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- (72) **Inventors; and**
- (71) **Applicants :** TARABICHI, Samih [US/AE]; Burjeel Hospital for Advanced Surgery, P.O.Box 32238, Dubai (AE). ELFEKKY, Mohamed M. [EG/AE]; Hatta Hospital Dubai Health Authority, Hatta PO box 4545, Dubai (AE).
- (74) **Agents:** MADDEN, Robert B. et al.; Schwegman, Lundberg & Woessner P.O. Box 2938, Minneapolis, Minnesota 55402 (US).
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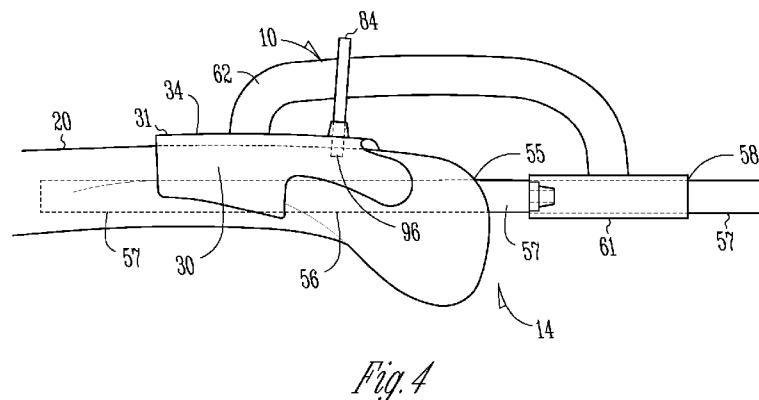
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(54) **Title:** REVISION JOINT REPLACEMENT DEVICE AND METHOD



(57) **Abstract:** A device to aid in performing a revision surgery on a joint can comprise: a body member having a bone facing bottom surface, an opposing top surface, a first end portion configured to be disposed on a bone, and a second end portion opposite the first end portion and configured to be disposed on the bone nearer to the joint relative to the first end portion; a connecting member attached to the body member and configured to extend beyond an end of the bone; and a guide member attached to the connecting member and including an opening configured to receive a cutting tool. The device can be sized and shaped based on a computed tomography scan of the bone, and the guide member can be configured so that when the device is installed on the bone, the longitudinal axis of the opening is aligned with a longitudinal direction of the bone.

REVISION JOINT REPLACEMENT DEVICE AND METHOD

CLAIM OF PRIORITY

5 [0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 61/925,305, filed on January 9, 2014, the benefit of priority of which is claimed hereby, and which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

10 [0002] This patent document pertains generally, but not by way of limitation, to a device and method to aid in installing an orthopedic implant in a revision surgery.

BACKGROUND

15 [0003] A revision surgery can be performed after an orthopedic implant has failed. The components of the implant may have worn out or broken, the patient body may have rejected the implant, or the bone and surrounding tissues may have become infected. Because the bones of the joint have already been altered due to the previous implant surgery, normal bone landmarks at the joint may no longer be
20 present. In addition, conventional X-ray or Computed Tomography (CT) scanning can be highly affected by echoing resulting from metal implant parts; thus a clear scan of the bone area near the metal implant can be difficult or nearly impossible to obtain. A revision surgery can thus be challenging due to infection, patient discomfort, or difficulty in obtaining an accurate depiction of the bone near the joint
25 line.

[0004] In a conventional revision surgery, in order to determine the final three dimensional positioning of an implant, an aperture can be drilled in the end of a femur for example for the placement of a femoral implant stem. A surgeon then needs to decide the “rotation” of the implant, in other words, twisting the implant or
30 provisional about the stem and fixing a final rotational position. The surgeon must then decide how far in or out the implant should be placed in the stem hole. This positioning can determine the ultimate joint line of the implant.

OVERVIEW

[0005] The present inventors recognized that it would be beneficial to provide devices and methods for revision surgery that, in comparison to
5 conventional revision surgery techniques, can lead to an accurate determination of the joint line and improved placement of a femoral stem of a femoral implant. The system and method of the present disclosure allows a surgeon to plan more of the revision surgery before operating on a patient. Preoperative planning can reduce the time required to complete the revision surgery and can improve placement of the
10 revision implant. This disclosure provides a novel and unique device and method for providing a reference “landing zone” or reference location to aid in installing a revision implant. Also disclosed is a method for recreating normal joint lines and configurations in a surgical environment where normal bone configurations are damaged, missing or previously removed. Using the device and method disclosed
15 herein, the final three dimensional positioning of the implant can be planned pre-operatively and built into a revision joint replacement device.

[0006] To further illustrate the revision joint replacement device and methods disclosed herein, a non-limiting list of examples is provided here:

[0007] In Example 1, a device to aid in performing a revision surgery on a
20 joint, the device can comprise: a body member having a bone facing bottom surface, an opposing top surface, a first end portion configured to be disposed on a bone, and a second end portion opposite the first end portion and configured to be disposed on the bone nearer to the joint relative to the first end portion; a connecting member attached to the body member and configured to extend beyond an end of
25 the bone at the joint; and a guide member attached to the connecting member and including an opening configured to receive a cutting tool, wherein the device is sized and shaped based on a computed tomography (CT) scan of the bone, and the guide member is configured so that when the device is installed on the bone, the longitudinal axis of the opening is aligned with a longitudinal direction of the bone.

[0008] In Example 2, the device of Example 1 can optionally be configured such that the body member can have at least one aperture formed in the body member that corresponds to at least one reference point for a bone cutting guide.

[0009] In Example 3, the device of Example 2 can optionally be configured such that the at least one reference point for the bone cutting guide includes a reference point for attaching a cutting guide used to set a joint line of a prosthetic implant.

[0010] In Example 4, the device of any one or any combination of Examples 2-3 can optionally be configured such that the at least one reference point for the bone cutting guide includes a reference point for attaching a cutting guide used to set a rotation of a prosthetic implant.

[0011] In Example 5, the device of any one or any combination of Examples 2-4 can optionally be configured such that the at least one reference point for the bone cutting guide is determined based on measurements of the bone from the CT scan and estimated dimensions of the bone using a digital library of bones, the estimated dimensions of the bone being unattainable from the CT scan.

[0012] In Example 6, the device of any one or any combination of Examples 2-5 can optionally be configured such that the at least one reference point for the bone cutting guide is determined based on a CT image of a healthy joint that is a mirror image of the joint.

[0013] In Example 7, the device of Example 6 can optionally be configured such that the joint is part of a left leg of a patient and the healthy joint is part of a right leg of the patient, or vice-versa.

[0014] In Example 8, the device of any one or any combination of Examples 1-7 can optionally be configured such that the device is sized and shaped based on a reference location on a computed tomography (CT) scan of the bone so that the bone facing bottom surface matches an external bone surface at a corresponding reference location on the bone.

[0015] In Example 9, the device of Example 8 can optionally be configured such that the body member includes a region with curvature on the bottom facing

surface so that when the device is installed at the reference location, the curvature matches at least 50 per cent of a circumference of the bone at the reference location.

[0016] In Example 10, the device of any one or any combination of Examples 8-9 can optionally be configured such that the guide member is oriented
5 so that when the device is installed at the reference location, the longitudinal axis of the guide member is offset from a longitudinal axis of a medullary canal of the bone.

[0017] In Example 11, the device of any one or any combination of Examples 1-10 can optionally be configured such that the body member is formed
10 of at least one of a metal or metal alloy.

[0018] In Example 12, the device of any one or any combination of Examples 1-11 can optionally be configured such that the body member has a flare such that the first end portion of the body member is narrower than the second end portion of the body member, and the flare matches a flare of the bone.

15 [0019] In Example 13, the device of any one or any combination of Examples 1-12 can optionally be configured such that the bone is a femur.

[0020] In Example 14, the device of any one or any combination of Examples 1-13 can optionally be configured such that the bone is a tibia.

[0021] In Example 15, the device of any one or any combination of
20 Examples 1-14 can optionally be configured such that the joint is a knee joint.

[0022] In Example 16, a system for performing a revision surgery on a knee joint, the system can comprise: a femoral implant configured to be installed on the bone so that a distal end of the implant approximates a normal joint line of the knee joint, the femoral implant including a stem; a bone plate including a body member
25 having a bone facing bottom surface; an opposing top surface; a first end portion configured to be disposed on a bone, and a second end portion opposite the first end portion and configured to be disposed on the bone nearer to the joint relative to the first end portion; a connecting member attached to the body member and configured to extend beyond an end of the bone at the joint; and a cutting tool guide
30 member attached to the connecting member and configured to guide forming of an

aperture to prepare the bone to receive the stem of the femoral implant in a medullary canal region of the bone.

[0023] In Example 17, a method for performing a revision implant surgery, the method can comprise the steps of: performing a CT scan of a joint that includes
5 a bone and an orthopedic implant attached to the bone, the CT scan performed prior to performing the revision implant surgery; determining a reference location on a surface of the bone based on images from the CT scan; forming a bone plate configured for attachment to the bone and configured to match a profile of the bone at or near the reference location, the bone plate including a guide member and at
10 least one aperture formed in the bone plate; fixing the bone plate to the bone at the reference location, wherein when the bone plate is fixed to the bone, the guide member is aligned with a longitudinal direction of the bone; and preparing a canal of the bone to receive a stem of a revision implant by using the guide member to guide a cutting tool in the canal of the bone.

[0024] In Example 18, the method of Example 17 can optionally be configured to further comprise the step of: forming at least one aperture in the bone for attaching a cutting guide based on a location of the at least one aperture in the bone plate when the bone plate is fixed to the bone at the reference location.

[0025] In Example 19, the method of Example 18 can optionally be
20 configured such that the location of the at least one aperture in the bone plate is based on a mirror image of a CT image of a healthy joint.

[0026] In Example 20, the method of any one or any combination of Examples 18-19 can optionally be configured such that the location of the at least one aperture in the bone plate is based on inputting CT scan measurements of the
25 bone into a databank of bone measurements to estimate normal dimensions of the bone.

[0027] In Example 21, the method of any one or any combination of Examples 18-20 can optionally be configured such that the at least one aperture in the bone for attaching the cutting guide is used to set a joint line of an implant.

[0028] In Example 22, the method of any one or any combination of Examples 18-21 can optionally be configured such that the at least one aperture in

the bone for attaching the cutting guide is used to set a rotation of a prosthetic implant.

[0029] In Example 23, the method of any one or any combination of Examples 17-22 can optionally be configured such that fixing the bone plate to the bone includes: placing the bone plate from a position that is located in a diaphysial direction from the reference location on the bone; and sliding the bone plate towards a metaphysis region of the bone until the bone plate locks onto the matching reference location.

[0030] In Example 24, a device to aid in performing a revision surgery, the device can comprise: a body member having a bone facing bottom surface; an opposing top surface; a first end portion configured to be disposed on a bone farther from the joint; a second end portion opposite the first end portion and configured to be disposed on the bone nearer to the joint, a portion of the bone facing bottom surface disposed on a metaphysis region of the bone; and a guide member connected to the body member and having a longitudinal axis aligned with a longitudinal direction of the bone, wherein the body member is configured to lock onto a specific reference location of the bone, the locking provided by a flared fit between the metaphysis region of the bone and the bone plate, and a perimeter of the body engaging at least 50% of a perimeter of the bone.

[0031] In Example 25, the revision joint replacement device, system, and method of any one or any combination of Examples 1-24 can optionally be configured such that all elements, operations, or other options recited are available to use or select from.

[0032] These and other examples and features of the revision joint replacement device and related method will be set forth in part in the following Detailed Description. This Overview is intended to provide non-limiting examples of the present subject matter—it is not intended to provide an exclusive or exhaustive explanation. The Detailed Description below is included to provide further information about the present insert press and related method.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0033] In the drawings, like numerals can be used to describe similar elements throughout the several views. Like numerals can be used to represent different views or configurations of similar elements. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.
- [0034] **FIG. 1A** illustrates an anterior view of a healthy knee joint.
- [0035] **FIG. 1B** illustrates an anterior view of a knee joint needing a revision surgery.
- 10 [0036] **FIG. 1C** illustrates an anterior view of a mirror image of the healthy knee joint of **FIG. 1A**.
- [0037] **FIG. 2** illustrates a top view of a long bone, such as a femur.
- [0038] **FIG. 3** illustrates an isometric bottom view of an example of a revision surgery device, in accordance with the present application.
- 15 [0039] **FIG. 4** illustrates a side view of the revision surgery device of **FIG. 3** (disposed on a bone), in accordance with the present application.
- [0040] **FIG. 5** illustrates a top view of the revision surgery device of **FIG. 3** (disposed on a bone), in accordance with the present application.
- [0041] **FIG. 6** illustrates a front view of the revision surgery device of **FIG. 3** (disposed on a bone), in accordance with the present application.
- 20 [0042] **FIG. 7** illustrates a front view of the revision surgery device of **FIG. 3** (disposed on a bone), in accordance with the present application.
- [0043] **FIG. 8** illustrates an isometric view of an example of a cutting guide, in accordance with the present application.
- 25 [0044] **FIG. 9** illustrates an isometric view of an example of a cutting guide, in accordance with the present application.
- [0045] **FIG. 10** illustrates a top view of an example of a revision surgery device as constructed in accordance with the present application.
- [0046] **FIG. 11** illustrates a top view of the revision surgery device of **FIG. 10** in accordance with the present application.
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[0047] FIG. 12 illustrates a side view of the revision surgery device of FIG. 10 in accordance with the present application.

[0048] FIG. 13 illustrates a cross sectional view of a portion of the revision surgery device of FIG. 12 in accordance with the present application.

5 [0049] FIG. 14 illustrates a side view of the revision surgery device of FIG. 10 in accordance with the present application.

[0050] FIG. 15 illustrates a cross sectional view of a portion of the revision surgery device of FIG. 14 in accordance with the present application.

[0051] FIG. 16 illustrates a side view of the revision surgery device of FIG. 10 in accordance with the present application.

[0052] FIG. 17 illustrates a cross sectional view of a portion of the revision surgery device of FIG. 16 in accordance with the present application.

DETAILED DESCRIPTION

15 [0053] The present disclosure uses CT scans or other comparable imaging processes to create a three dimensional model of a bone, which can provide a landing zone or distinct referencing location for a patient specific template or bone plate (a “device”). The model can be a virtual model, or a solid model created by conventional machining techniques or additive manufacturing techniques. The
20 landing zone or referencing location can be located on a bone surface that has enough distance from metallic prosthetic components that have been installed on a previous surgery so that a clear and accurate CT scan can be obtained. The landing zone or referencing location can be located on a bone surface that has enough distance from damaged or infected tissue, so that the referencing location itself can
25 remain intact throughout the revision surgery. For purposes herein, a long bone, such as a femur, is defined as having three basic regions - the diaphysis, the metaphysis and the epiphysis. The epiphysis is the area closest to the joint end of the bone and is usually the largest in diameter of the three regions. The diaphysis of the bone is a long narrow portion of the bone between the joint ends, and the
30 metaphysis is a flared section that forms a transition between the narrower diameter diaphysis and the larger diameter epiphysis.

[0054] A device or “bone template” can be formed that can have a bone contacting surface that matches the landing zone of the 3D model of the bone site. The device can be formed so that it can be placed “above” or in a diaphysal direction from the landing zone and moved towards the joint until the device,
 5 because of its shape and matching features, can “lock on” to the landing zone. Because the device or template is referenced to actual locations on the 3D model, various apertures, cutting slots, and/or drill guides can be provided that can aid in fitting a prosthetic that has been planned for use in combination with the patient specific device. In an example, normal joint lines can be maintained by the revision
 10 prosthetic and missing bone can be replaced through the use of spacers, cones, augments or bone cement. As an example, the disclosed device and method can be configured to operate in conjunction with a particular prosthetic manufacturer and a particular manufacturer’s method of installation.

[0055] **FIG. 1A** illustrates a depiction of a CT scan **50’** of a right knee joint **65**, which can include a femur **20’** and a tibia **21’**. The right knee joint **65** is healthy and has not been altered. A joint line **70’** can be a central axis line that is generally transverse to the direction of the femur **20’** and the tibia **21’**, making up a joint **14’**, which bends or flexes about the joint line **70’**. Although a bone can have more than one “joint”, in this document the joint **14’** (or a joint **14**) refers to the
 20 knee joint.

[0056] **FIG. 1B** illustrates a depiction of a CT scan **50** of a left knee joint **66**, which can include a femur **20** and a tibia **21**. The left knee joint **66** can require a revision surgery after removing a previously installed implant. When a surgeon is determining the joint line **70** for the revision implant, making additional cuts to
 25 remove infected or damaged tissue, or preparing the bone site **7**, normal landmarks **69** provided by a healthy knee are missing (see **FIG. 1A**). These landmarks, which can be seen in the right knee joint **65**, can include, for example, intercondyloid eminences **67** of the tibia **21’** or the condyle ends **68** of the femur **20’**. These landmarks are missing from the left knee joint **66**, because the femur **20** and the
 30 tibia **21** have been previously altered to fit the original prosthetic.

[0057] FIG. 1C illustrates a depiction of a mirror image 52 of the CT scan 50' of FIG. 1A. The femur 20', tibia 21' and joint line 70' of FIG. 1A, which illustrate a healthy right knee 65, can be used to create a mirror image in FIG. 1C to approximate what a healthy left knee could look like. See below for further description of FIG. 1C.

[0058] FIG. 2 illustrates a femur 20 having a distal end 29 and a proximal end 12. The femur 20 shown in FIG. 2 can be the femur 20 of the damaged left knee 66 of FIG. 1B. For simplicity and reference, the femur 20 in FIGS. 2, 4-7, and 10-11, may not be illustrated as damaged as femur 20 of FIG. 1B. The femur 20, or any long bone for example, has three main regions: a diaphysis region 22, a long narrow portion between the distal end 29 and the proximal end 12 of the a femur 20; the epiphysis region 24, a large end of the femur 20 closest to a joint 14 (formed between the femur 20 and a tibia, not shown); and a metaphysis region 23, a flared transition portion between the narrow diaphysis 22 and the larger epiphysis 24. The femur 20 can have a shape which can provide a longitudinal direction 18. The longitudinal direction 18 can be defined as a line collinear with or parallel to a longitudinal axis 25 of the femur 20, or within 30 degrees of the longitudinal axis 25, as in angle A.

[0059] FIG. 3 illustrates an isometric bottom view of a revision surgery device 10. The device 10 can include a body member 30 having a top surface 34 opposite a bone facing bottom surface 33. The body member 30 can extend from a first end portion 31 to a second end portion 32. A thickness 35 between the bone facing bottom surface 33 and the top surface 34 can be configured to give the body member 30 sufficient strength to allow firm fixation of the device 10 to a bone site 7, such as at a reference location 51 (see FIG. 1B). Fixation of the device 10 to the bone is described further below in references to FIGS. 4-7.

[0060] The contours of the bone facing bottom surface 33 can match the contours of an exterior surface 92 of the femur 20 (see FIG. 1B) such as at a pre-planned reference location 51 provided by 3D imaging. The shape and position of the reference location 51 is described further below and can be shaped or positioned in any desired manner or location. The device 10 can be manufactured from metals,

metal alloys, plastics, polymers, composites, ceramics or any material with enough suitable strength to form a rigid or semi-rigid component. The device **10** can be manufactured by conventional machining and forming techniques, by additive manufacturing techniques, or by manual forming techniques.

5 **[0061]** The device can be virtually designed, encoded, or formed using virtual or real models of a patient's bone developed from CT, x-ray or other means of bone imaging as a template for creating the geometry of the bone facing bottom surface **33** of the device **10**. The device **10** can be manually formed using a 3D model of a patient's bone as a template for the bone facing bottom surface **33** of the device **10**. Apertures, drilling and/or cutting guides, referencing/indexing marks for a contemplated prosthetic surgery can be built into the device **10** using virtual or real models of a patient's bone as a template. Any apertures, drilling or cutting guides formed as part of the device **10** can maintain referencing that relates to an original reference location and to the 3D imaging scans which are directly related to the patient's actual bone geometry. These features of the device **10** are described further below.

15 **[0062]** The device **10** can include a connecting member **62** that can extend from the top surface **34** of the body member **30** and can extend beyond the second end portion **32** of the body member **30**. The connecting member **62** can be attached or removable to the body member **30**. The connecting member **62** can be integrally connected to the body member **30**, or attached by other means such as threading, welding, gluing, bolting, pinning or other means known in the art. If the connecting member **62** is removable, it can be indexed so that a surgeon or technician can install the connecting member **62** to the body **30** in a precise position. The connecting member **62** can extend beyond the distal end **29** of the femur **20** (see **FIG. 4**). The connecting member **62** can have a circular, rectangular, flattened, oval or irregularly shaped cross-section. A guide member **61** can be attached to the connecting member **62**. The guide member **61** can have a circular, rectangular, flattened, oval or irregularly shaped cross-section. The device **10** can include more than one connecting member **62** and each can attach to one or a plurality of guide

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members **61**. For example, the guide member **61** can be supported by more than one extensions or connecting members **62** attached to the body **30**.

[0063] The guide member **61** can include an opening **58** that is configured to receive and guide a cutting tool **57** (see **FIG. 4**), such as a drill, a reamer, a burr, a mill or any cutting tool known to those skilled in the art. The guide member **61** is described further below. A bracket member **83** can be attached to the guide member **61** and can include a rotation referencing guide **78** (described more fully below).

[0064] **FIGS. 4-7** are illustrations of the device **10** of **FIG. 3** installed on the distal end **29** of the femur **20** of **FIG. 2**. Although the device **10** is illustrated as disposed on a femur **20**, the device **10** can be used on any bone having a flared portion near a joint. In **FIG. 4**, the first end portion **31** can be disposed farther away from a joint **14** of the femur **20**. The second end portion **32**, opposite the first end portion **31**, can be disposed nearer to the joint **14**. As shown in **FIG. 5**, the first end portion **31** can include a first width **44**, that can be generally transverse to the longitudinal axis **25** (see **FIG. 2**) of the femur **20**. The second end portion **32** can include a second width **45**, that can be generally transverse to the longitudinal axis **25** (see **FIG. 2**) of the femur **20**. In an example, the first width **44** can be narrower than the second width **45** and the body **30** can include a flare angle **B** that matches or approximates a flare angle of the metaphysis region **23** of the femur **20**.

[0065] As shown in **FIGS. 4** and **5**, the opening **58** of the guide member **61** can receive and guide a cutting tool **57** that can be used to create or enlarge an aperture **56** in the femur **20**. The aperture can coincide with the medullary canal of the femur **20** or deviate from the medullary canal. The guide member **61** can be used with removable drill guides that can allow a small initial drill hole and the guide member **61** can be sized to receive reamers for a final implant stem size. In another example, final reaming for an implant stem can be accomplished with the device **10** removed from the femur **20**. The position of the guide member **61** can be configured to match positions determined during pre-operative planning by a surgeon from 3D imaging. A position of the guide member **61** can be dependent upon the position of the body **30** on the femur **20**. The body **30** can have one or more fixation apertures located at a particular position on the body **30** so that the

body **30** can be securely fixed to the femur **20** before any bone cutting is performed using the guide member **61**.

[0066] A position of the guide member **61** on the femur **20** can determine, in part, a starting position **55** of the aperture **56** in the femur **20**. The position of the guide member **61** can determine the angle of the cutting tool **57** in an axial direction. An intramedullary pin can be placed in the aperture **56** and can be used as a reference for placement and positioning of bone cutting guides. The aperture **56** can be sized by reamers, drills or other cutting tools to provide a fit for the stem of a prosthetic implant or a provisional implant. The aperture **56** can form a reference axis line **72** (see **FIG. 5**).

[0067] **FIGS. 5** and **6** further illustrate device **10** installed on the bone and shows a rotation referencing guide **78** and a joint line referencing guide **79**. By using at least two additional reference points, such as the rotation referencing guide **78** and the joint line referencing guide **79**, in addition to the reference axis line **72**, a final implant position can be determined. The positioning of the two reference points **78** and **79** and the reference axis line **72** can be built into the device **10** with preoperative planning before the first incision of the revision surgery is performed. Because positioning of these referencing points can be planned pre-operatively, apertures for these referencing points can also be used to fix the device **10** to the femur **20**, before forming or enlarging the aperture **56** or making any bone resections. The joint line referencing guide **79** can guide a cutting tool to provide an aperture in the anterior side **27** of the femur **20**. A joint line referencing pin **84** can be received in a joint line aperture **96** (see **FIG. 4**) created using a joint line referencing guide, such as an additional joint line referencing guide **82** (described below).

[0068] The rotational referencing guide **78** can guide or position a drill, reamer or other cutting tool and provide an aperture for fixing positional rotation of a cutting guide or prosthetic component about the reference axis line **72** (see **FIG. 9**). In an example, an additional rotation referencing guide **81** can be provided that can provide a slightly different rotational positioning, allowing fine tuning options for the surgeon. The additional rotation referencing guide **81** can also match

rotational positioning of the rotation referencing guide **78** to provide greater accuracy or stability. The rotation referencing guide **78**, can be included in the bracket member **83** that can be attached to the guide member **61**. Structures such as brackets, lobes, or extensions can include or support the rotation referencing guide **78**, or any additional rotation referencing guides, such as aperture **81**, and can also extend from other portions of the body **30** such as from the second end portion **32**.

[0069] The joint line referencing guide **79** can guide or position a drill, reamer or other cutting tool and provide an aperture in the femur **20** for fixing a position along the reference axis line **72**. If a surgeon or technician determines that the joint line **70** (see **FIG. 8**) formed by the revision implant should be farther from the distal end **29** of the femur **20** in a proximal direction, the joint line referencing guide **79** can be positioned accordingly during preoperative planning. The joint line referencing guide **79** can determine how far in or out (proximally or distally) a stem of a femoral implant or provisional is positioned in the aperture **56** (see **FIG. 4**). In an example, an additional joint line referencing guide **82** can be provided that can provide a slightly different joint line positioning, allowing fine tuning options for the surgeon. The additional joint line referencing guide **82** can also match joint line positioning of the joint line referencing guide **79** to provide greater accuracy or stability.

[0070] The referencing features described herein (the reference axis line **72**, the rotation referencing guide **78** and the joint line referencing guide **79**) can be configured to operate with a particular manufacturer's prosthetic component installation process. Additional referencing guides such as apertures **82** or **81** can be provided in any possible combination to give an operating surgeon as many options as possible during a surgical procedure. As described above, because the reference axis line **72**, the rotation referencing guide **78**, and the joint line referencing guide **79** can be built into the device **10**, a three dimensional positioning of an implant or provisional in relation to the femur **20** can be determined once the device **10** "locks on" to a reference location **51**, as described further below. In other words, the present disclosure provides a device **10** and method for locating a revision implant (or provisional implant) in three dimensional space in relation to the bone by

determining the reference axis line **72**, which can become the axis of a femoral stem of the revision implant. The device **10** can establish the “twist” in the femoral stem through the rotational referencing guide **78** and can also establish the proximal/distal location of the femoral stem along the reference axis line **72**,
5 through the joint line referencing guide **79**.

[0071] FIGS **6** and **7** illustrate how the rotation referencing guide **78** can relate to the opening **58** of the guide member **61**. The opening **58** can provide the longitudinal axis **72** (see FIG. **5**) about which the rotational referencing guide **78** can be positioned and ultimately control the rotational position of an implant or
10 provisional implant about the stem of the implant. Implant component manufacturers can provide implant components with offset stems. Such offset stems can provide flexibility for implant procedures for irregular bone configurations. A bone may be bowed or have other features that may require a surgeon to use a prosthetic component with an offset stem feature. The surgeon can
15 plan such an offset position into the device **10** in designing a location of the guide member **61** on the device **10**. The guide member **61** in FIG. **6** can be centrally located between a medial condyle **90** and a lateral condyle **91**. In planning for an offset stem, a guide member **61'**, and an opening **58'** can be constructed to be offset as illustrated in FIG. **7** and be located, for example, more towards the medial
20 condyle **90'** (or in whatever offset position is desired).

[0072] Referring again to FIG. **1B**, in pre-operative planning a surgeon can work with 3D images, such as a CT scan or a bone model created from such a bone scan. Because the normal landmarks **69** (see FIG. **1A**) of the end of the femur **20** are not present in the case of a femur undergoing revision, the surgeon can use a
25 ‘landing zone’ or reference location **51** that can be on another surface of the bone, for example the anterior side **27** of the femur **20** in the metaphysis region **23**. Once this landing zone or reference location **51** has been determined, other reference points and locations can be measured and determined from the initial reference location **51**. The body member **30** of the device **10** can be formed so that a bone
30 facing bottom surface **33** (see FIG. **3**) can match the exterior surface **92** of the femur **20**.

[0073] During the placement and fitting of a prosthetic implant there can be two referencing procedures that can include 1) determination of the joint line and 2) rotation of the prosthetic in relation to the rotational axis of the reference axis line 72 as described in FIG. 5. As discussed above and referring to FIGS. 1A-1C, the surgeon cannot use conventional bone or joint landmarks 69, because the joint 14 has been greatly altered by the previous implant surgery. One method that can be used to determine a joint line of a joint requiring revision surgery, such as the left knee joint 66 of FIG. 1B, can be by creating a mirror image 52 of an image scan 50' of a healthy right knee 65. If a patient has an analogous matching joint that is healthy, for example a healthy right knee 65; a mirror image 52 of the CT scan 50' of the right knee 65 can be created which can approximate what a healthy left knee could look like, even though the left knee 66 has been altered considerably by a previous implant surgery. The mirror image 52 of FIG. 1C can include the same joint line 70' that is present in FIG. 1A in relation to the right knee 65. The mirror image 52 can aid in determining the positioning of the joint line 70 in relation to the femur 20 on the left knee 66 and in relation to a reference location 51. Such estimation can allow formation and/or placement of referencing apertures on the body member 30 of the device 10 such as the joint line referencing guide 79 (see FIG. 5).

[0074] Maintaining the joint line in a revision surgery can provide a beneficial surgical outcome. Even though much of the bone can be removed from an initial implant surgery or the revision surgery, the missing bone can be replaced by augments, spacers, cones, cement, or any other means known to those skilled in the art to build up or replace missing bone material and keep the outer dimensions of prosthetic components as close to the normal joint line as necessary.

[0075] In some revision surgeries, there may be no matching healthy joint such as the right knee 65 in FIG. 1A for producing the mirror image 52 of FIG. 1C. For example, patients that have had a double knee replacement do not have an un-resected knee joint. In these cases, the surgeon can input measurements obtained from a CT scan or other imaging of the femur 20 (see FIG. 1B) such as, for example, diameters at various locations on the bone, or distances from landmarks

that do exist, such as the head **17** of the femur **20** (see **FIG. 2**). Many measurements can be taken from imaging of the resected femur **20** and these measurements can be used in combination with a digital library that includes a databank of measurements from numerous representative bones. By comparing measurements taken from the resected femur **20** in **FIG. 1B**, to numerous representative bones, computer software can estimate what the length of the patient's bone was before any bone had been removed. Once the estimated normal length of the bone has been obtained, a joint line **70** can be accurately estimated.

[0076] **FIG. 8** illustrates a cutting guide **60** positioned on the femur **20**. In an example, the cutting guide **60** can also serve as a provisional implant. In a revision surgery, a surgeon can place provisional implants on the femur **20** to gauge a final implant position. Although the cutting guide **60** is shown in **FIG. 8**, this view can also approximate how a provisional implant or implant would appear in the final implant position. A joint line referencing pin **84** can be installed in the femur **20** to provide positioning for the cutting guide **60**. The joint line referencing pin **84** can be installed in an aperture formed using the joint line referencing guide **79** as described above (see **FIGS. 4** and **5**). Placement of such a reference point either closer or farther from the existing end of the femur **20** can control final positioning of the joint line **70**. Such a joint line referencing pin **84** can also be utilized to position a cutting guide **60** that can be used to prepare the femur **20** for a prosthetic implant by shaping the bone or removing unwanted bone material. In some instances more than one joint line referencing pin **84** can be used. The cutting guide **60** can provide numerous slots **89** that can serve as cut guides for making resections in the bone to fit an implant or in preparation for differently sized spacers or augments.

[0077] **FIG. 9** illustrates a cutting guide **88** positioned on the femur **20**. A rotational referencing pin **85** can be installed in the femur **20** to provide positioning for the cutting guide **88**. The rotational referencing pin **85** can be installed in an aperture formed using the rotational referencing guide **78** as described above (see **FIG. 5**). Placement of such a reference point can control final rotational positioning of the cutting guide **88** that can be used to prepare the femur **20** for a prosthetic

implant by shaping the bone or removing unwanted bone material. In some instances more than one rotational referencing pin **85** can be used. The cutting guide **88** can provide numerous slots **89'** that can serve as cut guides for making resections in the bone to fit an implant or in preparation for differently sized spacers or augments.

[0078] In **FIGS. 10-17**, device **10** is the device **10** of **FIGS. 3-6** except that for simplicity, the connecting member **61** and assorted features are not shown. **FIG. 10** illustrates how a device **10** “locks on” to a reference location **51** that is pre-operatively picked by a surgeon on a 3D imaging scan of the femur **20**. The surgeon can place the device **10** on the femur **20** at a location in a direction away from the joint **14**. The device **10** can have a bottom opening **46** (see also **FIG. 3**) that is wide enough that the device **10** can be placed on the bone exterior surface **92** in an area where a first bone width **87** is smaller than the bottom opening **46**. A matching reference location **51A** is shown on the device **10** and can correspond to the reference location **51** on the femur **20**. The device **10** can be slid towards the joint **14**. In the flared metaphysis region **23**, a second bone width **94** can be greater than the bottom opening **46** and because lower lobes **86** of the body **30** can be underneath the bottom half of the femur **20**, the device **10** cannot be lifted directly up off the femur **20**, once the device **10** has been slid far enough towards the joint **14**.

[0079] **FIG. 11** is an example of the device **10** moved all the way towards the joint **14**. Because of matching flares between the device **10** and the metaphysis region **23** of the femur **20**, the device **10** cannot move any farther towards the joint **14**. Because contours of the bone facing bottom surface **33** (see **FIG. 3**) are configured to match an exterior surface **92** (see **FIG. 10**) of the femur **20**, the device **10** can fit the femur **20** at the reference location **51** like a hand-in-glove or like a contoured piece of a jigsaw puzzle. The exterior surface **92** of the femur **20** is not perfectly round, but can have an elliptical shape or flattened sections that can prevent the device **10** from any rotational movement about the longitudinal axis **25** (see **FIG. 2**) of the femur **20**. The reference location **51** and the matching reference location **51A** can coincide and the device **10** can be temporarily fixed to the femur **20**.

[0080] FIGS. 12-17 provide different viewpoints of how the device 10 is “locked on” to the reference location 51 of the femur 20. As previously described, the diaphysis region 22 of the femur 20 can be narrower than the wider flared metaphysis region 23. The device 10 can be placed on the femur 20 at a location 99 far enough away from the joint 14 so that the first bone width 87 is less than the bottom opening 46 as in FIG. 13. At such a location, the bone facing bottom surface 33 can be lowered to engage the bone exterior surface 92 and the device 10 can be slid towards the joint 14.

[0081] In FIG. 14 the device 10 can be moved to location 99A and as shown in FIG. 15 a second bone width 94 can be wider than the bottom opening 46. Because the device 10 has not yet reached the reference location 51 of the femur 20, the bottom facing surface 33 is not tightly matching the exterior bone surface 92. Lower lobes 86 of the body 30 that are hidden in FIGS. 10 and 11 can be seen in FIGS. 15 and 17.

[0082] In FIG. 16 and the related cross sectional view, FIG. 17, the device 10 is shown at location 99B and cannot move any farther towards the joint 14 because of the matching flares between the bone facing bottom surface 33 and the bone exterior surface 92 of the metaphysis region 23. As a surgeon slides the device 10 towards the joint 14 he can feel the point when the device 10 cannot be moved any farther towards the joint 14. The femur 20 can have an elliptical shape 93 or have flattened features that are matched by the bone facing bottom surface 33. The matching features can prevent the device 10 from any rotational movement about the longitudinal axis 25 (see FIG. 2) of the femur 20. FIG. 17 illustrates the close fit between the bone facing bottom surface 33 and the bone exterior surface 92 after the body 30 has reached the reference location 51 (see FIG. 11). The circumference or perimeter of the body 30 can enclose or surround more the 50 percent of the circumference or perimeter of the femur 20. The lobes 86 can be disposed on a lower half 95 of the femur 20.

[0083] Although many of the examples disclosed in this document relate to femoral prosthetics, the revision joint replacement device and methods disclosed in

this document can be used in prosthetic devices or methods relating to any joint of a human or animal body.

[0084] The above Detailed Description includes references to the accompanying drawings, which form a part of the Detailed Description. The drawings show, by way of illustration, specific embodiments in which the present insert press and method can be practiced. These embodiments are also referred to herein as “examples.”

[0085] The above Detailed Description is intended to be illustrative, and not restrictive. For example, the above-described examples (or one or more elements thereof) can be used in combination with each other. Other embodiments can be used, such as by one of ordinary skill in the art upon reviewing the above description. Also, various features or elements can be grouped together to streamline the disclosure. This should not be interpreted as intending that an unclaimed disclosed feature is essential to any claim. Rather, inventive subject matter can lie in less than all features of a particular disclosed embodiment. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

[0086] In this document, the terms “a” or “an” are used to include one or more than one, independent of any other instances or usages of “at least one” or “one or more.” In this document, the term “or” is used to refer to a nonexclusive or, such that “A or B” includes “A but not B,” “B but not A,” and “A and B,” unless otherwise indicated. In this document, the terms “about” and “approximately” are used to refer to an amount that is nearly, almost, or in the vicinity of being equal to a stated amount. In this document, the term “patient” is intended to include mammals, such as for human applications or veterinary applications.

[0087] In the appended claims, the terms “including” and “in which” are used as the plain-English equivalents of the respective terms “comprising” and “wherein.” Also, in the following claims, the terms “including” and “comprising” are open-ended, that is, an assembly, kit, or method that includes elements in

addition to those listed after such a term in a claim are still deemed to fall within the scope of that claim. Moreover, in the following claims, the terms “first,” “second,” and “third,” etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

- 5 **[0088]** The Abstract is provided to allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims.

WHAT IS CLAIMED:

1. A device to aid in performing a revision surgery on a joint, the device comprising:
 - 5 a body member having a bone facing bottom surface, an opposing top surface, a first end portion configured to be disposed on a bone, and a second end portion opposite the first end portion and configured to be disposed on the bone nearer to the joint relative to the first end portion;
 - a connecting member attached to the body member and configured to
 - 10 extend beyond an end of the bone at the joint; and
 - a guide member attached to the connecting member and including an opening configured to receive a cutting tool, wherein the device is sized and shaped based on a computed tomography (CT) scan of the bone, and the guide member is configured so that when the device is installed on the bone, the longitudinal axis of
 - 15 the opening is aligned with a longitudinal direction of the bone.
2. The device of claim 1, wherein the body member has at least one aperture formed in the body member that corresponds to at least one reference point for a bone cutting guide.
- 20 3. The device of claim 2, wherein the at least one reference point for the bone cutting guide includes at least one of a joint line reference point for attaching a cutting guide used to set a joint line of a prosthetic implant and a rotation reference point for attaching a cutting guide used to set a rotation of a prosthetic implant.
- 25 4. The device of any of claims 2-3, wherein the at least one reference point for the bone cutting guide is determined based on measurements of the bone from the CT scan and estimated dimensions of the bone using a digital library of bones, the estimated dimensions of the bone being unattainable from the CT scan.

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5. The device of any of claims 2-3, wherein the at least one reference point for the bone cutting guide is determined based on a CT image of a healthy joint that is a mirror image of the joint.
- 5 6. The device of claim 5, wherein the joint is part of a left leg of a patient and the healthy joint is part of a right leg of the patient, or vice-versa.
7. The device of any of claims 1-3, wherein the device is sized and shaped based on a reference location on a computed tomography (CT) scan of the bone so
10 that the bone facing bottom surface matches an external bone surface at a corresponding reference location on the bone.
8. The device of claim 7, wherein the body member includes a region with curvature on the bottom facing surface so that when the device is installed at the
15 reference location, the curvature matches at least 50 percent of a circumference of the bone at the reference location.
9. The device of claim 7, wherein the guide member is oriented so that when the device is installed at the reference location, the longitudinal axis of the guide
20 member is offset from a longitudinal axis of a medullary canal of the bone.
10. The device of any of claims 1-3, wherein the body member has a flare such that the first end portion of the body member is narrower than the second end portion of the body member, and the flare matches a flare of the bone.
25
11. The device of any of claims 1-3, wherein the bone is a femur.
12. The device of any of claims 1-3, wherein the bone is a tibia.
- 30 13. A system for performing a revision surgery on a knee joint, the system comprising:

a femoral implant configured to be installed on the bone so that a distal end of the implant approximates a normal joint line of the knee joint, the femoral implant including a stem;

5 a bone plate including a body member having a bone facing bottom surface; an opposing top surface; a first end portion configured to be disposed on a bone, and a second end portion opposite the first end portion and configured to be disposed on the bone nearer to the joint relative to the first end portion;

a connecting member attached to the body member and configured to extend beyond an end of the bone at the joint; and

10 a cutting tool guide member attached to the connecting member and configured to guide forming of an aperture to prepare the bone to receive the stem of the femoral implant in a medullary canal region of the bone.

14. A method for performing a revision implant surgery, the method comprising
15 the steps of:

performing a CT scan of a joint that includes a bone and an orthopedic implant attached to the bone, the CT scan performed prior to performing the revision implant surgery;

20 determining a reference location on a surface of the bone based on images from the CT scan;

forming a bone plate configured for attachment to the bone and configured to match a profile of the bone at or near the reference location, the bone plate including a guide member and at least one aperture formed in the bone plate;

25 fixing the bone plate to the bone at the reference location, wherein when the bone plate is fixed to the bone, the guide member is aligned with a longitudinal direction of the bone; and

preparing a canal of the bone to receive a stem of a revision implant by using the guide member to guide a cutting tool in the canal of the bone.

30

15. The method of claim 14, further comprising the step of:
forming at least one aperture in the bone for attaching a cutting guide based on a location of the at least one aperture in the bone plate when the bone plate is fixed to the bone at the reference location.
- 5
16. The method of claim 15, wherein the location of the at least one aperture in the bone plate is based on a mirror image of a CT image of a healthy joint.
17. The method of claim 15, wherein the location of the at least one aperture in
10 the bone plate is based on inputting CT scan measurements of the bone into a databank of bone measurements to estimate normal dimensions of the bone.
18. The method of any one of claims 15-17, wherein the at least one aperture in the bone for attaching the cutting guide is used to set a joint line of an implant.
- 15
19. The method of any one of claims 15-17, wherein the at least one aperture in the bone for attaching the cutting guide is used to set a rotation of a prosthetic implant.
- 20
20. The method of any of claims 14-17, wherein fixing the bone plate to the bone includes:
placing the bone plate from a position that is located in a diaphysial direction from the reference location on the bone; and
sliding the bone plate towards a metaphysis region of the bone until the bone
25 plate locks onto the matching reference location.
21. A device to aid in performing a revision surgery, the device comprising:
a body member having a bone facing bottom surface; an opposing top surface; a first end portion configured to be disposed on a bone farther from the joint; a second
30 end portion opposite the first end portion and configured to be disposed on the bone

nearer to the joint, a portion of the bone facing bottom surface disposed on a metaphysis region of the bone; and

a guide member connected to the body member and having a longitudinal axis aligned with a longitudinal direction of the bone,

- 5 wherein the body member is configured to lock onto a specific reference location of the bone, the locking provided by a flared fit between the metaphysis region of the bone and the bone plate, and a perimeter of the body engaging at least 50% of a perimeter of the bone.

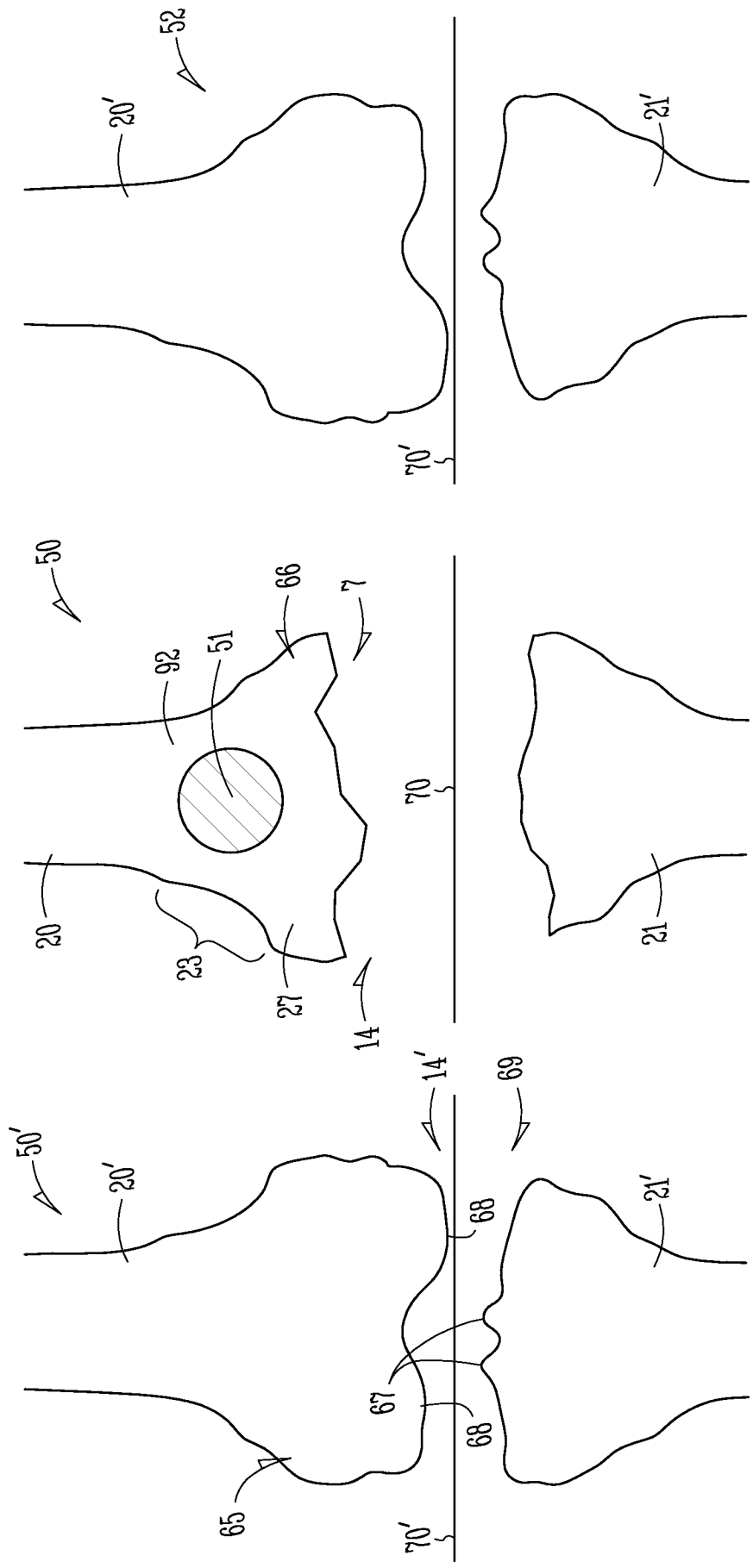


Fig. 1A

Fig. 1B

Fig. 1C

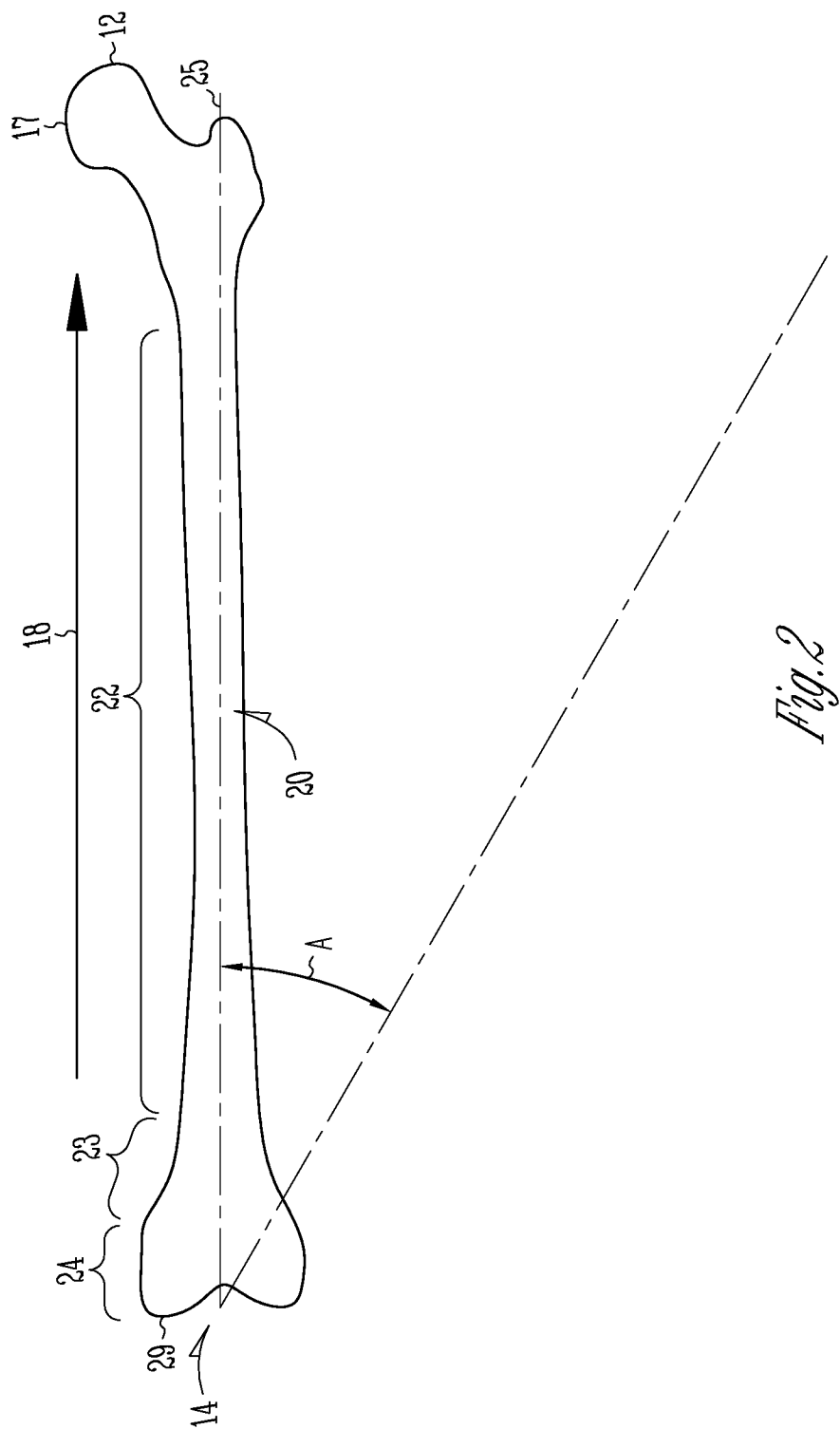


Fig. 2

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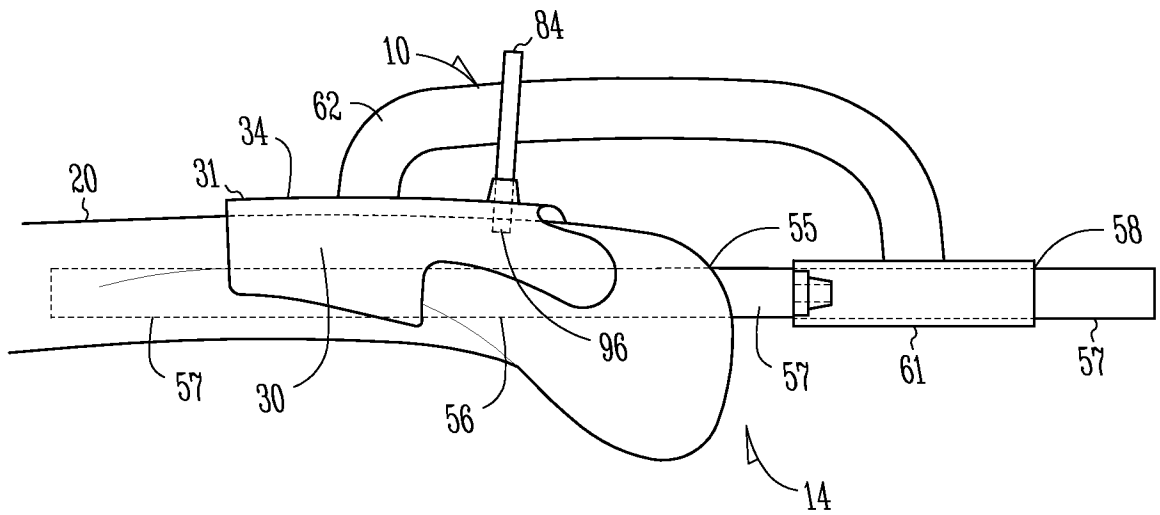


Fig. 4

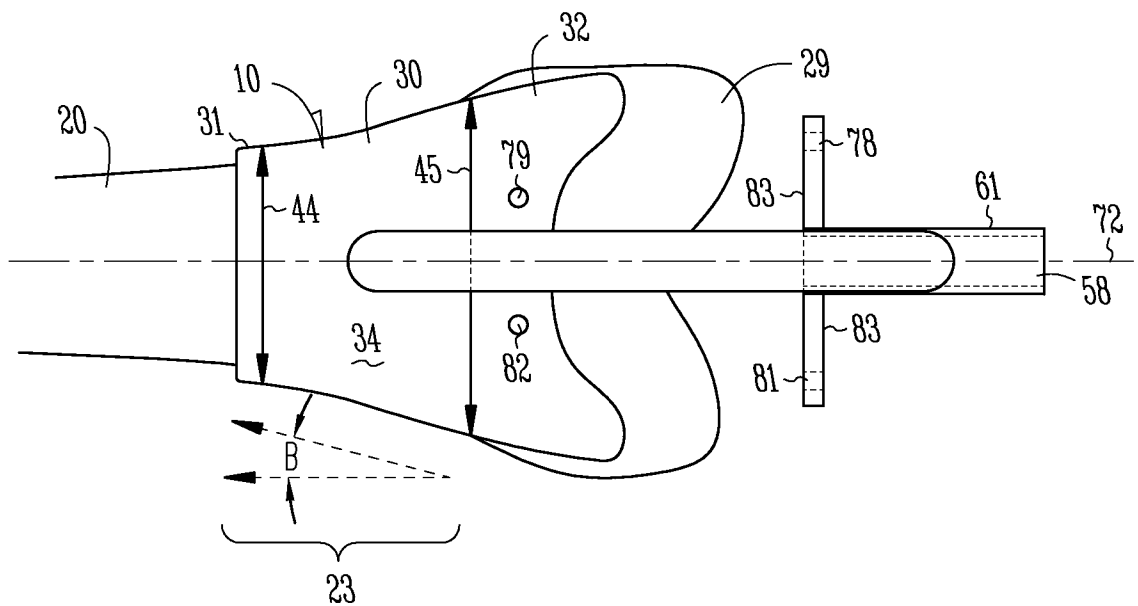


Fig. 5

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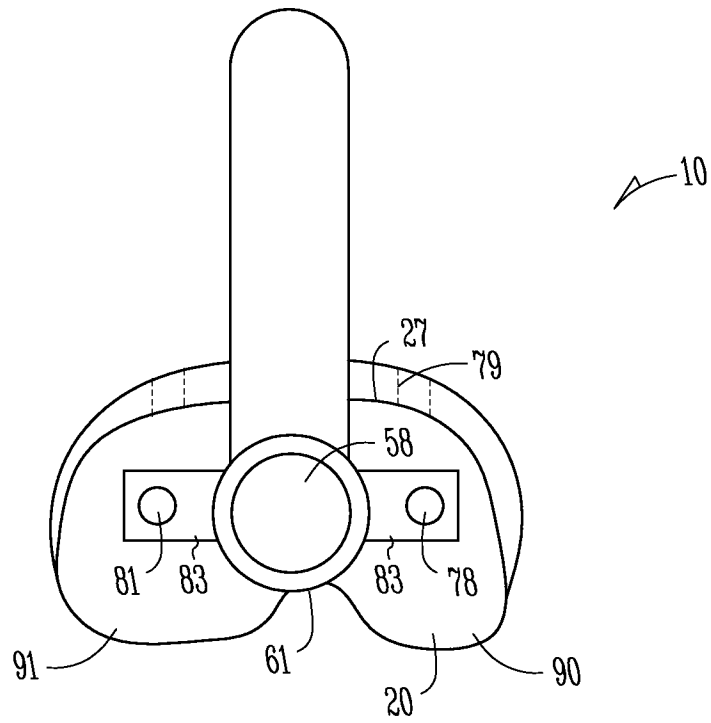


Fig. 6

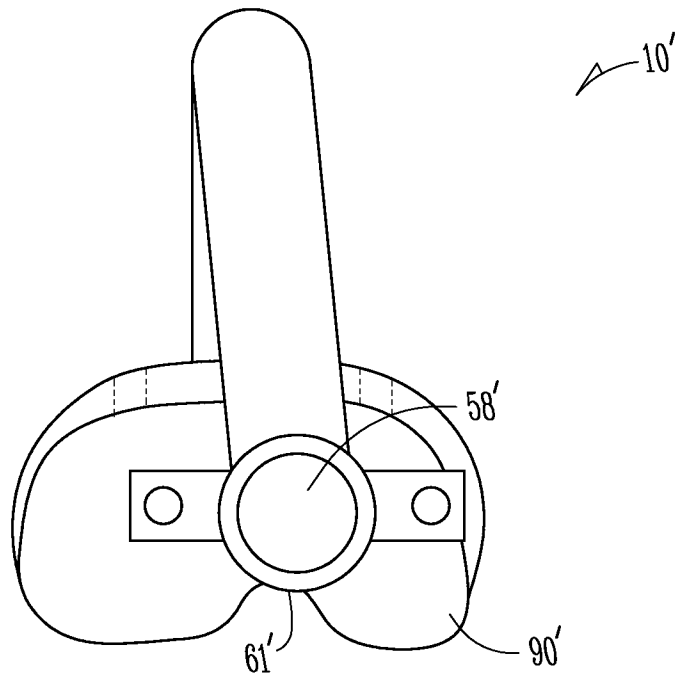


Fig. 7

6/11

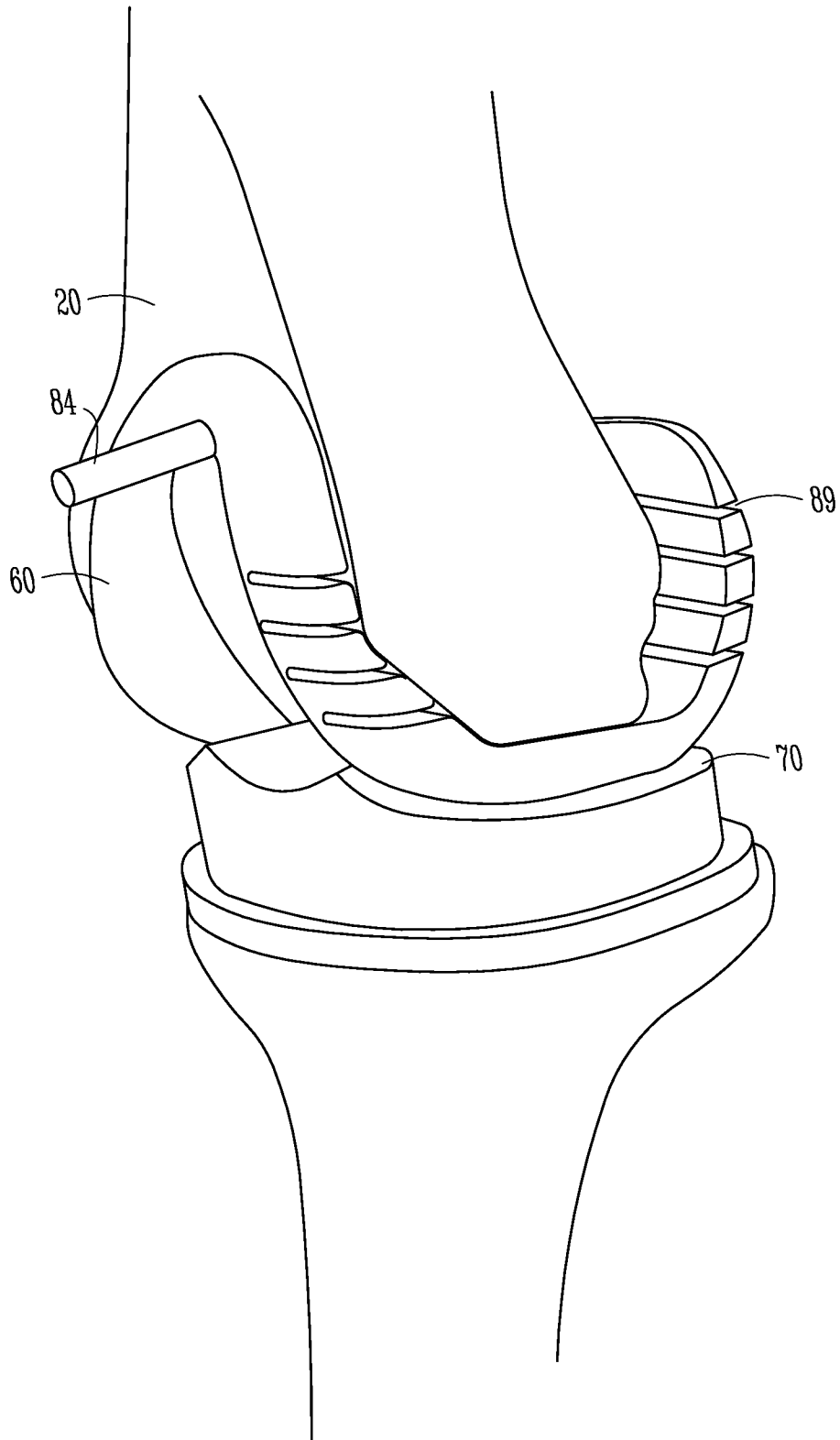


Fig. 8

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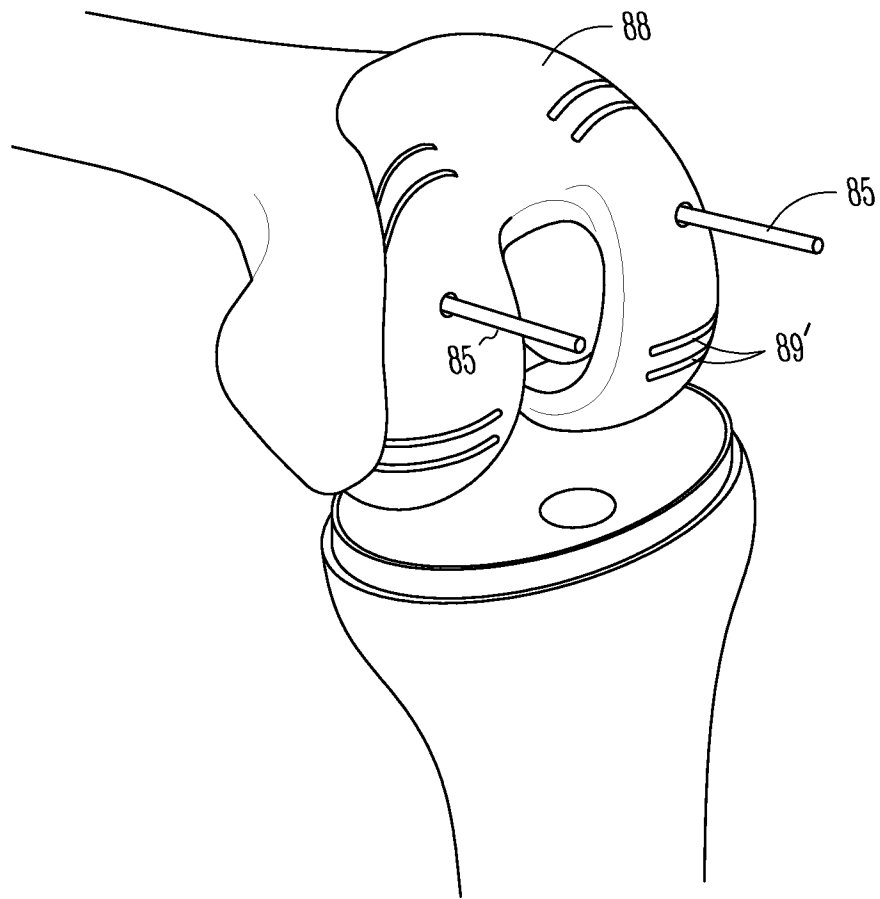
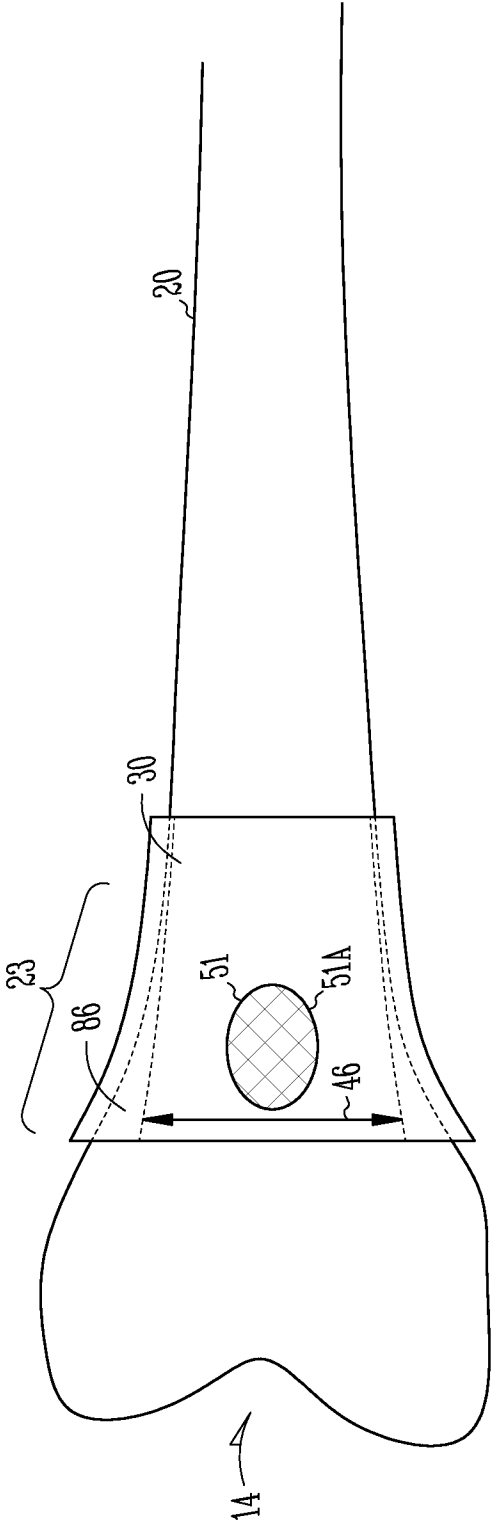
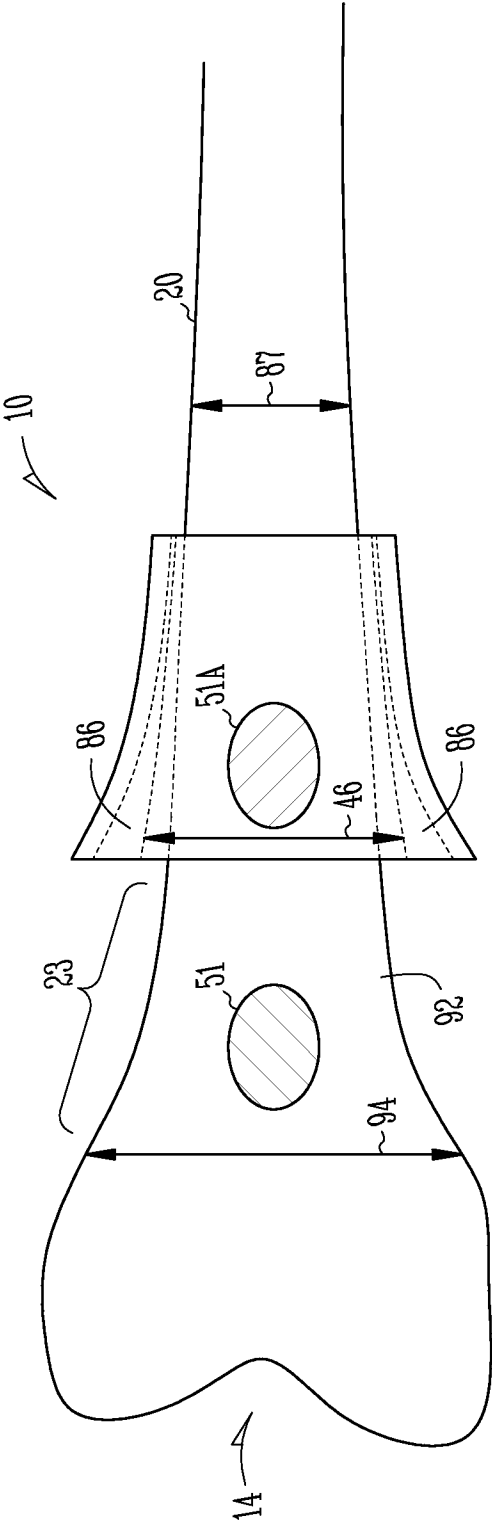
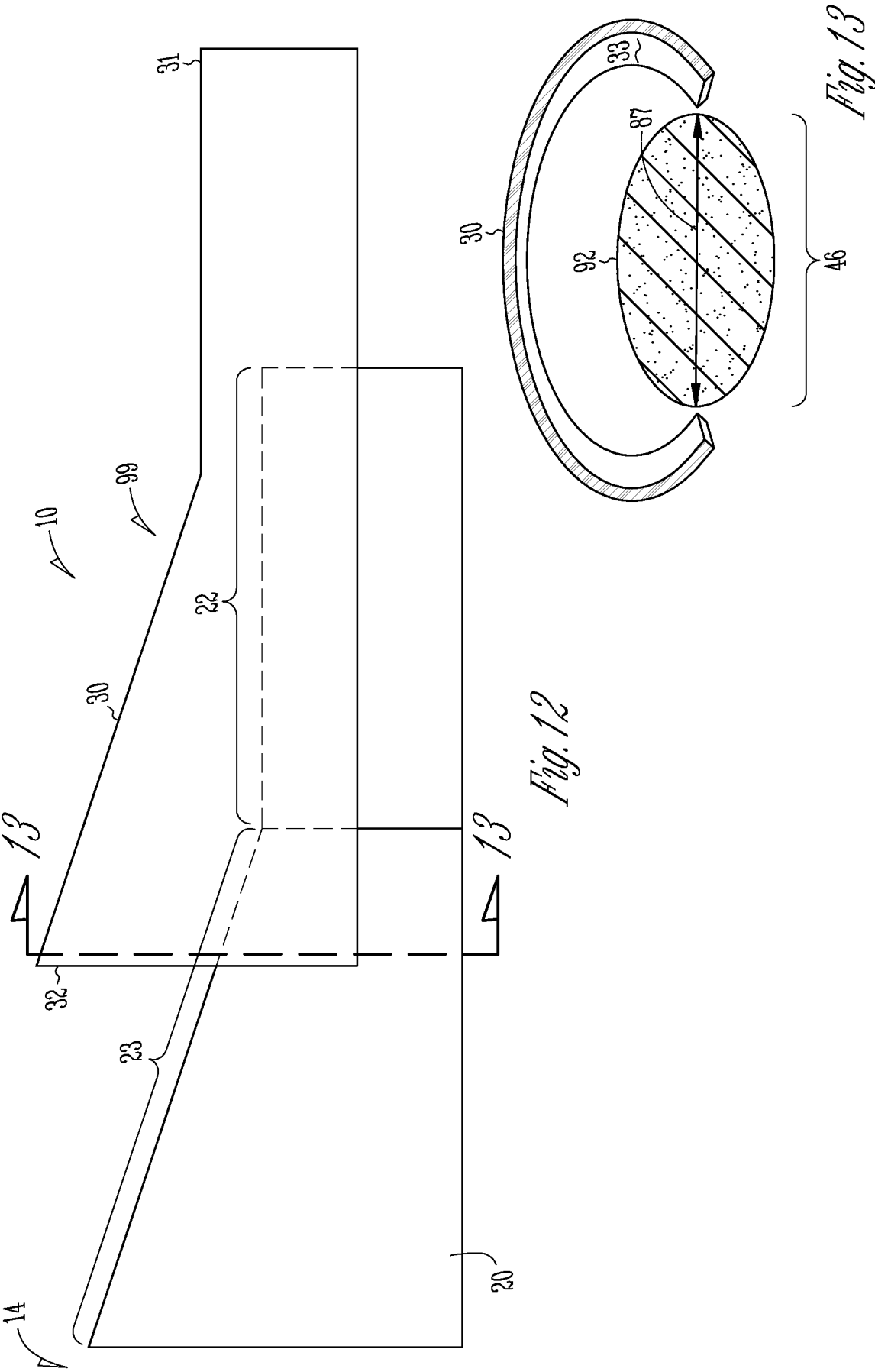
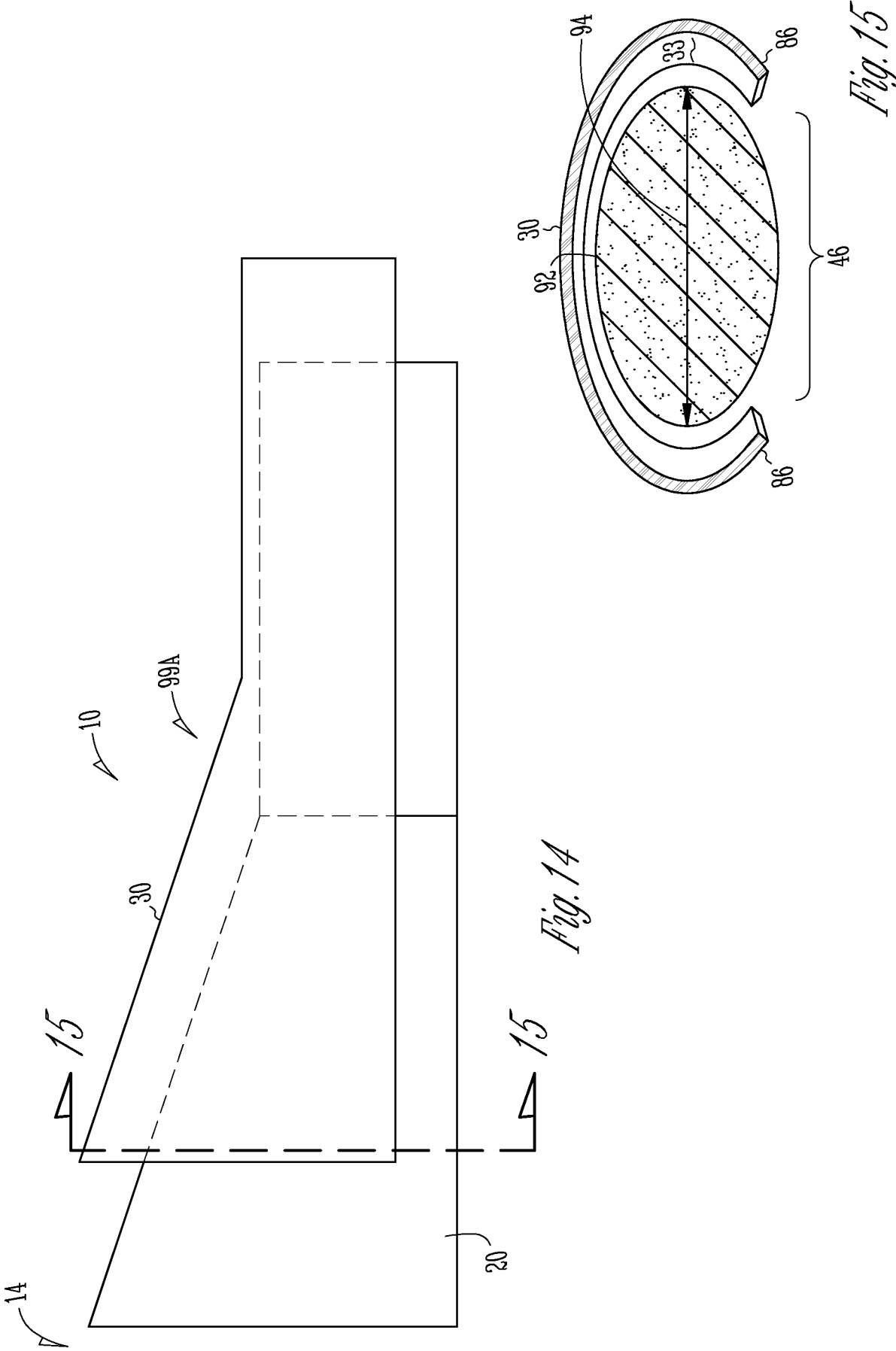
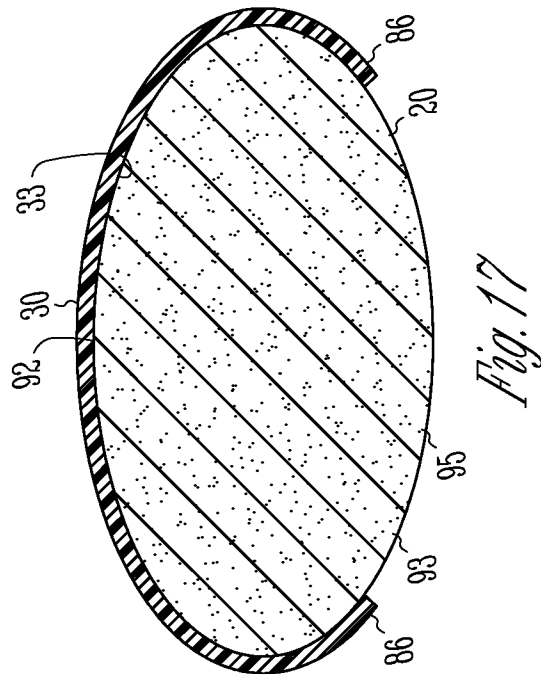
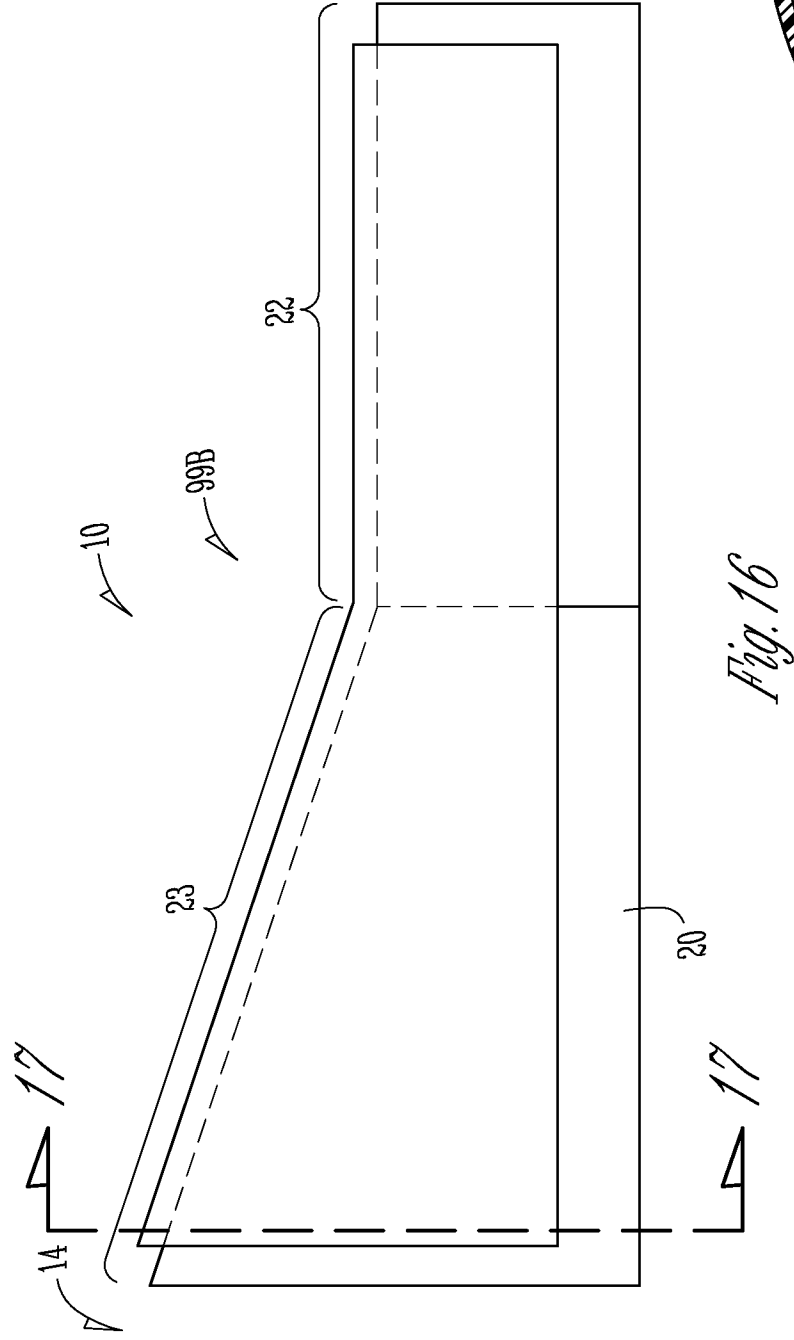


Fig. 9









INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/010452

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/15 A61B17/17
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 447 702 A (UNIV LEEDS [GB]) 24 September 2008 (2008-09-24)	1-7, 10-12
Y	page 26, lines 17-23; figures 3,24-27 page 42, line 10 - page 43, line 9 -----	9
X	WO 2013/136302 A1 (CUSTOM MED ORTHOPAEDICS PROPRIETARY LTD [ZA]) 19 September 2013 (2013-09-19) page 10, line 31 - page 11, line 30; figures 1-7 page 12, lines 18-22 page 13, line 29 - page 14, line 24 -----	1,7,8, 11,12,21
X	EP 0 947 169 A2 (HOWMEDICA [US] HOWMEDICA) 6 October 1999 (1999-10-06)	1-6,11, 13
Y	paragraphs [0069] - [0074]; figures 22A,27-34 ----- -/--	9



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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

25 March 2015

Date of mailing of the international search report

02/04/2015

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Fourcade, Olivier

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/010452

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/254093 A1 (WHITE JOHN R [US] ET AL) 8 October 2009 (2009-10-08) figures 1-4A -----	21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/010452

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.: **14-20**
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 14-20 relate to a method for treatment of the human body by surgery (Rule 39.1(iv) PCT) and were therefore not searched.
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.:
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 an 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2015/010452

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
GB 2447702	A	24-09-2008	AU 2008231636 A1	02-10-2008
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