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(54) **Title**: PATIENT-MATCHED ACETABULAR GUIDE

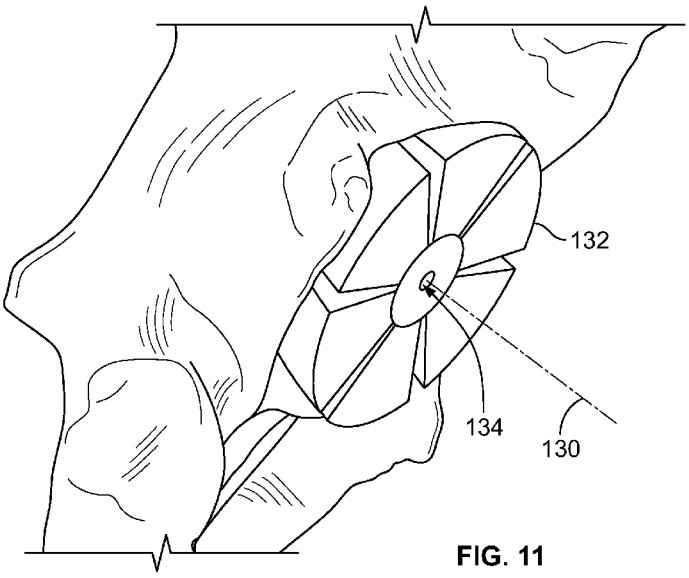

FIG. 11

(57) **Abstract**: Systems, devices, and methods for accurately aligning a reference pin within a patient's acetabulum are provided. A patient's acetabular anatomy is imaged and modeled using a computer modeling approach to identify landmarks on the patient's acetabulum. A coordinate system is applied to the anatomical model, and a desired implant axis is defined based on the applied coordinate system. A guide device is created with one or more guide passages aligned with the desired implant axis for accurately placing an acetabular reference pin. The guide devices are patient-matched to an individual patient's anatomy and are expandable to provide an adequate grip on the acetabulum during pin placement. A reference pin fixed into the acetabulum provides a reference axis that corresponds to the desired implant access and can be used for alignment of tools and implants in the acetabulum.

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PATIENT-MATCHED ACETABULAR GUIDE

Cross-Reference to Related Applications

[0001] This application claims the benefit of United States provisional application number 61/373,650, filed August 13, 2010, United States provisional application number 61/374,005, filed August 16, 2010, and United States provisional application number 61/461,096, filed January 13, 2011, the disclosures of which are hereby incorporated by reference in their entireties.

Background

[0002] Proper alignment of femoral and acetabular components implanted in hip replacement and revision surgeries is important for a successful implant. Improper alignment may lead to patient discomfort, hip dislocation, restricted movement, increased wear particles, increased bone removal during surgery, or other undesirable complications. The proper alignment is often defined by an implant axis, which can be defined by inclination and anteversion angles relative to the patient's anatomy and may mimic the natural axis of rotation of a patient's hip.

[0003] In hip surgery, proper alignment of a reamer or tool used for implant insertion, such as an impactor, is important to achieve desired inclination and anteversion angles and align implanted components with a desired implant axis of rotation. One approach to achieving proper alignment is to orient reaming and/or insertion tools freehand during surgery. Some reamers and insertion tools have an orienting post that the surgeon can point in a specific direction, e.g., towards the floor, to assist in achieving the desired alignment. This freehand approach requires the surgeon to manually align the tools properly and is subject to variation that occurs from human error when the surgeon deviates from the desired axis. An approach that uses external references, such as the floor, also suffers from patient variation as not all patients are situated in the exact same orientation during surgery. In addition, each patient has a unique anatomy that may have an optimal implant orientation that varies slightly from other patients.

Summary

[0004] Disclosed herein are systems, devices, and methods for placement of a reference pin into a patient's acetabulum according to a desired orientation. The systems, devices, and methods disclosed provide a guide that mates with the patient's anatomy and reduces wobbling and rotational movement to accurately align the guide according to the desired orientation.

[0005] In some embodiments, a guide for placement of an acetabular pin includes (1) a base member having a receptacle and first guide passage that receives an acetabular pin and (2) an expansion member that couples with the receptacle and has a second guide passage that receives the acetabular pin and aligns with the first guide passage when the expansion member is coupled to the base member. Coupling of the expansion member and base member causes expansion of at least a portion of the base member. In certain implementations, the expansion member is a tapered plug that contacts a corresponding tapered surface of the receptacle. In certain implementations, the receptacle is threaded, and the expansion member has tapered threads that are complementary to the threaded receptacle. The guide passage of either the base member or the expansion member may be a through-hole, a threaded hole, a funnel, or a collar.

[0006] In certain implementations, the base member has a plurality of arm portions positioned around a perimeter of the base member, and coupling of the expansion member and the base member causes at least one of the arms to expand radially. In certain implementations, the arms include a friction surface on an outer perimeter of the base member. Claws may be included on a base member with arms, and the claws move outward when the expansion member is coupled to the base member.

[0007] In some embodiments, the receptacle is substantially aligned with a central axis of the base member, and coupling of the expansion member and the base member causes uniform radial expansion of the base member. In other implementations, coupling the expansion member and base member causes non-uniform expansion of the base member. Coupling of the expansion member and the base member causes expansion of the receptacle without substantially expanding the first and second guide passages. The receptacle may have a third passage, and the expansion member may be disposed within the third passage.

[0008] In some embodiments, the base member is patient-matched based on at least one landmark of a patient's anatomy, and may include a marking that aligns the base member with a landmark of the patient's anatomy. Non-limiting examples of anatomical landmarks that a base member may be configured to match include an anterior inferior iliac spine, acetabular limbus, ischial spine, pubic tubercle, and acetabular notch.

[0009] In some embodiments, a method for placing a guide is provided and includes providing a base member having a first passage that receives a pin, disposing the base member at a patient site such that the first passage aligns with a desired anchor point on the patient site, and coupling an expansion member having a second passage to the base member, where the coupling expands at least a portion of the base member and aligns the second passage with the first passage.

[0010] In some implementations, coupling the expansion member to the receptacle comprises applying a force to wedge the expansion member into a receptacle on the base member. In certain other implementations, coupling the expansion member to the base member comprises rotating the expansion member to mate threads on the expansion member with a threaded receptacle on the base member.

[0011] The method further includes inserting a drill into the first and second passages and drilling a pilot hole at the anchor point in some embodiments. The method may also include inserting an acetabular pin into the first and second passages and fixing the acetabular pin at the anchor point. When an acetabular pin is fixed at the anchor point, the method may further include removing the expansion member, wherein the base member contracts when the expansion member is removed. The base member may be removed while the acetabular pin remains fixed to the anchor point thereafter.

[0012] Variations and modifications of these embodiments will occur to those of skill in the art after reviewing this disclosure. The foregoing features and aspects may be implemented, in any combination and subcombinations (including multiple dependent combinations and subcombinations), with one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented.

Brief Description of the Drawings

[0013] The foregoing and other objects and advantages will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings. These depicted embodiments are to be understood as illustrative and not as limiting in any way:

[0014] Figure 1 shows an illustrative pelvic anatomy with an axis of hip rotation;

[0015] Figure 2 shows an illustrative three-dimensional model of a patient's pelvis;

[0016] Figure 3 shows an illustrative portion of a model of a patient's pelvis including portions designated as the acetabular cup;

[0017] Figure 4 shows an illustrative model with a best-fit sphere matching the acetabular cup of the model;

[0018] Figure 5 shows an illustrative coordinate axis determined by points of interest on the spine;

[0019] Figure 6 shows an illustrative coordinate axis determined by points of interest on the pelvis;

[0020] Figure 7 shows an illustrative acetabular rim in a pelvic model;

[0021] Figure 8 shows an illustrative best-fit plane matching the acetabular rim of a pelvic model;

[0022] Figure 9 shows an illustrative best-fit sphere and a best-fit plane superimposed on a pelvic model;

[0023] Figure 10 shows an illustrative axis passing through a best fit sphere and oriented relative to a best-fit plane in a pelvic model;

[0024] Figure 11 shows an illustrative patient-matched device having a surface that conforms to the surface of a patient's acetabular cup and a drill guide oriented along the desired alignment axis.

[0025] Figure 12 shows an illustrative flow chart of basic information processing;

[0026] Figure 13 shows an illustrative pelvic anatomy with a pin placed into the acetabulum in line with a desired axis;

[0027] Figure 14 shows an illustrative pelvic anatomy with a guide placed into the acetabulum in line with a desired axis;

[0028] Figures 15-17 show an illustrative expandable cup-shaped acetabular guide;

[0029] Figures 18-21 show an illustrative expandable acetabular guide having arms and cutouts around the perimeter of the guide;

[0030] Figures 22-25 show an illustrative expandable acetabular guide having claws for gripping a surrounding bone anatomy; and

[0031] Figures 26-32 show an illustrative surgical procedure for using an acetabular guide to place an acetabular pin.

Detailed Description

[0032] To provide an overall understanding of the systems, devices, and methods described herein, certain illustrative embodiments will now be described. For the purpose of clarity and illustration, the systems, devices and methods will be described with respect to orthopedic knee and hip implants. It will be understood by one of ordinary skill in the art that the systems, devices and methods described herein may be adapted and modified as is appropriate, and may be employed in other suitable applications, such as for other types of joints and orthopedic implants. Such other additions and modifications will not depart from the scope hereof.

[0033] Figure 1 shows a patient's native pelvic anatomy and hip joints formed by the interaction of femoral head 100 and acetabulum 102. The ball-in-socket interface between the femoral head 100 and acetabulum 102 create a natural rotating hip joint. During hip replacement, it is often desirable to maintain the natural motion and rotation of a patients hip after an artificial hip is implanted into a patient. This natural rotation is illustrated in Figure 1 by the axis 101 that extends outward from the cup of the acetabulum 102, through femoral head 100, and along femoral neck 104. During surgery to place an implanted acetabular cup and femoral components to replace the native acetabulum 102, femoral head 100, and femoral neck 104, it may be preferable to orient the implanted components such that they

rotate along the same axis 101 as the native anatomy. The approaches discussed herein provide for alignment and orientation of references, tools, and implanted components to allow for closer alignment of implanted components with an axis such as the axis 101.

[0034] A successful hip implant substantially aligns with a desired implant axis defined relative to a patient's anatomy. A surgeon can use a patient's native anatomy to determine inclination and anteversion angles that define the desired axis. The hip into which the implant is being placed can be used to determine the desired orientation, or in some cases, the patient's anatomy may dictate using the contralateral hip to determine the appropriate orientation. The inclination and anteversion angles are used to orient instruments and/or implants in the patient's hip. The surgeon may determine these angles based on any appropriate three-dimensional coordinate system defined relative to the patient's pelvis. Once these angles are defined, they specify an axis along which the surgeon preferably reams and/or impacts the acetabulum to implant an acetabular shell or other hip implant.

[0035] A patient's anatomy including the pelvis may be imaged using a standard imaging technology such as X-ray, MRI, CT scanning, or other suitable imaging technology. This imaging data can then be imported into a computer-aided design ("CAD") or similar system and used as the basis for developing a multi-dimensional digital model of the patient's anatomy of interest through segmentation and other processing procedures.

[0036] Figure 2 shows an example of an image-based three-dimensional model 106 of a pelvis used to produce a patient matched implant. The model 106 may be derived from a CT scan, MRI, X-ray or other image of the patient's bone or other region. A coordinate system is applied to the model and used to define, for example, desired anteversion and inclination angles to be used in orienting an implant. One possible coordinate system within which to locate the digital model 106 of the patient's pelvis and to define the inclination and anteversion angles (and hence the desired implant axis) is the coordinate system of the imaging system in which the patient data is collected. The patient lies along the table in a known orientation, and this known orientation is used to apply coordinates to the images obtained from patient scans. For example, the table of an MRI scanner provides a two-dimensional orthogonal coordinate system, and an axis oriented perpendicular to the two-dimensional top of the MRI table defines a third orthogonal axis. Such an exemplary three-dimensional coordinate system 108 is shown by the x, y, and z axes in Figure 2. In the embodiment shown in Figure 1, if the patient lies on the MRI table flat on his or her back,

then the x- and y- axes would lie in the coronal plane and the z-axis would extend perpendicularly to the coronal plane, in the sagittal plane. The three-dimensional coordinate system 108 defined by the MRI table and the orientation of the patient on the table provides a known orientation of the patient's anatomy, including the pelvis, from which the desired anteversion and inclination angles can be specified. This coordinate system 108 can then be imported into the CAD system and used to define the desired anteversion and inclination angles and implant axis within the CAD system. In particular, because the position of the patient's pelvis within the coordinate system 108 defined by the MRI table geometry can be specified as desired simply by correctly orienting the patient on the table prior to scanning and keeping the patient stationary during the scanning process, the orientation of the model 106 of the pelvis within the imported coordinate system 108 will also be known.

[0037] With a multi-dimensional model of the patient's pelvis, portions of the pelvic model defining the acetabular cup are readily identified. Figure 3 shows a portion of the model 106 from Figure 2 with the parts of the model designated as the acetabular cup 110 shaded. Once the acetabular cup 110 is identified, the coordinate system 108 is used to determine the desired orientation for an implant in the acetabular cup 110. As shown in Figure 4, a sphere 112 that best fits the specified portions of the acetabular cup is obtained using known optimization techniques for fitting geometrical shapes such as spheres or planes to a set of data points, which in this case is provided by the designated acetabular cup 110 in the model 106. For example, a common CAD model approach utilizes stereolithographic triangles ("STL files") to define the elements that comprise a multi-dimensional CAD model. The triangles in the CAD model corresponding to the acetabular cup 110 are identified and used in the optimization process. Once the best-fit sphere 112 is obtained, an implant axis that passes through the center of the sphere 112 and gives the desired anteversion and inclination angles can be specified using the known coordinate system 108. This axis then defines the desired alignment axis for any tools and implants used. The desired anteversion and inclination angles may be determined based on any number of factors, including surgeon analysis and/or preference, implant geometry, a patient's native anatomy, the intended correction of the patient's anatomy, or any other suitable factors.

[0038] If the orientation of the patient is not captured during the scanning process, or for other reasons, one may apply a standard coordinate system or create or otherwise define a coordinate system to a pelvic model using points of interest on the patient's anatomy. For

example, as shown in Figure 5, in some embodiments, several points along the lumbar spinal column 114 of the pelvis could be identified on a model to define an axis 116 that runs along the lumbar spinal column 114 and is parallel to the vertical axis in the coronal plane (which, in some embodiments, could correspond to the y-axis of the coordinate system 108 shown in Figure 2). Other points located on the pelvis could be used to define the vertical in the sagittal plane (which, in some embodiments, could correspond to the z-axis shown in Figure 1). Additional axes could be defined using points of interest on the model of the pelvis to further register the model to a coordinate system and/or to identify desired anteversion and inclination angles. For instance, an axis 122 defined by a point 118 on or near the crest of the pubis and a point 120 on or near the anterior superior spine of the ilium, as shown in Figures 5 and 6, could be aligned to a plane having a patient-specific offset relative to the vertical in the coronal plane. The degree of offset of the vertical component of the pubis-ilium axis 122 projected onto a coronal plane may be measured with a medial-lateral x-ray which has a defined vertical axis to compare to the patient's anatomy. These two axes may be aligned to the imported coordinate system which would then align the pelvic model in the CAD system in substantially the same orientation as the patient's normal standing position would be. Any offsets may be set by the user. This alignment would allow identification of the preferred anteversion and inclination angles determined by the user with respect to the imported coordinate system in a CAD system.

[0039] In some embodiments, once a model of the patient's anatomy is imported into a CAD system, portions defining the acetabular rim can be specified in addition to portions defining the acetabular cup. Figure 7 illustrates an embodiment in which parts of the model comprising the acetabular rim 124 are designated. The designated patterns of the acetabular rim allow for a second reference to be defined and used with the reference sphere 112 to orient coordinate and implant axes on the acetabular model. A plane 126 that lies tangential to the acetabular rim 124 according to a best-fit criterion can then be obtained using known optimization techniques for fitting geometrical shapes such as planes to a set of data points. Another view of the best-fit plane 126 is shown in Figure 8.

[0040] Figure 9 shows an example of the best-fit sphere 112 and the best-fit plane 126 superimposed together over the three-dimensional model of the pelvis. A coordinate axis 128 is defined through the center of the best-fit sphere 112 and normal to the plane 126 to provide a coordinate system relative to the patient's anatomy within which the orientation of an axis

at the desired anteversion and inclination angles can be determined. In particular, once the plane 126 is obtained, an implant axis 130 that passes through the center of the best-fit sphere 112 (obtained as discussed above) and is oriented relative to the best-fit plane 126 to give the desired anteversion and inclination angles for an implant may be determined, as illustrated in Figure 10. In some embodiments, the position and trajectory of the implant axis 130 will be determined by a line perpendicular to the best-fit plane 126 and passing through the center of the best-fit sphere 112. In other embodiments, the surgeon, other user, or other feature of the system may offset the alignment axis 130 from this line in one or more degrees of freedom, based on patient specific data, desired implant system, or other suitable factors.

[0041] Once the implant axis 130 that gives the desired anteversion and inclination angles has been determined (which, in some embodiments, can be defined using one or a combination of the above described techniques), this pre-surgery planned axis 130 may be transferred to the operating theater through use of a patient-matched device having a surface that conforms to the surface of the patient's acetabular cup, for example, and a guide 132 oriented along the desired alignment axis, as shown in Figure 11. In this embodiment, the patient-matched guide 132 has been manufactured to include a conforming surface specific to the patient's anatomy (as determined by the multi-dimensional model) such that the patient-matched guide 132 fits into the patient's acetabulum in a unique, patient specific position and orientation that aligns a guide passage 134 of the guide 132 with the implant axis 130. A hole may then be drilled in the patient's acetabulum and a reference in the form of a pin, for example, may be inserted and used to orient the reaming and/or impacting processes. Techniques for rapid manufacture of patient-matched devices with conforming surfaces are known. Other patient-matched devices that do not utilize guide pins positioned in the acetabulum are also possible. In other embodiments, other systems or methods could be used to transfer the pre-operatively planned alignment axes to the operating room, such as by, but not limited to, robotic or other computer assisted navigational systems. In some embodiments, the planned alignment axes could be determined intra-operatively rather than pre-operatively.

[0042] Figure 12 illustrates a flow chart 136 of information flow and processing that occurs during the operation of the above discussed processes. In step 138, image data of a patient's anatomy is collected. In step 140, that collected data is sent to a CAD modeling and processing workstation or similar facility to create a model of the anatomy. After an implant

axis or other alignment mechanism is determined (e.g., via the processing discussed above), a patient-matched device that reproduces this alignment mechanism in the operating theater is manufactured at step 142 and sent to the surgeon or other user.

[0043] Using the modeling and guide approach discussed above, a reference pin can be inserted into a patient's acetabulum and used to facilitate accurate positioning of an acetabular implant in line with a desired implant axis. A pin placed into the acetabulum prior to implantation is used to align any tools, inserters or implants along a common axis that coincides with a desired axis of rotation for the implanted components. Figure 13 shows a reference pin 1000 inserted into an acetabulum 1002 for a particular patient. Notably, the pin 1000 is aligned along axis 1004 which coincides with the desired axis that is determined by modeling the patient's anatomy and analyzing the model to produce the axis 1004 for the particular patient. Because the pin 1000 is used to align any tools or implants that are placed into the acetabulum 1002, it is important that the pin is accurately placed in line with axis 1004. Inaccurate placement of a pin may lead to a faulty alignment of any tools or implants subsequently placed into the acetabulum 1002, which can lead to failed implants or other complications after surgery.

[0044] Freehand placement of a pin into an acetabulum along a desired axis is a difficult task. A guide for insuring accurate placement of a pin into an acetabulum is used to help avoid subsequent complications caused by inaccurate pin placement. Figure 14 shows a guide 1006 placed into a patient's acetabulum for guiding a pin during insertion. The guide 1006 has a center hole 1010 that is aligned with axis 1008, which represents a desired axis for seating an implant into the patient anatomy shown in Figure 14 and may correspond, for example, to the axis 1004 shown in Figure 13. The guide 1006 is designed so that the hole 1010 aligns with the axis 1008 and receives a pin for placement into the acetabulum. Because of the alignment of hole 1010, any pin inserted into the hole 1010 will also align with the axis 1008.

[0045] For the guide 1006 to provide accurate placement of a pin, the hole 1010 is preferably accurately aligned with the axis 1008. Misalignment of the hole 1010 and inaccurate placement of a pin can result in many of the same negative implications as freehand placement of the pin. In certain circumstances, the guide 1006 may not fit perfectly into a patient's acetabulum even if it is manufactured according to a model of the acetabulum. For example, spacing between the guide 1006 and the acetabulum may allow the guide 1006

to wobble and rotate within the acetabulum. Additionally, cartilage that lines the acetabulum has a slippery texture that may facilitate wobbling or rotational movement of the guide. This movement and spacing can change the alignment of the hole 1010 and may lead to inaccurate placement of a pin. To further insure accurate pin placement, the guide 1006 is patient matched and designed specifically to match with a specific patient's anatomy and is expandable to remove extra spacing from around the guide 1006 when it is placed into the acetabulum.

[0046] Figure 15 depicts a top view of a base member for an expandable guide for pin placement. The base member 1012 includes six segments 1014 that are separated by slots 1016, and has a receptacle 1018 with a guide passage 1020 through the center of the receptacle. The base member 1012 is designed and configured based on a patient-specific anatomic model so that the guide passage 1020 will be aligned with a desired implant axis when the base member 1012 is placed into the patient's acetabulum. To insure accurate placement of a pin through guide passage 1020 when the base member 1012 is placed into an acetabulum, the guide is expanded by insertion of an expansion member into receptacle 1018 to remove any spacing between the guide and the patient's acetabulum. Insertion of an expansion member that has a width wider than the width of receptacle 1018 applies an outward radial force to each of the segments 1014, for example, in the direction indicated by the arrow 1022. This force causes the base member 1012 to expand as each of the segments 1014 moves radially outward. The expansion makes the base member 1012 wider and occupies spacing that is left between the guide and a patient's acetabulum.

[0047] Figure 16 shows a perspective view of the base member 1012 shown in Figure 15 with an expansion member 1024. The expansion member 1024 is wider than the width of the receptacle 1018, and insertion of the expansion member 1024 spreads the segments 1014 and increases the diameter of the base member 1012. The expansion member 1024 may be coupled to the receptacle 1018 by any suitable mechanism. In certain implementations, the expansion member 1024 has a threading around its outside surface and the receptacle 1018 has a complementary threading on the interior of the receptacle. The threaded expansion member 1024 is placed into the receptacle 1018 and rotated such that the threads on the expansion member 1024 mate with the threading on the receptacle 1018 and the rotation drives the expansion member down into the receptacle. As the expansion member 1024 advances further into the receptacle, the radial force applied to the segments 1014 increases,

spreading the segments 1014 wider. In certain implementations, the expansion member 1024 is a tapered plug with a smooth tapered surface that contacts a complementary smooth tapered surface of the receptacle 1018 and produces an outward radial force while a downward force is applied to the expansion member 1024 to push the expansion member 1024 down into the receptacle 1018. In certain implementations, the expansion member and the receptacle include complementary ratchet mechanisms, or any other suitable mechanism for advancing the larger expansion member 1024 down into the receptacle 1018. The mechanism by which the expansion member 1024 couples to the receptacle 1018 is reversible, and the base member 1012 may either be expanded or contracted by advancing or removing the expansion member from the receptacle. Thus, the base member 1012 can be expanded when placed into the acetabulum to occupy gaps around the base member 1012 and then subsequently retracted to recreate gaps around the base member 1012 to facilitate easy removal of the base member 1012 from the acetabulum after a pin has been placed into the acetabulum.

[0048] In certain implementations, a torque or a downward force is required to advance the expansion member 1024 into the receptacle 1018. A limiting mechanism can be included on the expansion member 1024 to limit the maximum amount of torque or force that can be applied. Limiting the torque or force may be desired to avoid further injuring the acetabulum into which base member 1012 is placed, especially if the bone surrounding the acetabulum is weak or diseased. When a torque is required to couple the expansion member 1024 and the receptacle 1018, for example when the two components are threaded, the expansion member 1024 includes a torque-limiting feature to protect the surrounding acetabulum. Such feature may be a frangible portion of the expansion member 1024 designed to break off when a threshold torque is reached, or may be any other suitable mechanism of limiting torque.

[0049] The expansion member 1024 includes a guide passage 1026 through its center. The guide passage 1026 aligns with the guide passage 1020 of the base member 1012 when the expansion member 1024 is coupled to the receptacle 1018. The alignment of guide passages 1020 and 1026 allows an acetabular pin to be accurately placed through the base member 1012. Either of the guide passages 1020 and 1026 may be a through-hole, a threaded hole, a funnel, a collar, or any other suitable passage suitable for a particular application.

[0050] Figure 17 shows the guide of Figures 15 and 16 with the expansion member 1024 inserted into the receptacle 1018, expanding the base member 1012. The radial force created

when the expansion member 1024 is inserted into the base member 1012 causes the segments 1014 to move outward and opens the slots 1016 wider to accommodate the movement. In this expanded configuration, the guide has a total width shown by distance B that is wider than the unexpanded width shown by distance A in Figure 16. The extra width fills in extra space around the guide when the guide is placed into an acetabulum. When the guide is in the expanded configuration shown in Figure 17, the guide passage 1026 of the expansion member and guide passage 1020 of the base member are aligned to receive the pin that is subsequently aligned along the desired axis for an implant and a desired anchor point in the patient's acetabulum. The expansion of the guide causes the guide to tightly grip the patient's acetabulum and insures that the guide passages 1026 and 1020 are properly aligned and stable.

[0051] In certain implementations, a patient's acetabular anatomy requiring expanding the base member 1012 non-uniformly. For example, if a patient's acetabulum has a bone void or small divot in one region, extra expansion of the segment 1014 that faces that region after the expansion member 1024 has been coupled to the base member 1012 accommodates the bone void and provides a close mating around substantially the full perimeter of base member 1012. The selective extra expansion is performed after the base member 1012 is uniformly expanded by coupling with the expansion member 1024. For example, a wedge or other suitable secondary expansion member is placed in one of the slots 1016, and a downward applied force further increases the size of the slot and expands the two segments 1014 adjacent the slot 1016. This creates an extra expansion of the two adjacent segments that can be used, for example, to fill a bone void in the area of those segments. Other secondary expansion members for non-uniform expansion may be provided at the interface of the expansion member 1024 and the segments 1014, and may increase the expansion of only one of the segments 1014.

[0052] An acetabular pin is placed through the guide passage 1026 and secured to an anchor point in the acetabulum into which the guide is inserted. In certain implementations, a drill is placed through the guide passage 1026 and used to drill a pilot hole prior to insertion of the acetabular pin. The guide passages 1020 and 1026 may be lined with metal or another suitable reinforced material to reduce the creation of plastic debris that my result from interaction between an acetabular pin or drill and the material, for example a polymer, of the base member 1012 and expansion member 1024. Once the pin is in place, the expansion

member 1024 is decoupled from the receptacle 1018 and removed from the system over the pin, returning the base member 1012 to the retracted configuration shown in Figure 16 and releasing the base member's increased grip on the acetabulum. The base member 1012 is then removed over the inserted acetabular pin, leaving only the pin in place aligned with the desired axis and ready to be used to align subsequent tools and ultimately an implant.

[0053] In certain implementations, guides with different configurations that expand in different ways than the guide shown in Figures 15 through 17 may be used. Figure 18 shows a base member 1028 for a guide that is made of a plurality of arms 1030. The arms 1030 mate at the center of the base member 1028 to create a receptacle 1032 formed by an interior portion 1035 of each of the arms 1030, with a slot 1034 between each of the interior portions. The receptacle 1032 has a guide passage 1038 extending therethrough that is aligned with a desired implant axis when the base member 1028 is placed into a patient's acetabulum. As discussed above with respect to base member 1012 in Figures 15 through 17, the base member 1028 in Figure 18 is expandable. When an expansion member with a width larger than the receptacle 1032 is coupled with the receptacle, a radial outward force is produced that pushes each of the arms 1030 radially, for example in the direction shown by arrow 1036. This force causes the arms 1034 to move outward, expanding the base member 1028 as the arms 1030 separate and the size of the slots 1034 increases.

[0054] The base member 1028 is designed and manufactured to specifically fit the contours of a patient's anatomy, and can be customized to accommodate and match a bony landmark on the patient's anatomy. Non-limiting examples of bone landmarks that can be modeled and used for customization include an anterior inferior iliac spine, acetabular limbus, ischial spine, pubic tubercle, and acetabular notch. For proper rotational alignment of the base member 1028, one or more of the arms 1030 can be marked with an alignment marking 1037 that aligns with a bony landmark of a patient's anatomy when the base member 1028 is properly oriented within the patient's acetabulum.

[0055] Figure 19 shows an expansion member 1040 that can be coupled with receptacle 1032 to expand the base member 1028. The expansion member 1040 has a width that is slightly larger than the width of the receptacle 1032. The expansion member 1040 may mate with the receptacle 1032 by any suitable mechanism, including, but not limited to, the mating mechanisms discussed above with respect to expansion member 1024 and receptacle 1018 in Figure 16. When the expansion member 1040 is placed into the base member 1028, the

outward radial force causes movement of the arms 1030 and expansion of the base member 1028.

[0056] The base member 1028 also includes friction surfaces 1044 on the outer edges of the arms 1030. The friction surfaces 1044 create an even tighter grip on surrounding anatomy when the friction surfaces 1044 interact with a patient's acetabulum after expansion of the base member 1028. The friction surfaces 1044 may be textured surfaces similar to sand paper or may include small protrusions extending from the arms 1030 or may be any other type of surface suitable to produce a grip on surrounding anatomy.

[0057] When the base member 1028 is inserted into an acetabulum and expanded by coupling the expansion member 1040 with the receptacle 1032, a guide passage 1042 on the expansion member 1040 aligns with a desired implant axis for the patient and with a second guide passage on the bottom of the base member 1028 that is not shown in Figure 19. The alignment of these two guide passages enables the guide to receive an acetabular pin and align the acetabular pin with a desired anchor point in the acetabulum and along the desired implant axis.

[0058] Figure 20 shows the expanded configuration of base member 1028 after expansion member 1040 is coupled with the receptacle 1032. In the expanded configuration, the arms 1030 have moved radially outward and the slots 1034 have been widened to accommodate the expansion member 1040. The base member 1028 has a width shown by distance D in this expanded configuration which is wider than the distance C shown in Figure 19 for the unexpanded configuration. This increased width brings friction surfaces 1044 into closer contact with the surrounding acetabulum to give a tighter grip that holds the base member 1028 in place and reduces any wobbling movement within the acetabulum. The guide passage 1042, which is aligned with the guide passage in the bottom of the base member 1028, receives an acetabular pin and aligns the acetabular pin with the desired implant axis. The pin may be placed through the guide passage 1042 and secured directly to an anchor point in the acetabulum, or a drill may be placed through the guide passage 1042 to first drill a pilot hole at the anchor point in the acetabulum into which the pin is then placed through the guide passage 1042. Once the pin is in place, the expansion member 1040 is decoupled from the base member 1028 and removed over the pin. The base member 1028 is returned to the unexpanded configuration and is also removed over the implanted pin.

[0059] Because the base member 1028 is not a solid cup shaped member, proper alignment of guide passages is needed to insure accurate placement of the pin using base member 1028 and expansion member 1040. Figure 21 shows a cross section of the base member 1028 in its expanded configuration with expansion member 1040 inserted into the receptacle 1032. Two guide passages are shown in Figure 21, the guide passage 1042 of expansion member 1040 and the guide passage 1046 of the base member 1028. The expansion member and base member are designed and configured so that the guide passage 1042 is aligned with the guide passage 1046 in this expanded configuration. The alignment allows the two guide passages 1042 and 1046 to receive an acetabular pin and align the pin with the desired implant axis that runs through the center of the guide passages 1042 and 1046.

[0060] The configuration of the base member 1028 shown in Figures 18-21 may be preferable for certain applications of an acetabular pin guide. For example, the cutouts 1045 between the arms 1030, shown in Figure 21, allow the base member 1028 to accommodate any nuances of a patient's anatomy that extend inward from an acetabulum and would interfere with a full cup-shaped guide, such as the guide shown in Figures 15-17. Additionally, the base member 1028 may also allow for non uniform expansion to better accommodate a particular patient's anatomy. The base member 1028 may be configured so that two or more of the arms 1030 are attached rather than being separated by slots 1034. The connected arms would be unable to separate from each other as needed for the uniform expansion of the base member 1028. For example, if three of the arms 1030 were connected and a fourth arm was separated with slots 1034 on either side of the arm, insertion of an expansion member such as expansion member 1040 would cause a greater expansion of the base member 1028 in the direction of the single separated arm 1030 than in the direction of the other three arms. This type of base member may be preferable, for example, for a patient whose anatomy has a bone void along a section of the acetabulum. In this case, the base member 1028 can be aligned such that the free arm 1030 faces toward the void in the patient's acetabulum. Expansion of the base member 1028 would cause expansion of the free arm into the bone void while the three connected arm members remain in substantially the same configuration contacting the portions of the patient's acetabulum that do not contain voids.

[0061] Further designs and configurations of guides and base members may be utilized to meet certain applications, and additional features may be added to increase the alignment and

gripping of a guide with the patient's acetabulum. Figure 22 shows a base member 1048 that includes an additional gripping mechanism provided by claws 1050. The base member 1048 has multiple arms 1052 that are separated by slots 1054, and interior portions 1062 of the arms 1052 form a receptacle 1056 that has a guide passage 1058 therethrough.

[0062] The claws 1050 extend from exterior surfaces of the receptacle 1056 and are configured to move generally outward when an expansion member is coupled with the base member 1048. For example, when an expansion member that is larger than the width of the receptacle 1056 is placed into the receptacle, it exerts a force on the arms 1052 that is directed radially outward, for example in the direction shown by arrow 1060. The expansion member also causes the walls of the receptacle 1056 to move outward as the arms 1052 separate and the slots 1054 become wider. This outward movement of the walls of the receptacle moves the claws generally outward. Because of the cutouts 1061 between the arms 1052, shown in Figure 25, the claws 1050 are able move outward and engage a surrounding acetabular surface. This engagement gives the base member 1048 an increased grip and hold within the acetabulum to further resist any rotational or wobbling movement of the base member 1048.

[0063] Figure 23 shows an expansion member 1064 that is coupled with the base member 1048 to cause expansion of the base member. The width of the expansion member 1064 is slightly larger than the width of the receptacle 1056 such that when the expansion member 1064 is coupled with the receptacle it produces a radially outward force on the arms 1052. This force causes the arms to separate and move outward, increasing the size of the slots 1054. Additionally, the force moves the outer surfaces of the receptacle 1056, causing the claws 1050 to also move outward.

[0064] The base member 1048 includes friction surfaces 1068 on the outer surface of the arms 1052. The friction surfaces 1068 may be textured surfaces or may contain small protrusions that extend outward from the outer surface of the arms 1052. The friction surfaces 1068 may be substantially similar in form and function to friction surfaces 1044 discussed above with respect to Figure 19. With the addition of the claws 1050 and the friction surfaces 1068, the base member 1048 is configured to provide a tight grip to a patient's acetabulum when the base member 1048 is placed into the acetabulum and expanded.

[0065] The expanded configuration of the base member 1048 is shown in Figure 24. The expansion member 1064 is coupled with the receptacle of the base member 1048, causing the arms 1052 to move radially outward and increasing the size of the slots 1054. In addition to the arms 1052, the claws 1050 have also moved outward as a result of the interaction between the expansion member 1064 and the walls of the receptacle 1056. In this expanded configuration, the exterior surfaces of the arms 1052, including the friction surfaces 1068, come in close contact with the patient's acetabulum. The grip provided by arms 1052 is augmented by the claws 1050, which extend through the cutouts 1061 to contact the patient's acetabulum and increase the grip that resists movement of the base member 1048. The width of the base member 1048 is increased in the expanded configuration to a distance F which is larger than the distance E shown in the unexpanded configuration in Figure 23.

[0066] Figure 25 shows a cross section of the base member 1048 and expansion member 1064 in the expanded configuration in which the expansion member 1064 is coupled with the receptacle of the base member 1048. The expansion member 1064 includes a guide passage 1066 and the base member 1048 includes a guide passage 1070. For proper alignment and placing of an acetabular pin, the two guide members 1066 and 1070 must be properly aligned. The expansion member 1064 and base member 1048 are designed and configured so that when the expansion member 1064 is placed into the receptacle 1066, the two guide passages 1066 and 1070 are aligned with each other and with the desired implant axis and anchor point for a patient into which the base member 1048 is placed. Thus, in the expanded configuration, the base member and expansion member are configured to receive a pin through the guide passages 1066 and 1070 that is placed in line with the desired axis. A drill may also be placed through the two guide passages 1066 and 1070 to drill a pilot hole at an acetabular anchor point into which an acetabular pin is subsequently located by insertion through the two guide passages.

[0067] The guide systems and methods described herein are used to enhance the accurate placement of a pin and subsequent placement of an implant into a patient's acetabulum during surgery. Figures 26-32 show an illustrative surgical procedure for placing an implant that utilizes the guide systems and methods discussed herein. Figure 26 shows a patient's acetabulum 2000 with an implant axis 2002 extending through the acetabulum. The desired axis 2002 may be an axis determined for a particular patient, for example, from CT scans, X-rays or other imaging techniques using any of the model-based approaches discussed herein

to tailor an implant to an individual patient. To insure that all tools and implants placed into the acetabulum 2000 align with the axis 2002, a guide system is used to place a pin used for subsequent alignment for tools and implants into the acetabulum 2000.

[0068] In Figure 27, a guide base member 2004 is placed into the patient's acetabulum for pin alignment. The guide 2004 includes a guide passage 2010 that is aligned with the desired axis 2002 and an anchor point 2003 in order to align a pin placed through the guide passage 2010 with the axis. While the base member 2004 is designed and configured to fit the nuances of the patient's acetabular anatomy, gaps 2012 remain on either side of the base member 2004 when the base member is placed into the acetabulum. The gaps 2012 may cause problems, as they may allow the base member 2004 to wobble or rotate within the acetabulum. This movement can interfere with the alignment between the guide passage 2012 and the axis 2002 and anchor point 2003, and thus can cause inaccurate placement of a pin. To insure that the base member 2004 is properly aligned, the expansion member 2006 is inserted into the receptacle 2014 of the base member 2004. Because the width of expansion member 2006 is greater than the width of the receptacle 2014, insertion of the expansion member 2006 produces a force on the arms 2016 directed radially outward, causing the arms to move outward and close the gaps 2012 on the side of the base member 2004. Figure 28 shows the guide after the expansion member 2006 has been inserted and the base member 2004 has expanded to eliminate the gaps 2012. In this expanded configuration, the base member 2004 has a tight grip within the patient's acetabulum. Exterior surfaces of the base member 2004 now contact the patient's acetabulum at contact points 2018. At these contact points 2018, the base member 2004 may include a friction surface or other gripping surface on the outside of the base member 2004 to provide an increased grip on the patient's acetabulum. These friction surfaces may, for example, be substantially similar and have substantially the same form as the frictions surfaces 1068 discussed above with respect to Figure 23.

[0069] In the expanded configuration, the base member 2004 is held tight within the acetabulum and does not rotate or wobble significantly. The base member 2004 and expansion member 2006 also remain aligned with the desired axis 2002 and anchor point 2003 as the guide passage 2010 on the base member 2004 aligns with the guide passage 2008 on the expansion member 2006. This provides a passageway through the guide that allows

for placement of the pin through the center of the guide and alignment of that pin with the axis 2002.

[0070] In the expanded configuration shown in Figure 28, the guide is prepared to receive a pin for placement into the patient's acetabulum. Prior to placement of an acetabular pin, a drill may be provided and placed through the guide passages 2008 and 2010 to drill a pilot hole into the patient's acetabulum that is aligned with the axis 2002 at anchor point 2003. Whether a drill is used for a pilot hole or the pin is simply placed into the acetabulum without any pilot hole, an acetabular pin may be placed using the guide as shown in Figure 29. The pin 2020 is lowered into the guide through the guide passage 2008 and the guide passage 2010 and inserted into the patient's bone at anchor point 2003. Because of the alignment of the guide, the pin 2020 is aligned along the desired axis 2002 and provides an adequate reference point for subsequent use of tools and, ultimately, an implant. The pin 2020 includes a gripping surface 2022 around a lower portion of the pin 2020. The gripping surface 2022 may be threaded, may be a textured surface, may contain small protrusions, or may be any other type of surface suitable for providing a grip that holds the pin 2020 into the patient's bone after insertion at anchor point 2003.

[0071] Figure 30 shows the alignment of the pin 2020 after insertion into the patient's bone. As shown, the pin 2020 is in line with the desired axis 2002 and is securely held into the patient's bone at anchor point 2003 by the surface 2022 on the lower end of the pin 2020. With the pin 2020 in place, the expansion member 2006 is decoupled from the receptacle 2014 of the base member 2004 to release the grip of the base member 2004 on surrounding bone. After decoupling, the expansion member 2006 may be removed from the patient site by sliding the expansion member 2006 up over the top end of the pin 2020. The removal of the expansion member 2006 brings the base member 2004 back into its unexpanded configuration and recreates the gaps 2012 on either side of the base member 2004.

[0072] With the base member 2004 in the unexpanded configuration and the tightened grip on the patient's acetabulum removed, the base member 2004 is removed from the system by sliding it over the pin 2020. Removal of the base member 2004 leaves only the implanted pin 2020 in the patient's acetabulum. The pin 2020 is aligned with the patient matched axis 2002 and is ready for use in aligning any reamer, impactor, any other tool or implant that needs to be placed into the patient's acetabulum.

[0073] Figure 32 illustrates the use of the pin 2020 to align and insert a tool 2024 to prepare the patient's acetabulum. The tool 2024 is cannulated with passage 2026 using through the length of the tool 2024. The cannulated passage 2026 is able to receive the pin 2020 so that the tool can advance downward over the pin 2020 to push the head of the tool 2024 into the patient's acetabulum. The alignment of the tool 2024 using the pin 2020 insures that the tool remains aligned with the desired axis 2002 and prepares the acetabulum for proper placement of a subsequent implant. For example, the tool 2024 may be a reamer that is used to prepare a smooth surface in the patient's acetabulum to allow for proper fit of an acetabular shell. In order to insure that the implanted acetabular shell is aligned along the proper angle and axis, the tool 2024 is inserted over the pin 2020, and the head of the reamer is aligned so that the smooth surface created by the reamer is properly prepared and aligned and an orthopedic shell may subsequently be placed over the pin 2020 is in the correct orientation at the correct angle.

[0074] It is to be understood that the foregoing description is merely illustrative and is not to be limited to the details given herein. While several embodiments have been provided in the present disclosure, it should be understood that the disclosed systems, devices, and methods, and their components, may be embodied in many other specific forms without departing from the scope of the disclosure.

[0075] Variations and modifications will occur to those of skill in the art after reviewing this disclosure. The disclosed features may be implemented, in any combination and subcombinations (including multiple dependent combinations and subcombinations), with one or more other features described herein. The various features described or illustrated above, including any components thereof, may be combined or integrated in other systems. Moreover, certain features may be omitted or not implemented.

[0076] Examples of changes, substitutions, and alterations are ascertainable by one skilled in the art and could be made without departing from the scope of the information disclosed herein. All references cited herein are incorporated by reference in their entirety and made part of this application.

What is claimed is:

1. A guide for placement of an acetabular pin, comprising:

a base member having:

a first guide passage that receives an acetabular pin; and

a receptacle; and

an expansion member that couples with the receptacle and has a second guide passage that receives the acetabular pin and aligns with the first guide passage when the expansion member is coupled to the base member;

wherein coupling of the expansion member and base member causes expansion of at least a portion of the base member.

2. The device of claim 1, wherein the expansion member is a tapered plug.

3. The device of claim 1, wherein the receptacle is threaded, and the expansion member comprises tapered threads that are complementary to the threaded receptacle.

4. The device of claim 1, further comprising a friction surface on an outer perimeter of the base member.

5. The device of any of claims 1-4, further comprising a plurality of arm portions around a perimeter of the base member, wherein coupling of the expansion member and the base member causes at least one of the arm portions to expand radially.

6. The device of claim 5, further comprising claws that move outward when the expansion member is coupled to the base member.

7. The device of any of claims 1-4, wherein the guide passage of the base member is a through-hole, a threaded hole, a funnel, or a collar.

8. The device of any of claims 1-4, wherein the guide passage of the expansion member is a through-hole, a threaded hole, a funnel, or a collar.

9. The device of any of claims 1-4, wherein the receptacle is substantially aligned with a central axis of the base member, and coupling of the expansion member and base member causes uniform radial expansion of the base member.

10. The device of any of claims 1-4, wherein coupling of the expansion member and base member causes non-uniform expansion of the base member.

11. The device of any of claims 1-4, wherein the base member is patient-matched based on at least one landmark of a patient's anatomy.

12. The device of claim 11, wherein the base member further comprises a marking that aligns with a landmark of the patient's anatomy.

13. The device of claim 11, wherein the base member is configured to match at least one of an anterior inferior iliac spine, acetabular limbus, ischial spine, pubic tubercle, or acetabular notch of the patient's anatomy.

14. The device of any of claims 1-4, wherein coupling of the expansion member and the base member causes expansion of the receptacle while the first and second guide passages do not substantially expand.

15. The device of any of claims 1-4, wherein the receptacle has a third passage, and the expansion member is disposed within the third passage.

16. A method for placing a guide, said method comprising:

providing a base member having a first passage that receives a pin;

disposing the base member at a patient site such that the first passage aligns with a desired anchor point on the patient site;

coupling an expansion member having a second passage to the base member, wherein the coupling expands at least a portion of the base member and aligns the second passage with the first passage.

17. The method of claim 16, wherein coupling the expansion member to the receptacle comprises applying a force to wedge the expansion member into a receptacle on the base member.

18. The method of claim 16, wherein coupling the expansion member to the base member comprises rotating the expansion member to mate threads on the expansion member with a threaded receptacle on the base member.

19. The method of any of claims 16-18, further comprising inserting a drill into the first and second passages and drilling a pilot hole at the anchor point.

20. The method of any of claims 16-18, further comprising inserting an acetabular pin into the first and second passages and fixing the acetabular pin at the anchor point.

21. The method of claim 20, further comprising removing the expansion member, wherein the base member contracts when the expansion member is removed.

22. The method of claim 20, further comprising removing the base member, wherein the acetabular pin remains fixed to the anchor point after the base member is removed.

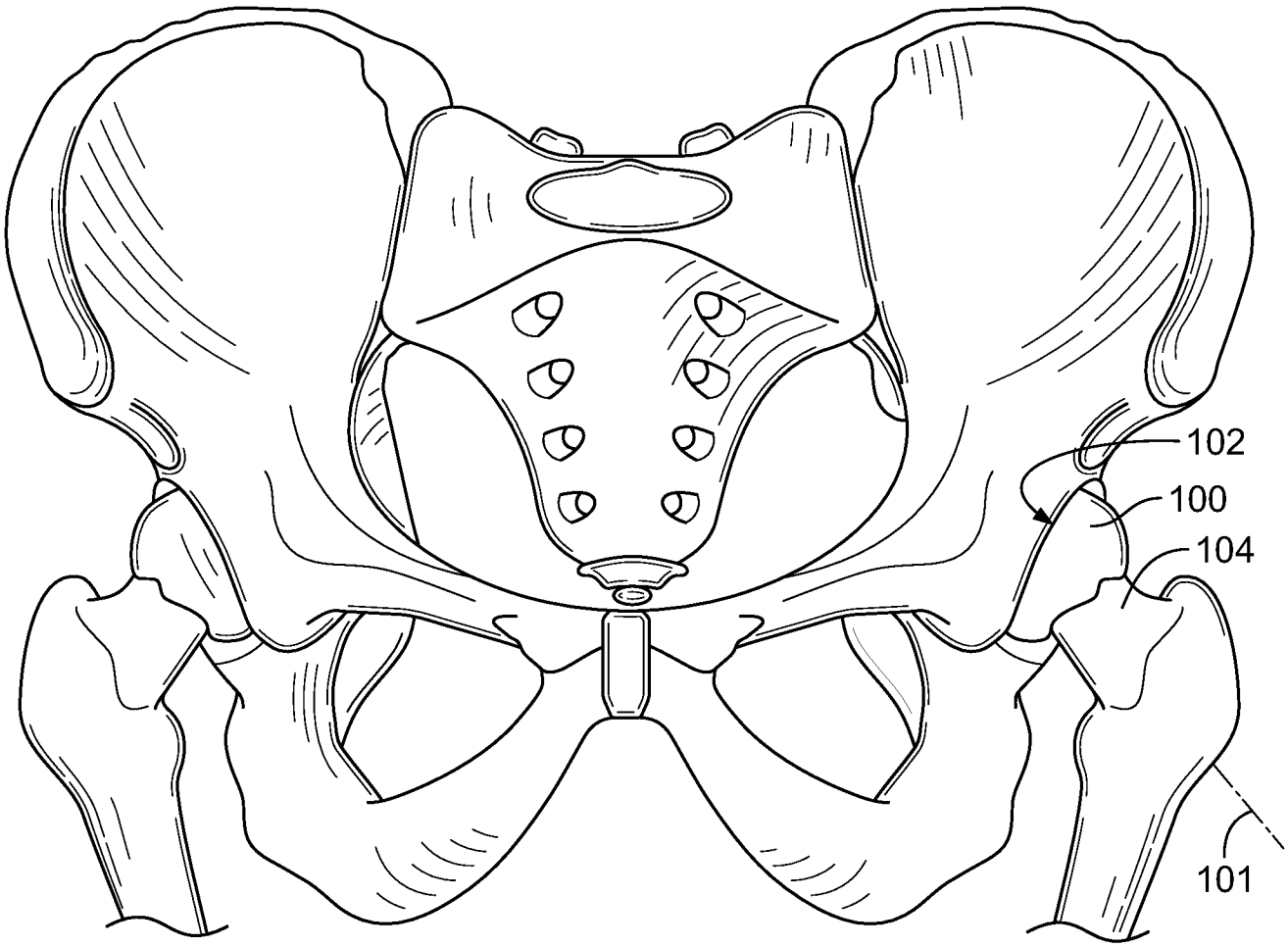

FIG. 1

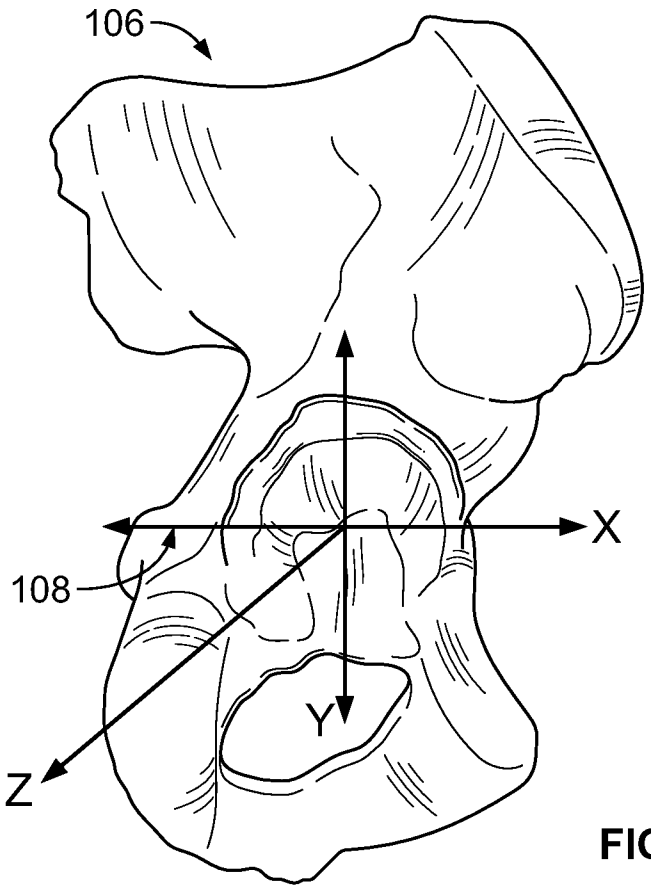

FIG. 2

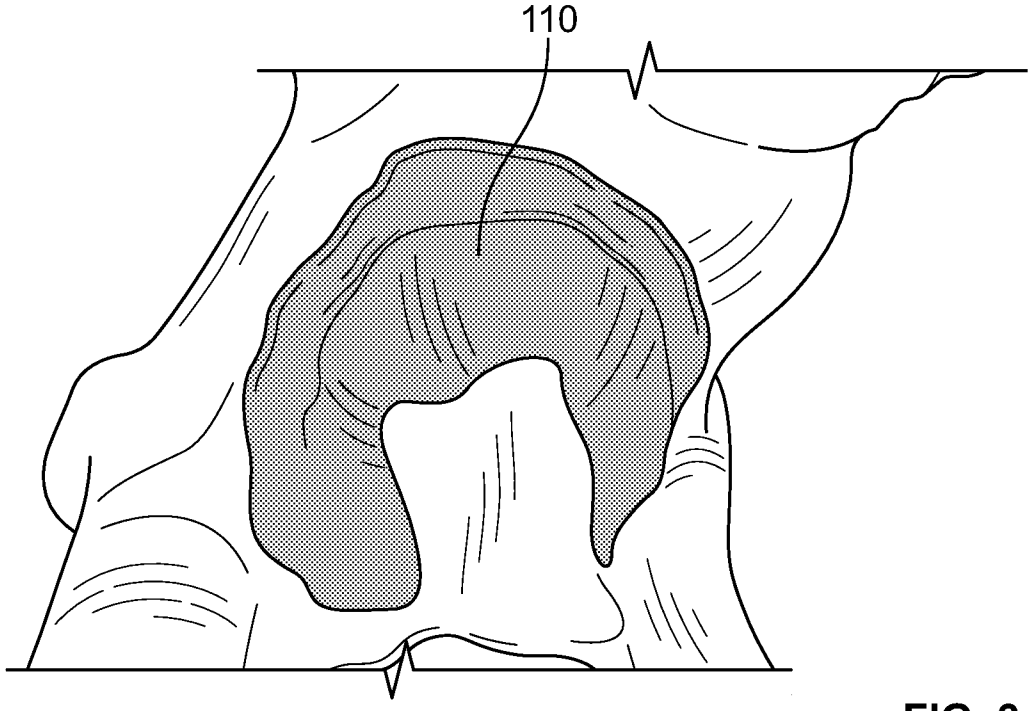

FIG. 3

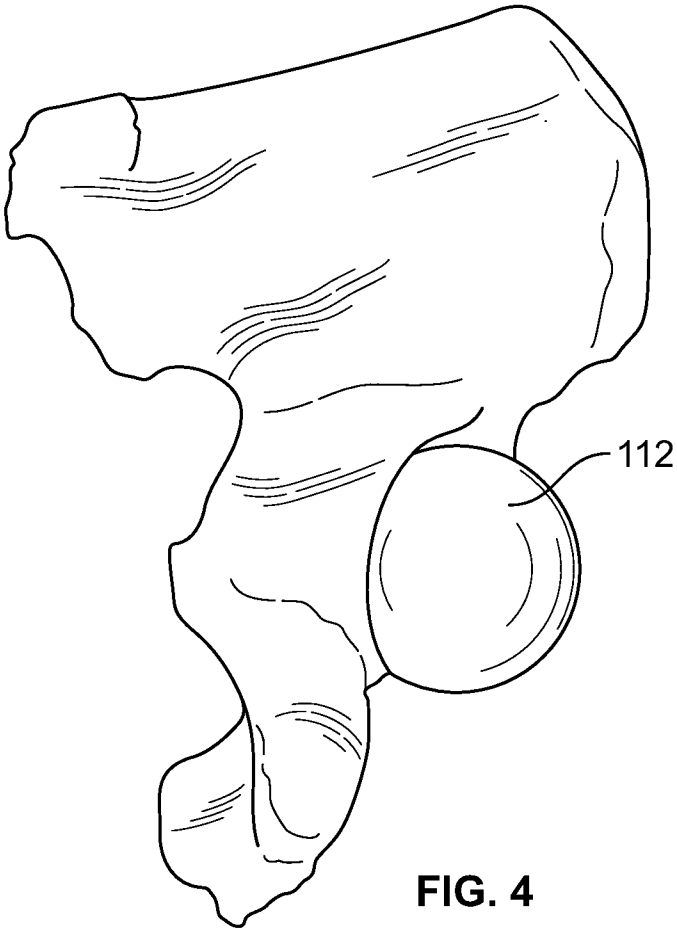

FIG. 4

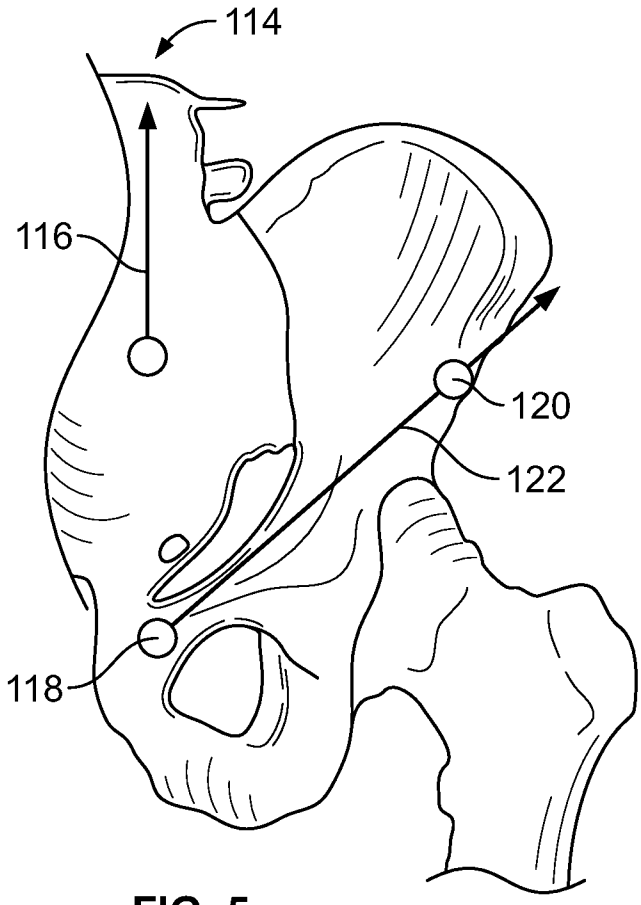

FIG. 5

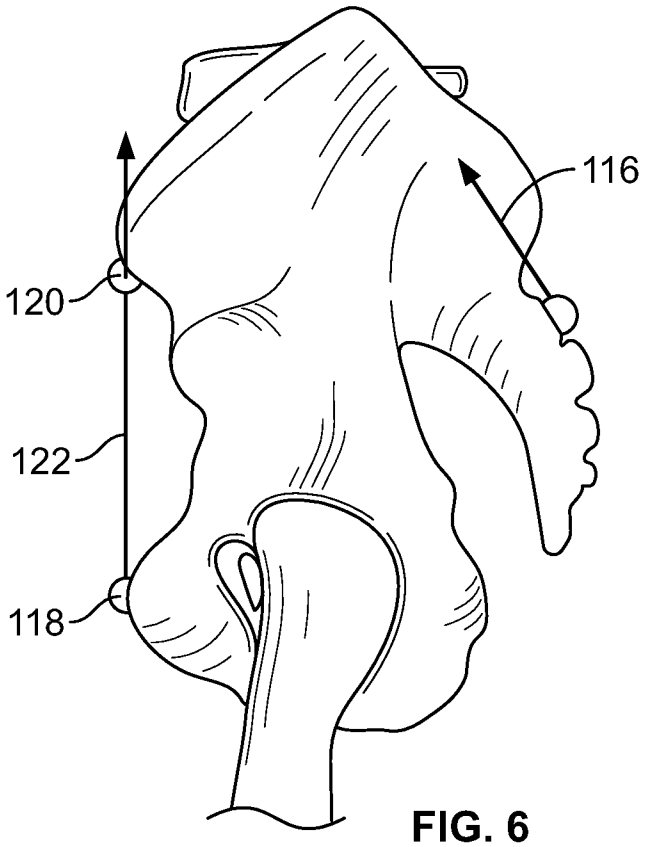

FIG. 6

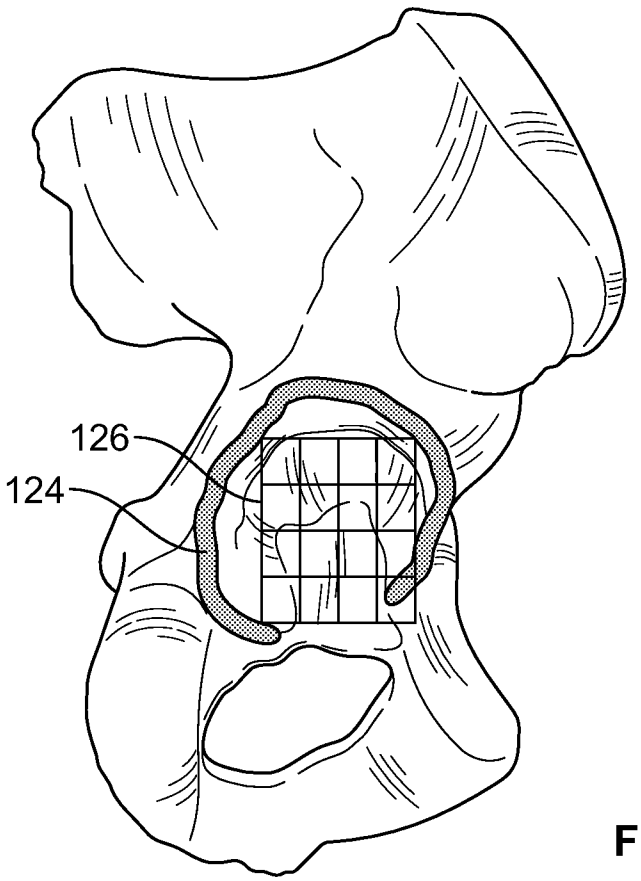

FIG. 7

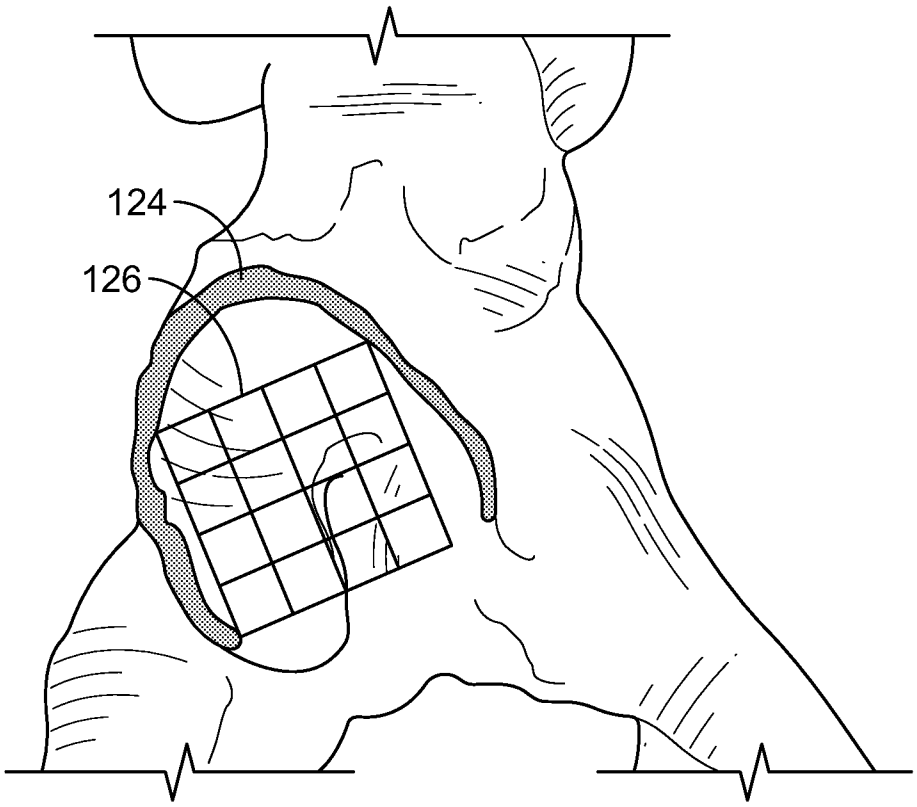

FIG. 8

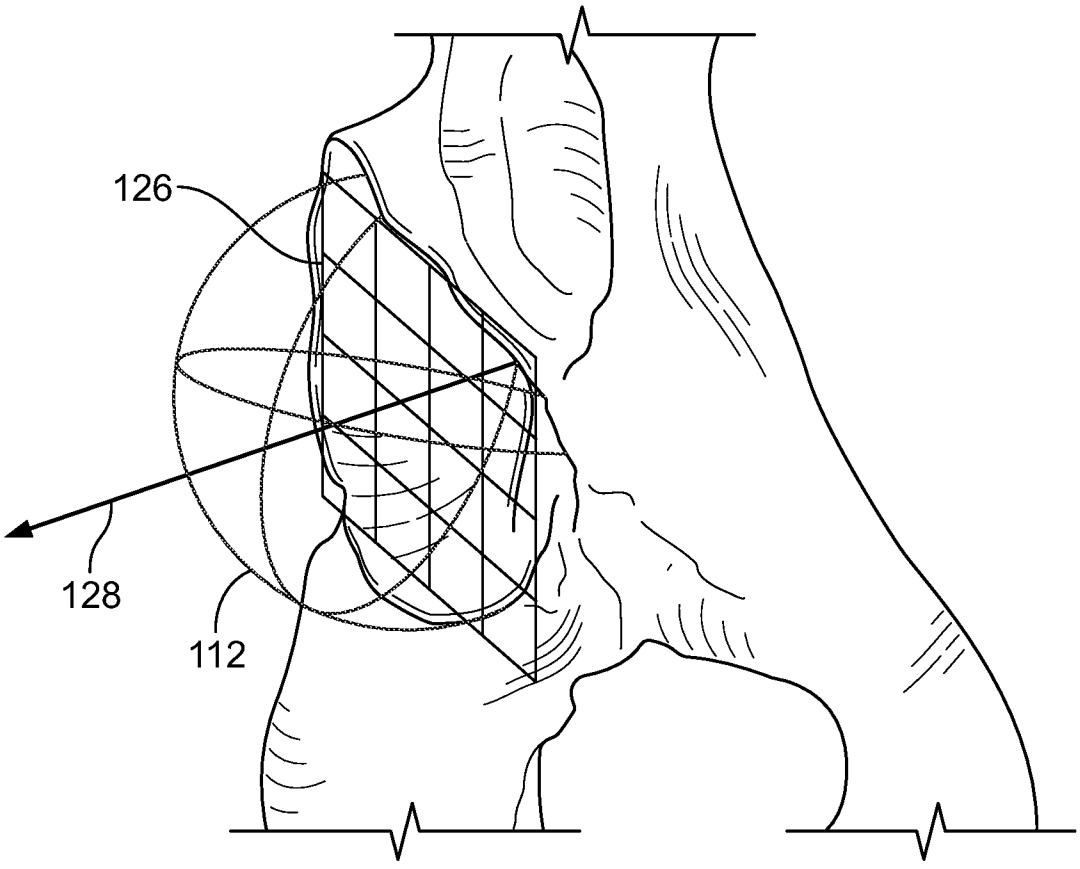

FIG. 9

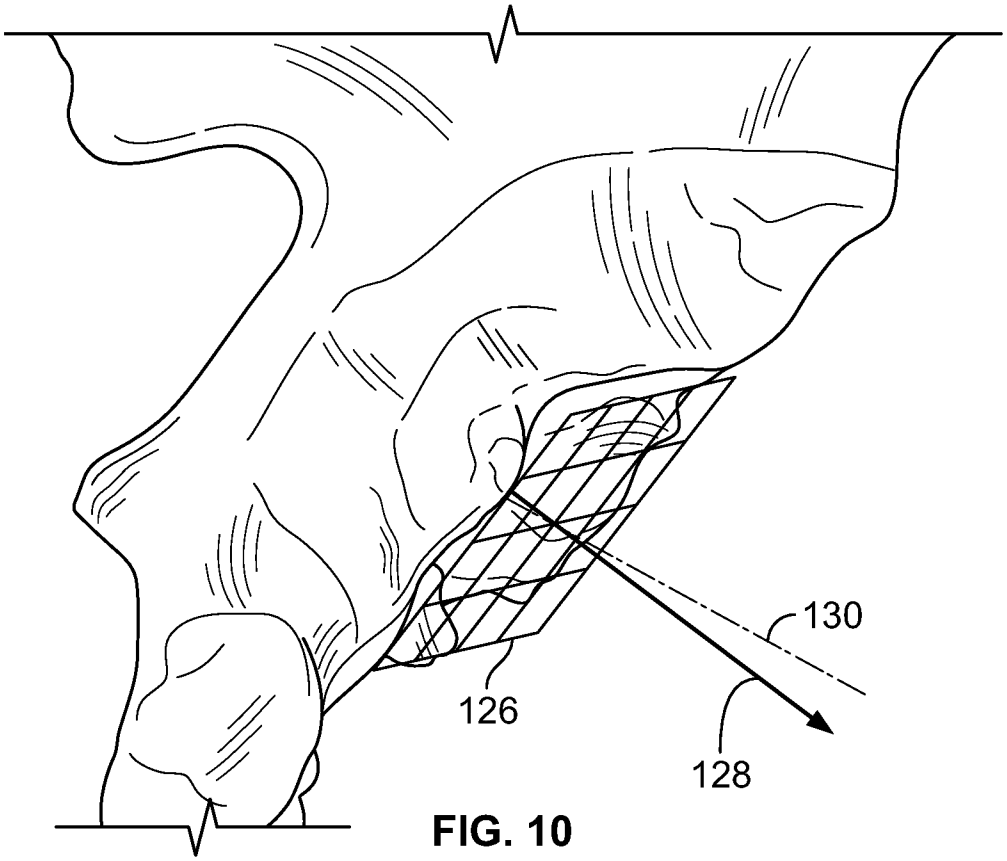

FIG. 10

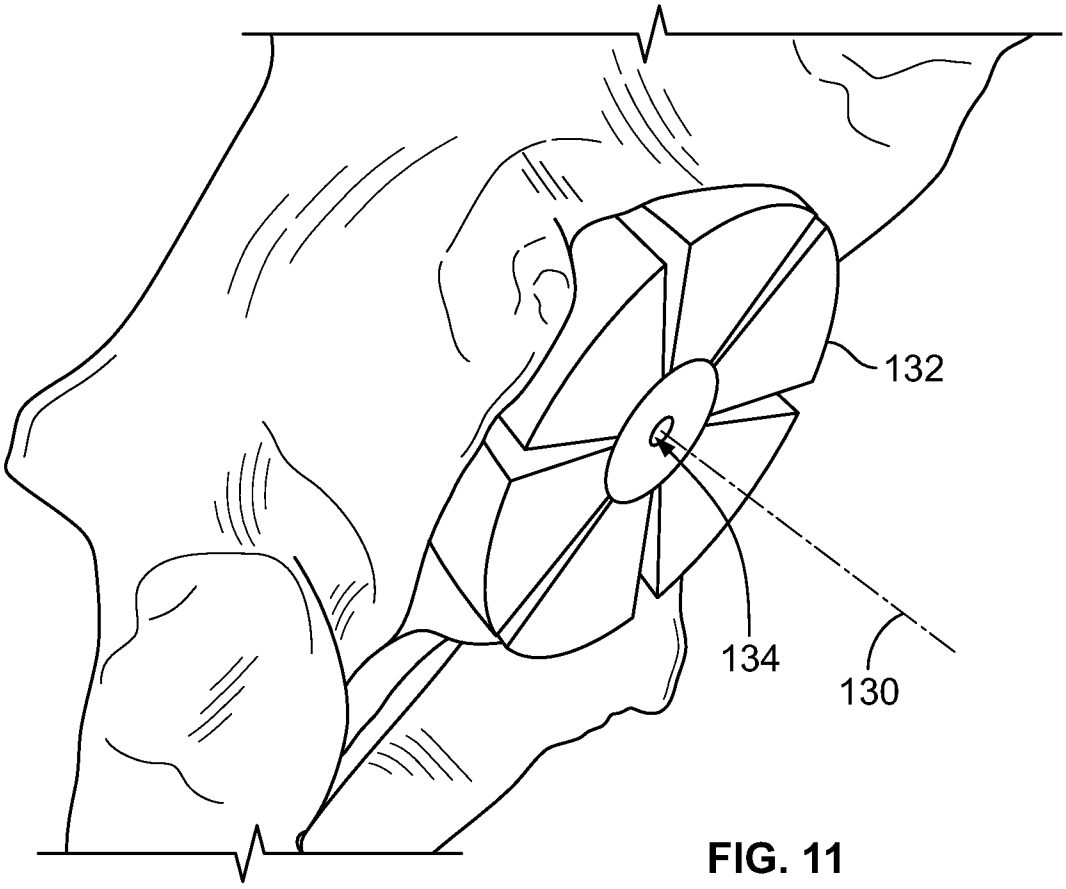

FIG. 11

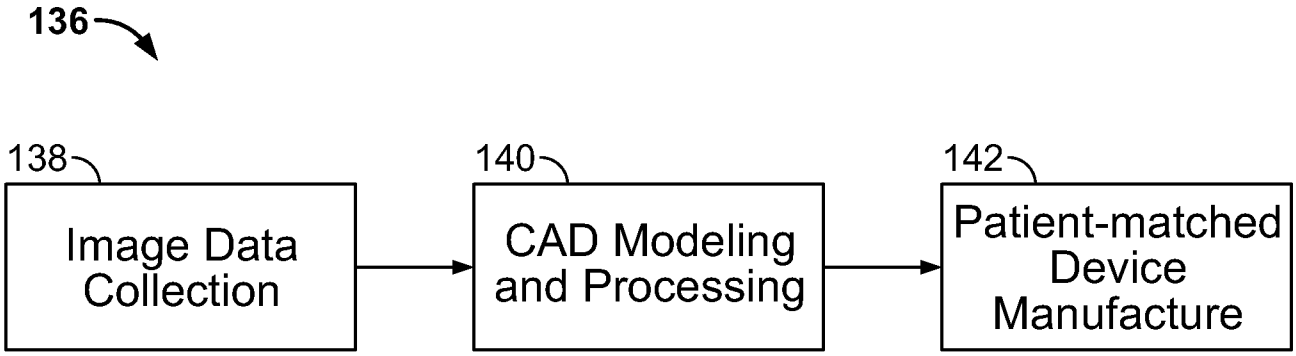
136
138
Image Data Collection
140
CAD Modeling and Processing
142
Patient-matched Device Manufacture

FIG. 12

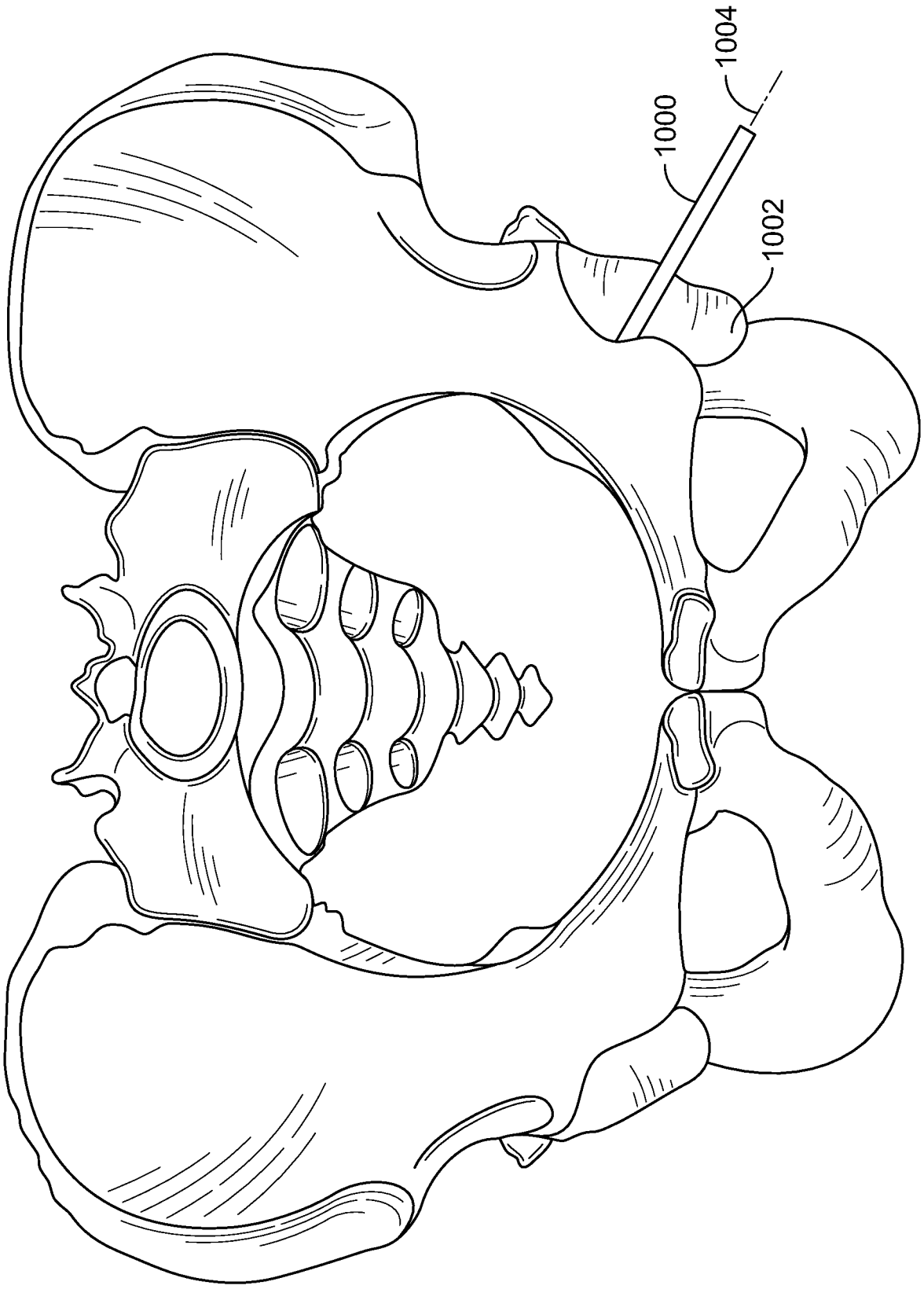

FIG. 13

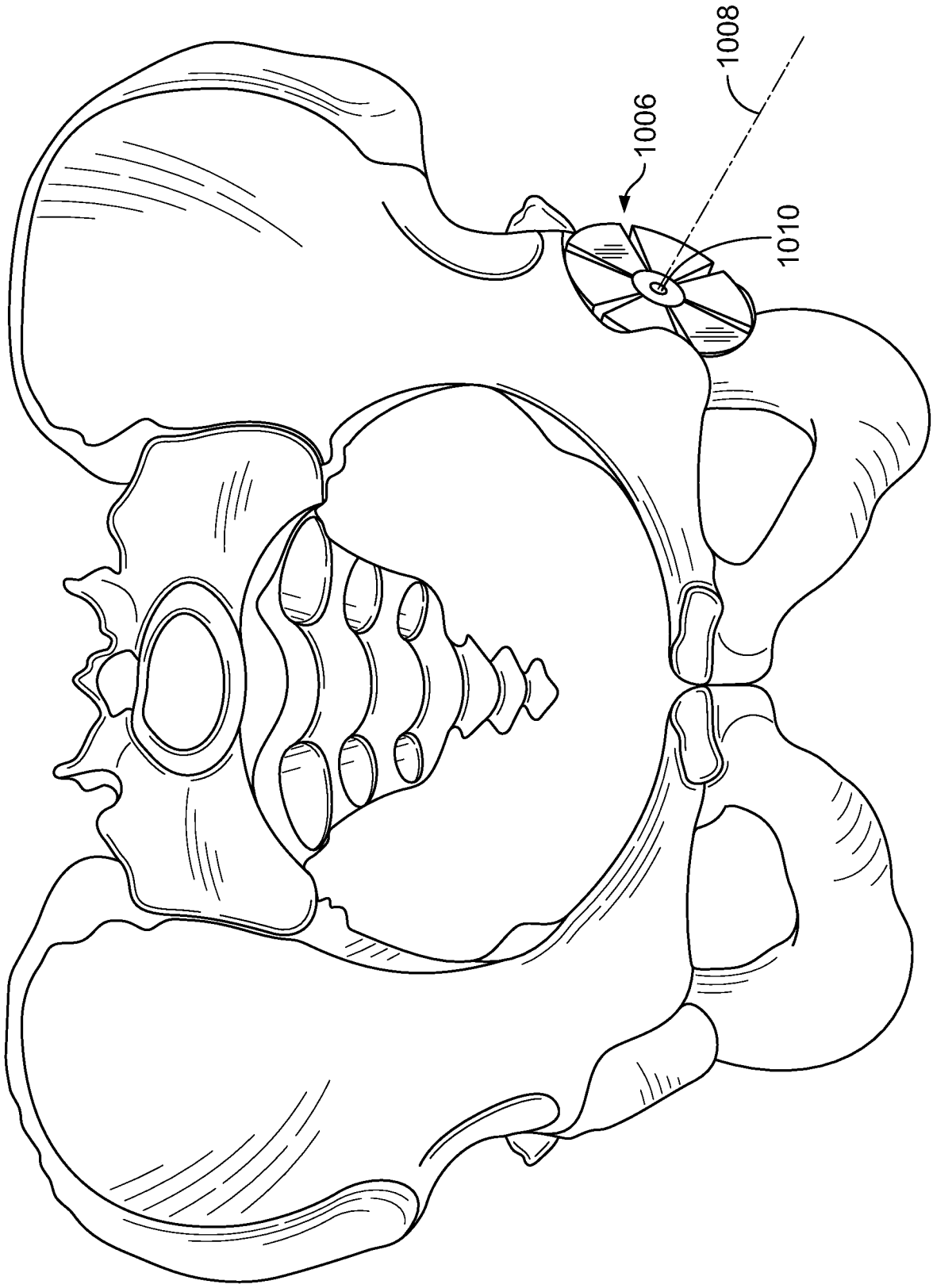

FIG. 14

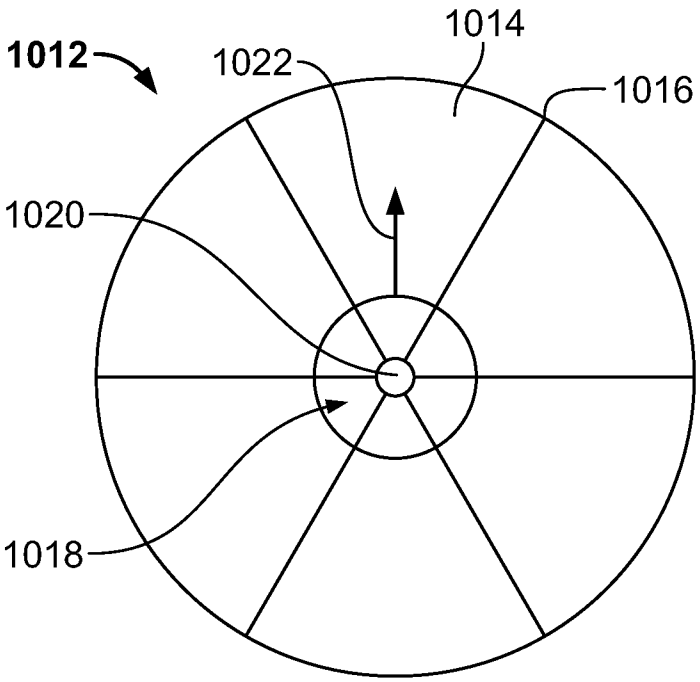

FIG. 15

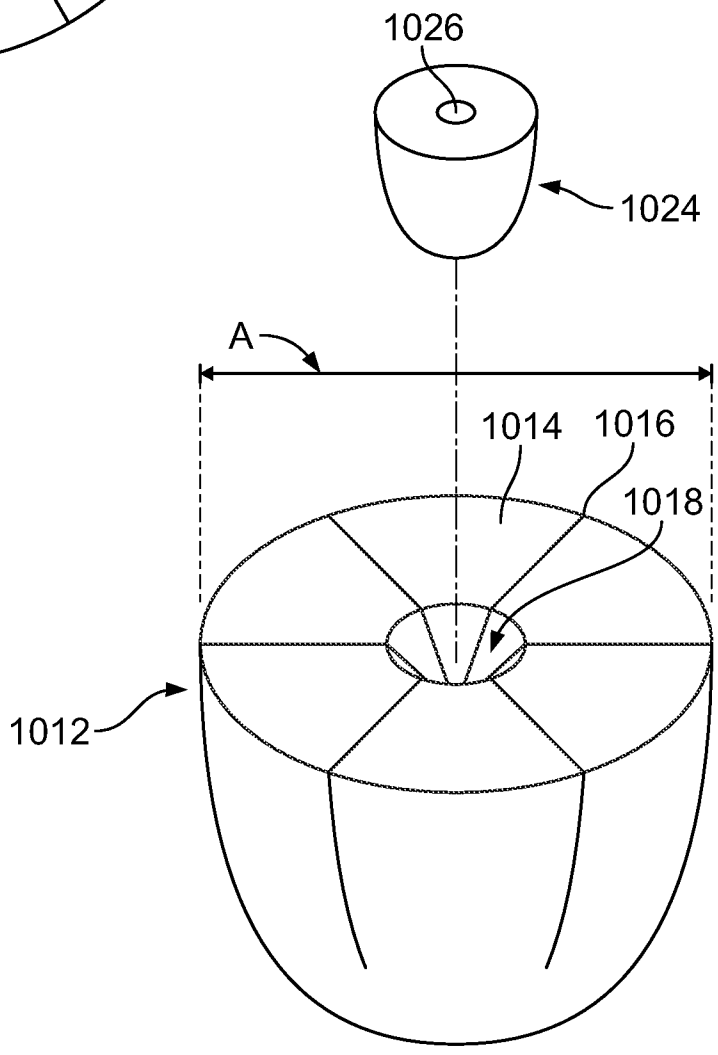

FIG. 16

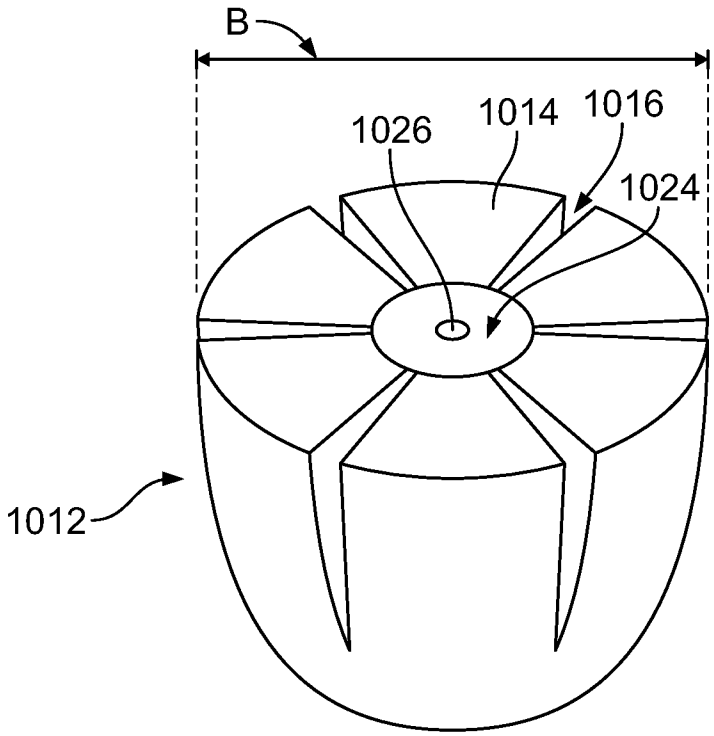
B
1026
1014
1016
1024
1012

FIG. 17

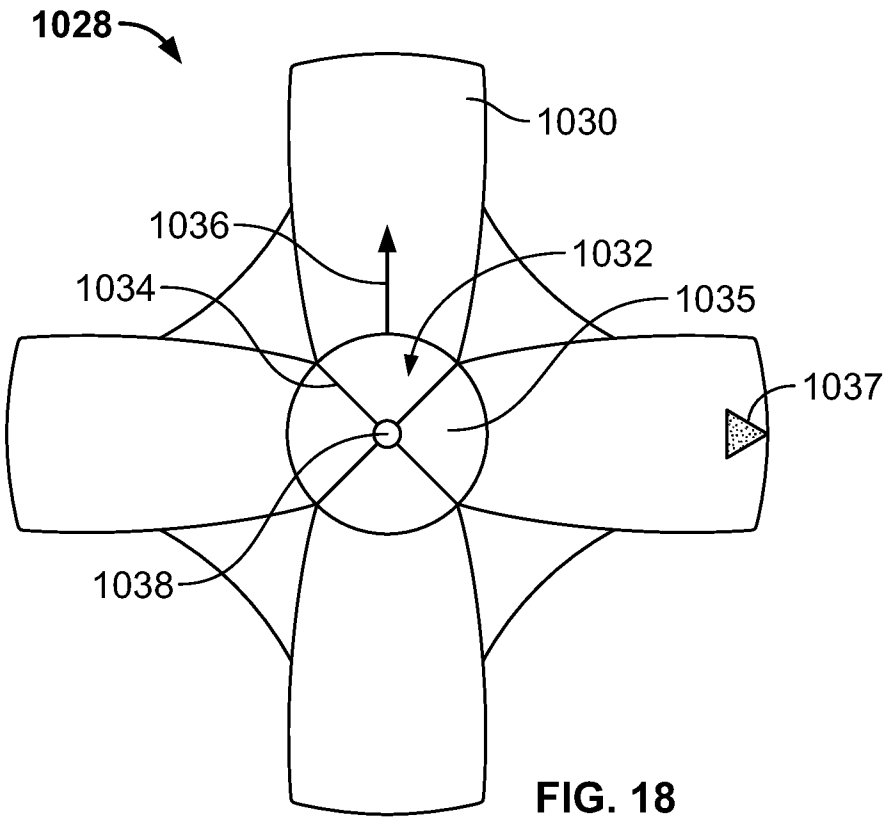
1028
1030
1036
1032
1034
1035
1037
1038

FIG. 18

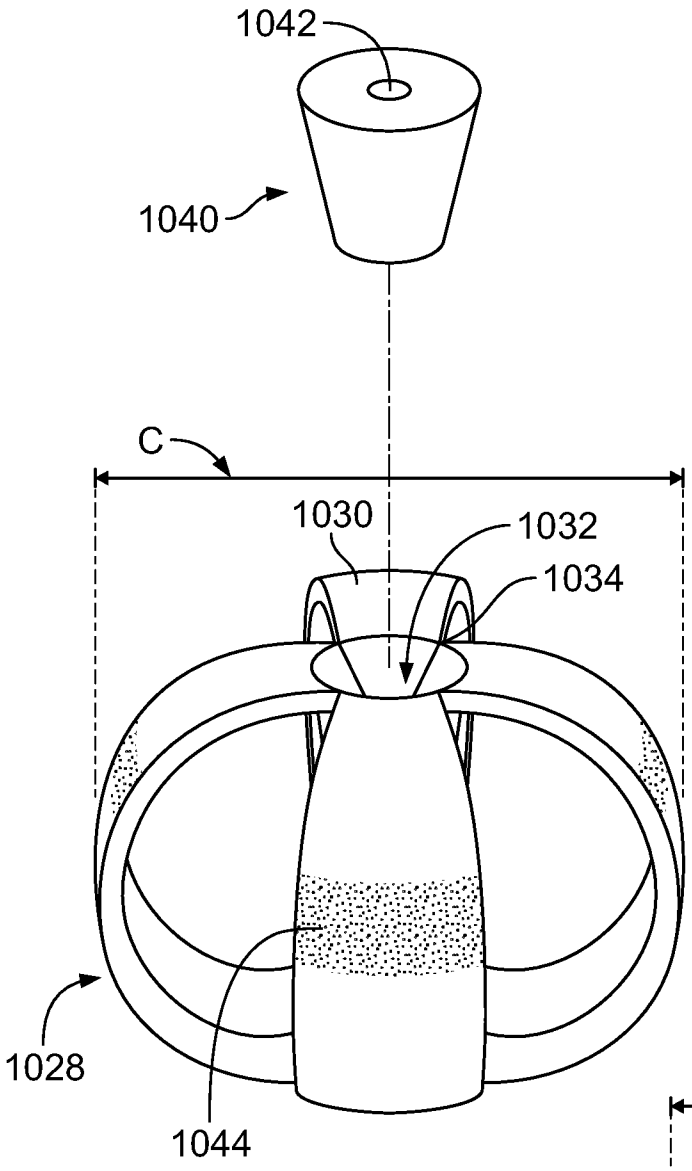
1042
1040
C
1030
1032
1034
1028
1044

FIG. 19

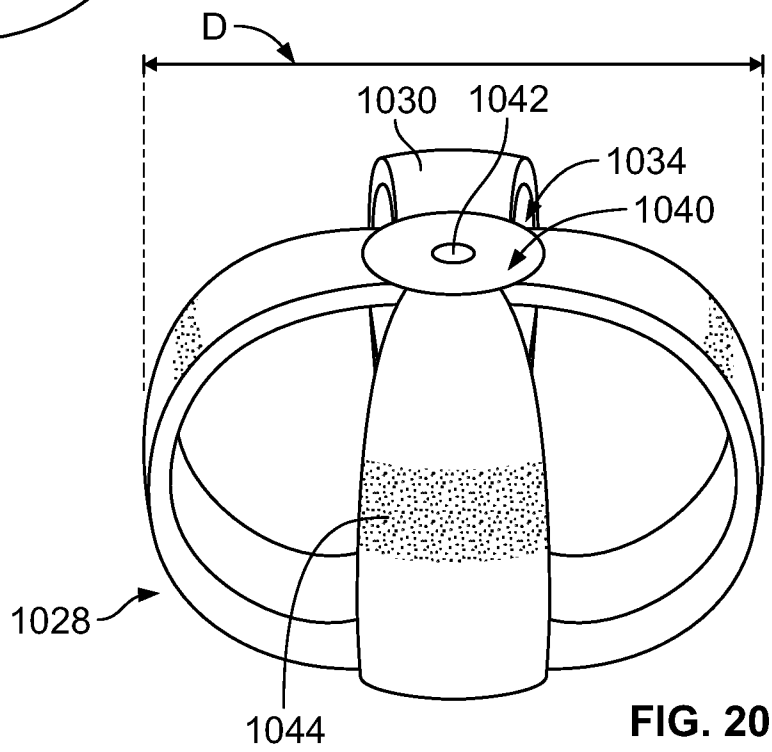
D
1030
1042
1034
1040
1028
1044

FIG. 20

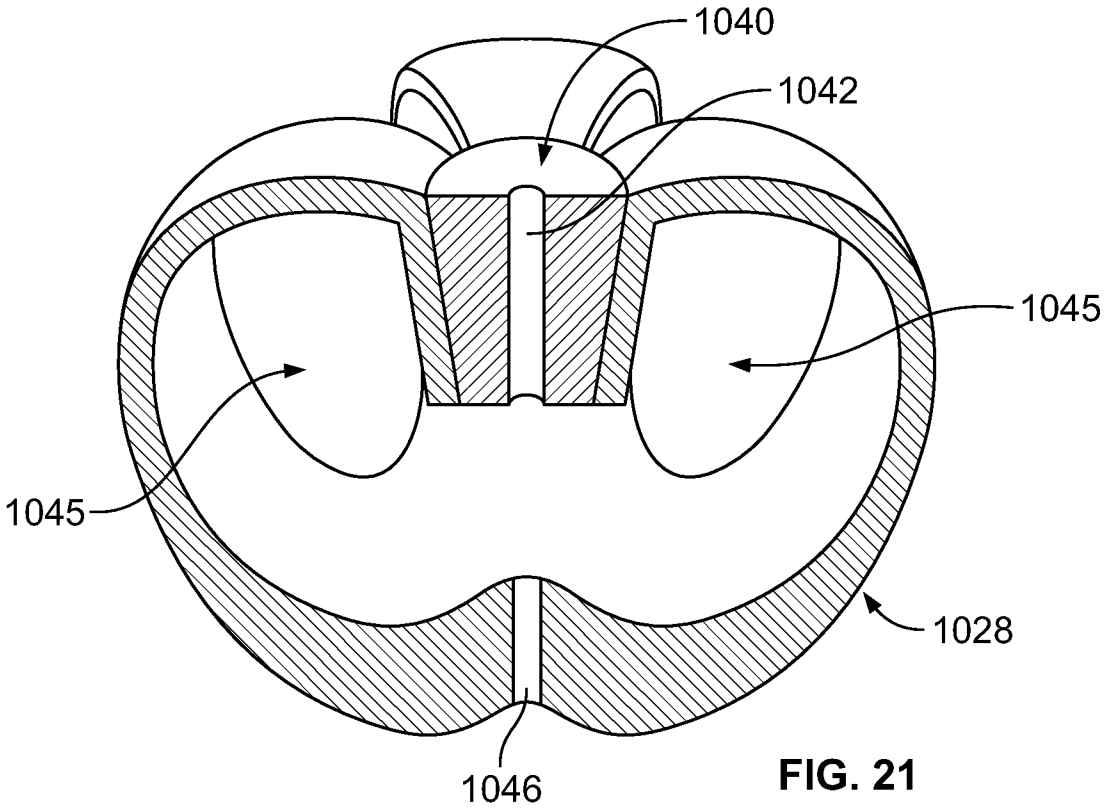
1040
1042
1045
1045
1028
1046

FIG. 21

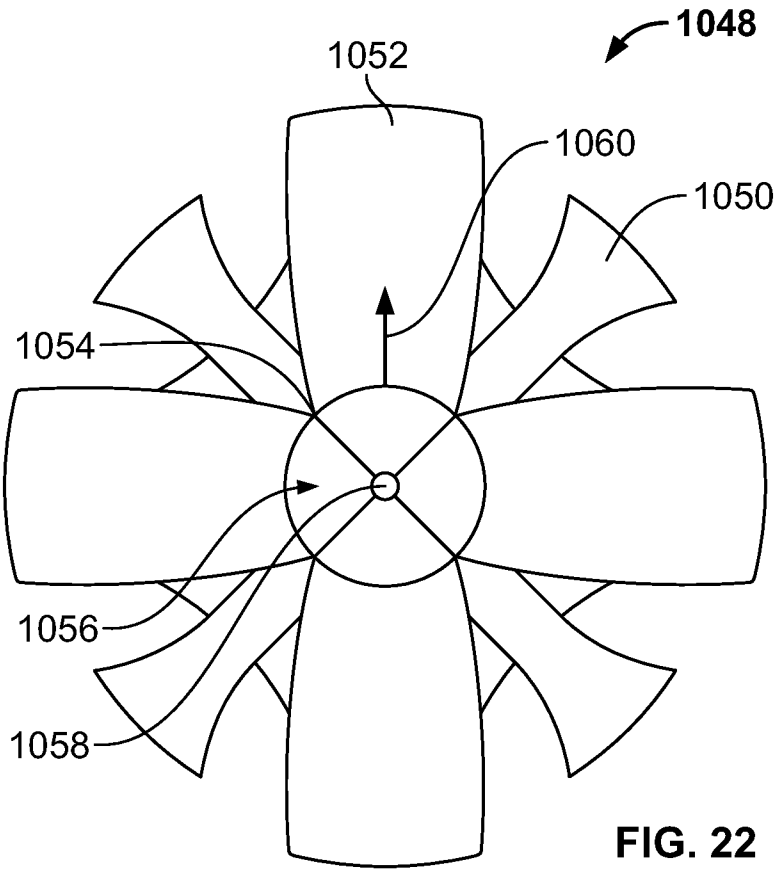
1048
1052
1060
1050
1054
1056
1058

FIG. 22

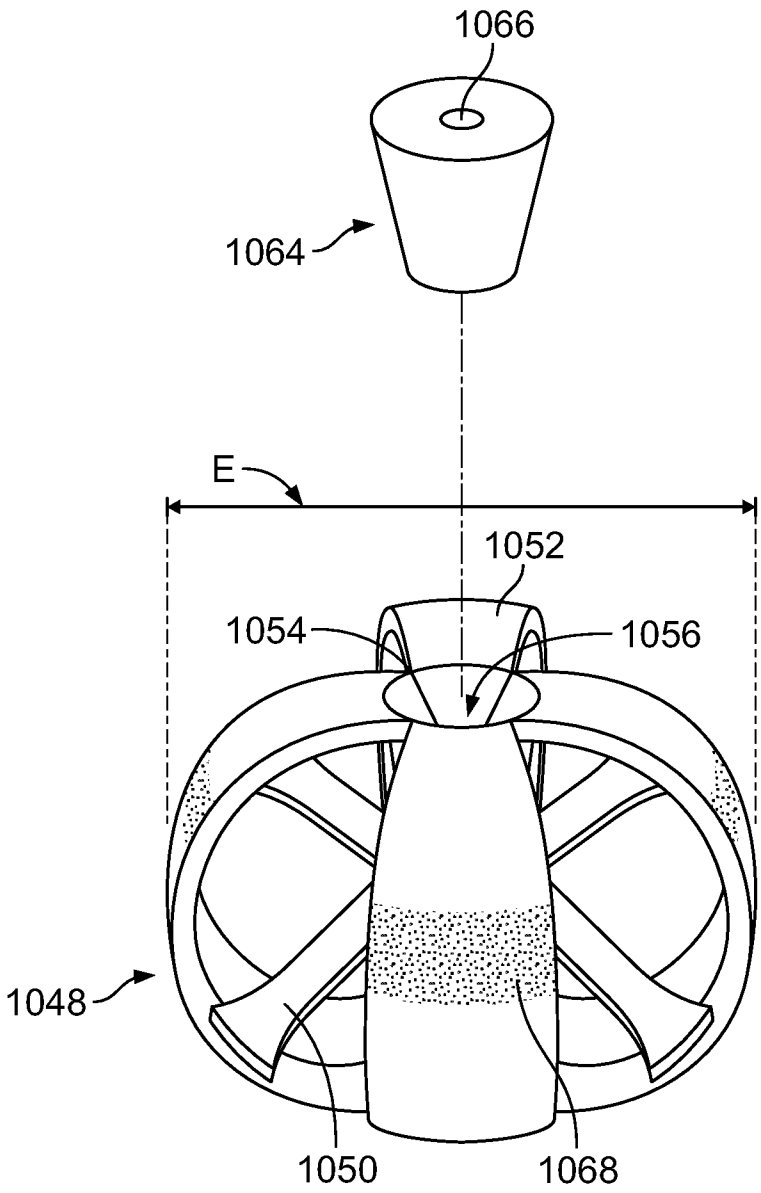

FIG. 23

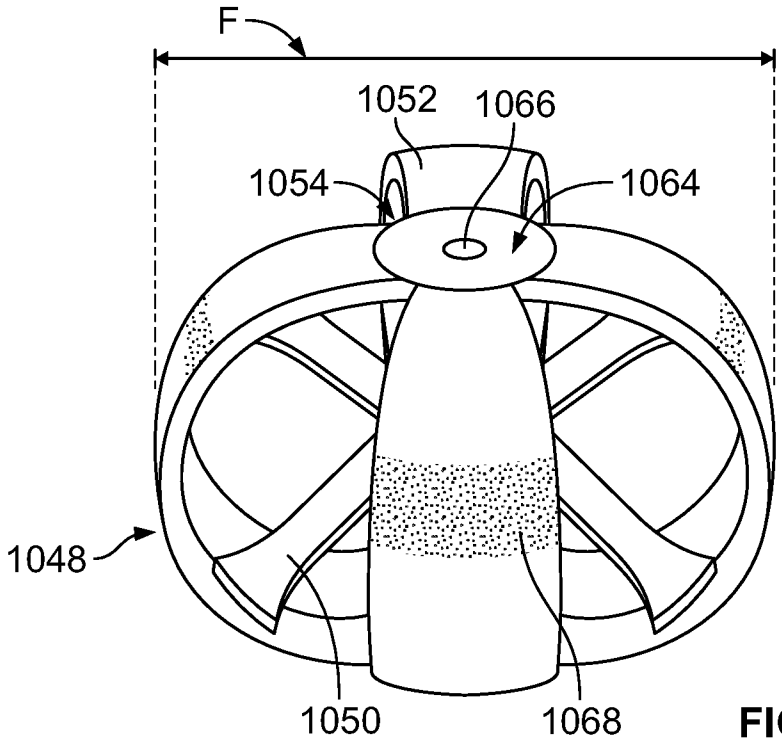
F
1052
1066
1054
1064
1048
1050
1068

FIG. 24

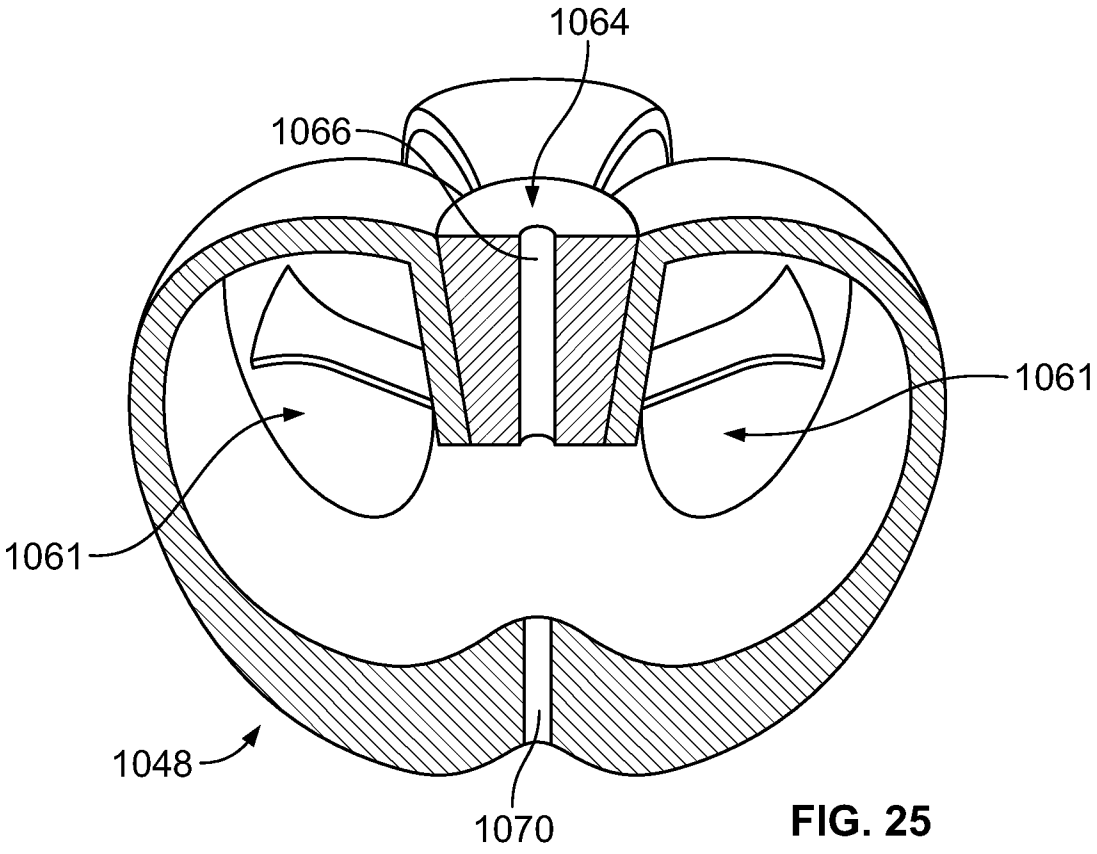
1064
1066
1061
1061
1048
1070

FIG. 25

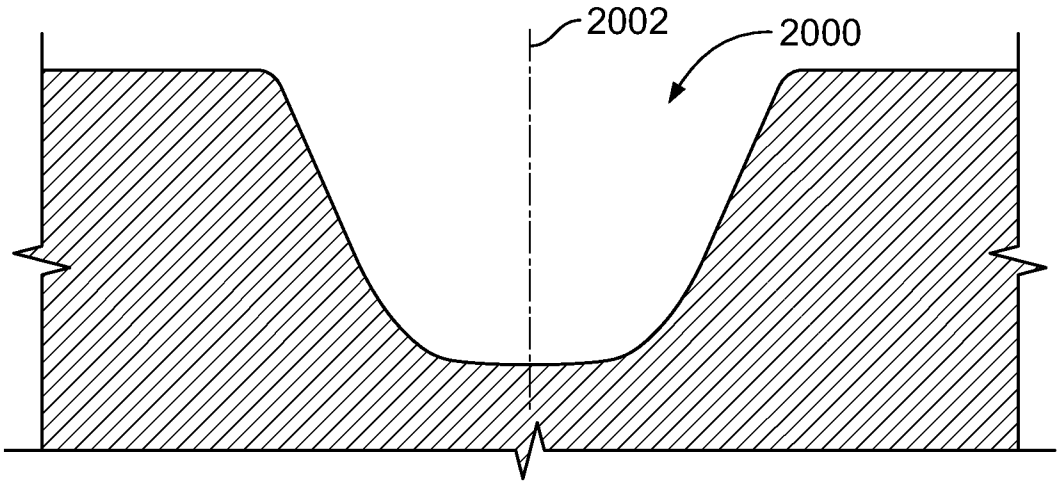
2002
2000

FIG. 26

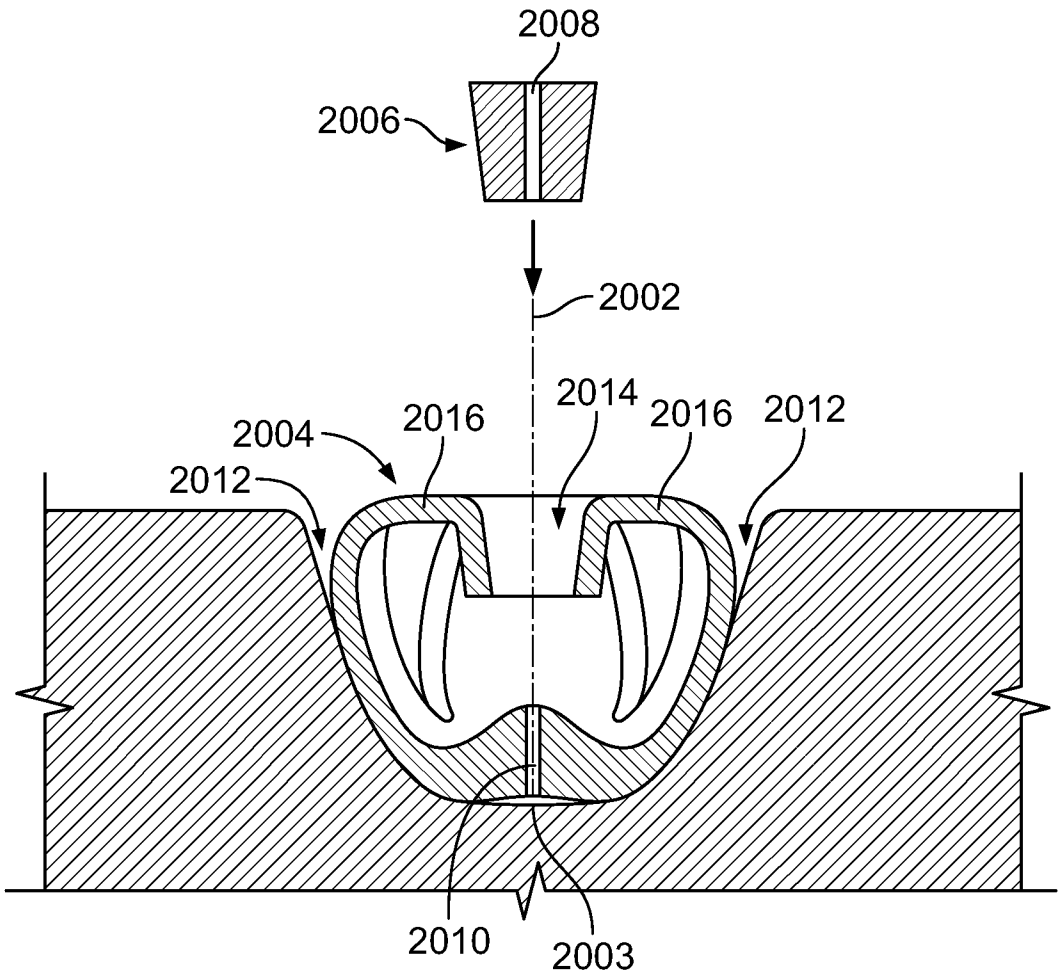
2008
2006
2002
2014
2004
2016
2016
2012
2012
2010
2003

FIG. 27

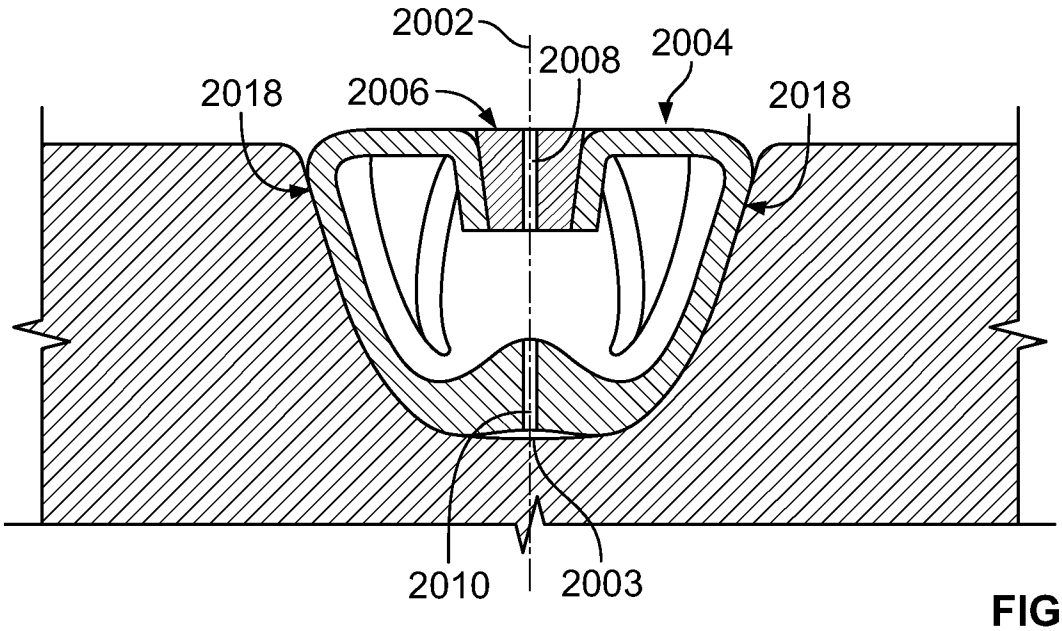
2002
2008
2004
2018
2006
2018
2010
2003

FIG. 28

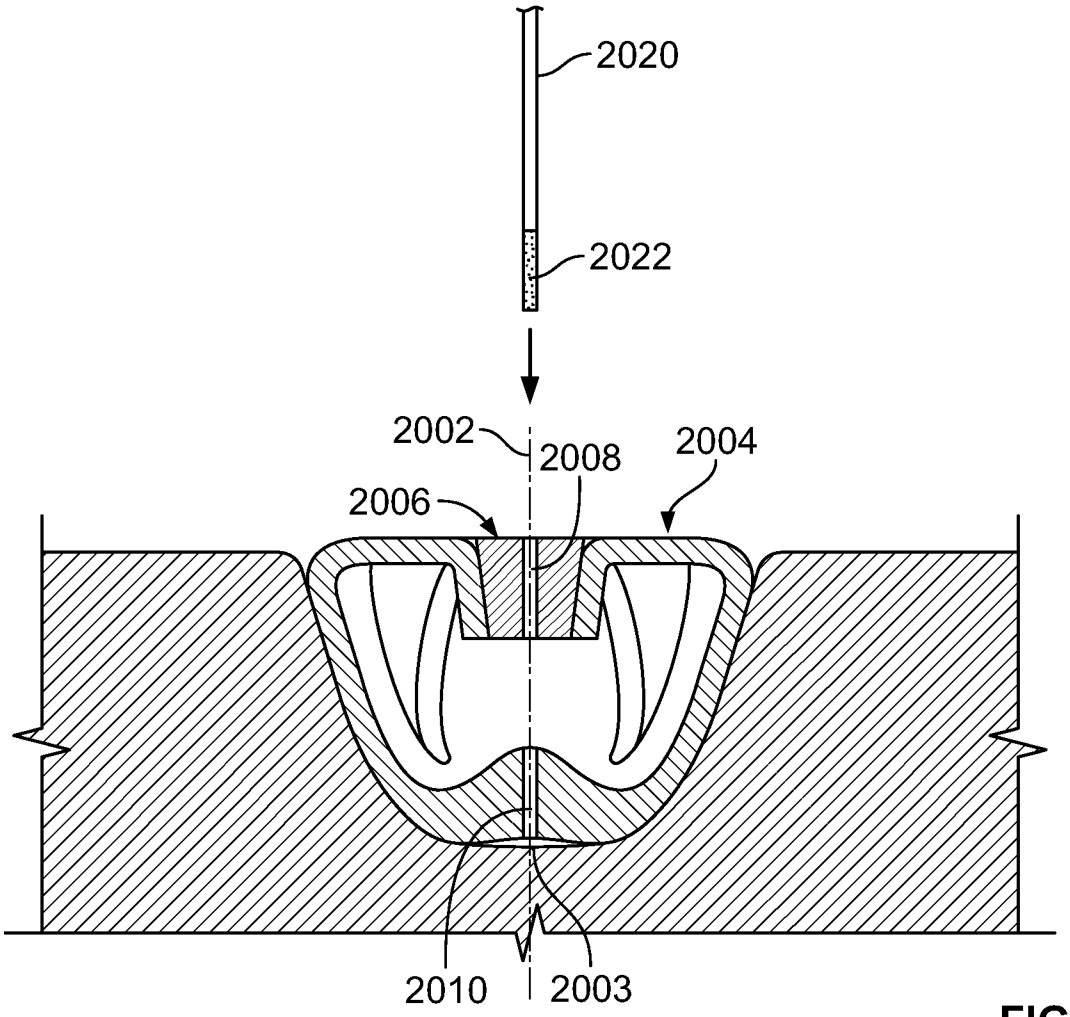
2020
2022
2002
2008
2004
2006
2010
2003

FIG. 29

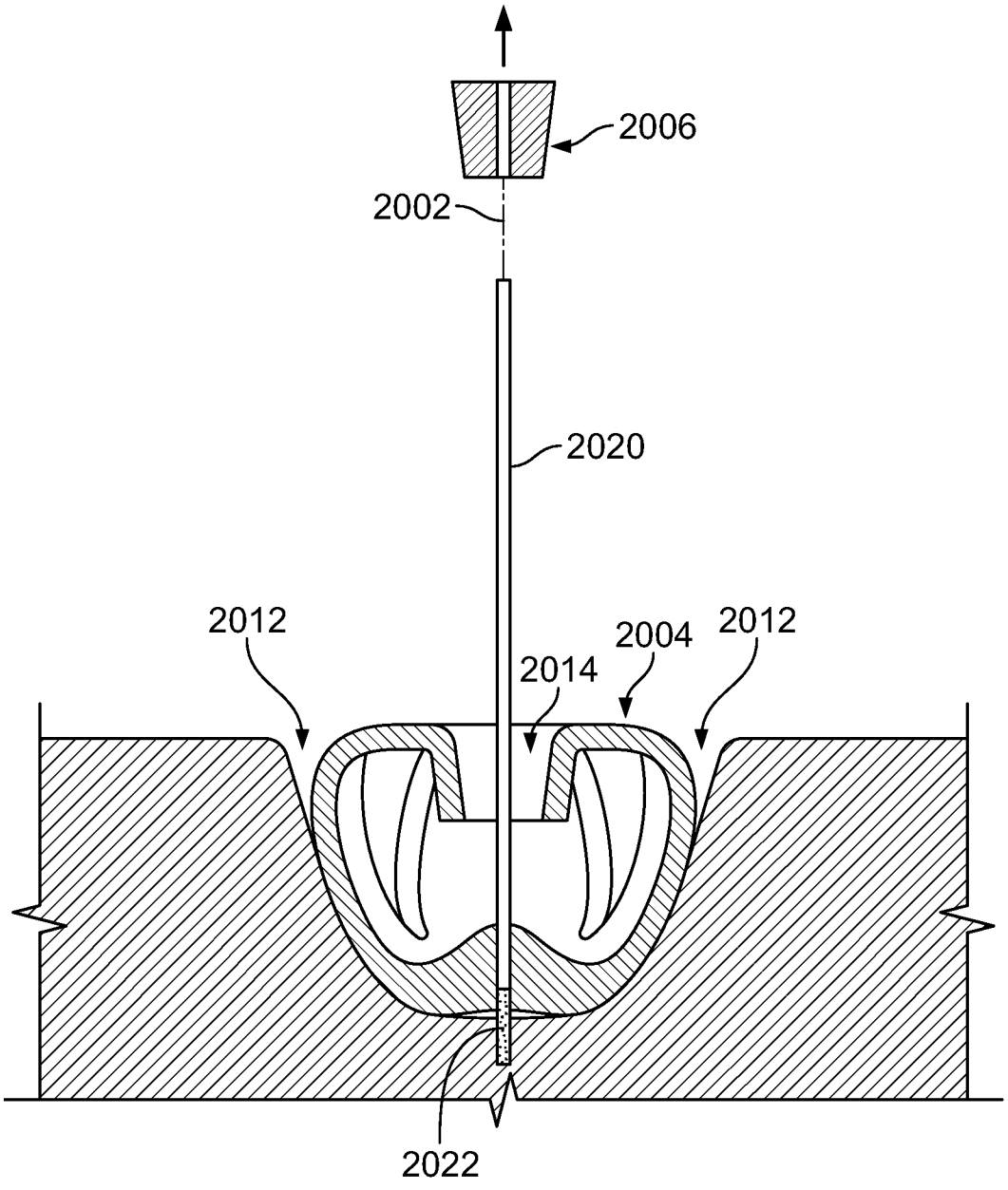

FIG. 30

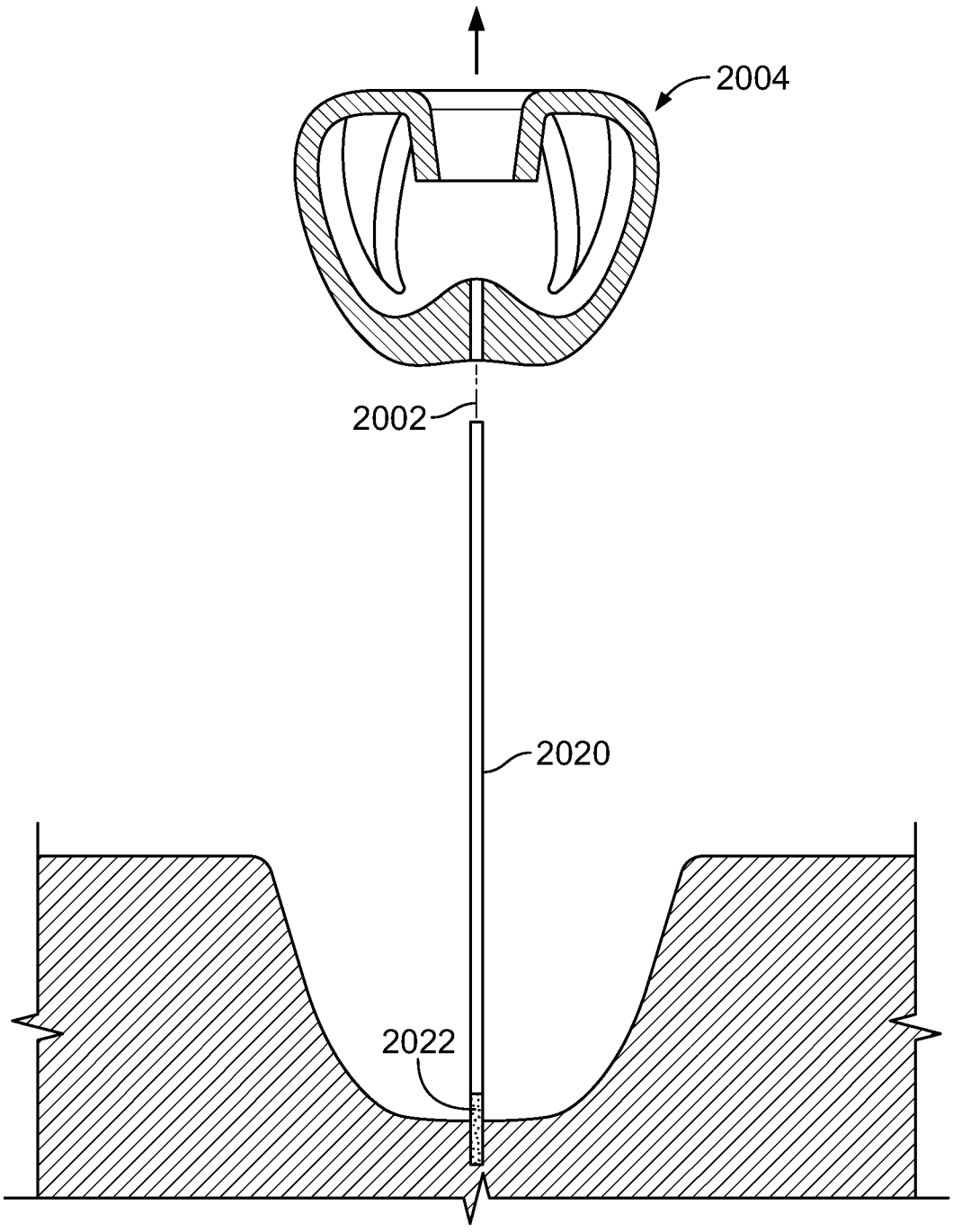

FIG. 31

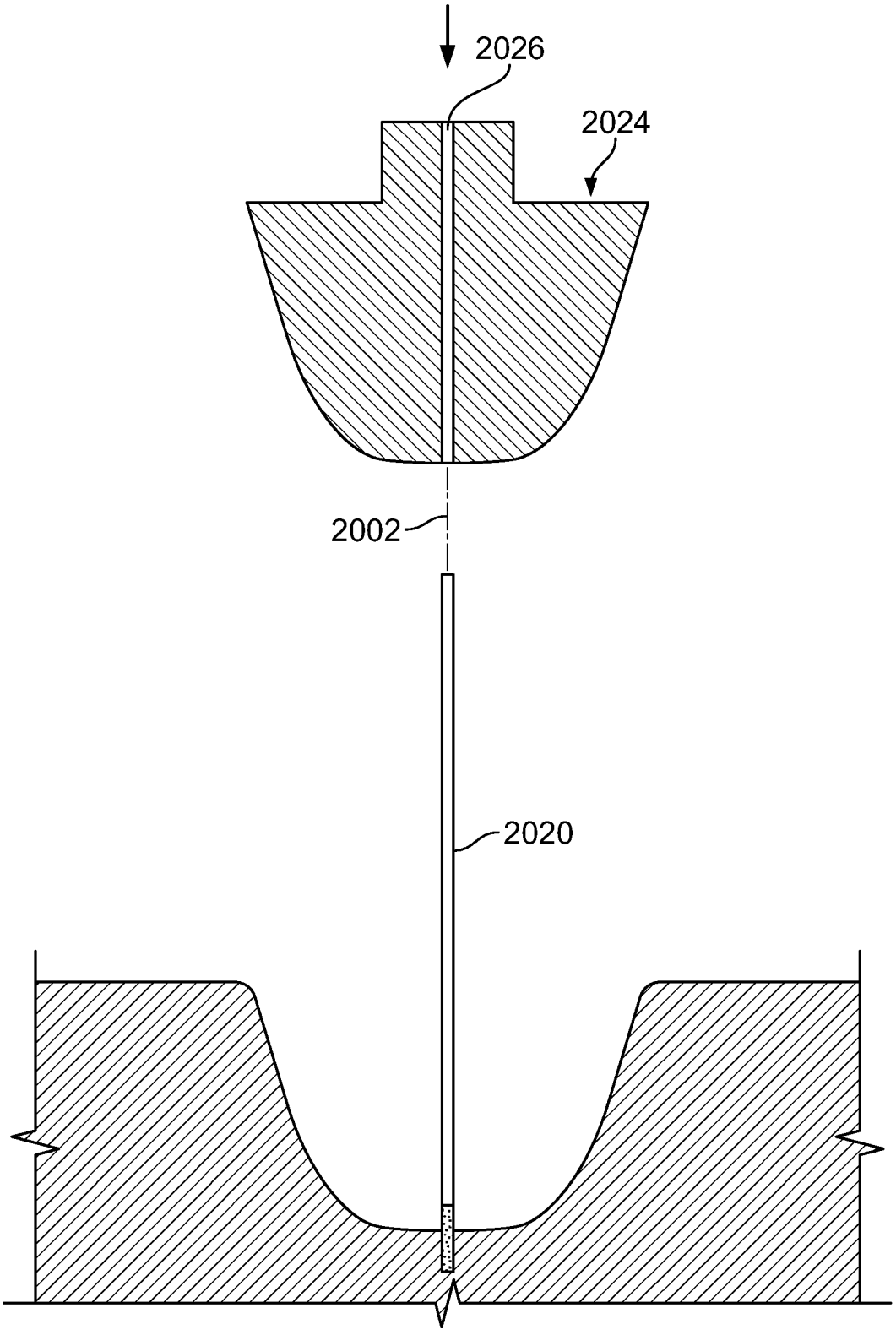

FIG. 32