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(54) Title: PATIENT-SPECIFIC BONE GRAFTING SYSTEM AND METHOD

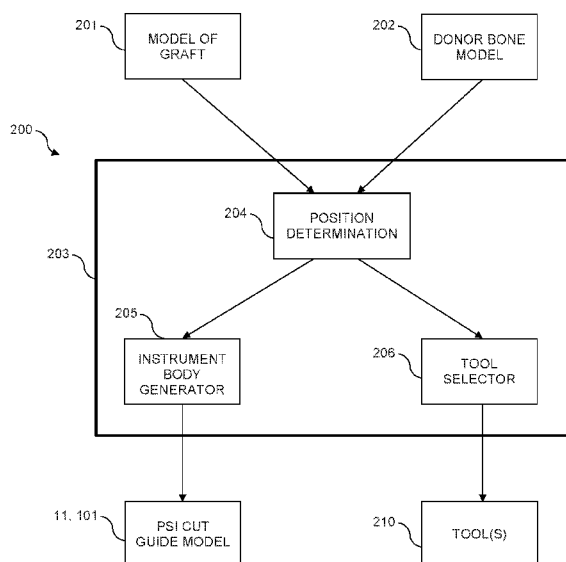


FIG. 30

(57) Abstract: A system for generating a model of a patient specific cut guide instrument for harvesting a graft comprises a model of a graft defined by an implant interface surface, a bone interface surface, and a spatial geometry therebetween, the model being specific to a patient. A patient-specific instrument generator outputs the model of the patient specific cut guide instrument, the patient-specific instrument generator including a position determination module for orienting and positioning at least a first guide axis, and for positioning an abutment on a model of a donor bone as a function of the spatial geometry, and an instrument body generator module for generating a model of the patient specific cut guide instrument comprising a body supporting a cut guide to perform a depth cut in the donor bone positioned and oriented as a function of a contact of the body with the abutment on the donor bone, and of the model of the graft.



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PATIENT-SPECIFIC BONE GRAFTING SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims the priority of United States Provisional Patent Application No. 62/167,686, filed on May 28, 2015, and incorporated herein
5 by reference.

TECHNICAL FIELD

[0002] The present application relates to orthopedic shoulder surgery and more particularly to patient-specific instrumentation used to harvest bone graft and implant same. For example, the system and method may be applied to reverse
10 shoulder arthroplasty, featuring humeral bone graft for eroded glenoids.

BACKGROUND OF THE ART

[0003] Bone grafts are occasionally used in orthopedic surgery. Bone grafts are used to fill gaps between a recipient bone and an implant. Bone autografts have the ability to be osteoinductive, osteogenic, and/or osteoconductive and therefore are an
15 advantageous choice for orthopedic surgery, to interface off-the-shelf implants to bone. Allografts are also commonly used.

[0004] For example, in reverse shoulder arthroplasty, the shoulder joint involves implants that replicate the native shoulder joint, but in a reverse arrangement with the scapula forming the joint head, and the humerus forming the socket. Reverse
20 shoulder arthroplasty is often used because of glenoid deformities and/or rotators cuff malfunction. Considering that the humerus must be machined and converted into a socket, there is a source of graft that can be used to correct glenoid deformities, and/or to create an interface between an implant and the glenoid. Humerus bone grafts may be harvested to compensate the bone loss due to glenoid
25 erosion. As subchondral bone has been shown to be effective in stabilizing glenoid implants more than cancellous bone, it is desirable to harvest grafts in the humerus.

[0005] However, grafting techniques involving for example autografts commonly involve some graft adaptation steps, e.g., machining, alterations, for the graft to have a desired geometry for subsequent implantation. However, such machining
30 steps may add time to a surgical procedure.

SUMMARY

[0006] It is an aim of the present disclosure to provide a method for harvesting a graft that addresses issues related to the prior art.

[0007] It is a further aim of the present disclosure that the method for harvesting a graft be used to harvest humeral bone grafts for reverse shoulder arthroplasty.

5 **[0008]** It is a still further aim of the present disclosure to provide patient-specific instruments for harvesting bone grafts for subsequent implantation.

[0009] It is a still further aim of the present disclosure that the patient-specific instruments be used in reverse shoulder arthroplasty.

[0010] Therefore, in accordance with a first embodiment of the present
10 disclosure, there is provided a method for harvesting a graft having at least an implant interface surface, a bone interface surface, and a planned spatial geometry therebetween, the method comprising: obtaining a cut guide instrument specific to a patient's anatomy; resurfacing an exposed surface of a donor bone to form one of
15 an implant interface surface and a bone interface surface of the graft; securing the cut guide instrument to the bone relative to resurfaced exposed surface; performing a depth cut in the donor bone to form the other of the implant interface surface and the bone interface surface of the graft with the planned spatial geometry; and harvesting the graft from the donor bone.

[0011] Further in accordance with the first embodiment, resurfacing the exposed
20 surface of the donor bone in some instances comprises resurfacing the exposed surface to form a planar surface used as the implant interface surface.

[0012] Still further in accordance with the first embodiment, performing the depth cut in some instances comprises forming the bone interface surface into another planar surface, the exposed surface being non parallel to the bone interface surface.

25 **[0013]** Still further in accordance with the first embodiment, harvesting the graft in some instances comprises forming a cylindrical body between the implant interface surface and the bone interface surface, an axis of the cylindrical body being normal to the implant interface surface.

[0014] Still further in accordance with the first embodiment, harvesting the bone
30 in some instances comprises securing an implant against the implant interface surface and removing the implant and graft from the donor bone.

[0015] Still further in accordance with the first embodiment, harvesting the graft in some instances comprises harvesting the graft to obtain the spatial geometry based

on one of the Walch glenoid indication and Favard glenoid indication in a reverse shoulder arthroplasty.

5 **[0016]** Still further in accordance with the first embodiment, harvesting the graft in some instances comprises harvesting the graft from a humerus being the donor bone, and further comprising implanting the graft and an implant onto the glenoid in reverse shoulder arthroplasty.

[0017] Still further in accordance with the first embodiment, the graft in some instances is implanted onto a recipient bone without further alterations to the graft after said harvesting from the donor bone.

10 **[0018]** Still further in accordance with the first embodiment, resurfacing the exposed surface in some instances comprises installing a guide rod and moving a resurfacing tool on the guide rod.

[0019] Still further in accordance with the first embodiment, securing the cut guide instrument on the bone in some instances comprises sliding the cut guide instrument
15 along the guide rod and into abutment with the exposed surface.

[0020] Still further in accordance with the first embodiment, a peg bore in some instances is formed in the graft, the peg bore being coaxial with a hole in the donor bone made by insertion of the guide rod.

[0021] Still further in accordance with the first embodiment, forming the peg bore
20 in some instances is removing the guide rod.

[0022] Still further in accordance with the first embodiment, resurfacing the exposed surface of the donor bone in some instances comprises resurfacing the exposed surface to form a spherical surface portion used as the bone interface surface.

25 **[0023]** Still further in accordance with the first embodiment, performing the depth cut in some instances comprises forming the implant interface surface into a planar surface.

[0024] Still further in accordance with the first embodiment, harvesting the graft in some instances comprises forming a cylindrical body between the implant interface surface and the bone interface surface, an axis of the cylindrical body being normal
30 to the implant interface surface.

[0025] Still further in accordance with the first embodiment, resurfacing the exposed surface in some instances comprises installing a first guide rod on the donor bone, and moving a resurfacing tool on the first guide rod to form said spherical surface portion.

- 5 **[0026]** Still further in accordance with the first embodiment, securing the cut guide instrument on the bone in some instances comprises sliding the cut guide instrument along the first guide rod and into abutment with the resurfaced exposed surface.

- [0027]** Still further in accordance with the first embodiment, harvesting the graft in some instances comprises installing a second guide rod with a second guide
10 channel of the cut guide instrument on the donor bone and sliding an instrument on the second guide rod.

[0028] Still further in accordance with the first embodiment, harvesting the graft in some instances comprises forming a peg bore in the graft, the peg bore being coaxial with a hole in the donor bone made by insertion of the second guide rod.

- 15 **[0029]** Still further in accordance with the first embodiment, forming the peg bore in some instances is removing the second guide rod.

- [0030]** Still further in accordance with the first embodiment, a patient specific alignment instrument in some instances has a receptacle receiving and conforming to the bone interface surface and a hole in the receptacle receiving and aligned with
20 the peg bore to install the implant onto the graft.

[0031] Still further in accordance with the first embodiment, the method in some instances further comprises sliding the patient specific alignment instrument along a guide pin to position and impact the implant and graft on the recipient bone.

- [0032]** In accordance with a second embodiment of the present disclosure, there
25 is provided a system for generating a model of a patient specific cut guide instrument for harvesting a graft, comprising: a model of a graft defined by an implant interface surface, a bone interface surface, and a spatial geometry therebetween, the model being specific to a patient; a patient-specific instrument generator for outputting the model of the patient specific cut guide instrument,
30 the patient-specific instrument generator including a position determination module configured to orient and position at least a first guide axis, and to position an abutment on a model of a donor bone as a function of the spatial geometry, and an instrument body generator module configured to generate a model of the patient

specific cut guide instrument comprising a body supporting a cut guide to perform a depth cut in the donor bone positioned and oriented as a function of a contact of the body with the abutment on the donor bone, and of the model of the graft, a first guide portion for alignment with the first guide axis, and at least one anchor guide for
5 securing the patient specific instrument cut guide on the donor bone as abutted with the abutment and aligned with the first guide axis, whereby the patient specific cut guide instrument is configured to be used for harvesting the graft for subsequent implanting without alterations to the spatial geometry of the graft.

[0033] Further in accordance with the second embodiment, the patient-specific
10 instrument generator in some instances further comprises a tool selector module for identifying at least one bone-altering tool to be used for at least one of resurfacing the donor bone and harvesting the graft.

[0034] Still further in accordance with the second embodiment, the position
15 determination module in some instances is further configured to determine a resurfacing of the donor bone to define the abutment, the resurfacing being to form a planar surface used as the implant interface surface.

[0035] Still further in accordance with the second embodiment, the instrument
20 body generator module in some instances is further configured to orient the cut guide in the body to form the bone interface surface into another planar surface, the exposed surface being non parallel to the bone interface surface.

[0036] Still further in accordance with the second embodiment, the tool selector
25 module in some instances is further configured to identify a bell saw to harvest the graft by forming a cylindrical body between the implant interface surface and the bone interface surface, an axis of the cylindrical body being normal to the implant interface surface.

[0037] Still further in accordance with the second embodiment, the instrument
body generator module in some instances is further configured to generate the model of the patient specific cut guide instrument based on one of the Walch glenoid indication and Favard glenoid indication in a reverse shoulder arthroplasty.

[0038] Still further in accordance with the second embodiment, a humerus in
30 some instances is the donor bone, and the graft is configured to be used to support an implant onto the glenoid in reverse shoulder arthroplasty.

[0039] Still further in accordance with the second embodiment, the guide portion in some instances is a guide channel sized to be used with a guide rod at the first guide axis.

5 **[0040]** Still further in accordance with the second embodiment, the tool selector module in some instances is further configured to select tools that are configured to slide along the guide rod and into contact with the abutment.

[0041] Still further in accordance with the second embodiment, the instrument body generator module in some instances is further configured to define a hole in the body, the hole being sized as a function of a peg bore to be formed in the graft,
10 the peg bore being coaxial with a hole in the donor bone made by insertion of the guide rod.

[0042] Still further in accordance with the second embodiment, the position determination module in some instances is further configured to determine a resurfacing of the donor bone to define the abutment, the resurfacing being to form a
15 spherical surface portion used as the bone interface surface.

[0043] Still further in accordance with the second embodiment, the instrument body generator module in some instances is further configured to orient the cut guide in the body to form the implant interface surface into a planar surface.

[0044] Still further in accordance with the second embodiment, the position
20 determination module in some instances is further configured to orient and position a second guide axis on the donor bone, the tool selector module identifies a bell saw to move along the second guide axis to harvest the graft by forming a cylindrical body between the implant interface surface and the bone interface surface, an axis of the cylindrical body being normal to the implant interface surface.

25 **[0045]** Still further in accordance with the second embodiment, the instrument body generator module in some instances is further configured to generate a model of a patient specific alignment instrument having a receptacle receiving and conforming to the bone interface surface and a hole in the receptacle receiving and aligned with a peg bore coincident with a hole along the second guide axis, to install
30 the implant onto the graft.

[0046] Still further in accordance with the second embodiment, the patient specific alignment instrument in some instances further comprises a guide pin and channel assembly to position and impact the implant and graft on the recipient bone.

[0047] Still further in accordance with the second embodiment, the tool selector module in some instances is further configured to select a resurfacing tool to move along a first guide rod coincident with the first guide axis on the donor bone for resurfacing the exposed surface into said spherical surface portion.

- 5 **[0048]** Still further in accordance with the second embodiment, the patient specific cut guide instrument for creating the graft in some instances comprises a model file including a spatial model of a graft defined by an implant interface surface and a bone interface surface of the graft and a spacing therebetween; the body including a baseplate adapted to be abutted against the abutment, the cut guide
10 adapted to receive therein a cut blade, and at least one depth leg spacing the base plate away from the cut guide; wherein the base plate, the cut guide slot and the at least one depth leg replicate parameters of the spatial model of the graft.

[0049] The feature or features of one embodiment may be applied to other embodiments, even though not described or illustrated, unless expressly prohibited
15 by this disclosure or the nature of the embodiments.

[0050] Some details associated with the present embodiments are described above and others are described below.

DESCRIPTION OF THE DRAWINGS

[0051] Fig. 1 is a perspective view of a humerus grafting patient-specific
20 instrument in accordance with a first embodiment of the present disclosure;

[0052] Fig. 2 is a schematic side view of the humerus grafting patient-specific instrument of Fig. 1;

[0053] Fig. 3 is a transverse view showing a planned positioning of a glenoid implant relative to a scapula;

25 **[0054]** Fig. 4 is the transverse view of Fig. 3, with a humerus graft positioned between the glenoid implant and the reamed glenoid;

[0055] Fig. 5 is a frontal view of a glenoid implant relative to a scapula in another embodiment;

[0056] Fig. 6 is a frontal view of the glenoid implant and scapula of Fig. 5, with a
30 humerus graft in the reamed glenoid;

[0057] Fig. 7 is a schematic view demonstrating a humerus with a guide rod;

- [0058] Fig. 8 is a schematic view of the humerus of Fig. 7, with a reamer on the guide rod;
- [0059] Fig. 9 is a perspective view of the humerus of Fig. 8, with the humerus grafting patient-specific instrument of Fig. 1 being slid on the guide rod;
- 5 [0060] Fig. 10 is a perspective view of the humerus of Fig. 9, with the humerus grafting patient-specific instrument being pinned to the humerus;
- [0061] Fig. 11 is a perspective view of the humerus of Fig. 10, with a cut blade guided by the humerus grafting patient-specific instrument of Fig. 1;
- [0062] Fig. 12 is a schematic side view of the humerus of Fig. 7, with a depth cut;
- 10 [0063] Fig. 13 is a schematic view of the humerus of Fig. 12, with a bell saw on the guide rod;
- [0064] Fig. 14 is a schematic view of the humerus of Fig. 13, with lateral cuts;
- [0065] Fig. 15 is a schematic view of the humerus of Fig. 14, with the glenoid implant inserted into a graft for removal;
- 15 [0066] Fig. 16 is a schematic view of the humerus of Fig. 16 with the humerus graft being harvested with the glenoid implant;
- [0067] Fig. 17 is a perspective view of a humerus grafting patient specific instrument in accordance with a second embodiment;
- [0068] Fig. 18 is a side view of a glenoid implant relative to a glenoid cavity in accordance with the second embodiment;
- 20 [0069] Fig. 19 is a perspective view of the humerus with a hemispherical reamer;
- [0070] Fig. 20 is a perspective view of the humerus of Fig. 19, with the humerus grafting patient-specific instrument of Fig. 17;
- [0071] Fig. 21 is a perspective view of the humerus of Fig. 20, with a cut blade used with the humerus grafting patient-specific instrument of Fig. 17;
- 25 [0072] Fig. 22 is a perspective view of the humerus of Fig. 21, with a guide pin being repositioned;
- [0073] Fig. 23 is a perspective view of the humerus of Fig. 22, with a depth cut thereon;
- 30 [0074] Fig. 24 is a perspective view of the humerus of Fig. 23, with a saw bell;

[0075] Fig. 25 is a perspective view of a patient-specific barrel with a harvested humerus graft;

[0076] Fig. 26 is a perspective view of the patient-specific barrel with impactor, glenoid implant and graft;

5 [0077] Fig. 27 is a side view of an impactor relative to the glenoid cavity in the process of implanting the glenoid implant and graft;

[0078] Fig. 28 is a side view of a reamer reaming the glenoid cavity for receiving the humerus graft harvested in Figs. 17 to 24;

10 [0079] Fig. 29 is a side view of the humerus graft, glenoid implant in the resurfaced glenoid cavity; and

[0080] Fig. 30 is a block diagram of a system for generating a model of a patient specific cut guide instrument for harvesting a graft, in accordance with the present disclosure.

DETAILED DESCRIPTION

15 [0081] Referring to the drawings, methods for harvesting a graft is generally shown. The illustrated methods show the harvesting of a graft on the humerus in a reverse shoulder arthroplasty, for example in an autograft or allograft situation (including a cadaver allograft). However, the methods may apply to other bones as well, for example using the iliac crest as a donor bone. For simplicity, the examples
20 of the present disclosure focus on a reverse shoulder arthroplasty with the humerus as donor bone, although other bones could be used in accordance with the present disclosure.

[0082] In Fig. 1, a humerus grafting patient-specific instrument is generally shown at 10. The humerus grafting patient-specific instrument 10 is said to be patient-specific, in that its geometry is modeled based on a planning for every patient's
25 unique anatomy, using imaging techniques. Stated differently, the humerus grafting patient-specific instrument 10 is developed subsequent to pre-operative steps by which a patient's anatomy is modeled and the implant position is defined. Hence, the humerus grafting patient-specific instrument 10 has an identity related to a patient,
30 and is most likely inadequate for being used with other patients, whereby the instrument 10 is typically a one-time use instrument. Accordingly, the humerus grafting patient-specific instrument 10 has a model file 11 of non-transient format which features a two-dimensional or three-dimensional model of the patient's

anatomy resulting from pre-operative imaging. The specific geometry of the components of the humerus grafting patient-specific instrument 10 are directly related to the contents of the model file 11.

5 [0083] The humerus grafting patient-specific instruments of the present disclosure are designed to carve out a graft in the native humerus (e.g., especially in autograft procedure, but also in allograft), which humerus graft will be used as an interface between a glenoid cavity and an implant. The humerus is therefore in this example the donor bone, whereas the scapula is the receiver bone. Accordingly, the model file 11 may define a specific spatial geometry for the humerus graft, featuring
10 a glenoid interface surface that will lie against the reamed glenoid, an implant interface surface against which an undersurface of the implant will lie, and lateral wall(s) between the glenoid interface surface and the implant interface surface. The humerus grafting patient-specific instruments and methods described herein are such that little or no machining steps are required on the humeral graft once
15 harvested. Indeed, some prior art techniques suggest removing a voluminous humeral graft, to then suggest the machining of the graft prior to grafting. The PSI technique taught herein allows the surgeon to plan the implant position with a graft, while execution is intraoperative.

[0084] Referring to Fig. 1, the instrument 10 is shown as having a base plate 12.
20 The base plate 12 is shown as being generally circular (i.e., disc-shaped) but other shapes are considered as well. A guide bore 13 is provided through the base plate 12 and will be used as described hereinafter as a guide for translational/rotational movements. One or more depth legs 14 project from the base plate 12 and support a cut slot 15 - with pin guides 15A - at ends opposite to the base plate 12. The cut
25 slot 15 is configured to receive a cut blade therein. As shown in Fig. 2, the length of the depth legs 14 is illustrated as H1 and H2 (determined using the surgeon planning of the implant relative to the glenoid). With reference to Fig. 3, it is shown that H1 and H2 may be representative of two distinct dimensions between a glenoid implant 20 and a glenoid cavity C, the glenoid implant 20 shown as having a base
30 plate 21 and a peg 22. The base plate 21 is optional in the implant 20, and supports a tapered head 23 that will be part of the shoulder joint. The H1 and H2 dimensions are based on a planning indication known as Walch glenoid indication, in which the glenoid cavity is reamed into a plane without sacrificing excessively the glenoid cavity surface. H1 and H2 are representative of the spacing between the base plate
35 21 and the reamed glenoid cavity C (i.e., the recipient site or location) as shown in

Fig. 4, whereby the harvesting of graft should have dimensions H1 and H2 to replicate the assembly shown in Fig. 4. The positioning of the glenoid implant 20 also takes into consideration a depth of insertion of the peg 22 in the shoulder blade S. Accordingly, the humerus grafting patient-specific instrument 10 is devised so as to harvest humerus graft G of Fig. 4.

[0085] Alternatively, the assessment of H1 and H2 may be based on a Favard glenoid indication as shown in Figs. 5 and 6. Whether the glenoid implanting is based on the Walch glenoid indication, the Favard glenoid indication or other implanting in which the glenoid surface is planar, the instrument 10 will be similar with, however, an adjustment of the length of the depth legs 14 as per dimensions H1 and H2, dependent on which of the indications will be used in the planning stages of surgery.

[0086] With the instrument 10 being created in pre-operative planning, a method for harvesting the humerus graft G may be performed using the instrument 10, as described hereinafter.

[0087] In Fig. 7, a guide rod 30 is positioned in the humerus H in preparing for the humerus grafting. Although not shown, the positioning of the guide rod 30 may result from the use of different pins and drills to properly orient the guide rod 30, to a desired depth. Other patient-specific instruments may be used to properly orient the guide rod 30, or other technologies such as inertial sensors.

[0088] Referring to Fig. 8, the guide rod 30 is used with a flat reamer 40. The flat reamer 40 is of the type having a hollow cylinder 41 at the end of which is a disc 42. Accordingly, by use of the reamer 40, the humerus H may have its head flattened as shown in Fig. 9. The flattened head could form the implant interface surface of the graft G. It is also considered to use the native surface without machining same, for example if it has a desired shape (e.g., substantially planar), or if the implant interface surface of the implant may be patient specifically shaped for complementary "negative" engagement with the native surface.

[0089] Once the head is flattened as in Fig. 9, the humerus grafting patient-specific instrument 10 may be slid onto the humerus H, using the guide rod 30 to form a joint with the base plate 12 of the instrument 10. The diameter of the guide bore 13 of the base plate 12 of the instrument 10 is sized so as to precisely fit onto the guide rod 30. Once the base plate 12 lays flat against the flattened surface of the humerus H (constituting the abutment), as shown in Fig. 10, the cut slot 15 may

be pinned to the humerus H by way of pin(s) 50. It is pointed out that, in the illustrated embodiment, the orientation of the instrument 10 relative to the humerus H is of lesser importance than the requirement for the base plate 12 to be flat and in abutment against the humerus H.

5 **[0090]** Referring to Fig. 11, with the instrument 10 pinned to the humerus H by the pins 50, cut blade 60 may be used in the cut slot 15 to perform a depth cut D, to define the glenoid interface surface of the graft G. It may be required to remove the guide rod 30 prior to performing the depth cut with the cut blade 60 so as not to have the guide rod 30 interfere with the cut blade 60. This is dependent on the depth of
10 the guide rod 30. In such a case, the pins 50 ensure that the instrument 10 remains anchored to the humerus H during the depth cut.

[0091] As shown in Fig. 12, once the depth cut D is made, the guide rod 30 may be reinserted into the humerus H, for a bell saw 70, also known as a cylindrical reamer, to be used to perform the lateral cut, as shown in Fig. 14. This results in the
15 detachment of the humerus graft G from a remainder of the humerus H. The bell saw 70 may have a depth scale thereon, to provide a visual display of depth.

[0092] In Fig. 15, there is illustrated a technique for removing the humerus graft G, using the glenoid implant 20. By this method, the glenoid implant 20 is forced into the humerus graft G, requiring for example the machining of a bore of adequate
20 dimension in the humerus graft G, until the base plate 21 of the glenoid implant 20 is flush against the surface of the humerus graft G. The humerus graft G is harvested as shown in Fig. 16 by pulling out the glenoid implant 20. At that point, it is possible to install the assembly of humerus graft G and glenoid implant 20 in the manner shown in Figs. 4 and 6, and this may require some reaming and peg drilling to the
25 glenoid cavity C. Fasteners of any appropriate type, and tools (e.g., impactor) may be used to properly implant the combination of the humerus graft G and glenoid implant 20. Also, cement or like adhesive can be used to fasten the graft to the implant.

[0093] The embodiment described above for the instrument 10 is commonly used
30 when glenoid deformities are generally planar, or machined to be planar as planned. This is a common occurrence and is advantageous as flat reaming minimizes subchondral bone sacrifice. The geometry of the graft G may be defined as having a cylindrical body. A peg bore may be defined along the central axis of the cylindrical body, for the implant peg to pass through the cylindrical body. The central axis of

the cylindrical body may be normal to the first end surface of the cylindrical body, whereas the second end surface of the cylindrical body is oblique. In other words, a plane in which lies the second end surface is not parallel to a plane in which lies the first end surface. The angle between the planes is less than 90 degrees, and is commonly between 5 and 45 degrees, although it could be out of that range.

Therefore, all three surfaces of the graft G may be machined, in three different steps, while being on the native bone. The machining of the peg bore may be in a fourth separate step, or may consist in the removal of the guide pin 30, the guide pin 30 being selected to have a diameter matching that of the peg 22. Although described as being donated by the humerus, the graft G may be harvested from other sites, such as the iliac crest.

[0094] Now that the humerus grafting patient specific instrument 10 has been described as used for a flat glenoid surface, another embodiment of a humerus grafting patient specific instrument is set forth, for a frusto-spherical glenoid cavity, i.e., the glenoid cavity is a sphere segment surface. Indeed, in some instances, the erosion is spherical with a glenoid surface medialization due to wear. This is for instance shown in Fig. 18.

[0095] Therefore, referring to Fig. 17, there is illustrated a humerus grafting patient specific instrument 100 to be used for hemispherical or frusto-spherical glenoid cavities. In similar fashion to the instrument 10, the instrument 100 is patient specific and has a model file 101 featuring modelisation of the patient's anatomy obtained pre-operatively. The instrument 100 has a first guide 102 and a second guide 103, both generally elongated cylindrical portions with channels of circular section that would be mounted onto pins and thus form sliding joints. A depth leg 104 projects from the first guide 102 and has a cut slot 105 (with pin guides 105A) at an end thereof.

[0096] Referring to Fig. 18, a schematic planning view is provided showing the desired positioning of the glenoid implant 20 relative to the glenoid cavity C. As observed, the glenoid cavity C has a circular outline (circle O shown in Fig. 18), indicative of a frusto-spherical cavity, with a distance D between an underface of the baseplate 21 of the glenoid implant 20 and a bottom of the glenoid cavity C. The depth D is representative of the height of the humerus graft G to be harvested from the humerus H. Moreover, angle α is also to be taken into consideration, as the angle between the axis of the peg 22 of baseplate 21 and line L. Line L passes

through point P at the intersection of the axis of the peg 22 with the circle O, and through the center of the circle. All these parameters are obtained preoperatively from the surgeon planning of the implanting procedure relative to the glenoid surface and are part of the model file 101. These parameters are descriptive of the spatial geometry of the graft G to interface the implant 20 to the reamed glenoid cavity C.

5 [0097] Referring to Fig. 19, in order to start the grafting procedure, a hemispherical reamer 110 is used to surface the humerus head H into a frusto-spherical shape. Hemispherical reamer 110 has a hollow cylinder 111 that is cannulated to be mounted on the guide rod 30. A saw edge 112 is sized as a function of the dimension of the diameter of the circle O of Fig. 18. Accordingly, various sizes of the hemispherical reamer 110 may be provided, with the operator selecting the appropriate size based on the pre-operative planning and on the model file 101. Hence, the reamed humerus head H has the glenoid interface surface machined onto it.

15 [0098] Once the humerus head has been shaped, the instrument 100 may be positioned thereon using the guide rod 30. The guide rod 30 serves as a shaft for the second guide 103, with the angle between the first guide 102 and the second guide 103 being angle α .

20 [0099] Referring to Fig. 21, once the instrument 100 abuts against the humerus H, it may be pinned using pin(s) 50. The guide rod 30 may be removed for the cut blade 60 to perform a depth cut of depth D, to form the implant interface surface of the graft G. Once the depth cut has been made, the guide 130 may be repositioned onto the humerus H, but this time using the first guide 102, as shown in Fig. 22.

25 [00100] Referring to Fig. 23, a drill tool 120 may then be used to machine a bore in the humerus H, which bore is sized based on the diameter of the peg 22 of the implant 20, as it will receive the peg 22 therein.

30 [00101] Referring to Fig. 24, the saw bell 70 may then be used in order to define the size of the graft G to be harvested. Accordingly, based on the preceding steps, humerus graft G is shaped for use in the configuration of Fig. 18, and may be harvested.

[00102] In order to implant it properly (or implant the graft G harvested using the instrument 10) and replicate the planning by setting the graft axial rotation appropriately, different tools may be devised, such as barrel 130 of Fig. 25. The

barrel 130 has a cavity 131 that is shaped in patient specific manner, in similar fashion to the instruments 10 and 100. As such, barrel 130 may have a model file. A peg bore 132 is a bottom of the cavity 131, and sized and positioned specifically based on the planned interrelation between the peg 22 and the graft G. Accordingly, the alignments of the peg bore 132, the barrel 130 and the peg bore in the humerus graft G ensure that a single orientation of the humerus graft G in the barrel 130 is achieved, for insertion of the peg 22 in the manner shown in Fig. 26. The barrel 130 further comprises a guide 133 that cooperates with a pin 134 to form a sliding joint.

[00103] As shown in Fig. 26, an impactor 140 has an implant end 141 devised to support the tapered head 23 of the implant 20. The impactor 140 also has at an opposite end an impact end 142 adapted to be impacted for implanting the implant 20. The impactor 140 also has a guide 143 that will collaborate with the pin 134. This is shown particularly in Fig. 27 in which it is observed that the impactor 140 is guided by the implanted pin 134 to perform the impacting action. The graft could be cemented to the baseplate and not impacted.

[00104] Referring to Fig. 28, it may however be necessary to machine the glenoid cavities C using a reamer 150 having an arcuate cutting tool 151. It is pointed out that the barrel 130 may be used to machine the glenoid cavities so as to define the peg bore into the glenoid. Accordingly, the implant 20 and the harvested graft G may be implanted in the reamed glenoid cavity C in the manner shown in Fig. 29.

[00105] The geometry of the graft G may be defined as having a cylindrical body, although an axial length of the cylindrical body may be close to zero at a location. A peg bore may be defined along the central axis of the cylindrical body, for the implant peg to pass through the cylindrical body. The central axis of the cylindrical body may be normal to the first end surface of the cylindrical body, whereas the second end surface of the cylindrical body is spherical. The center of the spherical surface is not aligned with the central axis of the cylindrical body, i.e., it is not coincident with the central axis. Therefore, all three surfaces of the graft G may be machined, in three different steps, while being on the native bone. The machining of the peg bore may be in a fourth separate step. The machining of the peg bore may be in a fourth separate step, or may consist in the removal of the guide pin 134, the guide pin 134 being selected to have a diameter matching that of the peg 22. Although described as being donated by the humerus, the graft G may be harvested from other sites, such as the iliac crest.

[00106] Therefore, the method can generally be described as a method for creating a graft. According to the method, a cut guide instrument 10 or 100 is obtained, and is specific to a patient's anatomy. The instrument 10 or 100 is the result of pre-operative planning in which the patient's anatomy is modeled, and the spatial geometry of a graft is defined from the surgeon planning by the planning software. Intraoperatively, an exposed surface of a donor bone is resurfaced, to form an implant interface surface (in the case of instrument 10) or a bone interface surface (in the case of instrument 100) of the graft G. The cut guide instrument 10 or 100 is then secured to the donor bone. Using the cut guide instrument 10 or 100, a depth cut is performed in the donor bone to form the other of the implant interface surface or the bone interface surface of the graft G. It may be required to further machine the graft G, or the graft G may be harvested right away, for example if the resurfacing has also been used to define the lateral surfaces of the graft G.

[00107] While the method described above provides an example of shoulder surface, the method could also be used with other joints, or for a non-reverse shoulder surgery.

[00108] Referring to Fig. 30, there is illustrated a system 200 for generating a model of a patient specific cut guide instrument, such as 10, 100, for harvesting a graft, such as G, for subsequent fabrication and used based on the methods illustrated in Figs. 1-29. In order to generate the model of the patient specific cut guide instrument, such for example at 11, 101 in Figs. 1, 17 and 30, the system 200 must have a model 201 of the graft G. The model 201 is for example the result of pre-operative planning, in which a virtual positioning and orienting of an implant is done on images of a bone. This may be illustrated for example by Figs. 3, 4 and 18, with the graft G being defined by an implant interface surface, a bone interface surface, and a spatial geometry therebetween. The model is specific to a patient, in that it results from an analysis of the patient's data (imagery of bone, for example in 3D, patient condition, etc). The system 200 may also have a model 202 of the donor bone, such as the humerus H. The graft G will be harvested in the donor bone, and therefore the system 200 determines how to alter the donor bone to harvest the graft G, using the model 202. As described previously, the patient specific cut guide instrument 10 is used for harvesting the graft for subsequent implanting without alterations to the outer surface of the graft G, i.e., after harvesting, the graft G already has a geometry corresponding to the model of the graft 201. Some trivial machining may occur after harvesting, such as machining a peg hole of appropriate

dimension in the hole remaining from the pin guide 30. However, such machining is not to alter the outer surface of the graft B, i.e., the cylindrical body and its ends.

[00109] A patient-specific instrument generator 203 outputs the model 11, 101 of the patient specific cut guide instrument 10, 100. The patient-specific instrument generator 203 has a processor unit for operating modules that generate data resulting in the model 11, 101, using models 201 and 202. The patient-specific instrument generator 203 may have a position determination module 204 for orienting and positioning a guide axis or axes, taking into consideration the spatial geometry of the graft G, via the model 201, to make sure there is sufficient bone available for the graft G, without damaging what must remain of the donor bone, as per model 202. As observed in Figs. 1-29, the axes are used to correctly position and orient the instrument 10, 100 on the donor bone, and to guide the tools altering the bone. The position determination module 204 may also position an abutment on the model 202 of a donor bone as a function of the spatial geometry. This may include identifying that the donor bone must be resurfaced to define the abutment, as in Figs. 8 and 19.

[00110] Once the position determination module 204 has produced the orientation and position of the axis, and determined the abutment (including resurfacing), an instrument body generator module 205 generates the model 11, 101 of the patient specific cut guide instrument 10, 100. As observed in Figs. 1-29, the instrument 10,100 has a body supporting a cut guide with the cut slot 15. The cut guide is used with a cutting tool, such as a saw, to perform a depth cut in the donor bone, the depth cut being positioned and oriented as a function of the contact of the body with the abutment on the donor bone, of the model 201 of the graft, and of the guide axis (axes). One or more guide channels are part of the body for alignment with the guide axis (axes). One or more anchor guides, such as the pin guides 15A, are located in the body of the instrument 10, 100 for securing the patient specific instrument cut guide 10, 100 on the donor bone as abutted with the abutment and aligned with the guide axis. The instrument body generator module 205 may also create other patient specific instruments, such as the barrel 130. The generator 205 outputs a model(s) 11, 101, in any appropriate format, such as non-transient instructions to machine the instrument 10, 100, a 3D printing file, etc.

[00111] In the system 200, the patient-specific instrument generator 203 may also have a tool selector module 206. The module 206 may identify the various bone-

altering tools, such as 30, 40, 70, 120, etc (concurrently as 210) to be used for resurfacing the donor bone, harvesting the graft, etc. The module 206 may also provide data such as depth of penetration in the case of the bell saw 70.

CLAIMS:

1. A method for harvesting a graft having at least an implant interface surface, a bone interface surface, and a planned spatial geometry therebetween, the method comprising:
 - obtaining a cut guide instrument specific to a patient's anatomy;
 - resurfacing an exposed surface of a donor bone to form one of an implant interface surface and a bone interface surface of the graft;
 - securing the cut guide instrument to the bone relative to resurfaced exposed surface;
 - performing a depth cut in the donor bone to form the other of the implant interface surface and the bone interface surface of the graft with the planned spatial geometry; and
 - harvesting the graft from the donor bone.
2. The method according to claim 1, wherein resurfacing the exposed surface of the donor bone comprises resurfacing the exposed surface to form a planar surface used as the implant interface surface.
3. The method according to claim 2, wherein performing the depth cut comprises forming the bone interface surface into another planar surface, the exposed surface being non parallel to the bone interface surface.
4. The method according to claim 3, wherein harvesting the graft comprises forming a cylindrical body between the implant interface surface and the bone interface surface, an axis of the cylindrical body being normal to the implant interface surface.
5. The method according to any one of claims 2 to 4, wherein harvesting the bone comprises securing an implant against the implant interface surface and removing the implant and graft from the donor bone.
6. The method according to any one of claims 1 to 4, wherein harvesting the graft comprises harvesting the graft to obtain the spatial geometry based on one of the Walch glenoid indication and Favard glenoid indication in a reverse shoulder arthroplasty.

7. The method according to any one of claims 1 to 4, wherein harvesting the graft comprises harvesting the graft from a humerus being the donor bone, and further comprising implanting the graft and an implant onto the glenoid in reverse shoulder arthroplasty.
8. The method according to any one of claims 1 to 4, further comprising implanting the graft onto a recipient bone without further alterations to the graft after said harvesting from the donor bone.
9. The method according to any one of claims 1 to 4, wherein resurfacing the exposed surface comprises installing a guide rod and moving a resurfacing tool on the guide rod.
10. The method according to claim 9, wherein securing the cut guide instrument on the bone comprises sliding the cut guide instrument along the guide rod and into abutment with the exposed surface.
11. The method according to claim 9, further comprising forming a peg bore in the graft, the peg bore being coaxial with a hole in the donor bone made by insertion of the guide rod.
12. The method according to claim 11, wherein forming the peg bore is removing the guide rod.
13. The method according to claim 1, wherein resurfacing the exposed surface of the donor bone comprises resurfacing the exposed surface to form a spherical surface portion used as the bone interface surface.
14. The method according to claim 13, wherein performing the depth cut comprises forming the implant interface surface into a planar surface.
15. The method according to claim 14, wherein harvesting the graft comprises forming a cylindrical body between the implant interface surface and the bone interface surface, an axis of the cylindrical body being normal to the implant interface surface.
16. The method according to claims 13 to 15, wherein resurfacing the exposed surface comprises installing a first guide rod on the donor bone, and moving a resurfacing tool on the first guide rod to form said spherical surface portion.

17. The method according to claim 16, wherein securing the cut guide instrument on the bone comprises sliding the cut guide instrument along the first guide rod and into abutment with the resurfaced exposed surface.
18. The method according to any one of claims 16 and 17, wherein harvesting the graft comprises installing a second guide rod with a second guide channel of the cut guide instrument on the donor bone and sliding an instrument on the second guide rod.
19. The method according to claim 18, wherein harvesting the graft comprises forming a peg bore in the graft, the peg bore being coaxial with a hole in the donor bone made by insertion of the second guide rod.
20. The method according to claim 19, wherein forming the peg bore is removing the second guide rod.
21. The method according to any one of claims 19 and 20, further comprising using a patient specific alignment instrument having a receptacle receiving and conforming to the bone interface surface and a hole in the receptacle receiving and aligned with the peg bore to install the implant onto the graft.
22. The method according to claim 21, wherein using the patient specific alignment instrument further comprises sliding the patient specific alignment instrument along a guide pin to position and impact the implant and graft on the recipient bone.
23. The method according to any one of claims 1 to 22, wherein harvesting the graft comprises harvesting a cadaver allograft.
24. A system for generating a model of a patient specific cut guide instrument for harvesting a graft, comprising:
- a model of a graft defined by an implant interface surface, a bone interface surface, and a spatial geometry therebetween, the model being specific to a patient;
 - a patient-specific instrument generator configured to output the model of the patient specific cut guide instrument, the patient-specific instrument generator including

a position determination module configured to orient and position at least a first guide axis, and to position an abutment on a model of a donor bone as a function of the spatial geometry, and

an instrument body generator module configured to generate a model of the patient specific cut guide instrument comprising a body supporting a cut guide to perform a depth cut in the donor bone positioned and oriented as a function of a contact of the body with the abutment on the donor bone, and of the model of the graft, a first guide portion for alignment with the first guide axis, and at least one anchor guide for securing the patient specific instrument cut guide on the donor bone as abutted with the abutment and aligned with the first guide axis,

whereby the patient specific cut guide instrument is configured to be used for harvesting the graft for subsequent implanting without alterations to the spatial geometry of the graft.

25. The system according to claim 24, wherein the patient-specific instrument generator further comprises a tool selector module configured to identify at least one bone-altering tool to be used for at least one of resurfacing the donor bone and harvesting the graft.

26. The system according to claim 25, wherein the position determination module is further configured to determine a resurfacing of the donor bone to define the abutment, the resurfacing being to form a planar surface used as the implant interface surface.

27. The system according to claim 26, wherein the instrument body generator module is further configured to orient the cut guide in the body to form the bone interface surface into another planar surface, the exposed surface being non parallel to the bone interface surface.

28. The system according to claim 27, wherein the tool selector module is further configured to identify a bell saw to harvest the graft by forming a cylindrical body between the implant interface surface and the bone interface surface, an axis of the cylindrical body being normal to the implant interface surface.

29. The system according to any one of claims 24 to 28, wherein the instrument body generator module is further configured to generate the model of the patient

specific cut guide instrument based on one of the Walch glenoid indication and Favard glenoid indication in a reverse shoulder arthroplasty.

30. The system according to any one of claims 24 to 28, wherein a humerus is the donor bone, and the graft is used to support an implant onto the glenoid in reverse shoulder arthroplasty.

31. The system according to claim 25, wherein the guide portion is a guide channel sized to be used with a guide rod at the first guide axis.

32. The system according to claim 31, wherein the tool selector module is further configured to select tools that are configured to slide along the guide rod and into contact with the abutment.

33. The system according to claim 31, wherein the instrument body generator module is further configured to define a hole in the body, the hole being sized as a function of a peg bore to be formed in the graft, the peg bore being coaxial with a hole in the donor bone made by insertion of the guide rod.

34. The system according to claim 25, wherein the position determination module is further configured to determine a resurfacing of the donor bone to define the abutment, the resurfacing being to form a spherical surface portion used as the bone interface surface.

35. The system according to claim 34, wherein the instrument body generator module is further configured to orient the cut guide in the body to form the implant interface surface into a planar surface.

36. The system according to claim 35, wherein the position determination module is further configured to orient and position a second guide axis on the donor bone, the tool selector module identifies a bell saw to move along the second guide axis to harvest the graft by forming a cylindrical body between the implant interface surface and the bone interface surface, an axis of the cylindrical body being normal to the implant interface surface.

37. The system according to claim 36, wherein the instrument body generator module is further configured to generate a model of a patient specific alignment instrument having a receptacle receiving and conforming to the bone interface

surface and a hole in the receptacle receiving and aligned with a peg bore coincident with a hole along the second guide axis, to install the implant onto the graft.

38. The system according to claim 37, wherein the patient specific alignment instrument further comprises a guide pin and channel assembly to position and impact the implant and graft on the recipient bone.

39. The system according to any one of claims 34 to 38, wherein the tool selector module is further configured to select a resurfacing tool to move along a first guide rod coincident with the first guide axis on the donor bone for resurfacing the exposed surface into said spherical surface portion.

40. The system according to any one of claims 24 to 39, wherein the patient specific cut guide instrument for creating the graft comprises

a model file including a spatial model of a graft defined by an implant interface surface and a bone interface surface of the graft and a spacing therebetween;

the body including a baseplate adapted to be abutted against the abutment,

the cut guide adapted to receive therein a cut blade, and

at least one depth leg spacing the base plate away from the cut guide;

wherein the base plate, the cut guide slot and the at least one depth leg replicate parameters of the spatial model of the graft.

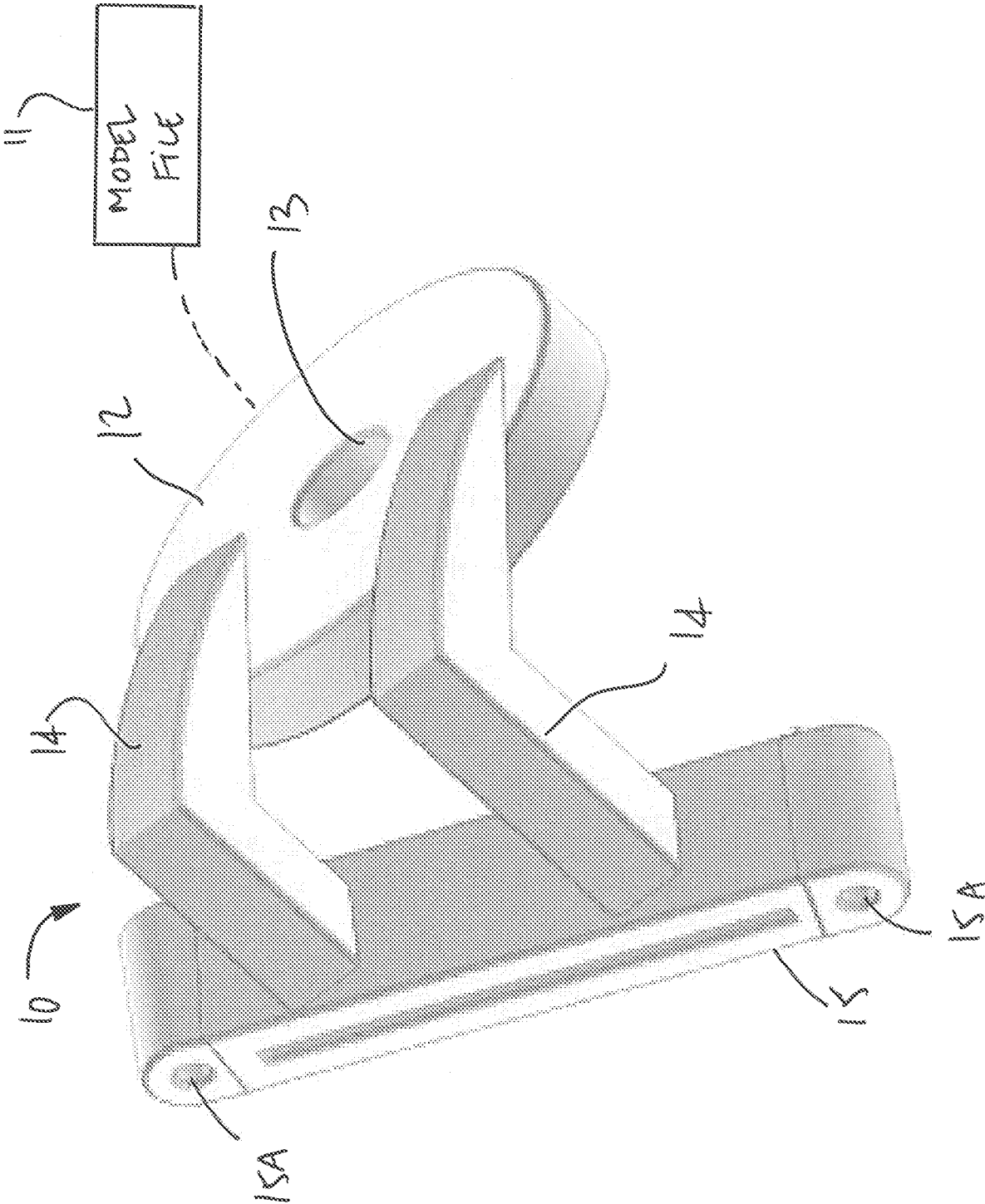


FIG. 1

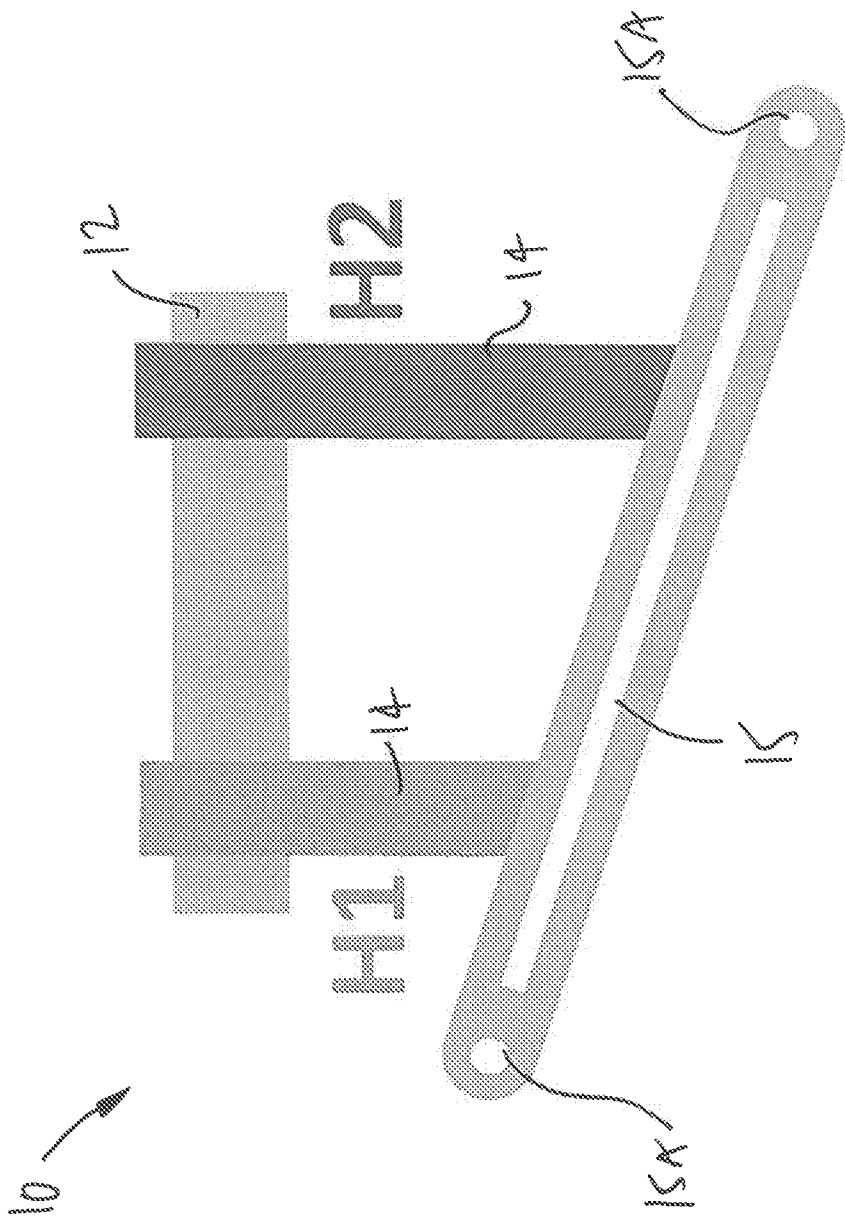
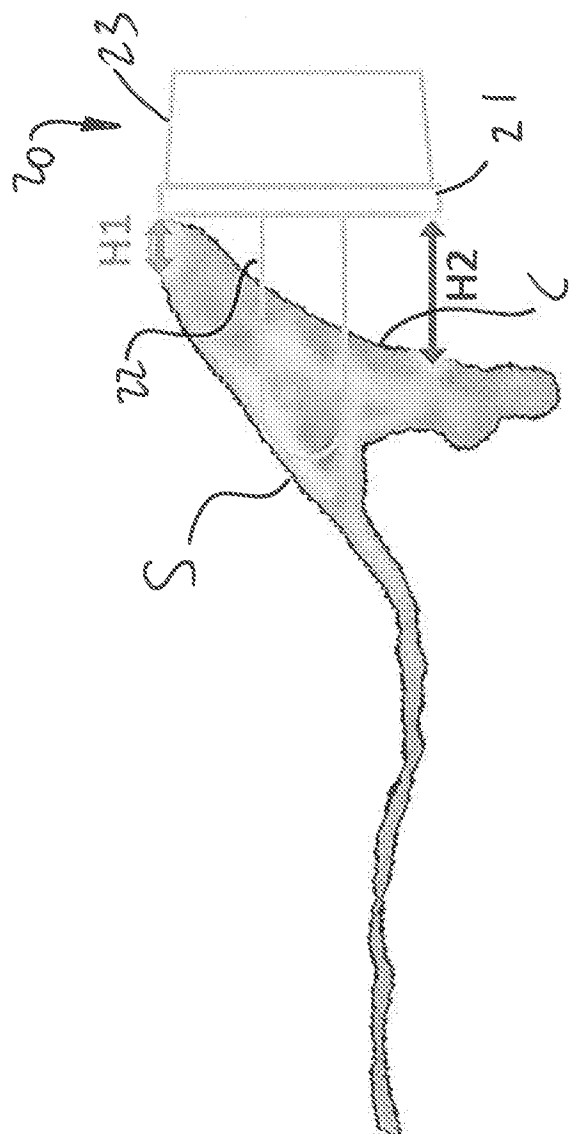
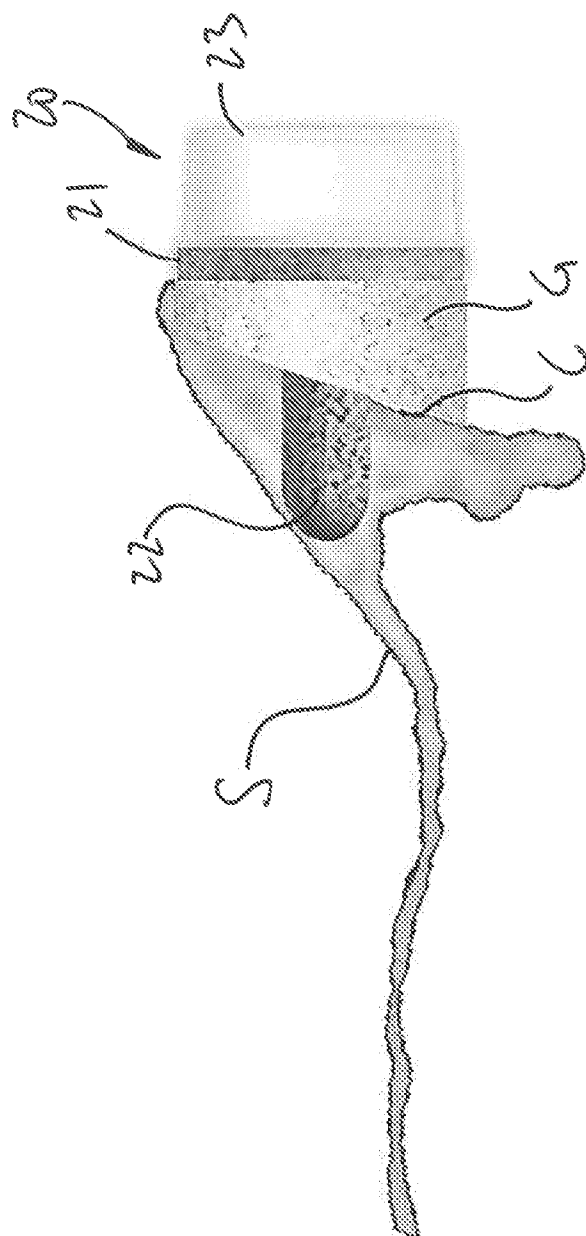


FIG. 2



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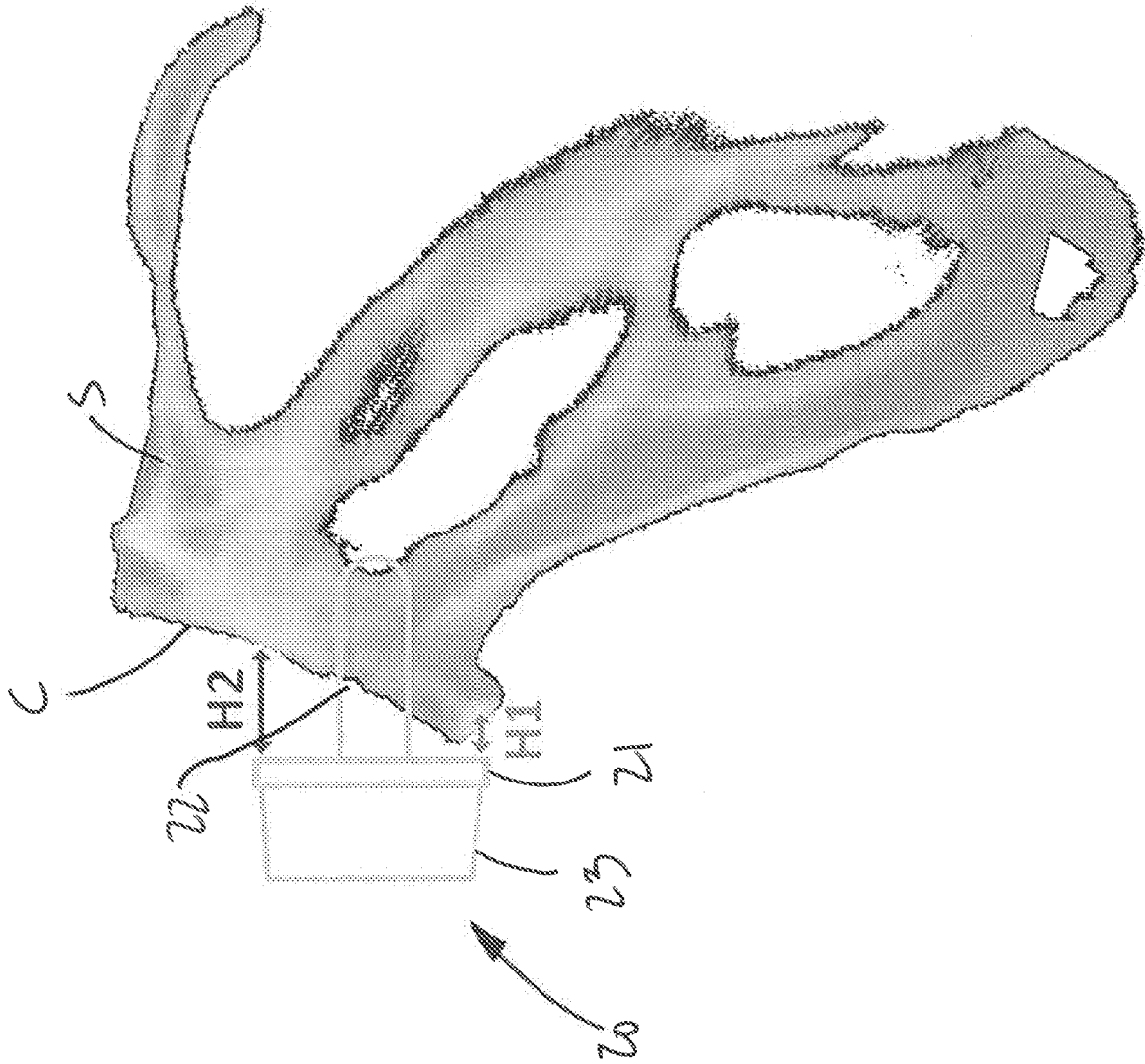
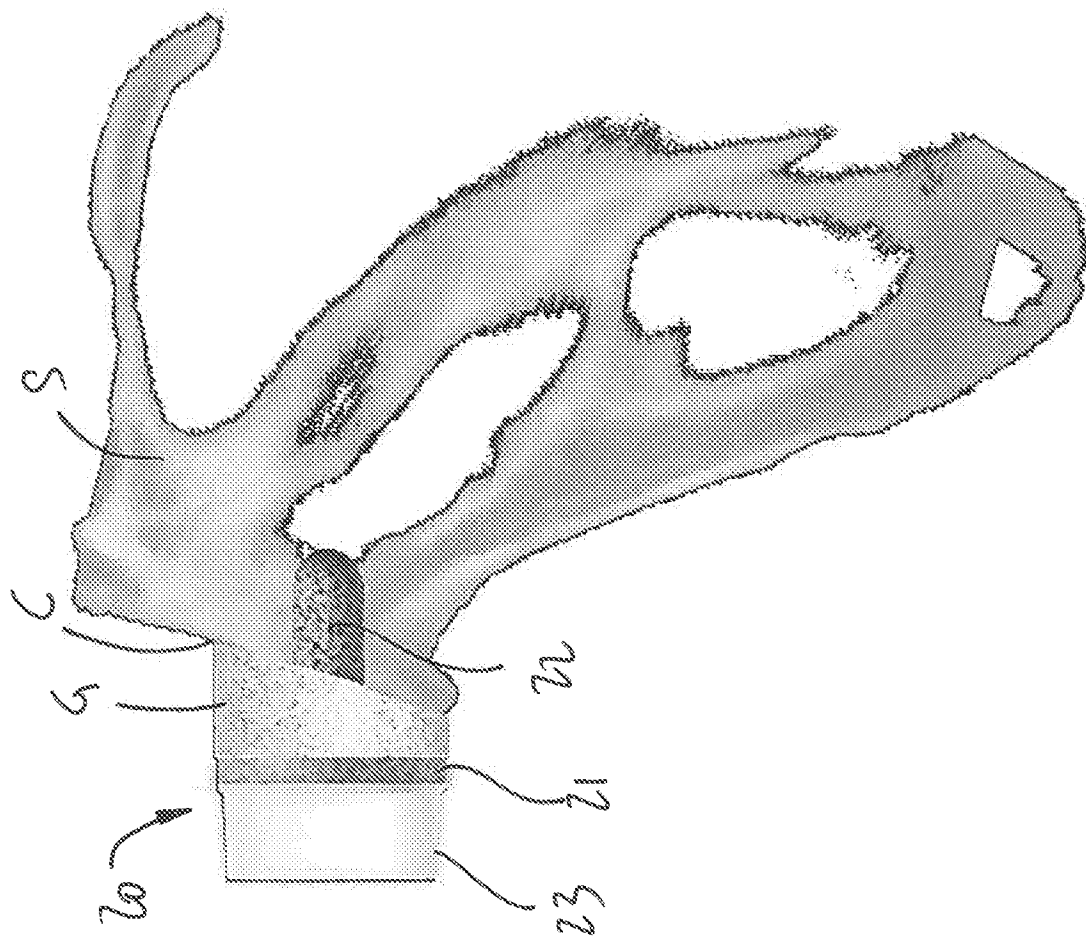


FIG. 5



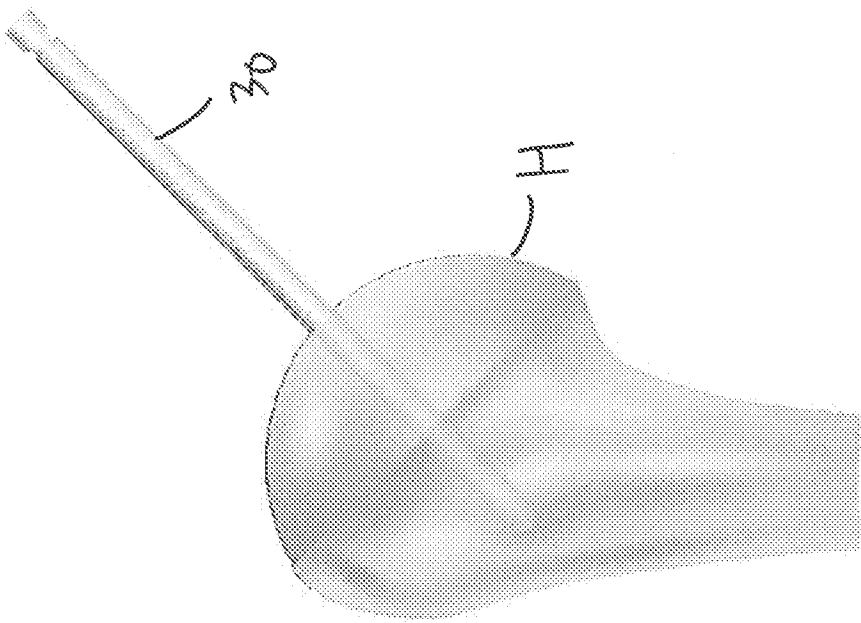


FIG. 7

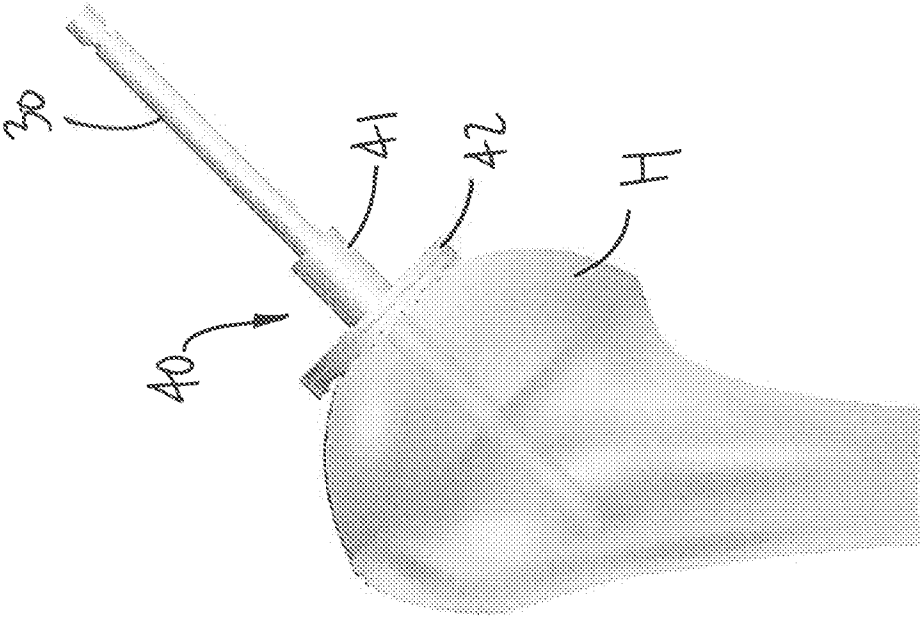


FIG. 8

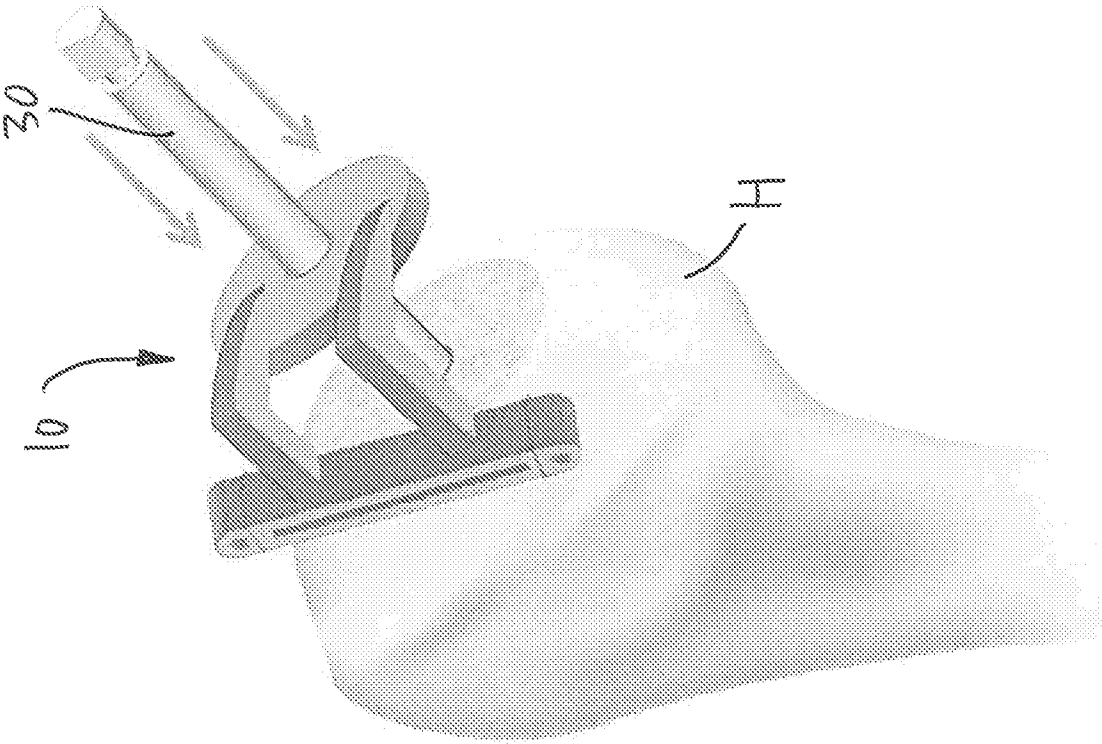


FIG. 9

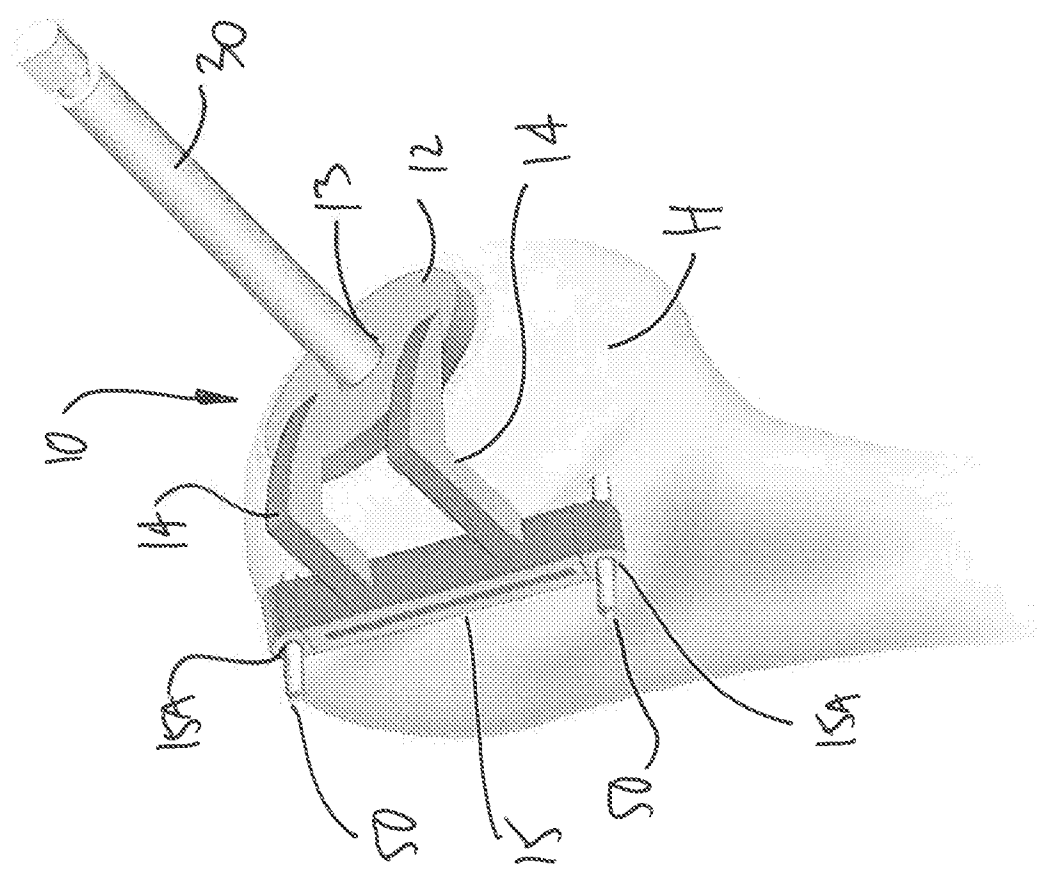


FIG. 10

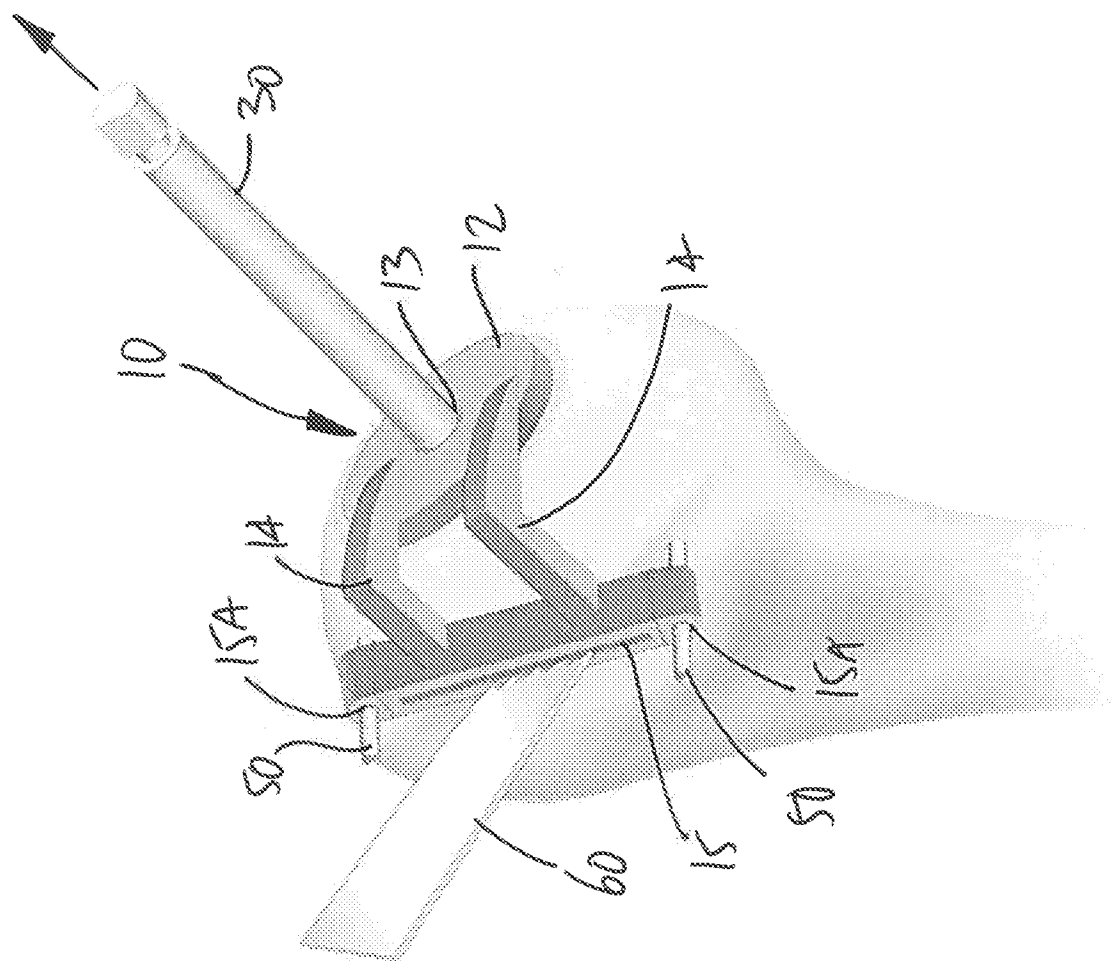


FIG. 11

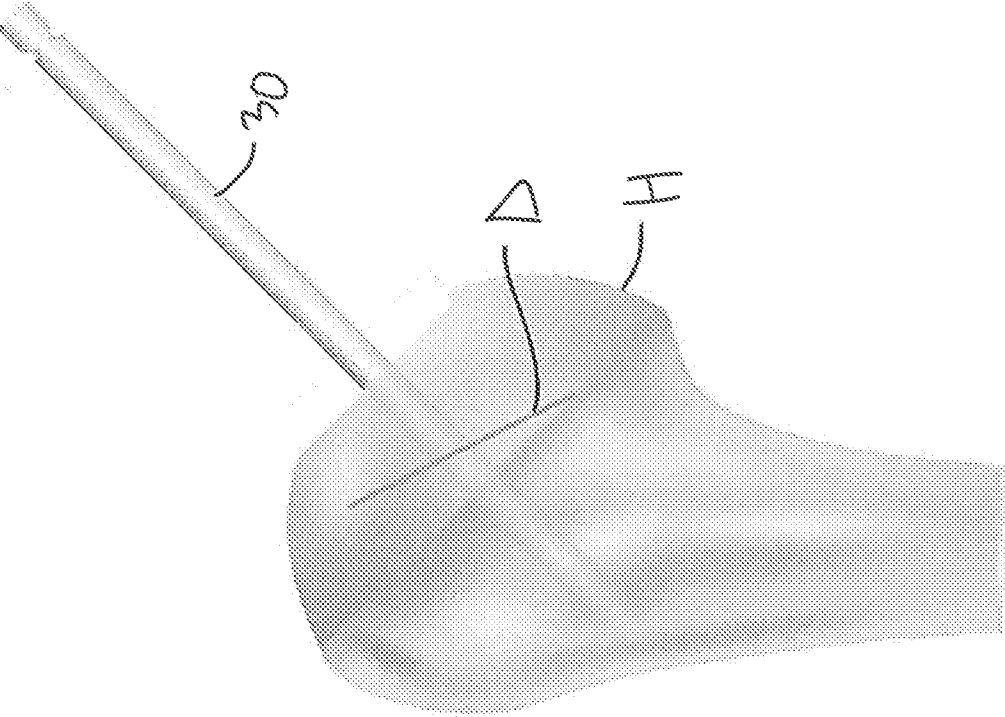


FIG. 12

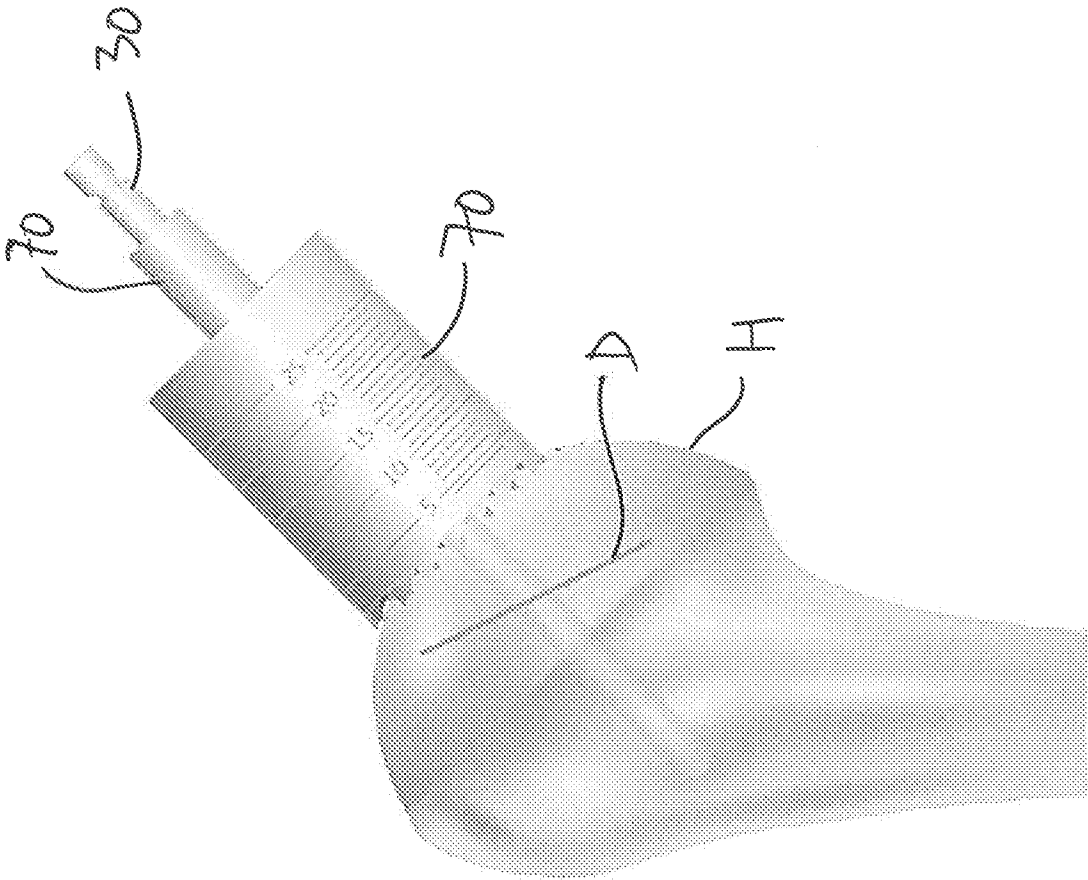


FIG. 13

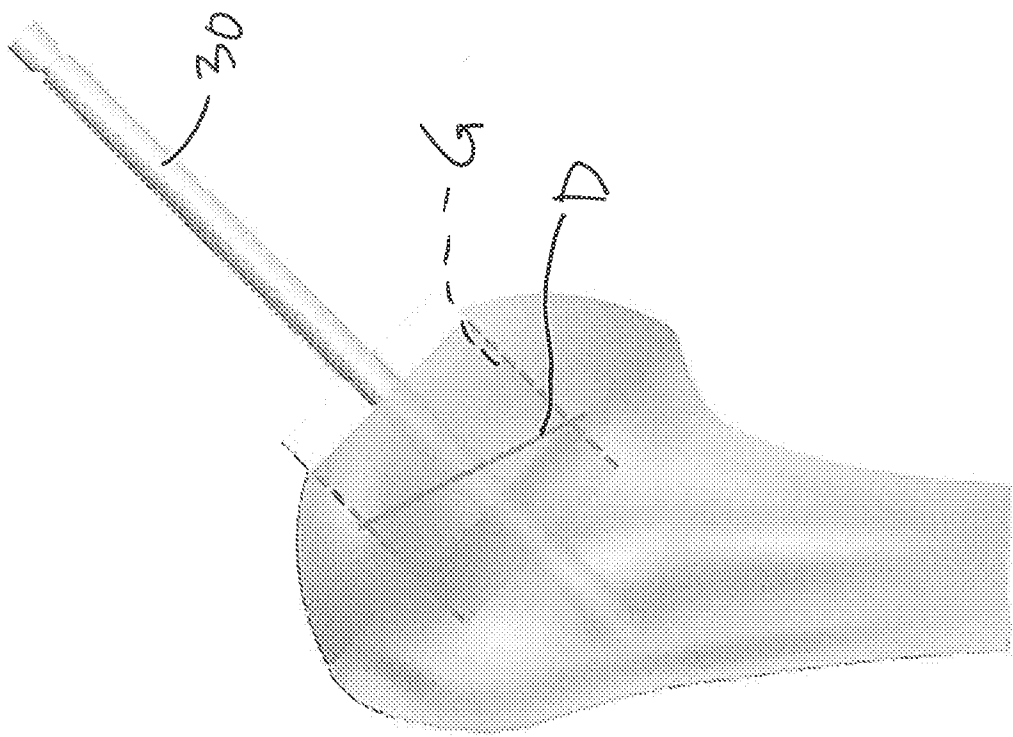


FIG. 14

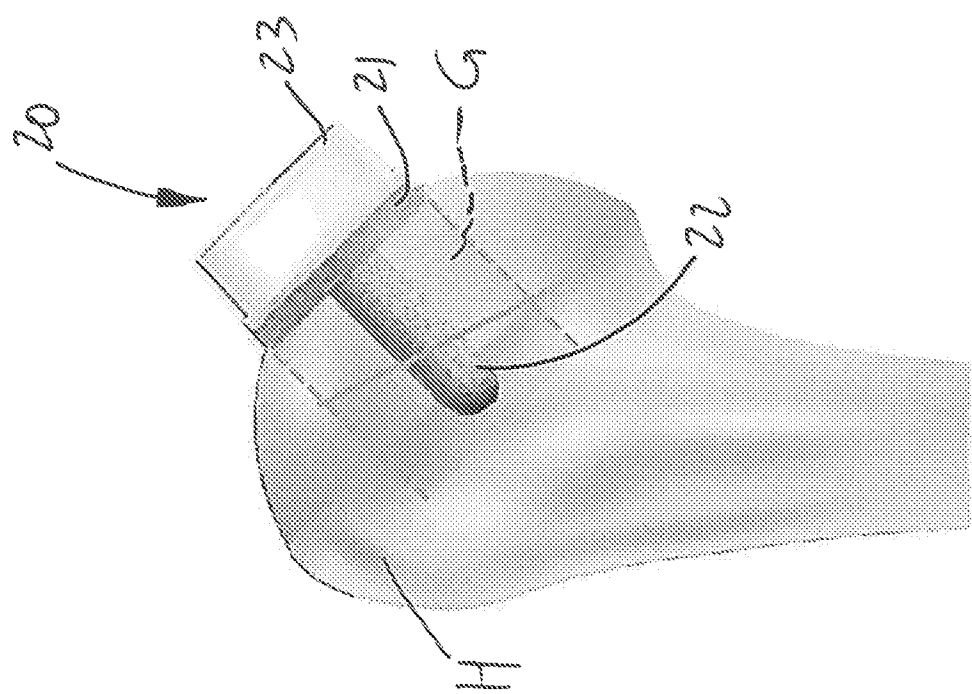


FIG. 15

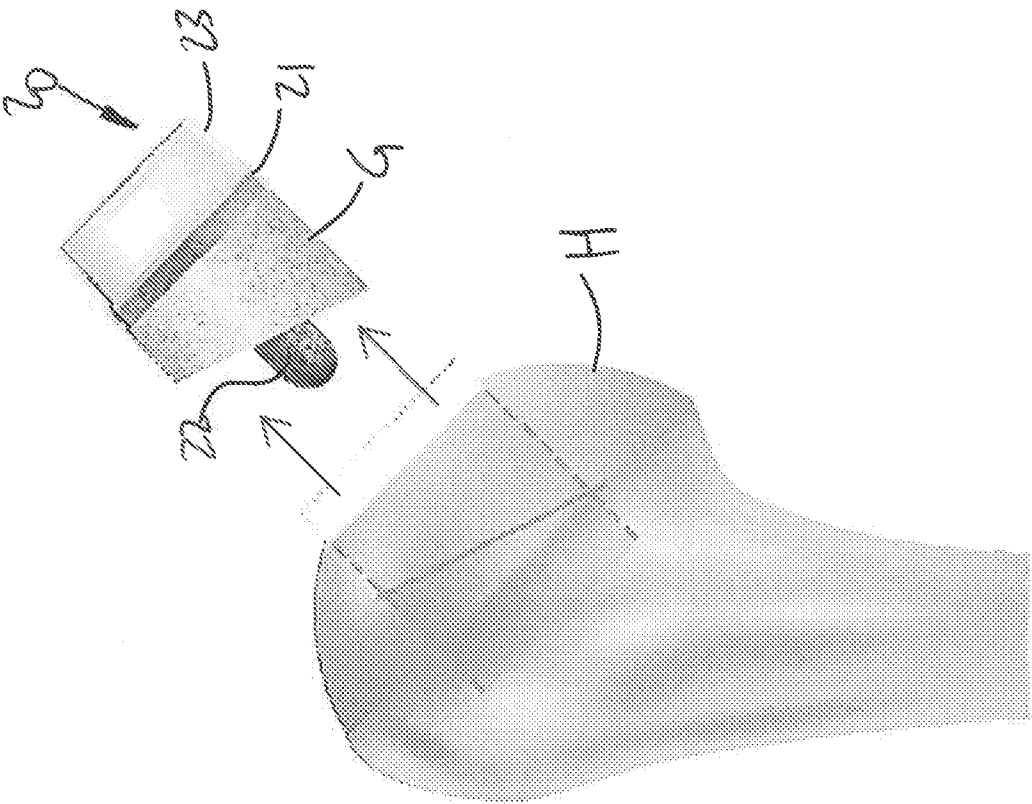


FIG. 16

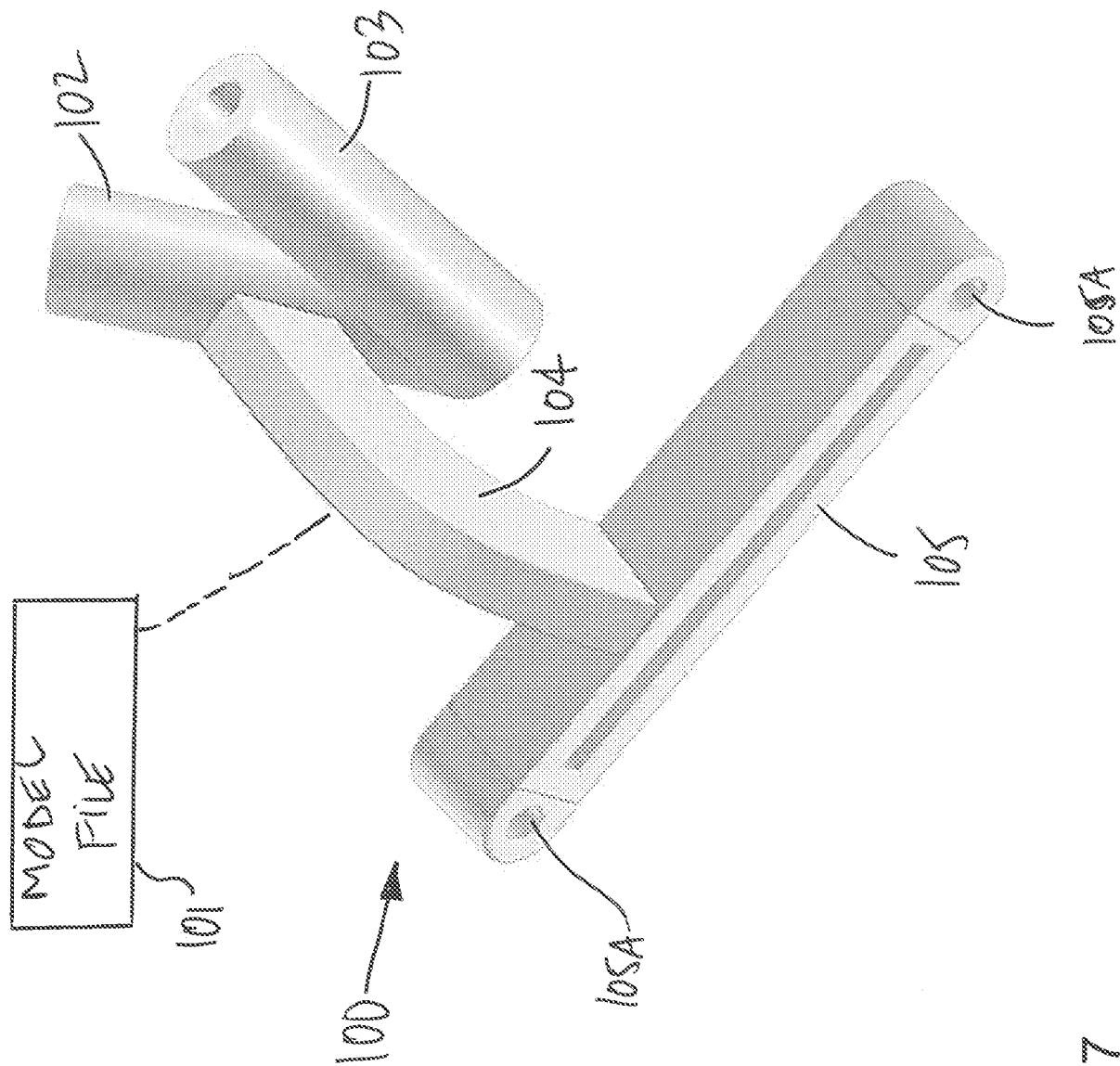


FIG. 17

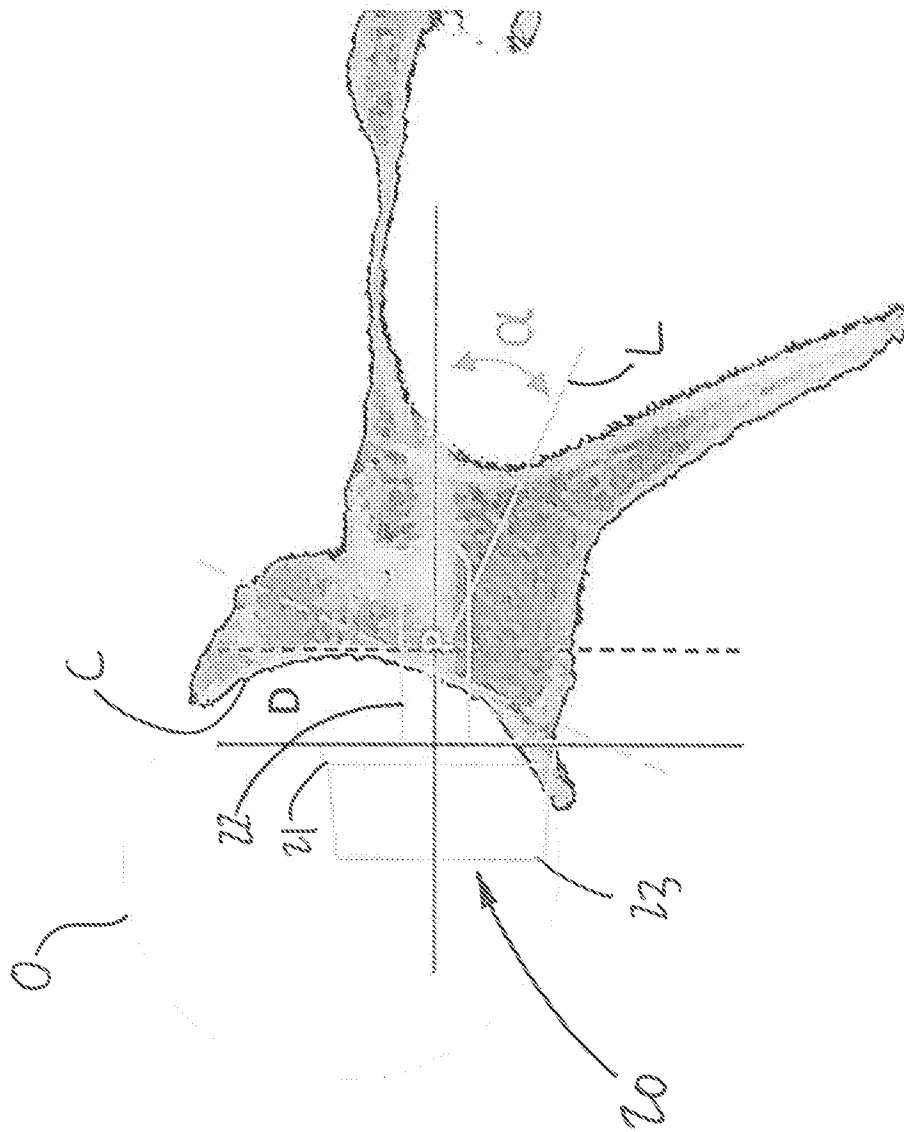


FIG. 18

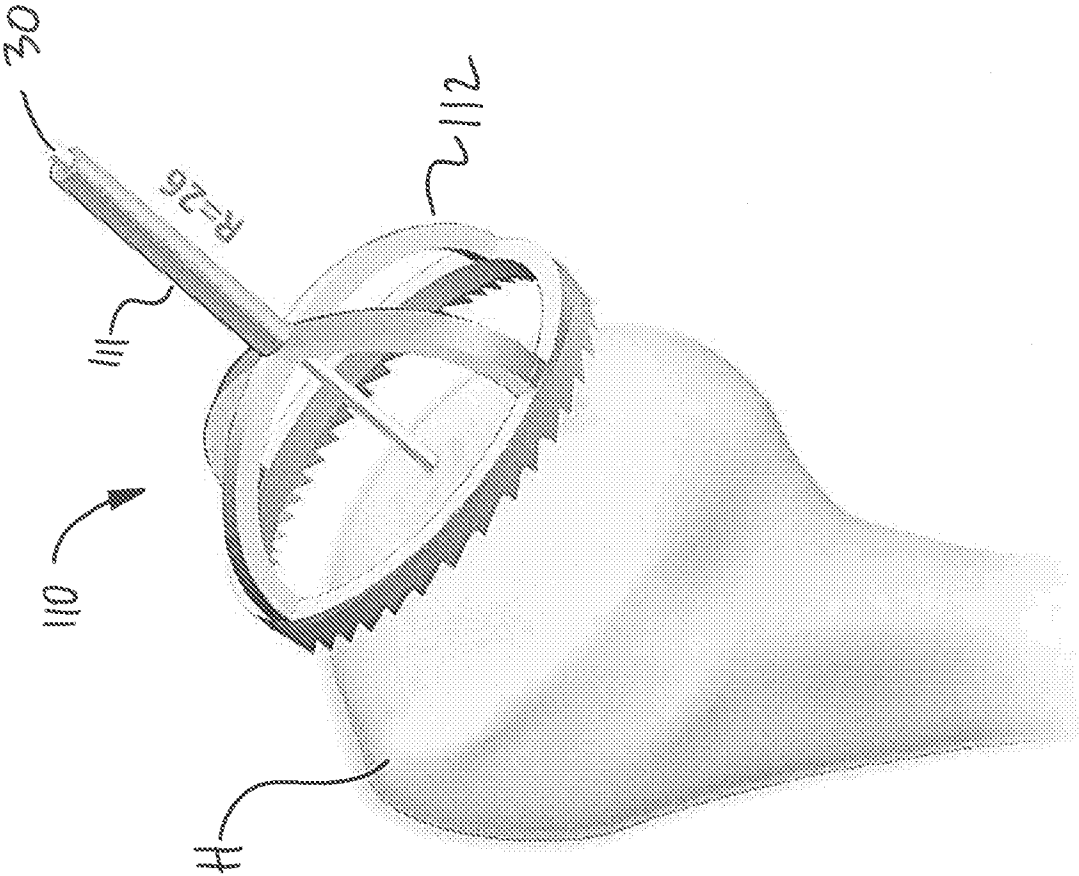


FIG. 19

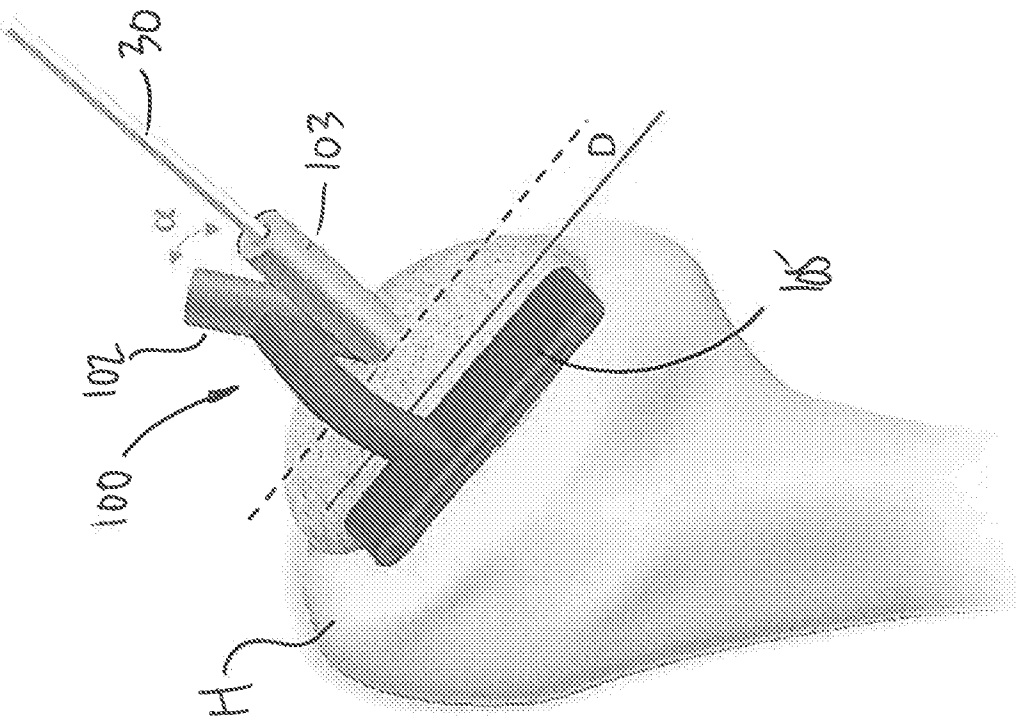


FIG. 20

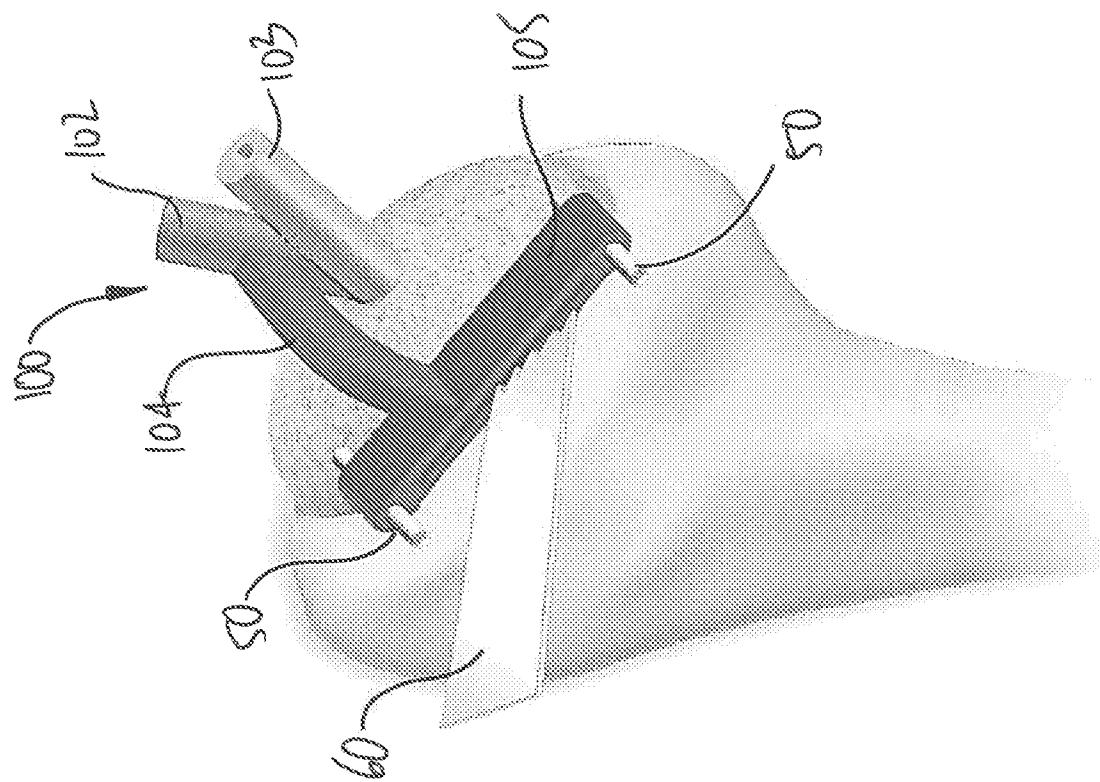


FIG. 21

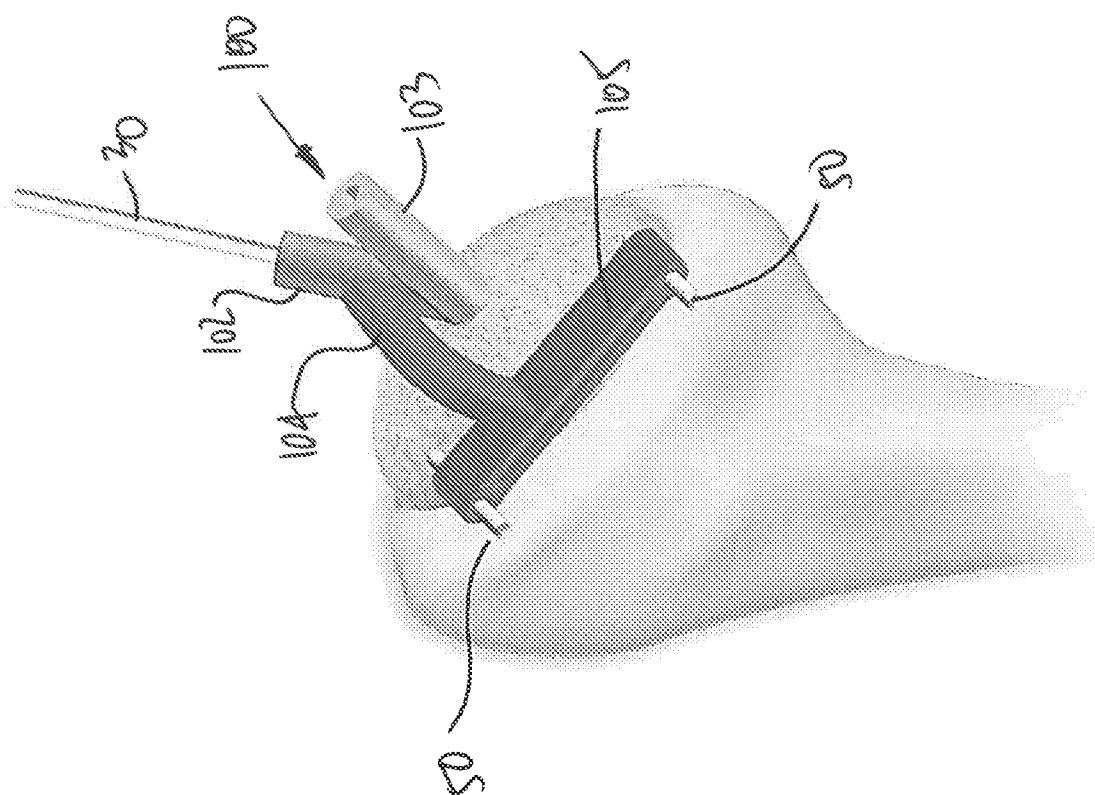


FIG. 22

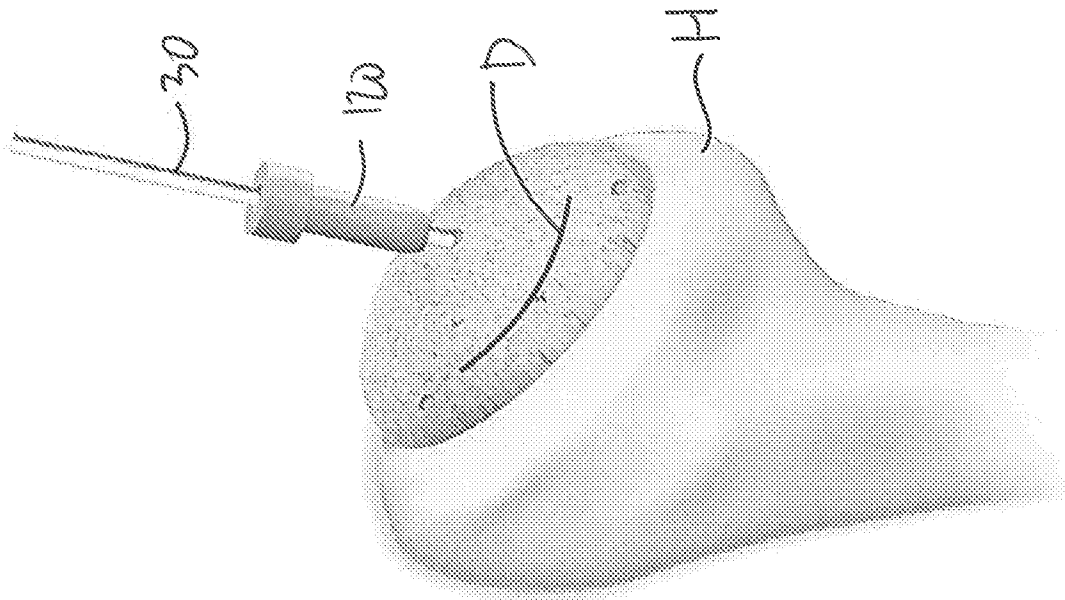


FIG. 23

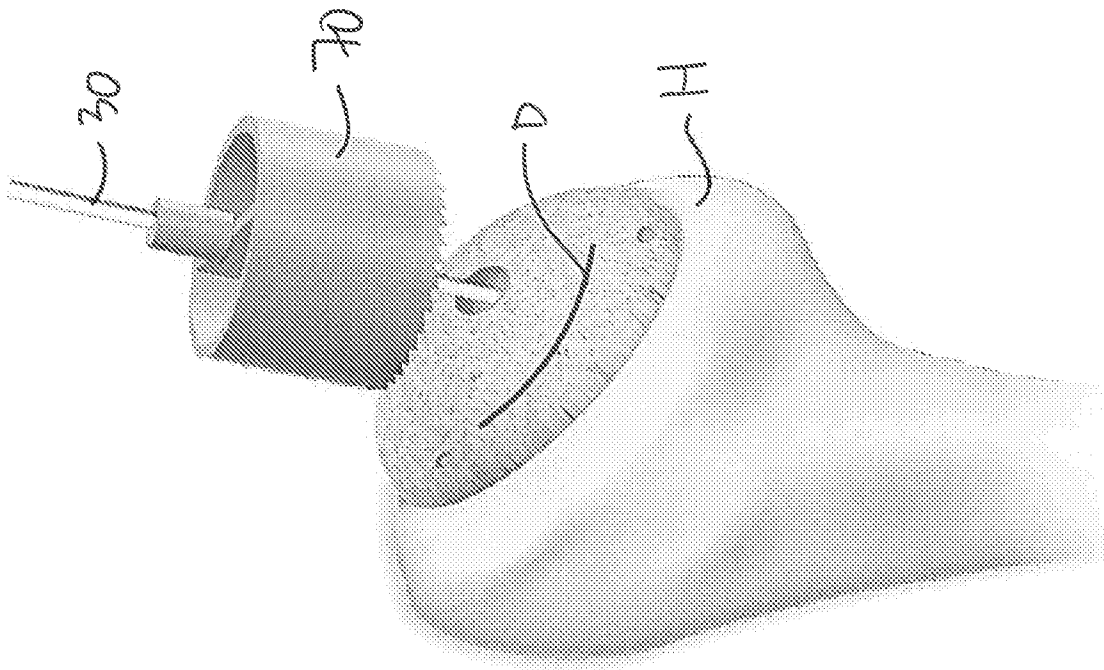


FIG. 24

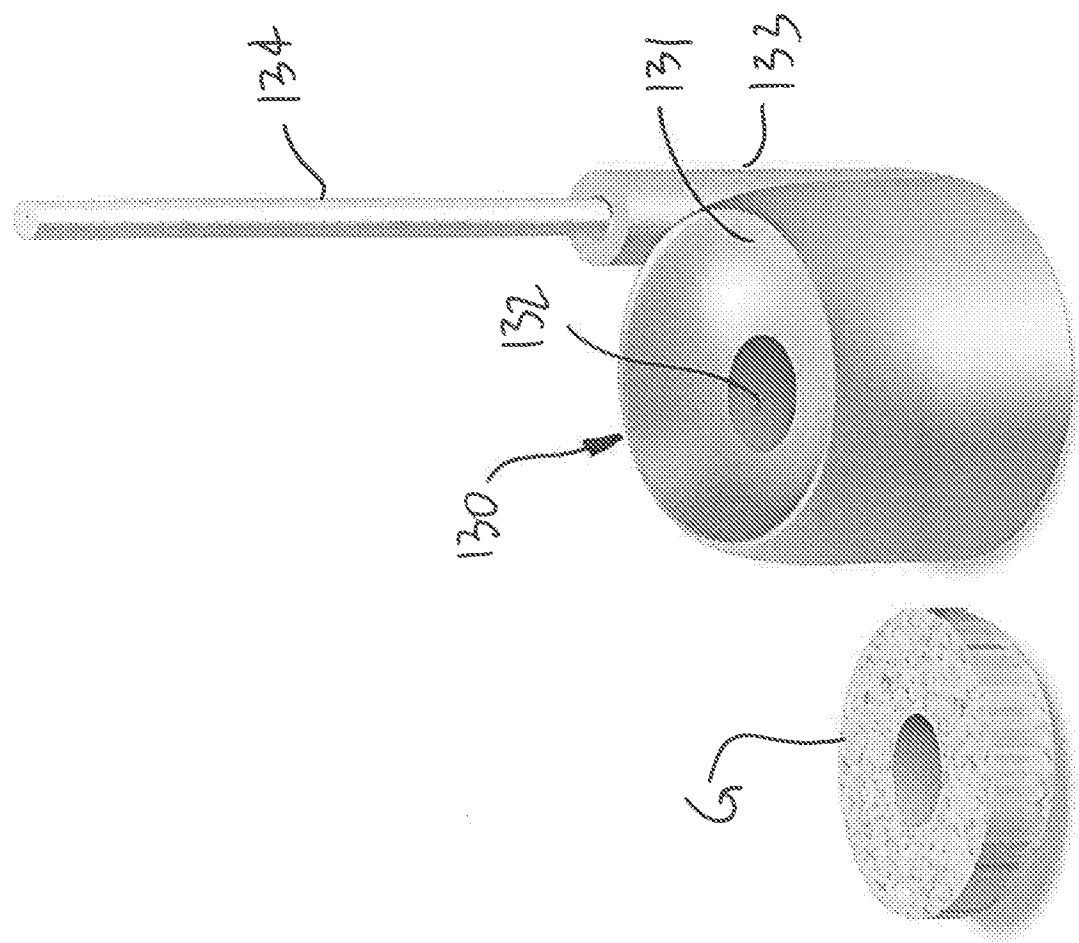


FIG. 25

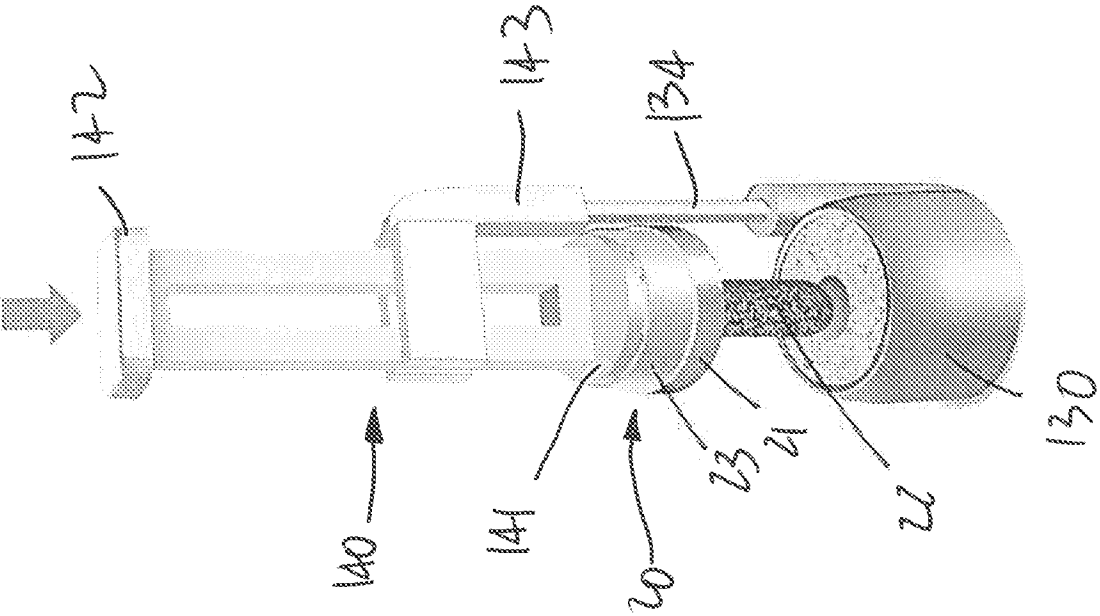


FIG. 26

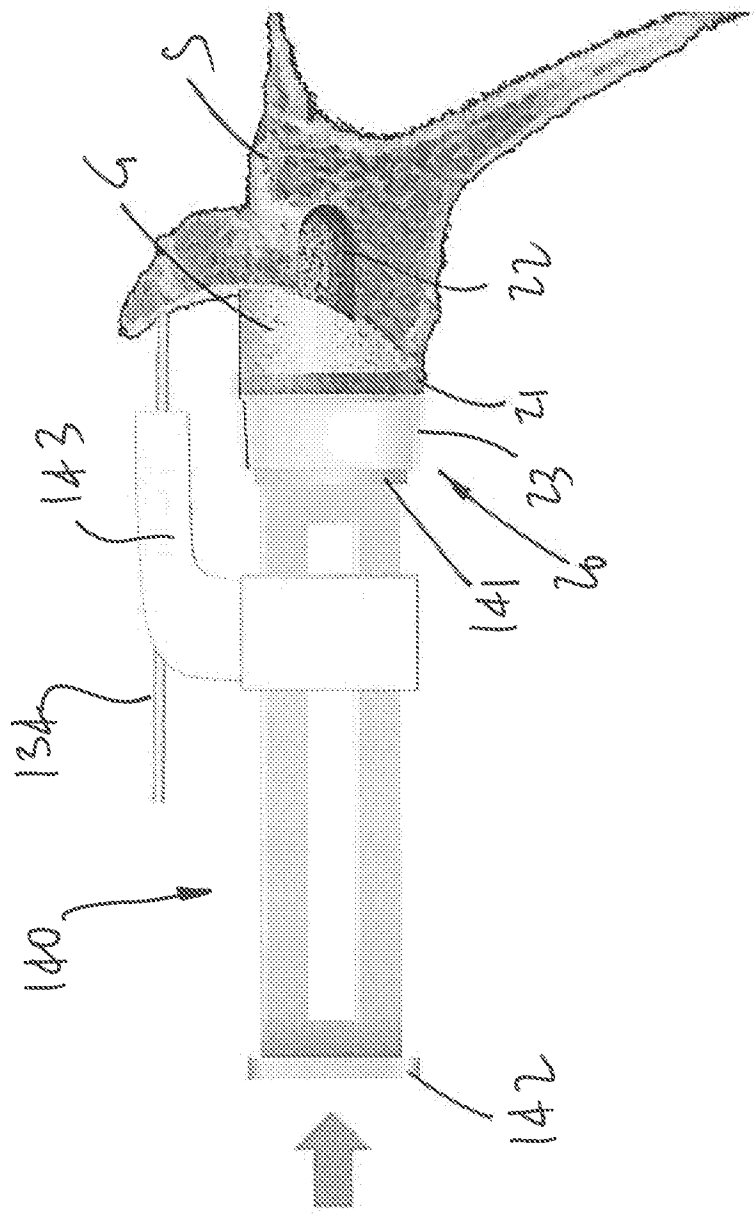


FIG. 27

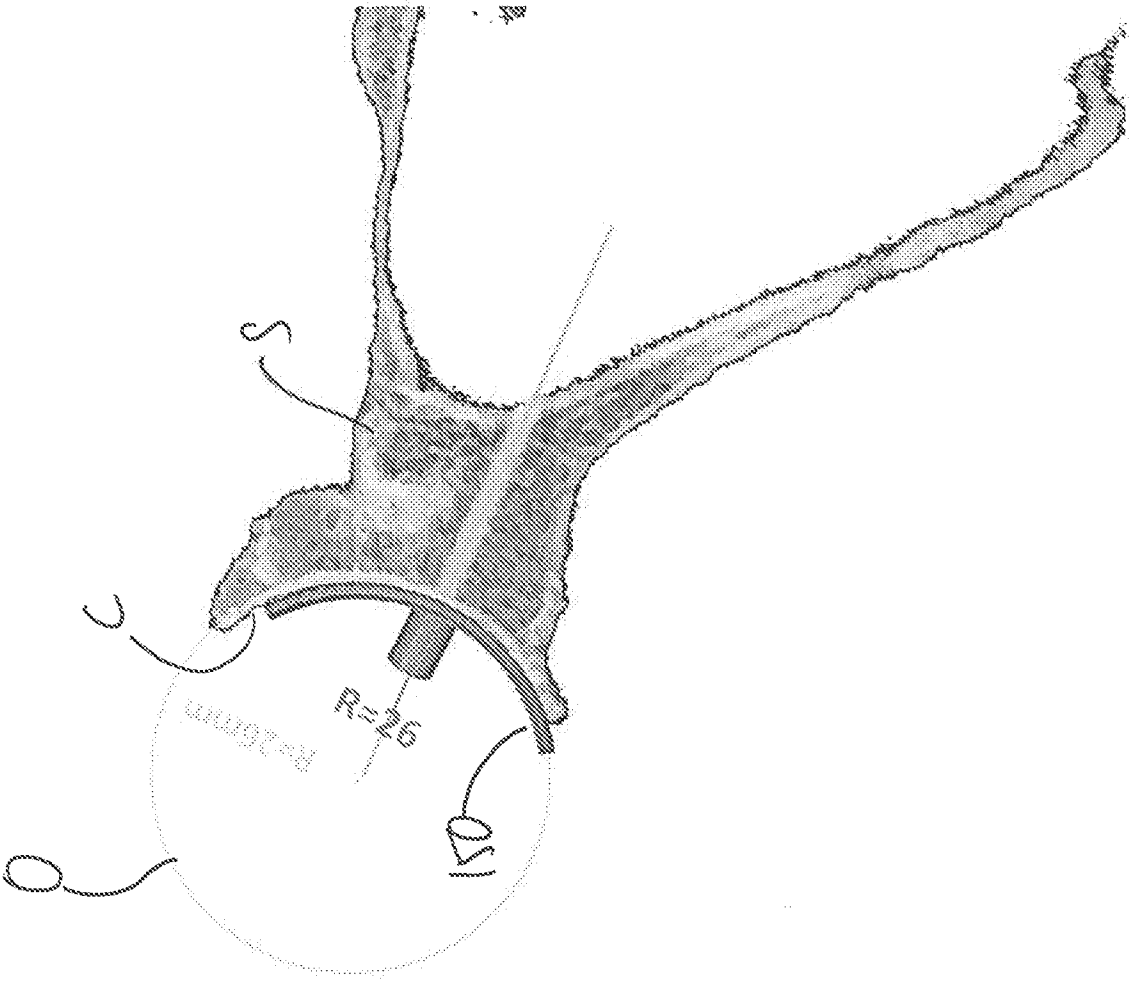


FIG. 28

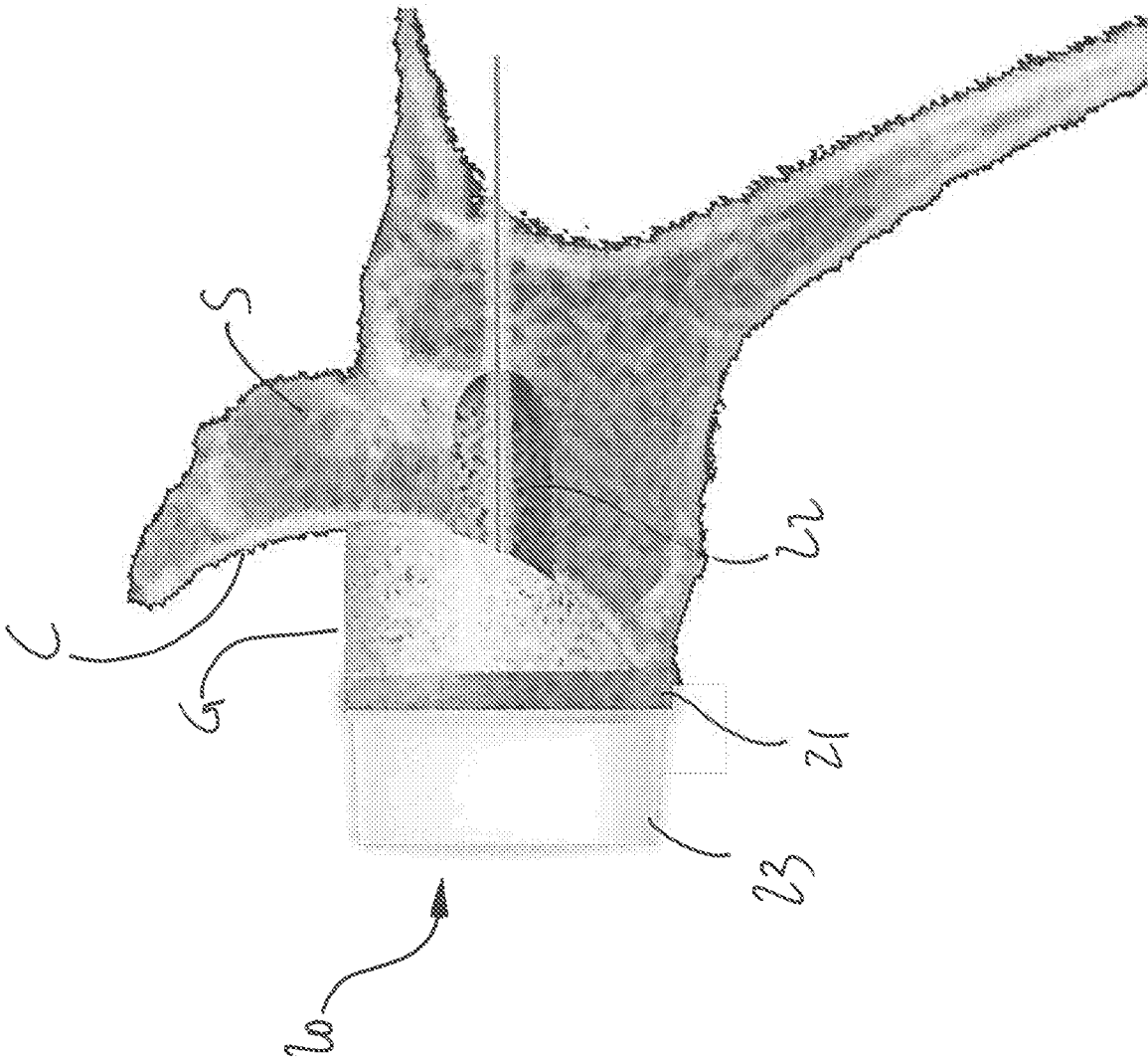


FIG. 29

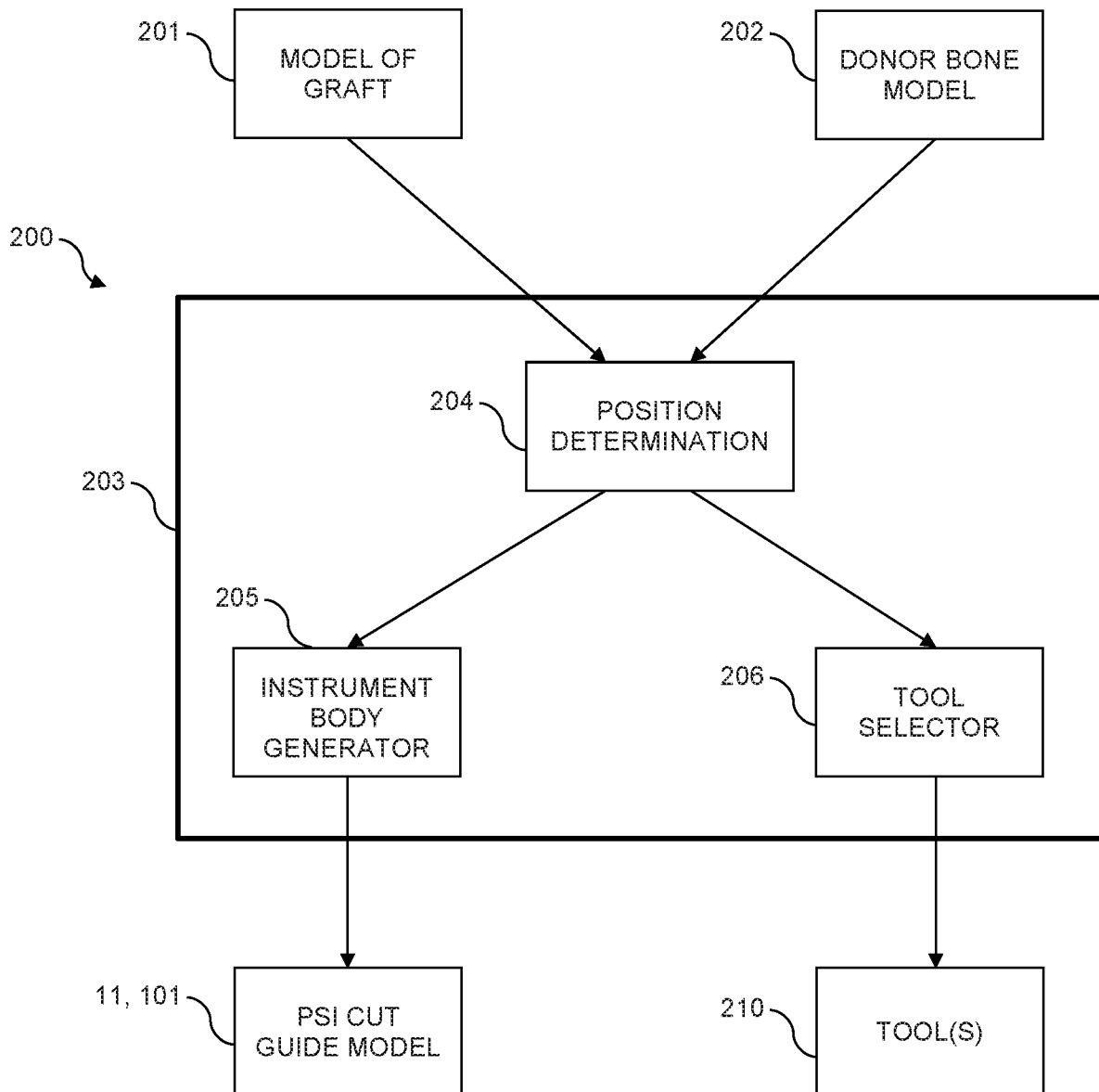


FIG. 30

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2016/034776

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G06F 19/00; A61B 5/00; A61B 5/107; A61B 17/16; A61B 19/00; A61F 2/30; A61F 2/46 (2016.01)

CPC - G06F 19/3437; A61B 5/00; A61B 5/107; A61B 5/1077; A61B 5/4836; A61B 5/742 (2016.05)

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

D. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC - A61B 5/00; A61B 5/107; A61B 17/16; A61B 19/00; A61F 2/30; A61F 2/46; G06F 19/00

CPC - A61B 5/00; A61B 5/107; A61B 5/1077; A61B 5/4836; A61B 5/742; A61B 17/16; A61B 17/1635; A61B 19/00

A61B 19/50; A61F 2/30; A61F 2/30756; A61F 2/46; A61F 2/4657; G06F 19/00; G06F 19/3437

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

USPC - 606/61; 606/80; 606/84; 606/102; 703/1 (keyword delimited)

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

Orbit, Google Patents, Google Scholar

Search terms used: geometry, bone graft, predetermined, guide, plug, donor, shape, orientation, instrument select

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---	US 2013/0191085 A1 (ZIMMER, INC. et al) 25 July 2013 (25.07.2013) entire document	1-5, 9-17 ---
Y		7
Y	US 2010/0087927 A1 (ROCHE et al) 08 April 2010 (08.04.2010) entire document	7
A	WO 2013/177389 A1 (ACCELERATED ORTHOPEDIC TECHNOLOGIES, INC.) 28 November 2013 (20.11.2013) entire document	1-17, 24-39
A	US 2014/0343554 A1 (INNOSPAN ENTERPRISES INC) 20 November 2014 (20.11.2014) entire document	1-17, 24-39
A	US 5,722,977 A (WILHELMY) 03 March 1998 (03.03.1998) entire document	1-17, 24-39

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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

"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

"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

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"&" document member of the same patent family

Date of the actual completion of the international search

01 August 2016

Date of mailing of the international search report

22 AUG 2016

Name and mailing address of the ISA/

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2016/034776

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 18-23, 40
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.