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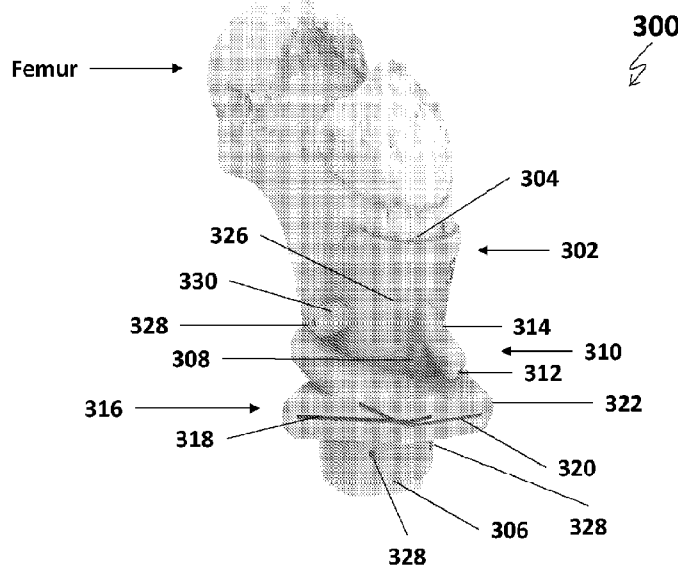


Figure 3A

(57) Abstract: The present invention, in some embodiments thereof, relates to a surgical guiding joint integration group (JIG) and, more particularly, but not exclusively, to a surgical guiding JIG for varus de rotation osteotomy (VDRO) procedure.



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METHODS AND APPARATUS FOR VARUS DE ROTATION OSTEOTOMY OPERATION
(VDRO) USING A GUIDING JIG

RELATED APPLICATION/S

5 This application claims the benefit of priority of U.S. Provisional Patent Application No. 63/472,392 filed on June 12, 2023, U.S. Provisional Patent Application No. 63/472,397 filed on June 12, 2023, and U.S. Provisional Patent Application No. 63/472,602 filed on June 13, 2023 the contents of which are incorporated herein by reference in their entirety.

10 FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to a surgical guiding joint integration group (JIG) and, more particularly, but not exclusively, to a surgical guiding JIG for varus de rotation osteotomy (VDRO) procedure.

Additional background art includes scientific publication “*3D-printed navigation template in proximal femoral osteotomy for older children with developmental dysplasia of the hip*”, by Pengfei Zheng et al. disclosing that “To explore the feasibility of 3D-printed navigation template in proximal femoral varus rotation and shortening osteotomy for older children with developmental dysplasia of the hip (DDH). The template-guided group achieved a better outcome; however, there was no significant difference. Application of the navigation template for older DDH children can
15 reduce the operation time, radiation exposure, and epiphysis damage, which also simplifies surgery and improves precision.”.

Additional background art includes scientific publication “*Correction of complex three-dimensional deformities at the proximal femur using indirect reduction with angle blade plate and patient-specific instruments: a technical note*”, by Lukas Jud et al. disclosing that “Using 3D
25 planning and PSI for complex corrective osteotomies at the proximal femur can be a useful tool in understanding the individual deformity and performing the aimed deformity reduction. The indirect reduction over the implant is a simple and valuable tool in achieving the desired correction, and concurrently, surgical exposure can be limited to a subvastus approach.”.

Additional background art includes scientific publication “*Mathematical calculation of the difference in shortening length after two types of proximal femoral varus and an investigation of their applicable conditions: an own-pair design*”, by Sun, Jian, et al. disclosing that “The results of the direct measurement method and the formula measurement method are shown in the table; the differences in the results of the femoral shortening length difference were not statistically
30 significant ($P > 0.05$). The limits of agreement (95%) of the difference values using Bland–Altman

analysis were between -0.50 and 0.46 mm, with a mean of -0.02 mm, indicating a high agreement between the two methods. $r = 0.99$ ($P < 0.05$) for the Pearson correlation analysis between the direct measurement method and the calculated method showed that the two methods were significantly correlated.”.

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SUMMARY OF THE INVENTION

Following is a non-exclusive list including some examples of embodiments of the invention. The invention also includes embodiments which include fewer than all the features in an example and embodiments using features from multiple examples, also if not expressly listed below.

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Example 1. A guiding JIG for use on a femoral bone during a VDRO procedure, having an osteotomy guide, comprising:

- a. a first cutting slot, shaped and sized to receive a first cutting tool;
- b. a second cutting slot, shaped and sized to receive a second cutting tool; and
- c. a frame defining the first cutting slot and the second cutting slot;

15

wherein the first cutting slot directs the first cutting tool to cut the femoral bone in a first desired path, and the second cutting slot directs the second cutting tool to cut the femoral bone in a second desired path.

Example 2. The guiding JIG according to example 1, wherein the first cutting slot and the second cutting slot are positioned relative to each other such that cutting the bone therethrough results in a bone wedge separated from the bone.

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Example 3. The guiding JIG according to example 2, wherein the bone wedge is triangular shape.

Example 4. The guiding JIG according to example 3, wherein said triangular shape comprises an angle equivalent to a desired correction angle.

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Example 5. The guiding JIG according to example 2, wherein the bone wedge has trapezoidal shape.

Example 6. The guiding JIG according to example 5, wherein said trapezoidal shape is according to a desired correction angle and a level of shortening of the femur.

Example 7. The guiding JIG according to any one of examples 1-6, wherein the first cutting tool and the second cutting tool are one and the same.

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Example 8. The guiding JIG according to any one of examples 1-7, wherein the first cutting tool and the second cutting tool are a saw.

Example 9. The guiding JIG according to any one of examples 1-8, wherein the guiding JIG comprises a guiding conduit configured to direct a guide implement into the center of the femur head.

Example 10. The guiding JIG according to example 9, wherein the guiding conduit
5 comprises a slit configured to shorten said guiding conduit.

Example 11. The guiding JIG according to example 9, wherein the guiding conduit comprises an inner lumen sufficiently large to accommodate the guide implement but sufficiently small to limit lateral movement of said guide implement therewithin.

Example 12. The guiding JIG according to example 9, wherein the guiding conduit is a
10 guiding conduit for a chisel; and wherein the guiding conduit comprises an inner lumen shaped as the selected chisel.

Example 13. The guiding JIG according to any one of examples 1-12, wherein the guiding JIG further comprises a distal guiding hole deviating from a femoral longitudinal shaft-neck axis, according to a desired level of rotation correction.

Example 14. The guiding JIG according to any one of examples 1-13, wherein the guiding
15 JIG further comprises a proximal guiding hole shaped and sized according to fixators of a selected plate.

Example 15. The guiding JIG according to any one of examples 1-14, wherein the guiding JIG comprises a JIG body having an inner surface with geometry which complements a geometry
20 of the femoral bone.

Example 16. A method for using a guiding JIG while performing a VDRO procedure on a femoral bone, comprising:

- a. providing a patient specific guiding JIG comprises an osteotomy guide;
- b. mounting the guiding JIG on the femoral bone;
- 25 c. cutting a bone wedge through the osteotomy guide of the guiding JIG.

Example 17. The method according to example 16, wherein the bone wedge is triangular shape.

Example 18. The method according to example 17, wherein said triangular shape comprises an angle equivalent to a desired correction angle.

Example 19. The method according to example 16, wherein the bone wedge has trapezoidal
30 shape.

Example 20. The method according to example 19, wherein said trapezoidal shape is according to a desired correction angle and a level of shortening of the femur.

Example 21. A guiding JIG for use on a femoral bone during a VDRO procedure, comprising:

- a. a guide body, shaped and sized to be deployed on the femoral bone;
- b. a guide conduit, defining a path into the center of the femur head; and
- 5 c. an osteotomy guide, defining at least one path for cutting the bone.

Example 22. The guiding JIG according to example 21, wherein the guide conduit is a guiding conduit for a guide implement.

Example 23. The guiding JIG according to example 21, wherein the guiding conduit is shaped according to a k-wire, having diameter less than 2 mm.

10 Example 24. The guiding JIG according to any one of examples 21-23, wherein the guiding conduit is a guiding conduit for chisel; said guiding conduit comprising a wall and an inner lumen, wherein the inner lumen shaped and sized according to a selected chisel.

Example 25. A method for performing VDRO procedure on a femoral bone using a single guiding JIG, said single guiding JIG comprising:

- 15 a. a guiding conduit for a guide implement defining a path into the center of the femur head; and
- b. an osteotomy guide, comprising:
 - i. a first cutting slot, shaped and sized to receive a first cutting tool; and
 - ii. a second cutting slot, shaped and sized to receive a second cutting tool;
- 20 where the first cutting slot and the second cutting slot positioned relative to each other such that cutting the bone therethrough results in a bone wedge;
- said method comprising:
- c. mounting the guiding JIG on the femoral bone;
- d. inserting a guide implement into the center of the femur head through guiding conduit
- 25 for a guide implement;
- e. cutting the femoral bone through the first cutting slot, using a first cutting tool;
- f. cutting the femoral bone through the second cutting slot, using a second cutting tool to create a bone wedge separating the femoral bone to distal fragment and proximal fragment.

Example 26. The method according to example 25, wherein the guiding JIG further comprises a distal guiding hole for rotation correction; and wherein the method further comprises a rotation correction of the femur using said distal guiding hole.

Example 27. The method according to example 26, wherein performing said rotation correction comprises:

a. applying operating tool on the distal fragment through the distal guiding hole to create a distal bore on the distal fragment, according to the position of the distal guiding hole on the guiding JIG;

b. removing the bone wedge; and

5 c. rotating the distal fragment so that the distal bore is aligned with the center of the femur head.

Example 28. The method according to example 25, wherein the single guiding JIG further comprises at least one proximal guiding hole, shaped and sized according to a fixator of a selected plate; and wherein the method further comprises drilling on the proximal fragment through the at
10 least one proximal guiding hole.

Example 29. The method according to example 28, wherein the method further comprises:

a. applying operating tool on the proximal fragment through the at least one proximal guiding hole, to create at least one proximal bore on the proximal fragment, according to the position of the at least one proximal guiding hole on the guiding JIG;

15 b. removing the guide implement from the bone, resulted in a bore at the center of the femur head; and

c. connecting a selected plate according to the bore at the center of the femur head, the at least one proximal bore and the distal bore.

Example 30. A method for performing a VDRO procedure on a femoral bone using a single
20 guiding JIG, wherein the single guiding JIG comprises:

a. a guiding conduit for a chisel defining a path into the center of the femur head; and

b. an osteotomy guide, comprising:

i. a first cutting slot, shaped and sized to receive a first cutting tool; and

ii. a second cutting slot, shaped and sized to receive a second cutting tool;

25 wherein the first cutting slot and the second cutting slot positioned relative to each other such that cutting the bone therethrough results in a bone wedge;

wherein the method comprises:

c. mounting the guiding JIG on the femoral bone;

d. inserting a chisel into the guide conduit for chisel;

30 e. impacting the chisel into the bone through the guide conduit for chisel;

f. cutting the femoral bone through the first cutting slot, using a first cutting tool; and

g. cutting the femoral bone through the second cutting slot, using a second cutting tool to create a bone wedge separating the femoral bone to proximal fragment, which includes the femur head and distal fragment, separated from the femur head.

Example 31. The method according to example 30, wherein the guiding JIG further comprises a distal guiding hole for rotation correction, and wherein the method further comprises performing a rotation correction of the femur using said distal guiding hole.

Example 32. The method according to example 31, wherein performing said rotation correction comprises:

a. applying operating tool on the distal fragment through the distal guiding hole to create a distal bore on the distal fragment, according to the position of the distal guiding hole on the guiding JIG;

b. removing the bone wedge; and

c. rotating the distal fragment so that the distal bore is aligned with the center of the femur head.

Example 33. The method according to example 32, wherein the applying operating tool on the distal fragment through the distal guiding hole is performed prior to performing osteotomy.

Example 34. A guiding JIG for use on a femoral bone during a VDRO procedure, comprising:

a. a JIG body at least partially circumferentially surrounding the femoral bone;

b. guiding elements positioned on the JIG body, comprising:

i. functional guiding elements, shape and sized for directing operating tools applied on the femoral bone; and

ii. fixating guiding elements, shape and sized for directing the insertion of fixators into the femur.

Example 35. The guiding JIG according to example 34, wherein said JIG body has a grip on the femoral bone.

Example 36. The guiding JIG according to example 34 or example 35, wherein said JIG body comprises an inner surface with a geometry that complements a geometry of the femoral bone.

Example 37. A guiding JIG for use on a femoral bone during a VDRO procedure, comprising:

a. a removable guide conduit for a guide implement;

b. a guide conduit for a chisel;

wherein the removable guiding conduit for guide implement mounted within the inner lumen of the guiding conduit for chisel.

Example 38. The guiding JIG according to example 37, wherein said removable guide conduit is configured for directing said guide implement into a center of the femur head.

Example 39. The guiding JIG according to example 37 or 38, wherein said removable guide conduit comprises:

- a. a wall defining an inner lumen; and
- b. said inner lumen, shaped and sized to receive a selected guide implement;

5 wherein the size of the inner lumen is sufficiently small to limit lateral movements of the selected guide implement therewithin.

Example 40. The guiding JIG according to example 37, wherein said guide conduit for a chisel is configured for directing said chisel into the center of the femur head.

10 Example 41. The guiding JIG according to example 37 or example 40, wherein said guide conduit for chisel comprises:

- a. a wall defining the inner lumen; and
- b. said inner lumen, shaped and sized to receive a selected chisel;

wherein the size of the inner lumen is sufficiently small to limit lateral movements of the selected chisel therewithin.

15 Example 42. The guiding JIG according to any one of examples 37-41, wherein the removable guiding conduit for guide implement is configured to be removed from the inner lumen of the guiding conduit for chisel while the guide implement remains inserted into the center of the femur head.

20 Example 43. The guiding JIG according to any one of examples 37-42, wherein upon removing the removable guiding conduit for the inner lumen guiding conduit for chisel, the guiding conduit for chisel is free to receive a selected chisel, threaded on the guide implement inserted within the center of the femur head.

Example 44. The guiding JIG according to any one of examples 37-43, wherein the removable guiding conduit for guide implement comprises a slit along the longitudinal axis thereof.

25 Example 45. A method for inserting a guide implement and a chisel into the center of the femur head using a single guiding JIG, wherein the single guiding JIG comprises:

- a. a guiding conduit for chisel, shaped and sized to receive a selected chisel; and
- b. a removable guiding conduit for a guide implement, shaped and sized to receive a selected guide implement, mounted within the guiding conduit for chisel;

30 the method comprises:

- c. mounting the guiding JIG onto the femoral bone, at the treatment site;
- d. inserting a selected guide implement into the center of the femur head through the removable guiding conduit for a guide implement;
- e. removing the removable guiding conduit for a guide implement;

f. loading a selected chisel on to the selected guide implement, inserted within the center of the femur head;

g. placing the selected chisel within the guide conduit for chisel, by passing the selected chisel along the selected guide implement;

5 h. impacting the chisel into the femur head through the guiding conduit for chisel.

Example 46. A method for impacting a chisel into a femoral bone using a guiding JIG, the guiding JIG comprising a guiding conduit for chisel, comprising an inner lumen; and a wall, the inner lumen shaped and sized according to a selected chisel; the method comprising:

a. mounting the guiding JIG onto the femoral bone, at the treatment site;

10 b. placing a chisel within the guiding conduit for chisel; and

c. impacting the chisel into the femoral bone through the guiding conduit for chisel.

Example 47. A method for designing a guiding JIG for a VDRO procedure, comprising:

a. receiving a scan image of a patient femur;

b. receiving input;

15 c. generating a 3D model of the femur at the treatment site;

d. identifying features of the femur;

e. calculating the correction angle by subtracting the fixation angle of the selected plate from the current shaft angle;

20 f. placing a representation of a first cutting plane perpendicular to the femoral head neck axis;

g. placing a representation of a second cutting plane, wherein the angle between the first and second plane is the correction angle;

h. placing a vector perpendicular to the cutting planes;

i. generating guiding elements representations; and

25 j. generating a 3D JIG body based on the 3D model of the femur at the treatment site.

Example 48. The method according to example 47, wherein the input comprises one or more of:

a. fixation angle of the selected plate;

b. type of the selected plate;

30 c. selected set of tools; and

d. surgical approach.

Example 49. The method according to example 47 or example 48, wherein the features of the femur comprise one or more of:

a. femoral head-neck axis;

b. femoral longitudinal shaft-neck axis; and
c. current shaft angle between the femoral head-neck axis and the femoral longitudinal shaft-neck angle.

Example 50. The method according to any one of examples 47-49, wherein the guiding elements representations comprises representations of functional guiding elements.

Example 51. The method according to example 50, wherein the representations of functional guiding elements comprise a representation of a guiding conduit, based on the head neck axis, wherein the guiding conduit defining a path into the center of the femur head.

Example 52. The method according to example 51, wherein the guiding conduit shaped and sized to receive a guide implement.

Example 53. The method according to example 51, wherein the guiding conduit shaped and sized to receive a chisel.

Example 54. The method according to example 50, wherein the guiding elements representations comprises a representation of an osteotomy guide comprising a support frame and one or more cutting slots, wherein said one or more cutting slots are based on the first and the second cutting planes.

Example 55. The method according to example 51, wherein the guiding elements representations further comprises representations of fixating guiding elements.

Example 56. The method according to example 55, wherein the representations of fixating guiding elements comprise a representation of a fixating guides holes based on the vector perpendicular to the cutting planes.

Example 57. The method according to any one of examples 47-56, wherein the representation of a first cutting plane perpendicular to the femoral head neck axis is placed along the femoral longitudinal shaft-neck axis according to a desired femur shortening.

Example 58. A guiding JIG for use during hip resurfacing, comprising:

- a. a JIG body, shaped and sized to be mounted on the femur head;
- b. a guiding conduit positioned on the JIG body and defining a path into the center of the femur head; and
- c. at least one osteotomy guide positioned on the JIG body and defining a path for cutting the femur head.

Example 59. The guiding JIG according to example 58, wherein the guiding conduit is sized and shaped to receive and direct a guide implement.

Example 60. The guiding JIG according to example 58 or 59, wherein the guiding conduit comprises a slit extending along a wall of said conduit, from a proximal end of said wall, facing

away from a femur neck, to a distal end of said wall, facing toward a femur neck, and ends at a portion of said wall not connected to the JIG body.

Example 61. The guiding JIG according to any of examples 58-60 , wherein the guide osteotomy comprises a cutting slot.

5 Example 62. The guiding JIG according to any of examples 58-61 , wherein the guide osteotomy comprises a supporting frame.

Example 63. The guiding JIG according to example 62, wherein said frame comprises at least one sturdy surface, positioned therewithin.

10 Example 64. The guiding JIG according to any of examples 58-63 , wherein the JIG body comprises an inner surface having a geometry which complements the geometry of the femur head of the patient, at the treatment site.

Example 65. The guiding JIG according to any of examples 58-64 , wherein the JIG body at least partially surrounds the femur head.

15 Example 66. The guiding JIG according to any of examples 58 to 8 , wherein the JIG body has a grip on the femoral head.

Example 67. The guiding JIG according to any of examples 58-66 , wherein the JIG body at least partially covers the femur neck.

20 Example 68. The guiding JIG according to any of examples 58-67 , comprising a measurable mark, designed to have a specific size and shape, configured to be measured to indicate that said guiding JIG is produced according to a desired design.

Example 69. A guiding JIG deployable in parts on a bone, comprising:

a. a JIG body comprising more than JIG parts, shaped and sized to be mounted on the bone; and

b. at least one guiding element positioned on the JIG body.

25 Example 70. The guiding JIG according to example 69, wherein more than one JIG portion comprises a first JIG portion and a second JIG portion, wherein said first JIG portion comprises an inner surface having a geometry that complements the geometry of bone at the treatment site, and wherein said second JIG portion configured to be aligned with at least one JIG portion.

30 Example 71. The guiding JIG according to example 70, wherein said second JIG portion comprises an an inner surface having a geometry that complements the geometry of bone at the treatment site.

Example 72. The guiding JIG according to example 70, wherein said first portion comprises a first geometry that interacts with a second geometry of said second portion; wherein said first geometry and said second geometry are complementary to each other.

Example 73. The guiding JIG according to any of example 72, wherein said first geometry comprises one or more protrusions and wherein said second geometry comprises one or more recesses shaped and sized to accommodate said one or more protrusions.

Example 74. The guiding JIG according to any of examples 72-73, wherein said first geometry comprises one or more recesses and wherein said second geometry comprises one or more protrusions shaped and sized to occupy said one or more protrusions.

Example 75. The guiding JIG according to any of examples 69-74, at least one guiding element comprises one or more of:

at least one guiding conduit shape and sized to direct a guide implement into the bone and at least one osteotomy guide, sized and shaped to direct a cutting tool into the bone.

Example 76. The guiding JIG according to example 75, wherein said at least one guiding conduit is positioned on the JIG body, defining a path into the center of the femur head, and wherein said at least one osteotomy guide is positioned on the JIG body defining a path for cutting the femur head or neck.

Example 77. The guiding JIG according to any of examples 69 to 76, wherein the bone is a femur head and the JIG is designed for a hip resurfacing procedure.

Example 78. The guiding JIG according to any of examples 69-76, wherein the bone is a femur neck and the JIG is designed for a hip replacement procedure.

Example 79. A guiding JIG having an adjustable osteotomy guide, comprising:

a. a JIG body, shaped and sized to be mounted on a bone; and

b. at least one osteotomy guide, comprising a first cutting surface and a second cutting surface, defining a cutting slot therebetween, wherein at least one of said first cutting surface or said second cutting surface is removable.

Example 80. The guiding JIG according to example 79, wherein the JIG body comprises more than one JIG portion, wherein more than one JIG portion comprises a first JIG portion comprises said first cutting surface and a second JIG portion comprises said second cutting surface, wherein one of said first JIG portion or said second JIG portion is removable.

Example 81. The guiding JIG according to example 80, wherein said first JIG portion is removable and comprises one or more grip holes, wherein said one or more grip holes are shaped and sized to accommodate a gripping tool.

Example 82. The guiding JIG according to example 81, wherein said second JIG portion comprises at least one fixating guide, sized and shaped for directing a fixator therethrough into the bone.

Example 83. The guiding JIG according to any of examples 79-82, comprising at least one detachable connection point between said first cutting surface and said second cutting surface.

Example 84. The guiding JIG according to example 83, wherein said at least one detachable connection point is defined by a sliding pin of said first cutting surface and a groove of said second cutting surface, wherein said groove is sized and shaped to receive the sliding pin and includes an opening that allows the sliding pin to exit therefrom upon movement.

Example 85. A guiding JIG for use during hip resurfacing or hip replacement procedure, comprising:

- a. a JIG body, shaped and sized to be mounted on the femur head;
- b. a plurality of osteotomy guides positioned on the JIG body wherein each osteotomy guide of said plurality of osteotomy guides defines a path for cutting the femur head.

Example 86. The guiding JIG according to example 85, wherein said plurality of osteotomy guides is in the form of a plurality of cutting slots

Example 87. The guiding JIG according to example 85, wherein said plurality of osteotomy guides are in the form of a plurality of a pair of tubular guiding conduits.

Example 88. The guiding JIG according to any of examples 85-87, comprising a guiding conduit positioned on the JIG body and defining a path into the center of the femur head.

Example 89. A method for performing hip resurfacing procedure on a femur head using a single guiding JIG, said single guiding JIG comprising:

- a. a JIG body, shaped and sized to be mounted on the femur head;
 - b. a guiding conduit positioned on the JIG body and defining a path into the center of the femur head; and
 - c. an osteotomy guide positioned on the JIG body and defining a path for cutting the femur head;
- said method comprising:
- d. mounting the guiding JIG on the femur head;
 - e. inserting a guide implement into the center of the femur head through guiding conduit for a guide implement;
 - f. cutting the femoral bone through a cutting slot, using the selected cutting tool, to create a bone portion separating from the femur head.

Example 90. The method according to example 89, wherein the JIG body further comprises an inner surface having geometry which completes the geometry of the femur head; and wherein the method further comprises aligning the guiding JIG on the femur head by fitting the geometry of the inner surface of the JIG with the geometry of the femur head.

5 Example 91. A method for designing a guiding JIG, comprising:

- a. creating a patient specific 3D simulation of the femur head;
- b. identifying features of the femur head;
- c. creating a footprint; and
- d. designing guiding elements.

10 Example 92. The method according to example 91, wherein the patient-specific 3D simulation of the femur head is based on a scan image of the femur head.

Example 93. The method according to example 91 or example 92, wherein said identifying comprises identifying the femur neck.

15 Example 94. The method according to any of examples 91-93, wherein said identifying comprises identifying the femoral neck-head axis.

Example 95. The method according to any of examples 91 to 37, further comprising thickening the footprint to represent a JIG body.

Example 96. The method according to any of examples 91-95, further comprising positioning the guiding elements on the footprint, each defining a path thereinto.

20 Example 97. The method according to any of examples 91 to 39, wherein said designing comprises designing one or more of:

- a. a guiding conduit for guide implement; and
- b. an osteotomy guide comprises a cutting slot, shaped and sized to receive a cutting tool.

25 Example 98. The method according to example 96, wherein said positioning the guiding conduit for guide implant comprises positioning in-line with the femoral neck-head axis, and protruding from the bone.

Example 99. The method according to example 96 or example 98, wherein said positioning comprises positioning a cutting slot perpendicular to the femoral neck-head axis.

30 Example 100. The method according to any to example 99, wherein said positioning locating the cutting slot on the femur head, at a distance from the femur neck.

Example 101. The method according to example 99, further comprising positioning the cutting slot on the femur neck and/or in proximity to the femur neck.

Example 102. The method according to any of examples 91-101, further comprising receiving an input from a physician.

Example 103. The method according to example 102, wherein the input from the physician comprises a selected implant, which defines the location of a cutting slot along the femoral neck-head axis.

Example 104. The method according to any of examples 91-103, further comprises
5 positioning at least one measurable geometry on the JIG.

Example 105. A guiding JIG, for femur head or neck surgery, obtained by a process comprising:

- a. creating a patient-specific 3D simulation of the femur head;
- b. identifying features of the femur head in the simulation;
- 10 c. creating a footprint based on the identified features; and
- d. designing guiding elements that are integrated into the guiding jig based on the footprint;
- and
- e. producing the guiding JIG.

Example 106. The guiding JIG according to example 105, wherein said identifying
15 comprises identifying the femur neck and the femoral neck-head axis.

Example 107. The guiding JIG according to example 105 or example 106, wherein said designing comprises designing one or more of at least one guiding conduit for a guide implement, and at least an osteotomy guide comprises a cutting slot, shaped and sized to receive a cutting tool. Unless otherwise defined, all technical and/or scientific terms used herein have the same
20 meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be
25 necessarily limiting.

As will be appreciated by one skilled in the art, some embodiments of the present invention may be embodied as a system, method or computer program product. Accordingly, some embodiments of the present invention may take the form of an entirely hardware embodiment, an entirely software embodiment (including firmware, resident software, micro-code, etc.) or an
30 embodiment combining software and hardware aspects that may all generally be referred to herein as a "circuit," "module" or "system." Furthermore, some embodiments of the present invention may take the form of a computer program product embodied in one or more computer readable medium(s) having computer readable program code embodied thereon. Implementation of the method and/or system of some embodiments of the invention can involve performing and/or

completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of some embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware and/or by a combination thereof, e.g., using an operating system.

5 For example, hardware for performing selected tasks according to some embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to some embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to some exemplary embodiments of method and/or
10 system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally
15 provided as well.

Any combination of one or more computer readable medium(s) may be utilized for some embodiments of the invention. The computer readable medium may be a computer readable signal medium or a computer readable storage medium. A computer readable storage medium may be, for example, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or
20 semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples (a non-exhaustive list) of the computer readable storage medium would include the following: an electrical connection having one or more wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, a portable compact
25 disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

A computer readable signal medium may include a propagated data signal with computer
30 readable program code embodied therein, for example, in baseband or as part of a carrier wave. Such a propagated signal may take any of a variety of forms, including, but not limited to, electromagnetic, optical, or any suitable combination thereof. A computer readable signal medium may be any computer readable medium that is not a computer readable storage medium and that can

communicate, propagate, or transport a program for use by or in connection with an instruction execution system, apparatus, or device.

Program code embodied on a computer readable medium and/or data used thereby may be transmitted using any appropriate medium, including but not limited to wireless, wireline, optical
5 fiber cable, RF, etc., or any suitable combination of the foregoing.

Computer program code for carrying out operations for some embodiments of the present invention may be written in any combination of one or more programming languages, including an object-oriented programming language such as Java, Smalltalk, C++ or the like and conventional procedural programming languages, such as the "C" programming language or
10 similar programming languages. The program code may execute entirely on the user's computer, partly on the user's computer, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server. In the latter scenario, the remote computer may be connected to the user's computer through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be
15 made to an external computer (for example, through the Internet using an Internet Service Provider).

Some embodiments of the present invention may be described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to embodiments of the invention. It will be understood that each block
20 of the flowchart illustrations and/or block diagrams, and combinations of blocks in the flowchart illustrations and/or block diagrams, can be implemented by computer program instructions. These computer program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable
25 data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

These computer program instructions may also be stored in a computer readable medium that can direct a computer, other programmable data processing apparatus, or other devices to function in a particular manner, such that the instructions stored in the computer readable medium
30 produce an article of manufacture including instructions which implement the function/act specified in the flowchart and/or block diagram block or blocks.

The computer program instructions may also be loaded onto a computer, other programmable data processing apparatus, or other devices to cause a series of operational steps to be performed on the computer, other programmable apparatus or other devices to produce a

computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide processes for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

Some of the methods described herein are generally designed only for use by a computer, and may not be feasible or practical for performing purely manually, by a human expert. A human expert who wanted to manually perform similar tasks, such as designing a JIG, might be expected to use completely different methods, e.g., making use of expert knowledge and/or the pattern recognition capabilities of the human brain, which would be vastly more efficient than manually going through the steps of the methods described herein.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

Figure 1A is an illustration of hip dislocation correction by varising de-rotation osteotomy (VDRO) procedure, in accordance with some exemplary embodiments of the invention;

Figure 1B is an illustration of the femur current shaft angle, in accordance with some exemplary embodiments of the invention;

Figure 1C is an illustration of the correction angle calculation, in accordance with some exemplary embodiments of the invention;

Figure 2 is a flowchart describing an exemplary process of VDRO procedure using a guiding JIG, in accordance with some exemplary embodiments of the invention;

Figures 3A-D are perspective views of guiding JIG for a VDRO process, in accordance with some exemplary embodiments of the invention;

Figure 3E is a rear view of a guiding JIG for a VDRO process, in accordance with some exemplary embodiments of the invention;

Figure 4A is a perspective view of a guiding JIG for a VDRO process using a chisel, in accordance with some exemplary embodiments of the invention;

Figure 4B-D are perspective views of a guiding JIG for a VDRO process using a guide implement and a chisel, in accordance with some exemplary embodiments of the invention;

Figure 5A is a perspective view of a variant of guiding JIG for a VDRO process using a chisel, in accordance with some exemplary embodiments of the invention;

Figure 5B is a perspective view of a variant of guiding JIG for a VDRO process, in accordance with some exemplary embodiments of the invention;

5 Figure 6 is a flowchart describing an exemplary workflow of a surgeon using guiding JIG during VDRO procedure, in accordance with some exemplary embodiments of the invention;

Figures 7A-C are a flow chart describing the workflow of a surgeon using guiding JIG during VDRO procedure, in accordance with some exemplary embodiments of the invention;

10 Figures 8A-C are a flow chart describing the workflow of a surgeon using guiding JIG during VDRO procedure using a chisel, in accordance with some exemplary embodiments of the invention;

Figures 9A-D are flow chart describing the workflow of a surgeon using a kit including a set of guiding JIGs, in accordance with some exemplary embodiments of the invention;

15 Figure 10 is a perspective view of a locking cannulated blade plate (LCB), which required chiseling of the bone, in accordance with some exemplary embodiments of the invention;

Figures 11 and 12 illustrate the rotation correction of the femur, in accordance with some exemplary embodiments of the invention;

Figures 13A-B is a flowchart describing an exemplary design process of a guiding JIG, in accordance with some exemplary embodiments of the invention;

20 Figures 14A-B are flowchart describing an exemplary feedback system in the design process of a guiding JIG, in accordance with some exemplary embodiments of the invention;

Figures 15A-B are top-level flowchart of an exemplary algorithm for designing a guiding JIG, in accordance with some exemplary embodiments of the invention;

25 Figures 16A-H and 17A-B are a detailed flowchart of an exemplary algorithm for designing a guiding JIG, in accordance with some exemplary embodiments of the invention;

Figures 18A-Z and 19A-G illustrate steps of the algorithm described in Figures 16A-H and 17A-B, in accordance with some exemplary embodiments of the invention;

Figures 20A-B are perspective views of a disassemblable guiding JIG for a VDRO process, in accordance with some exemplary embodiments of the invention;

30 Figures 21A-C are perspective views of a disassemblable guiding JIG for a, in accordance with some exemplary embodiments of the invention;

Figures 22A-C, are perspective views of a guiding JIG deployable in parts, in accordance with some exemplary embodiments of the invention;

Figures 23A-C are perspective views of a guiding JIG having a durable guiding element, in accordance with some exemplary embodiments of the invention;

Figure 23D, is a perspective view of a durable surface(s) for a guiding JIG, in accordance with some exemplary embodiments of the invention; and

Figure 23E is a sturdy surface(s) before being folded to achieve a three-dimensional form of the sturdy surface(s), in accordance with some exemplary embodiments of the invention.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to a surgical guide and, more particularly, but not exclusively, to a surgical guide for a VDRO (varus derotation osteotomy) procedure.

As used herein the terms “Guiding JIG” and/or “Surgical navigator” and/or “Surgical guide” and/or “patient-specific instrument (PSI)” means a “Surgical JIG”.

An aspect of some embodiments of the invention relates to a surgical navigator for a VDRO procedure, deployed on a femoral bone. In some embodiments, the surgical navigator encompasses (and/or surrounds), to some extent, the femoral bone, optionally providing a grip thereon. In some embodiments, the grip has the potential advantage of minimizing the requirement for an assistant holding the surgical navigator during the procedure. In some embodiments, the grip limits movements of the guiding JIG after alignment and before/after fixating thereof onto the bone, having the potential advantage of minimizing deviations from the aligned placement. In addition, in some embodiments, the inner surface of the surgical navigator conforms (and/or matches) to the bone geometry at the treatment site, having a potential advantage of further enhancing the grip on the bone.

An aspect of some embodiments of the invention relates to a surgical navigator (e.g., a single surgical navigator) for a VDRO procedure having two recesses for cutting the bone therethrough. In some embodiments, a bone osteotomy performed through the two recesses results in a bone segment separated from the bone, dividing the bone into two fractions. In some embodiments, the bone segment is optionally shaped as triangular, with an angle equivalent to the required correction angle. Alternatively, or additionally, the bone segment is shaped as trapezoidal, optionally, resulting from further shortening the femur. In some embodiments, each recess defines a path into the bone, for a cutting instrument to cut therethrough. In some embodiments, the relative position of the two recesses with respect to each other defines the shape and/or size of the bone

wedge. In some embodiments, this relative position is based on one or more preoperative computed calculations, having the potential advantage of minimizing the requirement for a physician to estimate the location and/or angle of the cuts on the bone. In some embodiments, one recess is sized and/or shaped to receive a specific cutting instrument whereas the other recess is sized and/or shaped to receive a different cutting instrument. Alternatively, or additionally, both recesses are shaped and sized to receive the same cutting instrument.

An aspect of some embodiments of the invention relates to a single surgical navigator for approaching a location in the femur head, for example, the center of the femur head, and for performing osteotomy on the bone. In some embodiments, the surgical navigator includes a passageway for a guide tool (such as a Kirschner wire, also referred to herein as K-wire). In some embodiments, the passageway for a guide directs the insertion of the guide tool into the center of the femur head. In some embodiments, the surgical navigator includes a passageway for a chisel. In some embodiments, the passageway for a chisel directs the insertion of a chisel into the center of the femur head.

In some embodiments, the single surgical navigator may direct the insertion of a guide tool into the femur head in any desired path and/or from any desired insertion location. As previously noted, in common practice the desired insertion path within the femur head is along an axis defining the center of the femur head, optionally, based on input from a surgeon. However, in some embodiments, another path is required. For example, the patient's congenital bone structure, previous treatments and/or implants, damage, and/or injuries to the bone may require an insertion path other than along said axis. In another example, a structure of a selected implant structure may require another insertion path than along said axis.

In some embodiments, the required insertion path through the bone and/or insertion point over the bone is required by the patient's physician, alternatively or additionally, said required insertion path and/or said insertion point is recommended by a computer program (optionally, comprises a ML component) which evaluates the bone structure (e.g., the bone image, such as a CT scan) and offers a path therewithin.

An aspect of some embodiments of the invention relates to a surgical navigator that allows and/or simplifies the removal thereof without removing a tool (e.g., a guide tool and/or an operating tool) deposited therewithin and inserted into the bone, from the bone.

In some embodiments, the surgical navigator comprises a passageway for directing a guide tool into a bone, and a wall defining said passageway. In some embodiments, a first end (e.g., first opening) of the wall is facing an operator, and a second end (e.g., second opening) is partially connected and/or partially positioned on the body of the surgical navigator. This partial positioning

allows a portion of the wall and/or a portion of the wall's second end to be free of the surgical navigator's body. In some embodiments, the wall comprises a slit and/or a cut extending from said first end to said free portion of the second end, allowing the wall to be opened and passing a guide tool inserted within the bone therethrough. In some embodiments, the wall is provided with said slit. Alternatively or additionally said slit is formed after inserting the guide tool through the passageway. In some embodiments, the wall comprises a line and/or an area designated to be cut/opened. Alternatively or additionally, the wall comprises marking for directing the formation of the slit.

In some embodiments, the slit is relatively wide, defining an opening on the wall for a tool to pass therethrough. In some embodiments, the opening is sufficiently small to maintain the passageway defined by the wall.

In some embodiments, the surgical navigator is designed such that the wall is positioned near and/or at an edge of the surgical navigator's body, allowing the formation of said free portion. This configuration has the potential advantage of facilitating the removal of the surgical navigator.

Alternatively or additionally, the body comprises an opening and/or a gap, located next to said free portion, allowing the free portion to be free (e.g., unconnected) to the surgical navigator's body. This configuration has the potential advantage of enabling the wall to be positioned at any desired location on the surgical navigator's body.

In some embodiments, the tool remaining within the bone can be further used. For example, a guide tool inserted within a femur head may be used for mounting a chisel thereon, for example, as commonly performed during VDRO procedures. In another example, a guide tool inserted within a femur head may be used for directing a second surgical navigator, for example, a surgical navigator for directing a chisel. In another example, a guide tool inserted within a femur head may be used for loading a cylindrical cutter thereon, for example, as commonly performed during hip resurfacing procedures.

In some embodiments, the surgical navigator's body is configured to be cut and/or torn around the inserted tool. In some embodiments, the body comprises lines and/or areas of thin material and/or spaced holes for directing and/or facilitating said cut and/or tear. In some embodiments, such lines and/or areas are marked for directing an operator while cutting the surgical navigator.

In some embodiments, the surgical navigator is comprised of segments, such that the connection of the segments forms the wall. For example, in some embodiments, each segment includes a part of the wall, and when the segments interface, the wall is assembled. After introducing a tool via the wall into the bone, the segments can be disconnected, disassembling the

wall and freeing the tool from the surgical navigator (e.g., during the removal of the surgical navigator) while the tool remains inserted within the bone.

An aspect of some embodiments of the invention relates to a method for inserting a chisel into the center of the femur head without requiring previous insertion of a guide into the center of the femur head, and/or loading the chisel over the guide, using a surgical navigator. In some
5 embodiments, the surgical navigator comprises a passageway shaped as the chisel. In some
embodiments, the passageway defines the progression of the chisel along the longitudinal axis
thereof, having the potential advantage of minimizing lateral and/or rotational movements
therewithin, during chiseling. In some embodiments, the passageway directs the chisel, carving the
10 bone, into the center of the femur head, optionally in a single possible configuration. In some
embodiments, this has the potential advantage of minimizing performance errors. In some
embodiments, a prior insertion of a guide into the center of the femur head for directing the
chiseling is less and/or not required, having the potential advantage of simplifying the procedure
and/or reducing the duration of the surgery. An aspect of some embodiments of the invention
15 relates to a single surgical navigator for inserting a guide into the center of the femur head and
subsequently impacting a chisel threaded on the inserted guide. In some embodiments, the surgical
navigator comprises a passageway for a guide, placed within a passageway for a chisel. In some
embodiments, the passageway for a guide is separable and can be withdrawn out of the passageway
for a chisel after the insertion of a selected guide into the center of the femur. In some embodiments,
20 the wall of the passageway for a guide comprises at least one notch thereon, having the potential
advantage of easing the removal of the passageway wall while the guide is left within the center of
the femur head, and optionally, protruding therefrom. In some embodiments, after withdrawing the
separable passageway for a guide, a chisel is loaded on the guide, and placed within the passageway
for chisel. Then, in some embodiments, the chisel carves the bone through the passageway for a
25 chisel, directing the carving along the head-neck axis of the femur head. In some embodiments, the
passageway for a chisel is shaped and/or sized according to the shape and/or size of the chisel,
having the potential advantage of minimizing the rotation of the chisel around the guide. In some
embodiments, the insertion of the guide device is at least partially visualized, having the potential
advantage of indicating the progress of the guide along a desired path, optionally into the center of
30 the femur head. In some embodiments, carving with a chisel loaded on a guide, through a
passageway for the chisel, has the potential advantage of further minimizing performance errors.
In some embodiments, the separable passageway for a guide allows to perform the insertion of a
guide into the center of the femur head and/or the bone carving with a chisel, using a single JIG,
having the potential advantage of simplifying the procedure and/or reducing the duration of surgery

An aspect of some embodiments of the invention relates to a pre-operative method of designing a surgical navigator, optionally comprising a feedback system. In some embodiments, the feedback system performs a feasibility examination of a pre-operative input, optionally received from a physician. In some embodiments, the feasibility examination further considers the patient-specific femur anatomy. In some embodiments, the input from the physician comprises a surgical approach, and/or a selected plate type, and/or a fixation angle of the plate, and/or a selected set of tools. In some embodiments, if the pre-operative input cannot be applied to the specific femur of the patient, then the feedback system notifies the physician. In some embodiments, optionally, the feedback system presents alternatives to the selected plate type, and/or fixation angle of the plate and/or selected set of tools, or any combination thereof. In some embodiments, the pre-operative input is a range of options for the feedback system to suggest preferred options, alternatively or optionally the pre-operative input lacks at least one parameter for defining the surgical guide design, then the feedback system offers completion for the missing information.

An aspect of some embodiments of the invention relates to a method for designing a surgical navigator with two recesses. In some embodiments, the two recesses are configured for performing osteotomy therethrough. In some embodiments, the method comprises customizing the surgical navigator to match a bone geometry of the patient's femur. In some embodiments, the method comprises identifying the femoral head-neck axis and determining a representation of a first recess vertical thereto. In some embodiments, the method comprises determining the location of a representation of a first recess according to the age of a child patient, and/or according to a desired level of femoral shortening. In some embodiments, the method comprises placing a representation of a second recess according to a desired correction angle. In some embodiments, the method comprises thickening the representation of the two recesses according to the geometry of a selected cutting instrument, optionally a single cutting instrument, alternatively or additionally, two different cutting instruments. In some embodiments, the method is performed automatically by a computer program.

An aspect of some embodiments of the invention relates to a surgical navigator sturdy upon contact with sharp objects, such as sharp tools (guide tools and/or working tools), and/or sharp bone residues. In some embodiments, the surgical navigator comprises a passageway for directing a guide tool and/or a fixator (such as a screw and/or a k-wire) and/or a recess for directing a cutting tool, defined by a wall. In some embodiments, the wall is sturdy when contacted by a sharp object, optionally introduced thereto. The term "sturdy" referred to herein, inter alia, as being resistant and/or substantially resistant to cuts, scratches and/or any other damage from contact with a sharp object. It should be noted that the term "sturdy" does not limit the material, properties and/or

structure of the wall. For example, in some embodiments, the wall can comprise and/or be formed from a rigid material, alternatively or additionally, the wall can comprise and/or be formed from a resilient material, optionally soft material.

In some embodiments, the wall comprises a sturdy element, such as one or more sturdy surfaces deployed therewithin. In some embodiments, the one or more sturdy surfaces conform to the shape of the wall's inner surface. In some embodiments the one or more sturdy surfaces comprises and/or formed of a metal, such as stainless steel. In some embodiments, one or more surfaces are flat, to potentially fit within a wall defining a recess for a cutting tool. In some embodiments, one or more surfaces are tubular, to potentially fit within a wall defining a passageway for a guide tool

An aspect of some embodiments of the invention relates to a surgical navigator mountable on a bone in parts and/or steps. In some embodiments, the surgical navigator is comprised of more than one segment where at least one segment is configured to be positioned on the bone, and at least one additional segment is configured to be positioned on the bone by connecting and/or interfacing with the at least one segment. In some embodiments, the at least one segment comprises an inner surface that fits steady on the bone surface, optionally, by having a geometry that complements the surface geometry of the bone. In some embodiments, the at least one additional segment comprises one or more geometry that can interact with (e.g., connect to) a corresponding geometry on the at least one segment. Mounting first the at least one segment and then the at least one additional segment potentially simplifies the deployment of the surgical navigator, having a particular use for relatively large surgical navigators. In some embodiments, the at least one additional segment comprises an inner surface having a geometry that complements the surface geometry as well. Mounting the segments in steps has the potential advantage of simplifying the match between the surgical navigator and the bone, having a particular use for relatively large surgical navigators.

An aspect of some embodiments of the invention relates to an adjustable osteotomy guide, for directing bone osteotomy. In some embodiments, the osteotomy guide comprises two cutting surfaces defining a recess therebetween for introducing a cutting tool therethrough. In some embodiments the two surfaces are connected, optionally to form a frame. The recess is located and/or oriented on the surgical navigator for directing a cutting tool in a desired path into the bone, optionally, a single path. In some embodiments, the distance between the two surfaces is sufficient to enable the entrance of a cutting tool but small enough to avoid lateral movements thereof.

During surgery, the need to increase the degrees of freedom of the operator and/or to improve its access to the bone may arise. In some embodiments, one of the cutting surfaces can be removed, such that osteotomy can be performed using a single cutting slot, thereby potentially increasing the operator degrees of freedom. In some embodiments, a cutting surface can be removed by disconnecting the two surfaces. In some embodiments, the first surface comprises one or more sliding pins and the second surface comprises one or more grooves shaped and/or sized to accommodate the one or more sliding pins. In some embodiments, upon pulling one surface in parallel to the other, one or more sliding pins slide out of the grooves and disconnect the two surfaces.

In some embodiments, the surgical navigator is comprised of at least two segments, optionally, two segments, each including one of the cutting slots. Removing one of the segments results in a single remaining cutting surface. Removing said segment potentially reveals the bone underneath, thereby potentially further increasing the operator's degrees of freedom. In some embodiments, the removed segment is selected according to an area of the bone that needs to be revealed. In addition, removing a segment of the surgical navigator has the potential advantage of simplifying the removal of a cutting surface. In some embodiments, one or both of the segments comprise one or more grip holes, optionally, shaped and/or sized according to a gripping tool.

In some embodiments, a surgical guide comprises more than one osteotomy guide (optionally, two osteotomy guides), such as a surgical JIG for a VDRO procedure, where at least one of the osteotomy guides is adjustable.

An aspect of some embodiments of the invention relates to a disassemblable surgical navigator for a VDRO procedure. In some embodiments, the surgical navigator comprises a detachable segment (e.g., a portion and/or a part), optionally located between two or more recesses directing bone osteotomy, optionally, defined by the two or more recesses. In some embodiments, the detachable segment is shaped and/or sized according to the surface of a bone wedge intended to be cut and/or separated from the bone, covered by the surgical navigator's body. The detachable segment enables the removal thereof from the disassemblable surgical navigator (after and/or during bone osteotomy) while maintaining the rest of the surgical navigator deployed on the bone fragments formed as a result of the osteotomy. In some embodiments, the detachable segment can be removed before the osteotomy to potentially increase the operator's degrees of freedom.

In some embodiments, removing the detachable segment forms a proximal segment of the surgical navigator, located on a proximal bone fragment and a distal segment of the surgical navigator, located on a distal bone fragment. In some embodiments, the proximal and distal segments of the surgical navigator direct the positioning and/or attachment of the bone fragments.

In some embodiments, after the bone fragments (together with the surgical navigator fragments) are joined, the proximal and/or distal fragments of the surgical navigator direct a plate to be deployed thereon. Upon plate placement above the surgical navigator's fragments, the fragments are removed, optionally, by tearing thereof, alternatively, or additionally, by disassembling thereof, and optionally, the plate is then fastened on the bone.

In some embodiments, the surgical navigator is comprised of the proximal segment, the detachable segment, and the distal fragments, optionally anchored to each other for being deployed as a single unit. Alternatively or additionally at least one of the segments is independent and the segments are deployed separately on the bone, optionally in parts, optionally aligned with respect to each other. In other embodiments, the proximal and distal segments are formed upon the removal of the detachable segment.

An aspect of some embodiments of the invention relates to a surgical navigator having at least one verification component for evaluating the reliability of a produced surgical navigator. In some embodiments, at least one verification component is designed to have a specific size and/or shape. A produced surgical navigator having a verification component sized and/or shaped according to the design thereof indicates that the produced surgical navigation is reliable (e.g., shaped and/or sized according to a desired design). In some embodiments, at least one verification component comprises a geometry design to have measurable shape and/or size. For example, the verification component is a coin, designed to have a specific diameter. In some embodiments, the surgical navigator is provided with a designated measurement tool, for example, which comprises a recess shape and/or sized to receive a verification coin. In some embodiments, the surgical navigator comprises more than one verification component, optionally, located distance from each other, optionally, on different portions of the surgical navigator, optionally, next to guiding elements of the surgical navigator. The more than one verification component has the potential advantage of improving the probability of detecting a faulty surgical navigator.

An aspect of some embodiments of the invention relates to a surgical navigator for performing osteotomy on a bone, defining a plurality (e.g., more than one) cutting paths within the bone, optionally, for an operator to select from.

In some embodiments, the surgical navigator comprises one or more osteotomy guides, wherein each osteotomy guide comprises a plurality of recesses (e.g., cutting slots) for directing a cutting tool therethrough. Each recess defines a different path into the bone, optionally, a single pathway.

In some embodiments, the surgical navigator comprises a plurality of passageways, each defining a different location on the bone and guiding a tool into the bone that is used as a mark for

performing osteotomy, optionally by using an additional surgical navigator that defines a cutting angle at the marked location. A surgical navigator comprising a plurality of passageways has the potential advantage of reducing and/or avoiding impairment of the mechanical strength of the surgical navigator while enabling path selection.

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Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways.

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Referring now to the drawings, figures 1A-C illustrating femur deformities correction by varising de-rotation osteotomy (VDRO) procedure, in accordance with some exemplary embodiments of the invention.

In a child (and/or an adult patient) with femur deformities **102** the head of the femur **104** (ball) is misaligned with the acetabulum (socket), and there is an abnormality in the current shaft angle **110** (shown in figure 1B) between the longitudinal femoral shaft-neck axis **106** (shown in figure 1B) and the femoral head-neck axis **108** (shown in figure 1B), and may also be referred to herein as the center of the femur head axis.

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The VDRO procedure is employed to restore the ball into the socket, by the correction of the current neck shaft angle **110**. A desired neck shaft angle **112** (shown in figure 1C) is achieved by cutting and removing a bone wedge from the femur. This bone osteotomy is preformed according to correction angle **114** (shown in figure 1C), calculated by subtracting the desired neck shaft angle **112** from the current neck shaft angle **110**. The removal of the bone wedge separates the femoral bone into two fragments. This separation allows the femur head to be tilted back into the acetabulum. Additionally, the femur can be rotated to address rotational deformities that may be present.

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To ensure that the bone heal correctly, the two fragments are held together with metal plate **116** fixed by screws. The plate is selected according to the fixation angle thereof, which defines the desired neck-shaft angle. The plate is usually removed after the bones have healed and strengthened.

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Referring now to figure 2, showing a flowchart describing an exemplary process of VDRO procedure using a guiding JIG, in accordance with some exemplary embodiments of the invention.

At **202**, a patient is selected for a VDRO procedure. In some embodiments, the patient suffers from anatomic changes on the femoral side (e.g., femoral anteversion, coxa valga). In some embodiments, the patient is an individual older than 2 years old with residual hip dysplasia.

At **204**, a guiding JIG is computer-designed and/or partially computer-designed.

5 In some embodiments of the invention, the design is fully-automated. In some embodiments of the invention, the design is semi-automated.

In some embodiments, a scanned image of the patient is used for the design of the guiding JIG, having the potential advantage of not requiring measurements of the exposed femoral bone. In some embodiments, the guiding JIG can be designed prior to surgery, having the potential
10 advantage of saving time during operation and/or minimizing the period of time in which the bone is exposed.

In some embodiments, alternatively or additionally, the guiding JIG can be designed and produced at any stage prior and/or during the VDRO procedure. In some embodiments, the computer-based and/or semi computer-based guiding JIG has the potential advantage of being
15 designed and/or produced in a relatively quick manner if a need arises after exposing the bone and/or during performing the procedure.

In some embodiments, the design is based on a 3D model of the femoral bone anatomy, generated from the scan image and on required preoperative input, optionally, from a physician. In some embodiments, the design is performed by a design software/system, optionally, based on
20 the patient's 3D model of the femoral bone. Optionally and/or additionally, the design is based on input from a surgeon optionally, according to an operative plan of the surgery.

In some embodiments of the invention, the design software/system comprises a feedback system configured for alerting if and when the preoperative input results in an unfeasible design. In some embodiments, optionally, feasible alternatives are suggested by the system. In some
25 embodiments of the invention, improved alternatives are suggested for a feasible design as well.

In some embodiments, the guiding JIG is designed to limit the degree of freedom of an operator, human surgeon, and/or robotic operator, performing the VRDO procedure. This limitation allows directing operating tools applied on the femoral bone in a desired path.

In some embodiments of the invention, the guiding JIG is designed to direct operating tools
30 in a single possible path into the bone. This design has the potential advantage of minimizing the risk of performance errors during surgery. In some embodiments of the invention, the guiding JIG is designed to allow more operation freedom to the operator, defining a range of possible paths into the bone. This design has the potential advantage of limiting performance error together with allowing the surgeon freedom to operate in unforeseen situations.

In some embodiments, the design of the guiding JIG is customized according to one or more of: the patient's anatomy, a selected plate, and/or a set of tools for performing the VDRO procedure.

At **206**, the guiding JIG is produced according to the customized design of step **204**. Optionally, the design is implemented by 3D printing, as further described in step **1320** of figure 13B.

At **208**, a VDRO procedure is performed by using the guiding JIG. In some embodiments, the guiding JIG is placed on the femur and is configured to act as a guide for an operator, optionally, a human surgeon, alternatively or additionally, a robotic operator. In some embodiments, the operator applies one or more operating tools on the femoral bone through the guiding JIG, which directs the progress of the operating tools to and/or within the bone. In some embodiments, performing VDRO using a guiding JIG has the potential advantage of minimizing performance errors. An additional potential advantage is that VDRO procedures can potentially be performed by operators having less and/or no training.

In some embodiments, the guiding JIG directs the operating tools into the femoral bone, optionally, in a single possible path, alternatively, in a limited range of possible paths. A potential advantage of this direction is that less visualization and/or no visualization is required. A potential advantage of minimizing visualization is the reduction of exposure to x-ray radiation.

In some embodiments, since the guiding JIG defines the place and/or angle of operations (such as drills and/or cuts) on the bone, an additional potential advantage is the evaluation and/or discretion of a physician on how to position the operating tools is less and/or not required.

In some embodiments, since the design and production of the guiding JIG can be completed prior to surgery and/or in a relatively quick manner at any stage during the, an additional potential advantage is that a time required for the design and production while the patient is cut-opened and under full anesthesia is reduced.

At **210**, a post-surgery follow-up on the patient is performed.

Referring now to figures 3A-E, showing perspective views of a guiding JIG **300** for a VDRO process, in accordance with some exemplary embodiments of the invention.

In some embodiments, guiding JIG **300** comprises a JIG body **302** and guiding elements positioned thereon.

In some embodiments, JIG body **302** comprises a proximal end **304** facing the femur head and a distal end **306**, facing away from the femur head.

In some embodiments, JIG body **302** further comprises an inner surface **301** (shown in figure 3E) and an outer surface **313**. In some embodiments, the inner surface **301** is configured to face the femoral bone, and the outer surface **313** is configured to face the operator. In some

embodiments, the geometry of inner surface **301** complements the geometry of the bone at the treatment site, so that guiding JIG **300** can be positioned steadily thereon optionally in a single possible configuration. In some embodiments, outer surface **303** comprises at least one mark designed to indicate (e.g., sign and/or point to) familiar anatomical landmarks upon properly placing guiding JIG **300** on the bone. Herein, proper placing of the guiding JIG on the bone is referred, *inter alia*, to aligning the JIG such that the geometry of its inner surface **301** matches the geometry of the bone. For example, guiding JIG **300** comprises at least one mark on outer surface **303** that points to the greater trochanter and/or lesser trochanter. This at least one mark potentially directs an operator to place the JIG over the bone and/or indicates improper positioning.

In some embodiments, JIG body **302** is sized and/or shaped to be deployed on a portion of the target bone (e.g., femur head) at a site intended for treatment.

In some embodiments, the guiding JIG body **302** partially circumferentially surrounds the femur, relative to the longitudinal shaft-neck of the femur. In some embodiments, optionally, the geometry of the JIG (surrounding the femur) provides a natural grip of the JIG on the bone. This grip may potentially reduce the need to fix the jig onto the bone using bone-penetrating fixator(s).

In some embodiments, JIG body **302** (e.g., the contact surface with the bone) is sufficiently large to enable a steady positioning of JIG **300** on the bone surface. In some embodiments, This steady positioning is achieved by the match between the geometry of the contact surface and the geometry of the bone surface, optionally, a single steady positioning. In some embodiments, the JIG body **302** is as small as possible (e.g., minimized) to potentially reduce the extent of required bone exposure, while still enabling steady positioning. In some embodiments, JIG body **302** is designed such that inner surface **305** includes a relatively complex 'topographic' area of the bone for potentially improving and/or facilitating the steady positioning of JIG **300**. In addition, JIG **300** designed to include a complex 'topographic' area of the bone potentially enables to decrease the size of JIG body **302** required for achieving said steady positioning, having the potential advantage of further reducing the extent of required bone exposure. For example, in some embodiments, JIG body **102** is designed to cover at least a portion of the femur neck and/or other are showing topographical change, optionally patient-specific areas.

In some embodiments, JIG body **302** encompasses and/or surrounds a portion of the femur head together with a portion of the femur neck (as shown for example in the figures, having the potential advantage of improving the match to the bone and/or facilitating achieving a steady positioning. In other embodiments, JIG body **302** encompasses and/or surrounds a portion of the femur head, potentially reducing and/or avoiding exposure of the femur neck.

In some embodiments, the guiding elements of guiding JIG **300** comprise functional guiding elements and/or fixating guiding elements.

In some embodiments, the functional guiding elements are positioned on JIG body **302** according to a desired path into the femoral bone. In some embodiments, the location and/or orientation of a functional guiding element on JIG body **302** defines said desired path into the femoral bone. In some embodiments, the shape and/or size of the functional guiding elements corresponds to the shape and/or size of the selected operating tools.

In some embodiments, the functional guiding elements of guiding JIG **300** comprise a guiding conduit for a guide implement **310**, such as a k-wire, directing the insertion of the guide implement into the center of the femur head.

In some embodiments, the guiding conduit for a guide implement **310** comprises an inner lumen **312**, and a wall **314**.

In some embodiments, the inner lumen **312** is shaped according to the shape of a selected guide implement. In some embodiments, the size of inner lumen **312** is large enough to accommodate the selected guide implement but limited to prevent lateral movement and/or rotation therewithin. For example, the guiding conduit has a diameter of about 2 mm (for example, 1.5 mm, 2.5mm, 3.1mm, 3.5mm), optionally, between about 2 mm and about 3mm. Optionally between about 1.5mm and about 3.5mm, optionally between about 0.5mm and about 5mm.

In some embodiments, the location and/or the orientation of guiding conduit **310** into the center of the femur head direct the progress of the guide implement into the center of the femur head, optionally in a single possible path, alternatively, in a range of possible paths.

In some embodiments, the location and/or orientation of guiding conduit for a guide implement **310** is defined by the head-neck axis of the femur head, so that an inserted guide implement will be in line with the head-neck axis of the femur head (e.g., guiding conduit for a guide implement **310** is inline with the head-neck axis). Alternatively or additionally, guiding conduit for a guide implement **310** can be located and/or oriented on JIG body **302** to direct a guide implement in any desired path within the bone (e.g., other than the head-neck axis), for example, if requested by a surgeon.

In some embodiments, the functional guiding elements of guiding JIG **300** comprise an osteotomy guide **316** including at least two cutting slots (**318** and **320**), and a support frame **322**, optionally, a single support frame for both cutting slots (**318** and **320**), alternatively or additionally, a support frame for one and/or each cutting slot. In some embodiments, the osteotomy guide **316** is configured to direct a cutting tool during the femoral bone osteotomy.

In some embodiments, the cutting slot **318** is sized and/or shaped to receive a first cutting implement, such as a cutting saw, according to the size and/or shape of the first selected cutting implement. In some embodiments, cutting slot **320** is sized and/or shaped to receive a second cutting implement, according to a size and/or shape of the second selected cutting implement. In some embodiments of the invention, the first cutting implement and the second cutting implement are one.

In some embodiments, the cutting slots (**318** and **320**) are wide enough to accommodate the selected cutting implement, but sufficiently narrow to limit lateral movement therewithin. For example, the cutting slots are 1 mm wide (for example, 0.5mm, 0.7mm, 1.1mm, 1.5mm), optionally, between about 2 mm and about 0.1mm. Optionally between about 1.5mm and about 0.5mm, optionally between about 3mm and about 1mm.

In some embodiments of the invention, the cutting slots **318** and **320** are conically shaped with a wider opening at the entrance of the slot, gradually narrowing towards the bone, having the potential advantage of easing the entrance of the cutting tool.

In some embodiments, the location of cutting slots **318** and **320** defines the osteotomy site. In some embodiments, the cutting slots **318** and **320** are positioned relative to each other such that cutting the bone therethrough results in a bone wedge, cut from the femur, separating the bone into a distal and proximal fragment. In some embodiments of the invention the location and/or orientation of cutting slots **318** and **320** define a triangular bone wedge, according to the desired correction angle. In some embodiments, optionally, or alternatively, when a shortening of the femur is required, the location and/or orientation of cutting slots **318** and **320** define a trapezoidal bone wedge. In some embodiments, optionally, by increasing the distance between the cutting slots **318** and **320**, which defined by the desired shortening of the femur.

In some embodiments of the invention, one cutting slot is perpendicular to the head-neck axis and the second cutting slot is positioned relative thereto according to the desired correct angle and/or shortening distance. In some embodiments, optionally, or alternatively one cutting slot is parallel to the head-neck axis of the femur head, and the second cutting slot is positioned relative thereto according to the desired correct angle, and/or shortening distance.

In some embodiments, the support frame **322** defines cutting slots **318** and **320**. In some embodiments, the depth of support frame **322** with relative to the radial direction of the longitudinal axis of the femur defines the depth of cutting slots **318** and **320**. In some embodiments, deeper cutting slots enhance the stabilization of the cutting tool thereinto, having the potential advantage of minimizing operation errors during osteotomy.

In some embodiments of the invention support frame **322** further stabilizes the structure of JIG body **302**.

In other embodiments, cutting slot **318** and/or **320** is defined by a recess on JIG body **302** which exposes the bone, for example, cutting slot 1622 as shown for example in figure 16A.

5 In some embodiments, the functional guiding elements of guiding JIG **300** further comprise a distal guiding hole **324** (shown in Figure 3C) for the alignment of the distal fragment with the proximal fragment of the femoral bone and/or for rotation correction of the femur.

10 In some embodiments, the distal guiding hole **324** is located between osteotomy guide **316** and distal end **306** of JIG body **302**, directing an operating tool to be applied onto the distal fragment of the femoral bone. In some embodiments of the invention, distal guiding hole **324** directs drilling for a locking screw of a selected plate, shaped and sized according to the dimensions and/or shape of the selected locking screws.

15 In some embodiments, a distal bore, on the distal bone fragment, resulting from penetrating the bone through distal guiding hole **324**, and a bore at the center of the femur, on the proximal bone fragment, resulting from penetrating the bone through guiding conduit for a guide implement **310**, define a single configuration relative to the longitudinal axis of the femur, for placing the selected plate (as shown in figures 11-12).

20 In some embodiments, if rotation correction is required, this means that the distal guiding hole **324** deviates from the longitudinal axis of guiding JIG **300**. In some embodiments, the degree of deviation is according to the level of rotation correction required. In some embodiments, if rotation correction is not required, this means that the distal guiding hole **320** is aligned with guiding conduit **310**.

25 In some embodiments, the functional guiding elements of guiding JIG **300** further comprise at least one proximal guiding hole **326** (shown in figure 3D). Proximal guide hole **326** is positioned to direct drilling onto the proximal fragment of the femur (optionally, before cutting the bone). In some embodiments, the location and number of the at least one proximal guiding hole **326** on JIG body **302** are defined according to the shape of the selected plate, for example locking proximal femur plate (LPF). In some embodiments, the size of the proximal drilling guiding hole **326** is defined by the fixators of the selected plate, such as a k-wire and/or a locking screw.

30 In some embodiments, the bore resulting from penetrating the bone through proximal drilling hole **326** is used for the alignment of the distal fragment relative to the femoral head-neck axis and minimizes the risk for translation deviation along the femoral head-neck axis when fixing the plate.

In some embodiments, optionally, the distal bore on the distal fragment resulted from penetrating the bone through distal guiding hole **324** and the at least one proximal bore at the proximal fragment of the femur, resulted from the penetrating the bone through at least one proximal drilling hole **326**, define a single configuration, for placing the plate.

5 In some embodiments of the invention, a guiding sleeve is mounted (not shown) on distal guiding hole **324** and/or on at least one proximal guiding hole **326**, having the potential advantage of enhancing the stability of an operating tool inserted therethrough.

In some embodiments, the length of the sleeve defines the depth and/or potential depth of insertion therethrough, having the potential advantage of minimizing the risk for over drilling into
10 the bone.

In some embodiments, the fixating guiding elements direct the insertion of fixators and are positioned (e.g., located and/or originated) on the guiding JIG so that the path of a fixator will not collide with the path dictated by the functional guiding elements.

In some embodiments, guiding JIG **300** comprises at least one fixation guiding hole **328** for
15 guiding the insertion of at least one fixator, such as but not limited to a k-wire. In some embodiments, the size of the at least one fixating guiding hole **328** is determined according to the fixator selected by the physician. In some embodiments, the at least one guiding hole is sized to accommodate the selected fixator, and to limit lateral movement therewithin.

In some embodiments, the location of the at least one fixating guiding hole **328** on guiding
20 JIG **300** determines the location of the at least one fixator. Optionally, the at least one fixating guiding hole **328** is located adjacent to the distal end of JIG body **302**, alternatively, or additionally, the at least one fixation guiding hole **310** is located at a side portion of JIG body **302**.

In some embodiments, optionally, a guiding sleeve **330** is mounted on fixating guiding hole **306** for directing the insertion angle of the fixator.

25 In some embodiments, optionally, guiding JIG **300** comprises one or more structure supports, such as structure support **308**, to maintain the shape thereof.

Optionally, structure support **308** is attached to guiding conduit **310**, for mechanical support. Optionally or additionally, structure support **308**, maintains the orientation of guiding conduit **310**, by fixating the angle between the guiding conduit **310** and the longitudinal axis of the
30 guiding JIG.

Optionally, structural support **308** is further attached to osteotomy guide **308**, maintaining the relative location of osteotomy site **316** and guiding conduit **310**.

In some embodiments, JIG body **302** is formed from an elastic material which maintains the structure thereof upon appliance and/or alignment on the femoral bone.

In some embodiments, this material has sufficient flexibility to be mounted over the femoral bone, and some degree of rigidity to be fixed thereon.

In some embodiments of the invention, JIG body **302** comprises regions of relatively higher rigidity and regions of relatively higher flexibility. Optionally, the relatively higher rigidity regions are used for structural support, optionally the regions of higher flexibility allow the JIG body to be mounted on the bone.

In some embodiments, optionally, regions of higher rigidity are thicker portions of JIG body **302**, whereas regions of higher flexibility are thinner portions of JIG body **302**.

In some embodiments, alternatively, or additionally, the different regions can be achieved by adding supplements such as plasticizers for enhancing flexibility and/or stiffeners for enhancing rigidity, alternatively or additionally, the different regions can be formed from different materials and/or composites distinguished by their rigidity and/or flexibility.

In some embodiments of the invention, structural support, such as structural support **308** is formed from the same material as JIG body **302**, alternatively or additionally, structural support **308** is formed from a substantially rigid material than the material of JIG body **302**, having the potential advantage of enhanced support with minimizing the size and/or required amount of material for structural support **308**.

In some embodiments of the invention guiding JIG **300** is used as a single guiding JIG, optionally or additionally, guiding JIG **300** is a part of a kit including a set of at least two guiding JIGs. In some embodiments of the invention guiding JIG **300** is used for insertion of a guiding implement into the center of the femur head, optionally, not comprising guiding osteotomy **316**.

Referring to figure 4A, showing a perspective view of a guiding JIG **400** for a VDRO process using a chisel, in accordance with some exemplary embodiments of the invention.

Guiding JIG **400** is identical to guiding JIG **300**, with the exception of the following variances:

The same reference numerals have been used to denote parts that are similar to those described for guide device **300**, with the prefix 4 replacing the prefix 3.

In some embodiments, guiding JIG **400** does not include guiding conduit for guide implement **310**.

In some embodiments, guiding JIG **400** is designed for a chisel-based plate and does not include at least one proximal guiding hole **326** for locking screws of the plate.

In some embodiments, guiding JIG **400** comprises a guiding conduit for a chisel **410** having an inner lumen **412**, and a wall **414**. In some embodiments, inner lumen **412** possesses the shape of the selected chisel.

A potential advantage of inner lumen **412** having the shape of the selected chisel is that there is no requirement for prior insertion of a K-wire for the chisel to be threaded on.

In some embodiments, the size of inner lumen **412** is large enough to accommodate the selected chisel but small enough to limit lateral movement and/or rotation of the chisel therewithin, having the potential advantage of minimizing undesired rotation and/or lateral deviation of the chisel upon impacting the bone.

In some embodiments, guiding conduit for a chisel **410** directs a chisel impacting the femur into the center of the femur head.

In some embodiments, the length of wall **414** is sufficiently long to stabilize the chisel placed within inner lumen **412**, while leaving an exposed portion of the inserted chisel to be impacted. The length of wall **414** defines the initial length of the exposed chisel portion which defines the depth of the chiseling into bone.

In some embodiments of the invention, the combination of the location of guiding conduit for chisel **410** together with the orientation thereof directs a chisel impacting the bone into the center of the femur head in only a single possible path. In some embodiments, guiding conduit for a chisel **410** is orientated on JIG body **402** according to a desired orientation of the chisel when chiseling the bone, for potentially forming a cavity within the bone shape, size, and/or orientated according to accommodate a corresponding portion of the chisel-based plate (e.g., a portion shaped and/or sized as the chisel).

In some embodiments, the location and/or orientation of guiding conduit for chisel **410** is defined by the femoral neck-head axis such that the guiding conduit for chisel **410** is in line with the head-neck axis. In other embodiments, the location and/or orientation of guiding conduit for chisel **410** defined a path into the bone other than inline by the femoral neck-head axis, optionally, any desired path, optionally, defined by a structure a selected chisel-based plate and/or by input of the surgeon.

In some embodiments, optionally, structure support **408** is attached to guiding conduit for chisel **410**, for mechanical support. Optionally or additionally, structure support **308**, maintains the orientation of guiding conduit for chisel **410**.

In some embodiments of the invention, the cavity at the center of the femur head, created by chiseling through guiding conduit for chisel **410**, and the distal bore formed by drilling through proximal guiding hole **424**, define a single configuration for placing the plate.

Referring now to figures 4B-D, showing a perspective view of a guiding JIG **400** for a VDRO process using a guide implement and a chisel, in accordance with some exemplary embodiments of the invention.

In some embodiments of the invention, guiding JIG **400** comprises a removable guiding conduit for a guide implement **440**, that can be mounted within guiding conduit for a chisel **410** (as shown for example in figures 4B-C. The removable guiding conduit for a guide implement is configured to direct a guide implement (e.g., a K-wire) into the center of the femur head (shown for example in Figure 4C), as described for guiding conduit for a guide implement **310** of guiding JIG **300**.

In some embodiments of the invention, the removable guiding conduit for a guide implement is attached and/or anchored to guiding conduit for a chisel **410**, optionally positioned within guiding conduit for a chisel **410**. This attachment (and/or anchoring) allows removable guiding conduit for a guide implement **440** to be positioned steady within guiding conduit for a chisel **410**, maintaining a desired position thereof for directing the insertion of a guide implement into the center of the femur head (and/or any other path into the bone, dictated by guiding conduit for a chisel **410**). In some embodiments, at least a portion **442** of removable guiding conduit for a guide implement **440** is shaped and/or sized to fit within wall **414** and occupy inner lumen **412**. In some embodiments, the outer surface of at least a portion **442** of removable guiding conduit for a guide implement is at least partially shaped and/or sized to complement the geometry of inner lumen **412** of guiding conduit for chisel **410**. In some embodiments, the friction between said outer surface and the inner surface of guiding conduit for chisel **410** (e.g., the inner surface of well **414**) maintains removable guiding conduit for a guide implement **440** at a steady position within lumen **412**. In some embodiments, removable guiding conduit for a guide implement **440** comprises a protruding portion **444** configured to protrude from guiding conduit for a chisel **410** when removable guiding conduit for a guide implement **440** is mounted therewithin. Protruding portion **444** potentially facilitates the insertion of a guide implement into removable guiding conduit for a guide implement **440** and/or facilitates the removal thereof.

In some embodiments, the removable guiding conduit for a guide implement is configured to be withdrawn from guiding JIG **400**, subsequent to the insertion of a guiding implement into the center of the femur head. In some embodiments of the invention the removable guiding conduit for a guide implement is withdrawn by cutting thereof, optionally or additionally, by pulling thereof. In some embodiments of the invention, the removable guiding conduit for a guide implement comprises a slit along the longitudinal axis thereof, having the potential advantages of easing the removal thereof while the guiding implement remains within the center of the femur head.

After the removal, guiding conduit for chisel **410** is free to receive a chisel threaded on the guide implement, inserted into the center of the femur head.

In some embodiments, the removable guiding conduit for a guide implement allows both the insertion of a guide implement and/or the insertion of a chisel into the center of the femur head, using a single JIG, having a potential advantage of reducing the procedure duration. In some embodiments, the insertion of the guide implement is visualized to minimize deviations from the path into the center of the femur head. The chisel is threaded on the guide implement, having the potential advantage of minimizing deviations of the chiseling from the path into the center of the femur head. An additional potential advantage is minimizing the rotation of the chisel around the guide implement by impacting the chisel through the guiding conduit for a chisel.

Referring to figure 5A, showing a perspective view of a guiding JIG **500** for a VDRO process, in accordance with some exemplary embodiments of the invention.

Guiding JIG **500** is a variant of guiding JIG **400**, having the same general functional elements.

In some embodiments, guiding JIG **500** comprises JIG body **502** having a larger surface area, compared to JIG body **402**. JIG body **502** partially circumferentially surrounds the femur, to a greater extent than the JIG body of guiding JIG **400**. This enhanced partial surrounding eases the alignment of JIG body **502** on the femur, compared to guiding JIG **400**. Additionally, or optionally, since the surface area of JIG body **502** is enhanced, guiding JIG **500** has an enhanced grip on the bone so less invasive fixating thereto is required.

In some embodiments, guiding guide **500** comprises at least one extension **530**. In some embodiments, extension **530** is an area having complement geometry to the bone anatomy, exceeding the boundaries of JIG body **502**. In some embodiments, extension **530** potentially provides an additional landmark for the alignment of JIG body **502** onto the femur. In addition, extension **530** enhanced the fixating of JIG body **502** onto the bone, having the potential advantage of further reducing and/or avoiding the need for invasive fixating.

In some embodiments, guiding JIG **500** comprises guiding conduit for chisel **510** having longer wall **514** compared to guiding JIG **400**. Optionally, structure support is attached to guiding conduit for chisel **510** to maintain the orientation thereof, optionally along the longitudinal axis of wall **514**.

In some embodiments, longer wall **514** defines deeper inner lumen **512** which has the potential advantage of enhancing the chisel stability.

In addition, the difference between the length of the chisel and the length of wall **514** defines the depth of the chiseling into the bone. Longer wall **514** defines a shorter portion of initial exposed chisel which defines a reduced chiseling depth.

In some embodiments of the invention, guiding conduit for chisel **510** can be shortened, for example, if a need arises during surgery. The shortening of the guiding conduit for chisel **510** increases the range of operating and/or the potential depth of chiseling.

In some embodiments of the invention guiding conduit for chisel **510** comprises at least one slit to ease the shortening thereof during surgery, and/or for indicating the modified depth of chiseling. In some embodiments, guiding JIG **500** comprises an osteotomy guide **516** having support frame **522** for guiding slots **518** and **520**. In some embodiments, support frame **522** extends beyond guiding slots **518** and **520**, partially surrounding circumferentially JIG body **502**. This extension has the potential advantage of enhancing the structural support of JIG body **502**.

In some embodiments, support frame **522** has reduced depth, relative to the radial axis of JIG body **502**, compared to support frame **322** of guiding JIG **300**. A less deep support frame defines less deep cutting slots **518** and **520** compared to cutting slots **318** and **320** of guiding JIG **300**.

The reduced depth of cutting slots **518** and **520** defines a less stable osteotomy guide, having the potential advantage of allowing some degree of freedom when cutting the bone. The degree of freedom can be beneficial when unexpected situations arise during surgery.

In some embodiments of the invention support frame **522** is relatively deep but comprises at least one slit to ease the shortening thereof during surgery.

Referring to figure 5B showing a perspective view of a guiding JIG **550** for a VDRO process, in accordance with some exemplary embodiments of the invention. Guiding JIG **550** is a variant of guiding JIG **300**.

In some embodiments, guiding JIG **550** differs from guiding JIG **300** by having at least one extension **530**, as described for guiding JIG **500**. In addition, in some embodiments, guiding JIG **550** comprises JIG body **502** having a larger surface, compared to JIG body **300**, as described for guiding JIG **500**.

In some embodiments of the invention guiding JIG **550** is a part of a kit including a set of guiding JIGs, so an osteotomy guide is not included, alternatively or additionally, guiding JIG **550** comprises an osteotomy guide, optionally, as described for guiding JIG **500**.

In some embodiments, guiding JIG **550** differs from guiding JIG **300** by having longer wall **554** of guiding conduit for a guide implement **522**, relative to the longitudinal axis thereof, compared to guiding conduit for a guide implement **310** of guiding JIG **300**.

In some embodiments, longer wall **554** defines deeper inner lumen **556** which has the potential advantage of enhancing the guide implement stability during insertion into the center of the femur head. Enhancing the stability of the guide implement within the guide conduit for guide

implement **552** has the potential advantage of directing the progress of the guide implement in a single possible path.

In some embodiments of the invention, guiding conduit for a guide implement **552** can be shortened, for example, if a need arises during surgery. The shortening of the guiding conduit for
5 guide implement **522** increases the range of operating therethrough.

Optionally, structure support is attached to guiding conduit for chisel **552** to maintain the orientation thereof, optionally along the longitudinal axis of wall **554** (not shown).

In some embodiments of the invention, a kit including a set of at least two guiding JIGs is provided.

10 In some embodiments of the invention the kit includes at least one of guiding JIGs **300** and/or **550**, and at least one of guiding JIG **400** and/or **500**.

In some embodiments of the invention guiding JIGs **300** and/or **550** are used for directing a guide, such as k-wire into the center of the femur head. Guiding JIG **400** and/or **500** are used for directing a chisel impacting the bone, into the center of the femur head and/or for performing
15 osteotomy. Guiding JIGs **300** and/or **550** do not comprise at least one proximal guiding hole **326**, optionally or additionally JIGs **300** and/or **550** do not comprise an osteotomy guide. In some embodiments of the invention a distal guiding hole is located at least on one of the guiding JIGs of the set, and/or on each guiding JIG of the set, having the potential advantage of allowing to applied operating tool therethrough in various situations throughout the procedure.

20 In some embodiments of the inventions, the fixating guiding holes of the first JIG are at the same location with respect to the femur anatomy such as the fixating guiding holes of the second JIG. The bores on the bone resulted from inserting fixators through the fixating guiding holes of the first JIG used as additional alignment indication for fixating the second JIG.

In some embodiments of the invention, the guiding JIG is configured to be used by a robotic
25 arm.

The guiding JIG comprises a camera for directing the robotic arm, optionally, the JIG body comprises a designated site for mounting the camera, optionally, shaped and/or sized according to the selected camera.

In some embodiments, the JIG body comprises at least one label, detectable by a camera of
30 the robotic arm. In some embodiments labels on the JIG body direct the progression of the robotic arm. In some embodiments, the at least one label is attached to the JIG body after production thereof, alternatively or additionally, the at least one label is inherently printed into the JIG body, optionally, during production thereof.

In some embodiments of the invention the insertion of the guiding JIG through the incision in the thigh, and/or placement of the guiding JIG onto the femur, is performed by a human operator. Alternatively, or additionally, the insertion and/or placement of the guiding JIG onto the femur is performed by the robotic arm.

5 In some embodiments, the JIG body comprises a marker, such as a metal screw, for evaluating the alignment of the guiding JIG onto the bone by visualization.

In some embodiments the location of the robotic arm is calibrated prior to operation, optionally by determining a desired distance between the robotic arm and the guiding JIG. In some embodiments of the invention, the progress of the robotic arm is monitored using a visualization
10 device, such as an X-ray device. The robotic arm is updated with a preoperative plane, including the desired path and/or paths into the femur. The robotic arm compares the progress thereof with the preoperative plane and alerts for deviations from the desired path and/or paths into the bone.

In some embodiments, the guiding elements of the guiding JIG have a conical shape, which widens towards the entrance thereof. This conical shape has the potential advantage of enhancing
15 tolerance for the insertion of operating tools by the robotic arm.

In some embodiments of the invention, the guiding elements are elongated, optionally, emerging out of the body. This has the potential advantage of allowing the robotic arm space for movement, external to the body. An additional potential advantage is minimizing the risk of the robotic arm injuring the bone and/or tissues.

20 Optionally, the elongated guiding elements are supported with sufficient structural support to maintain the stability thereof.

In some embodiments of the invention, the guiding elements comprise signs for the detection thereof by the robotic arm and/or for directing the entrance thereinto. In some embodiments, the wall of a guiding element comprises a colored sign, such as a red sign, detectable
25 by a camera of the robotic arm. Alternatively, or additionally, the robotic arm comprises an X-ray device, and the wall of a guiding element comprises a metal sign detectable by X-ray.

In some embodiments of the invention, the wall of the guiding elements comprises a plurality of marks, for example, parallel lines and/or rings, along the longitudinal axis thereof. The marks are configured to be bent and/or deformed if the guiding elements are bent and/or deformed.
30 This has the potential advantage of indicating if the robotic arm enters into a guiding element improperly.

In some embodiments of the invention, the guiding JIG comprises a barcode for updating the robotic arm with the preoperative plane, such as the selected plate type, the selected fixation angle of the plate, the selected set of tools, the selected surgical approach, specific surgical

instructions, the location of the guiding elements on the guide body, the distance between the guiding elements, the order of guiding elements to access, which guiding elements to access, depth limitation for insertion, optionally different limitation for each guiding element and/or any combination thereof.

5 In some embodiments of the invention, the barcode refers the robotic arm to an external database including the preoperative plane. Optionally, or additionally, the barcode comprises an RFID element including the preoperative plate.

In some embodiments, the fixating guiding elements are configured to receive a fixator of the robotic arm, shaped and/or sized according to a fixed pin of the robotic arm.

10 In some embodiments of the invention, the guiding JIG is configured to direct the placement of the plate. Optionally, the plate is first connected onto the guiding JIG, which comprises dedicated guiding elements for the insertion of the plate's blade and/or locking screws and/or guide implement such as a k-wire. The guiding JIG is configured to be removed after to the placement of the plate thereon. In some embodiments the JIG body is tearable, having the potential advantage of
15 easing the removal thereof after the placement of the plate thereon. Optionally, the JIG body comprises at least one slit thereon, having the potential advantage of easing the tearing of the JIG body.

In some embodiments of the invention JIG body comprises a plurality of slits, allowing the guiding JIG to be removed in parts.

20 In some embodiments of the invention the removal of the guiding JIG is performed by the robotic arm, alternatively or additionally, the removal is performed by a human operator.

Referring to figure 6, showing a flowchart describing an exemplary workflow of an operator using guiding JIG, during a VDRO procedure, in accordance with some exemplary embodiments of the invention.

25 At **602**, a patient is selected, optionally, a child patient, as described in step 202, of Figure 2.

At **604**, the guiding JIG is placed on the femoral bone, optionally, subsequently to bone exposure.

30 In some embodiments, the guiding JIG partially circumferentially surrounds the femur, relative to the longitudinal shaft-neck of the femur. In some embodiments of the invention, the guiding JIG grips the bone, having the potential advantage of minimizing the requirement of an assistant, holding and placing the guiding JIG prior to fixing thereof on the femoral bone.

In some embodiments, the guiding JIG is aligned onto the femur by reaching a match between the inner surface of the JIG body and the femoral bone geometry, at the treatment site.

Since the guiding JIG is customized according to the bone anatomy of the patient, the inner surface of the JIG body has a geometry that complements the anatomy of the femoral bone at the treatment site, having the potential advantage that the guiding JIG is positioned steady on the bone in a single possible configuration.

5 At **606**, operating tools are applied on the femoral bone according to the guiding JIG.

The guiding JIG directs operating tools into the femoral bone, through guiding elements positioned thereof. In some embodiments, the guiding elements have depth limitations defining a maximum depth for the insertion of operating tools therethrough.

10 In some embodiments of the invention, a single guiding JIG is used. Alternatively, or additionally, a kit including at least two guiding JIGs is used.

In some embodiments of the invention, the guiding JIG is first fixed onto the femur, optionally to maintain the aligned position described in step **602**. The fixating is done by inserting at least one fixator, for example, a k-wire, through fixating guiding elements, into the femur.

15 Upon fixating, the VDRO procedure is employed using functional guiding elements of the guiding JIG.

At **608**, the guiding JIG is being removed from the bone. Optionally in one piece.

At **610**, the bone position is corrected according to the marks and/or bores resulting from applying operating tools through the guiding JIG.

The distal fragment and the proximal fragment of the bone are being joined together.

20 The femur head is tilted back into the acetabulum. Optionally, the distal fragment is rotated for rotation correction of the femur.

At **612**, the plate is connected to fix the corrected position of the bone. The guiding JIG dictates bores on the bone which defines a single configuration for connecting the plate.

25 In some embodiments of the invention, the correction of the bone position can be done together with the connection of the plate. Optionally, the plate can be connected first to the head of the femur, then the distal fragment is rotated and joined with the proximal fragment, such that the distal bore fits to the plate.

30 Referring now to figures 7A-C showing a flowchart of an exemplary workflow for performing a VDRO procedure using guiding JIG **300**, in accordance with some exemplary embodiments of the invention.

This flow chart is a particular example of the flowchart shown in Figure 6.

At **702**, a patient is selected, as described in step 202 of Figure 2.

At **704**, the femoral bone is exposed, according to the selected surgical approach, optionally, selected by the physician, alternatively or additionally, suggested by the feedback system.

In some embodiments, the size of the incision is sufficient for introducing the guiding JIG.

5 In some embodiments, the guiding JIG design does not require measurements of the exposed bone, having the potential advantage of minimizing the required incision size and/or level of bone exposure.

10 In some embodiments of the invention, the incision size corresponds to the size of the guiding JIG inserted therethrough. Optionally or additionally, the JIG body is bendable and/or compressible, configured to be inserted in a bent and/or compressed form, optionally held by the operator. In some embodiments, the guiding JIG expands upon reaching the bone. This bent and/or compressed form has the potential advantage of minimizing the required incision size. In some embodiments, the surgical approach defines the location and/or the size of the required incision.

At **706**, the guiding JIG is placed onto the femoral bone, at the treatment site.

15 At **708**, the guiding JIG is aligned by fitting the inner surface thereof to the surface of the bone. In some embodiments of the invention, the geometry of the inner surface of the JIG body completes the geometry of the femoral bone, so that the guiding JIG fits onto the bone surface in one possible steady configuration.

20 At **710**, the guiding JIG is fixed onto the femoral bone, optionally, by at least one fixator, such as a k-wire. This fixating maintains the aligned position of the guiding JIG onto the bone. In some embodiments of the invention, the JIG body at least partially circumferentially surrounding the femur, optionally having a grip and/or some level of grip on the femoral bone. This grip has the potential advantage of minimizing the requirement of an assistant, holding the guiding JIG until the fixating thereof onto the bone, and/or allowing a single operator to perform the procedure.

25 In some embodiments, the at least one fixator is inserted through at least one fixating guiding hole of the guiding JIG. Each fixating guiding hole defines a path for a fixator, designed not to collide with the path of other fixators, and/or the path of other operating tools that will further be inserted through functional guiding elements.

30 At **712**, a guide implement, such as a k-wire, is inserted through the guiding conduit for a guide implement **310**. The guiding conduit for a guide implement directs the guide implement into the center of the femur head, optionally in a single possible path, alternatively or additionally, in a limited range of possible paths.

In some embodiments of the invention, the guiding conduit for a guide implement **310** can be shortened, optionally by the operator, having the potential advantage of increasing the range of

operation, if a need arises. Optionally, by cutting the guiding conduit for a guide implement **310**, optionally, according to slits thereon.

At **714**, an operating tool, such as a driller, is applied through the distal guiding hole of the guiding JIG. The distal guiding hole directs a drilling for alignment of the distal proximal fragment to the proximal fragment of the bone (optionally, prior to osteotomy), and/or for rotation correction of rotational deformities.

In some embodiments of the invention, this step can be performed in a prior and/or subsequent stage.

At **716**, an operating tool, such as a driller, is applied through the proximal guiding hole of the guiding JIG.

At **718**, a first cutting tool, such as a saw, is applied through the first cutting slot of the osteotomy guide on the guiding JIG.

At **720**, a second cutting tool, such as a saw, is applied through the second cutting slot of the osteotomy guide on the guiding JIG.

In some embodiments of the invention, the first and the second cutting tools are one.

The second cut results in a bone wedge separated from the femur. In some embodiments of the invention, the bone wedge has a triangular shape, according to the correction angle. Alternatively, or additionally, the bone wedge has a trapezoidal shape, optionally, when femur shortening is required. In some embodiments, the trapezoidal bone wedge is shaped according to the correction angle and the level of the shortening.

In some embodiments of the invention, one and/or both of the cutting slots direct the cutting tools cutting the bone, optionally in a single possible path. Alternatively, or additionally, in a limited range of possible paths. In some embodiments of the invention, the osteotomy guide can be shortened, optionally by the operator, having the potential advantage of increasing the range of operation through one and/or both of the cutting slots, if a need arises.

At **722**, fixators are removed. The at least one fixator inserted through the at least one fixing guiding hole of the guiding JIG is extracted from the bone.

At **722**, the guide implement is removed from the center of the femur head.

In some embodiments of the invention, this step can be performed in a prior and/or subsequent stage.

At **724**, the guiding JIG is removed from the bone and from the incision site.

At **728**, the bone wedge is removed, resulting in the separation of the femur into a distal fragment and a proximal fragment.

At **730**, the femur head is tilted to be directed toward the acetabulum. In some embodiments, the femur head is passively tilted subsequent to the bone wedge removal, alternatively or additionally, the femur head is actively tilted, optionally by the physician, until alignment of the femur head toward the acetabulum

5 In some embodiments, the guide implement inserted into the center of the femur head is removed subsequently to this tilting. The tilting is performed by tilting the guide implement.

At **732**, the distal fragment of the bone is aligned with the proximal fragment thereof. The bore on the bone distal fragment, resulted from the distal guiding hole, and the bore resulted from the guiding conduit for a guide implement, placed on the proximal bone fragment, are aligned.
10 Optionally, if rotation correction is required, the distal fragment is rotated to achieve this alignment (as shown in figures 11-12).

At **734**, the distal fragment and the proximal fragment of the bone are joined together.

At **736**, the selected plate is placed on the bone. The plate is positioned so that the holes of the plate are aligned with:

- 15 a. the bore at the center of the femur head, resulted from the insertion of a guide implement through the guiding conduit for a guide implement;
- b. the distal bore, on the distal fragment, resulted from applying an operating tool through the distal guiding hole; and
- c. the at least one proximal bore, on the proximal fragment, resulted from applying an
20 operating tool through the at least one proximal hole.

The placement of the plate according to the bore at the center of the femur head and the distal bore on the distal fragment defines a single configuration for placing the plate, according to the longitudinal neck-shaft axis of the femur.

Further aligning the plate with the at least one proximal bore, which results from the at least
25 one proximal guiding hole, limits the relative translation movement of the proximal and the distal bone fragments along the head-neck axis.

The placement of the plate according to the bore at the center of the femur head, the distal bore on the distal fragment and the at least one proximal bore on the proximal fragment define a single configuration for placing the plate.

30 At **738**, the plate is fixed to the femoral bone, optionally, by the insertion of fixators such as k-wires and/or locking screws.

In some embodiments of the invention steps 732-738 are concurrently performed and/or performed in a different order. For example, the plate can be first aligned and/or fixed into the

center of the femur head, then the distal fragment of the bone is aligned and/or rotated and/or joined with the proximal fragment according to the semi-placed plate.

At 740, a post-surgery follow-up of the patient is performed.

5 Referring to Figures 8A-C, showing a flowchart describing an exemplary workflow for performing a VDRO procedure using guiding JIG **400**, in accordance with some exemplary embodiments of the invention.

Steps **802-810** are as described in steps 702-710 of figures 7A-C, respectively.

10 At **814** a selected chisel is inserted through the guiding conduit for a chisel on the guiding JIG. The guiding conduit for a chisel directs the chisel impacting the bone into the center of the femur head without required prior insertion of a guide implement into the center of the femur head and/or threading the chisel thereon.

15 The guiding conduit for a chisel limits rotational and/or lateral movements of the chisel therewithin. The guiding conduit for a chisel directs the path of the chisel impacting the bone within the bone, optionally, in a single possible path, optionally or additionally in a limited range of possible paths. The difference between the lengths of the chisel and the guiding conduit for a chisel defines the depth of chiseling, having the potential advantage of minimizing over-chiseling.

20 In some embodiments of the invention, the guiding conduit for a chisel can be shortened, optionally by the operator, having the potential advantage of increasing the range of operation and/or increasing the depth of chiseling, if a need arises.

At **816**, the chisel is removed, by the extraction thereof from the bone through the guiding conduit for a chisel. In some embodiments of the invention, this step can be performed in a later stage.

Steps **816-826** are as described in steps **714,718-722,726-728** of figures 7A-C, respectively.

25 At **828**, the femur head is tilted to be directed toward the acetabulum.

In some embodiments of the invention, the chisel is removed subsequently to the tilting. The tilting is performed by tilting the chisel inserted through the center of the femur head.

30 At **830**, the distal fragment of the bone is aligned with the proximal fragment thereof. The bore on the bone distal fragment, resulted from the distal guiding hole, and the cavity into the center of the femur head, which resulted from the chiseling, placed on the proximal bone fragment, are aligned. Optionally, if rotation correction is required, the distal fragment is rotated to achieve this alignment (as shown in figures 11-12).

Steps **832** is as described in step **734** of figures 7A-C.

At **834**, the selected plate is placed on the bone. a. The plate is positioned so that the blade of the plate **1004** (shown in Figure 10) fits within the cavity into the center of the femur head, and a distal hole on the plate **1005** on the plate (shown in Figure 10) is aligned with the distal bore (shown in figure 12), on the distal fragment, resulted from applying operating tool through the distal guiding hole.

Optionally, this alignment defines a single configuration for placing the plate, according to the longitudinal neck-shaft axis of the femur, and the head-neck axis thereof.

At **836**, the plate is fixed to the femoral bone, optionally, by the insertion of locking screws.

In some embodiments of the invention steps 730-836 concurrently performed and/or performed in a different order. For example, the blade of the plate can be first inserted and fixed into the center of the femur head, then the distal fragment of the bone is aligned and/or rotated and/or joined with the proximal fragment according to the semi-placed plate.

Step **838** is as described in step **734** of Figure 7C.

Referring Figures 9A-D showing a flow chart describing the workflow of a surgeon using a kit including a set of guiding JIGs, in accordance with some exemplary embodiments of the invention.

Steps **902-904** are as described in steps **702-704** of Figure 8A, respectively.

At **906**, a first guiding JIG is placed on the femoral bone at the treatment site.

Steps **908-914** are as described in steps **708-714** of Figure 8A, respectively.

Regarding step 914, in some embodiments of the invention the distal guiding hole is alternatively or additionally positioned on the second guiding JIG, so that this step is performed after placing the second guiding JIG, optionally, before performing osteotomy.

At **916**, the fixators on the first guiding JIG are removed, by extracting thereof through the guiding fixing holes.

At **918**, the first guiding JIG is removed from the bone, and extracted (e.g., removed) from the incision site. The guide implement is left within the center of the femur head

At **920**, a second guiding JIG is placed on the femoral bone at the treatment site. In some embodiments of the invention, the second guiding has a JIG body equal and/or smaller than the first guiding JIG, which can be inserted through the incision to the bone. At **922**, the second guiding JIG is aligned onto the femoral bone as describes in step **708** in Figure 7A.

In addition, in some embodiments of the invention, the fixing guiding holes of the second guiding JIG are aligned with the fixing guiding holes of the first guiding JIG. The alignment of the second guiding JIG on the femur is further based on the fixing guiding holes of the second JIG

aligned over the bores resulting from inserting fixators through the fixing guiding holes of the first guiding JIG.

At **924**, the second guiding JIG is aligned onto the femoral bone as describes in step **710** in Figure 7A.

5 In addition, in some embodiments of the invention, the fixating guiding holes of the second guiding JIG direct the insertions of the fixators into the same path as the fixating guiding holes of the first guiding JIG, having the potential advantage of minimizing the invasive fixation bores on the bone.

At **926**, a selected chisel is threaded onto the guide implement.

10 At **928**, the chisel is passed over the guide implement to be placed within the guiding conduit for a chisel.

At **930**, the bone is impacted by the chisel, threaded on the guide implement.

The guiding conduit for a chisel directs the chiseling into the center of the femur head, having the potential advantage of minimizing the rotational movements of the chisel around the
15 longitudinal axis of the guide implement.

Impacting a chisel threaded on a guide implement inserted into the center of the femur head has the potential advantage that the guide implement further directing the chiseling toward the center of the femur head. The path of the guide implement within the femur head is first visualized, to minimize the risk of errors.

20 Steps **932-934** are as described in steps **718-720** of Figure 7B, respectively.

At **936**, the chisel is removed. Extracted from the bone and/or form the guiding conduit for a chisel. The chisel is threaded over the guiding implement away from the femur head.

At **938**, the guide implement is removed from the center of the femur head.

In some embodiments of the invention, the removal of the guiding implement is performed in a
25 later stage.

At **940**, the fixators of the second guiding JIG are removed from the bone and/or Extracted from the guiding holes (e.g., guiding holes for fixators) of the guiding JIG.

At **942**, the guiding JIG is removed.

Step **946**, as described in step **728** of figures 7A-C.

30 Step **948**, as described in step **730** of figures 7A-C.

Step **950**, as described in step **830** of figures 8A-C.

Step **952** is as described in step **734** of figures 7A-C.

Step **954-956** as described in **834-836** of figures 8A-C.

Step **956** is as described in step **734** of figures 7A-C.

Referring to Figures 13A-B, showing a concise flowchart, describing an exemplary design process of a guiding JIG, in accordance with some exemplary embodiments of the invention.

At **1302**, a scan image of the femoral bone of the patient is received, for example, a CT scan, alternatively or additionally, an image from X-ray visualization.

5 In some embodiments of the invention, the scan image is imaged prior to the design process so the design does not require the presence of the patient.

Alternatively, or additionally, the process design is done by a computer conjugated to an imaging device, having the potential advantage of scanning the femur of the patient and promptly designing the guiding JIG. In some embodiments of the invention, a 3D printer is further conjugated
10 so that the guiding JIG can be produced on-site, subsequent to the computer-design.

At **1304**, a computed 3D model of the femur is created, according to the scan image of the patient. The 3D model simulates the femoral bone anatomy of the patient.

At **1306**, a preoperative input is received, optionally, by the user. The combination of the preoperative input and the bone anatomy defines the design of the guiding JIG.

15 In some embodiments of the invention, the preoperative input includes:

- a. the selected fixation angle of the plate, which defines the correction angle;
- b. the type of the selected plate;
- c. the selected set of tools; and
- e. the surgical approach.

20 At **1308**, optionally, a feasibility test is performed, optionally, by a feedback system of the program. For example, the feasibility test considering the requested preoperative input, in light of the femoral bone anatomy.

Optionally, feedback regarding the feasibility of the requested guiding JIG is outputted. If the selected preoperative input gives a guiding JIG design that is not feasible the feedback system
25 informs the user and optionally offers feasible alternatives.

In some embodiments of the invention, the feedback system offers advantageous alternatives to a feasible guiding JIG design, as well.

At **1310**, functional guiding elements are placed on the 3D model. The location and orientation of the functional guiding elements are defined by the bone anatomy and/or the
30 preoperative input.

The size and shape of the functional guiding elements are defined by the type of the selected plate and/or the selected set of tools.

At **1312**, fixation guiding elements are placed on the 3D model. The size and/or shape of the fixation guiding elements are defined by the selected fixators and/or selected set of tools.

The location and orientation of the fixation guiding elements are defined according to the functional guiding elements and the femoral bone anatomy, so that the path of a fixator inserted therethrough does not collide with the path of other operating tools inserted through the functional guiding elements and/or other fixation guiding elements.

5 At **1314**, a JIG body is created. The JIG body comprises the functional guiding elements and the fixation guiding elements. The JIG body is customized according to the bone anatomy, having an inner surface configured to come in contact with the bone. In some embodiments of the invention, the inner surface has a geometry which completes the geometry of the femur at the site of deployment.

10 At **1316**, optionally, structural support elements are placed on the JIG body, optionally, for strengthening the three-dimensional structure of the guiding JIG, alternatively or additionally, for supporting the guiding elements on the JIG body, alternatively or additionally, for maintaining the relative distance between the guiding elements of the guiding JIG.

15 At **1328**, a quality test of the guiding JIG design is performed. In some embodiments, the quality test is digitized and performed prior to guiding JIG production, alternatively or additionally, the guiding JIG is produced and placed on a printed model of the femoral bone. In some embodiments, the alignment and/or stability of the JIG body on the bone model is evaluated. In addition, optionally, the guiding elements are measured to detect deformation results from printing errors. In some embodiments, the size of the inner of the guiding conduit for a guide implement
20 and/or the size of the lumen of the guiding conduit for a chisel and/or the cutting slots of the osteotomy guide are measured.

At **1320**, the guiding JIG design is produced, optionally, by 3D printing.

In some embodiments of the invention, the 3D printing is based on SLS (Selective Laser Sintering) technology, which uses powder as the source material for printing. Alternatively, or
25 additionally, 3D printing is based on SLA (Stereolithography) technology, which uses resin as the source material for printing.

The guiding JIG is printed from biocompatible materials, approved for subcutaneous contact. In some embodiments, the material used is PA12 (Nylon 12 or Polyamide 12), optionally, used in SLS technology.

30 In some embodiments, other biocompatible materials are used, optionally in SLS technology, alternatively or additionally, in other technologies, such as SLA technology.

In some embodiments, using additional and/or different materials requires adjustment of the thicknesses of the guiding JIG body and/or structural support elements and/or walls of guiding

elements thereof, optionally, to obtain a stable guiding JIG structure and/or desired level of flexibility and/or rigidity thereof.

In some embodiments, the materials are durable for a sterilization process and/or relatively easy to disinfect. In some embodiments, the material(s) are selected according to an input from a surgeon, for example, input regarding the sterilization process. In some embodiments of the invention the production is fully automated, alternatively or additionally, the production is semi-automated.

In some embodiments of the invention, the production is subsequent to the design process. In some embodiments of the invention the guiding JIG produced in a time interval from the design process based on a digitized file of the design.

In some embodiments, the method for designing a guiding JIG is similar and/or as described in Provisional Patent Application No. 63/472,602 filed on June 13, 2023, and/or in the PCT application derived therefrom, having a docket number of 100411, and the contents of which are hereby incorporated by reference.

In some embodiments, said designing a guiding JIG is performed using a user interface (UI) and/or a graphical user interface (GUI) as described in Provisional Patent Application No. 63/472,602 filed on June 13, 2023, and/or in the PCT application derived therefrom, having a docket number of 100411, and the contents of which are hereby incorporated by reference.

In some embodiments, the 3D representation of the JIG is automatically designed without necessarily requiring manual input. The features of the femur and/or foot print and/or guiding elements and/or other parameters described herein may be automatically selected according to a surgical plan defining a surgical indication. A 3D representation of the JIG may be automatically generated to comply with the surgical plan and/or features of the femur and/or foot print and/or guiding elements and/or other parameters described herein. A user may manually adapt the surgical plan and/or features of the femur and/or foot print and/or guiding elements and/or other parameters described herein, which may trigger an automatic adaption of the 3D representation of the JIG, rather than adapting the 3D representation of the JIG directly. For example, the user may adapt the location and/or shape of the footprint for automatically generating the adapted JIG, rather than adapting the JIG to fit the adapted footprint. The JIG may be 3D printed by a 3D printed according to the 3D representation.

Referring to Figures 14A-B, showing a flowchart describing an exemplary input-output system of the program for designing a guiding JIG, in accordance with some exemplary embodiments of the invention.

This flow chart is an elaboration of steps **1306-1308** described in figures 13A-B.

At **1402**, a scan image of the femoral bone of the patient is received, as described in step **1302** of Figure 13A.

At **1404**, a computed 3D model of the femur is created, simulating the bone anatomy of the patient, as described in step 1304 of Figure 13A.

At **1406**, a preoperative input is received, by a user of the program, optionally a physician. The combination of the preoperative input and the bone anatomy defines the design of the guiding JIG and/or set of at least two guiding JIGs.

In some embodiments of the invention, the preoperative input includes:

- a. the selected fixation angle of the plate, which defines the correction angle.
- b. the type of the selected plate;
- c. the selected set of tools; and
- d. the surgical approach.

Optionally, a range of options can be inputted, for receiving an optional design suggested by the feedback system of the program, considering the patient's anatomy. For example, a range of fixation angles and/or several plate types and/or several possible sets of operation tools, and/or any combination thereof and of additional possible input.

In some embodiments of the invention partial preoperative input can be received, optionally, the feedback system alerts for missing information, alternatively or additionally the feedback system suggests an optimal guiding JIG, including suggestions for the missing preoperative input.

At **1408**, the feasibility of the guiding JIG design, based on the preoperative input requirements and the bone anatomy, is tested.

In some embodiments of the invention, if the input includes a range of options each option is tested.

At **1410**, if the guiding JIG is defined by the preoperative input is confirmed to be feasible, the program conveys confirmation notice.

If the preoperative input includes a range of options which defines several guiding JIGs, the program conveys a confirmation notice if at least one guiding JIG is feasible.

In some embodiments of the invention the program displays the feasible guiding JIG designs, optionally sorted in descending order according to recommendation, alternatively or additionally the program indicates the advantages and/or disadvantages of each design.

At **1412**, if the guiding JIG is defined by the preoperative input is denied by the feasibility test, the program conveys an error notice. In some embodiments of the invention the program lists

the reasons for the unfeasibility, for unbinding example, if the selected plate type and/or selected correction angle does not correspond to the size of the bone, and/or if the selected set of tools doesn't correspond to the selected plate type and/or surgical approach.

At **1414**, optionally, the program suggesting alternative guiding JIG designs.

5 In case that the guiding JIG is defined by the preoperative input is unfeasible, the program suggests feasible alternatives. The alternative suggestions may include alteration of the fixation angle and/or type of plate and/or set of tools and/or surgery approach or any combination thereof. In some embodiments of the invention, the program indicates the benefits of each suggestion.

10 In case that the guiding JIG is defined by the preoperative input is feasible, the program may suggest beneficial alternatives. In some embodiments of the invention, the program indicates the benefits of each suggestion over the guiding JIG is defined by the preoperative input. The alternative suggestions may include alteration of the fixation angle and/or type of plate and/or set of tools and/or surgery approach or any combination thereof.

15 If the input includes a range of options, optionally, the program will display the optimal feasible design, alternatively, the program will display several feasible guiding JIG designs, optionally the program further displays alternative suggestions that may include alteration of the fixation angle and/or type of plate and/or set of tools and/or surgery approach or any combination thereof.

20 In some embodiments of the invention the program essays if a two stages surgery is preferable, for example in cases of relatively enhanced current shaft angle. The program suggests a fixation angle for the first surgery and optionally a fixation angle for the future second surgery.

At **1416**, the program receives feedback from the user. The user may confirm a suggested guiding JIG design or deny the guiding system suggestions.

25 At **1418**, if the user denied the proposed guiding JIG design and/or guiding JIG designs, the feedback system requests a new and/or modified preoperative input.

In some embodiments of the invention if the initial preoperative input results in an unfeasible guiding JIG, the feedback system proceeds to this stage.

At **1420**, the feasibility of the new and/or modified preoperative input is re-tested.

30 At **1422**, the user confirms at least one of the guiding JIG designs offered by the feedback system. The selected design is computer designed, optionally, a single guiding JIG, alternatively or additionally, a kit including a set of at least two guiding JIGs.

At **1424**, the selected guiding JIG and/or set of guiding JIGs are produced, as described in figure 13B, step **1320**.

Referring now to figures 15A-B, showing a top top-level flowchart of an exemplary algorithm for designing a guiding JIG, in accordance with some exemplary embodiments of the invention.

At **1502**, a 3D model of the formal bone is created, which simulates the bone anatomy of the patient.

At **1504**, optionally, the femur neck is identified.

At **1506**, the neck-head axis, at the center of the femur head, is identified.

At **1508**, the longitudinal femoral shaft-neck axis at the center of the femur is identified.

At **1510**, the correction angle is calculated. First, the current shaft angle between the neck-head axis and the longitudinal femoral shaft-neck axis is identified. Then, the selected desired shaft angle is selected and subtracted from the current shaft angle. the subtraction result is the correction angle.

At **1512**, a first cutting plane is created, vertical to the femoral head-neck axis.

At **1514**, a second cutting plane is created, a plane relative to the first cutting plane, according to the calculated correct angle.

At **1516**, a vector for fixating is created.

At **1518** representations of guiding elements into the center of the femur head, are created. These guiding elements are in line with the femoral head-neck axis. In some embodiments of the invention a representation of a guiding conduit for guide implement is created, alternatively or additionally, a guiding conduit for chisel is created.

At **1520** representations of guiding elements for cutting the bone are created. These guiding elements are positioned according to the first and second cutting planes. In some embodiments of the invention at al least one cutting slot, optionally two cutting slots and/or an osteotomy guide are created.

At **1522**, a representation of at least one fixating guiding element is created. The at least one representation of the fixating guiding element is in line with the vector for fixating. The vector for fixating defines a path which does not collide with the path of the representation of the functional guiding elements.

At **1524**, a representation of the JIG body is created, based on the simulation of the bone geometry.

At **1526**, optionally, representations of structural support elements are created.

At **1528**, the guiding JIG design is tested, as mentioned above.

At **1530**, the guiding JIG is produced, as described in step 1320, figures 13A-B.

Referring to figures 16A-G, and 17A-B showing a detailed flowchart of an exemplary method for designing a guiding JIG, in accordance with some exemplary embodiments of the invention.

At **1602** a scan image of the patient's femur is received, as described in Figure 13A step **1302**. In some embodiments of the invention, a digitized scan image is inputted, alternatively of additionally, a scan image is obtained on site and uploaded using a scanning device conjugated to a computer.

At **1604**, a 3D model of the femur is created, based on the scan image of the patient.

The 3D model of the femur is represented by a mesh file simulating the anatomy of the patient's femur, resulting from a segmentation of the scan image.

In some embodiments of the invention the 3D model simulates the femoral bone anatomy at the treatment site, alternatively or additionally, the 3D model simulates the femoral bone anatomy extending distally to include an enhanced area of the femur to allow the calculation of the rotation correction of the femur.

At **1606**, the 3D model which represents the anatomy of the femur, is deconstructed to naked lines and naked points, as shown in Figure 18A.

At **1608**, the naked vertices are compiled into a list, optionally including all the naked vertices, alternatively, including the majority of the naked vertices.

Referring first to A, in Figure 16A, which performed in concurrently with performing B.

At **1610**, the list of naked vertices is sorted according to Z-values which represent height, with respect to the longitudinal shaft-head axis of the femur, optionally, in descending order. Alternatively, or additionally, the list of naked vertices is filtered by height, with respect to the longitudinal shaft-head axis of the femur, to include the highest values.

At **1612**, the points from the naked vertices list, having the highest Z-value are compiled into a sup list. The sup list represents the proximal portion of the femur head **1802**, shown in Figure 18B. In some embodiments of the invention, the sup list includes about 500 points of the highest Z-values from the naked vertices list.

At **1614**, a fit sphere **1804** (shown in figure 18C), which represents the femur head is created by using a maximum number of naked points from the sup list, possible to represent the femur head.

At **1616**, a second sphere **1806** (shown in Figure 18D), is created based on the fit sphere **1804**. The second sphere is co-centered with the fit sphere. The size of the second sphere is expended relative to the fit sphere, optionally, one and a half times larger than the fit sphere.

The size of the second sphere can be adjusted to obtain an area where the geometry (boundary) thereof intersects in the femur neck, as shown in Figure 18D.

At **1618**, a contour **1808**), which represents the center of the femur head, is identified. The contour is at the intersection between the second sphere and the bone geometry is, as shown in figure 18E.

At **1620**, a midpoint **1810** located at the center of the area defined by contour **1808**, is identified, as shown in Figure 18F.

At **1621**, the femur head axis **1812** is represented by a line between the center of the fit sphere **1814**, and the midpoint representing the center of the femur neck **1810**, as shown in figure 18G.

At **1622**, a representation of a guide implement (not shown) is positioned at the center of the femur head and protruding therefrom. The guide implement is aligned with the femur head axis.

At **1623**, the representation of the guide implement is thickened to create a representation of a guide conduit into the center of the femur head.

Referring now to B, in Figure 16C, which as aforementioned, is concurrently with performing A.

At **1624**, the list of naked vertices is sorted according to Z-values which represent height, relative to the longitudinal shaft-neck axis, optionally, in ascending order. Alternatively, or additionally, the list of naked vertices is filtered by height to include the lowest values.

At **1626**, the points from the naked vertices list having the lowest Z-value are compiled into a sup list. The sup list represents a distal portion of the femur **1818**, shown in Figure 18H. In some embodiments of the invention, the sup list includes about 500 points of the lowest Z-values from the naked vertices list.

At **1628**, a fit plane **1820** is created by using the points of the sup list compiled at step **1726**, as shown in Figure 18I.

At **1630**, a second plane **1822** is created. Second plane **1822** is proximally to fit plane **1820**, optionally, offsets in about 50 mm from fit plane **1820**, as shown in figure 18J. In some embodiments, the second plane is created proximally to ensure that the measurement is performed in an area that is not too distal.

At **1632**, the Intersection curve between the fit plane and the femur anatomy is represented by a contour **1824**, as shown in figure 18K.

At **1634**, the Intersection curve between the second plane and the femur anatomy is represented by a contour **1826**, as shown in figure 18K.

At **1636**, the midpoint **1828** at the center of the area defined by contour **1824**, and the midpoint **1830** at the center of the area defined by contour **1826**, are identified, as shown in Figure 18L.

At **1638**, the longitudinal femur shaft-neck axis **1832** (shown in figure 18M) is represented by a line between midpoint **1828** and midpoint **1830**.

At **1640**, the current neck shaft angle **1834** (shown in figure 18N) between the femur head-neck axis **1810** and the longitudinal femur shaft-neck axis is identified.

At **1642**, the selected plate **1836** is represented, as shown in figure 18O. The fixation angle of the selected plate defines a desired neck shaft angle **1838** as shown in Figure 18Q.

The selection is based on the angles of the plates available in a kit, for example, 100, 110, 115 degrees.

At **1644**, the representation of the selected plate **1836** is placed on the 3D model of the femur, and the representation of the blade of the plate **1837** is aligned with the femur head-neck axis **1810**, as shown in Figure 18P.

At **1646**, the correction angle **1840** is calculated, by subtracting the fixation angle **1838** from the current shaft-neck angle **1834**, as shown in figure 18Q.

At **1648**, a plane along curve **1840** is created, perpendicular to the femur head-neck axis, as shown in Figure 18R. The plane along curve represents a first cutting plane. The plane along curve is placed distally to the intersection between the neck-head axis of the femur and the representation of the bone anatomy **1841**, relative to the head-neck axis. In some of the inventions the distance from intersection **1841** is 14 mm for a child and/or 10 mm for an infant.

At **1650**, an axis **1842** at the intersection between the plane along curve **1840** and the femoral bone anatomy, is created, as shown in figure 18S.

At **1652**, an angled plane **1844** is created, based on the axis **1840** at the intersection between the plane along curve **1842** and the femoral bone anatomy, and at the correction angle **1840**, relative to the plane along curve, as shown in figure 18T. The angled plane **1844** represents a second cutting plane.

At **1654**, the representation of a bone wedge defined by the intersection of the plane along curve and the angled plane is subtracted from the 3D model of the bone anatomy, as shown in Figure 18U. The subtraction of the bone wedge creates a representation of the distal fragment of the bone **1846** and the proximal fragment of the bone **1848**.

At **1656**, a rotation axis is created, at the center of the femur neck, based on the intersection of the plane along curve and angled plane, as shown in figure 18V.

At **1658**, a representation of the distal fragment of the femur **1846** is rotated, based on the rotation axis to achieve post position.

At **1660**, optionally, the position of the plate representation **1836** is aligned and/or corrected by translation, as shown in Figure 18X.

5 At **1662**, a representation of the selected chisel **1850** is placed, according to the representation of the plate, as shown in Figure 18Y.

At **1664**, the representation of the chisel **1850** is thickened, to create a representation for chisel guide **1852**, as shown in figure 18Z. Optionally, the representation of the chisel **1850** is thickened to create a representation for chisel guide **1852** with 0.2 tolerance for 2.5 mm thick chisel.

10 At **1666**, the first cutting plane is thickened, according to a selected first cutting tool geometry, to create a representation for a first cutting slot **1854**, as shown in Figure 19A.

At **1668**, the second cutting plane is thickened, according to a selected second cutting tool geometry, to create a representation for a second cutting slot **1856**, as shown in Figure 19A.

15 In some embodiments of the invention, the first cutting tool and the second cutting tool has the same geometry. In some embodiments of the invention, the cutting tool geometry requires that the first cutting plane and the second cutting plane are thickened to 1 mm.

At **1670**, the cutting slots **1854** and **1856** are thickened to create a frame therefor, which defines a representation for an osteotomy guide for cutting tools **1858**, shown in figure 19B.

20 At **1672**, at least one vector **1860** perpendicular to the cutting slots **1854** and **1856**, is created, as a basis for generating a fixation guiding element, as shown in figure 19C.

At **1674** a representation of a fixation cylinder **1862** based on the vector **1860** perpendicular to the cutting slots, is created, as shown in figure 19D. In some embodiments of the invention, the fixation cylinder **1862** has a diameter of 1.6 mm.

25 At **1676**, a fit geometry box **1864** is created, surrounding the representation of the osteotomy guide **1858** and the cylinder **1862**, as shown in figure 19E.

At **1678**, a footprint **1866** is created, defined by the overlap of the fit geometry box with the femoral bone anatomy.

At **1680**, the footprint is thickened, to create a representation of the JIG body **1868**. In some embodiments of the invention, the footprint is thickened to 2.5 mm.

30 Referring to C, describing the design of guiding JIG **300** and/or **550**, optionally, for used standalone, alternatively or additionally, as a part of a kit including at least two guiding JIG.

At **1682**, the representation of the JIG body is combined with the representation of the guide conduit into the center of the femur head.

At **1684**, the representation of the JIG body is further combined with the representation of the osteotomy guide. In some embodiments of the invention, the designed guiding JIG is part of a set, including additional guiding JIG with osteotomy guide, so that the osteotomy guide representation is not combined.

5 At **1686**, the representation of the JIG body is further combined with the at least one fixation cylinder.

At **1688**, the representation of the bone geometry is subtracted from the 3D model.

At **1690**, the representation of the guide implement geometry is further subtracted from the 3D model.

10 At **1692**, the representation of the cutting slots is further subtracted from the 3D model. If the guiding JIG design does not include an osteotomy guide this step is not performed.

At **1694**, the representation of the at least one fixation cylinder geometry is further subtracted from the 3D model.

15 At **1696**, structural support is added. Optionally by generating a fit box geometry, optionally, 3 mm thick. The fit box geometry extends from the center of the representation of the guide conduit into the center of the femur head, relative to the longitudinal axis thereof, to the representation of the osteotomy guide.

At **1698**, the guiding JIG is produced, as described in step **1530** of figures 15A-B.

20 Referring to D, describing the design of guiding JIG **400** and/or **500**, optionally, for used standalone, alternatively or additionally, as a part of a kit including at least two guiding JIGs.

At **1702**, the representation of the JIG body is combined with the representation of the chisel guide into the center of the femur head.

At **1704**, the representation of the JIG body is further combined with the representation of the osteotomy guide.

25 At **1706**, the representation of the JIG body is further combined with the at least one fixation cylinder.

At **1708**, the representation of the bone geometry is subtracted from the 3D model.

At **1710**, the representation of the cutting slots is further subtracted from the 3D model

At **1712**, the representation of the chisel geometry is further subtracted from the 3D model.

30 At **1714**, the representation of the at least one fixation cylinder geometry is further subtracted from the 3D model.

At **1716**, structural support is added. Optionally by generating a fit box geometry, optionally, 3 mm thick. The fit box geometry extends from the center of the representation of the

chisel guide into the center of the femur head, relative to the longitudinal axis thereof, to the representation of the osteotomy guide.

At **1718**, the guiding JIG is produced, as described in step **1530** of figures 15A-B.

A disassemblable guiding JIG

Referring now to figures 20A-B, showing perspective views of a disassemblable guiding JIG **2000** for a VDRO process, in accordance with some exemplary embodiments of the invention.

Guiding JIG **2000** is similar to other guiding JIG described herein, the same reference numerals have been used to denote parts that are similar to those described for other guiding JIG, with the prefix 20.

In some embodiments, guiding JIG **2000** comprises a removable portion **2050** (e.g., a removable part and/or a removable segment), optionally located between cutting slot **2018** and cutting slot **2020**. In some embodiments, removable portion **2050** corresponds to the bone wedge separated and/or intended to be cut from the bone (e.g., shaped, sized, and/or positioned as the bone wedge). In some embodiments, after and/or during performing osteotomy (e.g., removing said bone wedge) removable portion can be removed remaining a proximal portion **2052** (e.g., a proximal part and/or a proximal segment), and a distal portion **2054** (e.g., a distal part and/or a distal segment), of guiding JIG **2000** mounted on the bone. Proximal portion **2052** remains on a proximal fragment of the bone and distal portion **2054** remains on a distal portion of the bone. Then the distal bone fragment and the proximal bone fragment can be positioned relative to each other while the portions **2052** remain on the bone fragments. In some embodiments proximal portion **2052** and distal portion **2054** are used to guide said positioning, optionally, by aligning proximal portion **2052** and distal portion **2054**.

In some embodiments, each cutting slot **2018** and **2020** is defined by two surfaces (also referred to herein as cutting surfaces, as described for example for guide osteotomy **1920** of guiding JIG **1900**. In some embodiments, removable portion **2050** comprises a proximal cutting surface **2058** of cutting slot **2018** (e.g., the distal cutting slot) and a distal cutting surface **2056** of cutting slot **2020** (e.g., the proximal cutting slot) so that upon removal of removable portion **2050**, proximal portion **2052** remains with proximal cutting surface **2060** and distal portion **2054** remains with distal cutting surface **2062**. In some embodiments, surfaces **2060** and **2062** are used to guide the attachment of the proximal bone fragment to the distal bone fragment by joining the two surfaces together. Alternatively or additionally, distal portion **2054** comprises at least one mark (not shown) configured to be joined with a complementary mark of proximal portion **2052**, thereby positioning the distal bone fragment in a desired positioning with respect to the proximal bone fragment. In some embodiments, the at least one mark is positioned circumferentially on the distal portion **2054**

according to a desired rotation correction. In some embodiments, distal portion **2054** can be aligned with proximal portion **2052** by aligning a distal guiding element (such as distal guiding hole **324**) with a proximal guiding element (such as conduit 312 and/or proximal guide hole **326**).

In some embodiments, each distal portion **2054** and proximal portion **2052** comprises at least fixating guide **2024** for directing a fixator therethrough for anchoring each JIG portion to the bone (upon the removal of portion **2050**).

In some embodiments, removable portion **2050** can be disassembled from JIG body **2002** (e.g., guiding JIG **2000**). Alternatively or additionally, removable portion **2050** can be cut out of JIG body **2000**, optionally, after and/or during performing osteotomy. In some embodiments, removable portion **2050** comprises guiding lines for directing cutting thereof.

In some embodiments, portions **2052** and/or **2054** comprises at least one guide hole and/or conduit for directing the deployment of a plate (such as proximal drilling hole **326**). In some embodiments, once the proximal and the distal bone fragment are joined together, a plate can be mounted on top of portions **2052** and/or **2054**, then the portions **2052** and/or **2054** can be removed from therebeneath and further fastening the plate to the bone. In some embodiments, portions **2052** and/or **2054** are comprised of sup-portions allowing the disassembly and removal thereof. alternatively or additionally, portions **2052** and/or **2054** are cuttable and/or tearable allowing to be removed by cutting and/or tearing thereof. In some embodiments, portions **2052** and/or **2054** comprise line(s) and/or area(s) on JIG body **2002** having a thin material and/or spaced holes, for potentially facilitating and/or directing the JIG cutting and/or tearing.

In some embodiments, removable portion **2050** can be removed from guiding JIG **2000** (and/or from the bone) prior to the osteotomy. The osteotomy can then be performed using proximal cutting surface **2060** and/or proximal cutting surface **2062**, optionally by cutting the bone along and adjacent to the surfaces. Performing osteotomy using the cutting surfaces potentially increases the operator's degrees of freedom, for example, if needed during surgery. For example, removing removable portion **2050** potentially allows lateral movements and/or angle adjustment of the cutting tool.

Grip holes

In some embodiments, a guiding JIG (e.g., guiding JIG **2000**) comprises one or more grip holes for gripping thereof and/or a portion thereof. Optionally, the one or more gripping holes are located on removable portion **2050** for potentially simplifying the removal thereof when and/or if needed.

Referring now to figures 21A-C, showing perspective views of a disassemblable guiding JIG **2100** for a, in accordance with some exemplary embodiments of the invention. It should be understood that the feature of grip holes is demonstrated on guiding JIG **2100** (designed for a hip replacement procedure) to allow a person having skills in the art to understand the invention and is not intended to limit the invention in any way. The feature of grip holes can be employed on various other guiding JIGs, including guiding JIGs for VDRO described herein.

In some embodiments, guiding JIG **2100** (and/or any other guiding JIG described herein) comprises one or more grip holes **2040** for holding guiding JIG **2100**, optionally using a gripping tool. For example, guiding JIG **2100** may be gripped at one or more grip holes during a positioning, repositioning, alignment, and/or removal of guiding JIG **2100** and/or a portion thereof. Optionally, one or more grip holes **2040** are shaped and/or sized according to a selected gripping tool.

In some embodiments, guiding JIG **2000** comprises a portion **2132** intended for removal before and/or after osteotomy and a portion **2130** intended to remain on the bone after said removal. In some embodiments, portion **2132** comprises one or more grip holes **2040**, having a potential advantage or simplifying the removal thereof.

Connections of a guiding JIG portions

Referring still to figures 21A-C. In some embodiments, guiding JIG **2100** comprises at least one connection point **2142** for connecting between portion **2132** and portion **2130**. This connection potentially enables deploying guiding JIG **2100** as a single unit, optionally, having a sufficient contact surface for aligning the JIG body **2102** on the bone surface. In some embodiments, at least one connection point **2142** is defined by a geometry on portion **2132** (e.g., on surface **2125**) and a complementary geometry on portion **2130** (e.g., on surface **2124**). For example, in some embodiments, portion **2132** comprises one or more protrusions, while portion **2030** comprises one or more recesses shaped and/or sized to accommodate these protrusions, and/or vice versa. In some embodiments, these protrusions are in the form of sliding pins, shaped and/or sized to be moved along channel-shaped recesses with an open end to allow disconnection. In some embodiments, said geometries are located at a center portion of osteotomy guide **2120**, as shown for example in the figures. In other embodiments, said geometries are located at one and/or both sides of osteotomy guide **2020**, for potentially allowing to cut through cutting slot **2122**.

Alternatively or additionally, cutting surfaces **2124**, **2125** are produced (e.g., 3D printed) connected at at least one connecting point **2140**, optionally, intended to be cut and/or torn, thereby separating portion **2132** from portion **2030**. In some embodiments, osteotomy guide **2120** is produced as a frame that can be cut to form separated cutting surfaces **2124**, **2125**. In some

embodiments, at least one connecting point **2140** is marked for directing cutting thereof. In some embodiments, at least one connecting point **2140** comprises spaced holes over JIG body **2102** and/or a thin layer of JIG body **2102** for potentially directing and/or facilitating the cut.

5 **A guiding JIG deployable in parts.**

In some embodiments, guiding JIG **2000** (shown for example in Figures 20A-B) is comprised of three separated portions proximal portion **2052**, removable portion **2050** and distal portion **2054**. In some embodiments, said portions are attached to form a single unit upon JIG deployment that can be separated upon JIG removal, allowing removal in parts and/or steps.

10 In some embodiments, guiding JIG **2000** can be mounted on the bone in parts, defined by the portions thereof.

Referring now to Figures 22A-C, showing perspective views of guiding JIG **2200** deployable in parts, in accordance with some exemplary embodiments of the invention.

It should be understood that the feature of deployable in parts is demonstrated on guiding
15 JIG **2200** (designed for a hip resurfacing procedure) to allow a person having skills in the art to understand the invention and is not intended to limit the invention in any way. The feature of deployable in parts can be employed on various other guiding JIGs, including guiding JIGs for VDRO described herein.

In some embodiments, guiding JIG **2200** (e.g., JIG body **2202**) is comprised of more than
20 one JIG portion (e.g., JIG parts) allowing thereof to be deployed on a target site in parts. This deployment has a potential advantage of facilitating mounting JIG **2200** on the bone, potentially, while not comprising a match, optionally a singular steady match, between the guiding JIG and the bone surface at the treatment site. It is to be noted that said deployment in parts may have a particular use in guiding JIGs having relatively large and/or complex JIG body **2202**.

25 In some embodiments, guiding JIG **2200** comprises at least one portion **2230** (e.g., at least one part and/or segment), configured to be aligned with the bone geometry and at least one additional portion **2232** (e.g., at least one additional part and/or segment configured to be aligned with at least one portion **2230**. Alternatively or additionally, at least one additional portion **2232** is configured to be aligned with the bone geometry as well.

30 In some embodiments, at least one portion **2230** comprises an inner surface configured to face the bone (e.g., femur head) having a geometry that complements the geometry of the bone at the treatment site. This complementation allows guiding JIG **1800** to be positioned steadily on the bone, optionally, in a single possible configuration. In some embodiments, at least one portion **2230** is selected and/or defined according to the bone surface and/or structure. For example, at least

one portion **2230** is configured to be deployed on a bone portion having protrusions and/or depression, potentially simplifying the alignment of at least one portion **2230** over the bone.

In some embodiments, at least one portion **2230** comprises at least one engagement point **2234** for aligning at least one additional portion **2232** thereto. optionally or additionally, at least one engagement point **2234** enables additional portion **2232** to connect to at least one portion **2230**. This connection has the potential advantage of reducing and/or avoiding the insertion of fixator(s) for fixing additional portion **2232**.

In some embodiments, at least one engagement point **2234** comprises a geometry that interacts with a complementary geometry **2236** of at least one additional portion **2232**. The interaction geometrically interferes with relative movements between the geometry of engagement point **2234** and complementary geometry **2236**, thereby fixing and/or anchoring at least one portion **2232** to at least one portion **2230** and/or to the bone.

For example, at least one engagement point **2234** comprises at least one protrusion shaped and/or sized to fit within at least one recess of complementary geometry **2236**. Alternatively or additionally, at least one engagement point **2234** comprises at least one recess shaped and/or sized to accommodate at least one protrusion of complementary geometry **2236**.

In some embodiments, at least one additional portion **2232** is configured to partially cover at least one portion **2230**. In some embodiments, at least one engagement point **2234** is positioned on an outer surface of portion **2230** configured to be covered by at least one portion **2232** whereas complementary geometry **2236** is positioned on an inner surface of portion **2232** configured to cover at least one portion **2232**. Alternatively or additionally, at least one additional portion **2232** is configured to be adjacent to at least one portion **2230**, optionally, not covering at least one portion **2130**. In such embodiments, at least one engagement point **2234** and complementary geometry **2236** are located at the contact interface between at least one additional portion **2232** and to at least one portion **2230**.

In some embodiments, guiding JIG **2200** enables a removal thereof in parts, having the potential advantage of facilitating the JIG removal procedure.

A removable guiding element

In some embodiments, a guiding JIG for VDRO procedure comprises a guiding conduit into the femur head, optionally the center of the femur head, comprising a slit thereon which enables the removal of the guiding JIG while a tool deposited therewithin and inserted into the bone, remains within the bone. In some embodiments, such a slit can be used in a first guiding JIG designed for inserting a guide implement (e.g., K-wire) into the center of the femur head, and be

removed from the bone without removing the guide implement, then, a second guiding JIG can be mounted thereon, optionally, a guiding JIG having a guide conduit shaped and/or sized to receive a chisel. In some embodiments, the guide conduit for a chisel may comprise a slit as well for potentially simplifying introducing the guide implement thereinto.

5 Still referring to Figures 22A-C, showing, inter alia, a guiding JIG having a guide conduit **2212** with a slit **2218**.

It should be understood that the feature of guiding conduit with a slit is demonstrated on guiding JIG **2200** (designed for a hip replacement procedure) to allow a person having skills in the art to understand the invention and is not intended to limit the invention in any way. The feature of
10 guiding conduit with a slit can be employed on various other guiding JIGs, including guiding JIGs for VDRO described herein.

In some embodiments, guiding conduit **2212** comprises a slit **2218** extending from proximal end **2218** of guiding JIG **2200**, (defined by the proximal end of conduit **1612**), to the distal end of the conduit, at a circumferential location thereon where there is no connection to JIG body **2202**.
15 Slit **2218** potentially enables inserting a guide implement (e.g., a K-wire and/or a sleeve) therethrough and then removing guiding JIG **1600** while said guide implement remains inserted within the femur head.

In some embodiments, a guiding conduit is sized and/or shaped to receive a guide implement (such as a K wire), such as guiding conduit **310** shown in Figure 3A. In some
20 embodiments, the diameter of inner lumen **312** is about 3.5 mm for accommodating a guide implement having a diameter of about 3 mm. For example, 2-4mm, or 1.5-5 mm, 3-6mm or about 2.5 mm, or lower or higher or intermediate ranges or diameters. In other embodiments, guiding conduit **2212** is sized and/or shaped according to a reducer, optionally shaped as a removable sleeve (not shown), the reducer, comprises an inner lumen for inserting the selected guide implement
25 therethrough. In some embodiments, the sleeve defines a cylindrical shape to inner lumen **2215**. In some embodiments, the reducer is placed within guiding conduit **2212** and reduces the effective diameter thereof. The reducer comprises an inner lumen for inserting a K-wire thereto and into the bone, directed according to the position and/or orientation of guiding conduit **2212**. After inserting the K-wire into the bone, the reducer can be removed from the proximal opening of guiding conduit
30 **2212**.

In some embodiments, slit **2218** is relatively wide, defining an opening in wall **2214** (e.g., a distance between circumferential ends **2213**, **2215** of wall **2214**), as shown for example in figures 16A-B. This opening potentially enables and/or facilitates the removal of a guiding JIG while a guide implement is inserted through conduit **2212**. In some embodiments, slit **2218** is sufficiently

narrow for a reducer, optionally shaped as a cylindrical sleeve, to occupy lumen **2214** without passing through slit **2218**. In some embodiments, slit **2218** is sufficiently wide for allowing a guide implement (such as a K-wire), inserted into the reducer, to pass through slit **2218**, after the reducer is removed. In some embodiments, the diameter of inner lumen **2218** is about 12.5 mm for accommodating a reducer (e.g., a sleeve) having a diameter of 12 mm. For example, 5-12 mm, or 10-15 mm, or 4-13mm or about 11 mm, or lower or higher or intermediate ranges or diameters. In some embodiments, the arc length of slit **2218** is about 3 mm potentially allowing a K-wire having a diameter of about 2 mm to pass therethrough. For example, 2.5-4.5 mm, or 2.5-5 mm, or 2-3mm or about 3.2 mm, or lower or higher or intermediate arc lengths.

In some embodiments, slit **2218** is relatively thin, allowing wall **2214** to maintain a tubular shape (e.g., allowing the circumferential ends **2213**, **2215** of wall **2214** to contact each other) during the insertion of a guide conduit **2212** and to be opened when removing guiding JIG **2200**.

Alternatively or additionally, slit **2218** is defined by a line on wall **2214**, intended to be cut/torn while and/or before removing JIG **2200**. In some embodiments, slit **2218** and/or a portion thereof comprises a thin layer of material, and/or spaced holes that define said line. In some embodiments, said line is in the form of a straight, alternatively or additionally, the line can have any other shape, such as curved and/or jagged.

In some embodiments, slit **2218** extends parallel to the longitudinal axis of guiding conduit **2212**, alternatively or additionally, slit **2218** at least partially surrounds conduit **2212**.

Sturdy guiding elements

Referring now to Figure 23A-C, showing perspective views of a guiding JIG **2300** having a sturdy guiding element, in accordance with some exemplary embodiments of the invention.

Referring also to Figure 23D, showing a perspective view of a sturdy surface(s) for a guiding JIG, in accordance with some exemplary embodiments of the invention.

Referring also to Figure 23E, showing a sturdy surface(s) before being folded to achieve a three-dimensional form of the sturdy surface(s), in accordance with some exemplary embodiments of the invention.

It should be understood that the feature of a sturdy guiding element is demonstrated on guiding JIG **2300** (designed for a hip replacement procedure) to allow a person having skills in the art to understand the invention and is not intended to limit the invention in any way. The feature of a sturdy guiding element can be employed on various other guiding JIGs, including guiding JIGs for VDRO described herein.

In some embodiments, guiding JIG **2300** (e.g., and/or any other guiding JIG described herein) comprises one or more guiding elements, resistant to contact with a sharp operating tool and/or sharp bone residues formed during surgery. This resistance has the potential advantage of reducing and/or avoiding damaging the JIG during surgical procedures which might impair the function thereof. An additional potential advantage is reducing and/or avoiding the creation of JIG residues (segments and/or crumbles from the JIG) that may undesirably remain within the patient's body.

In some embodiments, guiding JIG **2300** comprises a sturdy osteotomy guide **2320**.

In some embodiments, the inner lumen of supporting frame **2324** and/or a portion thereof is covered by one or more sturdy surface(s) **2344**, defining a sturdy contact surface(s). Said sturdy contact surface(s), potentially having resistance to scratches and cuts when operating tools and/or sharp bone residues contacting thereof. In some embodiments, one or more sturdy surface(s) **2344** are, shaped and/or sized to be mounted within supporting frame **2324**, optionally, according to the shape of supporting frame **2324**. In other embodiments, osteotomy guide **2320** comprises a cutting surface (e.g., a single cutting surface) (for example cutting surface **2124** and/or **2125**) so one or more sturdy surface(s) **2344** are, shaped and/or sized to be mounted on said cutting surface, optionally, shaped as a surface. In some embodiments, one or more sturdy surface(s) **2344** comprises two sturdy surface(s), optionally parallel to each other, as shown for example in Figure 21D. Optionally, the two sturdy surface(s) are connected at a connection area and/or line **2349**.

In some embodiments, one or more sturdy surface(s) **2344** comprises and/or is made of metal, such as stainless steel and/or titanium alloys.

In some embodiments, a guiding JIG may comprise a sturdy guiding conduit (e.g., guiding conduit **112**). In some embodiments, sturdy guiding conduit **e** comprises a sturdy surface therewithin, optionally, shaped as a tube and or a tube segment. A sturdy guiding conduit may have a particular use upon drilling therethrough and/or upon introducing sharp and/or rough implements, such as screws.

In some embodiments, one or more sturdy surface(s) **2344** are customized (e.g., shaped and/or sized) according to a selected operating tool and/or according to a guiding JIG design. In some embodiments, the guiding JIG is designed (e.g., shaped and/or sized) to fit onto one or more sturdy surface(s) **2344**, optionally, customized sturdy surface(s) **2344**, alternatively or additionally, a shelf sturdy surface(s) **2344**. For example, in some embodiments, supporting frame **2324** is shaped and/or sized to accommodate one or more sturdy surface(s) **2344**, such that one or more sturdy surface(s) **2344** are positioned adjacent to the inner walls of supporting frame **2324**.

In some embodiments, one or more sturdy surface(s) **2344** comprises at least one anchor for connecting to a guiding element (e.g., support frame **2324** and/or cutting surfaces). In some embodiments, at least one anchor is in the form of at least one folded end **2346** of one or more sturdy surface(s) **2344**, optionally two folded ends, shaped and/or sized to grip the edges of the guiding element (e.g., the edges of support frame **2344**). Alternatively or additionally, one or more sturdy surface(s) **2344** comprises additional anchor **2348** optionally in the form of a plate and/or an arm which presses the outer surface of the support frame **2344** against the one or more sturdy surface(s) **2344**. This press potentially allows sturdy surface(s) **2344** to cling to the inner surface of support frame **2344** and/or grip a wall of the support frame **2344** (and/or a cutting surface) by pressing it between additional anchor **2348** and the support frame **2324**.

In some embodiments, one or more sturdy surface(s) **2344** is produced in a flat form, as shown for example in Figure 21E. For example, in some embodiments, one or more sturdy surface(s) **2344** is manufactured and/or cut to have a flat foldable form. In some embodiments, the flat form is folded, for example at the center thereof (e.g., at connection area/line **2349**) to obtain a desired three-dimensional shape.

Verification elements

Referring still to Figure 23C, showing, *inter alia*, a perspective view of guiding JIG having a verification element **2350**, in accordance with some exemplary embodiments of the invention. It should be understood that the feature of a verification element is demonstrated on guiding JIG **2300** (designed for a hip replacement procedure) to allow a person having skills in the art to understand the invention and is not intended to limit the invention in any way. The feature of a verification element can be employed on various other guiding JIGs, including guiding JIGs for VDRO described herein.

In some embodiments, a guiding JIG (e.g., each of the guiding JIGs described herein, such as guiding JIG 100 and/or 200) comprises a verification element **2350** for potentially evaluating that a produced JIG is shaped and/or sized according to a desired design (also referred to herein as a proper production of JIG and/or a JIG properly produced).

In some embodiments, verification element **2350** (e.g., a measurable mark) comprises dimensional elements, designed to have a specific size and/or shape. A produced guiding JIG having a verification element that presents deviation from the pre-designed shape and/or size thereof may indicate improper production on the JIG and/or undesired deformation thereof. This deviation can be detected for example by measuring and/or observing the verification element **2350**. This detection potentially indicates to that a produced guiding JIG may be defective, having

the potential advantage of reducing and/or avoiding the risk of performing surgery and/or any other medical procedures using a defective JIG.

For example, the verification element may be in the form of a round coin designed to have a specific diameter, a ring with a specific outer and inner diameter, a triangle any quadrilateral with defined side lengths, and/or any other shape having defined dimensions.

In some embodiments, the JIG is provided with a dedicated measuring device that comprises a recess, shaped and/or sized according to the pre-designed shape and/or size of the verification element. A verification element of a produced JIG that fits within said recess and complements the shape and/or size thereof potentially indicates proper production of the JIG (e.g., a production achieving a desired design).

Alternatively or additionally, distortion of the shape and/or size of the verification element and/or of a shape printed thereon can be evaluated using image processing of the JIG.

In some embodiments, the guiding JIG comprises more than one verification element, optionally, distance for each other, optionally on different portions of the guiding JIG body. Identification of the proper production of more than one verification element potentially improves the induction reliability of a proper JIG production. In some embodiments, a verification element is positioned on and/or next to each guiding element of the JIG.

In some embodiments, alternatively or additionally to dimensional elements, the verification element comprises resolution elements, optionally in the form of fine details such as small features, thin walls, and intricate patterns. The resolution elements can be visually inspected (by the human eye and/or by image processing) optionally under magnification, to evaluate the production resolution. In some embodiments, the resolution elements are designed to indicate the reliability of relatively fine features such as the details of inner surface **105** (e.g., that should match the topography of the bone).

General

As used herein with reference to quantity or value, the term “about” means “within $\pm 20\%$ of”.

The terms “comprises”, “comprising”, “includes”, “including”, “has”, “having” and their conjugates mean “including but not limited to”.

The term “consisting of” means “including and limited to”.

The term “consisting essentially of” means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps

and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular forms “a”, “an” and “the” include plural references unless the context clearly dictates otherwise. For example, the term “a compound” or “at least one
5 compound” may include a plurality of compounds, including mixtures thereof.

Throughout this application, embodiments of this invention may be presented with reference to a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically
10 disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as “from 1 to 6” should be considered to have specifically disclosed subranges such as “from 1 to 3”, “from 1 to 4”, “from 1 to 5”, “from 2 to 4”, “from 2 to 6”, “from 3 to 6”, etc.; as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein (for example “10-15”, “10 to 15”, or any pair of numbers linked by these another such range indication), it is meant to include any number (fractional or integral) within the indicated range limits, including the range limits, unless the context clearly dictates otherwise. The phrases “range/ranging/ranges between” a first indicate number and a second indicate number and “range/ranging/ranges from” a first indicate number
20 “to”, “up to”, “until” or “through” (or another such range-indicating term) a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numbers therebetween.

Unless otherwise indicated, numbers used herein and any number ranges based thereon are approximations within the accuracy of reasonable measurement and rounding errors as understood
25 by persons skilled in the art.

As used herein the term “method” refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and
30 medical arts.

As used herein, the term “treating” includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

It is the intent of the applicant(s) that all publications, patents and patent applications referred to in this specification are to be incorporated in their entirety by reference into the specification, as if each individual publication, patent or patent application was specifically and individually noted when referenced that it is to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting. In addition, any priority document(s) of this application is/are hereby incorporated herein by reference in its/their entirety.

WHAT IS CLAIMED IS:

1. A guiding JIG for use on a femoral bone during a VDRO procedure, having an osteotomy guide, comprising:
 - a. a JIG body, shaped and sized to be mounted on the femur head
 - b. a first cutting slot, positioned on the JIG body and shaped and sized to receive a first cutting tool;
 - c. a second cutting slot, positioned on the JIG body and shaped and sized to receive a second cutting tool;wherein the first cutting slot directs the first cutting tool to cut the femoral bone in a first desired path, and the second cutting slot directs the second cutting tool to cut the femoral bone in a second desired path.
2. The guiding JIG according to claim 1, wherein the first cutting slot and the second cutting slot are positioned relative to each other such that cutting the bone therethrough results in a bone wedge separated from the bone.
3. The guiding JIG according to claim 2, wherein the bone wedge is triangular in shape.
4. The guiding JIG according to claim 3, wherein said triangular shape comprises an angle equivalent to a desired correction angle.
5. The guiding JIG according to claim 2, wherein the bone wedge is trapezoidal in shape.
6. The guiding JIG according to claim 5, wherein said trapezoidal shape is according to a desired correction angle and a level of shortening of the femur.
7. The guiding JIG according to claim 1, wherein said JIG body comprises an inner surface having a geometry that complements the geometry of the femoral bone, at the treatment site.

8. The guiding JIG according to claim 7, wherein the JIG body at least partially surrounds the femur head.
9. The guiding JIG according to claim 8, wherein the JIG body has a grip on the femoral head.
10. The guiding JIG according to claim 1, comprising a first frame shaped and sized for directing a cutting tool to said first cutting slot.
11. The guiding JIG according to claim 10, comprising a second frame shaped and sized for directing a cutting tool to said second cutting slot.
12. The guiding JIG according to claim 11, wherein one or both of said first frame and said second frame comprise an inner lumen sufficiently large to accommodate a cutting tool but sufficiently small to limit lateral movement of said cutting tool therewithin.
13. The guiding JIG according to claim 11, wherein said first frame is oriented on the JIG body to define a first insertion angle into the bone, relative to a femoral longitudinal shaft-neck axis, and wherein the second first frame is oriented on the JIG body to define a second insertion angle into the bone, relative to a femoral longitudinal shaft-neck axis.
14. The guiding JIG according to claim 1, wherein the guiding JIG comprises a guiding conduit configured to direct a guide implement into the center of the femur head.
15. The guiding JIG according to claim 14, wherein the guiding conduit comprises a slit extending along a wall of said conduit, from a proximal end of said wall, facing away from a femur neck, to a distal end of said wall, facing toward a femur neck, and ends at a portion of said wall not connected to the JIG body.
16. The guiding JIG according to claim 14, wherein the guiding conduit comprises a horizontal slit with respect to a longitudinal axis of said guiding conduit, wherein said horizontal slit is configured to shorten said guiding conduit.

17. The guiding JIG according to claim 14, wherein the guiding conduit comprises an inner lumen sufficiently large to accommodate the guide implement but sufficiently small to limit lateral movement of said guide implement therewithin.

18. The guiding JIG according to claim 17, wherein the guiding conduit is shaped according to a k-wire, having a diameter less than 2 mm.

19. The guiding JIG according to claim 14, wherein the guiding conduit is a guiding conduit for a chisel; and wherein the guiding conduit comprises an inner lumen shaped as a selected chisel.

20. The guiding JIG according to claim 19, comprising a removable guide conduit for a guide implement configured to be placed in and removed from within the inner lumen of the guiding conduit for the chisel.

21. The guiding JIG according to claim 19, comprising a removable portion of the guiding JIG, wherein said removable portion is located between the first cutting slot and the second cutting slot, shaped and sized to divide the guiding JIG into two portions upon the removal thereof.

22. The guiding JIG according to claim 1, comprising a measurable mark, designed to have a specific size and shape, configured to be measured to indicate that said guiding JIG is produced according to a desired design.

23. The guiding JIG according to claim 12, wherein at least one of said first frame and said second frame comprises at least one sturdy surface, positioned therewithin.

24. The guiding JIG according to claim 23, wherein the at least one sturdy surface comprises a pair of connected sturdy surfaces, shaped and sized to fit within an inner lumen of one or both of said first frame and said second frame.

25. The guiding JIG according to claim 1, wherein the guiding JIG further comprises a distal guiding hole deviating from a femoral longitudinal shaft-neck axis, according to a desired level of rotation correction.

26. The guiding JIG according to claim 1, wherein the guiding JIG further comprises a proximal guiding hole shaped and sized according to fixators of a selected plate.

27. A guiding JIG for use on a femoral bone during a VDRO procedure, comprising:

- a. a guide body, shaped and sized to be deployed on the femoral bone;
- c. a first osteotomy guide and a second osteotomy guide, configured to separate the bone into a proximal bone fragment and a distal bone fragment; and
- d. a removal portion of the guiding JIG, located between a first osteotomy guide and a second osteotomy guide, and shaped and sized to divide the guiding JIG into a proximal JIG portion and a distal JIG portion, wherein the proximal JIG portion is located on the proximal bone fragment and the distal JIG portion is located on the distal bone fragment.

28. A guiding JIG for use on a femoral bone during a VDRO procedure, comprising:

- a. a guide body, shaped and sized to be deployed on the femoral bone;
- b. a guide conduit, defining a path into the center of the femur head; and
- c. an osteotomy guide, defining at least one path for cutting the bone.

29. The guiding JIG according to claim 28, wherein the guide conduit is a guiding conduit for a guide implement.

30. The guiding JIG according to claim 28, wherein the guiding conduit is shaped according to a k-wire, having a diameter less than 2 mm.

31. A guiding JIG for use on a femoral bone during a VDRO procedure, comprising:

- a. a JIG body at least partially circumferentially surrounding the femoral bone;
- b. guiding elements positioned on the JIG body, comprising:
 - i. functional guiding elements, shaped and sized for directing operating tools applied on the femoral bone; and
 - ii. fixating guiding elements, shaped and sized for directing the insertion of fixators into the femur.

32. The guiding JIG according to claim 31, wherein said JIG body has a grip on the femoral bone.

33. The guiding JIG according to claim 32, wherein said JIG body comprises an inner surface with a geometry that complements a geometry of the femoral bone.

34. A guiding JIG for use on a femoral bone during a VDRO procedure, comprising:
a. a removable guide conduit for a guide implement;
b. a guide conduit for a chisel, comprises an inner lumen shaped as a selected chisel;
wherein the removable guiding conduit for the guide implement mounted within the inner lumen of the guiding conduit for chisel.

35. The guiding JIG according to claim 34, wherein said removable guide conduit comprises an inner lumen shaped and sized to receive a selected guide implement, and a wall having an outer surface at least partially shaped as the inner lumen of said guide conduit for a chisel.

36. The guiding JIG according to claim 34 or claim 35, wherein said JIG body comprises an inner surface with a geometry that complements a geometry of the femoral bone.

37. A guiding JIG for use on a femoral bone during a VDRO procedure, comprising:
a. a removable guide conduit for a guide implement;
b. a guide conduit for a chisel;
wherein the removable guiding conduit for a guide implement is mounted within the inner lumen of the guiding conduit for a chisel.

38. The guiding JIG according to claim 35, wherein the removable guiding conduit for a guide implement is configured to be removed from the inner lumen of the guiding conduit for a chisel while the guide implement remains inserted into the center of the femur head.

39. The guiding JIG according to claim 38, wherein the removable guiding conduit for a guide implement comprises a slit along the longitudinal axis thereof.

40. A method for designing a guiding JIG for a VDRO procedure, comprising:
a. generating a patient-specific 3D simulation of the femur at the treatment site;
b. receiving input;
c. identifying features of the femur;

- d. generating a footprint; and
- e. designing guiding elements based on said features of the femur.

41. The method according to claim 40, wherein said generating is preceded by receiving a scan image of a patient's femur, and wherein said generating comprises generating a patient specific 3D simulation of the femur at the treatment site based on said scan image.

42. The method according to claim 40, wherein said receiving comprises receiving input comprises one or more of:

- a. fixation angle of a selected plate;
- b. type of a selected plate;
- c. selected set of tools; and
- d. surgical approach.

43. The method according to claim 40, wherein said identifying comprises identifying one or more of:

- a. femoral head-neck axis;
- b. femoral longitudinal shaft-neck axis; and
- c. current shaft angle between the femoral head-neck axis and the femoral longitudinal shaft-neck angle.

44. The method according to claim 43, further comprising calculating a correction angle by subtracting the fixation angle of the selected plate from the current shaft angle.

45. The method according to claim 43, wherein said designing comprises:

- a. placing a representation of a first cutting plane perpendicular to the femoral head-neck axis;
- b. placing a representation of a second cutting plane, wherein the angle between the first and second plane is the correction angle;
- c. placing a vector perpendicular to the cutting planes;
- d. placing a representation of a first osteotomy guide comprising a support frame, based on the first cutting plane, and placing a representation of a second osteotomy guide comprising a second support frame based on the second cutting plane.

46. The method according to claim 45, wherein said designing comprises placing a representation of a guiding conduit, in line with the head-neck axis, wherein the guiding conduit is shaped and sized to receive a selected guide implement.

47. The method according to claim 45, said designing comprises placing at least one representation of a fixating guiding element based on the vector perpendicular to the first cutting plane and the second cutting plane.

48. A guiding JIG for a VDRO procedure, designed by a process comprising:

- generating a patient-specific 3D simulation of the femur at the treatment site;
- receiving input related to the femur simulation;
- identifying features of the femur from the simulation;
- generating a footprint based on the identified features;
- designing guiding elements that are incorporated into the guiding jig based on the footprint.

49. The guiding JIG according to claim 48, wherein said identifying comprises identifying one or more of:

- femoral head-neck axis;
- femoral longitudinal shaft-neck axis; and
- current shaft angle between the femoral head-neck axis and the femoral longitudinal shaft-neck angle.

50. The guiding JIG according to claim 48, wherein said designing comprises:

- placing a representation of a first cutting plane perpendicular to the femoral head-neck axis;
- placing a representation of a second cutting plane, wherein the angle between the first and second plane is a by subtraction between a fixation angle of the selected plate and the current shaft angle; and
- placing a representation of a first osteotomy guide based on the first cutting plane, and placing a representation of a second osteotomy based on the second cutting plane.

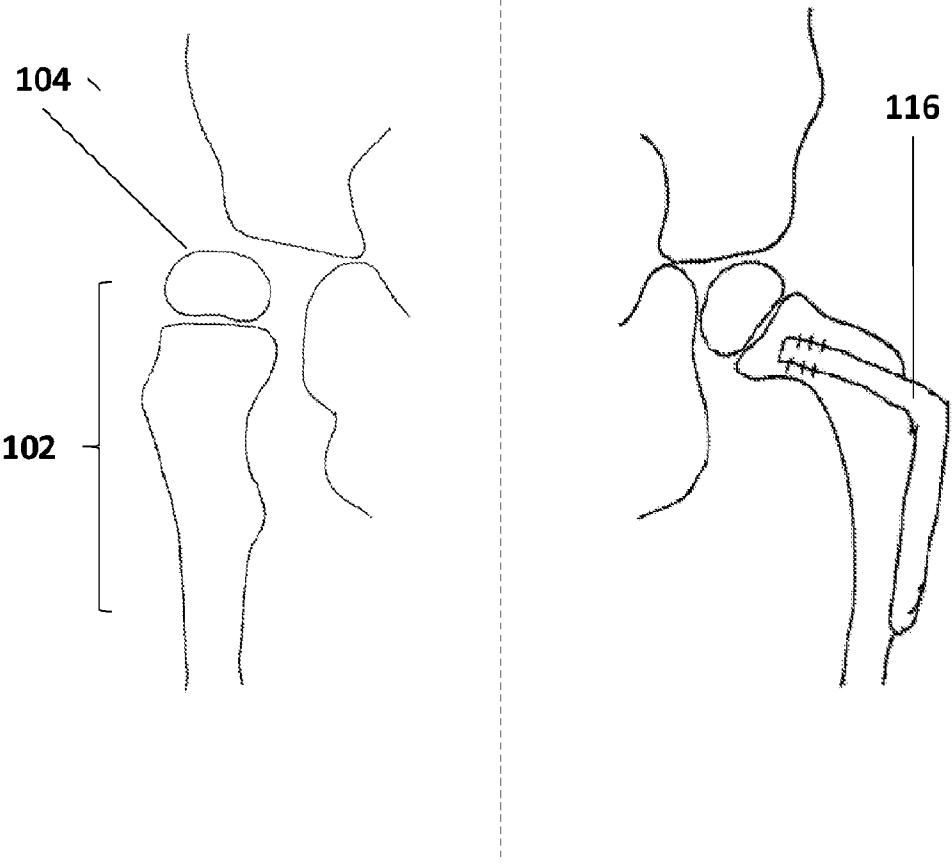


Figure 1A

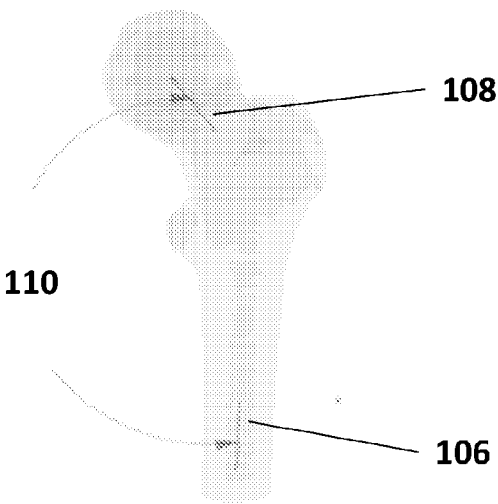


Figure 1B

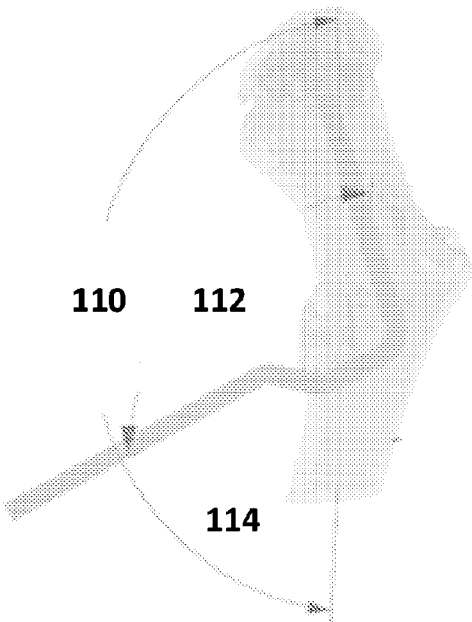
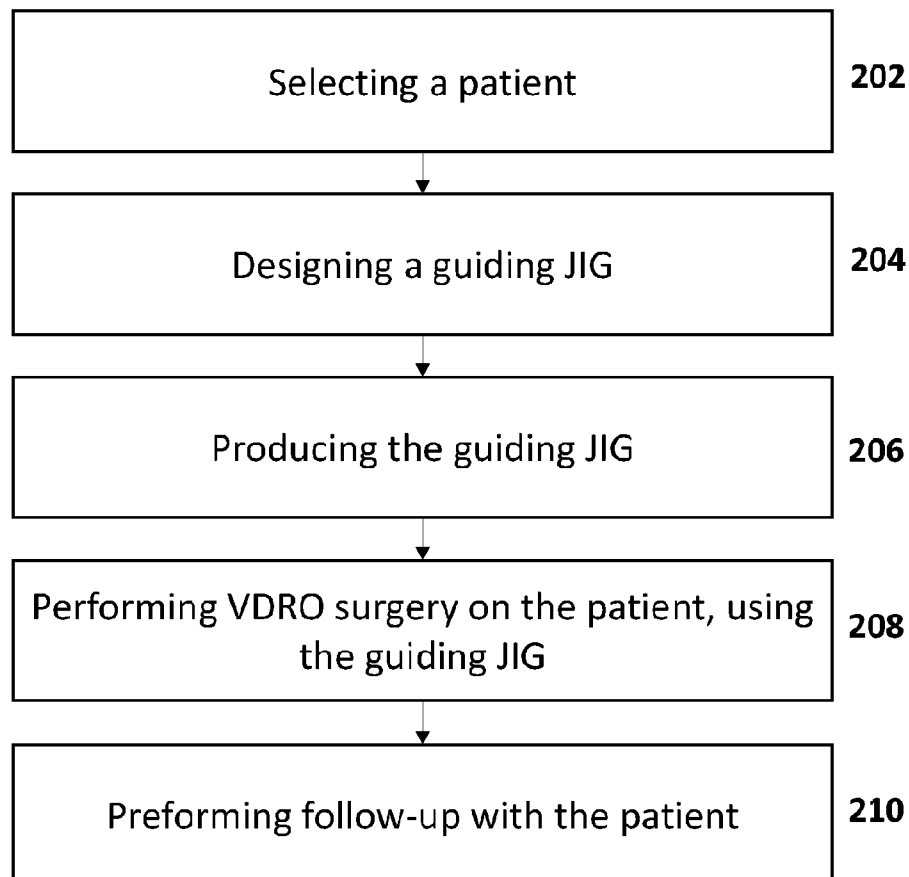


Figure 1C

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**Figure 2**

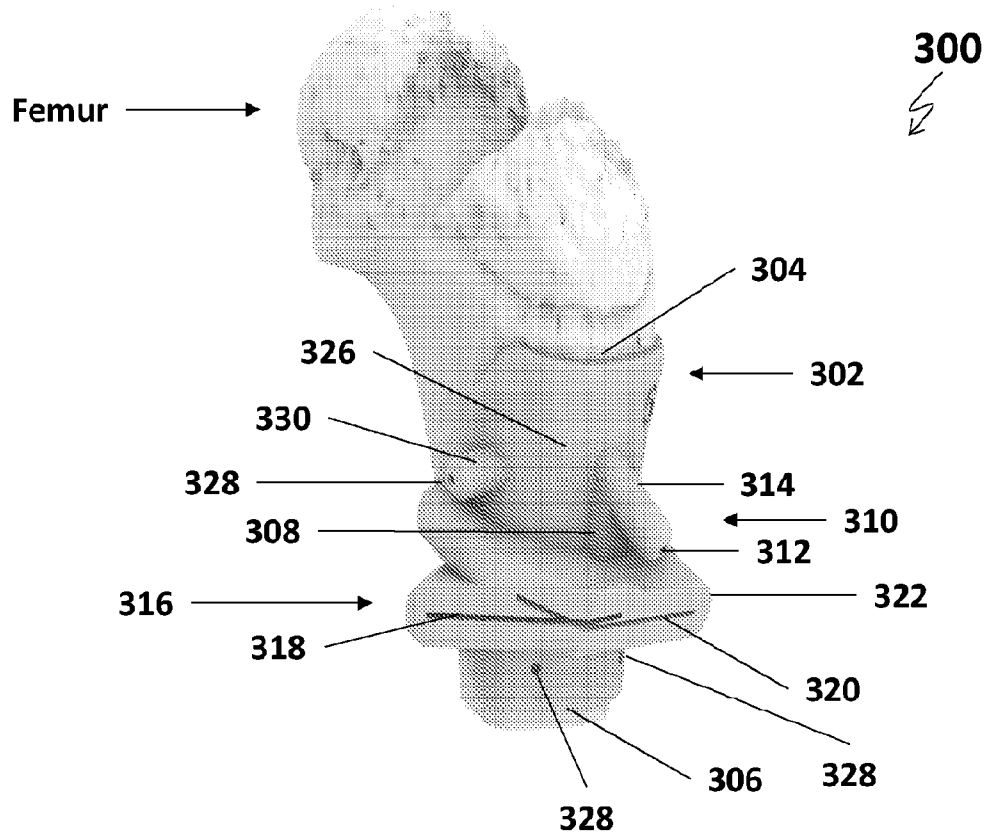


Figure 3A

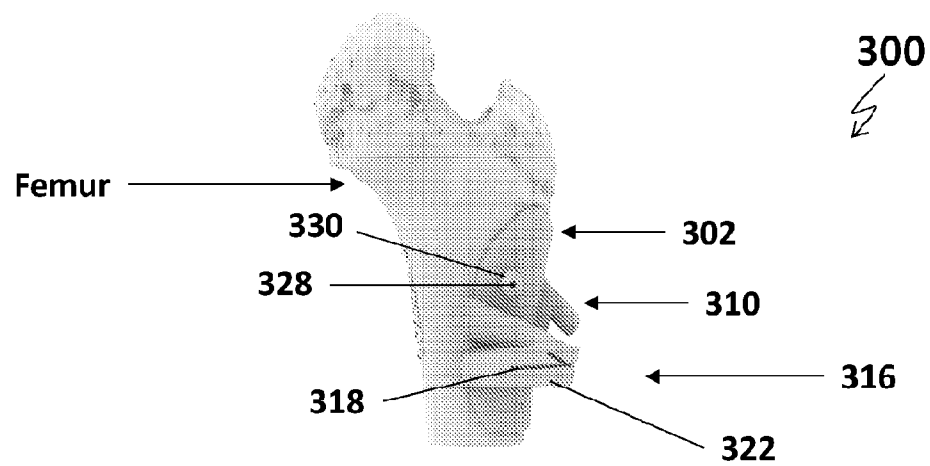


Figure 3B

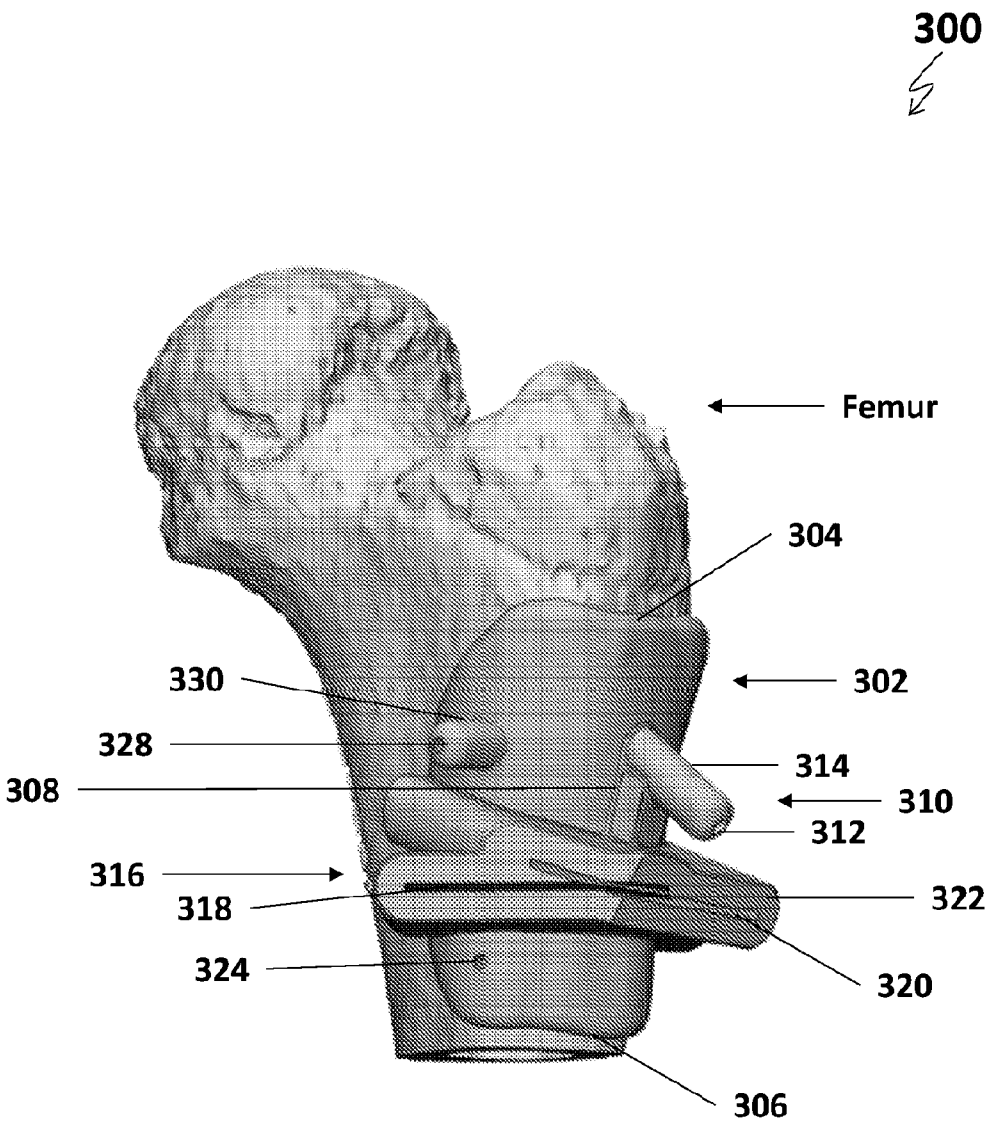


Figure 3C

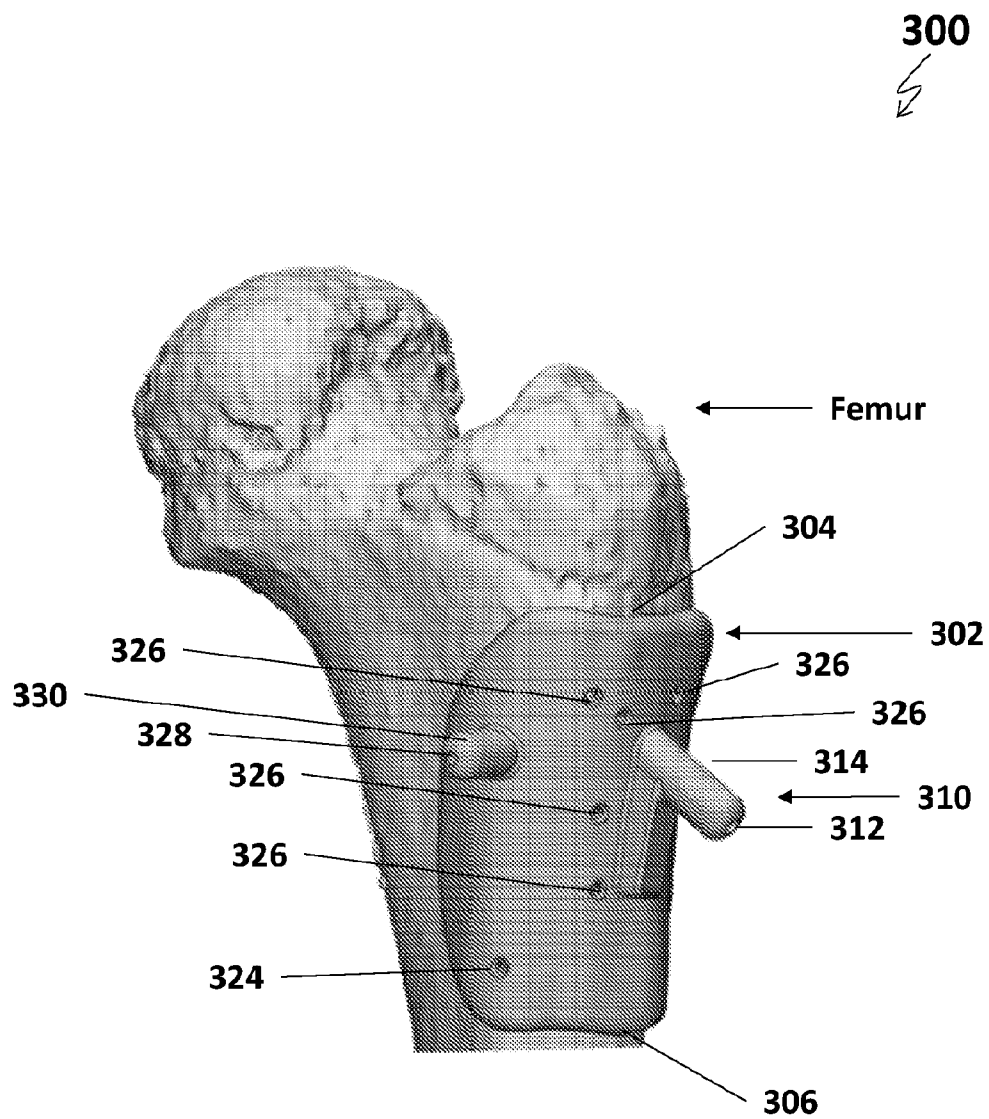


Figure 3D

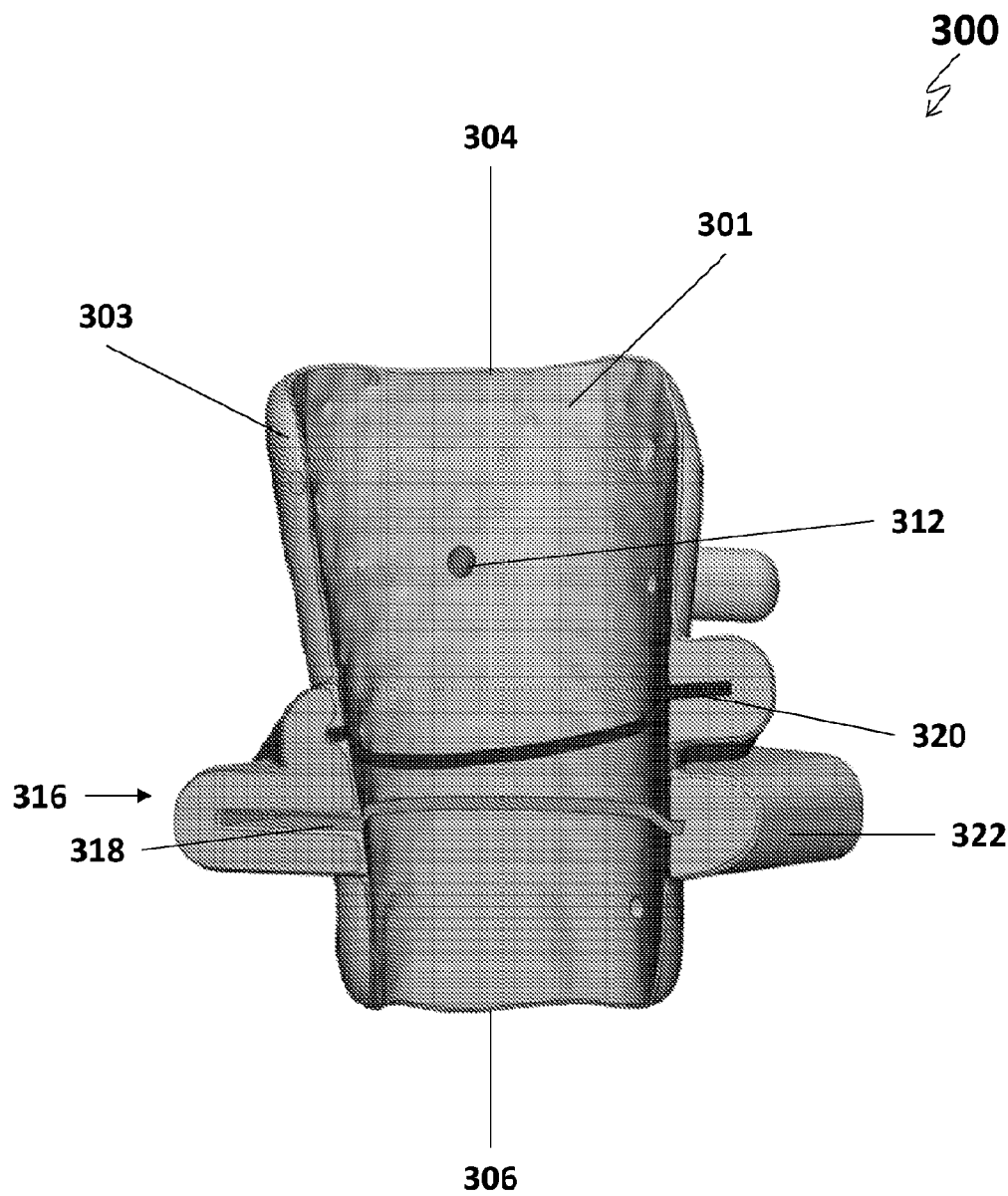


Figure 3E

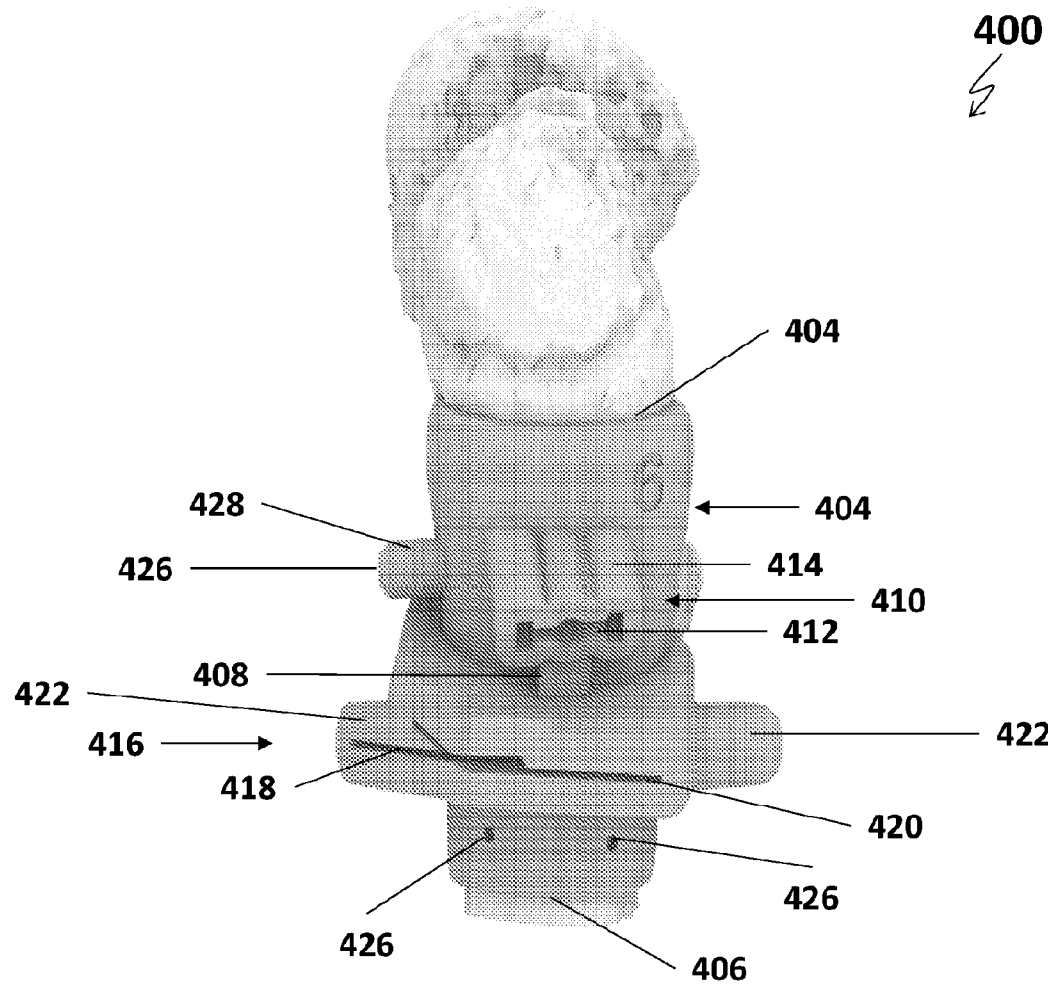


Figure 4A

400
↙

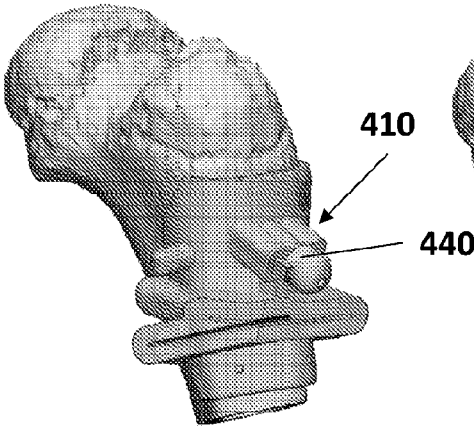


Figure 4B

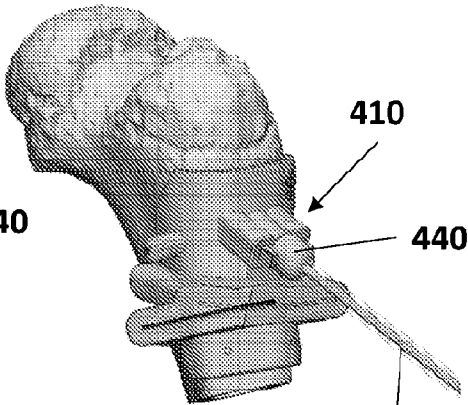


Figure 4C

Guide
implement

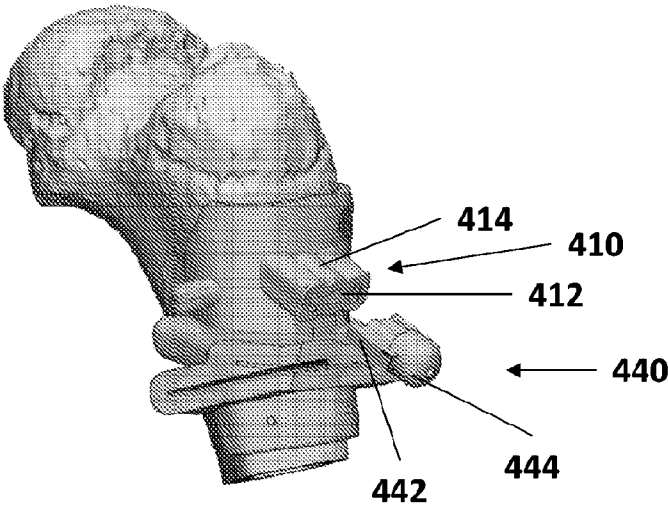


Figure 4D

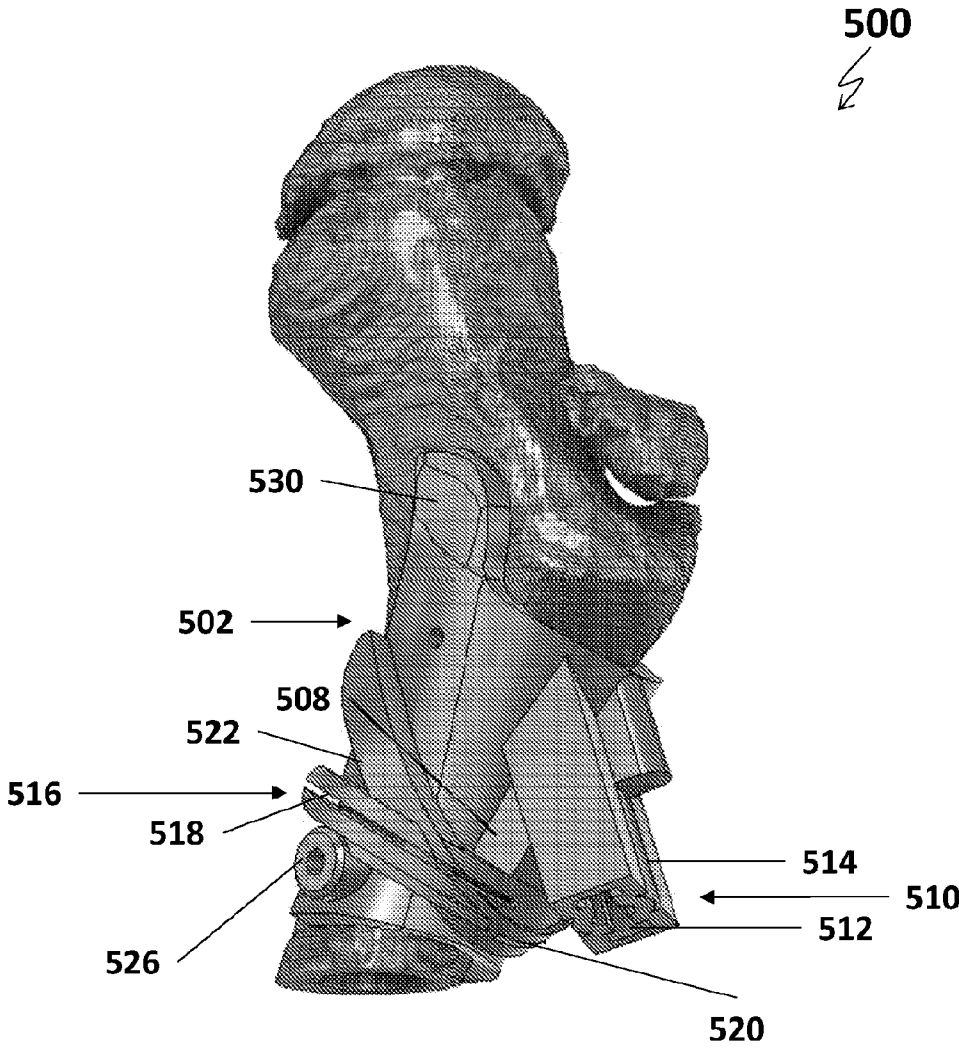


Figure 5A

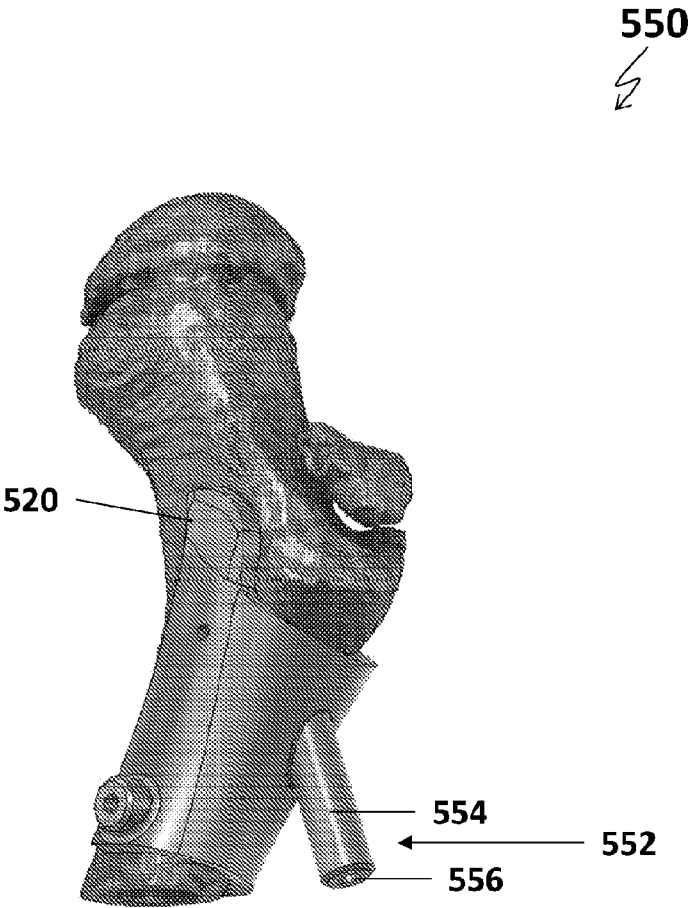
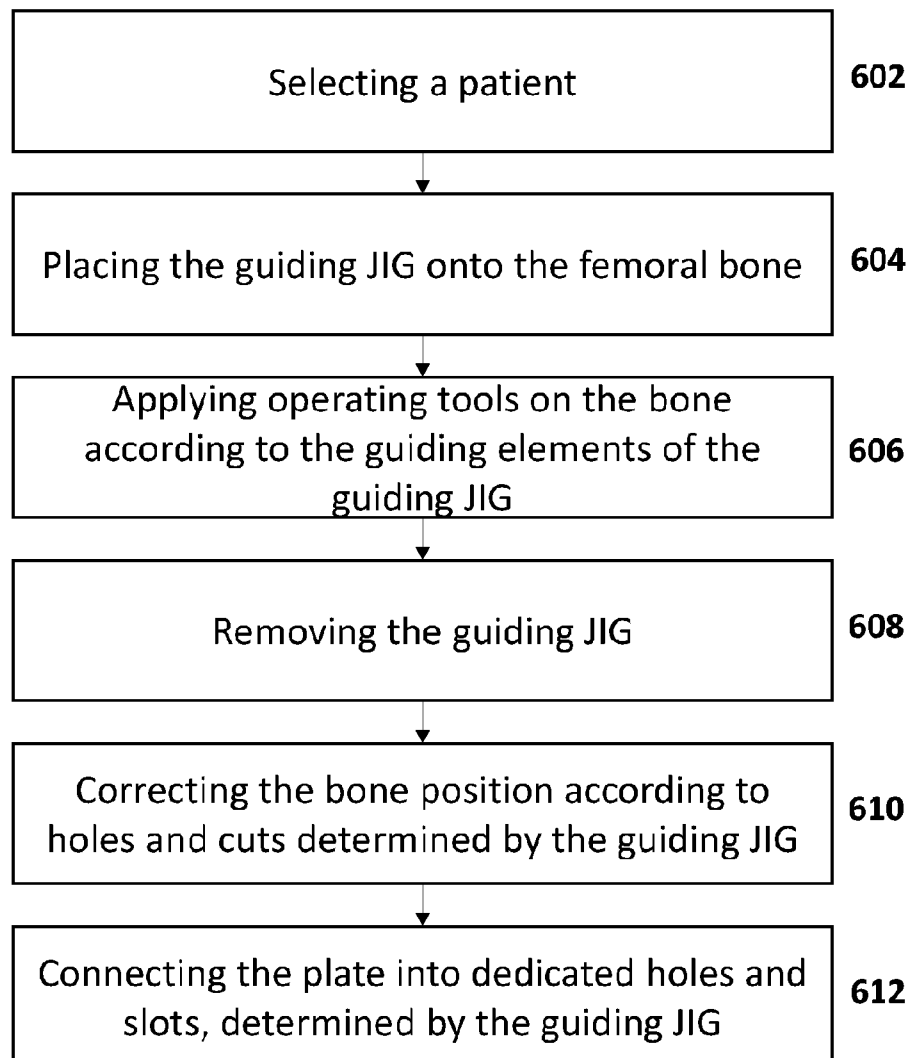
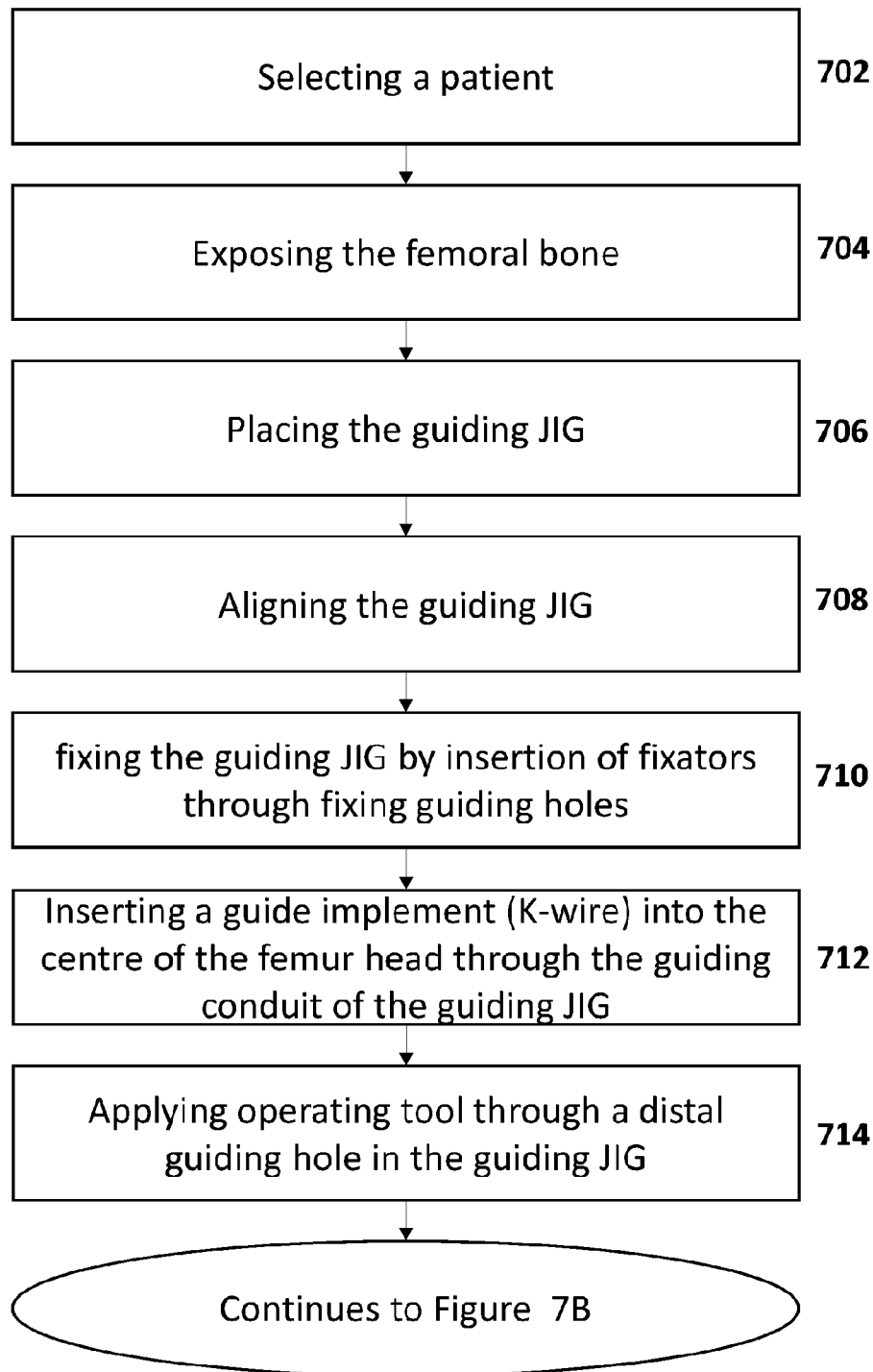


Figure 5B

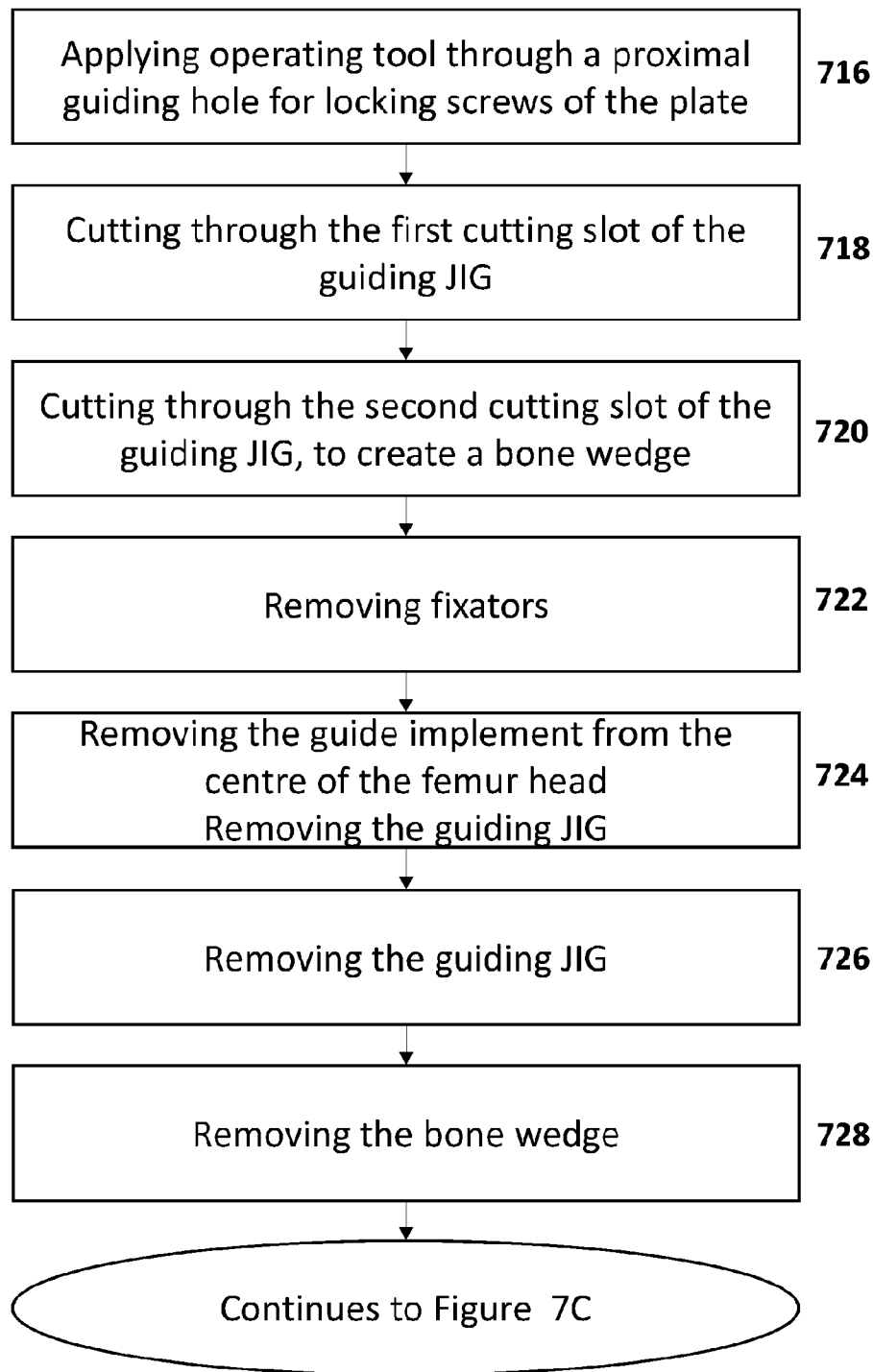
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**Figure 6**

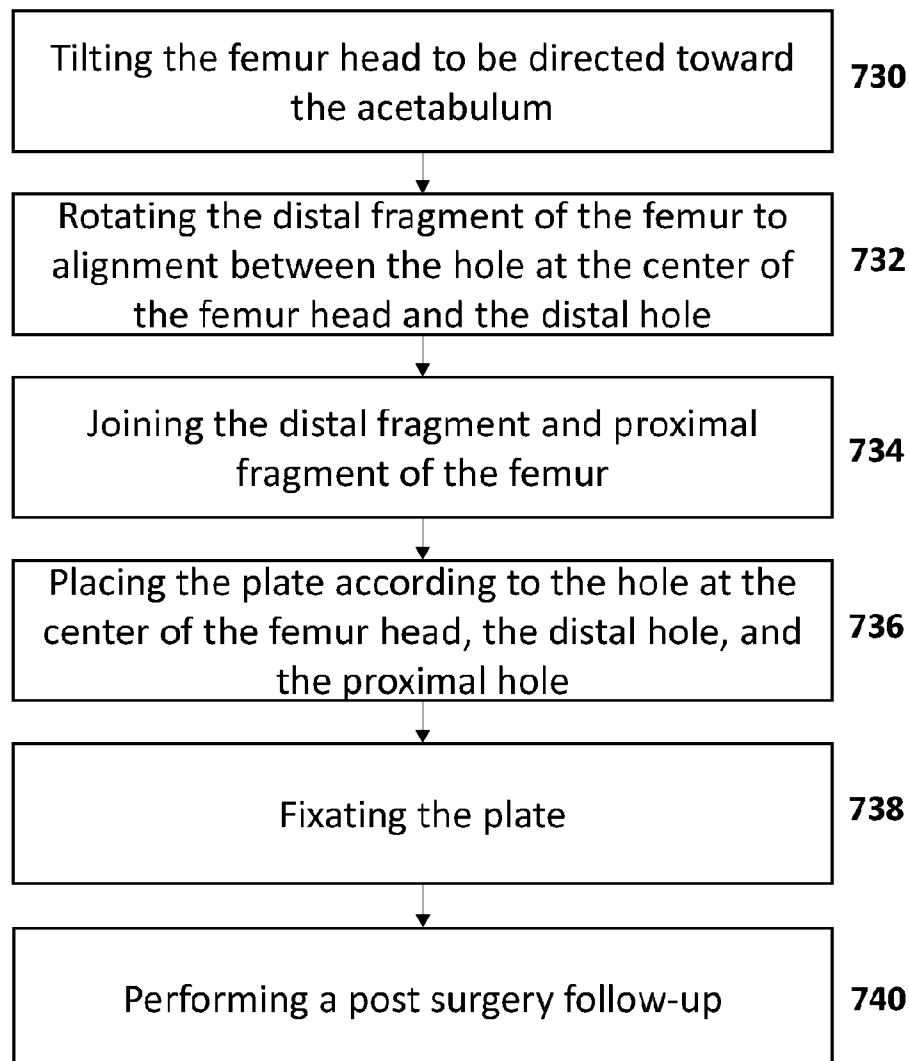
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**Figure 7A**

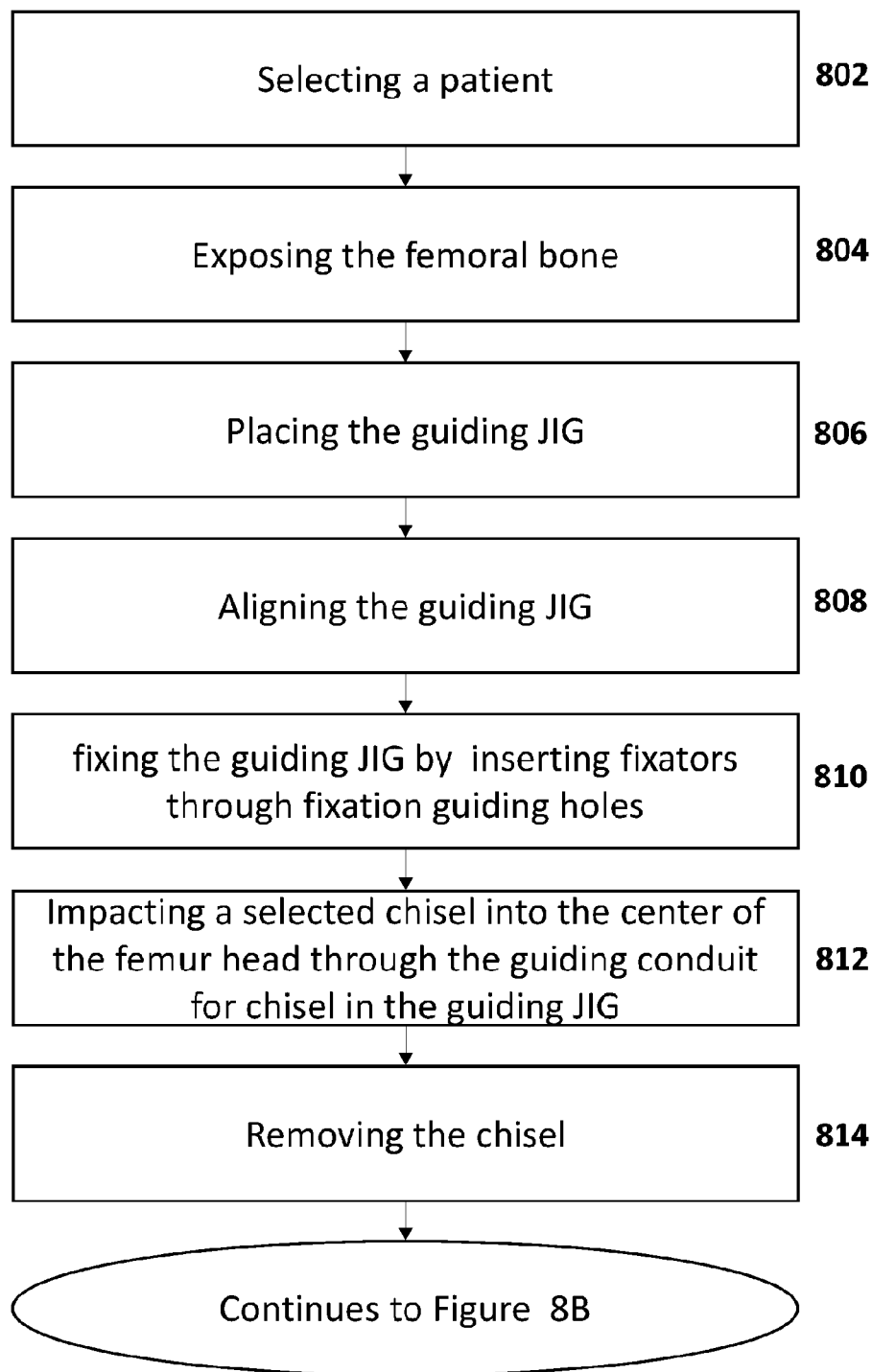
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**Figure 7B**

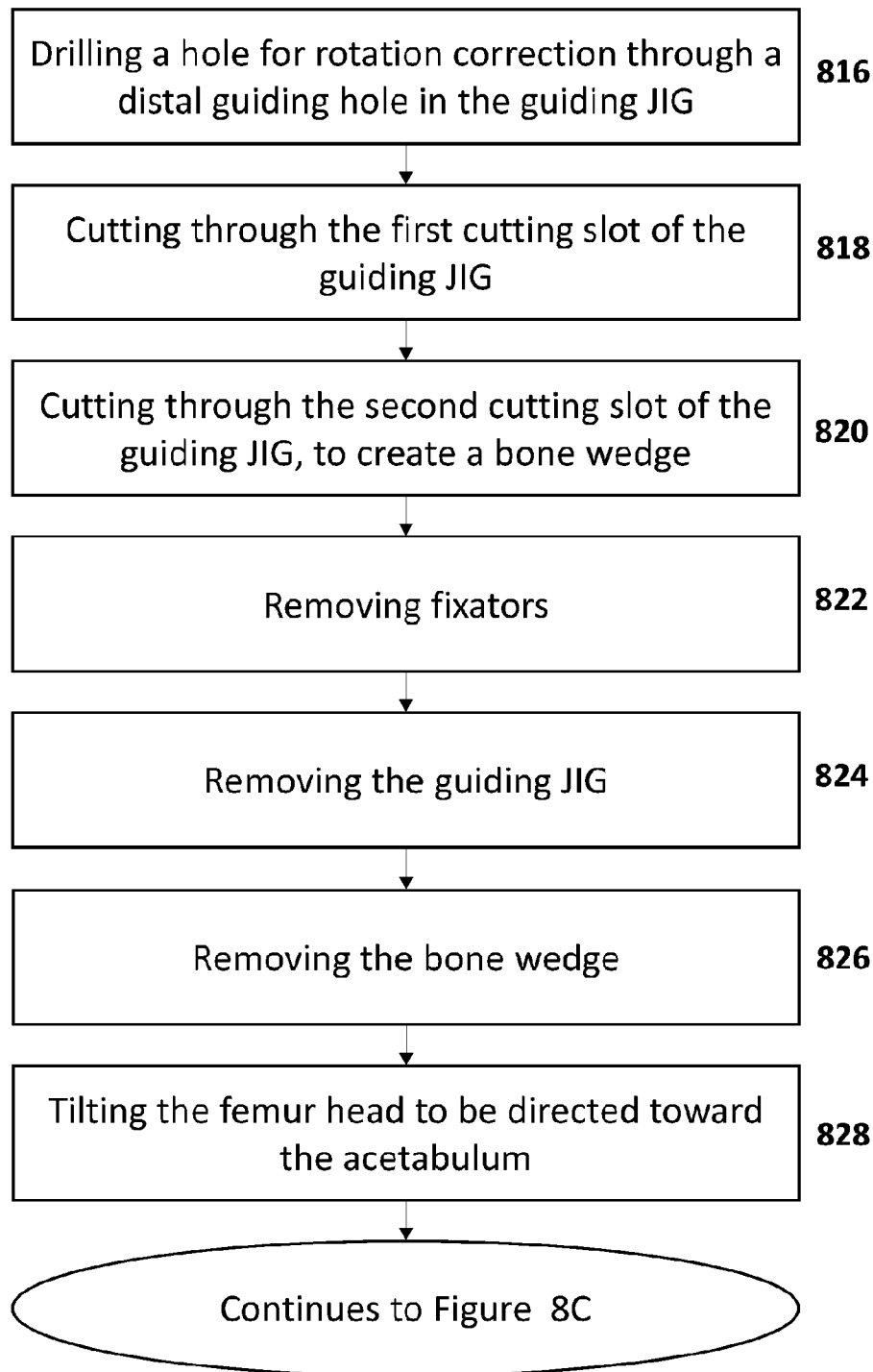
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**Figure 7C**

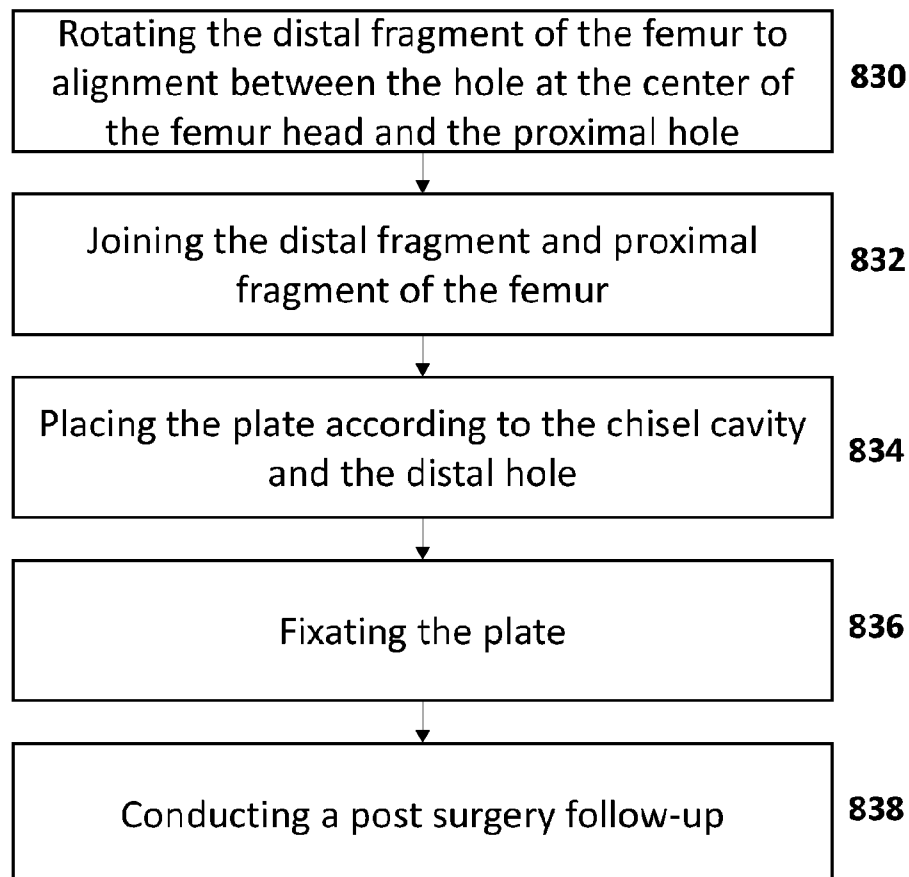
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**Figure 8A**

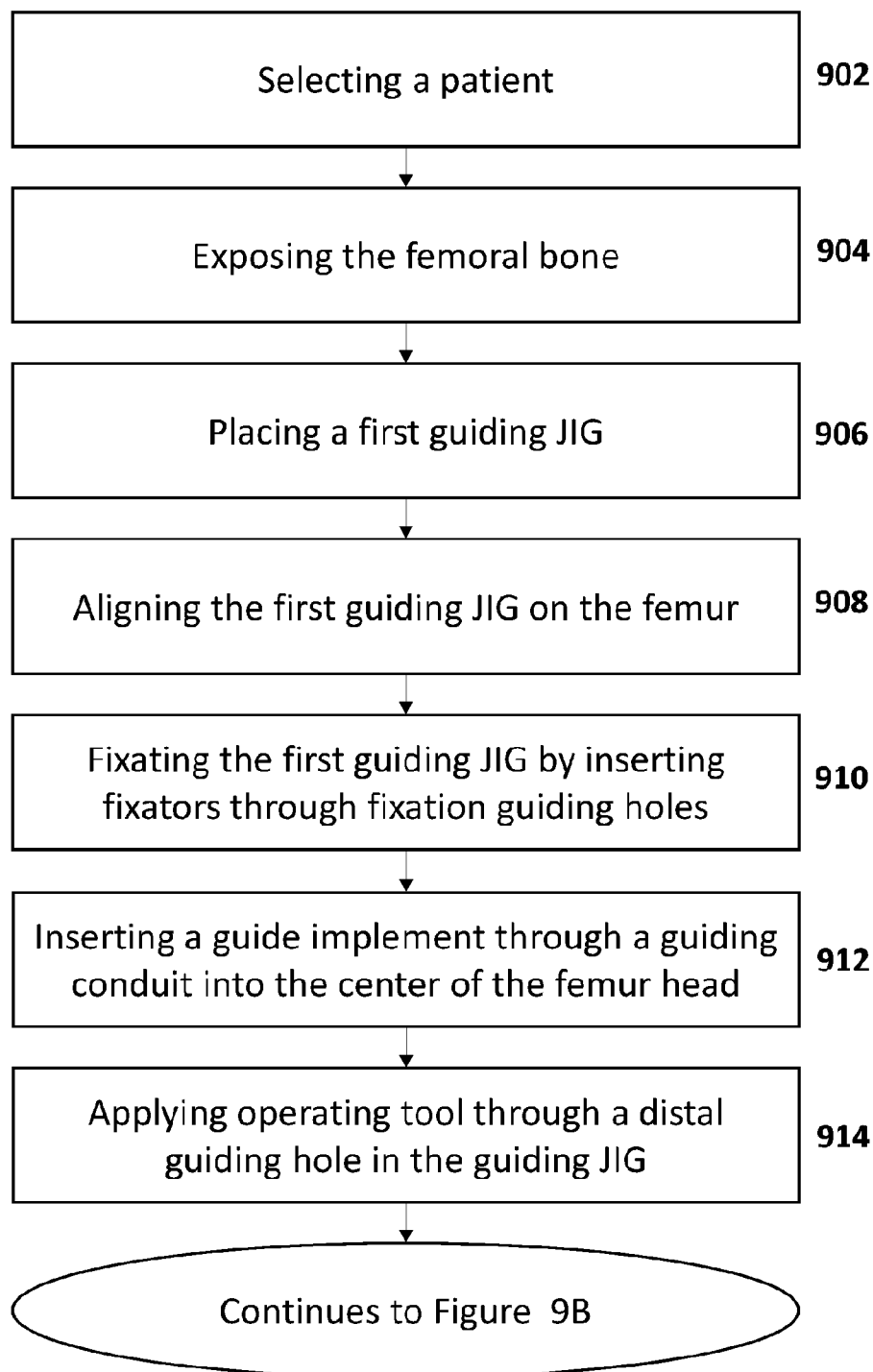
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**Figure 8B**

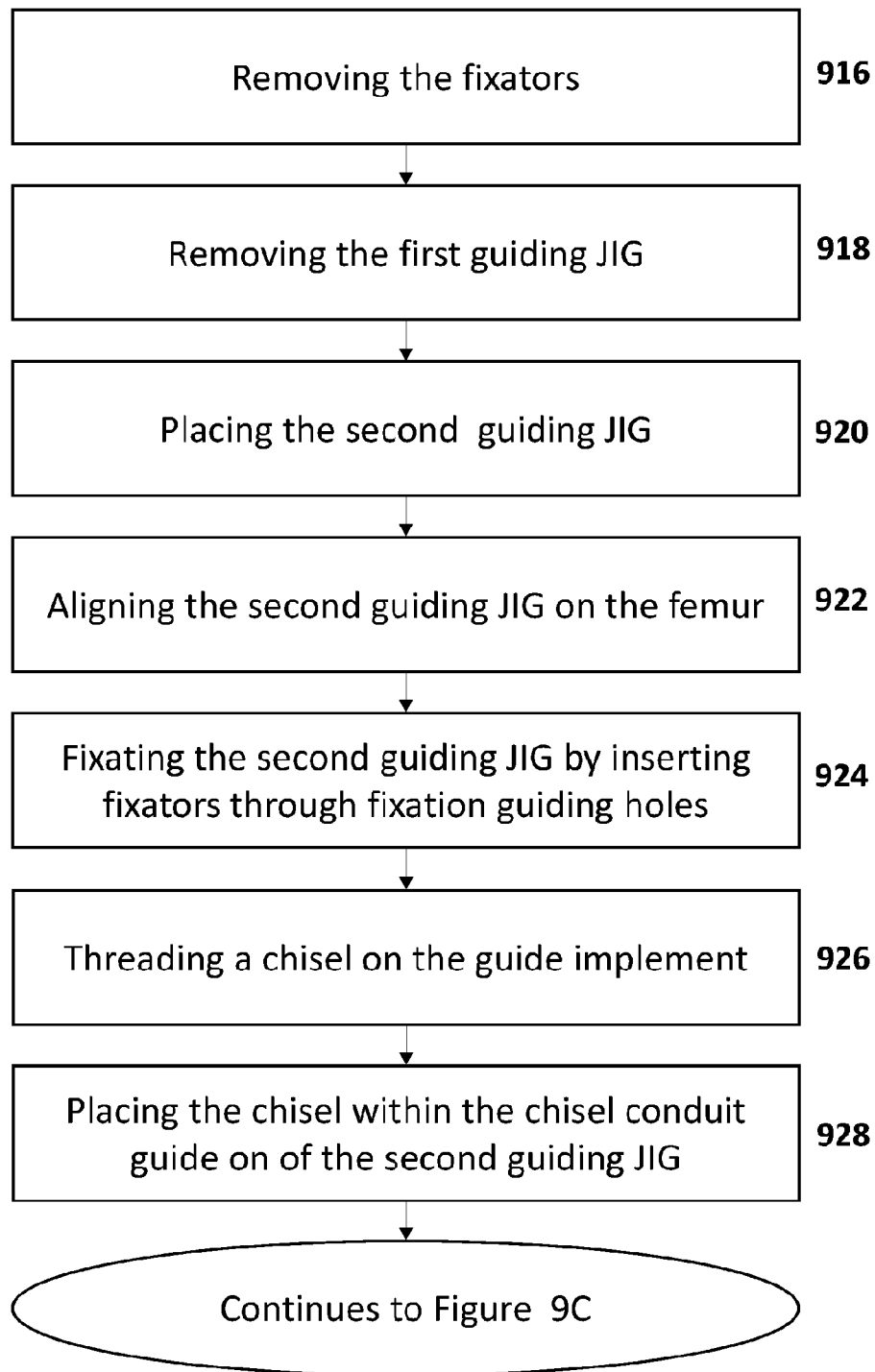
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**Figure 8C**

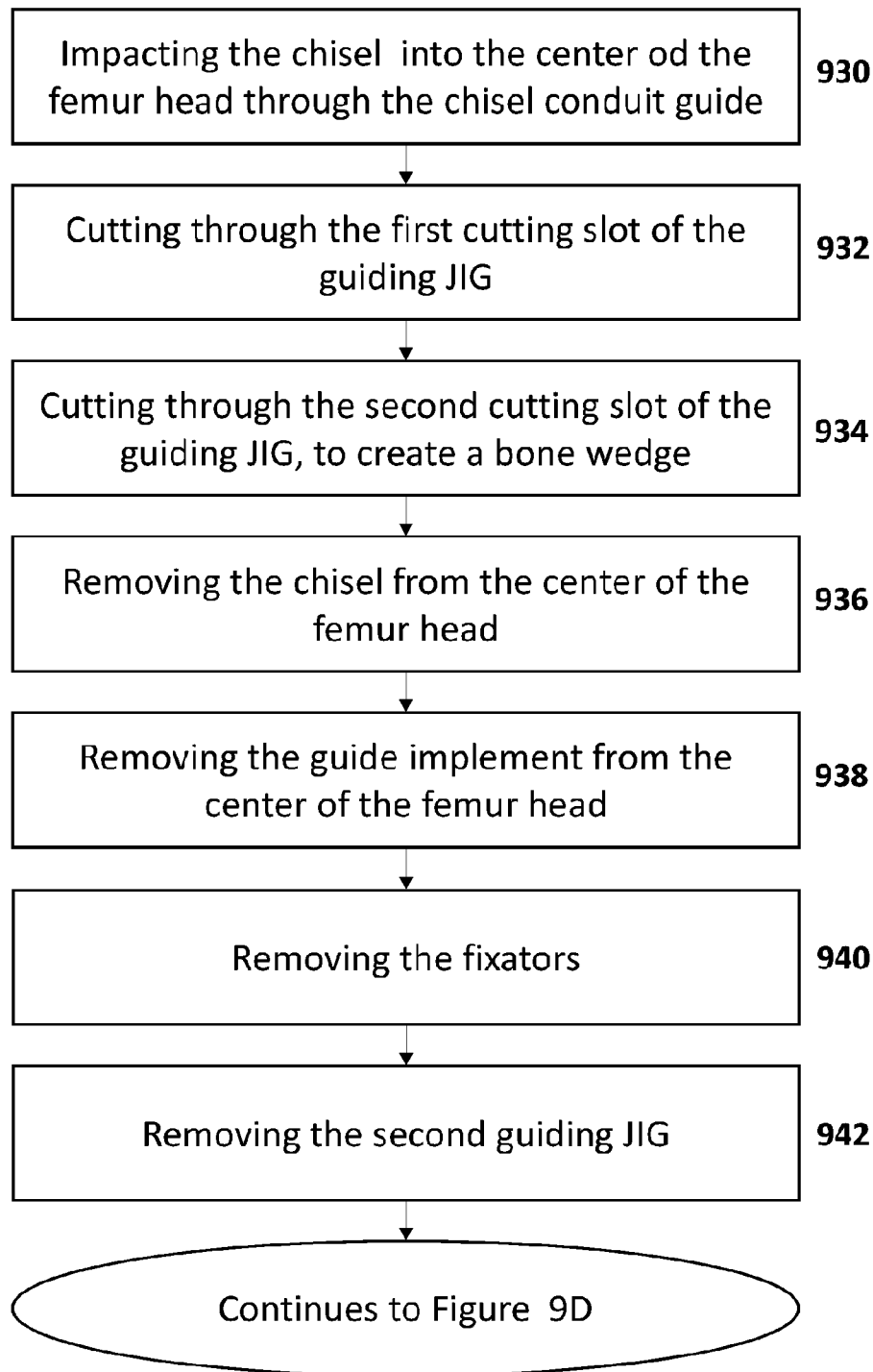
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**Figure 9A**

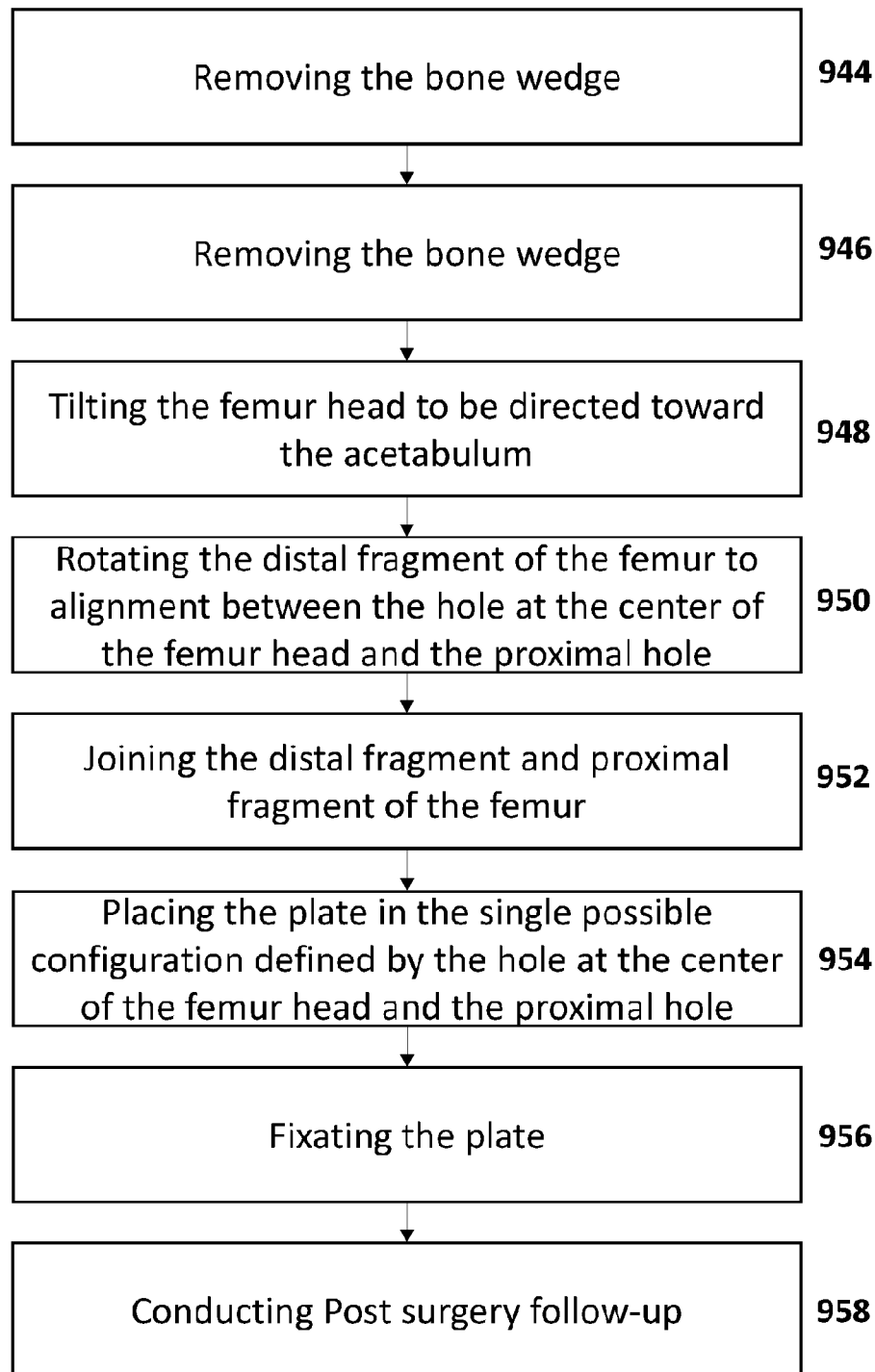
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**Figure 9B**

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**Figure 9C**

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**Figure 9D**

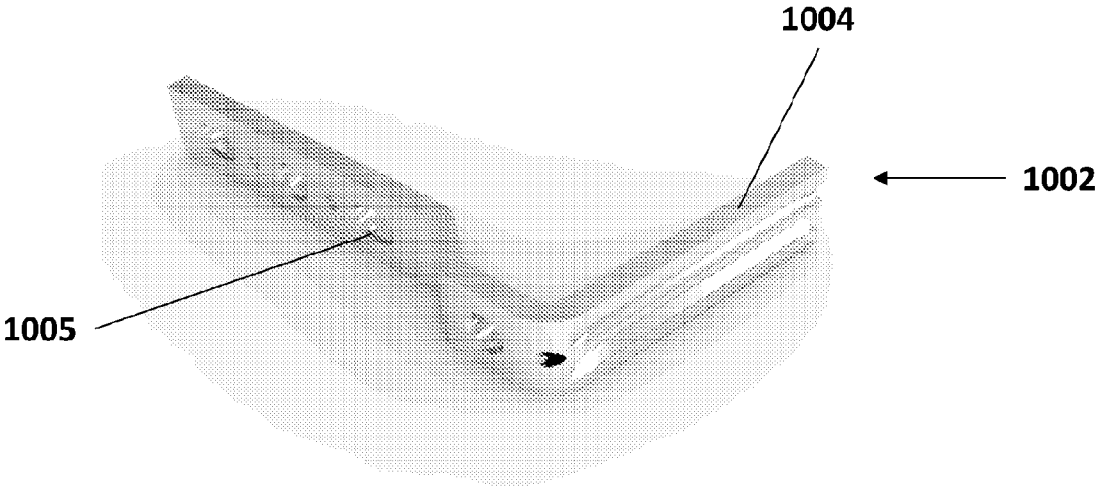


Figure 10

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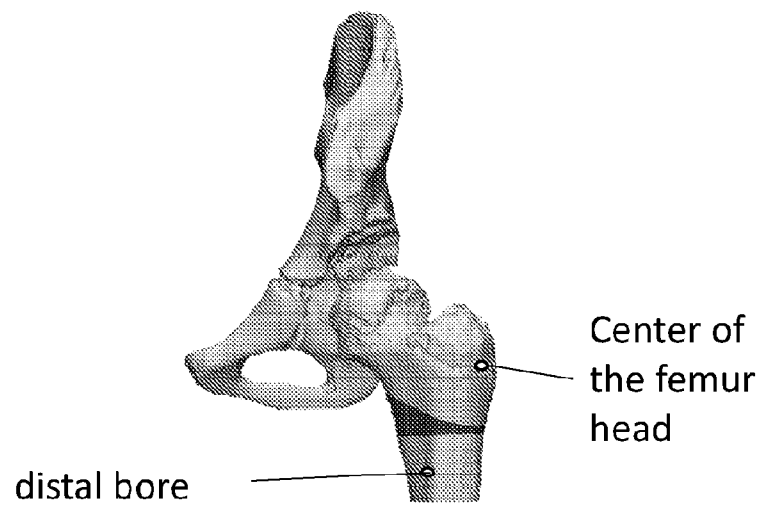


Figure 11

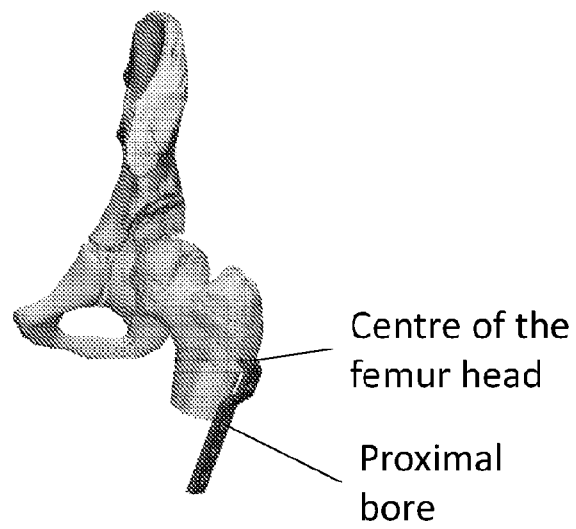
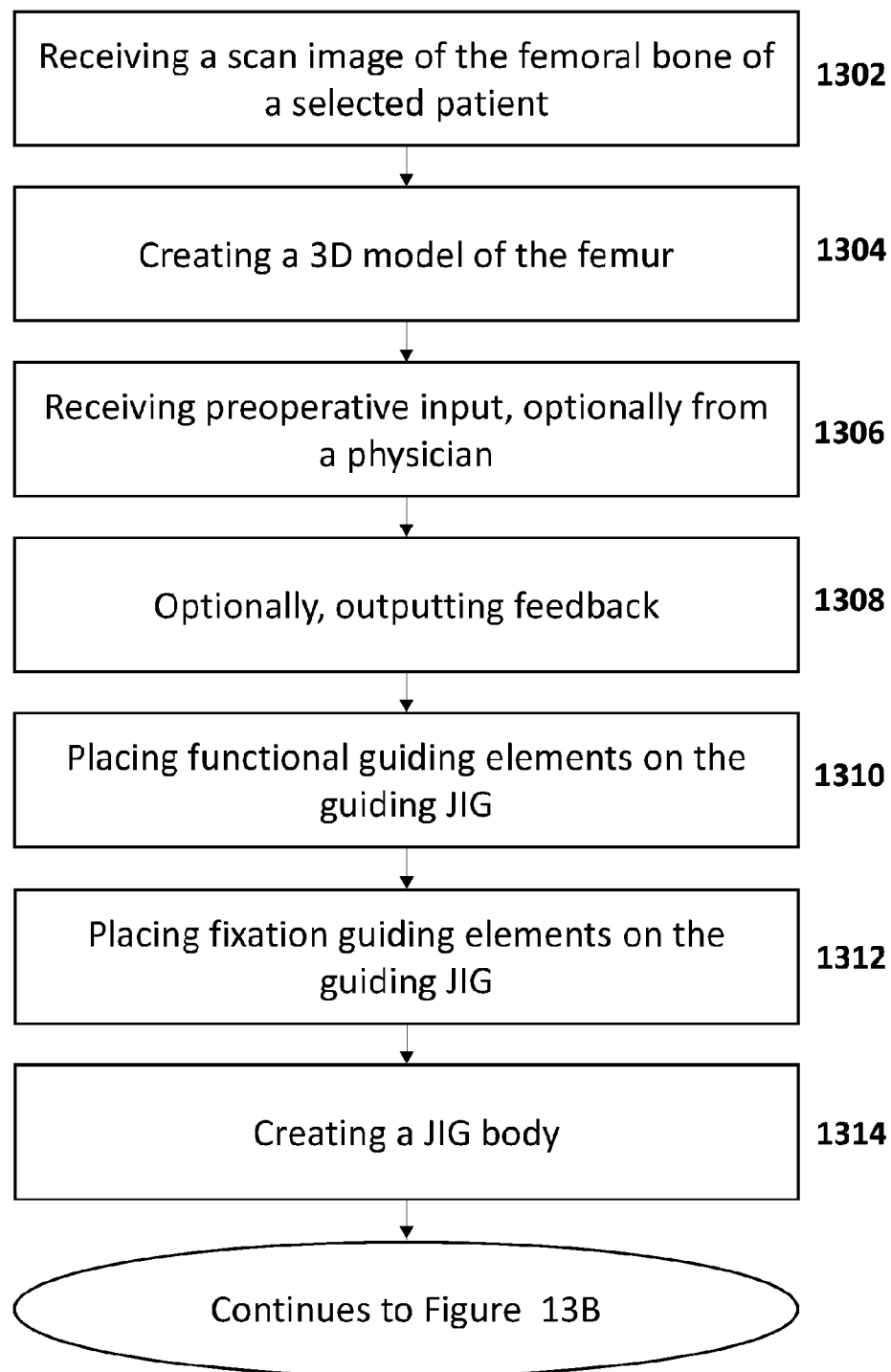
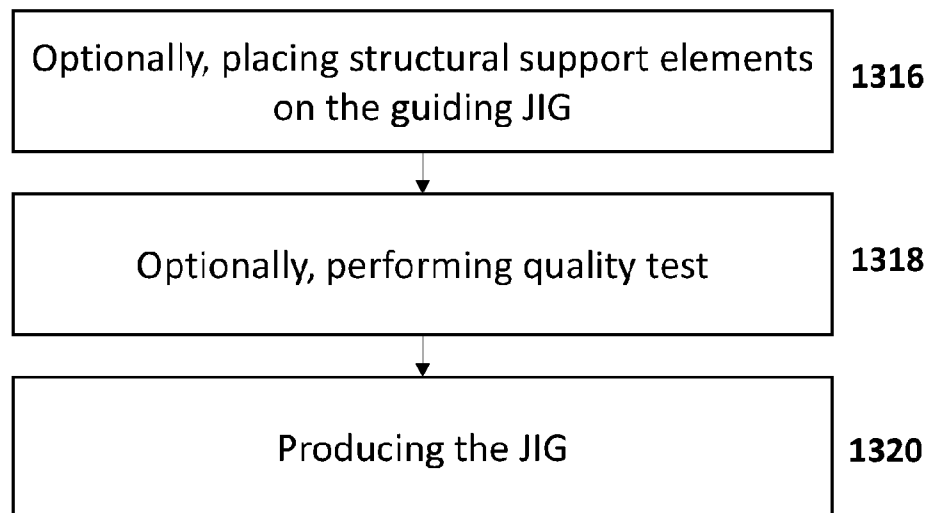


Figure 12

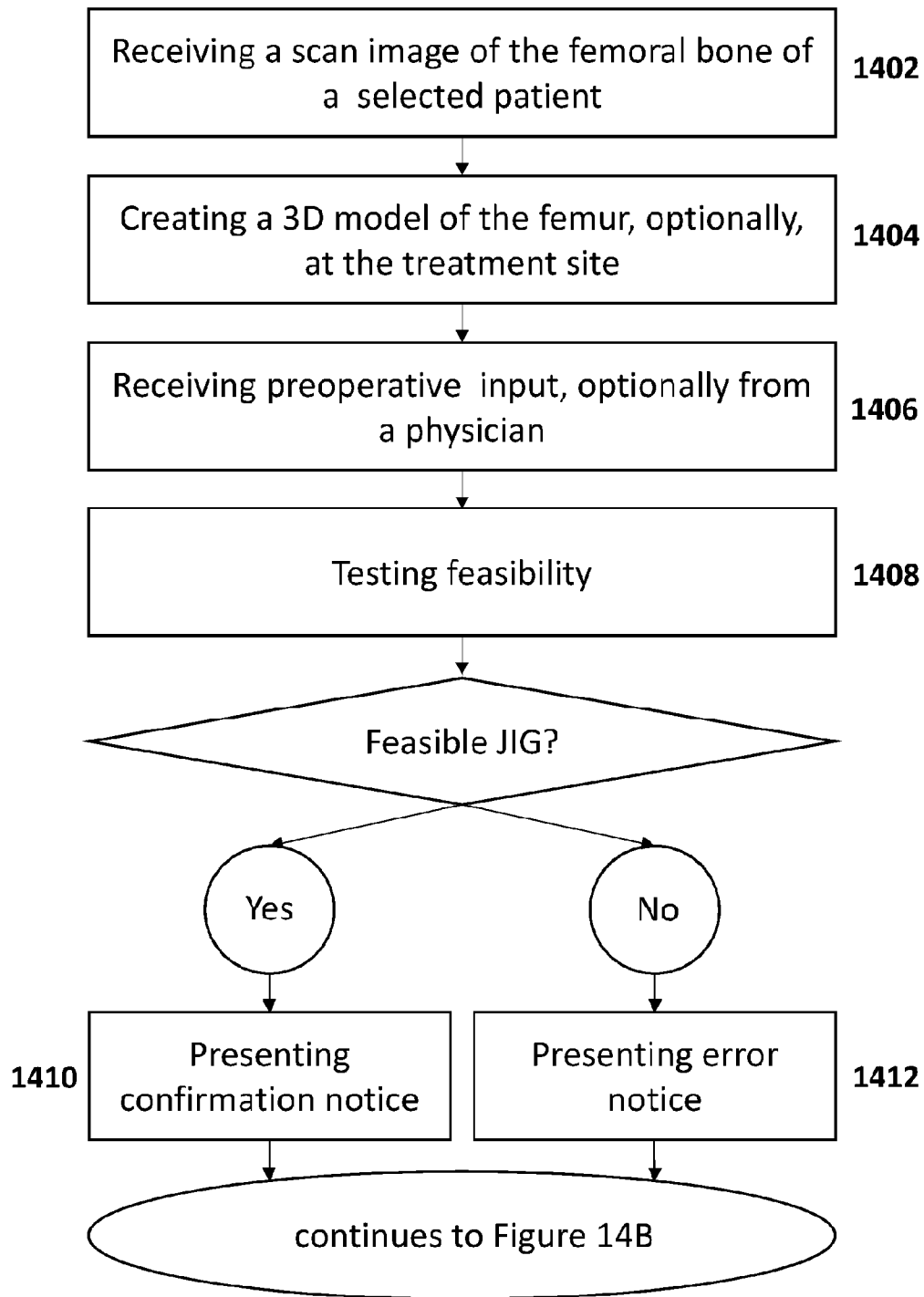
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**Figure 13A**

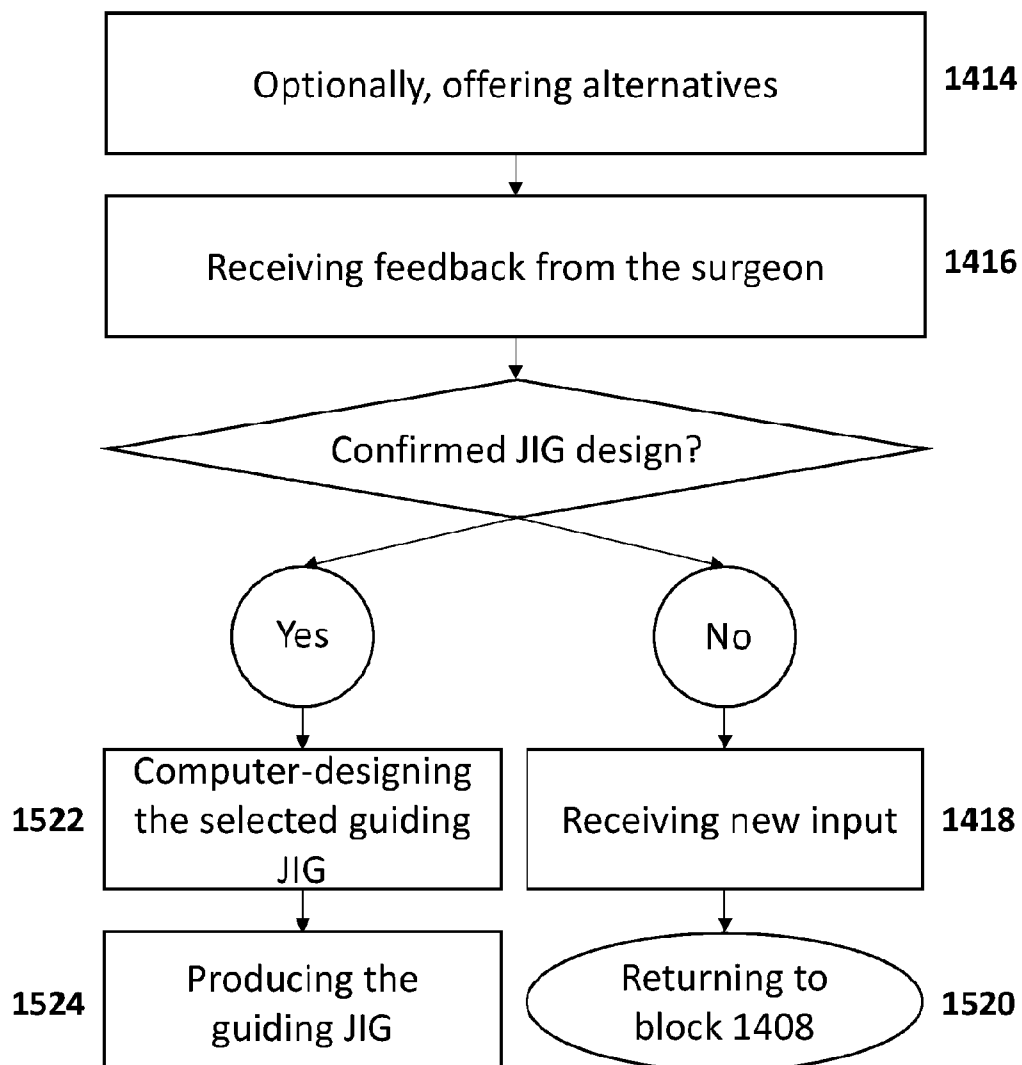
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**Figure 13B**

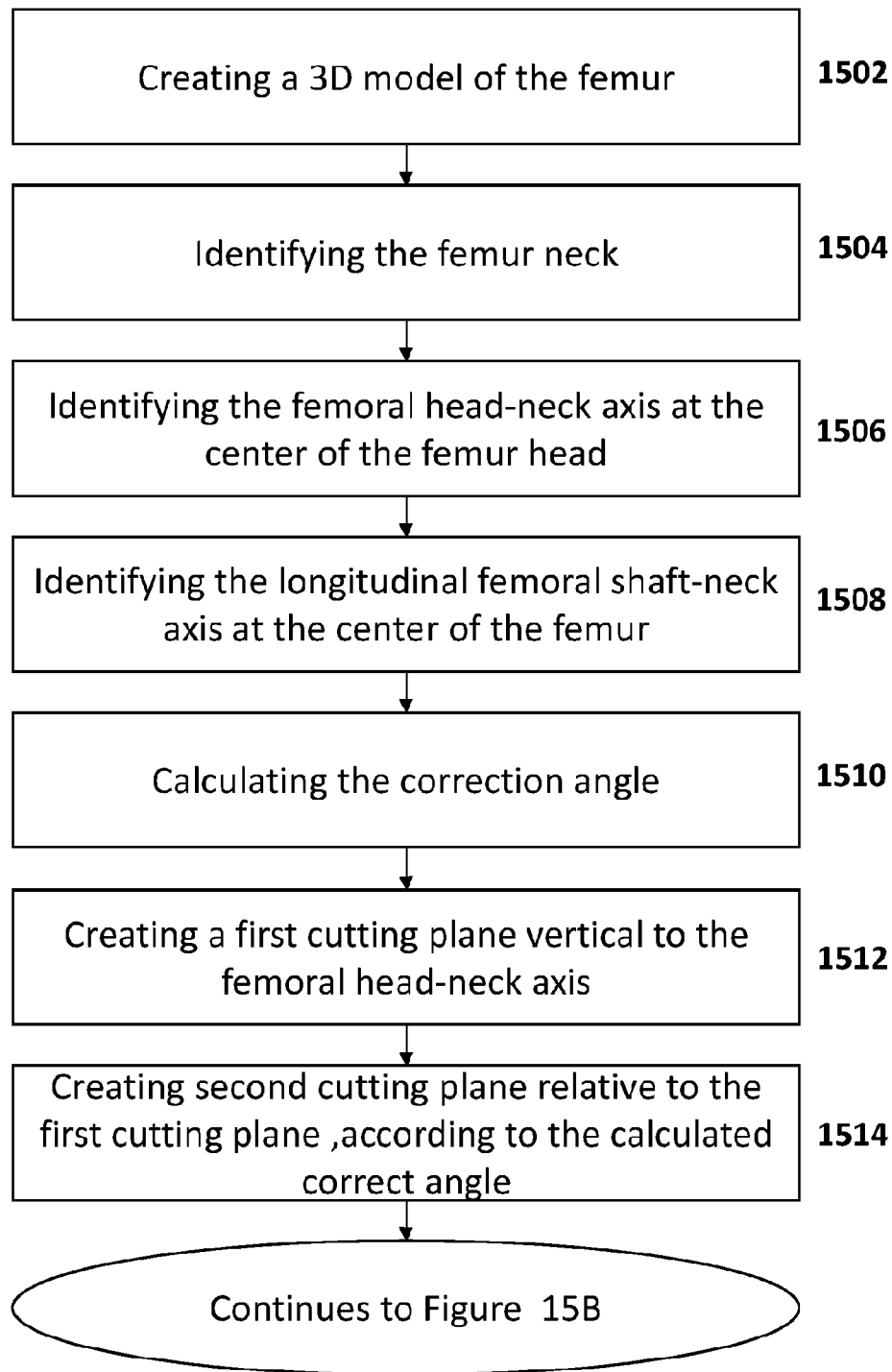
27/56

**Figure 14A**

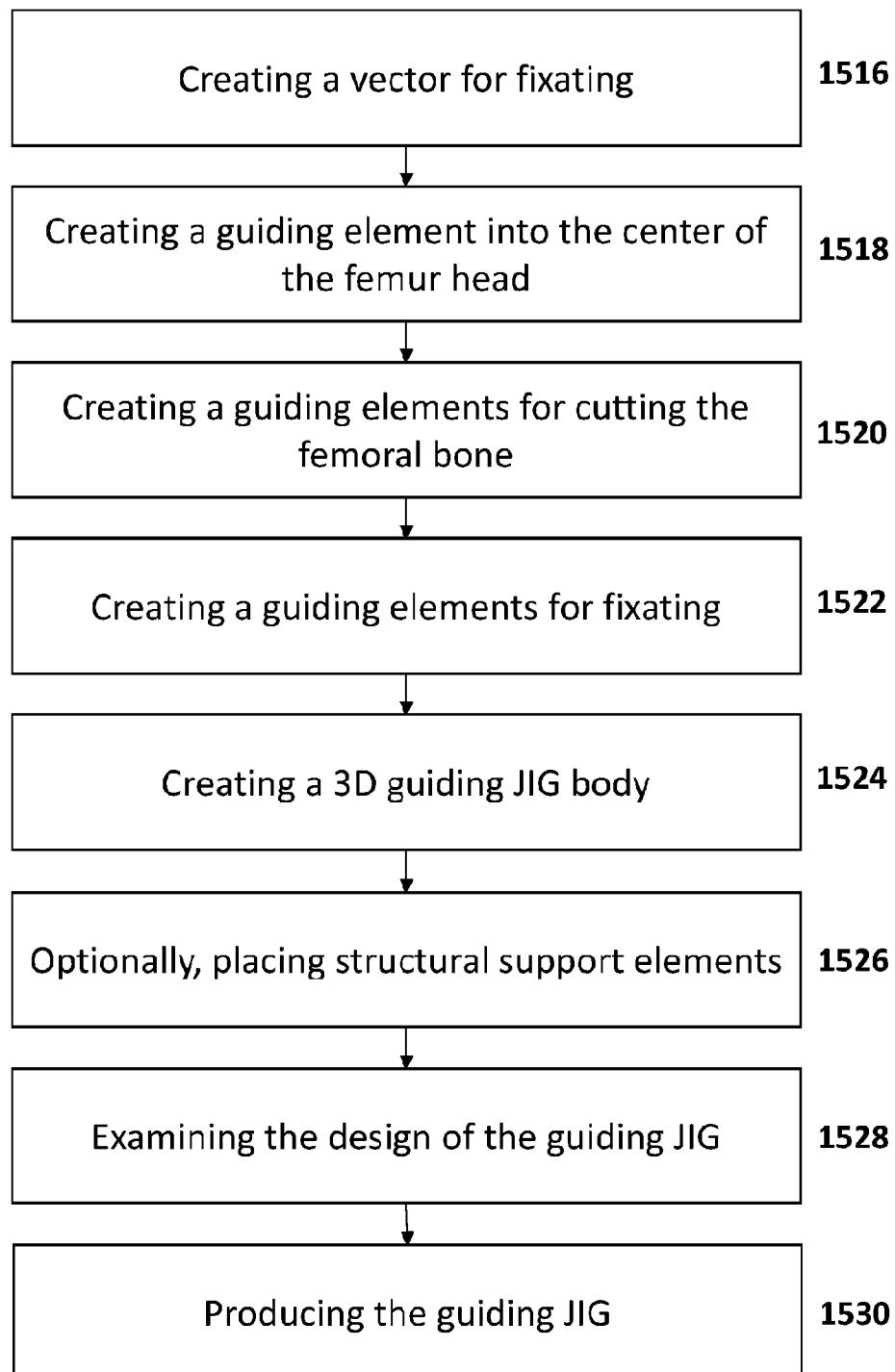
28/56

**Figure 14B**

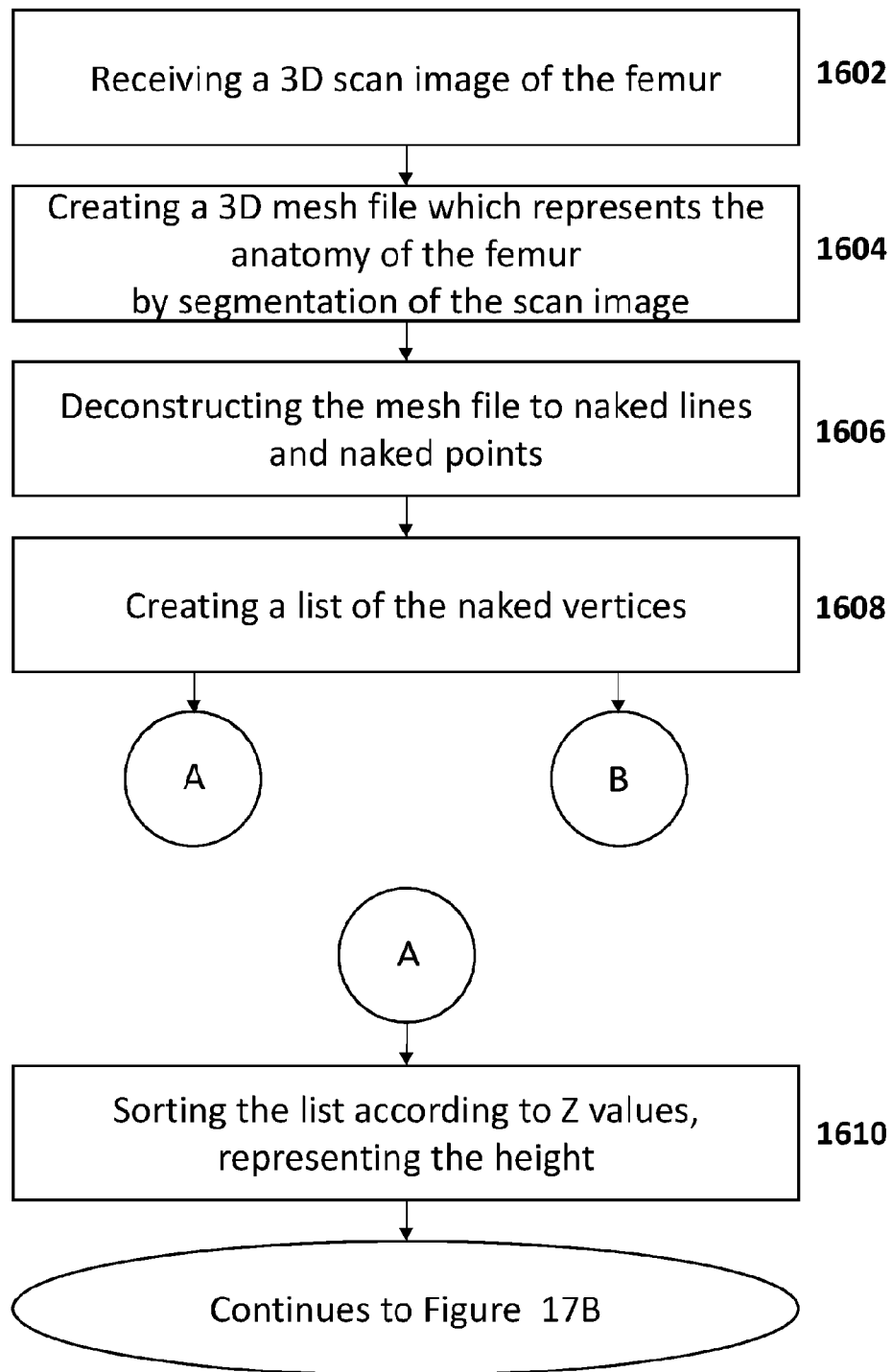
29/56

**Figure 15A**

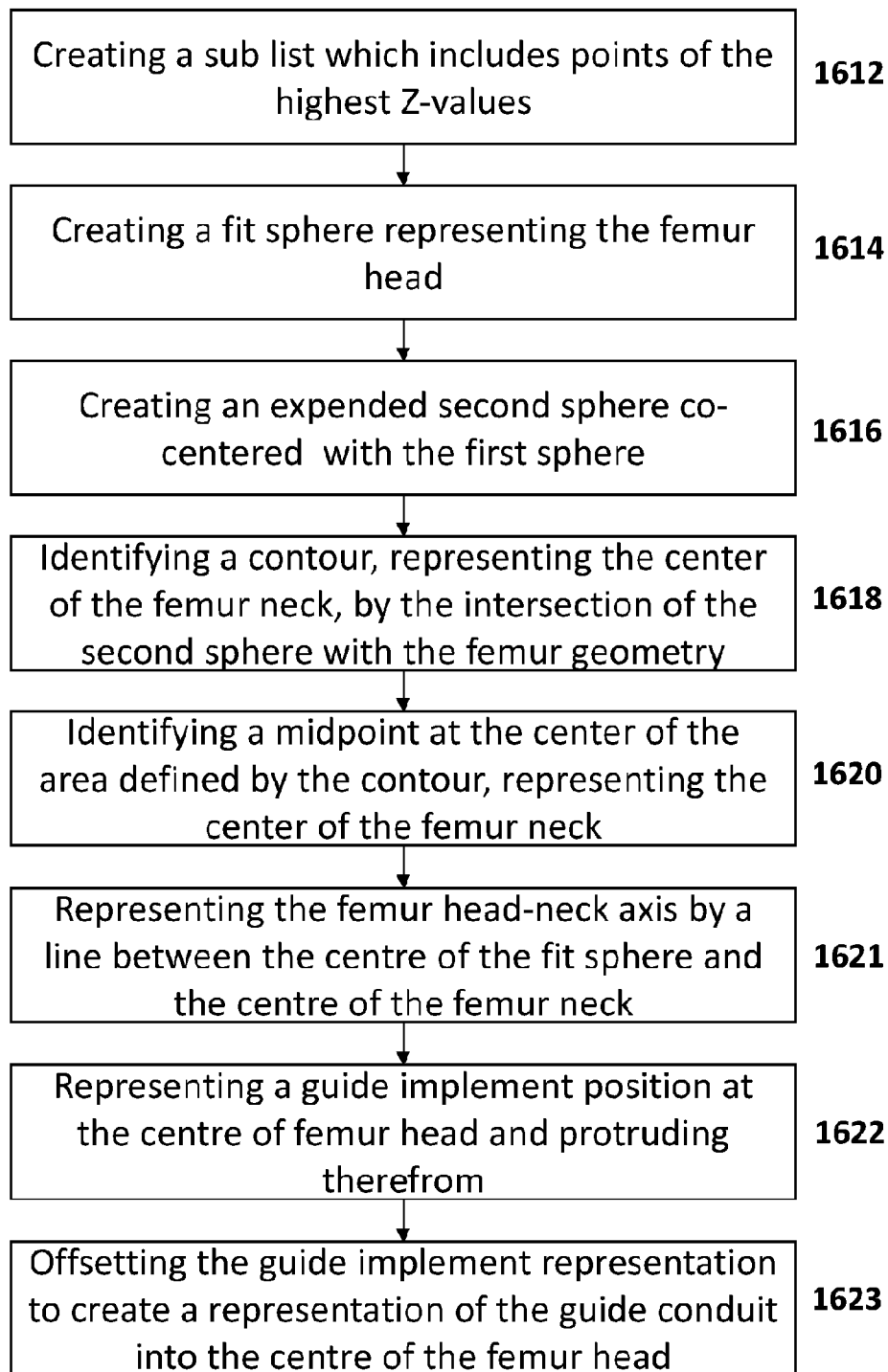
30/56

**Figure 15B**

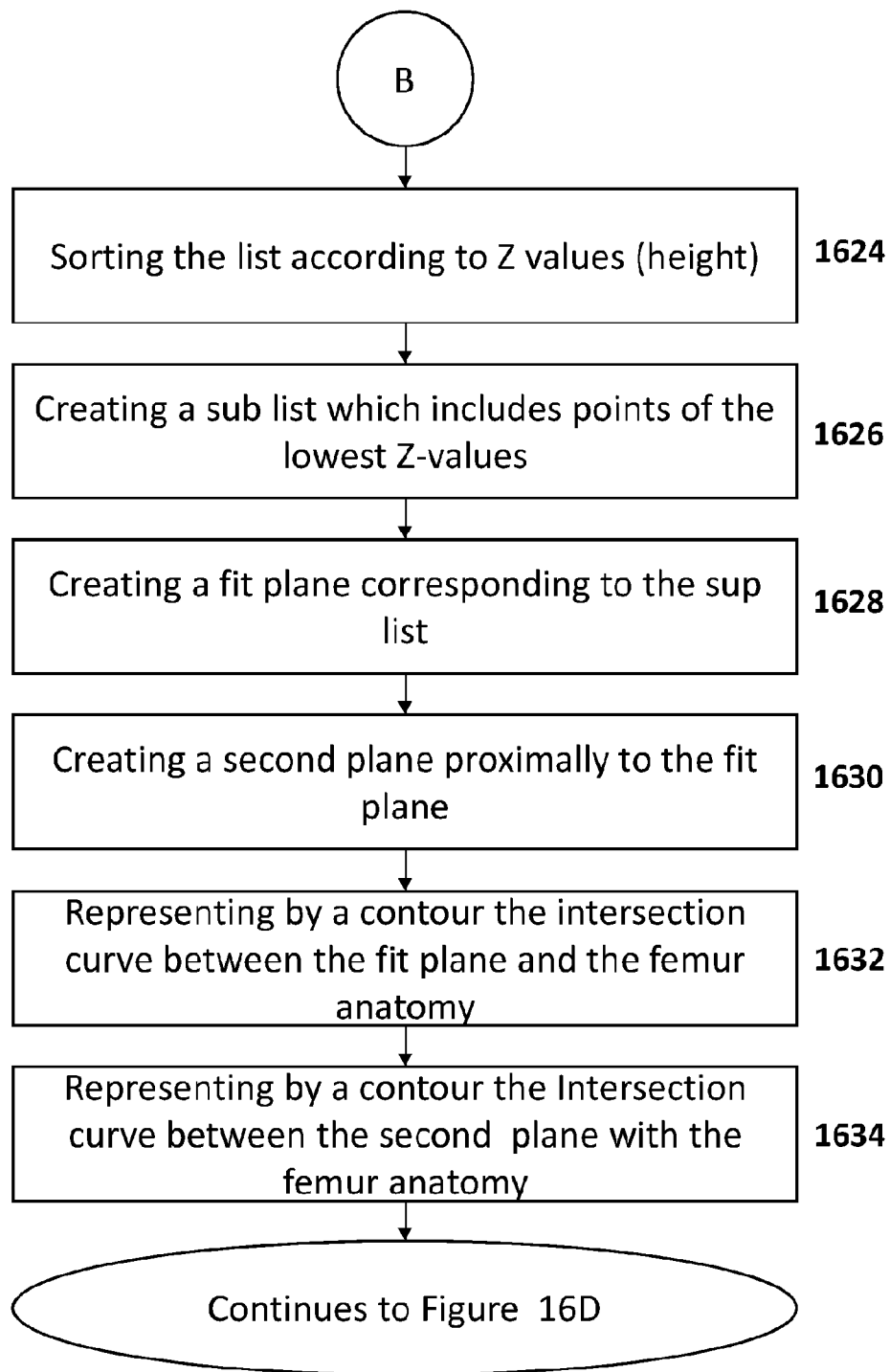
31/56

**Figure 16A**

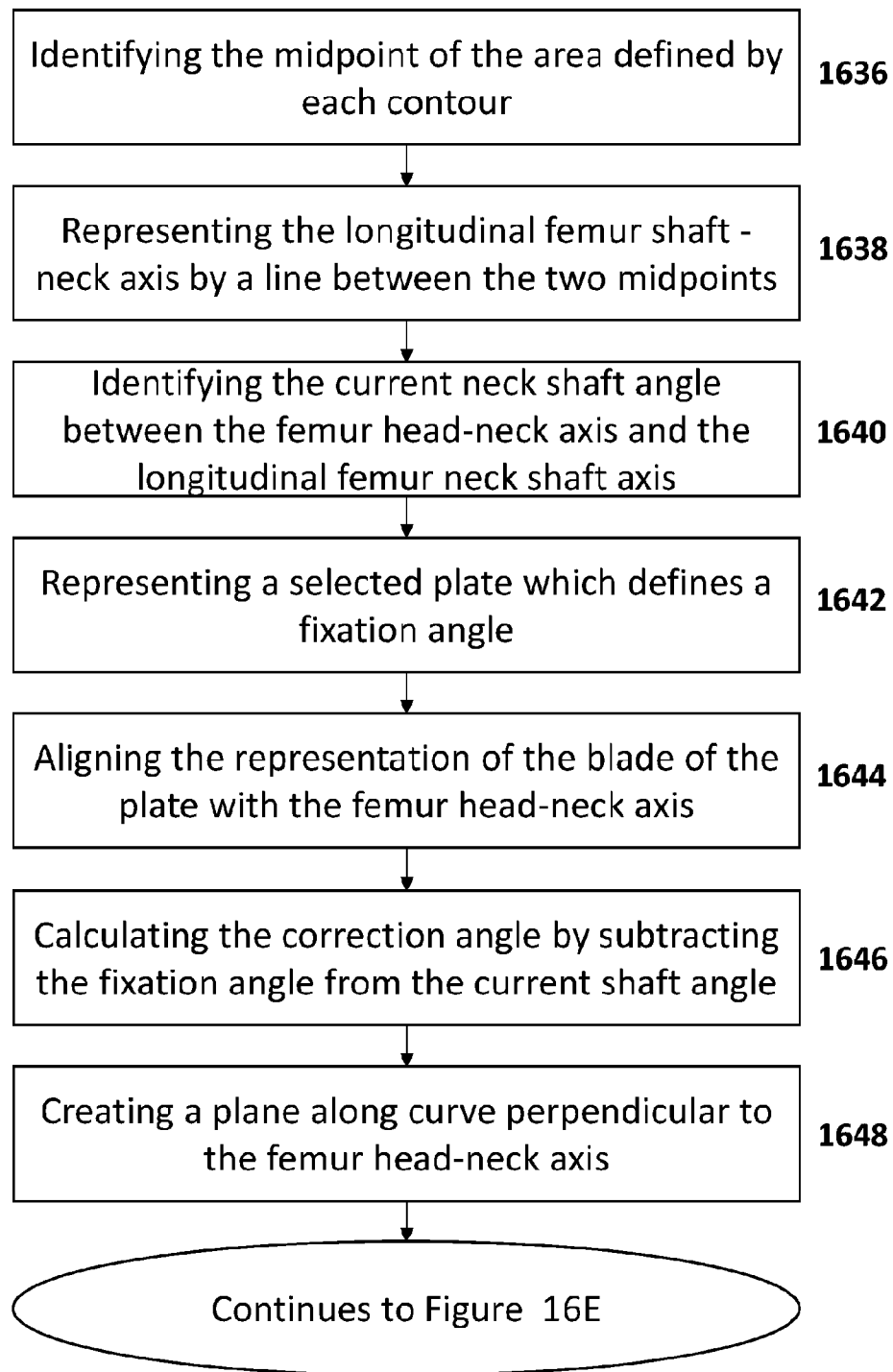
32/56

**Figure 16B**

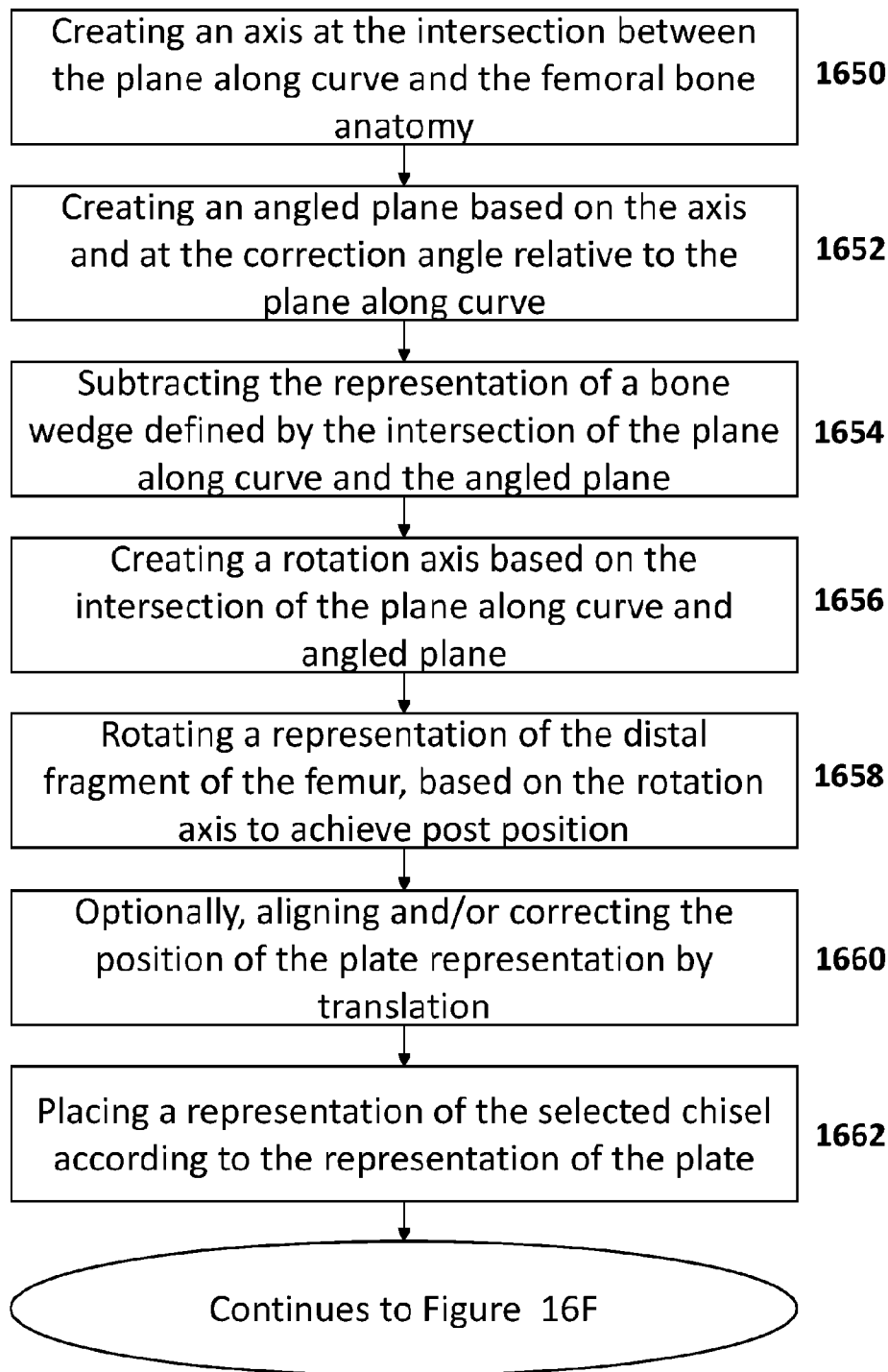
33/56

**Figure 16C**

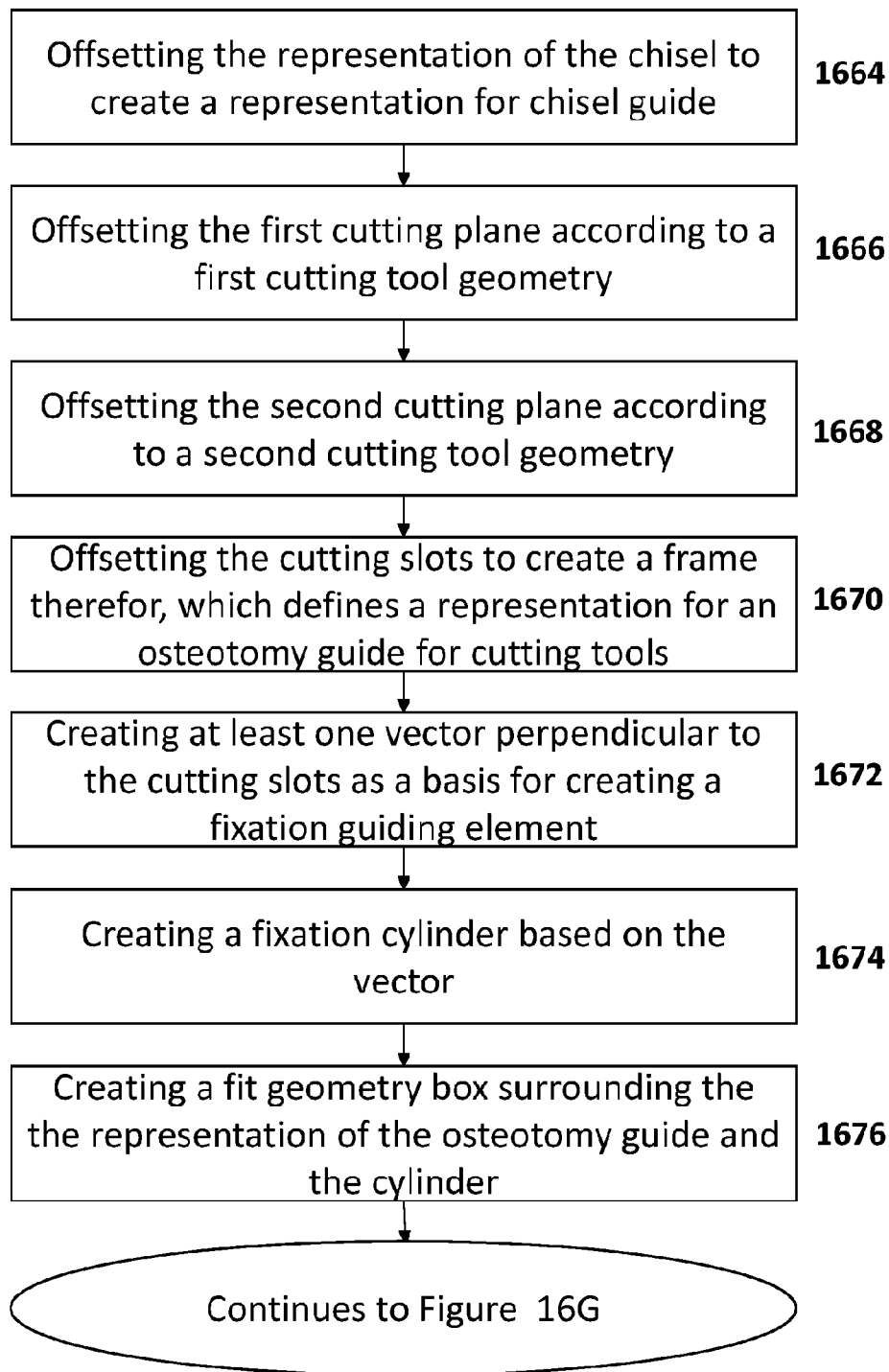
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**Figure 16D**

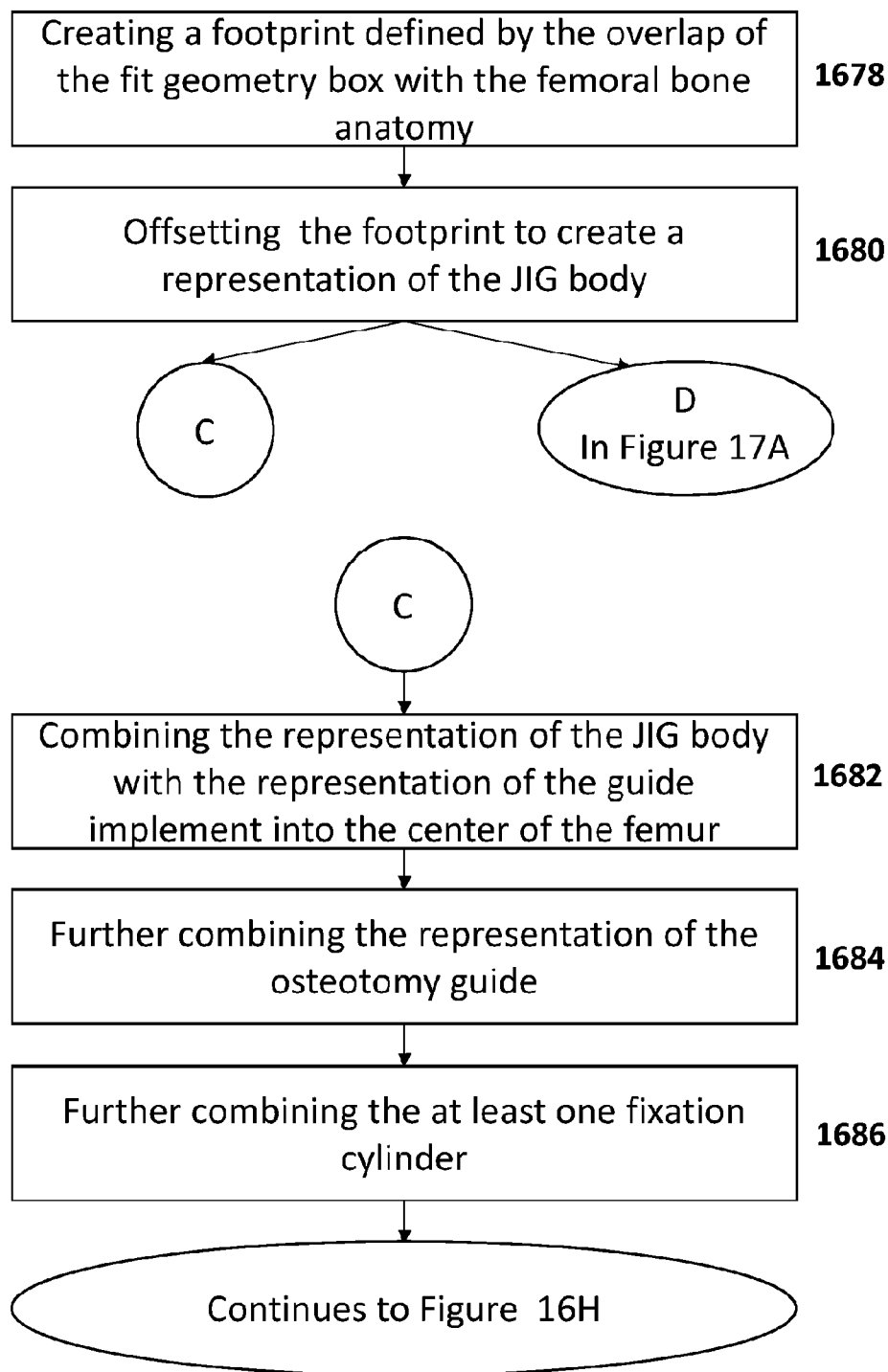
35/56

**Figure 16E**

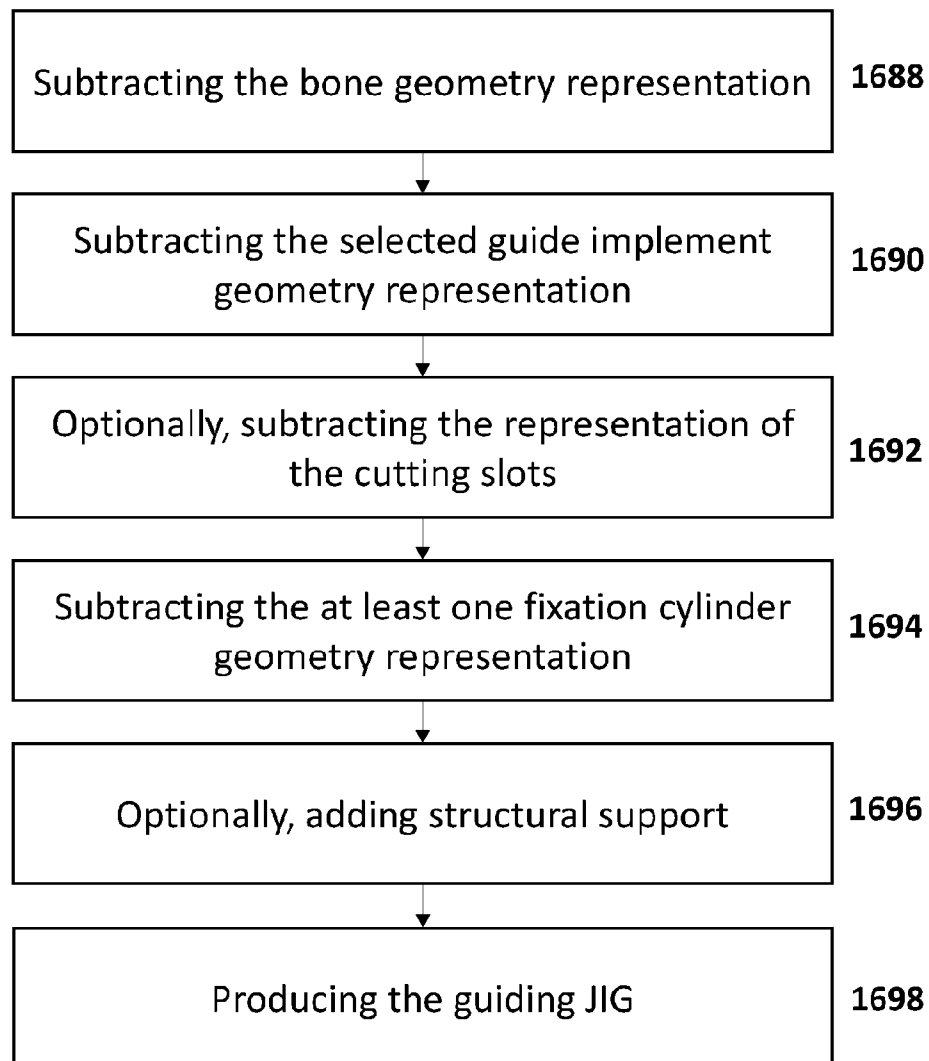
36/56

**Figure 16F**

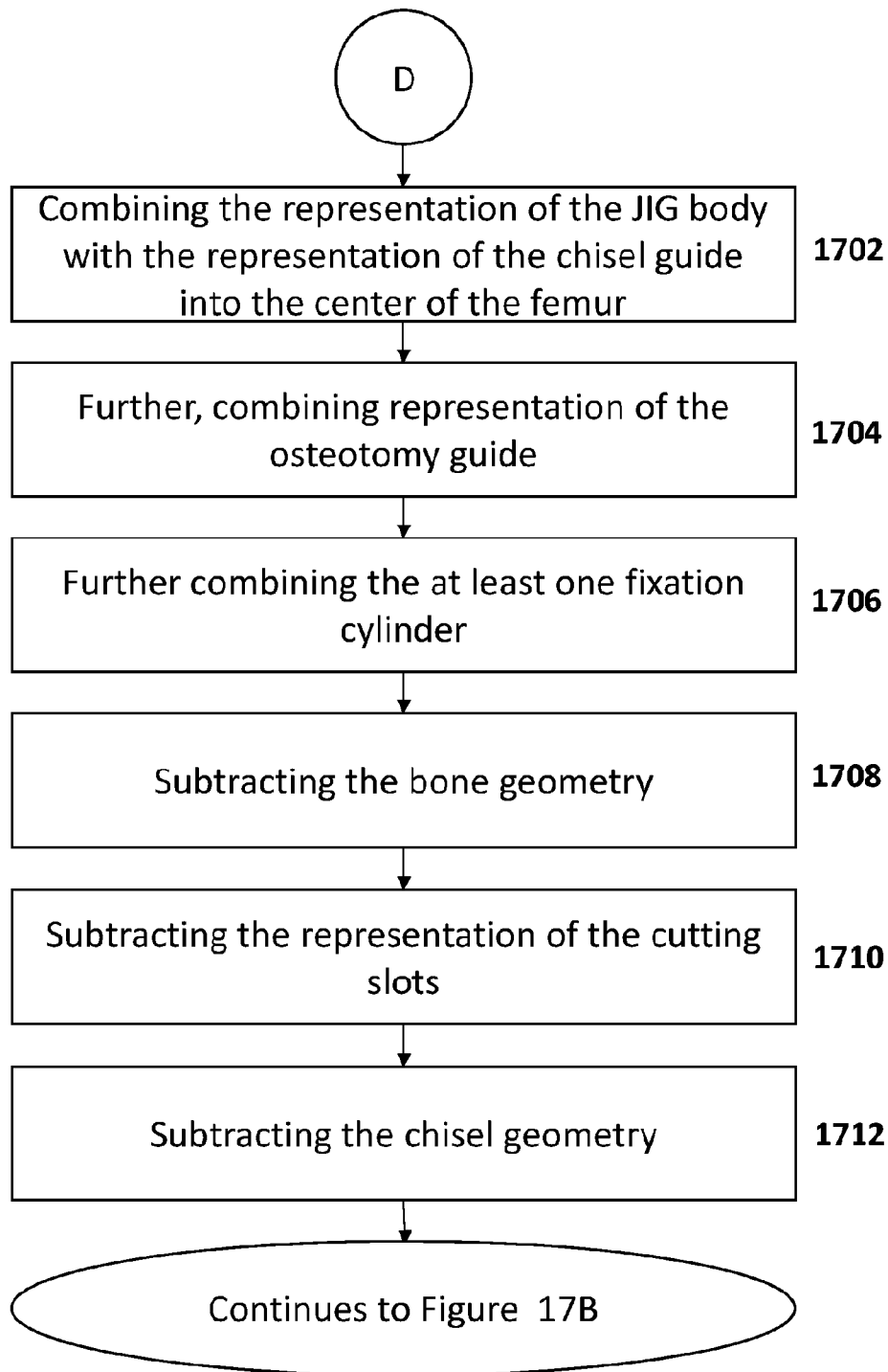
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**Figure 16G**

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**Figure 16H**

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**Figure 17A**

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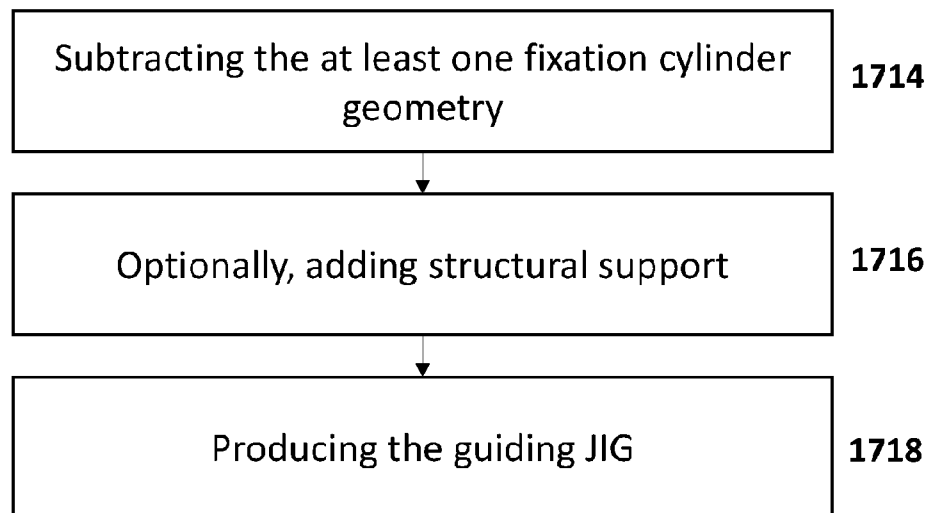
**Figure 17B**



Figure 18A

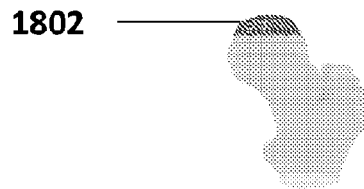


Figure 18B

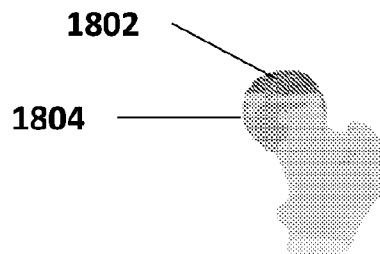


Figure 18C

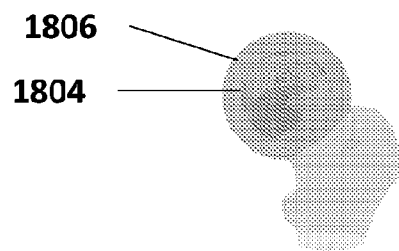


Figure 18D

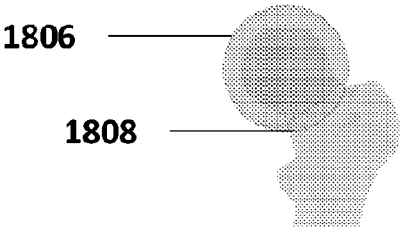


Figure 18E

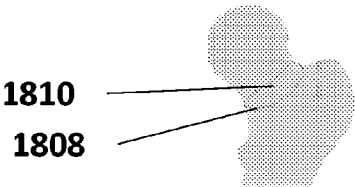


Figure 18F

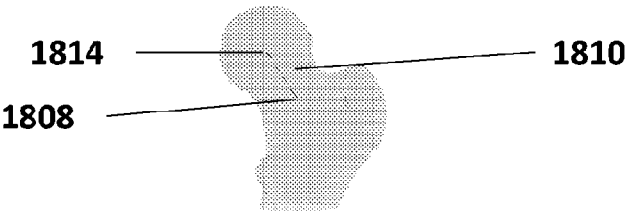


Figure 18G

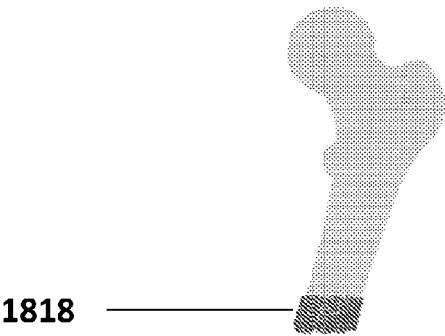


Figure 18H

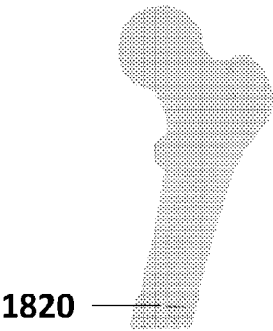


Figure 18I

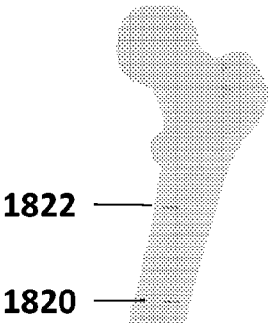


Figure 18J

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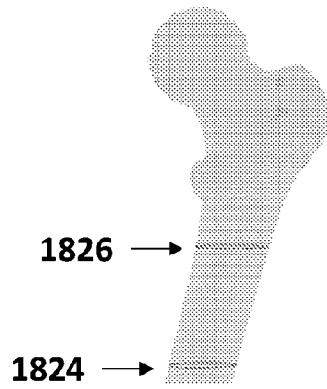


Figure 18K

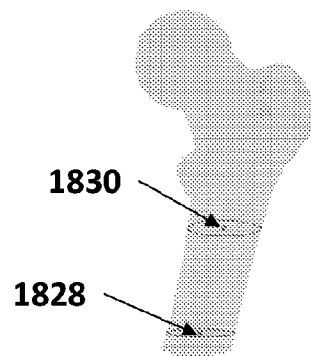


Figure 18L

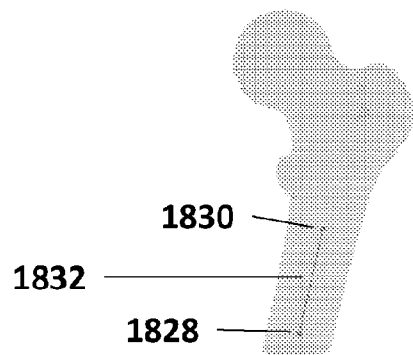


Figure 18M

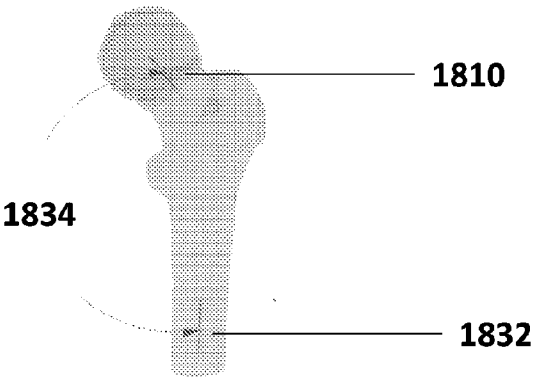


Figure 18N

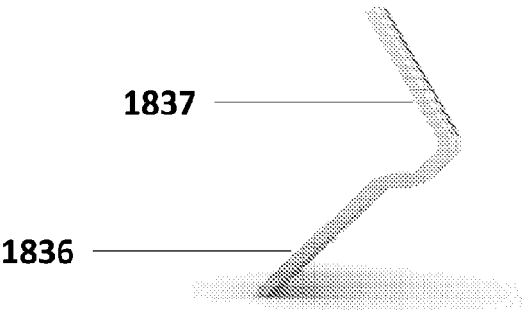


Figure 18O

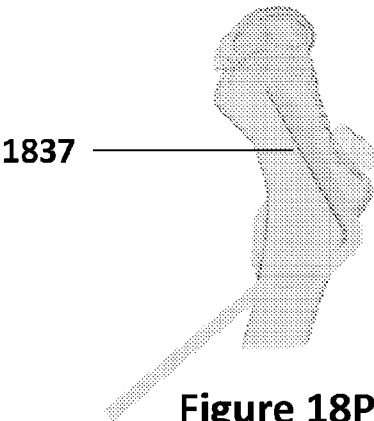


Figure 18P

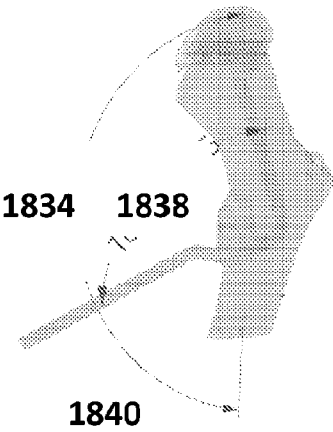


Figure 18Q

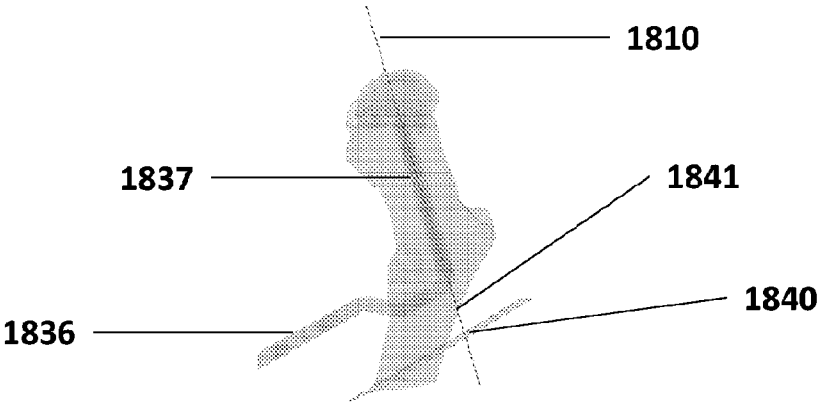


Figure 18R

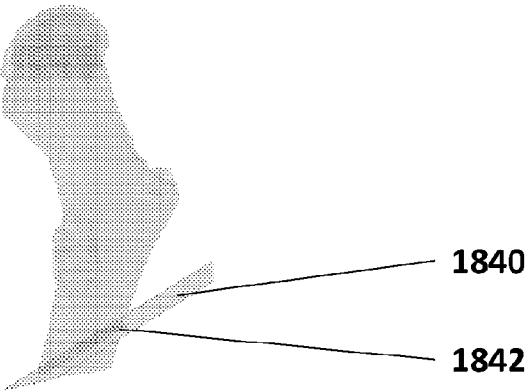


Figure 18S

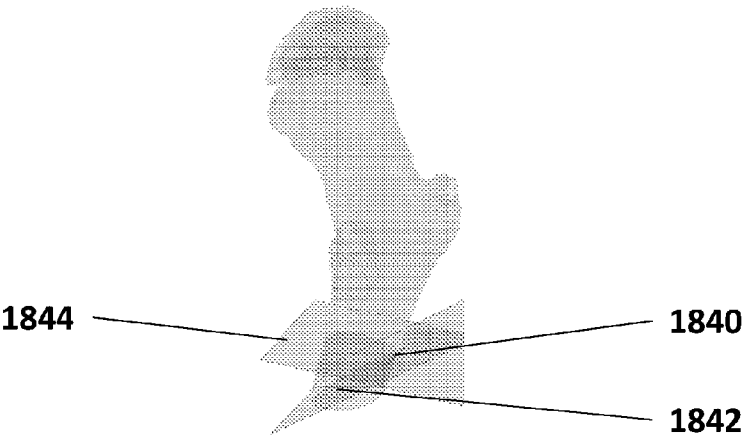


Figure 18T

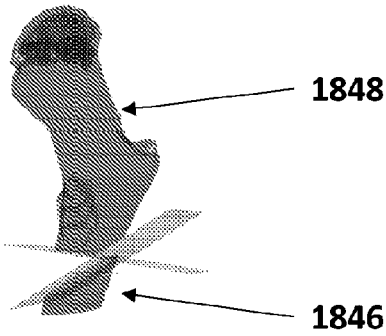


Figure 18U



Figure 18V

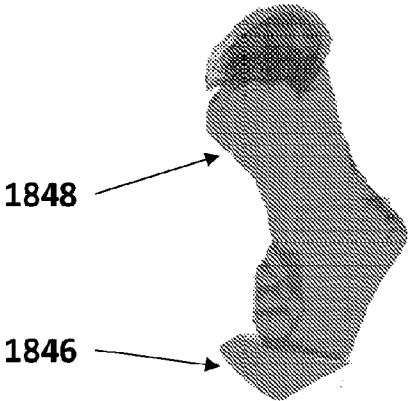


Figure 18W

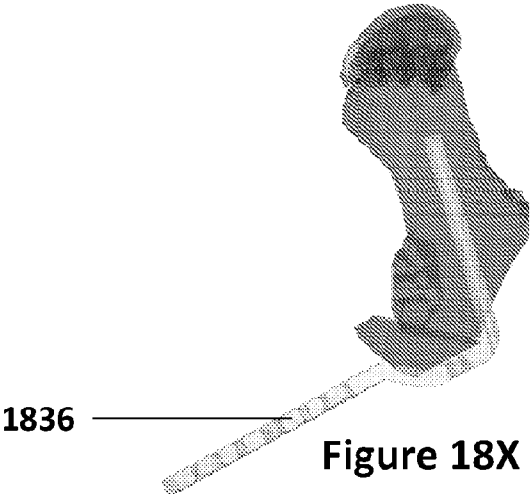


Figure 18X

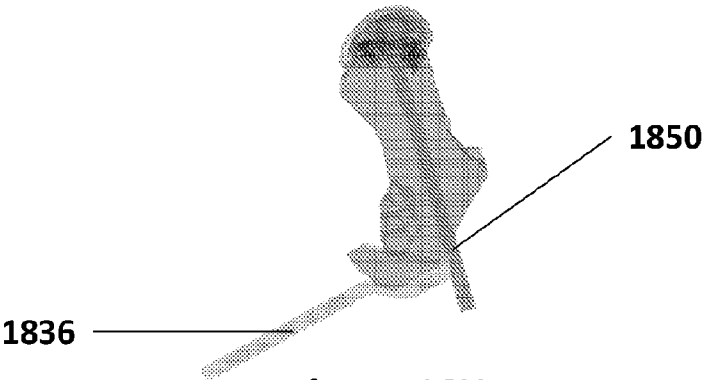


Figure 18Y

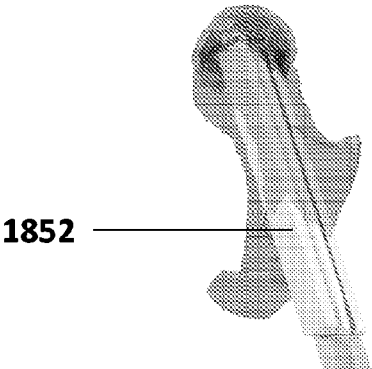


Figure 18Z

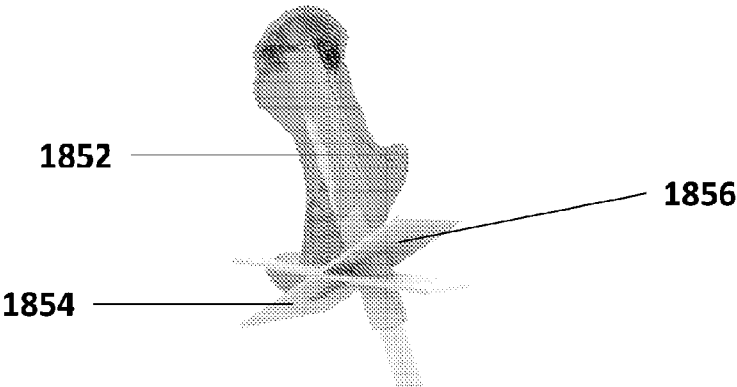


Figure 19A



Figure 19B

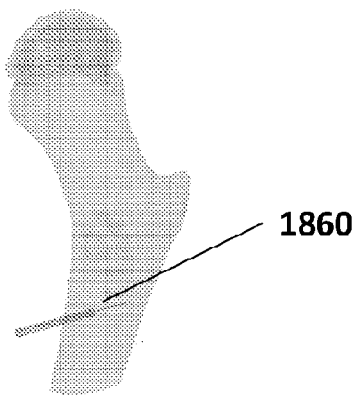


Figure 19C

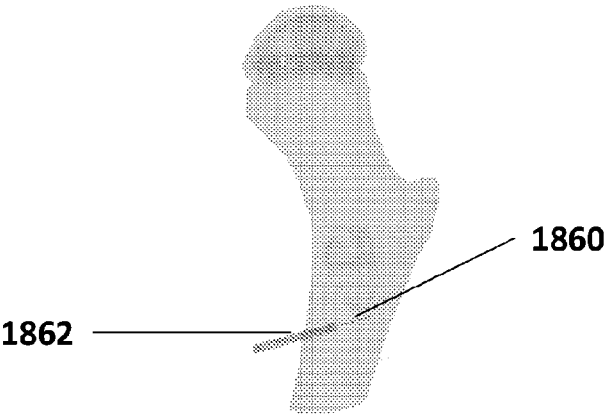


Figure 19D



Figure 19E

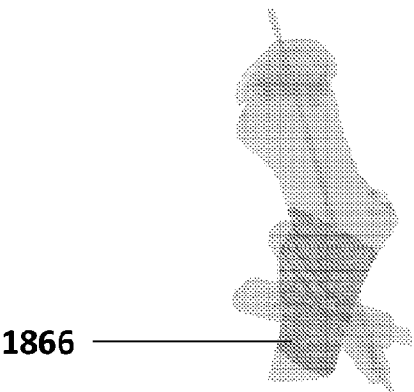


Figure 19F

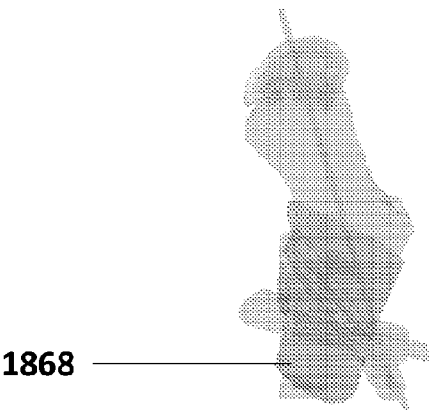


Figure 19G

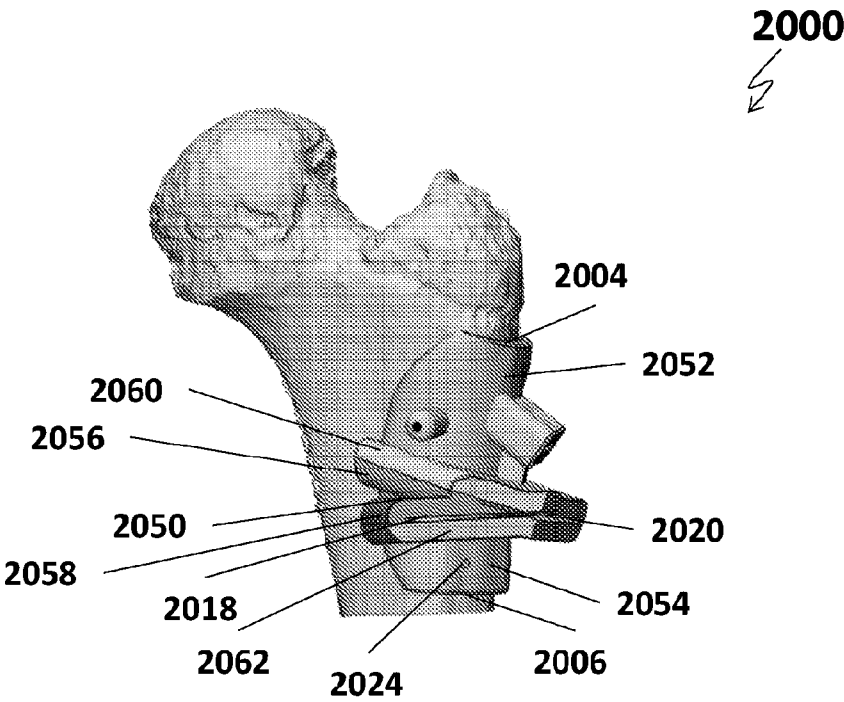


Figure 20A

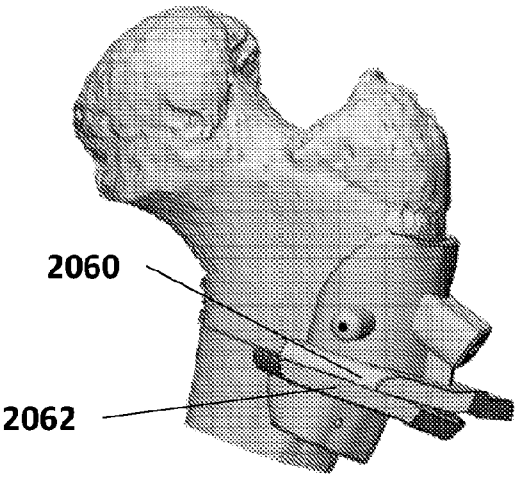


Figure 20B

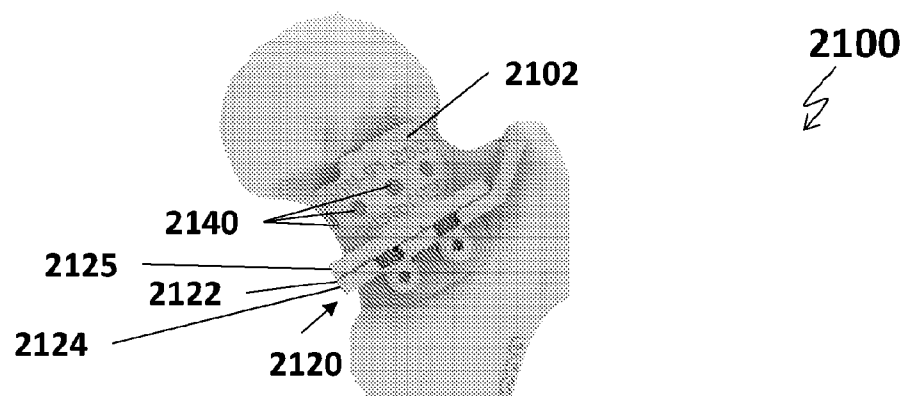


Figure 21A

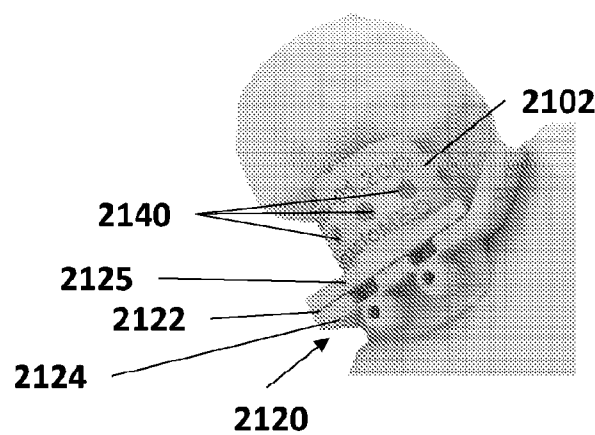


Figure 21B

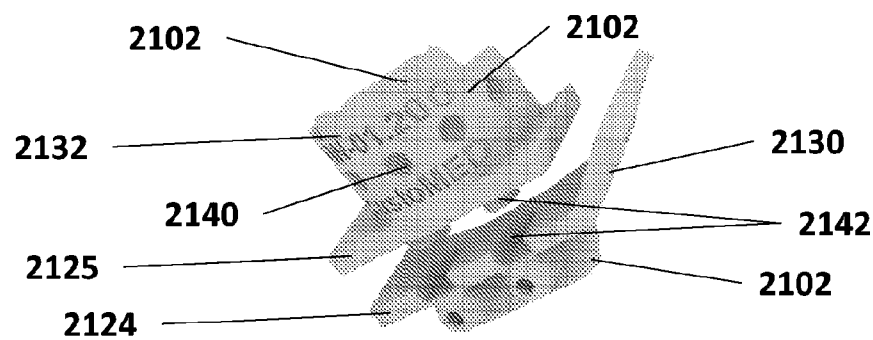


Figure 21C

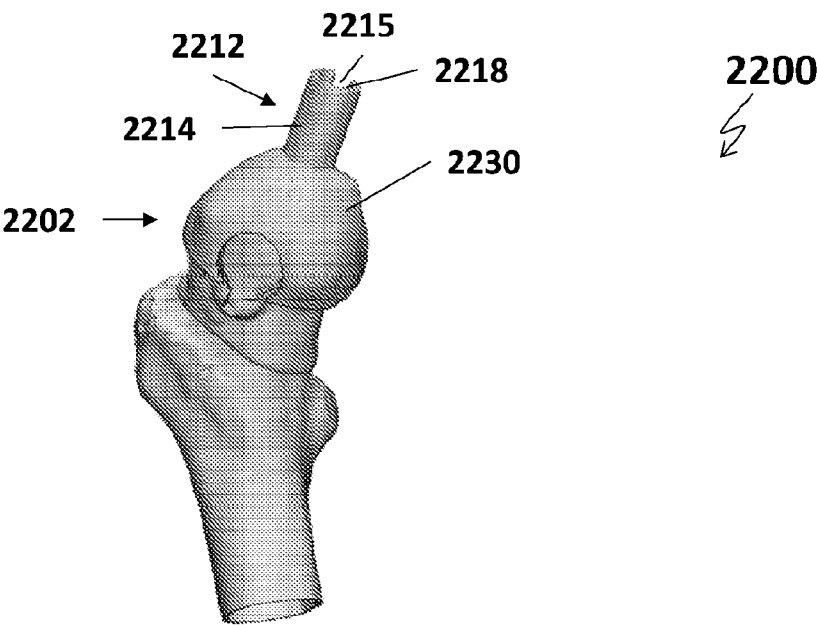


Figure 22A

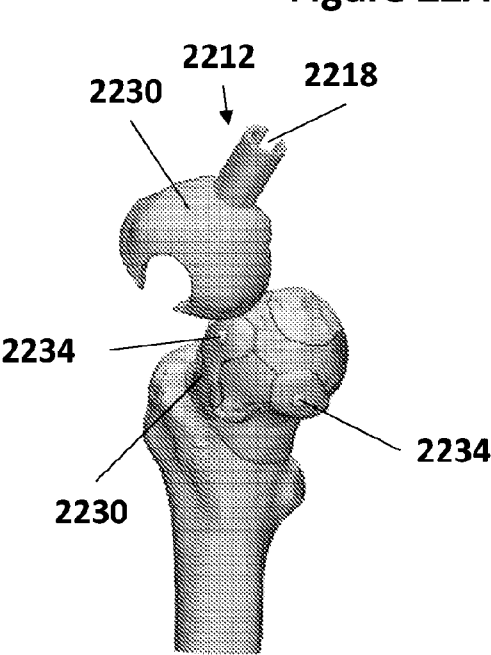


Figure 22B

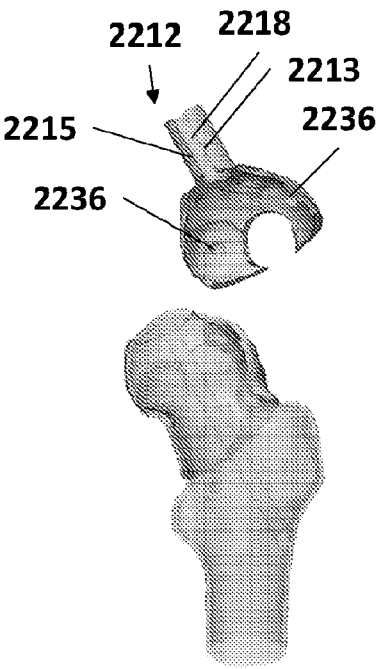


Figure 22C

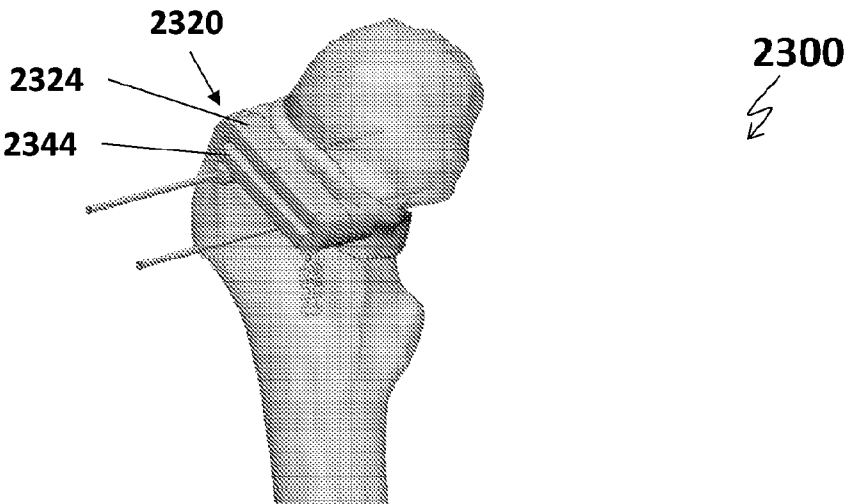


Figure 23A

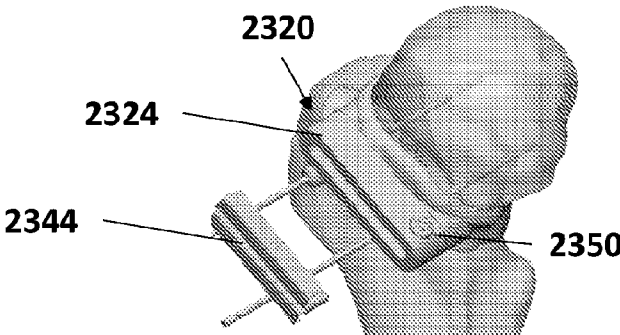


Figure 23C

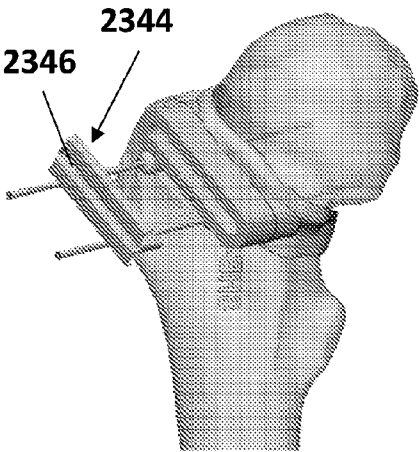


Figure 23B

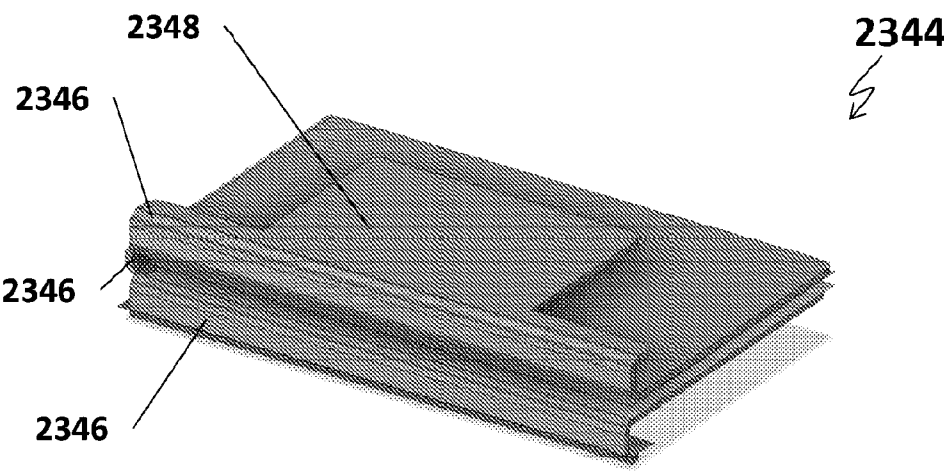


Figure 23D

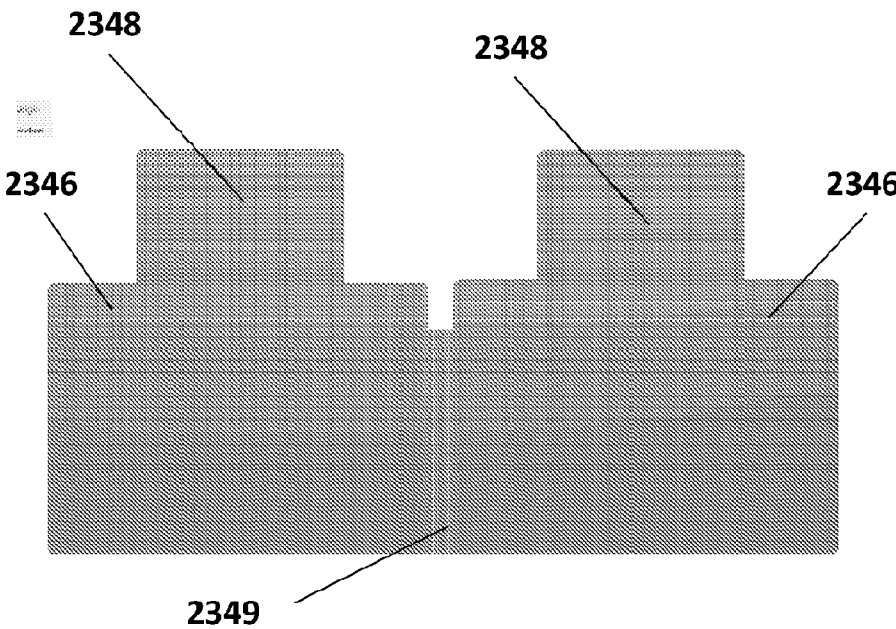


Figure 23E