the distal end of the tibia. The tibial anatomic axis is the line along the center of the tibial shaft. The transepicondylar axis is the line connecting the most prominent points of the  
20 epicondyles. The cylindrical axis is the line connecting the centers of the condyles when the condyles are approximated by coaxial cylinders. A detailed discussion of the various joint-related axes and the relation of the transepicondylar axis 406 and cylindrical axis 408 is provided in Eckhoff et al, *Three-Dimensional Mechanics, Kinematics, and Morphology of the Knee Viewed in Virtual Reality*, J Bone Joint Surg Am. 87:71-80, 2005, which is incorporated  
25 herein by reference.

[0043] The relation of the femoral mechanical axis 402 to the anatomic axis 410 for the femur is illustrated in FIG. 5. The femoral and tibial mechanical axes 402, 404 may or may not coincide, as illustrated in FIG. 3. In the following  
30 discussion, reference is made to a single mechanical axis 401 encompassing the femoral and tibial mechanical axes 402, 404. The alignment procedure illustrated in FIG. 2 makes use of the mechanical, anatomic, transepicondylar

and cylindrical axes in various degrees. The present teachings, however, are not limited to this alignment procedure. Multiple alignment procedures can be provided to accommodate the experience and preference of individual surgeons. For example, the alignment procedure can be based on the anatomic and mechanical axes, or can be substantially based on the cylindrical axis. Further,  
5 the alignment procedure can be deformity-specific, such that is adapted, for example, to a valgus or varus deformity.

**[0044]** With continued reference to FIG. 2-5 and 7, in the image space, the tibial component 504 can be aligned 90° to the mechanical axis 401, at aspect 90. In the frontal plane, the femoral component 502 can be aligned 90°  
10 to the mechanical axis 401, at aspect 100. The femoral component 502 can be positioned for "x" mm distal resection, at 110, where "x" can be about 9 mm or as other measurement as indicated for a specific patient. The femoral component 502 can be rotated until its distal surfaces are at 90° to the distal femoral bow  
15 (component flexion/extension), at 120. The femoral component 502 can be moved anteriorly/posteriorly until the posterior medial condyle resection is greater or equal to "x" mm, at aspect 130.

**[0045]** The femoral component size can be determined by observing the anterior resection relative to anterior cortex, at 140. If the femoral size is  
20 adjusted, the new size can be positioned at the same location relative to the distal and posterior cut planes.

**[0046]** The cylindrical axis 408 of the femur can be located, at aspect 150. The tibia can be flexed 90° relative to the femur about the cylindrical axis 408, at aspect 160. The femoral component 502 can be rotated about the  
25 medial condyle until a rectangular flexion space is achieved, at aspect 170. Alternatively, the rotation can be relative to the transepicondylar axis, anterior/posterior axis, and posterior condylar axis, or a combination of all four axes. The femoral component 502 can be centered or lateralized on the femur, at aspect 180. The location for various distal holes for locating the femoral  
30 resection block can be also determined.

**[0047]** Referring to FIGS. 6, and 8-15B, an exemplary alignment guide 600 and method of use is illustrated in connection with the patient's femur 80.



Reference numbers 200-250 relate to aspects of the method of FIG. 6 and are described in connection with the instruments shown in FIGS. 8-15B for the femur 80.

**[0048]** The alignment guide 600 includes an inner guide surface 640  
5 designed to closely conform, mate and match the femoral joint surface 82 of the patient in three-dimensional space such that the alignment guide 600 and the femoral joint surface are in a nesting relationship to one another. Accordingly, the alignment guide 600 can conform, mate and snap on or "lock" onto the distal surface of the femur 80 in a unique position determined in the final surgical plan,  
10 at 200. The alignment guide 600 can have variable thickness. In general, the alignment guide 600 can be made as thin as possible while maintaining structural stiffness. For example, certain areas around and adjacent various securing or guiding apertures 602, 606 can be thickened to provide structural support for guiding a drill or for holding a drill guide or supporting other tools or  
15 devices. Exemplary thickened areas 642 are indicated with dotted lines in FIGS. 9A and 9B. Other areas can be cut out for viewing the underlying bone or cartilage of femoral joint surface 82. Viewing areas 644 are indicated with dotted lines in FIGS. 9A and 9B.

**[0049]** Referring to FIGS. 10A and 10B, the alignment guide 600 can  
20 be secured to the femoral joint surface 82 with fixation members or fasteners 624, such as, for example, spring pins, or other securing fasteners that are received through distal apertures 602 of the alignment guide 600. Locating holes 602a corresponding to the apertures 602 of the alignment guide 600 can be drilled in the distal femur 80 to locate a femoral resection block or other  
25 cutting device 620, such as a 4-in-1 cutting block, at 220. The alignment guide 600 can also include guiding apertures 606. Guiding apertures 606 are shown in the anterior-medial side relative to the femur 80, but can also be made in the anterior side of the femur 80 or in other locations and orientations. The guiding apertures 606 can be counter-bored and have a partially open portion 608 in  
30 their perimeter for sliding the alignment guide off pins or other fasteners without removing such fasteners, as shown in FIG. 13A and discussed below.

[0050] Referring to FIGS. 11A and 11B, a drill guide 700 can be placed in alignment with the guiding apertures 606. The drill guide 700 can include a body 702 having guiding bores 704 corresponding to the guiding apertures 606. The guiding bores 704 can have portions 706 that extend beyond the body 702 and into the guiding apertures 606 for facilitating alignment. The drill guide 700 can also include a handle 710 extending sideways from the body 702 and clear from the drilling path.

[0051] Referring to FIGS. 11C, guide elements 604, such as pins or other fasteners, for example, can be drilled through the guiding bores 704 of the drill guide 700 on the anterior or anterior-medial side of the femur 80, at aspect 210 of the method of FIG. 6. The guide elements 604 can be parallel or at other angles relative to another. The guide elements 604 can define a plane that is parallel to a distal resection plane for the femur.

[0052] Referring to FIG. 12A, the drill guide 700 can be removed. Referring to FIGS. 12B-13B, the fasteners 624 can be removed, and the alignment guide 600 can be removed from the femur 80 by sliding the alignment guide 600 off the guide elements 604 through the open portions 608 of the guiding apertures 606 without removing the guide elements 604 at the anterior/medial corner of the knee, at aspect 230 of FIG. 6.

[0053] The guide elements 604 can be used to prepare the joint surfaces for the prosthesis by mounting cutting guides/blocks for resecting the joint surface. Alternatively, a robotic arm or other automated, guided or computer controlled device that can guide the resections based on the pre-operative surgical plan can be mounted on the guide elements 604 and assist the surgeon in preparing the joint surface for the prosthesis.

[0054] Referring to FIGS. 14A and 14B, exemplary distal cutting blocks 610a, 610b that can be mounted over the guide element 604 for making the distal resection, at aspect 640 of FIG. 6, are illustrated. A third fixation element 605, obliquely oriented relative to the guide elements 604 can also be used. The distal cutting blocks 610a, 610b can have an inner surface 612a, 612b that generally follows the shape of the femur 80 to a lesser or greater degree. The distal cutting blocks 610a, 610b can be disposable or re-usable.

**[0055]** Referring to FIGS. 15A and 15B, after the distal resections are made with the distal cutting block 610a or 610b, the femoral resection block 620 can be mounted with pegs or other supporting elements 622 into the holes 602a corresponding to the fasteners 624. The femoral resections can be made using, for example, a cutting blade 630 through slots 632 of the femoral resection block 620, at aspect 250 of FIG. 6.

**[0056]** Referring to FIGS. 6 and 16A-D, an exemplary alignment guide 600 is illustrated in connection with the patient's tibia 81. Reference numbers 260-300 relate to aspects of the method of FIG. 6 and are described in connection with the instruments shown in FIGS. 16A-16D for the tibia.

**[0057]** The alignment guide 600 can conform, nestingly mate in three-dimensional space and snap on or "lock" by design onto the tibia 81 in a unique position, at aspect 260 of FIG. 6. The alignment guide 600 can wrap around the anterior-medial edge of the tibia 81, as shown in FIG. 16A. The drill guide 700 can be aligned with the counter-bored guiding apertures 606 of the alignment guide 600, as shown in FIG. 16B. Two or more guide elements 604 can be placed on the anterior medial side of the tibia, at aspect 270 of FIG. 6. An additional fixation element can also be used for additional securing for the alignment guide 600. The drill guide 700 and the alignment guide 600 can be removed, leaving behind the guide elements 604 attached, at aspect 280 of FIG. 6, and as shown in FIG. 16C. A disposable or reusable tibial cutting block 750 can be slid over the guide elements 604, at aspect 290 of FIG. 6, and as shown in FIG. 16D. The tibial cutting block 750 can include a series of holes 752, allowing the cutting block 750 to be translated proximally or distally to adjust the level of the distal resection. The tibial resection can be made, at 300.

**[0058]** The present teachings provide patient-specific alignment guides that can be used for alignment in orthopedic surgery. Each alignment guide includes an inner surface that nestingly mates and conforms in three-dimensional space with a corresponding joint surface of a specific patient. The alignment guides can be used for locating guide elements on the joint surface. After the alignment guides are removed, cutting guides or other cutting devices, including automated or robotic devices, can be mounted on the guide elements

for making various resection cuts. Because the alignment guides are not used for cutting, the alignment guides do not require substantive thickness to extend anteriorly, and consequently have a lower profile, and less weight. Additionally, because the alignment guides are removed before cutting, the present teachings  
5 provide increased ability to visualize the cuts and the cutting process.

**[0059]** The foregoing discussion discloses and describes merely exemplary arrangements of the present teachings. One skilled in the art will readily recognize from such discussion, and from the accompanying drawings, that various changes, modifications and variations can be made therein without  
10 departing from the spirit and scope of the present teachings.

## CLAIMS

What is claimed is:

1. A method of pre-operative planning for an orthopedic procedure in  
5 a patient comprising:  
obtaining scan data associated with a joint of the patient;  
preparing a three-dimensional image of the joint based on the scan  
data;  
preparing an interactive initial surgical plan based on the scan  
10 data;  
sending the surgical plan to a surgeon;  
receiving a finalized surgical plan from the surgeon; and  
preparing an image of a patient-specific alignment guide.
- 15 2. The method of claim 1, wherein preparing an interactive initial  
surgical plan comprises aligning the joint based on mechanical or anatomic axes  
of the joint.
3. The method of claim 2, further comprising aligning the joint based  
20 on a cylindrical or transepicondylar axis of the joint.
4. The method of claim 1, further comprising generating tool path data  
for making the alignment guide.
- 25 5. The method of claim 4, further comprising:  
making the alignment guide; and  
sending the alignment guide to the surgeon.
6. The method of claim 4, further comprising sterilizing the alignment  
30 guide.
7. The method of claim 1, wherein preparing an image of an initial

patient-specific alignment guide for the joint includes conforming an inner surface of the alignment guide to a portion of a joint surface.

8. The method of claim 7, further comprising forming resection-guiding apertures in the alignment guide.

9. The method of claim 1, wherein sending the surgical plan to a surgeon includes sending the surgical plan in electronic form.

10. The method of claim 1, wherein sending the surgical plan to a surgeon includes sending the surgical plan in a storage medium or over the Internet or by e-mail.

11. A device made based on pre-operative planning for an orthopedic procedure in a patient, the device comprising:

a three-dimensional inner surface shaped to contact and mate with a three-dimensional portion of the joint surface of a specific patient;

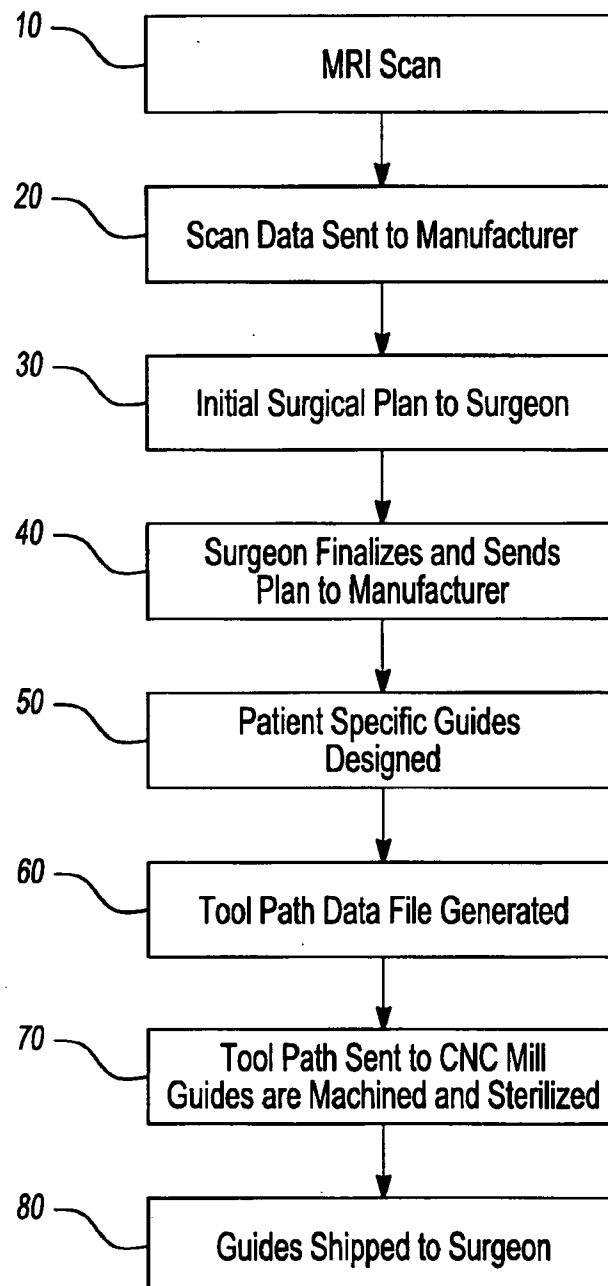
at least one guiding aperture having a perimeter with an open portion, the guiding aperture extending through a thickness of the device; and

a reinforcement area surrounding the guiding aperture.

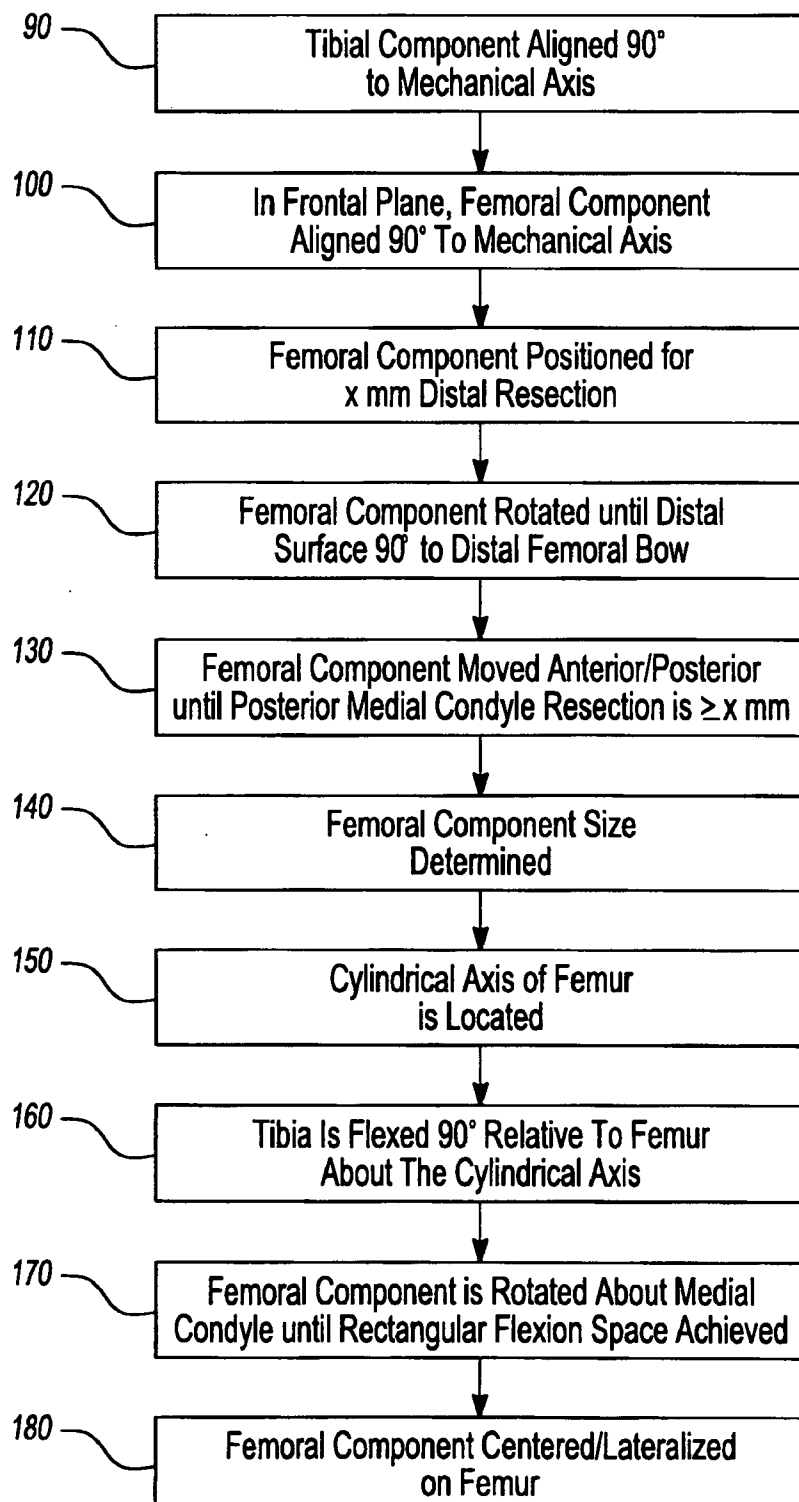
12. The device of claim 11, wherein the reinforcement area provides structural support for a tool insertable into the guiding aperture.

13. The device of claim 11, further including an enlarged opening forming a viewing window.

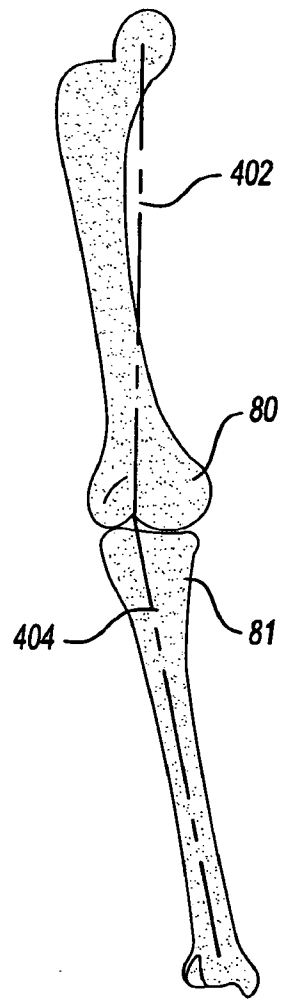
1/14

**Fig-1**

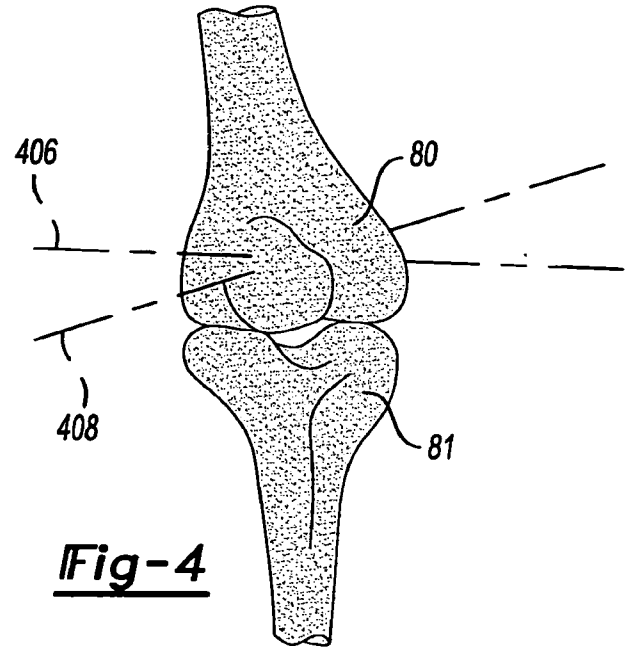
2/14

**Fig-2**

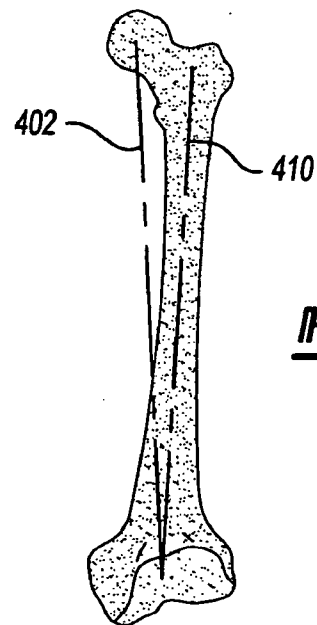




**Fig-3**

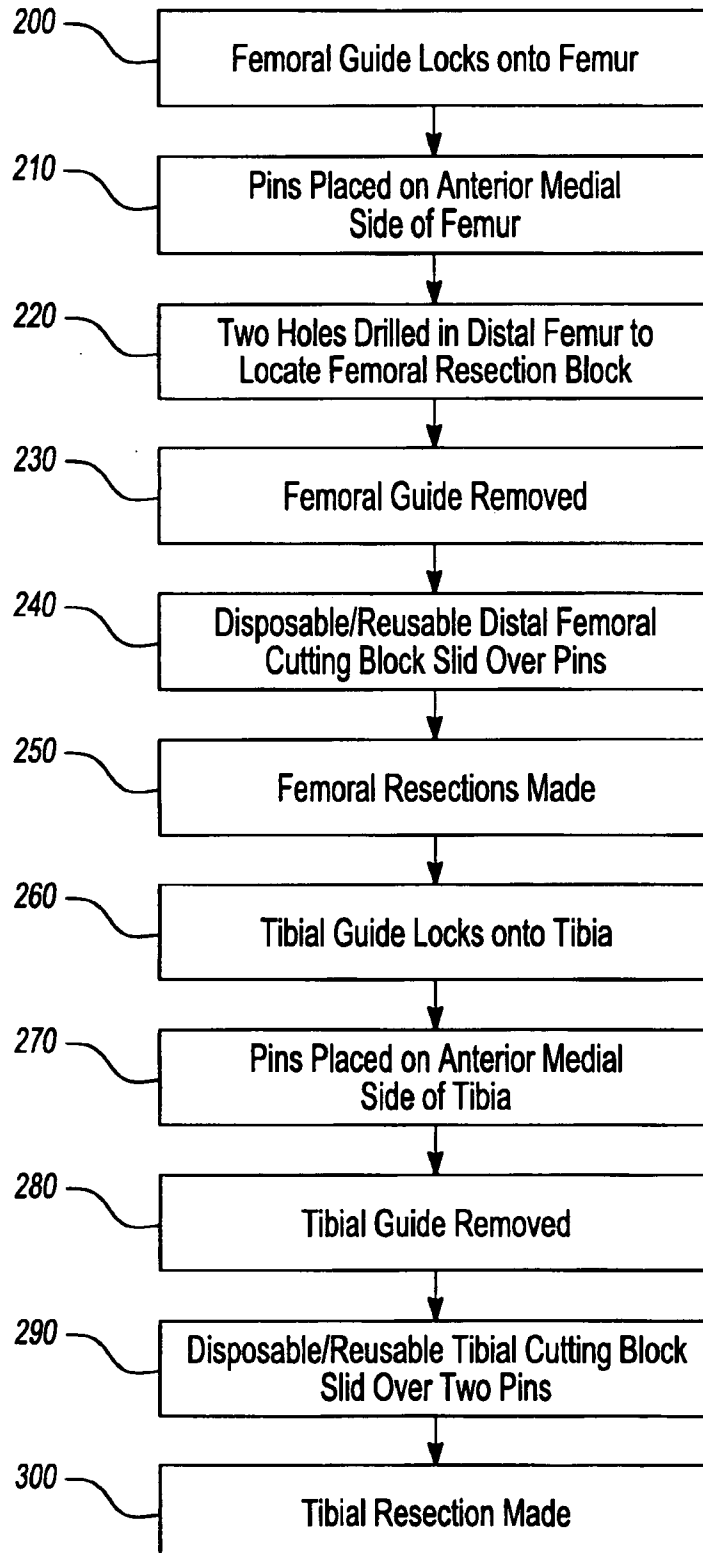


**Fig-4**

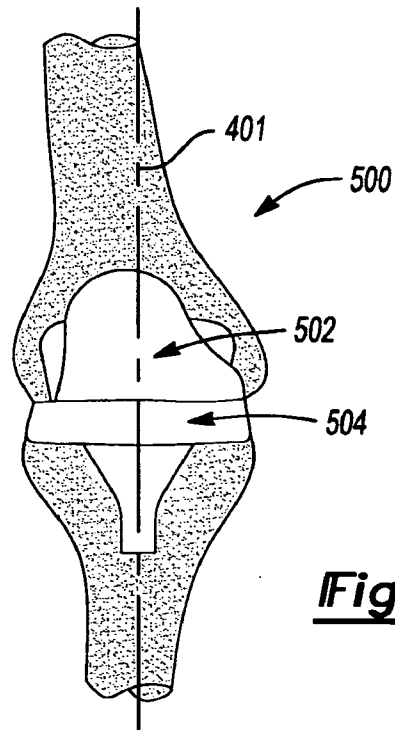


**Fig-5**

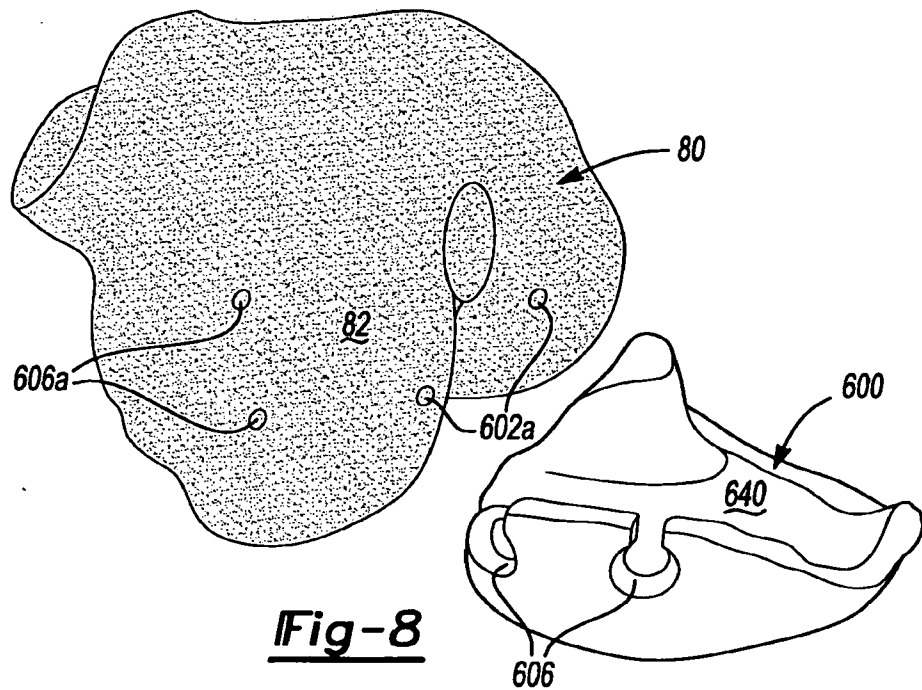
4/14

**Fig-6**

5/14

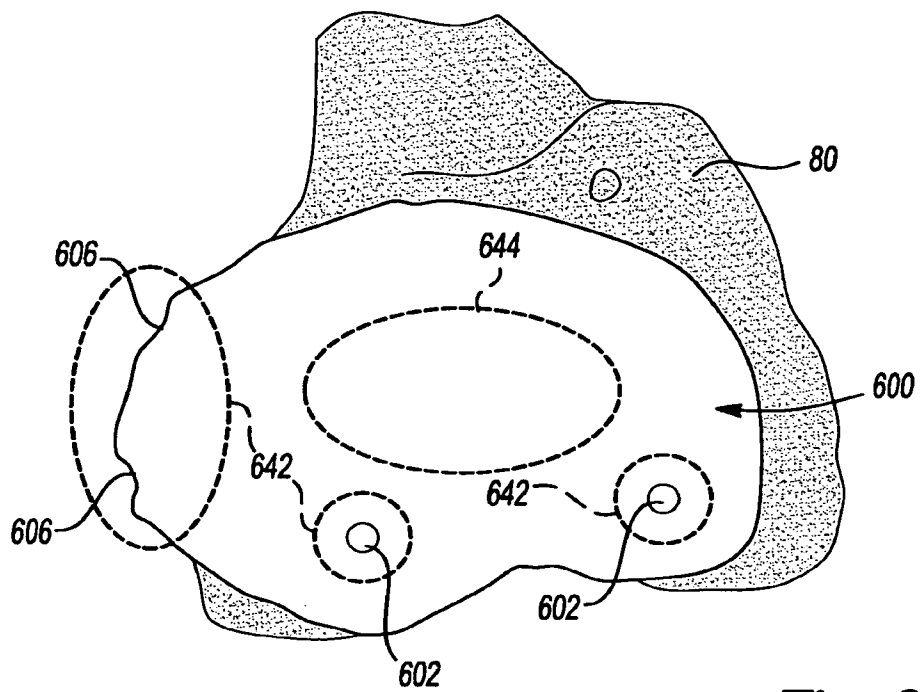


**Fig-7**

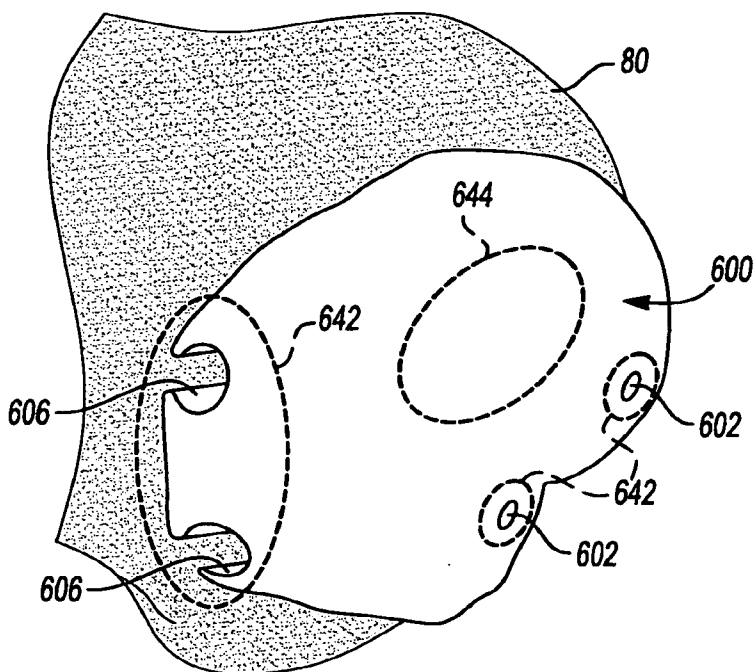


**Fig-8**

6/14



**Fig-9A**



**Fig-9B**

7/14

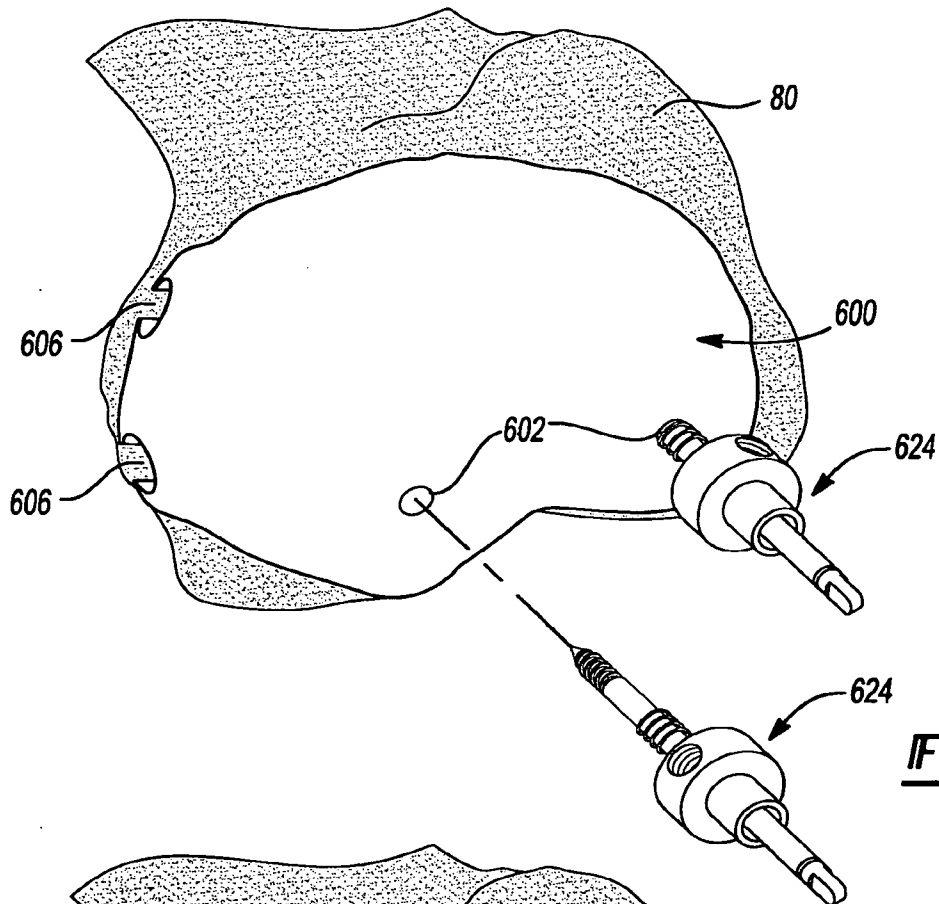


Fig-10A

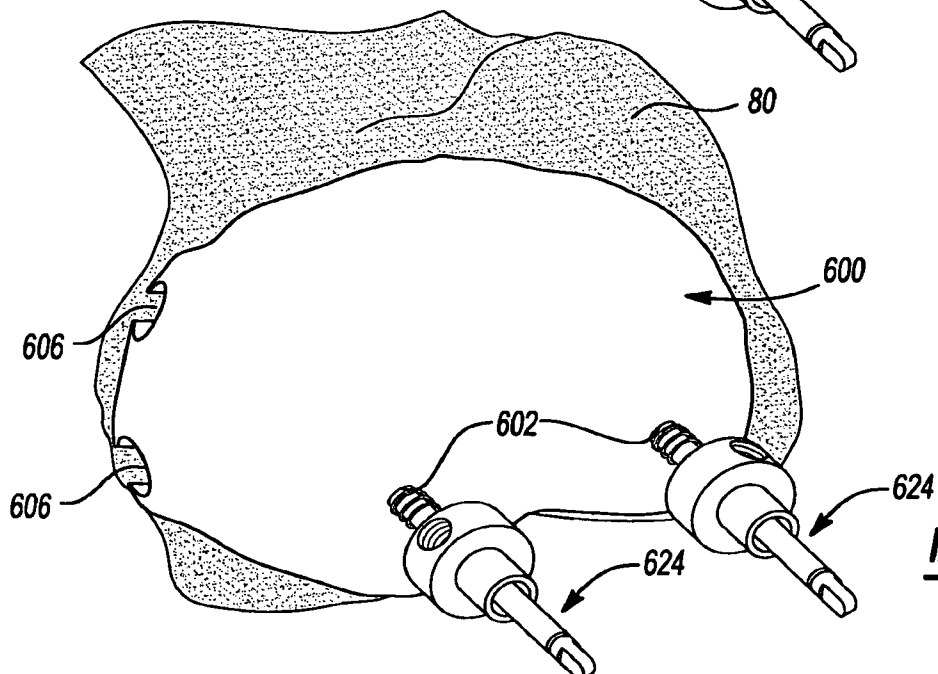
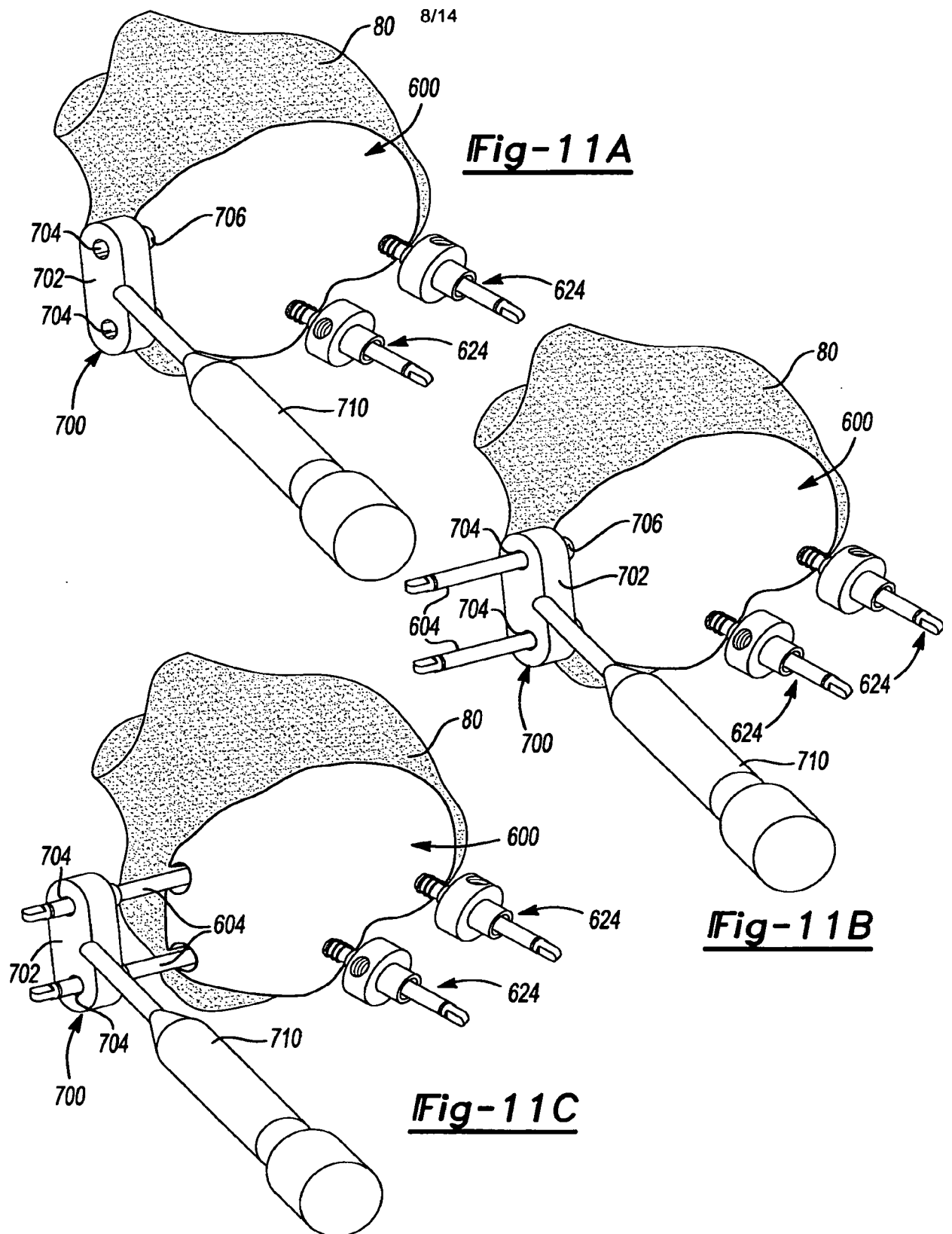
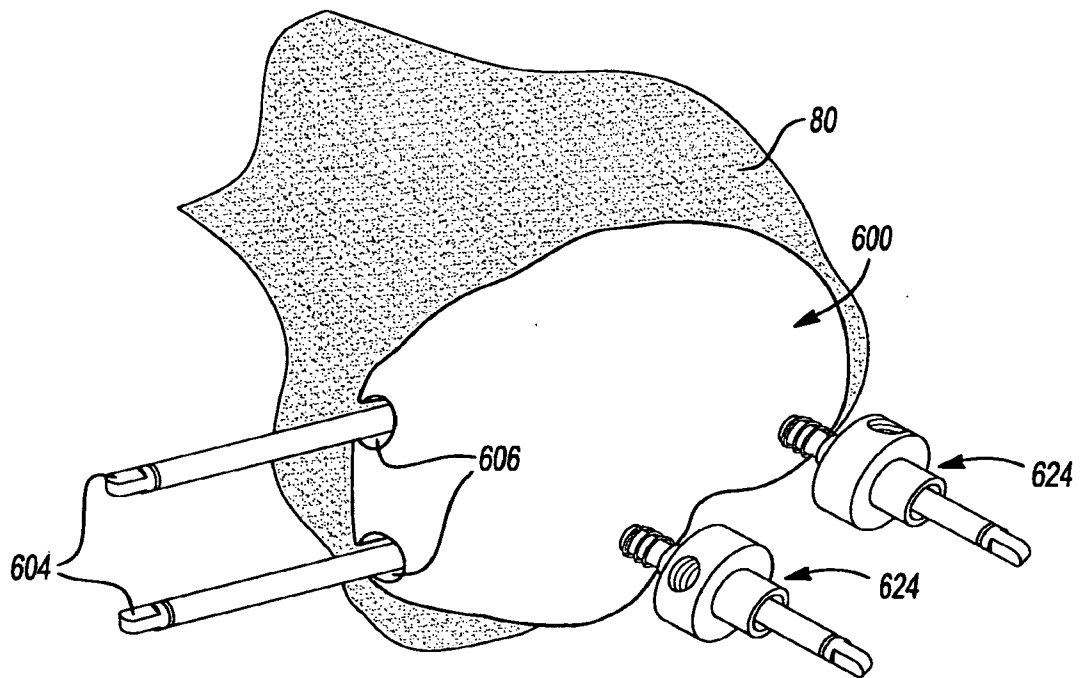


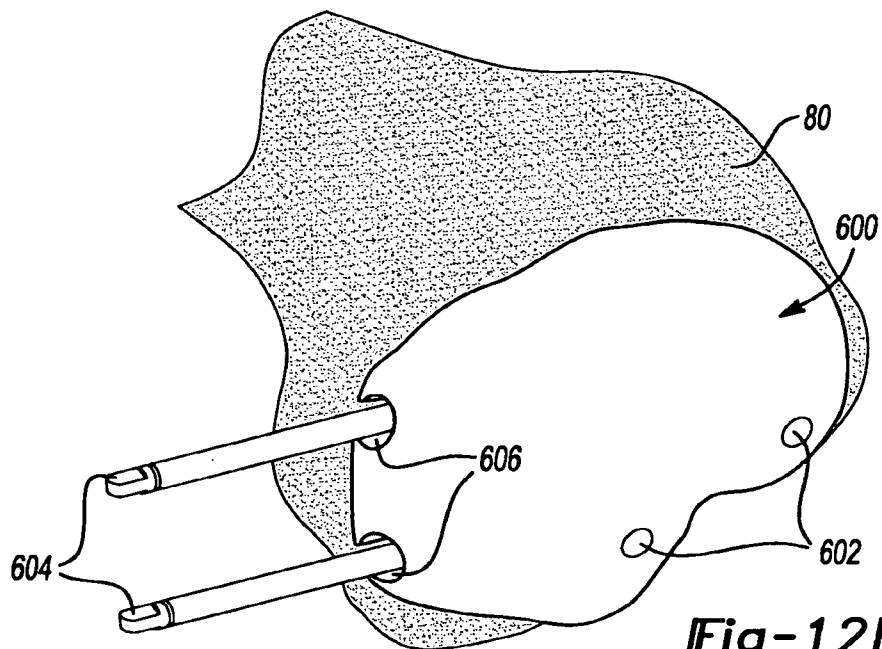
Fig-10B



9/14

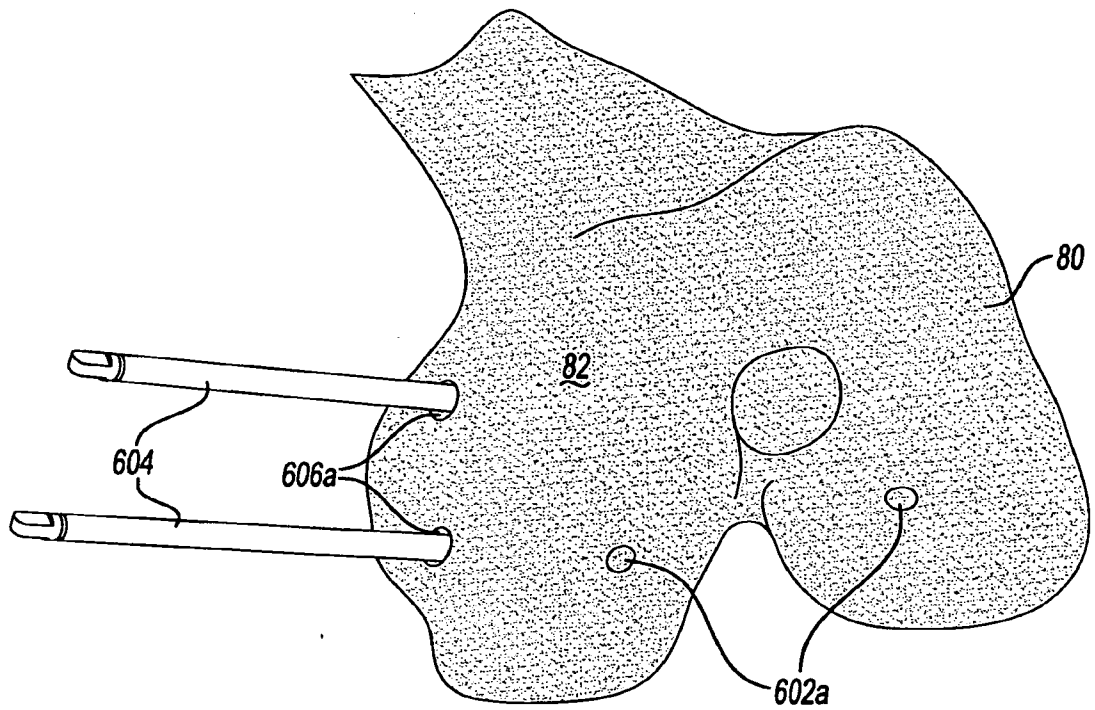


**Fig-12A**

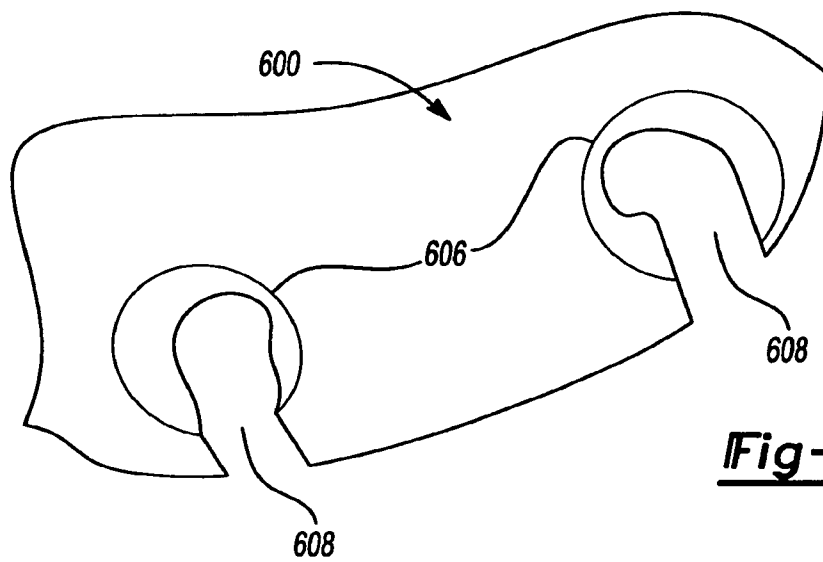


**Fig-12B**

10/14

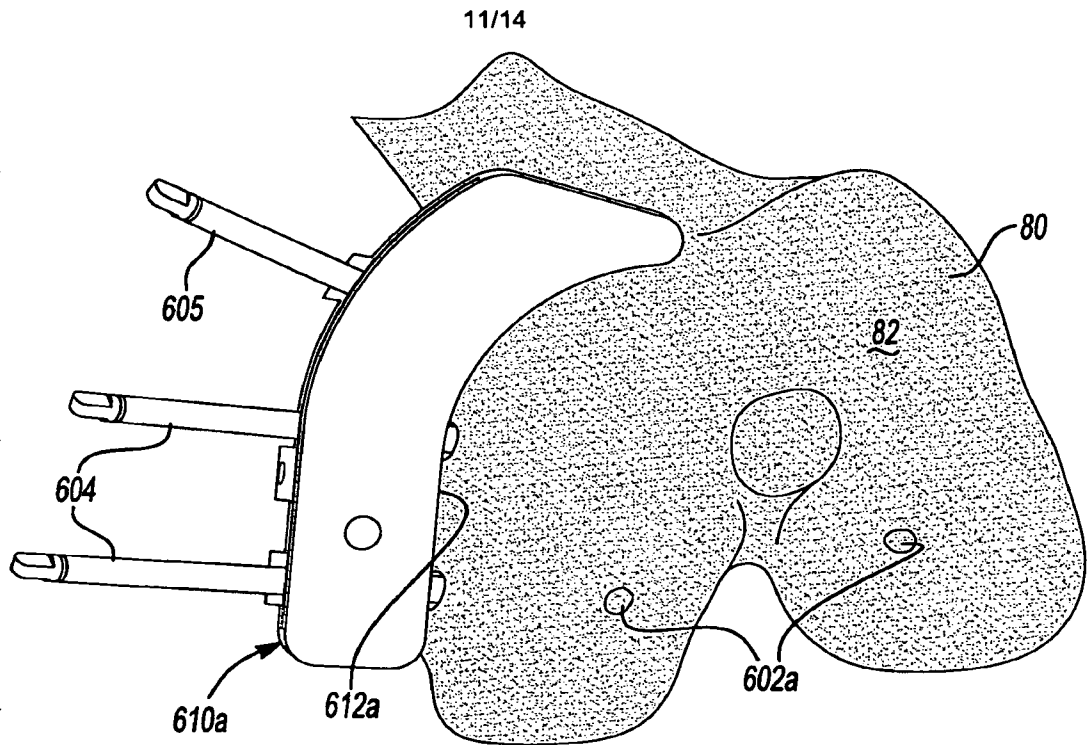


**Fig-13A**

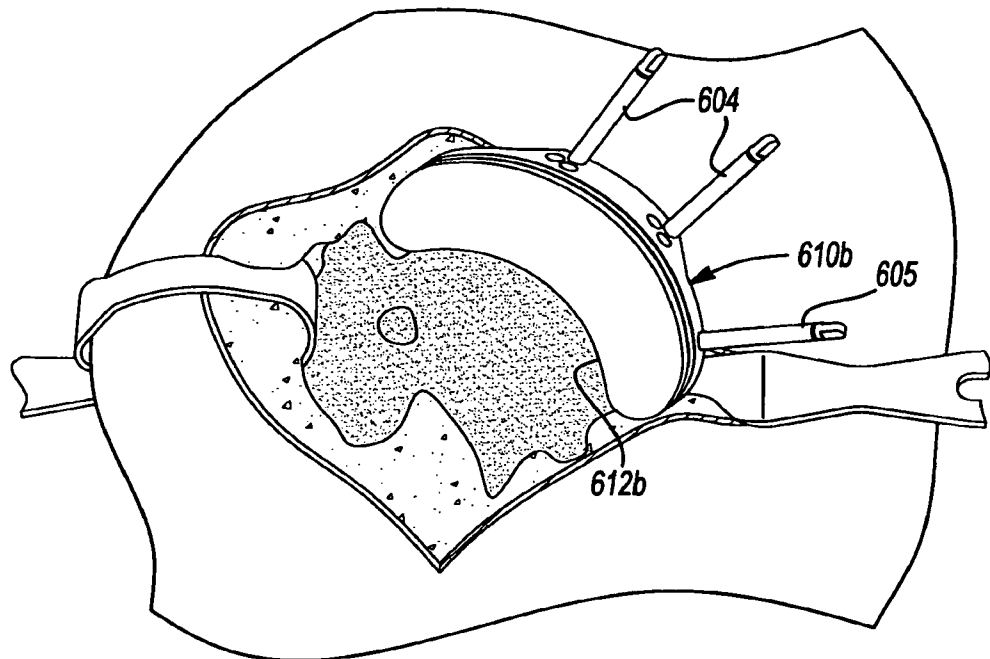


**Fig-13B**



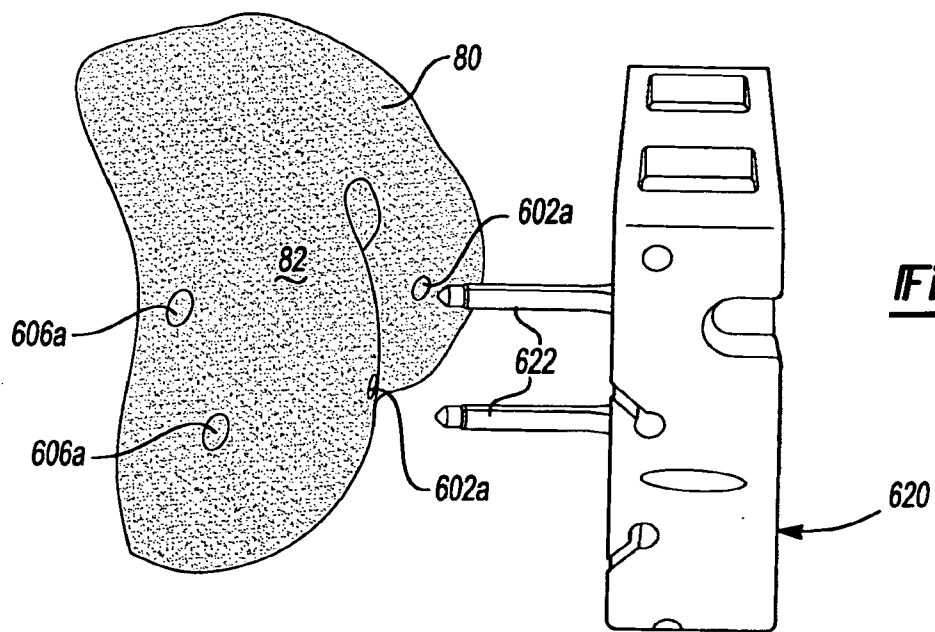


**Fig-14A**

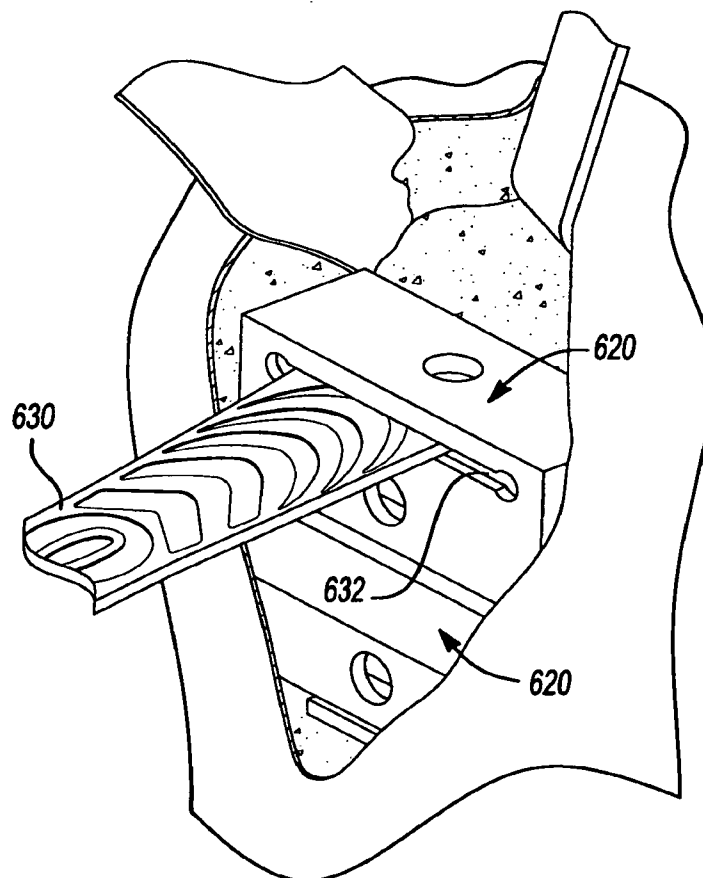


**Fig-14B**

12/14

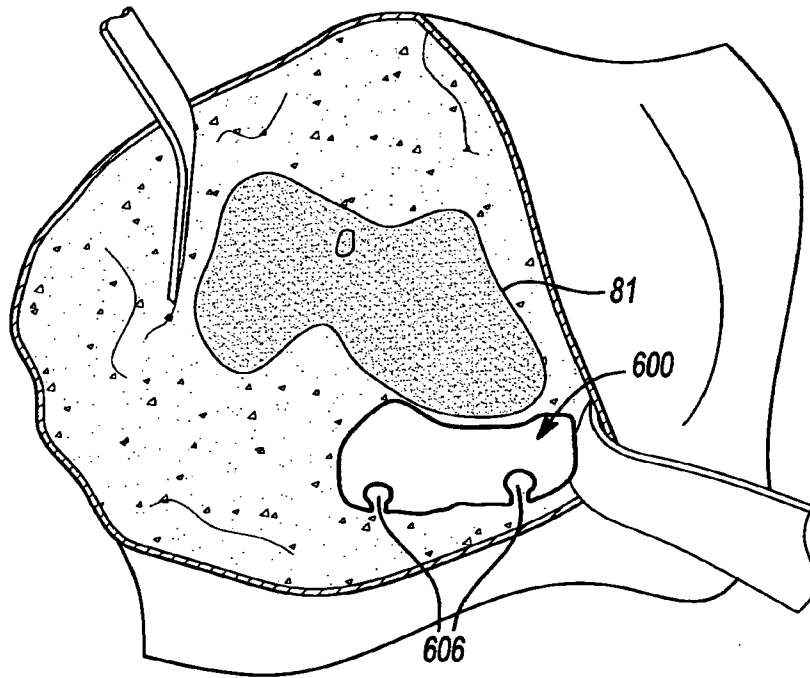


**Fig-15A**

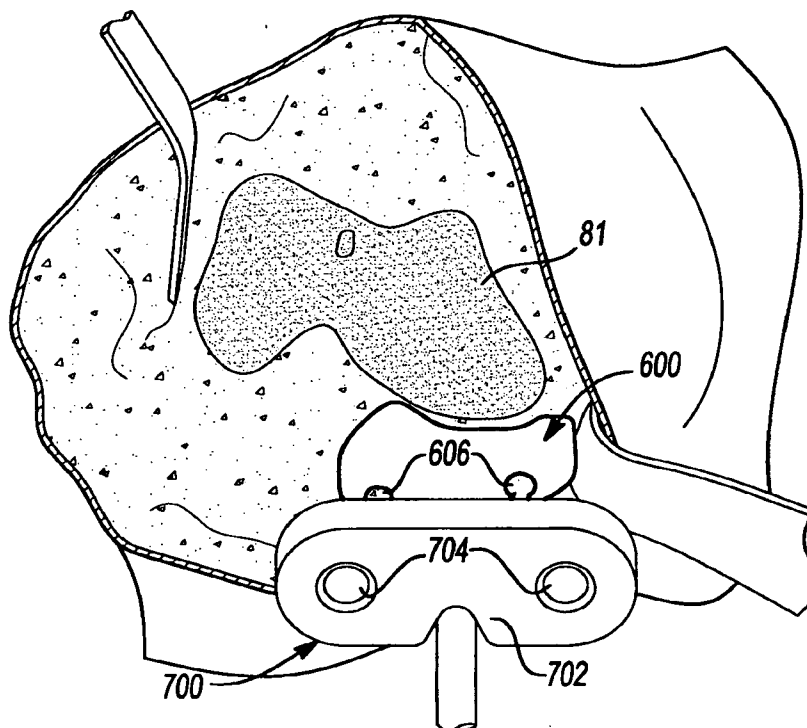


**Fig-15B**

13/14

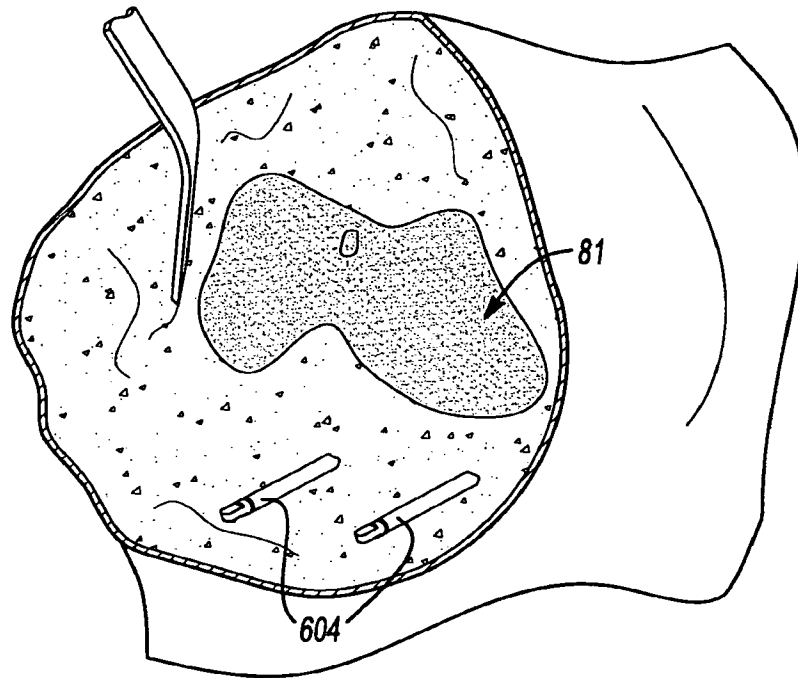


**Fig-16A**

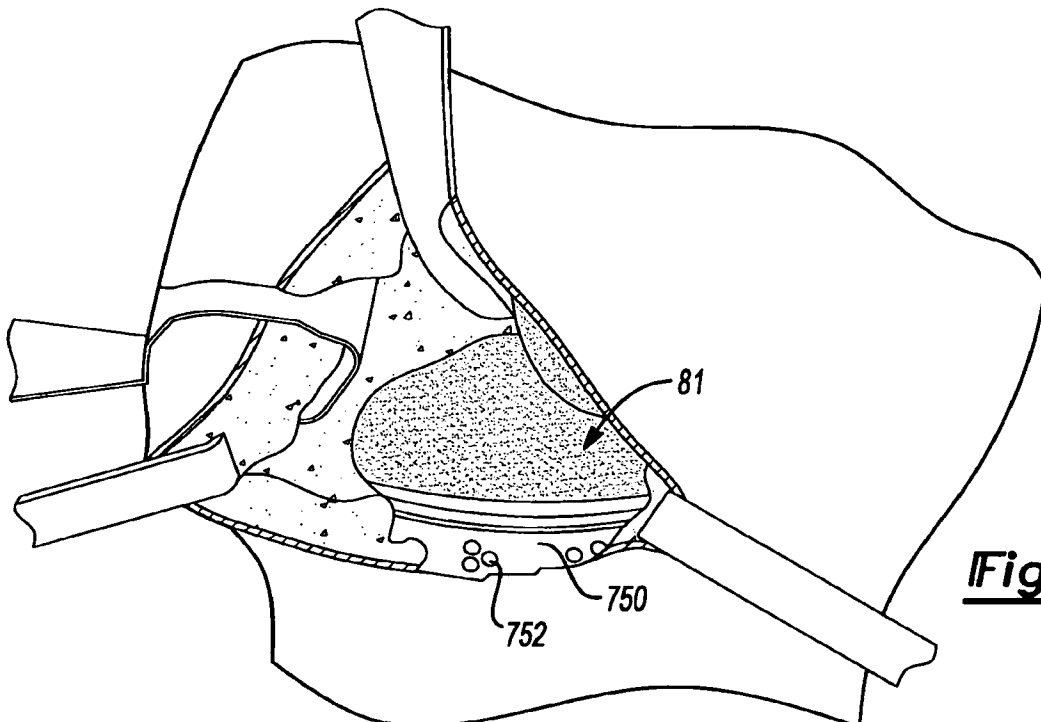


**Fig-16B**

14/14



**Fig-16C**



**Fig-16D**