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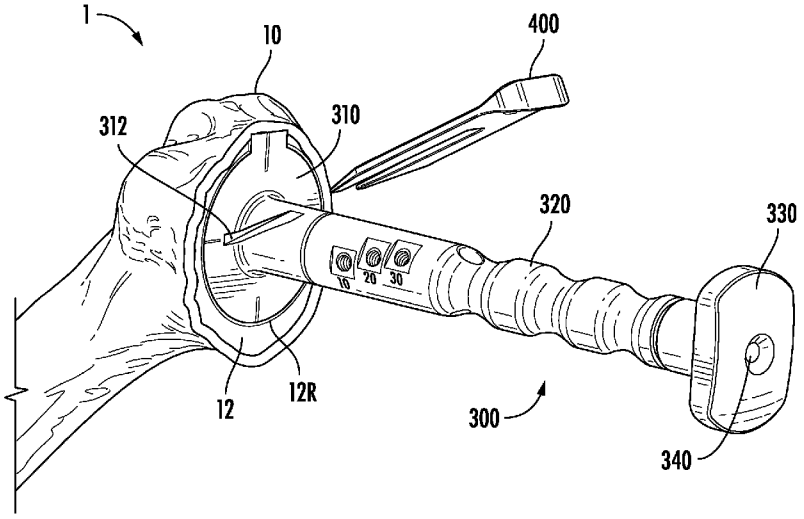

FIG. 8

(57) Abstract: A broach tool for use in preparing an implantation site of a humeral head for implantation of a humeral prothesis therein includes a cylindrical sleeve that fits concentrically around a pin anchored in the implantation site, so that the broach is guided by the pin, and a broach head that has an outer profile formed on the portion thereof that faces towards and is driven against the implantation site. This outer profile engages against the implantation site to form alignment features, or slots, in the implantation site. These alignment features aid a surgeon in properly aligning a compactor with the implantation site after the pin has been removed, the compactor being used for forming the interior of the implantation site to allow the insertion of the humeral prosthesis therein.

WO 2024/258725 A1

[Continued on next page]

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IMPLANTATION INSTRUMENTS FOR SHOULDER PROSTHESIS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a non-provisional of, and claims the benefit of the filing date of, U.S. provisional patent application number 63/472,755, which was filed June 13, 2023, and U.S. provisional patent application number 63/547,455, which was filed November 6, 2023. Each of these applications is incorporated herein in its entirety.

FIELD OF THE DISCLOSURE

[0002] The present disclosure relates generally to orthopedic tools and methods for preparing bone surfaces for a joint replacement prosthesis. Specifically, the present disclosure relates to systems and methods for forming a reference point on and/or within a bone to allow for compaction of the bone in a direction that is not perpendicular to the plane in which the bone surface has been cut or resected.

BACKGROUND OF THE DISCLOSURE

[0003] During conventional bone preparation procedures for humeral prosthesis implantation, surgeons must work in two directions to prepare the implantation site on the humeral head for the implantation of the prosthesis therein and/or the attachment of the prosthesis thereto. When performing such conventional bone preparation procedures, it is necessary to ensure that, during compaction for preparing an implant cavity, the compactor is maintained in a prescribed orientation (e.g., angle) based on the selected prosthesis being implanted into the humerus and also the anatomy (e.g., shape of the humerus of the patient) of the patient. Failure to maintain the prescribed orientation can

cause varus/valgus and/or flexion/extension misalignments that would cause the prosthesis to not fit properly onto/within the implantation site. However, there is no clear landmark for a surgeon to reference to ensure that the compactor is being driven into the implantation site at the appropriate angle. Thus, a need exists for implantation systems and methods that form landmarks or reference points within a surgical implantation site that allow a surgeon to more readily ensure that the compactor is driven into the implantation site in the prescribed orientation.

SUMMARY

[0004] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended as an aid in determining the scope of the claimed subject matter.

[0005] Disclosed herein is a broaching system configured for use in preparing an implantation site for implantation of a humeral prosthesis therein. The broaching system includes at least a broach and an osteotome. The broach includes a broach head, a broach stem, and an osteotome slot. The osteotome is configured for removable insertion into and through the osteotome slot for forming one or more alignment features within the implantation site to aid a surgeon to properly align a compactor with the implantation site.

[0006] In any of the preceding or subsequent examples, the osteotome slot is formed at an inclined, non-zero angle relative to a longitudinal axis of the broach stem.

[0007] In any of the preceding or subsequent examples, the osteotome slot is continuous and uninterrupted from the broach stem to and through the broach head.

[0008] In any of the preceding or subsequent examples, the osteotome has a length such that, when the osteotome is inserted fully into the osteotome slot, a distal portion of the osteotome protrudes out of the osteotome slot and into the implantation site to form the one or more alignment features.

[0009] In any of the preceding or subsequent examples, the broach stem and the broach head each have a bore formed therein that is configured to receive therein a pin that is implanted within the implantation site, the bore being continuous and uninterrupted within and between the broach stem and the broach head.

[0010] In any of the preceding or subsequent examples, the osteotome has a U-shaped profile, with two legs that extend substantially parallel to each other and a base that extends between and connects the two legs, such that the two legs are spaced apart from each other by the base.

[0011] In any of the preceding or subsequent examples, the osteotome slot is formed around and is not coincident with the bore.

[0012] In any of the preceding or subsequent examples, the broach head has a protruding ridge that extends away from the broach stem and is configured for forming a further alignment feature within the implantation site

[0013] In any of the preceding or subsequent examples, the protruding ridge has, on one side thereof, a curved edge and, on the opposite side thereof, an inclined edge that forms an obtuse angle relative to the bottom surface of the protruding ridge that connects the curved edge to the inclined edge.

[0014] In any of the preceding or subsequent examples, the one or more alignment features extend substantially coaxially with a longitudinal axis of a humerus in which the implantation site is formed.

[0015] Also disclosed herein is a method for performing a broaching procedure to prepare an implantation site for implantation of a humeral prosthesis therein. The method includes providing a broach and providing an osteotome. The broach includes a broach head, a broach stem, and an osteotome slot. The method includes inserting the osteotome into and through the osteotome slot for forming one or more alignment features within the implantation site to aid a surgeon to properly align a compactor with the implantation site. The osteotome is inserted within the osteotome slot in a manner than allows subsequent removal of the osteotome from the osteotome slot without damaging the one or more alignment features formed by the osteotome.

[0016] In any of the preceding or subsequent examples, the osteotome slot is formed at an inclined, non-zero angle relative to a longitudinal axis of the broach stem.

[0017] In any of the preceding or subsequent examples, the osteotome slot is continuous and uninterrupted from the broach stem to and through the broach head.

[0018] In any of the preceding or subsequent examples, the osteotome has a length such that, when the osteotome is inserted fully into the osteotome slot, a distal portion of the osteotome protrudes out of the osteotome slot and into the implantation site to form the one or more alignment features.

[0019] In any of the preceding or subsequent examples, the broach stem and the broach head each have a bore formed therein; and the bore is continuous and uninterrupted within and between the broach stem and the broach head. The method

includes receiving, within the bore, a pin that is implanted within the implantation site to maintain a prescribed alignment of the broach to the implantation site.

[0020] In any of the preceding or subsequent examples, the osteotome has a U-shaped profile, with two legs that extend substantially parallel to each other and a base that extends between and connects the two legs, such that the two legs are spaced apart from each other by the base.

[0021] In any of the preceding or subsequent examples, the osteotome slot is formed around and is not coincident with the bore.

[0022] In any of the preceding or subsequent examples, the broach head has a protruding ridge that extends away from the broach stem for forming a further alignment feature within the implantation site

[0023] In any of the preceding or subsequent examples, the protruding ridge has, on one side thereof, a curved edge and, on the opposite side thereof, an inclined edge that forms an obtuse angle relative to the bottom surface of the protruding ridge that connects the curved edge to the inclined edge.

[0024] In any of the preceding or subsequent examples, the one or more alignment features extend substantially coaxially with a longitudinal axis of a humerus in which the implantation site is formed.

[0025] Examples of the present disclosure provide numerous advantages. In one non-limiting example advantage, a user of the systems disclosed herein can reliably ensure proper alignment of a broach with an implantation site while simultaneously being able to form alignment features within the implantation site by the insertion of an osteotome through the osteotome slot formed in the broach. In another non-limiting example

advantage, the osteotome can be removed from the osteotome slot, thereby allowing the formation of the alignment features within the implantation site that are aligned with the longitudinal humeral axis, then allowing for disengagement of the broach from the implantation site after the osteotome is removed from the osteotome slot, so as to not damage the alignment features formed by the osteotome during disengagement of the broach from the implantation site. Thus, it is advantageous to be able to form alignment features within the implantation site that extend in different directions from each other.

[0026] Further features and advantages of at least some of the examples of the present invention, as well as the structure and operation of various examples of the present invention, are described in detail below with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] By way of example, specific examples of the disclosed device will now be described, with reference to the accompanying drawings, in which:

[0028] **FIG. 1** shows a portion of a humerus bone with a portion of the humeral head resected therefrom for implantation of a prosthesis at/in the implantation site formed by the resection;

[0029] **FIG. 2** shows the implantation site formed on the humeral head, with a sizing template installed over the implantation site and a pin installed in the humeral head in a central location as defined by the sizing template;

[0030] **FIG. 3** shows a reamer installed concentrically over and around the pin;

[0031] **FIG. 4** shows the reamer of **FIG. 3** applied to the implantation site to remove a portion of the interior bone mass of the humeral head at the implantation site;

[0032] **FIG. 5** shows the implantation site after the reamer has been removed, with the pin not shown to more clearly illustrate the shape of the implantation site after the reaming procedure has been performed;

[0033] **FIG. 6** shows a broach according to the presently disclosed subject matter installed concentrically over and around the pin;

[0034] **FIG. 7** shows the broach of **FIG. 6** fully engaged within the implantation site during a broaching procedure to form a broached implantation site;

[0035] **FIG. 8** shows an osteotome that is insertable within the osteotome slot of the broach shown in **FIGS. 6** and 7 for forming a lateral alignment slot internal to the humerus at the implantation site;

[0036] **FIG. 9** shows another example for a broach with an osteotome slot formed therein.

[0037] **FIG. 10** shows the broached implantation site after the broaching procedure, including after insertion and removal of the osteotome from the osteotome slot of the broach during the broaching procedure;

[0038] **FIG. 11** shows a first stage compactor for performing an initial compaction step of the interior bone mass of the humeral head to have a prescribed shape at the implantation site;

[0039] **FIG. 12** shows the first stage compactor of **FIG. 11** being aligned with and partially engaged with the alignment features of the broached implantation site;

[0040] **FIG. 13** is an internal sectional view of the first stage compactor of **FIG. 11** fully engaged within the humeral head at the broached implantation site to form an initially compacted implantation site.

[0041] **FIG. 14** shows a second stage compactor for performing a further compaction step of the interior bone mass of the humeral head to have a prescribed shape at the implantation site, the second stage compactor being shown aligned with the alignment features of the implantation site, which are formed by the first stage compactor, for insertion of the second stage compactor into the implantation site;

[0042] **FIG. 15** is an internal sectional view of the humeral head, with the second stage compactor inserted to a depth of a base of the initially compacted implantation site;

[0043] **FIG. 16** is an internal sectional view of the humeral head, with the second stage compactor having been fully driven into the initially compacted implantation site to form a prepared implantation site; and

[0044] **FIG. 17** shows an example of a prosthesis that can be inserted into the prepared implantation site of **FIG. 16** as part of a prosthetic implantation procedure.

[0045] **FIG. 18** is a side view of a portion of the prosthesis of **FIG. 17**, with the prosthetic humeral head omitted from the prosthesis.

[0046] **FIGS. 19A-D** show steps performed using another example of a broach to guide insertion of a second guide pin within the humeral shaft, the second guide pin being used to guide a movement of the example compactors disclosed herein to maintain a proper orientation of such compactors with the implantation site.

[0047] The drawings are not necessarily to scale. The drawings are merely representations, not intended to portray specific parameters of the disclosure. The

drawings are intended to depict various examples of the disclosure, and therefore are not considered as limiting in scope. In the drawings, like numbering represents like elements.

DETAILED DESCRIPTION

[0048] The subject matter described herein relates generally to a surgical broach that aids, in conjunction with an osteotome that is removably insertable within an osteotome slot formed in the broach, in ensuring proper alignment of a compactor with the implantation site in a compaction step that is performed after removal of the surgical broach from the implantation site. In a conventional broaching procedure, the broach is driven into the internal bone mass to form an initial vertical alignment slot. However, there is no landmark that indicates to a surgeon at what angle the first stage compactor should be inclined relative to the planar surface of the implantation site to ensure that the first stage compactor is properly aligned with the longitudinal humeral axis. Failure to form the void/cavity at the proper angle within the humeral head and humeral shaft is known to result in an anatomically incorrect alignment of the prosthesis relative to the implantation site and/or humeral head, which can cause reduced and/or painful post-operative mobility of the joint for the patient, requiring further treatment. Thus, the example surgical broach and osteotome disclosed herein are useful as a system to form visual landmarks that aid a surgeon in ensuring proper alignment of a surgical compactor with the humeral shaft to, in turn, ensure proper fixation of the prosthesis to the humeral head.

[0049] **FIG. 1** shows a humerus, generally designated **1**, with a humeral head **10** and a humeral shaft **20**, the humeral shaft **20** extending in the direction of the longitudinal

humeral axis **1A**. As a first step, a portion of the humeral head **10** to be replaced with the prosthesis (see, e.g., **700**, **FIGS. 17** and **18**) is first identified and then resected, as shown in **FIG. 1**, to form a base implantation site **12**. The base implantation site **12** has a substantially planar surface across the outer surface (e.g., the surface created during resection of the portion of the humeral head **10**) thereof. Next, one or more templates **110** are then, as shown in **FIG. 2**, applied over the base implantation site **12** to determine a size of the base implantation site **12**. The template **110** that is determined to best fit the base implantation site **12**, as determined by the surgeon, determines the size of the prosthesis to be implanted in the humerus **1** of the patient. After the appropriate template **110** has been selected, a longitudinally-extending pin **100** is inserted into the base implantation site **12**, at a location designated by the template **110** (e.g., the center of the base implantation site **12**). Thus, the placement of the pin **100** is generally determined by the selection of the appropriate template **110** by the surgeon. The pin **100** is oriented at a generally 90° angle relative to the plane defined by the outermost surface of the base implantation site **12**.

[0050] Next, as shown in **FIG. 3**, a reamer, generally designated **200**, is inserted over and around the pin **100** (e.g., coaxially) to maintain a substantially perpendicular alignment of the reamer **200** relative to the base implantation site **12**. The reamer **200** has a reamer head **210** that is rigidly attached to a reamer stem **220**. Alignment of the reamer with the base implantation site **12** is maintained by the reamer stem **220** being in the form of a hollow cylinder (e.g., having a longitudinally-extending hollow bore formed along the entire length of the reamer stem **220**). The bore of the reamer stem **220** advantageously has an internal diameter that is larger, to at least some degree, than the

diameter of the pin **100**. The bore of the reamer stem **220** extends, in a continuous and uninterrupted manner, along the entire length of the reamer **200**, including through the reamer head **210** and the reamer stem **220**. The hollow bore of the reamer **200** receives the pin **100** therein. The reamer head **210** has cutting surfaces that, when the reamer head **210** is rotated (e.g., by a rotary tool) against the base implantation site **12**, removes internal bone material (e.g., within the base implantation site **12**).

[0051] During the reaming procedure, the reamer **200** is advanced along the longitudinal axis of the pin **100**, from the position shown in **FIG. 3** to the position shown in **FIG. 4**, in which the reamer head **210** is substantially coplanar with the base implantation site **12** in the plane defined where the reamer head **210** is joined to the reamer stem **220**. Thus, when reamer **200** is in the position shown in **FIG. 4**, the cutting surface(s) of the reamer head **210** have formed a cavity **14**, or "bowl region," which is shown in **FIG. 5**. The cavity **14** has a prescribed shape and depth that extends from the resection plane that initially defines, as shown in **FIG. 1**, the base implantation site **12** on the humeral head **10**, thus forming the reamed implantation site **12R**, as shown in **FIG. 5**.

[0052] The reamer head **210** has a circumferential flange that extends radially about (e.g., away from) the upper edge of the reamer head **210** to define a stop surface, thereby aiding the surgeon in ensuring that the cavity **14** is reamed to the prescribed depth and also aiding the surgeon in ensuring that the reamer is not advanced too far along the longitudinal axis of the pin **100**, which would cause the cavity **100** to have too great of a depth. **FIG. 5** shows the reamed implantation site **12R**, as well as the cavity **14** or bowl region thereof, that is formed by the reamer **200**. The reamed implantation site **12R** is shown in **FIG. 5** with the pin **100** omitted for clarity of illustration, however, the pin **100**

is not removed from the humeral head **10** immediately after the reaming procedure is completed.

[0053] The reamer **200** is then removed from the pin **100** and, as shown in **FIG. 6**, a broach, generally designated **300**, is then inserted over and around the pin **100** (e.g., coaxially) to maintain a substantially perpendicular alignment of the broach **300** relative to the pin **100** and, thus, to the reamed implantation site **12R**, at least since the pin **100** is rigidly inserted within the reamed implantation site **12R**. The broach **300** has a broach stem **320** that is generally in the form of a hollow cylinder that has an outer wall with a longitudinally-extending bore formed along the entire length of the broach stem **320**, so that the pin **100** can pass through the bore **340**. The outer wall of the broach stem **320** can, but is not required to, have a generally annular shape or profile. The bore **340** advantageously has an internal diameter that is larger, to at least some degree, than the diameter of the pin **100**. The bore **340** extends, in a continuous and uninterrupted manner, along the entire length of the broach **300**, including through the broach head **310** and the broach stem **320**. The hollow bore **340** of the broach **300** receives the pin **100** therein. Thus, the pin can pass through the portion of the bore **340** within the broach head **310** and into and/or through the portion of the bore **340** within the broach stem **320**.

[0054] The broach **300** also has, attached to the proximal end of the broach stem **320**, a broach head **310**. The broach head **310** has a bowl portion **314** that is shaped substantially similarly to the cavity **14** of the reamed implantation site **12R**, as shown in **FIGS. 5** and **6**. The broach head **310** also has a protruding ridge **316** that is formed on and extends away from an outer surface of the bowl portion **314**. The protruding ridge **316** is configured to contact the internal surfaces of the reamed implantation site **12R** to

form a vertical alignment slot, generally designated **16V** (see, e.g., **FIG. 10**) within the reamed implantation site **12R** of the humeral head **10** to aid in insertion of the prosthesis (see, e.g., **700**, **FIG. 17**) within a prepared implantation site. The broach stem **320** also has, at the distal end thereof, an impactor surface **330** formed integrally (e.g., such that the entire broach **300** has a unitary structure). The impactor surface **330** is a surface that allows a surgeon to strike the broach **300** to thereby drive the broach head **310** into and against the inner surface of the cavity **14** at the reamed implantation site **12R**. The broach stem **320** is advantageously longer than the portion of the pin **100** that protrudes from the surface of the reamed implantation site **12R**, so that no portion of the pin **100** protrudes through and/or beyond the impactor surface **330** while the broach **300** is in use (e.g., being struck by a surgeon). After the broach **300** is properly aligned with the reamed implantation site **12R**, the impactor surface **330** is impacted until the surface of the broach head **310**, by which the broach head **310** is attached to the broach stem **320**, is flush with the outer surface of the reamed implantation site **12R**.

[0055] The broach **300** also has an osteotome slot **312** that extends from the broach stem **320** into the broach head **310**. The osteotome slot **312** is inclined at a non-zero angle relative to the longitudinal axis of the broach stem **320**. In one example, the non-zero angle can be between about 1° to about 90°. In a more specific example, the non-zero angle can be between about 25° to about 75°. In a still more specific example, the non-zero angle can be between about 30° to about 70°. In a yet more specific example, the non-zero angle can be between about 45° to about 60°. In another example, the non-zero angle can be between about 30° to about 45°. The osteotome slot **312** is formed in and/or through the broach head **310**. In the example broach **300** illustrated herein, the osteotome

slot **312** is formed partially in and around the outer wall of the broach stem **320**. In the example shown herein, no portion of the osteotome slot **312** is coincident with any portion of the bore **340** of the broach **300**, either in the broach head **310** or in the broach stem **320**. The osteotome slot **312** is shaped to receive an osteotome, generally designated **400**, within the osteotome slot **312**.

[0056] The osteotome **400** has a generally U-shaped profile, as can be seen in **FIG. 8**. Thus, the osteotome slot **312** is formed as two generally longitudinally-extending portions into and through which the "legs" of the U-shaped base of the osteotome **400** are inserted. These portions of the osteotome slot **312** are formed around and on opposite sides of the bore **340** in the broach stem **320** and broach head **310**. Thus, a first portion of the osteotome slot **312** is formed on an opposite side of the bore **340** from the second portion of the osteotome slot **312**.

[0057] A plurality of broaches **300**, each with a different angle of inclination for the osteotome slot **312**, can be provided. The broach **300** is selected by the surgeon based on the anatomical shape of the humerus **1**, which can be determined during resection of the humeral head **10**. The broach **300** that has an angle of inclination of the osteotome slot **312** that is the closest (e.g., out of all of the broaches **300** provided to the surgeon) to parallel, or at least substantially parallel (e.g., ±15°, ±10°, ±5°, ±3°, ±2°, or ±1°), to the longitudinal humeral axis **1A** is selected for use during the broaching procedure. Thus, when the broach **300** is driven into the reamed implantation site **12R**, as shown in **FIG. 7**, the osteotome slot **312** of the broach **300** is advantageously parallel to, or at least substantially parallel to, the longitudinal humeral axis **1A**.

[0058] While the broach **300** is held in the position shown in **FIG. 7**, the osteotome **400** shown in **FIG. 8** is aligned with the osteotome slot **312** and the "legs" of the osteotome **400** are each inserted into a corresponding one of the portions of the osteotome slot **312**. The osteotome **400** is fully inserted into the osteotome slot **312**, which may require application of force, such as, for example, using a mallet to strike the base of the osteotome **400**, such that the base of the U-shaped profile is in contact (e.g., direct contact) with the outer surface of the outer wall of the broach stem **320** when the osteotome **400** is fully inserted within the osteotome slot **312**. As used herein, the "base" of the U-shaped profile of the osteotome **400** is the portion that is directly attached to both of the "legs" of the osteotome **400**, such that the "legs" extend away from the "base" at the opposing ends of the "base" of the osteotome **400**. When fully inserted into the osteotome slot **312**, the osteotome **400** forms a lateral alignment slot (see **16L**, **FIG. 10**). The "legs" of the U-shaped profile of the osteotome **400** are advantageously spaced apart from each other by a distance that is the same as or less than a width of the protruding ridge **316**, such that the lateral alignment slot(s) **16L** intersect(s) with (e.g., forming a continuous cavity with) the vertical alignment slot **16V**, as shown in **FIG. 10**. The lateral alignment slots **16L** can, in some instances, be referred to herein as "anterior" and "posterior" slots, respectively.

[0059] The osteotome **400** is removed from the osteotome slot **312** before the broach **300** is removed (e.g., by sliding along the pin **100**) from the broached implantation site **12B**, so as to advantageously avoid the osteotome **400** from disturbing the broached implantation site **12B** during removal of the broach **300** from the broached implantation site **12B**. After removal of the osteotome **400** from the osteotome slot **312** and,

subsequently, of the broach **300** from the broached implantation site **12B**, the broach **300** and the osteotome **400** have formed the broached implantation site **12B**, an example of which is shown in **FIG. 10**.

[0060] **FIG. 9** shows a sectional view of an example broach **300**. The broach head **310** has a bowl portion **314** and is attached to the broach stem **320**, as is shown in **FIGS. 6-8**. However, in the broach **300** of **FIG. 9**, the protruding ridge **316** is larger and differently shaped than for the broach shown in **FIGS. 6-8**. The protruding ridge **316** has, on one side, a curved edge **316CE** and, on the opposite side, an inclined edge **316IE**. The broach head **310** is advantageously positioned such that the curved edge **316CE** extends towards (e.g., is closest to, relative to the inclined edge) the humeral shaft **320**. The inclined edge **316IE** defines an extended edge **316EE** that extends radially outwardly by a prescribed distance, beyond the outer circumferential edge of the bowl portion **314**, so as to form a portion of the vertical alignment slot (see, e.g., **16V**, **FIG. 10**) to have a space or region that allows for insertion of the ridge area (see **718**, **FIG. 18**) of the prosthesis base. The broach stem **320** and broach head **310** shown in **FIG. 9** have an osteotome slot **312** formed therethrough, the broach **300** shown in **FIG. 9** having an osteotome **400** shown inserted within the osteotome slot **312**. The shape and functionality of the osteotome **400** and osteotome slot **312** of the example broach **300** shown in **FIG. 9** is substantially identical to the osteotome **400** and osteotome slot **400** of the example broach **300** shown in **FIGS. 6-8**.

[0061] The placement of the broach **300** and the insertion of the osteotome **400** within the osteotome slot **312** determines the final position of the prosthesis (see **700**, **FIG. 17**) being implanted. In particular, for humeral prosthetic implantation procedures,

the direction of extension of the humerus (i.e., the longitudinal humeral axis **1A**) is inclined at a non-zero and non-perpendicular angle relative to the plane in which the implantation site **12** is formed. In order to ensure adequate fixation of the prosthesis **700** within the humerus **1**, it is necessary for the compactor (see **500**, **FIGS. 11-13**, and **600**, **FIGS. 14-16**) to be driven into the broached implantation site **12B** at this inclined angle relative to the plane of the outer surface of the broached implantation site **12**, such that a cavity with lateral and vertical alignment slots **16L**, **16V** corresponding to the alignment features of the prosthesis **700** to be inserted therein can be formed internal to the humerus **1** for fixation of the prosthesis **100** implanted therein, by fasteners (e.g., screws) and also ossification. The formation of alignment features (e.g., lateral and vertical alignment slots **16L**, **16V**) that extend in two different planes within the broached implantation site **12B** before compaction advantageously allows a surgeon to ensure that the first stage compactor **500** (see **FIGS. 11-13**) is also aligned with the longitudinal humeral axis **1A** by simultaneously aligning the vertical fins **516V** of the first stage compactor **500** with the vertical alignment slot **16V** and also the lateral fins **516L** of the first stage compactor **500** with the lateral alignment slots **16L**, ensuring proper alignment of the first stage compactor **500** relative to the longitudinal humeral axis **1A** in at least two (2) dimensions or planes.

[0062] After the broaching procedure is complete, one or more compactors is/are applied to the broached implantation site **12B** to form a partially or fully compacted implantation site. **FIG. 11** shows an example of such a first stage compactor, generally designated **500**. The first stage compactor **500** has a compactor head **510** that is rigidly attached to a compactor stem **520**. The compactor head **510** has a vertical fin **516V** that,

when in the aligned orientation shown in **FIGS. 12** and **13**, is aligned with the vertical alignment slot **16V** of the broached implantation site **12B** shown in **FIG. 10**. The compactor head **510** also has a lateral fin **516L** that extends away from the vertical fin **516V**, on opposite sides of the vertical fin **516V**. When the first stage compactor **500** is in the aligned orientation shown in **FIGS. 12** and **13**, the lateral fin **516L** is aligned with the lateral alignment slot **16L** of the broached implantation site **12B** shown in **FIG. 10**. The vertical fin **516V** and the lateral fin **516L** intersect each other (e.g., at about 90°), such that the vertical fin **516V** is bisected by the lateral fin **516L** or, stated differently, the lateral fin **516L** is bisected by the vertical fin **516V**. The vertical fin **516V** and the lateral fin **516L** extend, when in the fully engaged position shown in **FIG. 13**, deeper than the vertical alignment slot **16V** and the lateral alignment slot **16L**, respectively. Thus, when the first stage compactor **400** is in the fully engaged position shown in **FIG. 13**, the vertical fin **516V** will have enlarged the vertical alignment slot **16V** to be larger than the vertical alignment slot **16V** of the broached implantation site **12B**, which was formed initially by the protruding ridge **316** of the broach **300**, and the lateral fin **516L** will have enlarged the lateral alignment slot **16L** to be larger than the lateral alignment slot **16L** of the broached implantation site **12B**, which was initially formed by the insertion of the osteotome **400** into and at least partially through the osteotome slot **312** of the broach **300**.

[0063] During each subsequent compaction procedure, the respective depths of the vertical alignment slot **16V** and of the lateral alignment slot **16L** are increased by insertion of compactors (e.g., **500**, **600**) having progressively larger vertical fins **516V**, **616V** and lateral fins **516L**, **616L** than the previously used compactor.

[0064] An example of a second stage compactor, generally designated **600**, is shown in **FIGS. 14-16**. The second stage compactor **600** has a compactor head **610** that is rigidly attached to a compactor stem **620**. The second stage compactor **600** has lateral and vertical fins **616L**, **616V** that are generally arranged at the same angle to each other as the lateral and vertical fins **516L**, **516V** of the first stage compactor **500**, but the lateral and vertical fins **616L**, **616V** of the second stage compactor **600** have a more elongated shape than the lateral and vertical fins **516L**, **516V** of the first stage compactor **500**, so as to progressively enlarge and elongate the lateral and vertical alignment slots **16L**, **16V** in the implantation cavity of the implantation site **12**, this implantation cavity extending within and through the humeral head **10** and substantially coaxially towards and into the humeral shaft **20**. This sequential enlarging of the lateral and vertical alignment slots **16L**, **16V** continues until a final compactor, which has lateral and vertical fins that are substantially the same size as (e.g., the same size as, or within 10% or 5% of the size thereof in any dimension) the corresponding alignment features of the prosthesis base that is to be implanted in the implantation site **12**, is inserted into the implantation site **12**, thus forming a fully compacted implantation site that is ready for insertion of the prosthesis **700** therein. In this non-limiting example, the second stage compactor **600** is the "final compactor" described herein. However, in some examples, additional compactors (e.g., third, fourth, *etc.*) may be provided to sequentially shape the implantation cavity during a series of sequentially performed compaction procedures or steps.

[0065] **FIG. 17** shows an example humeral prosthesis, generally designated **700**, with a prosthesis base **710** that is inserted within (e.g., implanted within) the implantation

cavity at the implantation site. The prosthesis **700** has a prosthetic humeral head **720** that is attached (e.g., rigidly or permanently, or in a removable manner) to the prosthesis base **710**. The prosthesis base **710** has lateral and vertical fins **716L**, **716V** that are formed to align with the lateral and vertical alignment slots **16L**, **16V**, respectively, that are formed within the implantation cavity of the fully compacted implantation site that is produced during the final compaction procedure. **FIG. 18** shows features of the prosthesis base **710** of the example humeral prosthesis **700** shown in **FIG. 17**, with the prosthetic humeral head **720** not shown in **FIG. 18** to better illustrate the features of the prosthesis base **710**. The example prosthesis **700** has a prosthetic humeral head **720** that, when fully inserted within the implantation cavity, sits substantially flush with (e.g., coplanar to) the resection plane that defines the implantation site **12** on the outer surface of the humeral head **10**, such that the prosthetic humeral head **720** acts as an anatomically correct replacement for the portion of the humeral head **10** that was resected.

[0066] The prosthesis base **710** has a stem, or vertical fin **716V**, that extends through the humeral head **10** and, preferably, into the humeral shaft **20**, at least in part, when the prosthesis base **710** is implanted within the implantation cavity. The vertical fin **716V** is substantially the same size and shape as the vertical alignment slot **16V**. The prosthesis base **710** has lateral fins **716L** that extend from the vertical fin **716V** in positions corresponding to the lateral alignment slots **16L**. The prosthesis base **710** has a ridge area **18** that fits within a region of the vertical alignment slot **16V** that is formed by the extended edge **316EE** of the protruding ridge **316** of the broach **300** during the broaching procedure, or step. The prosthesis base **710** also has a bowl portion **714** that is positioned within the bowl region **14** of the base implantation site **12**, such that the outermost

surface of the prosthesis base **710** is substantially coplanar with the plane formed by the initial resection of the portion of the humeral head **10**. The general shape of the bowl profile **714P** of the bowl portion **714** is shown in broken lines in **FIG. 18**.

[0067] **FIGS. 19A-19D** show features of a further alternate example of a broach, generally designated **300**, that can be used as part of an alternate method of performing the broaching procedure discussed elsewhere herein in relation to **FIGS. 6-9**. The broach **300** shown can be used together with or as an alternative to the broaches **300** shown in **FIGS. 6-9**. According to this example of **FIGS. 19A-19D**, the broach **300** is used, when in the position shown in **FIG. 19B** (corresponding to the position shown in **FIG. 7**), to guide insertion of a second guide pin **102** into the humeral head **10** and/or the humeral shaft **20**. The second guide pin **102** is inserted through the broach **300** and into the implantation site **12** at an angle so as to be at substantially the same angle, relative to the longitudinal humeral axis **1A**, as the lateral alignment slot(s) **16L** that are shown in **FIG. 10**. The second guide pin **102** may, in some instances, be inserted substantially parallel to the longitudinal humeral axis **1A**. In some instances, the second guide pin **102** may be inserted through the broach **300** without first removing the first guide pin **100** (e.g., the pin **100** shown installed in **FIG. 2**). It is preferred, however, if the first guide pin **100** is removed before the second guide pin **102** is installed, so that the second guide pin **102** can be installed through the center of the implantation site **12**, so as to reduce off-axis effects.

[0068] The second guide pin **102** is installed to guide movement of the compactors (see **500**, **600**, **FIGS. 11-16)** relative to the implantation site **12**, providing a mechanism for ensuring mechanical alignment of such compactors **500**, **600** relative to the

implantation site **12** during the subsequent compaction steps. This use of the second guide pin **102** to guide alignment of the compactors **500**, **600** along the longitudinal humeral axis **1A** is shown in **FIG. 19D**. For ease of illustration, only the first compactor head **510** is shown in **FIG. 19D**. Advantageously, to allow for removal of the first guide pin **100** from the implantation site **12** prior to the insertion of the second guide pin **102** into the implantation site **12**, the broach stem **320** may be removably attached to the broach head **310**, thereby allowing the broach head **310** to remain in place within the implantation site **12** while the broach stem **320** is disconnected from the broach head **310** and the first guide pin **100** is removed from the implantation site **12**. This removable attachment of the broach stem **320** and broach head **310** can be achieved by a threaded interface (e.g., in the manner of a screw and nut). After the first guide pin **100** is removed, the second guide pin **102** is installed in the implantation site **12** through the broach head **310**. The broach stem **320** may be reattached to the broach head **310** before installation of the second guide pin **102** in the implantation site **12**. The broach head **310** and the broach stem **320** may, when attached together, thus form a continuous channel (e.g., bore **340**, see **FIGS. 7** and **8**) that passes through the broach head **310** and broach stem **320** for guiding the second guide pin **102** into the implantation site, as shown in **FIG. 19B**. Once the second guide pin **102** has been inserted in the implantation site **12**, the broach **302** is removed from the implantation site **12** in the direction defined by the longitudinal axis of the second guide pin **102**. The second guide pin **102** can then be used to guide the movement of a compactor **500**, **600** on/into the implantation site **12**.

[0069] While the present disclosure refers to certain examples, numerous modifications, alterations, and changes to the described examples are possible without

departing from the sphere and scope of the present disclosure. Accordingly, it is intended that the present disclosure not be limited to the described examples, but that it has the full scope defined by the language of the specification, and equivalents thereof, as would be understood by persons having ordinary skill in the art. The discussion of any example is meant only to be explanatory and is not intended to suggest that the scope of the disclosure, including the claims, is limited to these examples. In other words, while illustrative examples of the disclosure have been described in detail herein, it is to be understood that the inventive concepts may be otherwise variously embodied and employed, and that the descriptions of such examples herein are intended to be construed to include such variations, except as limited by the prior art.

[0070] The foregoing discussion has been presented for purposes of illustration and description and is not intended to limit the disclosure to the form or forms disclosed herein. For example, various features of the disclosure are grouped together in one or more examples or configurations for the purpose of streamlining the disclosure. However, it should be understood that various features of the certain examples or configurations of the disclosure may be combined in alternate examples, or configurations. Any example or feature of any section, portion, or any other component shown or particularly described in relation to various examples of similar sections, portions, or components herein may be interchangeably applied to any other similar example or feature shown or described herein. Additionally, components with the same name may be the same or different, and one of ordinary skill in the art would understand each component could be modified in a similar fashion or substituted to perform the same function.

[0071] As used herein, an element or step recited in the singular and proceeded with the word "a" or "an" should be understood as not excluding plural elements or steps, unless such exclusion is explicitly recited. Furthermore, references to "one example" of the present disclosure are not intended to be interpreted as excluding the existence of additional examples that also incorporate the recited features.

[0072] The phrases "at least one," "one or more," and "and/or," as used herein, are open-ended expressions that are both conjunctive and disjunctive in operation. The terms "a" (or "an"), "one or more" and "at least one" can be used interchangeably herein. All directional references (e.g., proximal, distal, upper, lower, upward, downward, left, right, lateral, longitudinal, front, back, top, bottom, above, below, vertical, horizontal, radial, axial, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present disclosure, and do not create limitations, particularly as to the position, orientation, or use of this disclosure. Connection references (e.g., engaged, attached, coupled, connected, and joined) are to be construed broadly and may include intermediate members between a collection of elements and relative to movement between elements unless otherwise indicated. As such, connection references do not necessarily infer that two elements are directly connected and in fixed relation to each other. All rotational references describe relative movement between the various elements. Identification references (e.g., primary, secondary, first, second, third, fourth, etc.) are not intended to connote importance or priority but are used to distinguish one feature from another. The drawings are for purposes of illustration only and the dimensions, positions, order and relative to sizes reflected in the drawings attached hereto may vary.

CLAIMS

We claim:

1. A broaching system configured for use in preparing an implantation site for implantation of a humeral prosthesis therein, the broaching system comprising at least:

a broach comprising:

a broach head;

a broach stem; and

an osteotome slot; and

an osteotome that is configured for removable insertion into and through the osteotome slot for forming one or more alignment features within the implantation site to aid a surgeon to properly align a compactor with the implantation site.

2. The broaching system according to claim 1, wherein the osteotome slot is formed at an inclined, non-zero angle relative to a longitudinal axis of the broach stem.

3. The broaching system of claim 1 or claim 2, wherein the osteotome slot is continuous and uninterrupted from the broach stem to and through the broach head.

4. The broaching system of any of claims 1-3, wherein the osteotome has a length such that, when the osteotome is inserted fully into the osteotome slot, a distal portion of the osteotome protrudes out of the osteotome slot and into the implantation site to form the one or more alignment features.

5. The broaching system of any of claims 1-4, wherein the broach stem and the broach head each have a bore formed therein that is configured to receive therein a pin that is implanted within the implantation site, the bore being continuous and uninterrupted within and between the broach stem and the broach head.

6. The broaching system of claim 5, wherein the osteotome has a U-shaped profile, with two legs that extend substantially parallel to each other and a base that extends between and connects the two legs, such that the two legs are spaced apart from each other by the base.

7. The broaching system of claim 6, wherein the osteotome slot is formed around and is not coincident with the bore.

8. The broaching system of any of claims 1-7, wherein the broach head has a protruding ridge that extends away from the broach stem and is configured for forming a further alignment feature within the implantation site

9. The broaching system of claim 8, wherein the protruding ridge has, on one side thereof, a curved edge and, on the opposite side thereof, an inclined edge that forms an obtuse angle relative to the bottom surface of the protruding ridge that connects the curved edge to the inclined edge.

10. The broaching system of claim 1, wherein the one or more alignment features extend substantially coaxially with a longitudinal axis of a humerus in which the implantation site is formed.

11. A method for performing a broaching procedure to prepare an implantation site for implantation of a humeral prosthesis therein, the method comprising:

providing a broach comprising:

a broach head;

a broach stem; and

an osteotome slot;

providing an osteotome; and

inserting the osteotome into and through the osteotome slot for forming one or more alignment features within the implantation site to aid a surgeon to properly align a compactor with the implantation site;

wherein the osteotome is inserted within the osteotome slot in a manner than allows subsequent removal of the osteotome from the osteotome slot without damaging the one or more alignment features formed by the osteotome.

12. The method according to claim 11, wherein the osteotome slot is formed at an inclined, non-zero angle relative to a longitudinal axis of the broach stem.

13. The method of claim 11 or claim 12, wherein the osteotome slot is continuous and uninterrupted from the broach stem to and through the broach head.

14. The method of any of claims 11-13, wherein the osteotome has a length such that, when the osteotome is inserted fully into the osteotome slot, a distal portion of the osteotome protrudes out of the osteotome slot and into the implantation site to form the one or more alignment features.

15. The method of any of claims 11-14, wherein:

the broach stem and the broach head each have a bore formed therein; and

the bore is continuous and uninterrupted within and between the broach stem and the broach head;

the method comprising:

receiving, within the bore, a pin that is implanted within the implantation site to maintain a prescribed alignment of the broach to the implantation site.

16. The method of claim 15, wherein the osteotome has a U-shaped profile, with two legs that extend substantially parallel to each other and a base that extends between and connects the two legs, such that the two legs are spaced apart from each other by the base.

17. The method of claim 16, wherein the osteotome slot is formed around and is not coincident with the bore.

18. The method of any of claims 11-17, wherein the broach head has a protruding ridge that extends away from the broach stem for forming a further alignment feature within the implantation site

19. The method of claim 18, wherein the protruding ridge has, on one side thereof, a curved edge and, on the opposite side thereof, an inclined edge that forms an obtuse angle relative to the bottom surface of the protruding ridge that connects the curved edge to the inclined edge.

20. The method of claim 11, wherein the one or more alignment features extend substantially coaxially with a longitudinal axis of a humerus in which the implantation site is formed.

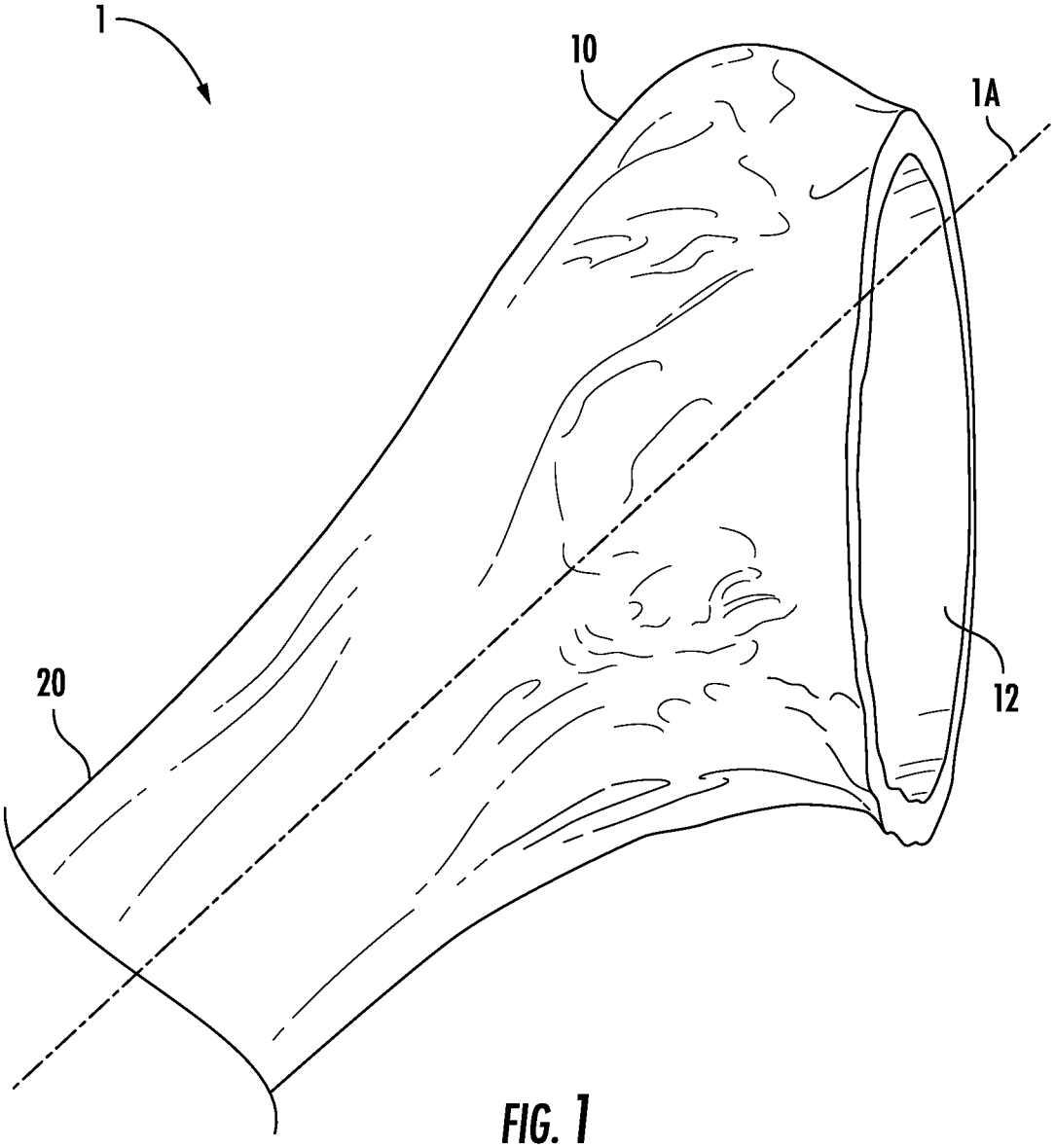

FIG. 1

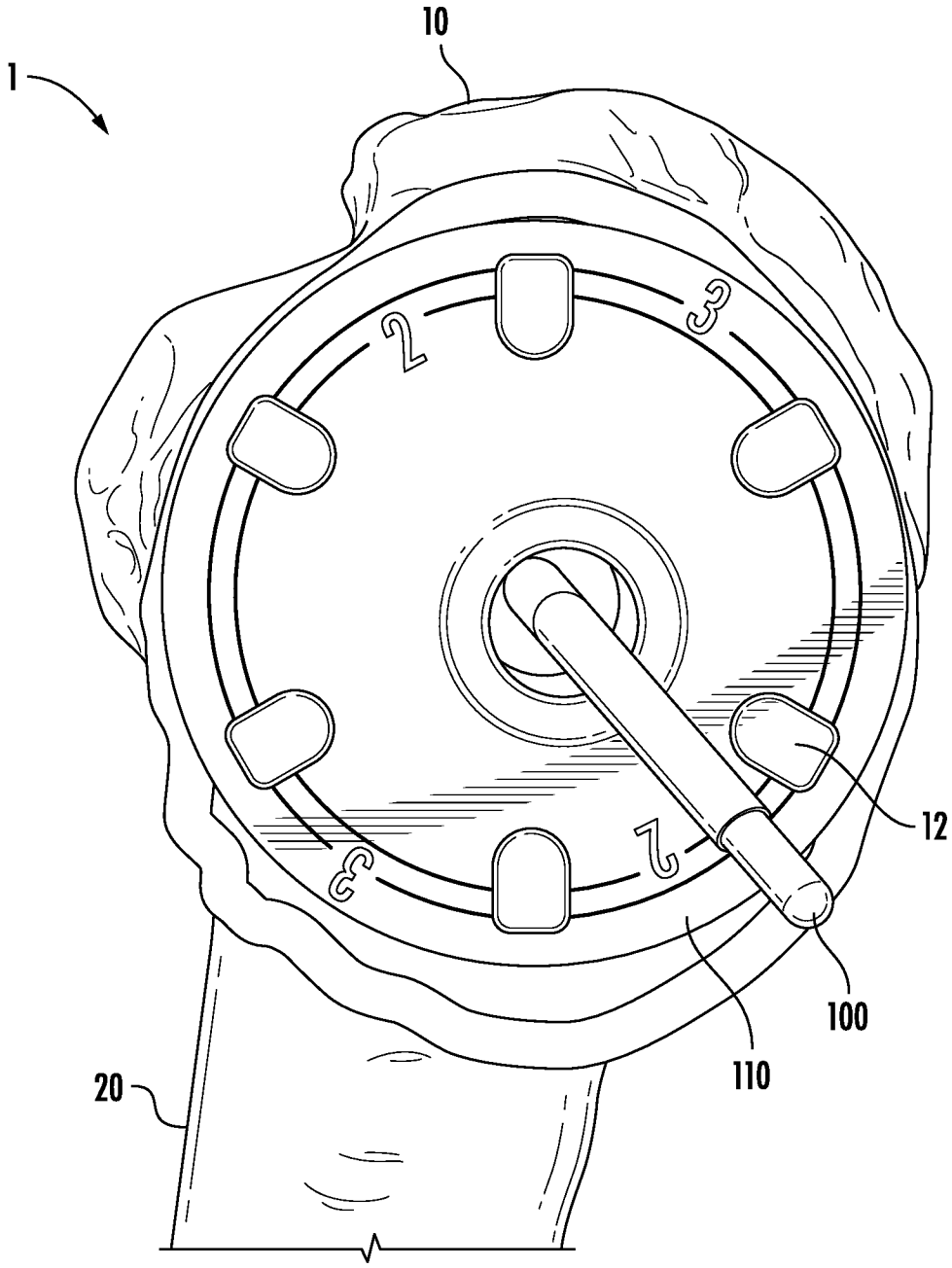

FIG. 2

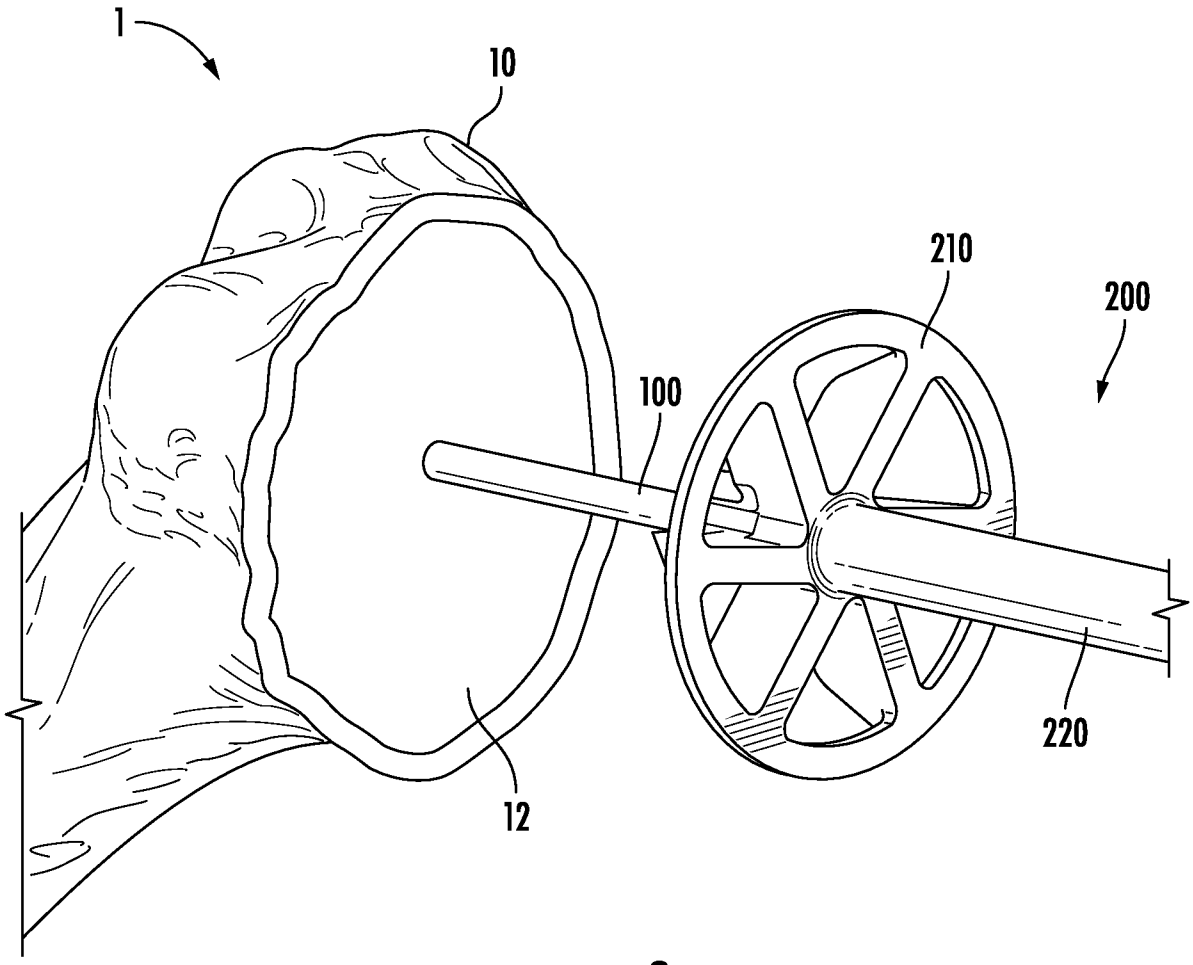

FIG. 3

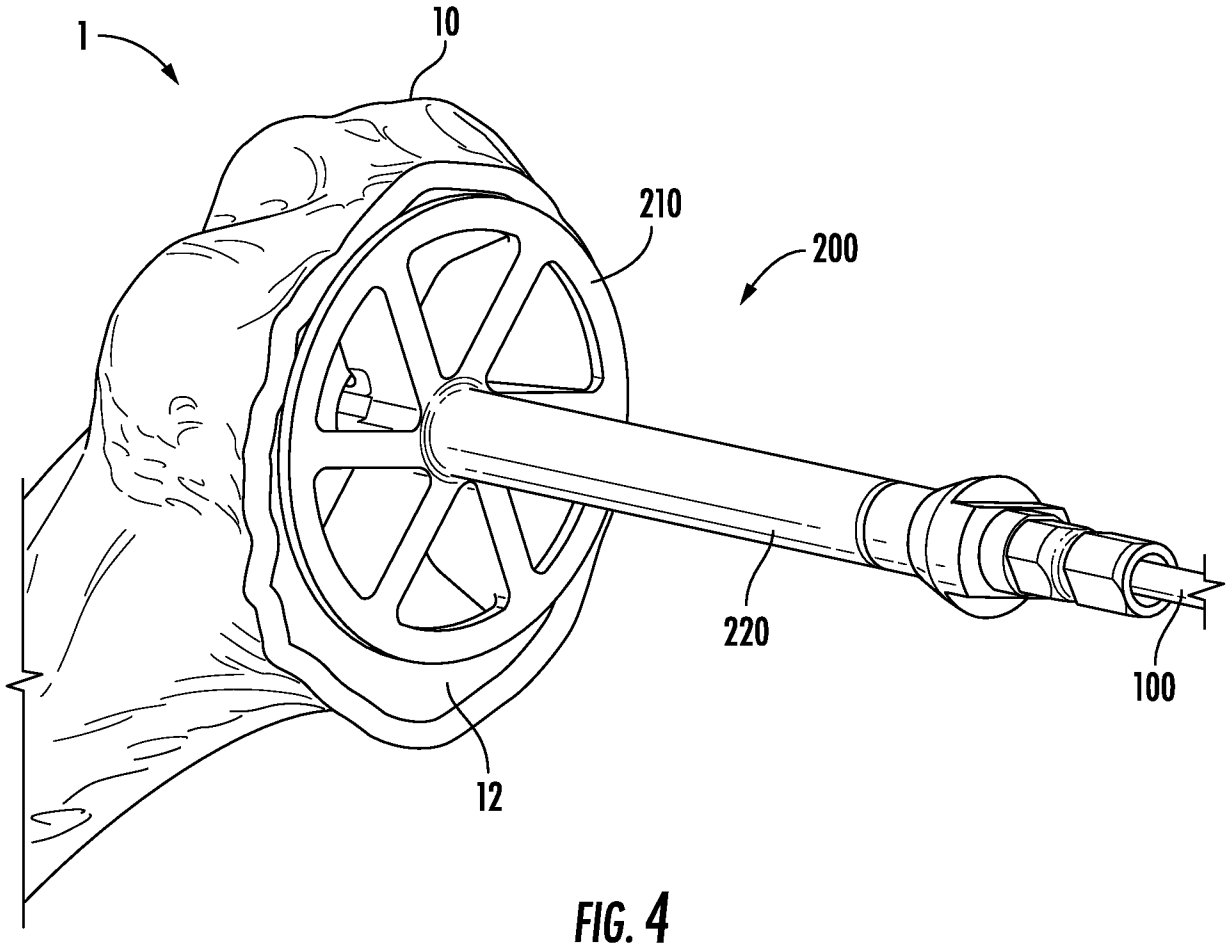

FIG. 4

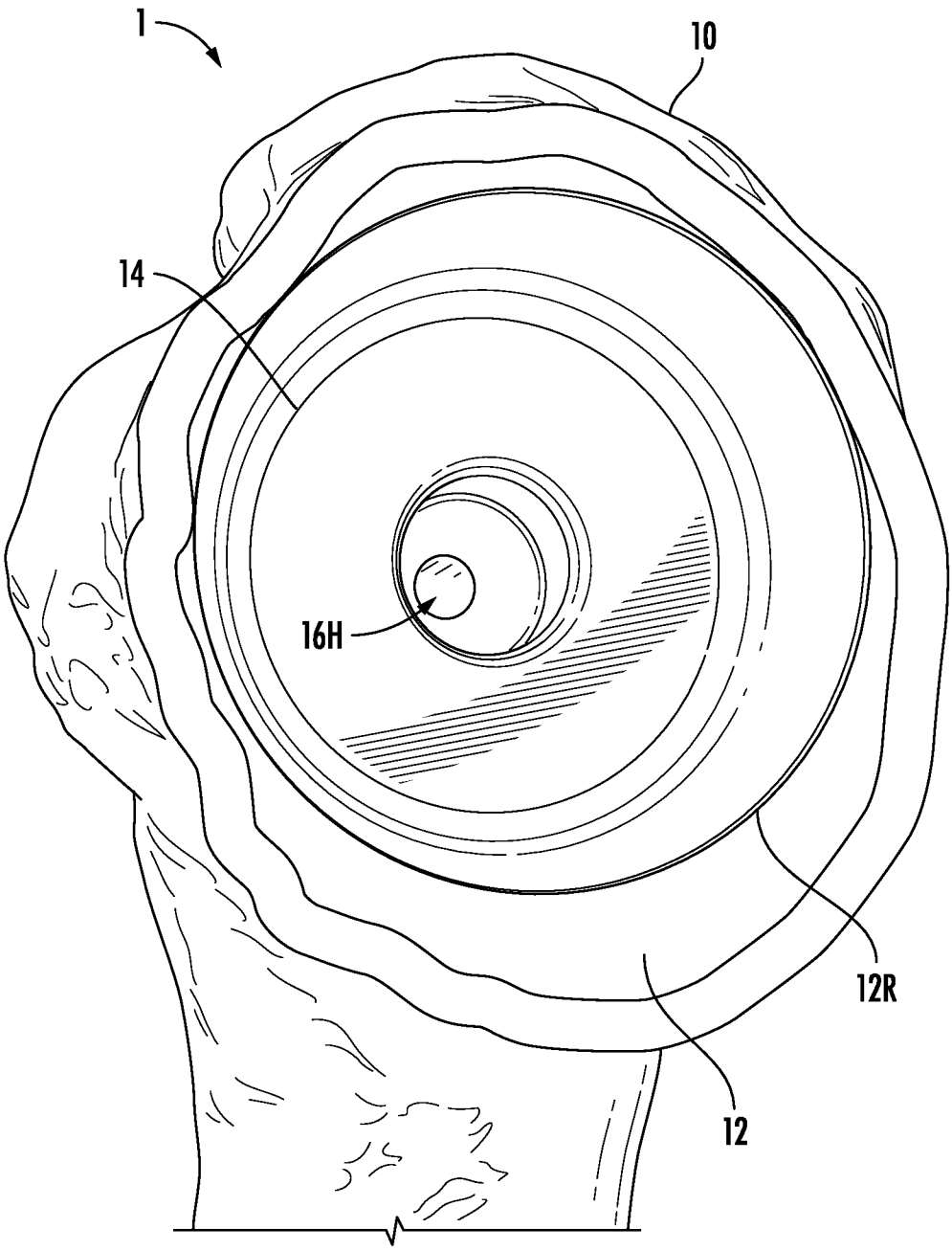

FIG. 5

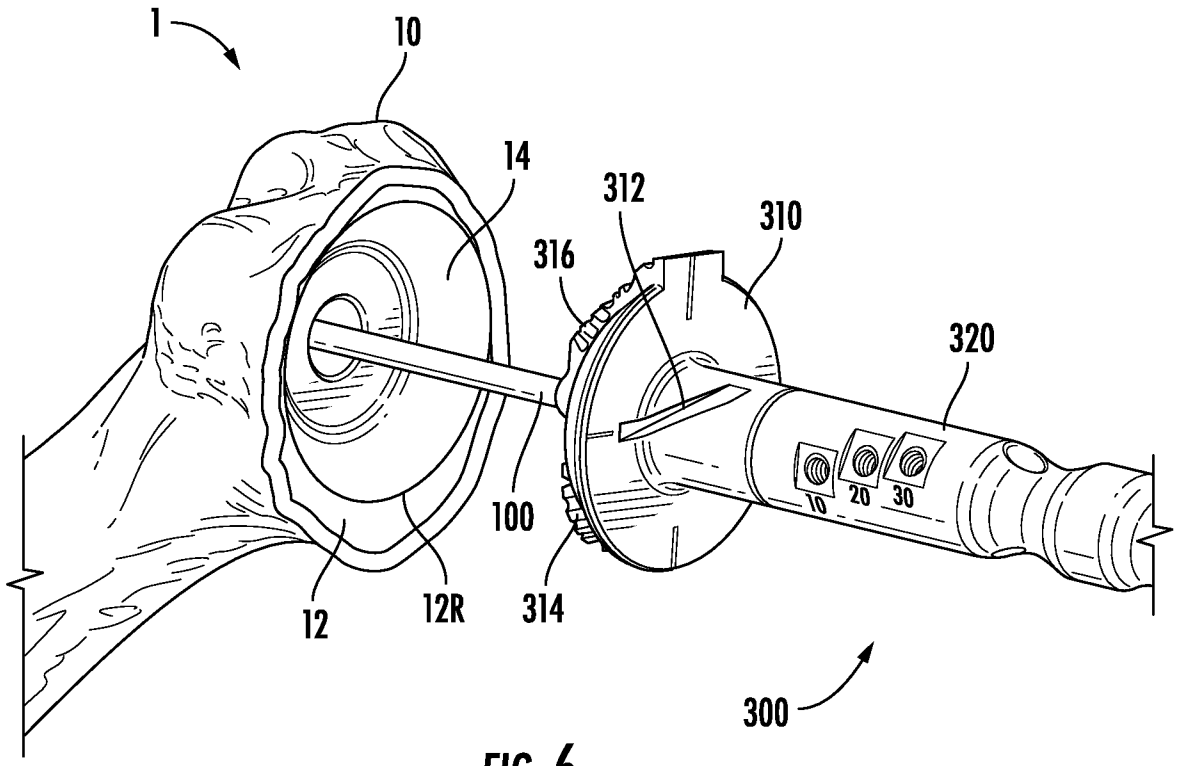

FIG. 6

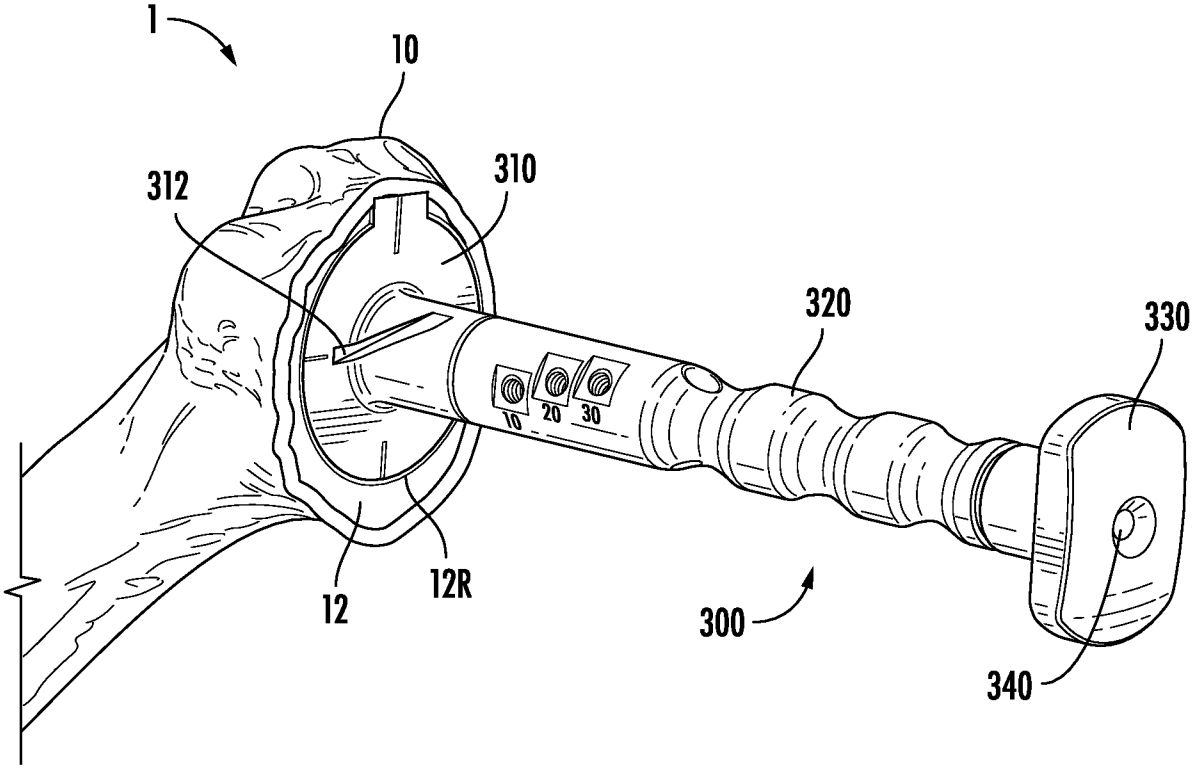

FIG. 7

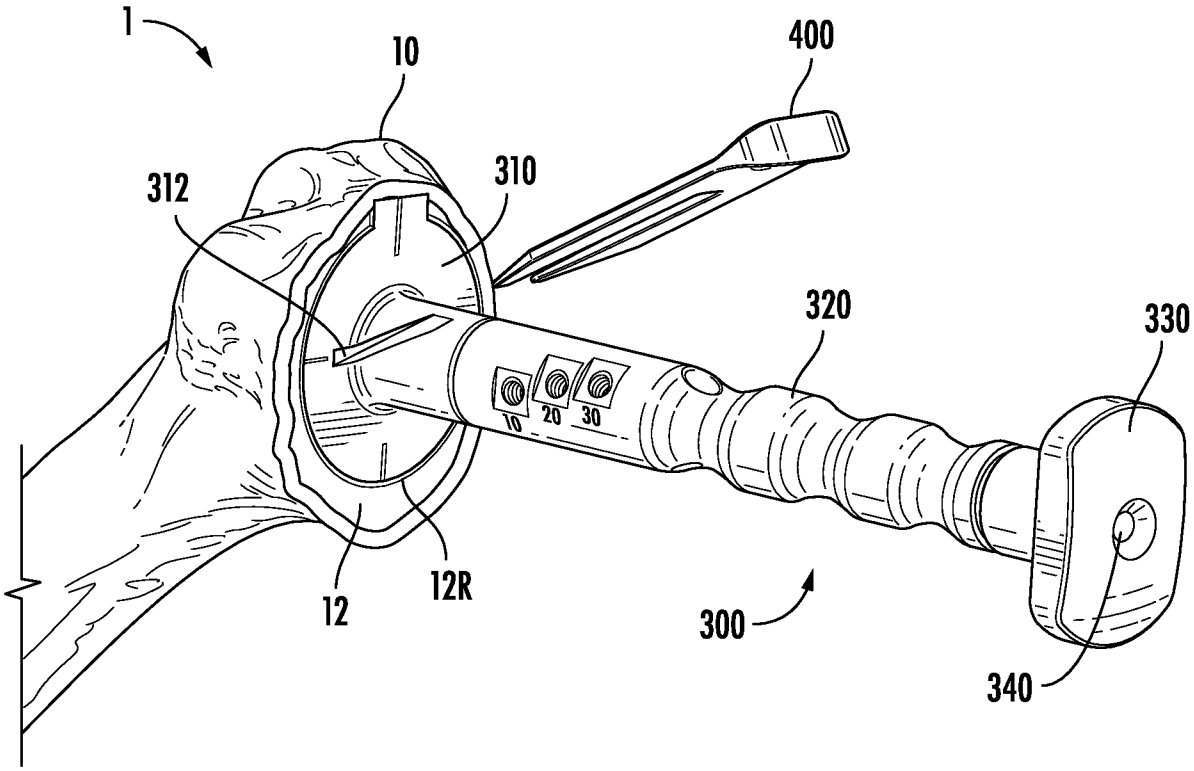

FIG. 8

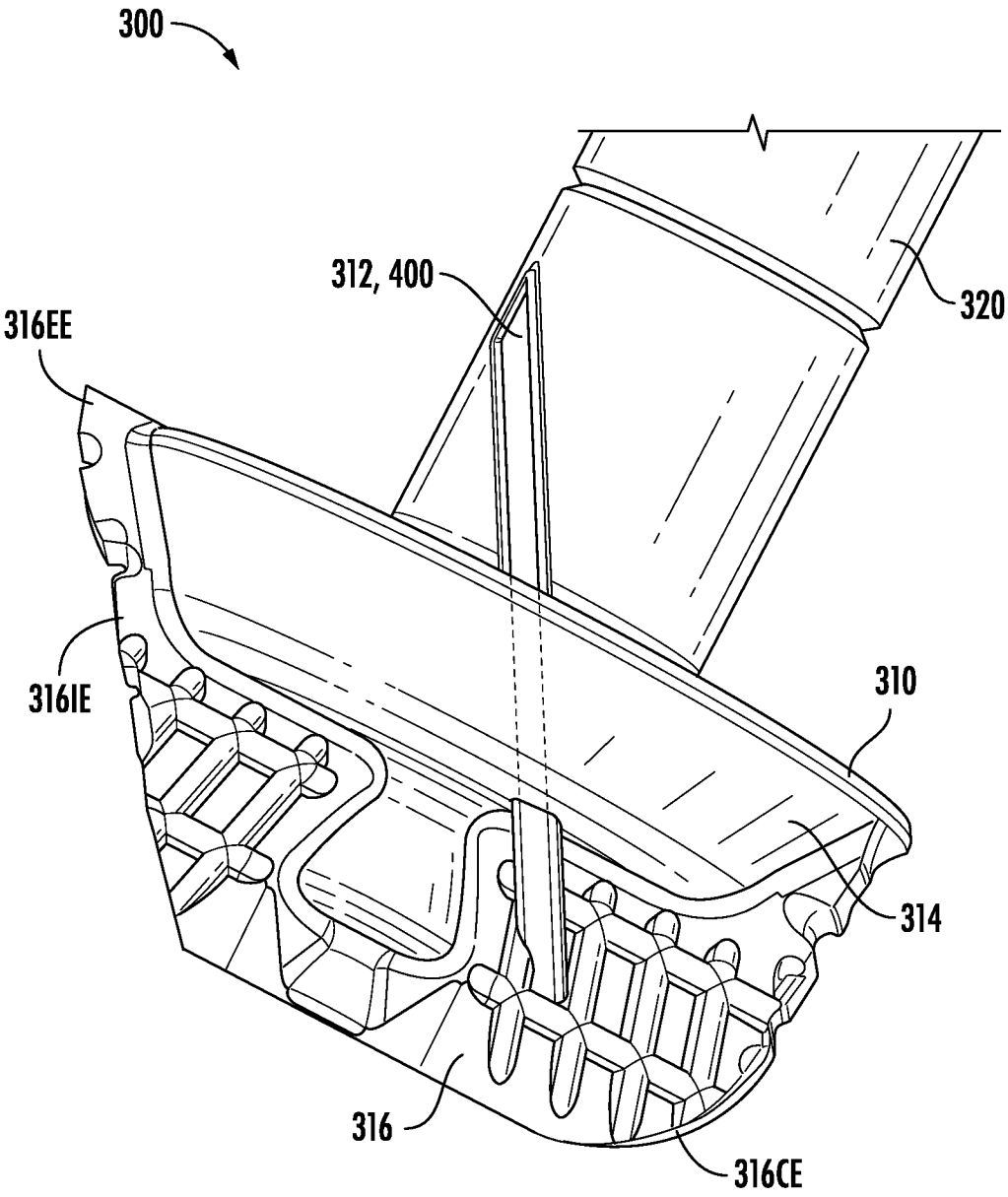

FIG. 9

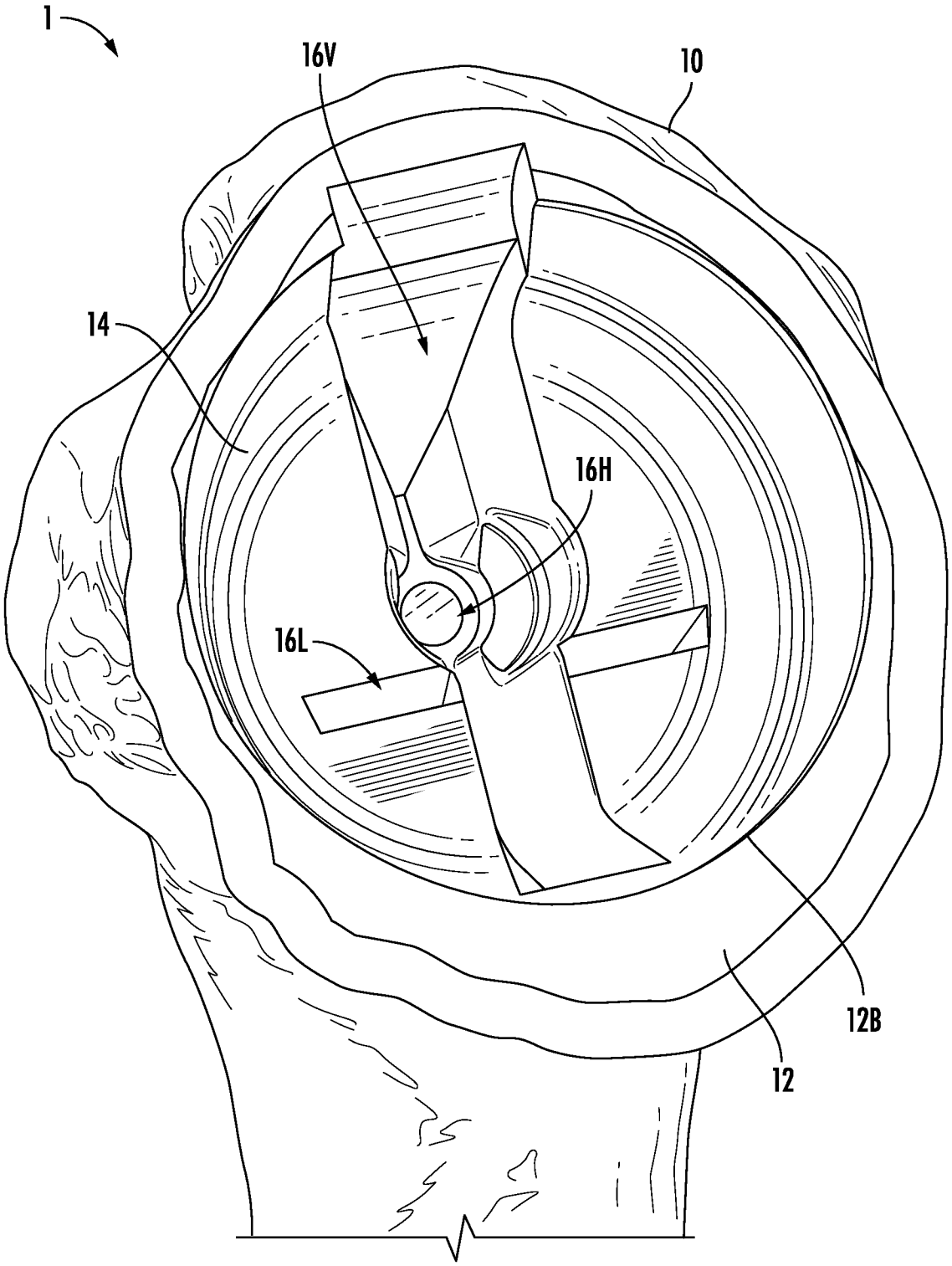

FIG. 10

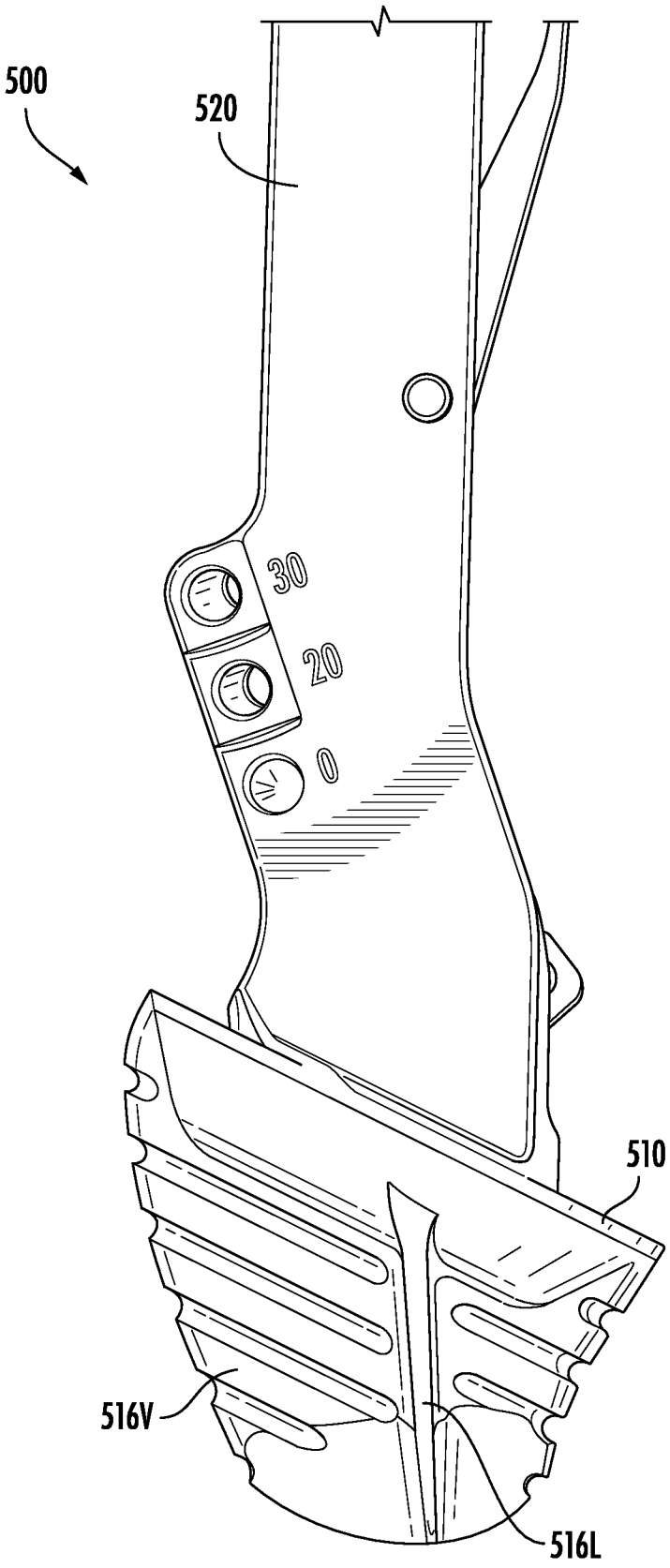

FIG. 11

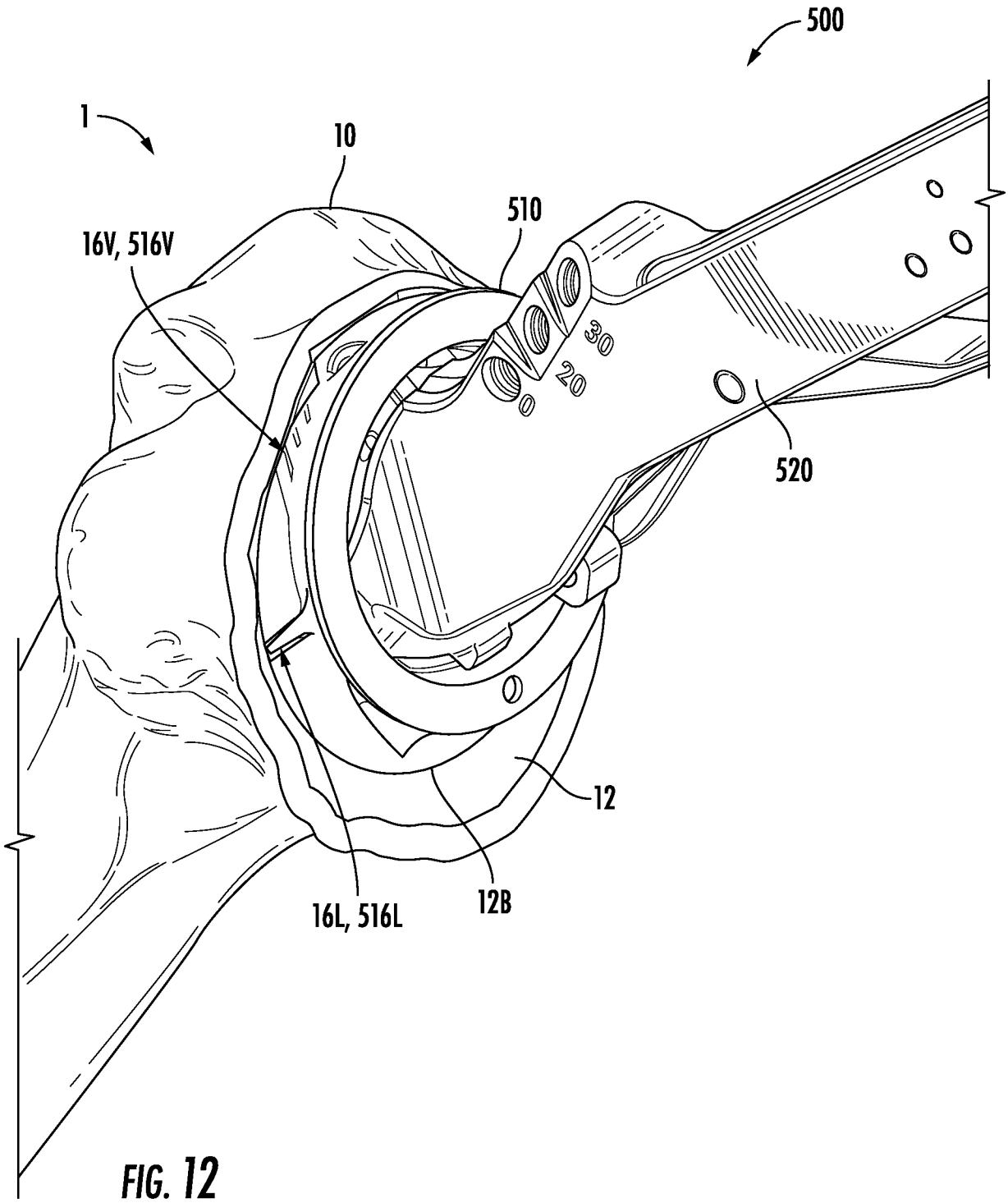

FIG. 12

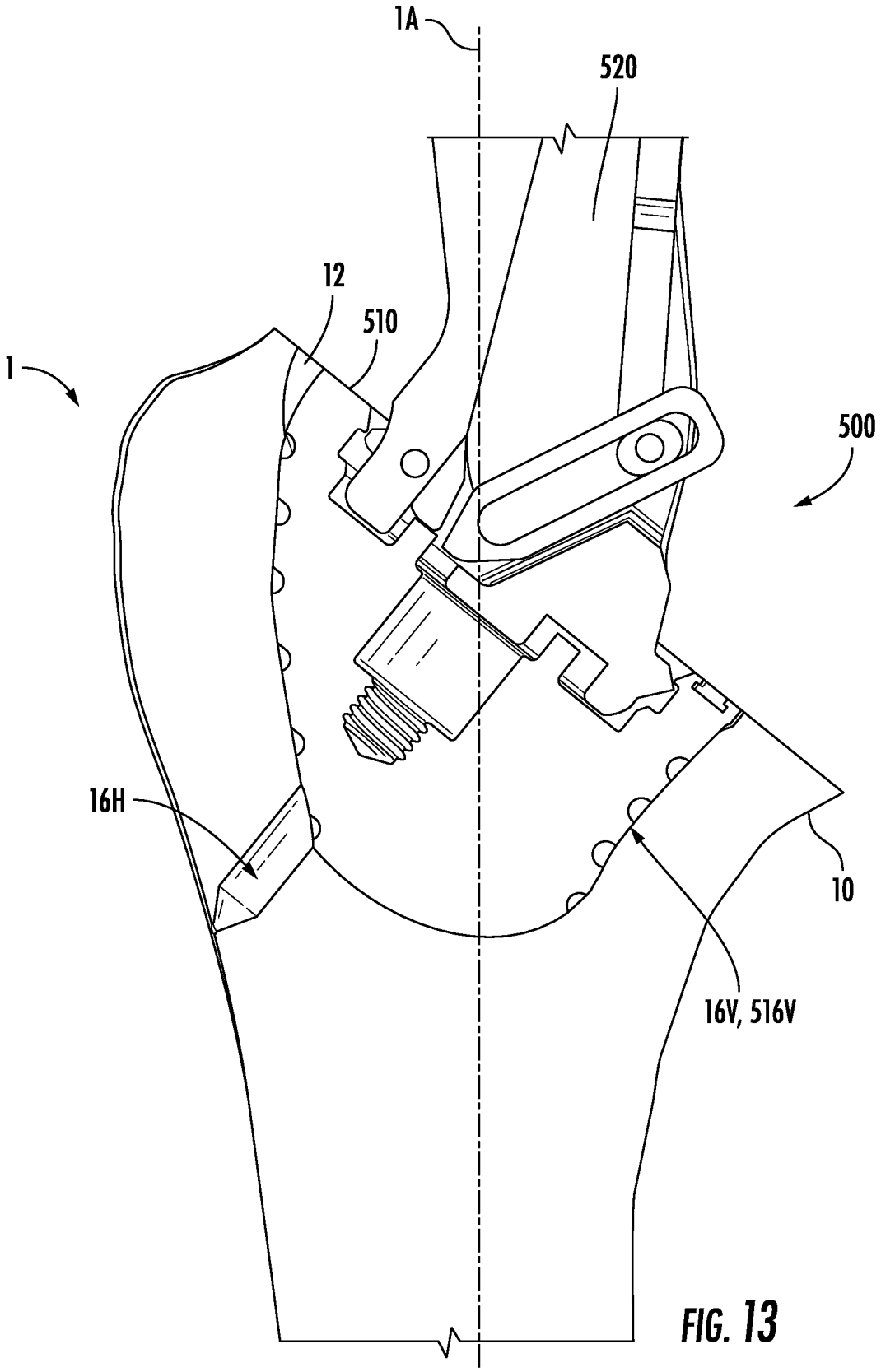

FIG. 13

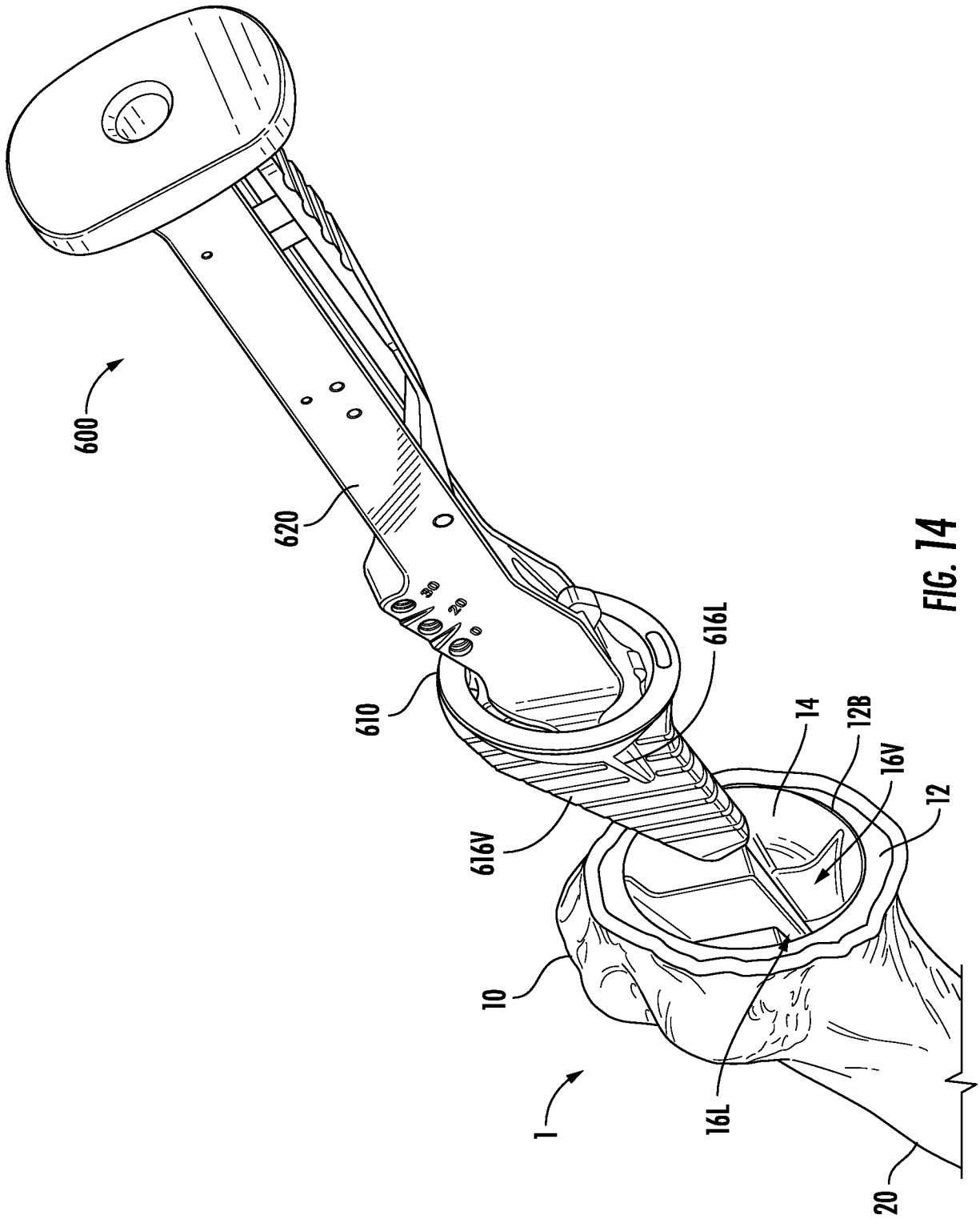

FIG. 14

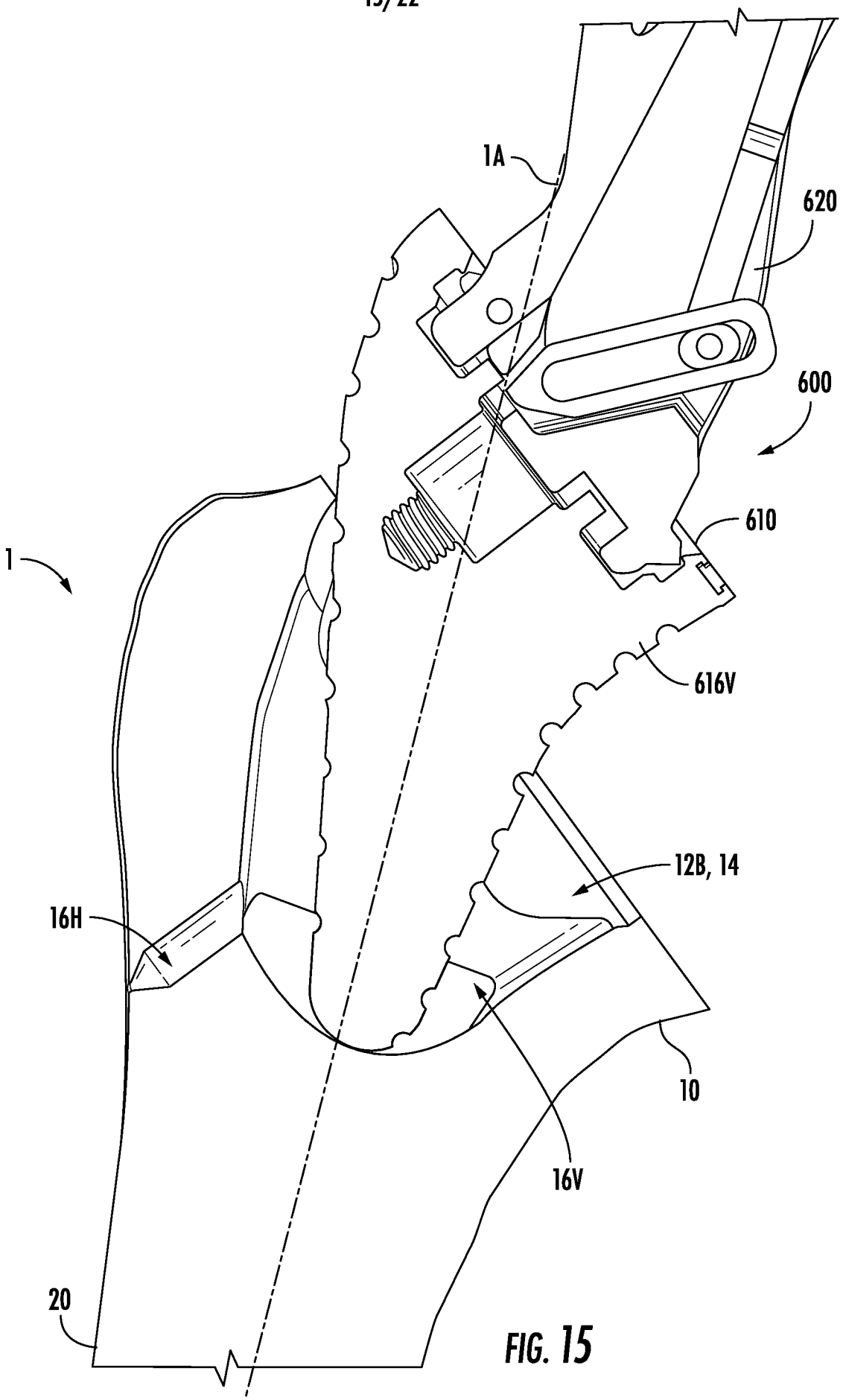

FIG. 15

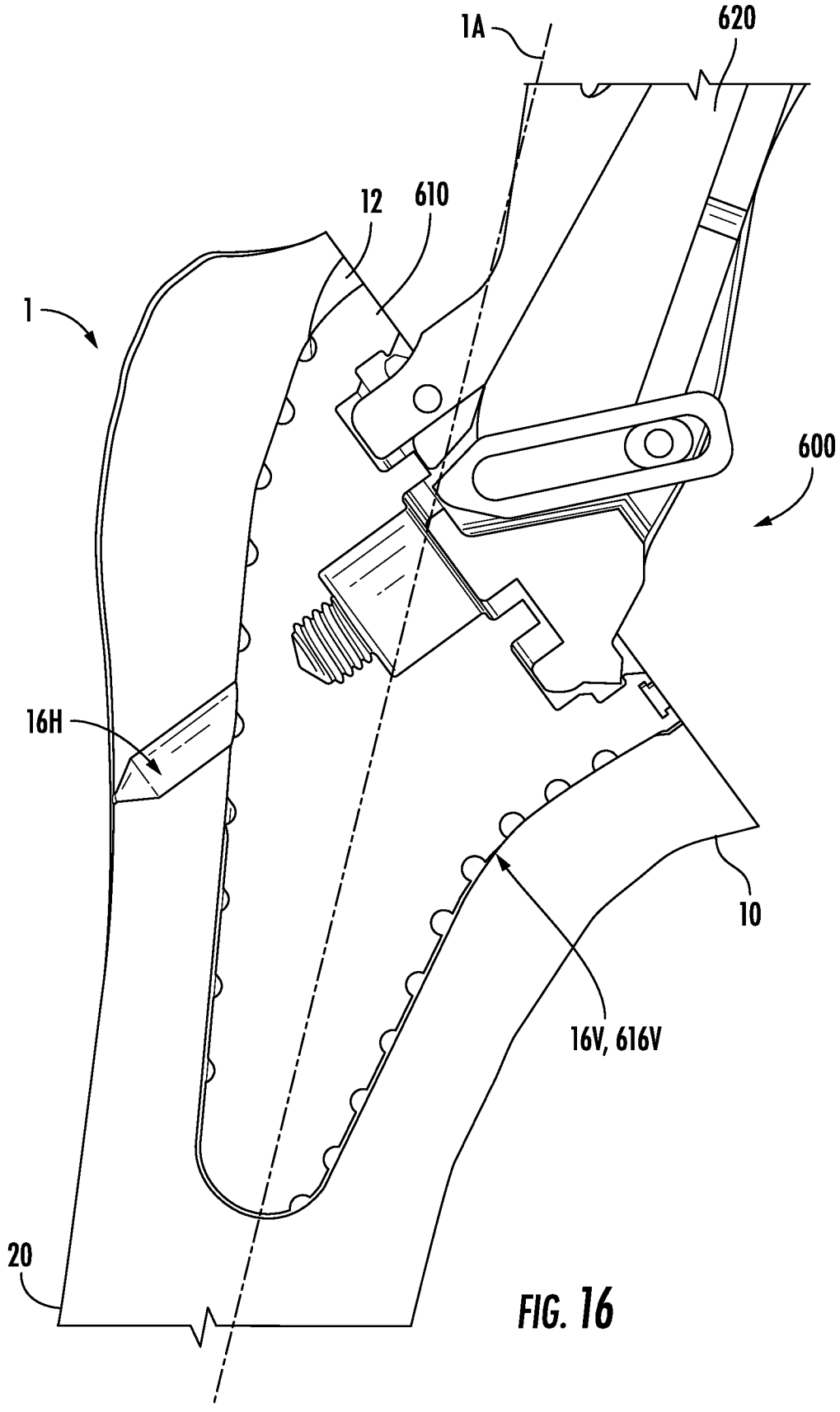

FIG. 16

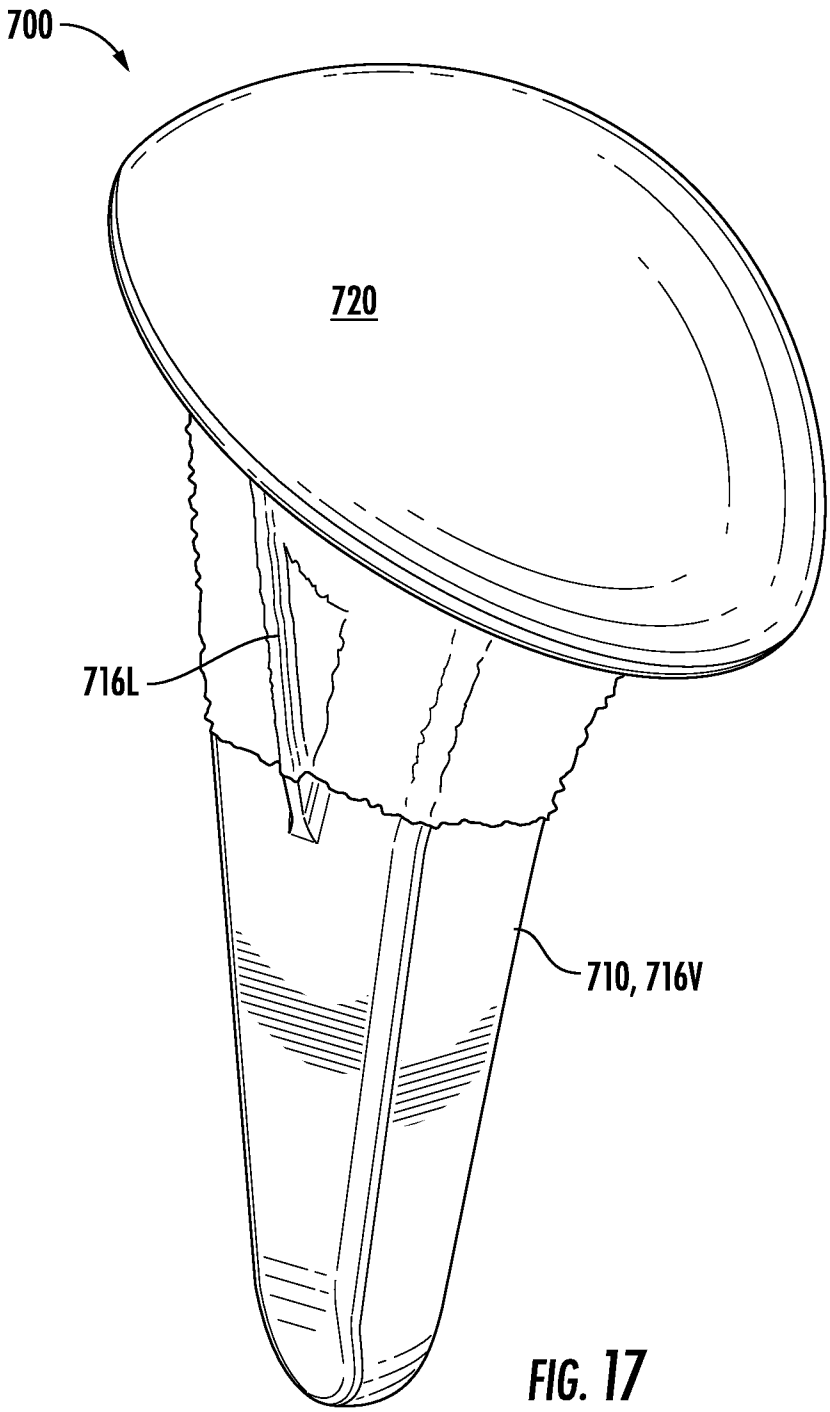

FIG. 17

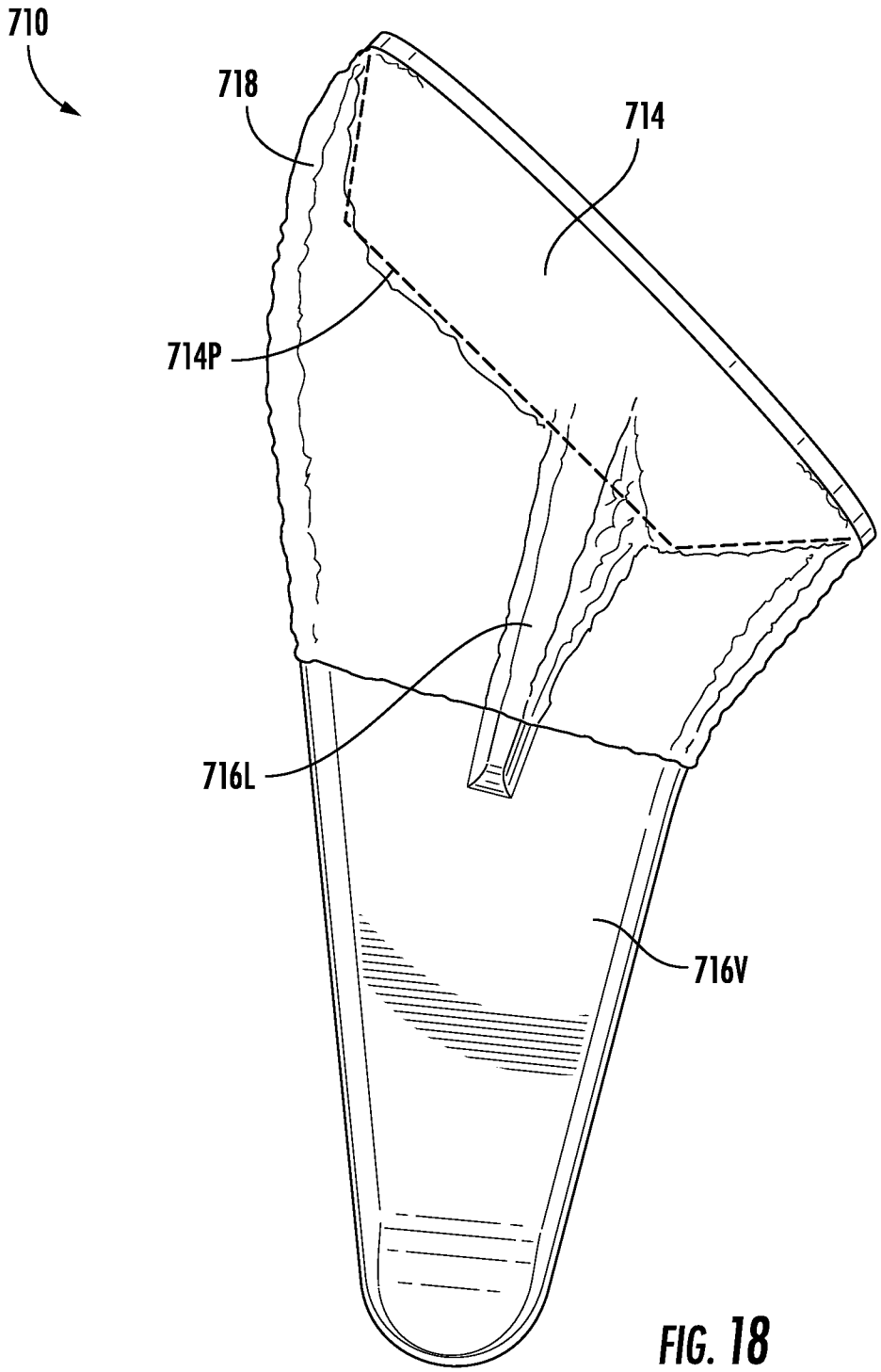

FIG. 18

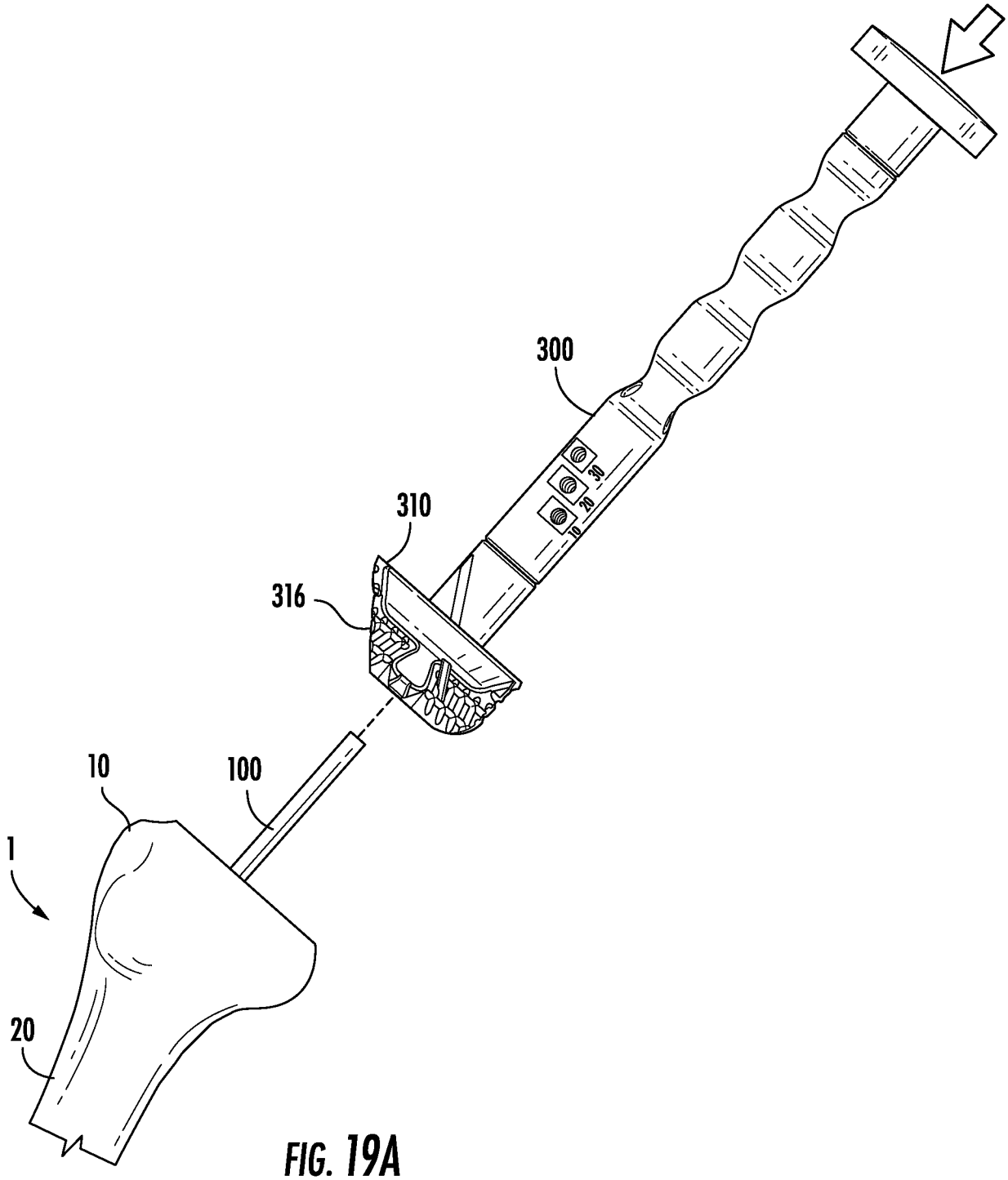

FIG. 19A

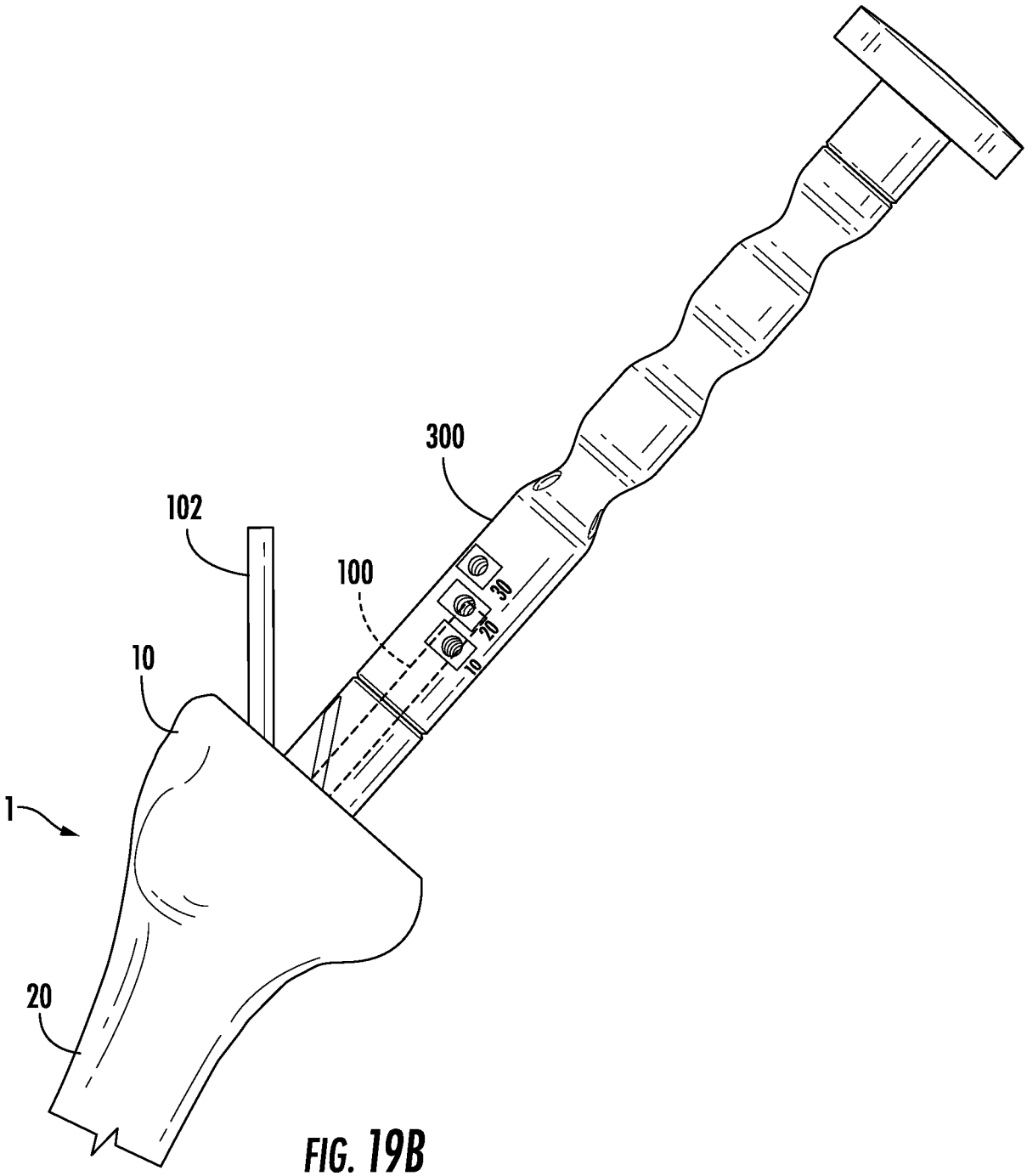

FIG. 19B

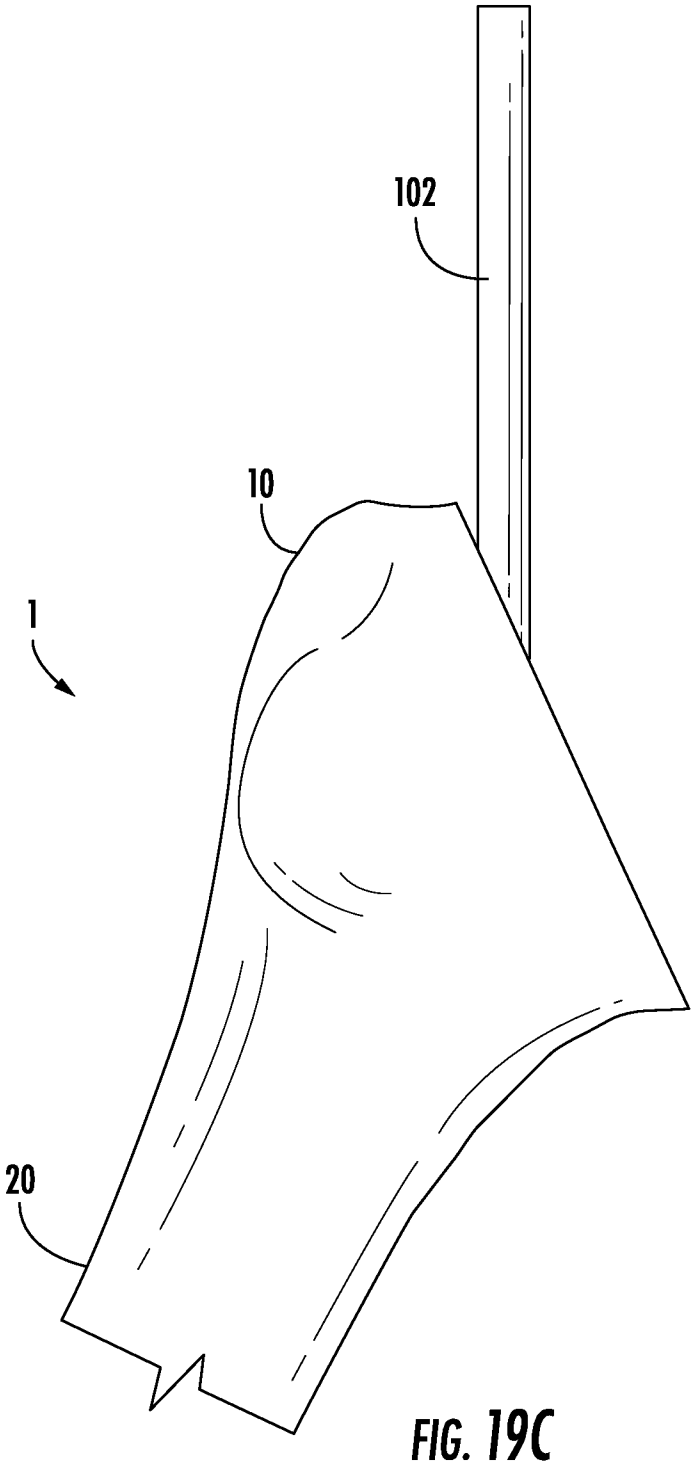

FIG. 19C

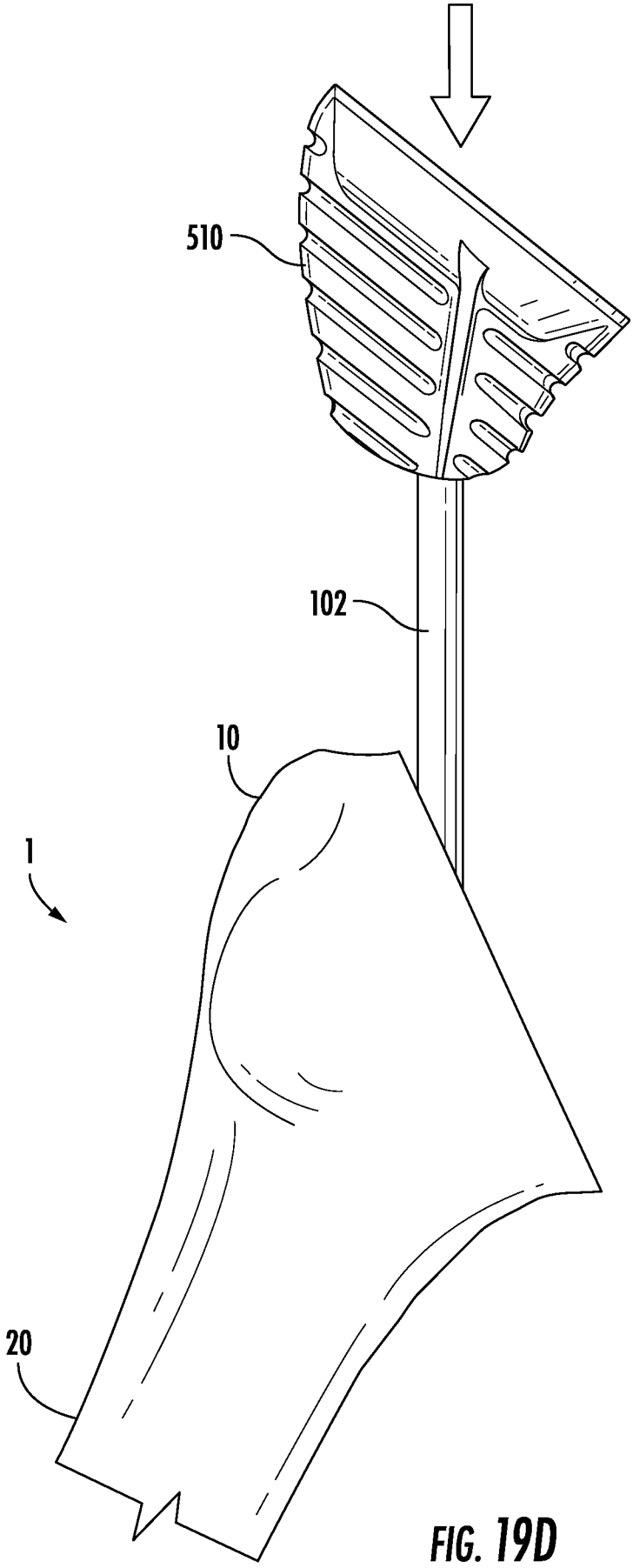

FIG. 19D

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2024/032717

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/16 A61B17/17
ADD. A61B17/88

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/287266 A1 (SIKORA GEORGE [US] ET AL) 6 October 2016 (2016-10-06)	1-4,8,10
A	paragraph [0106] - paragraph [0111]; figures 19A-21	5-7,9

X	US 5 041 117 A (ENGELHARDT JOHN A [US]) 20 August 1991 (1991-08-20)	1,2,4,10
A	column 4, line 60 - column 5, line 65; figures 5-9	3,5-9

X	US 2014/257495 A1 (GOLDBERG STEVEN S [US]) 11 September 2014 (2014-09-11)	1,2,4,8, 10
A	paragraph [0098] paragraph [0106] - paragraph [0107]; figures 28A-28C paragraph [0115]; figures 40A-40C	3,5-7,9

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[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

* Special categories of cited documents :

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 August 2024	06/09/2024

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Croatto, Loredana

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2024/032717

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2018/103967 A1 (ROUYER GUILLAUME [FR] ET AL) 19 April 2018 (2018-04-19) paragraph [0116] - paragraph [0124]; figures 12-17	1,2,4,8, 10 3,5-7,9

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/032717

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 11-20
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 11-20

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.3), should the problems which led to the Article 17(2) PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2024/032717

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016287266 A1	06-10-2016	US 2016287266 A1	06-10-2016
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		US 2017239058 A1	24-08-2017
		WO 2014164265 A1	09-10-2014
US 2018103967 A1	19-04-2018	FR 3057454 A1	20-04-2018
		US 2018103967 A1	19-04-2018