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[Continued on next page]

(54) Title: PATIENT-SPECIFIC AND PATIENT-ENGINEERED ORTHOPEDIC IMPLANTS

(57) Abstract: Disclosed herein are methods and devices for repairing a knee joint, including customizable and/or highly selectable implants and/or implant components for each patient to provide optimal fit and function.

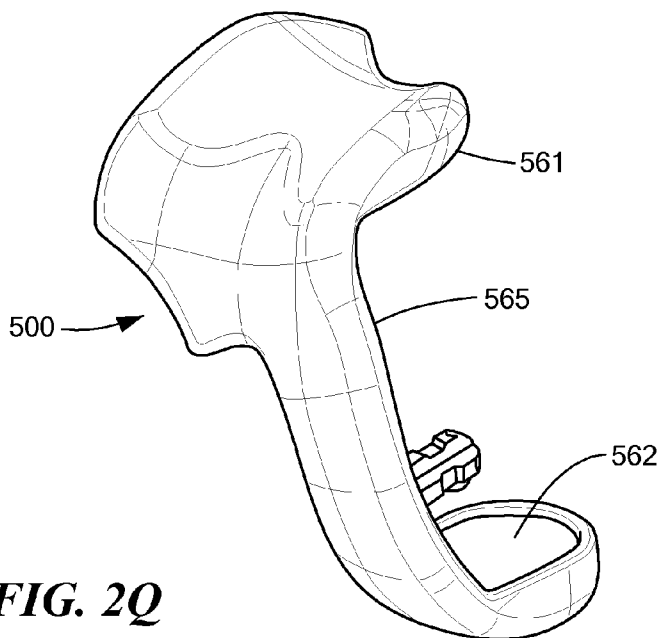


FIG. 2Q



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PATIENT-SPECIFIC AND PATIENT-ENGINEERED ORTHOPEDIC IMPLANTS**CROSS REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims priority to U.S. Ser. No. 61/284,022, filed December 11, 2009, entitled "Patient-Specific and Patient-Engineered Orthopedic Implants."

[0002] This application is related to U.S. patent application Ser. No. 11/537,318, entitled "Joint Arthroplasty Devices," filed Sept. 29, 2006, which in turn is a continuation-in-part of U.S. patent application Ser. No. 10/997,407, entitled "Patient Selectable Knee Joint Arthroplasty Devices," filed Nov. 24, 2004, which in turn is a continuation-in-part of U.S. patent application Ser. No. 10/752,438, entitled "Patient Selectable Knee Joint Arthroplasty Devices," filed Jan. 5, 2004.

[0003] This application is also related to U.S. patent application Ser. No. 10/752,438, entitled "Patient Selectable Knee Joint Arthroplasty Devices," filed Jan. 5, 2004.

[0004] All of the above patent applications, as well as patent applications and other references mentioned herein below, are hereby incorporated by reference in their entireties.

TECHNICAL FIELD

[0005] The present invention relates to orthopedic methods, systems and devices and more particularly, to joint implants and methods for designing and manufacturing the same.

BACKGROUND

[0006] Traditional joint implants are known in the art. For example, one of the most common types of joint prosthetic devices is a knee implant including a femoral component and a tibial component. Other joint implants are associated with, for example, the hip and shoulder.

[0007] Implantation of traditional prosthetic devices is usually associated with loss of underlying tissue and bone. With some devices, serious long-term complications associated with the loss of significant amount of tissue and bone can include infection, osteolysis and

also loosening of the implant. Such joint arthroplasties can be highly invasive and require surgical resection of the entire, or a majority of the, articular surface of one or more bones involved in the repair. Typically with these procedures, the marrow space is fairly extensively reamed in order to fit the stem of the prosthesis within the bone. Reaming results in a loss of a patient's bone stock and over time subsequent osteolysis can frequently lead to loosening of the prosthesis. Further, the area where the implant and the bone mate degrades over time requiring the prosthesis to eventually be replaced. Since the patient's bone stock is limited, the number of possible replacement surgeries also is limited for joint arthroplasty. In short, over the course of fifteen to twenty years, and in some cases even shorter time periods, the patient can run out of therapeutic options ultimately resulting in a painful, non-functional joint.

[0008] Moreover, currently available traditional implants can be misaligned with a patient's anatomical structures and thereby jeopardize the resultant joint congruity. Poor alignment and poor joint congruity can, for example, lead to instability of the joint. Further, traditional implant solutions do not take into account the fact that roughly 80% of patients undergoing knee surgery have a healthy lateral compartment and only need to repair the medial condyle and the patella. An additional 10% only have damage to the lateral condyle. Thus, 90% of patients do not require the entire condylar surface repaired.

[0009] Thus, there is a need for joint implants and systems that integrate with a patient's anatomical structures. In particular, there is a need for implants and implant systems that take into account the patient-specific damage to be repaired and minimizes bone loss due to implantation requirements. Moreover, there is a need for implants and implant systems that provide an improved functional joint and improve the anatomic result of the joint correction procedure by providing surfaces that more closely resemble, or optimize, the joint anatomy of a patient.

SUMMARY

[00010] Some embodiments described herein provide novel devices and methods for replacing a portion (for example, a diseased area and/or area slightly larger than the diseased area) of a joint (for example, one or more of cartilage, meniscus and bone) with one or more

implants, where the implant(s) achieve an anatomic, near anatomic, and/or optimized fit with the surrounding structures and tissues. In cases where the devices and/or methods include an element associated with the underlying articular bone, some embodiments also provide that the bone-associated element can achieve a near anatomic alignment with the subchondral bone. In addition, some embodiments provide for the preparation of an implantation site with one or more cuts. Asymmetrical components can also be provided to improve the anatomic functionality of the repaired joint by providing a solution that closely resembles the natural knee joint anatomy or an optimized knee joint anatomy. The improved anatomic results, in turn, leads to an improved functional result for the repaired joint. Some embodiments also provide a kit that includes one or more implants used to achieve optimal joint correction.

[00011] In certain aspects, implants and methods are provided for a joint of one or more of the knee, hip, ankle, shoulder, elbow, wrist, and hand. In certain embodiments, the implant devices and methods may be used for knee implants and procedures in a bicompartamental arthroplasty that covers portions or all of one femoral condyle, medial or lateral, and the trochlea. These devices may be fixed or non-mobile bearing or they can be mobile bearing.

BRIEF DESCRIPTION OF THE DRAWINGS

[00012] FIG. 1A is a block diagram of a method for assessing a joint in need of repair wherein the existing joint surface is unaltered, or substantially unaltered, prior to receiving the selected implant. FIG. 1B is a block diagram of a method for assessing a joint in need of repair wherein the existing joint surface is unaltered, or substantially unaltered, prior to designing an implant suitable to achieve the repair. FIG. 1C is a block diagram of a method for developing an implant and using the implant in a patient.

[00013] FIGS. 2A-2S depict an implant suitable for placement on the femoral condyle. FIG. 2A is a top view of the inferior surface of the implant showing a chamfer cut. FIG. 2B is a slightly perspective view of the superior surface of the implant. FIG. 2C is a perspective side view of the implant from a first direction. FIG. 2D is a slightly perspective side view of the implant from a second direction. FIGS. 2E-F are side views of the implant showing the bearing loads. FIGS. 2G and H illustrate an alternative embodiment wherein the implant has

lateral rails. FIG. 2I illustrates another embodiment wherein the implant has an anchoring keel. FIG. 2J is an axial view of a femur with the implant installed on the femoral condyles. FIG. 2K is an anterior view of the knee joint without the patella wherein the implant is installed on the femoral condyle. FIG. 2L is an anterior view of the knee joint with an implant of FIG. 2A implanted on the femoral condyles along with an implant suitable for the tibial plateau, such as that shown in FIG. 5. FIGS. 2M-N depict a device implanted within the knee joint. FIG. 2O depicts an alternate embodiment of the device which accommodates a partial removal of the condyle. FIGS. 2P-S illustrate alternative embodiments of the implant having one or more cuts.

[00014] FIG. 3 illustrates a bicompartamental implant having an anterior cut and a posterior cut that are substantially parallel to the patient's femoral axis.

[00015] FIGS. 4A and 4B illustrate bicompartamental implants overlaid with a traditional primary TKA implant.

[00016] FIG. 5 shows a tibial implant for mating with the condylar portion of the bicompartamental implant, implanted on the tibia.

[00017] FIG. 6A illustrates an exemplary anterior flange of a bicompartamental implant or implant component. FIG. 6B illustrates a bicompartamental implant that includes a substantially straight proximal flange edge.

[00018] FIG. 7A illustrates an exemplary PF region of a bicompartamental implant. FIG. 7B illustrates an exemplary implant PF region having a trochlear groove with a coronal curvature and a sagittal curvature. FIGS. 7C- 7D illustrate coronal curvature radii (i.e., radii of curvature and/or tangent radii of curvature) and sagittal curvature radii in the PF region of an implant. FIG. 7E illustrates a bicompartamental implant component that includes a PF region having a coronal curvature and a sagittal curvature that are engineered to optimize movement of a patella implant component. FIG. 7F illustrates a bicompartamental implant that includes a PF region having a coronal curvature that is engineered and a sagittal curvature that is patient-specific.

[00019] FIG. 8A illustrates the condylar portion or surface of a bicompartmental implant. FIG. 8B illustrates a coronal curvature and a sagittal curvature of a condylar surface of an implant. FIGS. 8C and 8D illustrate coronal curvature radii and sagittal curvature radii in the condylar region of an implant.

[00020] FIG. 9A illustrates a variety of peg configurations that can be used as part of an implant. FIG. 9B illustrates an implant peg having a “+” or cross-like configuration.

[00021] FIGS. 10A-G illustrate a device as shown in FIG. 2 along with a graphical representation of the cross-sectional data points comprising the surface map.

[00022] FIGS. 11A-C illustrate an alternate design of a device, suitable for a portion of the femoral condyle, having a two piece configuration.

[00023] FIGS. 12A-J depict a whole patella (FIG. 12A) and a patella that has been cut in order to install an implant (FIG. 12B). A top view and a side view of a suitable patella implant are shown in FIGS. 12C-D superimposed on a patella to illustrate the location of the implant dome relative to the patellar ridge. FIGS. 12E-F illustrate the implant superimposed over a patella. FIGS. 12G-J illustrate an alternate design for the patella implant based on a blank (FIG. 12G).

[00024] FIGS. 13A-C depict representative side views of a knee joint with any of the devices taught installed therein. FIG. 13A depicts the knee with a condyle implant and a patella implant. FIG. 13B depicts an alternate view of the knee with a condyle implant and a patella implant wherein the condyle implant covers a greater portion of the surface of the condyle in the posterior direction. FIG. 13C illustrates a knee joint wherein the implant is provided on the condyle, the patella and the tibial plateau. FIG. 13D shows another embodiment of the implant of FIG. 2 in place on a femur, with a patellar implant of FIG. 12.

[00025] FIGS. 14A-D depict a frontal view of the knee joint with any of the devices taught installed therein. FIG. 14A depicts the knee with a tibial implant. FIG. 14B depicts the knee with a condyle implant. FIG. 14C depicts a knee with a tibial implant and a condyle implant. FIG. 14C depicts a knee with a bicompartmental condyle implant and a tibial implant.

[00026] FIG. 15A shows images of a particular patient's femur and patella. FIG. 15B illustrates three different bicompartmental implants or implant components (Designs 1-3) and a bicompartmental implant or implant component having no bone cuts ("Baseline"). FIGS. 15C-15E illustrate an implant design and bone resection for a bicompartmental implant that includes only a single, posterior bone cut.

[00027] FIGS. 16A-16C illustrate the implant of FIGS. 15C-15E in place on a femur.

[00028] FIGS. 17A-17C illustrate an implant design and bone resectioning for a bicompartmental implant that includes both a posterior bone cut and an anterior bone cut.

[00029] FIGS. 18A-18C illustrate the implant of FIGS. 17A-17C in place on a femur.

[00030] FIGS. 19A-19C illustrate an implant design and bone resectioning for a bicompartmental implant that includes posterior and anterior bone cuts and that was engineered to optimize trochlear groove fit with a patellar implant component.

[00031] FIGS. 20A-20C illustrate the implant of FIGS. 19A-19C in place on a femur.

[00032] FIGS. 21A-21C illustrate an implant design and bone resectioning for a bicompartmental implant that includes posterior and anterior bone cuts, was engineered to optimize trochlear groove fit with a patellar implant component, and that includes a different flex-cut than the design of FIGS. 19A-19C.

[00033] FIGS. 22A-22C illustrate the implant of FIGS. 21A-21C in place on a femur.

DETAILED DESCRIPTION

[00034] As will be appreciated by those of skill in the art, methods recited herein may be carried out in any order of the recited events which is logically possible, as well as the recited order of events. Furthermore, where a range of values is provided, it is understood that every intervening value, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed. Also, it is contemplated that any optional feature described herein may be set forth and claimed independently, or in combination with any one or more of the features described herein.

[00035] Methods and compositions described herein can employ, unless otherwise indicated, images derived from conventional and digital methods of x-ray imaging and processing, x-ray tomosynthesis, ultrasound including A-scan, B-scan and C-scan, computed tomography (CT scan), magnetic resonance imaging (MRI), optical coherence tomography, single photon emission tomography (SPECT) and positron emission tomography (PET) within the skill of the art. Such techniques are explained fully in the literature and need not be described herein. See, for example, X-Ray Structure Determination: A Practical Guide, 2nd Edition, editors Stout and Jensen, 1989, John Wiley & Sons, publisher; Body CT: A Practical Approach, editor Slone, 1999, McGraw-Hill publisher; X-ray Diagnosis: A Physician's Approach, editor Lam, 1998 Springer-Verlag, publisher; and Dental Radiology: Understanding the X-Ray Image, editor Laetitia Brocklebank 1997, Oxford University Press publisher. See also, The Essential Physics of Medical Imaging (2nd Ed.), Jerrold T. Bushberg, et al.

[00036] Some embodiments described herein provide methods and compositions for repairing joints, particularly for repairing articular cartilage and for facilitating the integration of a wide variety of cartilage repair materials into a subject. Among other things, certain techniques described herein allow for the customization of cartilage repair material to suit a particular subject, for example in terms of size, cartilage thickness and/or curvature. When the shape (e.g., size, thickness and/or curvature) of the articular cartilage surface is an exact or near anatomic fit with the non-damaged cartilage or with the subject's original cartilage, the success of repair is enhanced. The repair material can be shaped prior to implantation and such shaping can be based, for example, on electronic images that provide information regarding curvature or thickness of any "normal" cartilage surrounding the defect and/or on curvature of the bone underlying the defect. Thus, some embodiments provide, among other things, for minimally invasive methods for partial joint replacement. The methods require only minimal or, in some instances, no loss in bone stock. Additionally, unlike traditional implants and related techniques, certain methods described herein help to restore the integrity of the articular surface by achieving an exact or near anatomic match between the implant and the surrounding or adjacent cartilage and/or subchondral bone.

[00037] Some embodiments described herein provide methods and compositions for repairing joints that includes cutting or resecting one or more portions of a patient's bone, for example, subchondral bone. Among other things, certain implants and techniques described herein provide implants and implant components that include one or more patient-specific and/or patient-engineered surfaces that are customized for a patient, for example in terms of size, thickness and/or curvature, to supply an anatomic, near anatomic, and/or optimized fit with one or more of the patient's anatomical structures and/or a structure of another implant component. The patient-specific and/or patient-engineered aspects or features of an implant can be shaped prior to implantation and can be based on patient-specific data, for example, as obtained via electronic images of the patient's anatomical features. In this way, unlike traditional implants and related techniques, certain methods described herein help to restore or optimize a patient's joint by achieving an anatomic, near anatomic, or optimized match between the implant or implant component and one or more other structures in the joint.

[00038] Advantages of embodiments described herein can include, but are not limited to, (i) customization of joint repair, thereby enhancing the efficacy and comfort level for the patient following the repair procedure; (ii) eliminating the need for a surgeon to measure the defect to be repaired intraoperatively in some embodiments; (iii) eliminating the need for a surgeon to shape the material during the implantation procedure; (iv) providing methods of evaluating curvature of the repair material based on bone or tissue images or based on intraoperative probing techniques; (v) providing methods of repairing joints with only minimal or, in some instances, no loss in bone stock; (vi) improving postoperative joint congruity; (vii) improving the postoperative patient recovery in some embodiments and (viii) improving postoperative function, such as range of motion.

[00039] Thus, the methods described herein allow for the design and use of joint repair material that more precisely fits the defect (for example, site of implantation) or the articular surface(s) and, accordingly, provides improved repair of the joint.

1. Assessment of Joints and Alignment

[00040] The methods and compositions described herein can be used to treat defects resulting from disease of the cartilage (for example, osteoarthritis), bone damage, cartilage

damage, trauma, and/or degeneration due to overuse or age. Some embodiments allow, among other things, a health practitioner to evaluate and treat such defects. The size, volume and shape of the area of interest can include only the region of cartilage that has the defect, but preferably include contiguous parts of the cartilage surrounding the cartilage defect.

[00041] As will be appreciated by those of skill in the art, size, curvature and/or thickness measurements can be obtained using any suitable technique. For example, one-dimensional, two-dimensional, and/or three-dimensional measurements can be obtained using suitable mechanical means, laser devices, electromagnetic or optical tracking systems, molds, materials applied to the articular surface that harden and “memorize the surface contour,” and/or one or more imaging techniques known in the art. Measurements can be obtained non-invasively and/or intraoperatively (for example, using a probe or other surgical device). As will be appreciated by those of skill in the art, the thickness of the repair device can vary at any given point depending upon patient’s anatomy and/or the depth of the damage to the cartilage and/or bone to be corrected at any particular location on an articular surface.

[00042] FIG. 1A is a flow chart showing steps taken by a practitioner in assessing a joint. First, a practitioner obtains a measurement of a target joint 10. The step of obtaining a measurement can be accomplished by taking an image of the joint. This step can be repeated, as necessary 11 to obtain a plurality of images in order to further refine the joint assessment process. Once the practitioner has obtained the necessary measurements, the information is used to generate a model representation of the target joint being assessed 30. This model representation can be in the form of a topographical map or image. The model representation of the joint can be in one, two, or three dimensions. It can include a physical model. More than one model can be created 31, if desired. Either the original model or a subsequently created model, or both, can be used. After the model representation of the joint is generated 30, the practitioner can optionally generate a projected model representation of the target joint in a corrected condition 40, for example, from the existing cartilage on the joint surface, or by providing a substantially negatively matching surface for the opposing joint surface, or a combination thereof. This step can be repeated 41 as necessary or desired. Using the difference between the topographical condition of the joint and the projected image of the joint, the practitioner can then select a joint implant 50 that is suitable to achieve the

corrected joint anatomy. As will be appreciated by those of skill in the art, the selection process 50 can be repeated 51 as often as desired to achieve the desired result. Additionally, it is contemplated that a practitioner can obtain a measurement of a target joint 10 by obtaining, for example, an x-ray, and then select a suitable joint replacement implant 50.

[00043] As will be appreciated by those of skill in the art, the practitioner can proceed directly from the step of generating a model representation of the target joint 30 to the step of selecting a suitable joint replacement implant 50 as shown by the arrow 32. Additionally, following selection of suitable joint replacement implant 50, one or more of the steps of obtaining measurement of target joint 10, generating model representation of target joint 30, and generating projected model 40, can be repeated in series or in parallel as shown by the flow 24, 25, 26.

[00044] FIG. 1B is an alternate flow chart showing steps taken by a practitioner in assessing a joint. First, a practitioner obtains a measurement of a target joint 10. The step of obtaining a measurement can be accomplished by taking an image of the joint. This step can be repeated, as necessary 11 to obtain a plurality of images in order to further refine the joint assessment process. Once the practitioner has obtained the necessary measurements, the information is used to generate a model representation of the target joint being assessed 30. This model representation can be in the form of a topographical map or image. The model representation of the joint can be in one, two, or three dimensions. The process can be repeated 31 as necessary or desired. It can include a physical model. After the model representation of the joint is assessed 30, the practitioner optionally can generate a projected model representation of the target joint in a corrected condition 40. This step can be repeated 41 as necessary or desired. Using the difference between the topographical condition of the joint and the projected image of the joint, the practitioner then can design a joint implant 52 that is suitable to achieve the corrected joint anatomy, repeating the design process 53 as often as necessary to achieve the desired implant design. The practitioner also can assess whether providing additional features, such as rails, keels, lips, pegs, cruciate stems, or anchors, cross-bars, and/or other features will enhance the implant's performance in the target joint.

[00045] As will be appreciated by those of skill in the art, the practitioner can proceed directly from the step of generating a model representation of the target joint 30 to the step of designing a suitable joint replacement implant 52 as shown by the arrow 38. Following the design of a suitable joint replacement implant 52, one or more of the steps of obtaining measurement of target joint 10, generating model representation of target joint 30, and generating projected model 40, can be repeated in series or parallel as shown by the flow 42, 43, 44.

[00046] FIG. 1C is a flow chart illustrating the process of selecting an implant for a patient. First, using the techniques described above or those suitable and known in the art, the size of area of diseased cartilage or cartilage loss is measured 100. This step can be repeated multiple times 101, as desired. Once the size of the cartilage defect is measured, the thickness of adjacent cartilage can optionally be measured 110. This process also can be repeated as desired 111. Either after measuring the cartilage loss or after measuring the thickness of adjacent cartilage, the curvature of the articular surface is then measured 120. Alternatively, the subchondral bone can be measured. As will be appreciated measurements can be taken of the surface of the joint being repaired, or of the mating surface in order to facilitate development of the best design for the implant surface. This process also can be repeated as desired 121.

[00047] Once the surfaces have been measured, the user either selects the best fitting implant contained in a library of implants 130 or generates a patient-specific implant 132. In addition, patient-specific cuts to the patient's bone optionally can be designed and an implant having the corresponding bone cut angles and surfaces can be selected or generated. These steps can be repeated as desired or necessary to achieve the best fitting implant for a patient, 131, 133. As will be appreciated by those of skill in the art, the process of selecting or designing an implant can be tested against the information contained in the MRI or x-ray of the patient to ensure that the surfaces of the device achieves a good fit relative to the subject's joint surface. Testing can be accomplished by, for example, superimposing the implant image over the image for the subject's joint. Once it has been determined that a suitable implant has been selected or designed, the implant site can be prepared 140, for

example by removing cartilage or bone from the joint surface, or the implant can be placed into the joint 150.

[00048] The joint implant selected or designed achieves anatomic, near anatomic, and/or optimized fit with the modified and/or unmodified articular surface of the patient's joint while presenting a mating surface for the opposing joint surface that replicates the natural joint anatomy or an optimized joint anatomy. Both the existing surface of the joint can be assessed as well as the desired resulting surface of the joint. This technique is particularly useful for implants that are not anchored into the bone.

[00049] As will be appreciated by those of skill in the art, the physician, or practitioner can obtain a measurement of a target joint 10 and then either design 52 or select 50 a suitable joint replacement implant.

2. Repair Materials

[00050] A wide variety of materials can be used in the practice of the implants described herein, including, but not limited to, plastics, metals, crystal free metals, ceramics, biological materials (for example, collagen or other extracellular matrix materials), hydroxyapatite, cells (for example, stem cells, chondrocyte cells or the like), or combinations thereof. Based on the obtained information, such as measurements, regarding the defect and the articular surface and/or the subchondral bone, a repair material can be formed or selected. Further, using one or more of the techniques described herein, a cartilage replacement or regenerating material can a curvature that fits into a particular cartilage defect, follows the contour and shape of the articular surface, and/or matches the thickness of the surrounding cartilage. The repair material can include any combination of materials, and typically includes at least one non-pliable material, for example materials that are not easily bent or changed.

2.1 Metal and Polymeric Repair Materials

[00051] Currently, joint repair systems often employ metal and/or polymeric materials including, for example, prostheses which are anchored into the underlying bone (e.g., a femur in the case of a knee prosthesis). See, e.g., U.S. Pat. No. 6,203,576 to Afriat, et al. issued Mar. 20, 2001 and U.S. Pat. No. 6,322,588 to Ogle, et al. issued Nov. 27, 2001, and

references cited therein. Various metals can be selected based on any criteria known in the art. For example, material selection can be based on resiliency to impart a desired degree of rigidity. Non-limiting examples of suitable metals include silver, gold, platinum, palladium, iridium, copper, tin, lead, antimony, bismuth, zinc, titanium, cobalt, stainless steel, nickel, iron alloys, cobalt alloys, such as Elgiloy®, a cobalt-chromium-nickel alloy, and MP35N, a nickel-cobalt-chromium-molybdenum alloy, and Nitinol™, a nickel-titanium alloy, aluminum, manganese, iron, tantalum, crystal free metals, such as Liquidmetal® alloys (available from LiquidMetal Technologies, www.liquidmetal.com), other metals that can slowly form polyvalent metal ions, for example to inhibit calcification of implanted substrates in contact with a patient's bodily fluids or tissues, and combinations thereof.

[00052] Suitable synthetic polymers include, without limitation, polyamides (e.g., nylon), polyesters, polystyrenes, polyacrylates, vinyl polymers (e.g., polyethylene, polytetrafluoroethylene, polypropylene and polyvinyl chloride), polycarbonates, polyurethanes, poly dimethyl siloxanes, cellulose acetates, polymethyl methacrylates, polyether ether ketones, ethylene vinyl acetates, polysulfones, nitrocelluloses, similar copolymers and mixtures thereof. Bioresorbable synthetic polymers can also be used such as dextran, hydroxyethyl starch, derivatives of gelatin, polyvinylpyrrolidone, polyvinyl alcohol, poly[N-(2-hydroxypropyl) methacrylamide], poly(hydroxy acids), poly(epsilon-caprolactone), polylactic acid, polyglycolic acid, poly(dimethyl glycolic acid), poly(hydroxy butyrate), and similar copolymers can also be used.

[00053] Other appropriate materials include, for example, the polyketone known as polyetheretherketone (PEEK™). This includes the material PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at the web site, www.matweb.com, or see Boedeker at the web site, www.boedeker.com). Other sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com).

[00054] It should be noted that the material selected also can be filled. For example, other grades of PEEK also are available and contemplated, such as 30% glass-filled or 30% carbon filled, provided such materials are cleared for use in implantable devices by the FDA or other

regulatory body. Glass filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that portion which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon filled PEEK offers wear resistance and load carrying capability.

[00055] As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable have very low moisture absorption, and good wear and/or abrasion resistance, can be used. The implant can also be comprised of polyetherketoneketone (PEKK).

[00056] Other materials that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further, other polyketones can be used as well as other thermoplastics.

[00057] Reference to appropriate polymers that can be used for the implant can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated Jan. 10, 2002 and entitled Bio-Compatible Polymeric Materials; PCT Publication WO 02/00275 A1, dated Jan. 3, 2002 and entitled Bio-Compatible Polymeric Materials; and PCT Publication WO 02/00270 A1, dated Jan. 3, 2002 and entitled Bio-Compatible Polymeric Materials.

[00058] The polymers can be prepared by any of a variety of approaches including conventional polymer processing methods. Preferred approaches include, for example, injection molding, which is suitable for the production of polymer components with significant structural features, and rapid prototyping approaches, such as reaction injection molding and stereo-lithography. The substrate can be textured or made porous by either physical abrasion or chemical alteration to facilitate incorporation of the metal coating. Other processes are also appropriate, such as extrusion, injection, compression molding and/or machining techniques. Typically, the polymer is chosen for its physical and

mechanical properties and is suitable for carrying and spreading the physical load between the joint surfaces.

[00059] More than one metal and/or polymer can be used in combination. For example, one or more metal-containing substrates can be coated with polymers in one or more regions or, alternatively, one or more polymer-containing substrates can be coated in one or more regions with one or more metals.

[00060] The system or prosthesis can be porous or porous coated. The porous surface components can be made of various materials including metals, ceramics, and polymers. These surface components can, in turn, be secured by various means to a multitude of structural cores formed of various metals. Suitable porous coatings include, but are not limited to, metal, ceramic, and polymeric (e.g., biologically neutral elastomers such as silicone rubber, polyethylene terephthalate and/or combinations thereof) coatings or combinations thereof. See, e.g., U.S. Pat. No. 3,605,123 to Hahn, issued Sep. 20, 1971. U.S. Pat. No. 3,808,606 to Tronzo issued May 7, 1974 and U.S. Pat. No. 3,843,975 to Tronzo issued Oct. 29, 1974; U.S. Pat. No. 3,314,420 to Smith issued Apr. 18, 1967; U.S. Pat. No. 3,987,499 to Scharbach issued Oct. 26, 1976; and German Offenlegungsschrift 2,306,552. There can be more than one coating layer and the layers can have the same or different porosities. See, e.g., U.S. Pat. No. 3,938,198 to Kahn, et al., issued Feb. 17, 1976.

[00061] The coating can be applied by surrounding a core with powdered polymer and heating until cured to form a coating with an internal network of interconnected pores. The tortuosity of the pores (e.g., a measure of length to diameter of the paths through the pores) can be important in evaluating the probable success of such a coating in use on a prosthetic device. See, also, U.S. Pat. No. 4,213,816 to Morris issued Jul. 22, 1980. The porous coating can be applied in the form of a powder and the article as a whole subjected to an elevated temperature that bonds the powder to the substrate. Selection of suitable polymers and/or powder coatings can be determined in view of the teachings and references cited herein, for example based on the melt index of each.

2.2 Biological Repair Material

[00062] Repair materials can also include one or more biological material, either alone or in combination with non-biological materials. For example, any base material can be designed or shaped and suitable cartilage replacement or regenerating material(s) such as fetal cartilage cells can be applied to be the base. The cells then can be grown in conjunction with the base until the thickness (and/or curvature) of the cartilage surrounding the cartilage defect has been reached. Conditions for growing cells (e.g., chondrocytes) on various substrates in culture, *ex vivo* and *in vivo* are described, for example, in U.S. Pat. No. 5,478,739 to Slivka et al. issued Dec. 26, 1995; U.S. Pat. No. 5,842,477 to Naughton et al. issued Dec. 1, 1998; U.S. Pat. No. 6,283,980 to Vibe-Hansen et al., issued Sep. 4, 2001, and U.S. Pat. No. 6,365,405 to Salzmann et al. issued Apr. 2, 2002. Non-limiting examples of suitable substrates include plastic, tissue scaffold, a bone replacement material (e.g., a hydroxyapatite, a bioresorbable material), or any other material suitable for growing a cartilage replacement or regenerating material on it.

[00063] Biological polymers can be naturally occurring or produced *in vitro* by fermentation and the like. Suitable biological polymers include, without limitation, collagen, elastin, silk, keratin, gelatin, polyamino acids, cat gut sutures, polysaccharides (e.g., cellulose and starch) and mixtures thereof. Biological polymers can be bioresorbable.

[00064] Biological materials used in the methods described herein can be autografts (from the same subject), allografts (from another individual of the same species), and/or xenografts (from another species). See, also, International Patent Publications WO 02/22014 to Alexander et al. published Mar. 21, 2002 and WO 97/27885 to Lee published Aug. 7, 1997. In certain embodiments, autologous materials are preferred, as they can carry a reduced risk of immunological complications to the host, including re-absorption of the materials, inflammation and/or scarring of the tissues surrounding the implant site.

[00065] In certain embodiments, a probe is used to harvest tissue from a donor site and to prepare a recipient site. The donor site can be located in a xenograft, an allograft or an autograft. The probe is used to achieve a good anatomic match between the donor tissue sample and the recipient site. The probe is specifically designed to achieve a seamless or

near seamless match between the donor tissue sample and the recipient site. The probe can, for example, be cylindrical. The distal end of the probe is typically sharp in order to facilitate tissue penetration. Additionally, the distal end of the probe is typically hollow in order to accept the tissue. The probe can have an edge at a defined distance from its distal end, e.g. at 1 cm distance from the distal end and the edge can be used to achieve a defined depth of tissue penetration for harvesting. The edge can be external or can be inside the hollow portion of the probe. For example, an orthopedic surgeon can take the probe and advance it with physical pressure into the cartilage, the subchondral bone and the underlying marrow in the case of a joint such as a knee joint. The surgeon can advance the probe until the external or internal edge reaches the cartilage surface. At that point, the edge can prevent further tissue penetration thereby achieving a constant and reproducible tissue penetration. The distal end of the probe can include one or more blades, saw-like structures, or tissue cutting mechanism. For example, the distal end of the probe can include an iris-like mechanism consisting of several small blades. The blade or blades can be moved using a manual, motorized or electrical mechanism thereby cutting through the tissue and separating the tissue sample from the underlying tissue. Typically, this can be repeated in the donor and the recipient. In the case of an iris-shaped blade mechanism, the individual blades can be moved so as to close the iris thereby separating the tissue sample from the donor site.

[00066] In certain other embodiments, a laser device or a radiofrequency device can be integrated inside the distal end of the probe. The laser device or the radiofrequency device can be used to cut through the tissue and to separate the tissue sample from the underlying tissue.

[00067] In certain embodiments, the same probe can be used in the donor and in the recipient. In certain other embodiments, similarly shaped probes of slightly different physical dimensions can be used. For example, the probe used in the recipient can be slightly smaller than that used in the donor thereby achieving a tight fit between the tissue sample or tissue transplant and the recipient site. The probe used in the recipient can also be slightly shorter than that used in the donor thereby correcting for any tissue lost during the separation or cutting of the tissue sample from the underlying tissue in the donor material.

[00068] Any biological repair material can be sterilized to inactivate biological contaminants such as bacteria, viruses, yeasts, molds, mycoplasmas and parasites. Sterilization can be performed using any suitable technique, for example radiation, such as gamma radiation.

[00069] Any of the biological materials described herein can be harvested with use of a robotic device. The robotic device can use information from an electronic image for tissue harvesting.

[00070] In certain embodiments, the cartilage replacement material has a particular biochemical composition. For instance, the biochemical composition of the cartilage surrounding a defect can be assessed by taking tissue samples and chemical analysis or by imaging techniques. For example, WO 02/22014 to Alexander describes the use of gadolinium for imaging of articular cartilage to monitor glycosaminoglycan content within the cartilage. The cartilage replacement or regenerating material can then be made or cultured in a manner, to achieve a biochemical composition similar to that of the cartilage surrounding the implantation site. The culture conditions used to achieve the desired biochemical compositions can include, for example, varying concentrations. Biochemical composition of the cartilage replacement or regenerating material can, for example, be influenced by controlling concentrations and exposure times of certain nutrients and growth factors.

3. Implant components

[00071] Information on thickness and curvature of the cartilage and/or subchondral bone can be used to create a physical model of the surfaces of the articular cartilage and/or of the underlying bone. This physical model can be representative of a limited area within the joint or it can encompass the entire joint. This model can also take into consideration the presence or absence of a meniscus as well as the presence or absence of some or all of the cartilage. For example, in the knee joint, the physical model can encompass only the medial or lateral femoral condyle, both femoral condyles and the notch region, the medial tibial plateau, the lateral tibial plateau, the entire tibial plateau, the medial patella, the lateral patella, the entire patella or the entire joint. The location of a diseased area of cartilage can be determined, for

example using a 3D coordinate system or a 3D Euclidian distance as described in WO 02/22014.

[00072] In this way, the size of the defect to be repaired can be determined. This process takes into account that, for example, roughly 80% of patients have a healthy lateral component. As will be apparent, some, but not all, defects can include less than the entire cartilage. Thus, in certain embodiments, the thickness of the normal or only mildly diseased cartilage surrounding one or more cartilage defects is measured. This thickness measurement can be obtained at a single point or, preferably, at multiple points, for example 2 point, 4-6 points, 7-10 points, more than 10 points or over the length of the entire remaining cartilage. Furthermore, once the size of the defect is determined, an appropriate therapy, for example, a repair system (also referred to as an articular repair system), including one or more implants or implant components, can be selected such that as much as possible of the healthy, surrounding tissue is preserved.

[00073] In certain embodiments, the curvature of the articular surface can be measured to select, design, and/or shape the repair material. Further, both the thickness of the remaining cartilage and the curvature of the articular surface can be measured to design and/or shape the repair material. Alternatively, the curvature of the subchondral bone can be measured and the resultant measurement(s) can be used to select, design, and/or shape a replacement material. For example, the contour of the subchondral bone can be used to re-create a virtual implant surface. The subchondral bone shape in the diseased areas can be measured. A virtual contour then can be created by projecting the subchondral bone surface into the cartilage surface, whereby the projected subchondral bone surface establishes the margins of the implant. In shaping the device, the contours can be configured to mate with existing anatomical structures or to account for the removal of anatomical structures.

3.1 Femoral bicompartamental implant component

[00074] This section and the following subsections describe various features of embodiments of a bicompartamental implant or implant device 500. In the design and manufacture of these embodiments, the measurements for one or more aspects or features of any embodiment can be patient-specific, engineered, patient-engineered, or standard. It is

understood that any of the patient-specific, engineered, patient-engineered, and/or standard aspects or features described below can be combined in an embodiment.

[00075] FIGS. 2A-2V illustrate a type of implant or implant component suitable for repairing a damaged condyle as disclosed herein. As shown in FIG. 2A, the implant 500 is configured such that it covers only one of the lateral or medial femoral condyles 510. The implant also covers at least a portion of the patellar surface of the femur 512. Accordingly, since this type of implant covers two compartments of the femoral aspect of the knee, it is referred to as a bicompartamental implant or implant component.

[00076] The implant optionally can oppose one or more implants or opposing joint surfaces. FIG. 2C is a perspective side view of the implant of FIG. 2A. As shown in FIG. 2C, the superior surface 502 of the implant 500 is curved to correspond to the curvature of the femoral condyle that it mates with and the portion of the patellar surface of the femur that it covers. One or more pegs 530 can be provided to assist in anchoring the implant to the bone. Additionally, as described more fully below, one or more angled surface(s) 503 can be provided on an superior surface 502 of the condyle component that conforms to an optionally provided cut made on the surface of the joint surface with which the implant mates.

[00077] FIG. 2D illustrates a perspective top view of the implant 500 shown in FIG. 2A. As is appreciated from this view, the inferior surface 504 of the implant 500 is configured to conform to the projected shape of the femoral condyles, e.g., the shape healthy femoral condyles would present to the tibial surface in a non-damaged joint.

[00078] FIG. 2E is a view of the implant 500 showing a hatched three point loading support area which extends from a top portion 513 to a line (plane 17) and from a line (plane 18) to a bottom portion 515. Also illustrated are the pegs 530 extending from the superior surface. FIG. 2F illustrates the superior surface of the implant 500 with the pegs 530 extending from the superior surface. FIG. 2F also illustrates the hatched cantilever loading support area, which extends from the line (plane 18) to the top portion 513 of the implant. The loading forces and directions for each support condition are based on physiological load

encounters. Table 1 shows the Physiological Loadings taken from a study by Seth Greenwald.

Table 1
Physiological Loadings¹

Set-up	"1"	"2"	"3"
Flexion Angle (degree)	0°	60°	90°
Normal Force N (lbs.)	2,900 (652)	3,263 (733.5)	3,625 (815)
Normal Force Case	Walking (4.0 x BW ²)	Stair Descent (4.5 x BW ²)	Stair Ascent (5.0 x BW ²)

²Body Weight (BW) taken as a 60 year old male, with 173 cm height for an average body weight of 74 kg (163 lbs).

¹"Tibial Plateau Surface Stress in TKA: A Factor Influencing Polymer Failure Series III - Posterior Stabilized Designs;" Paul D. Postak, B.Sc., Christine S. Heim, B.Sc., A. Seth Greenwald, D. Phil.; Orthopaedic Research Laboratories, The Mt. Sinai Medical Center, Cleveland, Ohio. Presented at the 62nd Annual AAOS Meeting, 1995.

[00079] Using the implant 500, three point loading occurs from Set-up 1 (2900 N). To replicate a worst case loading scenario, a 75/25 load distribution (75% of 2900 N=2175 N) is used. The loading is concentrated on a 6 mm diameter circular area located directly below and normal to the peg on the bearing surface.

[00080] Turning to the cantilever loading shown in FIG. 2F, the loading occurs from Set-up 3, or 90 degrees, at a 75/25 load distribution (75% of 3625 N=2719 N). As with the above example, the loading is concentrated on a 6 mm diameter circular area located at the center of the posterior-most portion of the medial condyle normal to the flat cut surface of the posterior condyle.

[00081] FIGS. 2G and H illustrate alternate embodiments of the implant 500 having a rail design that provides one or more rails 521 along medial and/or lateral sides of the implant 500. The rail 521 can be positioned so that it extends along a portion of the medial 517 and/or lateral 519 sides before communicating with the angled surface 503. One or more side rails 521 can be provided.

[00082] FIG. 2I illustrates another embodiment of an implant 500 having a keel design. A keel 523 (or centrally formed rail) is provided on the superior surface of the implant. In this

embodiment, the keel 523 is located on the surface of the implant, but not at the sides. The keel can be centered, as shown, substantially centered, or located off-center.

[00083] FIG. 2J illustrates the axial view of the femur 1000 having a lateral condyle 1002 and a medial condyle 1004. The intercondylar fossa is also shown 1006 along with the lateral epicondyle 1008 and the medial epicondyle 1010. The patellar surface of the femur 1012 is also illustrated. The implant 500, illustrated in FIG. 2A, is shown covering the lateral condyle and a portion of the patellar surface of the femur 1012. The pegs 530 also are shown that facilitate anchoring the implant 500 to the condyle and patellar surface.

[00084] FIG. 2K illustrates a knee joint 1020 from an anterior perspective. The implant 500 is implanted over the lateral condyle. FIG. 2L illustrates a knee joint 1020 with the implant 500 covering the medial condyle 1004. As illustrated in FIGS. 2K and L, the shape of the implant 500 corresponding to the patella surface can take on a variety of curvatures.

[00085] Turning to FIGS. 2M and 2N, the implant 500 is positioned such that it communicates with an implant 200 designed to correct a defect in the tibial plateau.

3.4.1 Cut regions of superior surface

[00086] As shown in FIGS. 2A-2N, the implant 500 can include an angled surfaces (also referred to herein as a cut surface or cut region or bone cut or cut) 503 on the superior surface 502 (also referred to herein as the inner, bone-facing surface). The one or more angled surfaces 503 can be provided to communicate with a modified (e.g., resected) or worn surface of an anatomical structure, for example, cartilage and/or bone. The femoral bicompartamental implants or implant components 500 shown in FIGS. 2A-2N include a single, posterior bone cut. Embodiments that include a posterior bone cut also can include one or more contoured surface(s) for mating to one or more bone and/or cartilage surfaces, as well as one or more additional cuts, such as one or more posterior cuts, one or more anterior cuts, one or more distal cuts, one or more chamfer cuts, and/or one or more oblique cuts. An example of an oblique cut is shown in FIG. 2O. Specifically, as shown in FIG. 2O, the implant 500 can have a superior surface 502 which substantially conforms to the surface of the condyle but which has at least one flat portion corresponding to an oblique cut on the bone as shown in FIG. 2O. FIG. 2P illustrates an implant 500 having a contoured surface

560 for mating with the joint surface and a posterior cut 562, a distal cut 563, and a chamfer cut 564. In this embodiment, no anterior cut is provided.

[00087] In certain embodiments, the bicompartamental implant 500 includes an anterior cut. For example, the superior surface of an implant 500 can include one or more contoured surfaces for mating to one or more bone and/or cartilage surface(s) and a single, anterior cut for mating to a modified (e.g., resected) bone surface. Alternatively, the superior surface can include one or more contoured surfaces for mating to one or more bone and/or cartilage surfaces, an anterior cut for mating to a cut bone surface, and one or more additional cuts, such as one or more additional anterior cuts, one or more posterior cuts, one or more distal cuts, one or more chamfer cuts, and/or one or more oblique cuts for mating to one or more modified (e.g., resected) bone surfaces.

[00088] In certain embodiments, the superior surface of a bicompartamental implant 500 can consist primarily of cut surfaces (i.e., without any portion being an uncut, contoured surface). The cut surfaces can include one or more anterior cuts, one or more posterior cuts, one or more distal cuts, one or more chamfer cuts, and/or one or more oblique cuts.

[00089] In preferred embodiments, the bicompartamental implant or implant component 500 includes an anterior cut and a posterior cut on the superior surface. Certain preferred embodiments also can include on the superior surface, between the anterior cut and posterior cut, one or more contoured surface(s) for mating to one or more bone and/or cartilage surfaces. FIGS. 2Q and 2R illustrate a preferred embodiment of a bicompartamental implant or implant component 500 having a contoured surface 565 for mating with an unmodified anatomical structure and an anterior cut 561 and a posterior cut 562 for mating with modified anatomical structures. FIG. 2R shows the same implant 500 as in FIG. 2Q, but from a different angle. One or more of the anterior cut, the posterior cut, and the contoured surface can be patient-specific, for example, designed using patient-specific data to be an anatomic or near-anatomic match to the patient's anatomic structure. Alternatively or additionally, one or more of the anterior cut, the posterior cut, and the contoured surface can be selected, for example, from a library.

[00090] In certain embodiments, the anterior cut and/or the posterior cut (and/or optionally any one or more other cuts) on the superior surface can be engineered. For example, one or more bone cuts can be designed to match one or more resected bone surfaces that themselves are designed or selected to meet a target or parameter, such as minimizing the amount of resected bone. To the extent that patient-specific data is used to engineer an optimized bone cut for the implant 500, the implant 500 and/or implant bone cut can be understood to be patient-engineered.

[00091] This engineering aspect can allow for one or more cuts to the patient's bone that resects less bone than is required for a traditional primary total knee arthroplasty ("TKA") implant. For example, one or more of the optimized bone cuts can allow less than 12 mm, less than 10 mm, less than 8 mm, less than 6 mm, and/or less than 4 mm of bone resected from the surface of the femur. For example, FIG. 2S illustrates the implant 500 of FIGS. 2Q and 2R engaging a model of a femur 566. The implant 500 is overlaid with an outline of a traditional primary TKA implant 568. As shown in the figure, the anterior cut 561 for implant 500 retains more bone than the anterior cut 571 for the traditional primary TKA implant 568. Similarly, the posterior cut 562 for implant 500 retains more bone than the posterior cut 572 for the traditional primary TKA implant 568. Accordingly, the design of implant or implant component 500 can allow for a subsequent surgery to the knee, if required at a later date, to be performed with a traditional primary implant rather than as a revision surgery.

[00092] In certain embodiments, one or both of the anterior and posterior cuts on the superior surface of the bicompartamental implant or implant component 500 can be substantially parallel to the patient's femoral axis, including having one or both cuts slightly oblique to the femoral axis. FIG. 3 illustrates a bicompartamental implant or implant component 500 having an anterior cut 561 and a posterior cut 571 that are substantially parallel to the patient's femoral axis 575. In the figure, the anterior cut 561 is slightly oblique to the femoral axis.

[00093] In certain embodiments, one or both of the anterior and posterior cuts can be substantially non-parallel to the patient's femoral axis. For example, one or both of the anterior and posterior cuts can be substantially angled posteriorly or "flexed" one or more

degrees in the direction of a knee in flexion. This can help reduce the amount of bone resected on the anterior flange and can line up resection planes close to a typical primary TKA, which can aid in applying a primary TKA implant as a replacement, should a replacement be necessary.

[00094] For example, one or both of the anterior and posterior cuts can be rotated or flexed posteriorly (e.g., in flexion) by 5 degrees, 5 or more degrees, 7 degrees, 7 or more degrees, 7-8 degrees, 7.5 degrees, 7.5 or more degrees, 8 degrees, 8 or more degrees, 10 degrees, 10 or more degrees, 12.5 degrees, 12.5 or more degrees, 15 degrees, and/or 15 or more degrees. FIGS. 4A and 4B illustrate bicompartamental implants or implant components 500 overlaid with a traditional primary TKA implant 568. In FIG. 4A, the implant or implant component 500 includes a cut profile and pegs flexed 7.5 degrees from the femoral mechanical axis, with an anterior cut 561 cut that is 1 degree divergent from the profile and a posterior cut 571 that is 6 degrees divergent from the profile. In FIG. 4B, the implant or implant component 500 includes a cut profile and pegs flexed 15 degrees from the mechanical axis, with an anterior cut 561 cut that is 2 degrees divergent from the profile and a posterior cut 571 that is 5 degrees divergent from the profile.

[00095] As shown in FIG. 4B, an implant or implant component 500 including anterior and posterior cuts 561, 571 in planes flexed 7.5 degrees minimizes the bone resected for the anterior cut and lines up resection planes close to a traditional TKA implant. Accordingly, in certain embodiments, the bicompartamental implant or implant component 500 allows for a subsequent revision using a traditional TKA implant.

[00096] As with cuts that are substantially parallel to the patient's femoral axis, cuts that are substantially non-parallel to the patient's femoral axis, for example, cuts that lie in a particular flexed plane, can include cuts that are slightly oblique to the particular flexed plane.

[00097] One or more features of a tibial implant component can be preoperatively engineered based on patient-specific data to provide to the patient an optimized fit with respect to one or more parameters. For example, an engineered bone preserving tibial implant component can be designed and/or selected based on one or more of the patient's

joint dimensions as seen, for example, on a series of two-dimensional images or a three-dimensional representation generated, for example, from a CT scan or MRI scan. FIG. 5 shows a tibial implant 200 for mating with the condylar portion of the bicompartamental implant, implanted on a model of a tibia.

3.4.2 Contoured portion of superior surface

[00098] As discussed above, a femoral bicompartamental implant or implant component 500 can include on its superior surface one or more contoured surface areas for mating to one or more of the patient's bone or cartilage surfaces. In certain embodiments, the topography of one or more of these contoured surfaces can substantially negatively match (e.g., be a negative complement to) the patient's bone and/or cartilage surface. For example, in certain embodiments, the topography of one or more of the contoured surfaces is designed using patient-specific data to substantially match one or more of the patient's bone or cartilage surfaces.

3.1.3 Anterior flange

[00099] FIG. 6A illustrates an exemplary anterior flange 576 of a bicompartamental implant or implant component 500. In certain embodiments, the bicompartamental implant or implant component 500 includes an anterior flange that allows for substantial coverage of the patella-femoral ("PF") region, which includes the region of the distal femur that contacts the patella during flexion and extension. A short anterior flange, for example, one that does not cover a substantial portion of the PF contact area, can cause the patella to catch or clunk against the proximal edge of the implant as the patella moves across the PF region during the extension-flexion motion.

[000100] In certain embodiments, the bicompartamental implant or implant component 500 includes a flange edge that is patient-specific. For example, in certain embodiments, one or more anterior flange edges, such as the proximal edge, the lateral edge, and/or the medial edge, can be designed using patient-specific data to be an anatomic or near-anatomic match to the patient's anatomic structure. In certain embodiments, the one or more anterior flange edges can be designed from patient-specific data to supply an anterior flange having more than a specified minimum coverage of the patient's PF region. For example, certain

embodiments include an anterior flange that supplies 30%, greater than 30%, 40%, greater than 40%, 50%, greater than 50%, 60%, greater than 60%, 70%, greater than 70%, 80%, greater than 80%, 90%, greater than 90%, 95%, greater than 95%, and/or 100% coverage to the PF region contact area at full extension. In certain embodiments, the patient-specific flange coverage substantially matches and covers the resected bone surface, thereby reducing blood loss from resected bone. In addition, one or more patient-specific flange edges can help to minimize gaps or overhang between the flange edge and the patient's anatomic structure. Such gaps, sometimes referred to as air-balls, typically are filled with cement during the surgical implantation of a traditional implant. However, loose cement can be a primary cause of premature implant wear.

[000101] In certain embodiments, the bicompartamental implant or implant component 500 includes an anterior flange edge that is engineered. For example, one or more aspects or features of the anterior flange, such as length, width, thickness, or edge design, can be designed to match a resected bone surface that itself is designed or selected to meet a target or parameter. To the extent that patient-specific data is used to engineer an optimized feature or aspect of the anterior flange, the implant 500, anterior flange, and/or engineered aspect or feature of the flange can be understood to be patient-engineered.

[000102] In certain embodiments, the bicompartamental implant or implant component 500 includes an anterior flange edge that is standard. For example, as illustrated in FIG. 6B, the bicompartamental implant or implant component 500 can include a substantially straight proximal flange edge.

3.4.4 Thickness and width

[000103] The bicompartamental implant or implant component 500 can include varying thicknesses and/or widths across the entire implant or portions of the implant. In certain embodiments, the bicompartamental implant or implant component 500 includes one or more thicknesses and/or widths that are patient-specific. For example, the implant thickness, entirely or in part, can be designed using patient-specific data to match the corresponding thickness of the patient's anatomical structure that the implant replaces. Similarly, the

implant width, entirely or in part, can be designed using patient-specific data to match the corresponding width of the patient's anatomical structure.

[000104] In certain embodiments, the bicompartamental implant or implant component 500 includes one or more thicknesses and/or widths that are engineered. For example, the implant thickness, entirely or in part, and/or the implant width, entirely or in part, can be engineered to include an optimized thickness or width. To the extent that patient-specific data is used to engineer an optimized width and/or thickness, the implant 500, engineered width, and/or engineered thickness can be understood to be patient-engineered.

[000105] In certain embodiments, the bicompartamental implant or implant component 500 includes a PF region having a reduced thickness relative to a traditional implant thickness. For example, relative to a traditional implant thickness of 3-4 mm, the bicompartamental implant or implant component 500 can include a PF region thickness that is reduced by 1 mm, greater than 1 mm, 2 mm, greater than 2 mm, 3 mm, and/or greater than 3 mm. In certain embodiments, an engineered minimum thickness can be used to prevent overstuffing of the PF joint and reduce the risks of limited flexion/extension patella catching and subluxation that are typically observed with traditional bicompartamental implants. For example, in certain embodiments, the thickness between the anterior cut on the superior surface and the PF region on the inferior surface of the bicompartamental implant or implant component 500 can be engineered to include a minimum thickness of 3 mm, 3 mm or less, 2.5 mm, 2.5 mm or less, 2.0 mm, 2.0 mm or less, 1.5 mm, 1.5 mm or less, 1.0 mm, and/or 1 mm or less.

[000106] In certain embodiments, the thickness and/or width of an implant 500 can fall within standardized parameters. For example, the implant 500 can include thicknesses between 2.0 mm and 4.0 mm. In certain embodiments, the width of the implant can be designed to be 1-2 mm shorter than the width of the coronal surfaces of the patient's distal femur.

3.4.5 PF region of inferior surface

[000107] FIG. 7A illustrates an exemplary PF region 578 of a bicompartamental implant or implant component 500. As exemplified in FIG. 7B, the PF region includes a trochlear

groove having a coronal curvature 579 and a sagittal curvature 580. In certain embodiments, the bicompartamental implant or implant component 500 includes a PF region having one or more curvatures that are patient-specific, entirely or in part. For example, with reference to FIGS. 7C and 7D, one or more coronal curvature radii 581 and/or one or more sagittal curvature radii 582 can be designed using patient-specific data to match the corresponding radii of the patient's PF region.

[000108] In certain embodiments, the bicompartamental implant or implant component 500 includes a PF region having one or more curvatures that are standard or engineered, entirely or in part. For example, again with reference to FIGS. 7C and 7D, one or more coronal curvature radii 581 and/or one or more sagittal curvature radii 582 can be standard or engineered. For example, one or more radii can be engineered to optimize movement of the patella in the trochlear groove. A coronal curvature can include constant and/or varying radii. Similarly, a sagittal curvature can include constant and/or varying radii. In certain embodiments, one or both of the coronal curvature 579 and sagittal curvature 580 are engineered to optimize movement in the trochlear groove of a corresponding patellar implant component. FIG. 7E illustrates a bicompartamental implant component 500 that includes a PF region having a coronal curvature and a sagittal curvature that are engineered to optimize movement of a patella implant component.

[000109] The engineered and optimized curvatures can be derived from computer modeling and software automation, which can include steps to smooth or normalize patient-specific data. To the extent that patient-specific data is used to engineer an optimized coronal curvature and/or sagittal curvature of the trochlear groove in the implant 500, the implant and/or corresponding engineered curvature can be understood to be patient-engineered.

[000110] In certain preferred embodiments, the bicompartamental implant or implant component 500 includes a PF region having a coronal curvature that is engineered, at least in part, and a sagittal curvature that is patient-specific, at least in part. FIG. 7F illustrates a bicompartamental implant or implant component 500 that includes a PF region having a coronal curvature that is engineered and a sagittal curvature that is patient-specific. For example, the coronal curvature can be selected by choosing from a family of standard curvatures the one standard curvature that is most similar to the radii of the patient's

corresponding coronal curvature. Alternatively, the coronal curvature can be selected by choosing from a family of standard curvatures a standard curvature with larger radii in order to achieve a less constraining biomechanical situation, or with smaller radii in order to achieve a more constraining biomechanical situation with the patella during knee motion.

[000111] In certain embodiments, the implant or implant component includes a trochlear groove coronal curvature having radii with lengths that are 20-25 mm, and/or 21-23 mm, and/or 22 mm. In certain embodiments, the implant or implant component includes a trochlear groove coronal curvature having radii with lengths that are 30-35 mm, and/or 31-33 mm, and/or 32 mm.

[000112] In certain embodiments, the bicompartamental implant or implant component 500 includes a PF region that is rotated externally, for example, the anterior resection and corresponding anterior portion of the implant 500 can be rotated externally by about 2 degrees, 2-3 degrees, 3 degrees, 3-4 degrees, 4 degrees, and/or by more than 4 degrees. This allows for a PF region with a relatively lower lateral condylar crest and trochlear groove and can provide additional relief from over-stuffing on the lateral side and reduction in the risk of subluxation and clunking. In certain embodiments, the bicompartamental implant or implant component 500 includes a PF region having a trochlear groove that is positioned laterally relative to the patient's trochlear groove, for example, by more than 1 mm, by 1-3 mm, and/or by 2 mm. In certain embodiments, the bicompartamental implant or implant component 500 includes a PF profile that is engineered to conform to the shape of a corresponding patella implant component.

[000113] The optimized PF profiles described above can: (1) allow for anatomy correction of defects while still maintaining useful patient-specific qualities such as trajectory and positioning; (2) lower stress on implant due to better conformity and the ability to balance out anatomy (such as high lateral ridge); (3) allow for smoother transition from relieved PF area to 3-4 mm main load bearing implant thickness; and/or (4) help maintain proper minimum (e.g., 3.0 mm) implant thickness of a relieved implant required to ensure proper implant strength.

3.4.6 Condylar region of inferior surface

[000114] As shown in FIG. 8A, the bicompartamental implant or implant component 500 includes a condylar portion or surface 583. The condyle surface is the primary load bearing surface of an implant or implant component. Accordingly, the design of this surface, and the design for how it engages the opposing tibial surface, can affect implant wear and kinematics, particularly the proper motion of the implant at the joint. As with the PF region trochlear groove described above, and as shown in FIG. 8B, the condylar surface of an implant or implant component 500 includes a coronal curvature 584 and a sagittal curvature 585.

[000115] In certain embodiments, the bicompartamental implant or implant component 500 includes a condylar surface having one or more curvatures that are patient-specific, entirely or in part. For example, with reference to FIGS. 8C and 8D, one or more coronal curvature radii 586 and/or one or more sagittal curvature radii 587 can be designed using patient-specific data to match the corresponding radii of the patient's condylar curvatures.

[000116] In certain embodiments, the bicompartamental implant or implant component 500 includes a condylar surface having one or more curvatures that are standard or engineered, entirely or in part. For example, again with reference to FIGS. 8C and 8D, one or more coronal curvature radii 586 and/or one or more sagittal curvature radii 587 can be standard or engineered. For example, condylar coronal curvature radii and/or sagittal radii at the anterior portion of the implant or implant component can be optimized, for example, by lowering the radii lengths to allow for less restrained movement of the patella in the trochlear groove. Similarly, condylar coronal curvature radii and/or sagittal radii at the distal and/or posterior portions of the implant or implant component can be similarly optimized to allow a greater surface area of the condyle to move against the tibial surface. A coronal curvature can include constant and/or varying radii. Similarly, a sagittal curvature can include constant and/or varying radii. In certain embodiments, one or both of the coronal curvature 584 and sagittal curvature 585 are engineered to optimize movement with a corresponding patellar implant component or with a corresponding tibial implant component.

[000117] The engineered and optimized curvatures can be derived from computer modeling and software automation, which can include steps to smooth or normalize patient-specific data. To the extent that patient-specific data is used to engineer an optimized condylar

coronal curvature and/or condylar sagittal curvature for the implant 500, the implant and/or corresponding engineered curvature can be understood to be patient-engineered.

[000118] In preferred embodiments, the bicompartamental implant or implant component 500 is designed to include a condylar, bearing surface having a sagittal curvature with, at least in part, patient-specific radii and a coronal curvature with a standard curvature. For example, the coronal curvature can be selected by choosing from a family of standard curvatures the one standard curvature that is most similar to the external radii of the patient's corresponding femoral condyle. Alternatively, the coronal curvature can be selected by choosing from a family of standard curvatures a standard curvature with larger radii in order to achieve a less constraining biomechanical situation, or with smaller radii in order to achieve a more constraining biomechanical situation during knee motion.

[000119] The coronal radius of a typical human femoral condyle can range from 20 to 30 mm. In certain embodiments, the coronal radius of the condyle on a bicompartamental implant or implant component 500 can be greater than 20 mm, greater than 30 mm, between 20 and 40 mm, or between 30 and 40 mm.

[000120] In certain embodiments, the bicompartamental implant or implant component 500 design also can include a small cut (also referred to as a dive in) on the anterior portion of the condyle that is not covered by the implant. This can aid in sinking the edge of the implant or implant component into this bone cut and can allow for a smooth surface transition from cartilage to implant, for example, for patellar movement across the surface.

3.4.7 Pegs

[000121] A variety of peg configurations can be used for a bicompartamental implant or implant component 500. Exemplary configurations are illustrated as 901-911 of FIG. 9A. In certain embodiments, the peg cross-section can be round, as in 901, 902, 907, 908, 909, 910 and 911. In certain embodiments the peg cross-section can include a "+" or cross-like configuration, as shown in FIG. 9B, which is a close-up of 903 of FIG. 9A, which may aid in manufacturing. For example, in layering processes (used to create a casting blank), such as stereolithography (SLA), selective laser sintering (SLS), or fused deposition modeling (FDM), generating the curved edges of a blank typically is more difficult than that of casting

the straight-edges of a blank. Accordingly, the straight-edges of the “+” configured peg may allow for a simpler and better defined blank used in the casting process as compared to a round peg.

[000122] A variety of peg sizes can be used for a bicompartamental implant or implant component 500. For example, a 7 mm peg, such as a “+” configured peg, can be used. The peg can be oriented on the device at any angle. For example, one or more pegs can be oriented in line with the femoral mechanical axis. Alternatively, one or more pegs can be oriented at an anterior-leaning angle as the peg extends from the implant, as shown in FIG. 4A. For example, one or more pegs can be oriented anteriorly 5 degrees, 5-10 degrees, 10 degrees, 10-15 degrees, and/or 15 degrees in an anterior-leaning angle relative to the femoral mechanism axis. The pegs can be oriented at the same angle or at different angles as one or both of the anterior and posterior cuts of the implant or implant device 500.

3.4.8 Deriving a patient-specific shape

[000123] FIGS. 10A-10G illustrate the implant 500 of FIG. 2 with a graphical representation of the cross-sections 610, 620 from which a surface shape of the implant is derived. FIG. 10A illustrates a top view of the implant 500 sitting on top of the extracted surface shape 600. This view of the implant 500 illustrates a notch 514 associated with the bridge section of the implant 512 which covers the patellar surface of the femur (or the trochlea region) to provide a mating surface that approximates the cartilage surface. As will be appreciated by those of skill in the art, the shape of an implant designed for the medial condyle may not necessarily be the same or a mirror-image of the implant designed for the lateral condyle because of differences in anatomy. Thus, for example, the notch 514 may not be present in an implant designed for the medial condyle and the patellar surface of the femur. Therefore, the implant can be designed to include all or part of the trochlea region or to exclude it entirely.

[000124] FIG. 10B illustrates a bottom view of the implant 500 layered over another derived surface shape 601. FIG. 10C is a bottom view showing the implant 500 extending through the extracted surface shape 600 shown in FIG. 10A. FIG. 10D is a close-up view of the FIG. 10C showing the condylar wing of the implant covering the extracted surface 600.

FIG. 10E illustrates a top posterior view of the implant 500 positioned over the graphical representation of the surface shape 600. FIG. 10F is an anterior view of the implant 500 on the graphical representation of the surface shape 600 and FIG. 10G is a bottom-posterior view of the implant 500 on the graphical representation of the surface shape 600.

3.4.9 Two-component bicompartamental device

[000125] FIG. 11A-11C illustrate an implant 700 for correcting a joint similar to the implant 500 above. However, implant 700 includes two components. The first component 710 engages a condyle of the femur, either medial or lateral depending on the design. The second component 720 engages the patellar surface of the femur. As discussed with the previous embodiments, the surfaces of the implant 700 can be configured such that the distal surface 722 (e.g., the surface that faces the tibial plateau) is shaped based on a projection of the natural shape of the femur compensating the design for valgus or varus deformities and/or flattening of the surface of the femur. Alternatively, the distal surface can be shaped based on the shape of the tibial plateau to provide a surface designed to optimally mate with the tibial plateau. The proximal surface 724 (e.g., the surface that engages the femoral condyle) can be configured such that it substantially negatively matches the surface of the femur in either its damaged condition or its modified condition. Likewise, the proximal surface can have one or more flattened sections 726 that form, e.g., bone cuts. Additionally, the surface can include mechanisms facilitating attachment 728 to the femur, such as keels, teeth, cruciate stems, and the like. The medial facing portion of the condyle implant can have a tapered surface 730 while the lateral facing portion of the patellar component also can have a tapered surface such that each component presents tapered surfaces 730 to the other component.

[000126] By dividing the surfaces of the medial and lateral compartments into independent articulating surfaces, as shown in FIGS. 11A-11C, the implant provides improved fit of the conformal surfaces to the subchondral bone. Additionally, the lateral-anterior portion of the femur is shielded from stress which could cause bone loss. Also, the smaller size of each component of the implant enables the implant to be placed within the joint using a smaller incision. Finally, the wear of the patellar component may be improved.

3.2 Patellar implant component

[000127] FIGS. 12A-12F illustrate a patella 800 with an implant 810. The implant 810 can have one or more pegs, cruciate stems, or other anchoring mechanisms, if desired. As will be appreciated by those of skill in the art, other designs can be arrived at using the teachings of this disclosure. FIG. 12A illustrates a perspective view of an intact patella 800. FIG. 12B illustrates the patella 800 wherein one surface of the patella 800 has been cut to form a smooth surface 802 to mate with an implant. FIG. 12C illustrates the patella 800 with an implant 810 positioned on the smooth surface 802. The implant 810 has a plate structure 812 that abuts the smooth surface of the patella 802 and a dome 814 positioned on the plate 812 so that the dome is positioned *in situ* such that it matches the location of the patellar ridge. The implant 810 can be configured such that the edge of the plate is offset 1 mm from the actual edge of the patella, as illustrated. As will be appreciated by those of skill in the art, the plate 812 and dome 814 can be formed as a single unit or formed from multiple components. FIG. 12D is a side view of the implant 810 positioned on the patella 800. As shown, the dome is positioned on the implant such that it is off-center. Optimal positioning of the dome can be determined by the position of the patellar ridge.

[000128] Turning to FIGS. 12E-12F, the implant 810 is shown superimposed on the unaltered patella 800 in order to illustrate that the position of the dome 814 of the implant corresponds to the location of the patellar ridge.

[000129] FIGS. 12G-J illustrate an alternative design for the patellar implant. FIG. 12G illustrates the implant 850 in its beginning stages as a blank with a flat inferior surface 852 having pegs 854 extending there from for anchoring to the patella. The articular or superior surface 860 has a rounded dome 856, and a round plate section 858 that can be machined to match the bone cut. The articular surface 860 takes on the appearance of a “hat” or sombrero, having a dome with a rim. The center of the dome 856 also is the center of the bearing surface. The rim 858 is cut to conform to the needs of the particular patient. FIG. 12J illustrates an implant which has been formed from the blank shown in FIGS. 12G-I. FIG. 12I shows a plurality of possible cut lines 862, 862' for purposes of illustration.

3.3 Combinations of implant components

[000130] FIGS. 13A-13C illustrate a lateral view of a knee having a combination of the implants described herein. In FIG. 13A, an implant covering the condyle 900, is illustrated. Suitable implants can be, for example, those shown in FIGS. 2-11. The portion of the condyle covered anterior to posterior can include the entire weight bearing surface, a portion thereof, or a surface greater than the weight bearing surface. Thus, for example, the implant can be configured to terminate prior to the sulcus terminalis or after the sulcus terminalis (e.g., the groove on the femur that coincides with the area where load bearing on the joint surface stops). As shown in FIGS. 13A-13B, a patellar implant 910 can also be provided. FIG. 13C illustrates a knee having a condyle implant 900, a patellar implant 910, and an implant for the tibial plateau 200. FIG. 13D shows a sombrero patellar implant 850 of FIG. 12 matched with another embodiment of a bicondylar implant placed on a model of a femur. This embodiment shows a portion 1301 of the implant 500 extending down the healthy condyle to provide additional patella coverage and tracking.

[000131] FIGS. 14A-14D provide an alternate view of the coronal plane of a knee joint with one or more implants described above implanted therein. FIG. 14A illustrates a knee having a tibial implant 200 placed therein. FIG. 14B illustrates a knee with a condyle implant 300 placed therein. As described above, a plurality of the implants taught herein can be provided within a joint in order to restore joint movement. FIG. 14C illustrates a knee joint having two implants therein. First, a tibial implant 200 is provided on the tibial plateau and a second implant 300 is provided on the facing condyle. The implants can be installed such that the implants present each other mating surfaces, as illustrated. Other combinations will be appreciated by those of skill in the art. Turning to FIG. 14D, a tibial implant 200 is provided along with a bicompartamental condyle implant 500. As discussed above, these implants can be associated with the same compartment of the knee joint, but need not be.

[000132] In another embodiment, the superior face of the implants 300, 400 or 500 can be shaped according to the femur. The shape can preferably be derived from the movement patterns of the femur relative to the tibial plateau thereby accounting for variations in femoral shape and tibiofemoral contact area as the femoral condyle flexes, extends, rotates, translates

and glides on the tibia. The movement patterns can be measured using any current or future test know in the art such as fluoroscopy, MRI, gait analysis and combinations thereof.

[000133] In various embodiments, a joint implant may include two or more components that are slideably engageable forming a mobile bearing, as described in U.S. Patent Publication No. 2007-0100462. The mobile bearing can help provide more unconstrained or more physiologic motion in the joint, for example, knee motion of the femur relative to the tibia. In various embodiments, the joint implant may have one or more mobile bearings. The various components used for the mobile bearing joint implant may be composed of metal, plastic, ceramic or any other material know in the art. Different components may be composed of different materials, e.g. one metal and one plastic. Alternatively, only the same material may be used for the bearing surfaces, e.g. ceramic. The bearing surfaces of each component may vary in material composition e.g. ceramic on the side facing the femoral condyle and metal on the undersurface.

4. Implant libraries

[000134] As described herein, repair systems of various sizes, curvatures and thicknesses can be obtained. These repair systems can be catalogued and stored to create a library of systems from which an appropriate system for an individual patient can then be selected. In other words, a defect, or an articular surface, is assessed in a particular subject and a pre-existing repair system having a suitable shape and size is selected from the library and, optionally, can be processed for further manipulation (e.g., shaping) and implantation.

5. Manufacturing

5.1 Shaping

[000135] In certain instances shaping of the repair material (e.g., of the repair system implant(s) and/or implant component(s)) may be required before or after formation (e.g., to achieve a desired thickness), for example, where the thickness of the required repair material is not uniform (e.g., where the patient-specific, patient-engineered, and/or standard dimensions require different thicknesses).

[000136] The replacement material can be shaped by any suitable technique including, but not limited to, casting techniques, mechanical abrasion, laser abrasion or ablation, radiofrequency treatment, cryoablation, variations in exposure time and concentration of nutrients, enzymes or growth factors and any other means suitable for influencing or changing the desired shape feature, such as thickness. See, e.g., WO 00/15153 to Mansmann published Mar. 23, 2000; If enzymatic digestion is used, certain sections of the replacement or regenerating material can be exposed to higher doses of the enzyme or can be exposed longer as a means of achieving different thicknesses and curvatures of the replacement or regenerating material in different sections of said material.

[000137] The material can be shaped manually and/or automatically, for example, using a device into which a pre-selected thickness and/or curvature has been input and then programming the device using the input information to achieve the desired shape. In addition to, or instead of, shaping the repair material, the site of implantation (e.g., bone surface, any cartilage material remaining, etc.) can also be shaped by any suitable technique in order to enhance integration of the repair material.

5.2 Sizing

[000138] The repair system can be formed or selected so that it achieves an anatomic or near anatomic fit or match with the surrounding or adjacent cartilage, subchondral bone, menisci and/or other tissue. Alternatively or in addition, the repair system can be engineered or selected so that it achieves an optimized fit or match with the surrounding or adjacent cartilage, subchondral bone, menisci, other tissue, and/or other implant structure in the joint. The shape of the repair system can be based on the analysis of an electronic image (e.g. MRI, CT, digital tomosynthesis, optical coherence tomography or the like). If the repair system is intended to replace an area of a diseased or modified anatomic structure, the anatomic, near anatomic, or optimized fit can be achieved based, at least in part, on a virtual reconstruction of the shape of the patient's healthy joint or an ideal joint in an electronic image.

[000139] In certain embodiments, a near normal cartilage surface at the position of the defect can be reconstructed by interpolating the healthy cartilage surface across the defect or area of disease. This can, for example, be achieved by describing the healthy cartilage by

means of a parametric surface (e.g. a B-spline surface), for which the control points are placed such that the parametric surface follows the contour of the healthy cartilage and bridges the defect or area of disease. The continuity properties of the parametric surface can provide a smooth integration of the part that bridges the defect or area of disease with the contour of the surrounding healthy cartilage. The part of the parametric surface over the area of the defect or area of disease can be used to determine the shape or part of the shape of the repair system to match with the shape of the cartilage surface.

[000140] In other embodiments, a near normal cartilage surface at the position of the defect or area of disease can be reconstructed using morphological image processing. In a first step, the cartilage can be extracted from the electronic image using manual, semi-automated and/or automated segmentation techniques (e.g., manual tracing, region growing, live wire, model-based segmentation), resulting in a binary image. Defects in cartilage can appear as indentations that can be filled with a morphological closing operation performed in 2-D or 3-D with an appropriately selected structuring element. The closing operation is typically defined as a dilation followed by an erosion. A dilation operator sets the current pixel in the output image to 1 if at least one pixel of the structuring element lies inside a region in the source image. An erosion operator sets the current pixel in the output image to 1 if the whole structuring element lies inside a region in the source image. The filling of the defect or area of disease creates a new surface over the area of the defect or area of disease that can be used to determine the shape or part of the shape of the repair system to match with the surrounding cartilage or subchondral bone.

[000141] As described above, the repair system can be formed or selected from a library or database of systems of various sizes, curvatures and thicknesses so that it achieves a near anatomic fit or match, or an optimized fit, with the surrounding or adjacent cartilage and/or subchondral bone. These systems can be pre-made or made to order for an individual patient. In order to control the fit or match of the repair system with the surrounding or adjacent cartilage or subchondral bone or menisci and other tissues preoperatively, a software program can be used that projects the repair system over the anatomic position where it is implanted. Suitable software is commercially available and/or readily modified or designed by a skilled programmer.

[000142] In yet another embodiment, the repair system can be projected over the implantation site using one or more 3-D images. The cartilage and/or subchondral bone and other anatomic structures are extracted from a 3-D electronic image such as an MRI or a CT using manual, semi-automated and/or automated segmentation techniques. A 3-D representation of the cartilage and/or subchondral bone and other anatomic structures as well as the repair system is generated, for example using a polygon or NURBS surface or other parametric surface representation. For a description of various parametric surface representations see, for example Foley, J. D. et al., Computer Graphics: Principles and Practice in C; Addison-Wesley, 2nd edition, 1995).

[000143] The 3-D representations of the cartilage and/or subchondral bone and other anatomic structures and the repair system can be merged into a common coordinate system. The repair system can then be placed at the desired implantation site. The representations of the cartilage, subchondral bone, menisci and other anatomic structures and the repair system are rendered into a 3-D image, for example application programming interfaces (APIs) OpenGL[®] (standard library of advanced 3-D graphics functions developed by SGI, Inc.; available as part of the drivers for PC-based video cards, for example from www.nvidia.com for NVIDIA video cards or www.3dlabs.com for 3Dlabs products, or as part of the system software for Unix workstations) or DirectX[®] (multimedia API for Microsoft Windows[®] based PC systems; available from www.microsoft.com). The 3-D image can be rendered showing the cartilage, subchondral bone, menisci or other anatomic objects, and the repair system from varying angles, e.g. by rotating or moving them interactively or non-interactively, in real-time or non-real-time.

[000144] The software can be designed so that the repair system, including surgical tools and instruments with the best fit relative to the cartilage and/or subchondral bone is automatically selected, for example using some of the techniques described above. Alternatively, the operator can select a repair system, including surgical tools and instruments and project it or drag it onto the implantation site using suitable tools and techniques. The operator can move and rotate the repair systems in three dimensions relative to the implantation site and can perform a visual inspection of the fit between the repair system and the implantation site. The visual inspection can be computer assisted. The

procedure can be repeated until a satisfactory fit has been achieved. The procedure can be performed manually by the operator; or it can be computer-assisted in whole or part. For example, the software can select a first trial implant that the operator can test. The operator can evaluate the fit. The software can be designed and used to highlight areas of poor alignment between the implant and the surrounding cartilage or subchondral bone or menisci or other tissues. Based on this information, the software or the operator can then select another implant and test its alignment. One of skill in the art will readily be able to select, modify and/or create suitable computer programs for the purposes described herein.

[000145] In another embodiment, the implantation site can be visualized using one or more cross-sectional 2-D images. Typically, a series of 2-D cross-sectional images are used. The 2-D images can be generated with imaging tests such as CT, MRI, digital tomosynthesis, ultrasound, or optical coherence tomography using methods and tools known to those of skill in the art. The repair system can then be superimposed onto one or more of these 2-D images. The 2-D cross-sectional images can be reconstructed in other planes, e.g. from sagittal to coronal, etc. Isotropic data sets (e.g., data sets where the slice thickness is the same or nearly the same as the in-plane resolution) or near isotropic data sets can also be used. Multiple planes can be displayed simultaneously, for example using a split screen display. The operator can also scroll through the 2-D images in any desired orientation in real time or near real time; the operator can rotate the imaged tissue volume while doing this. The repair system can be displayed in cross-section utilizing different display planes, e.g. sagittal, coronal or axial, typically matching those of the 2-D images demonstrating the cartilage, subchondral bone, menisci or other tissue. Alternatively, a three-dimensional display can be used for the repair system. The 2-D electronic image and the 2-D or 3-D representation of the repair system can be merged into a common coordinate system. The repair system can then be placed at the desired implantation site. The series of 2-D cross-sections of the anatomic structures, the implantation site and the repair system can be displayed interactively (e.g. the operator can scroll through a series of slices) or non-interactively (e.g. as an animation that moves through the series of slices), in real-time or non-real-time.

5.3 Rapid Prototyping

[000146] Rapid prototyping is a technique for fabricating a three-dimensional object from a computer model of the object. A special printer is used to fabricate the prototype from a plurality of two-dimensional layers. Computer software sections the representations of the object into a plurality of distinct two-dimensional layers and then a three-dimensional printer fabricates a layer of material for each layer sectioned by the software. Together the various fabricated layers form the desired prototype. More information about rapid prototyping techniques is available in U.S. Patent Publication No. 2002/0079601A1 to Russell et al., published Jun. 27, 2002. An advantage to using rapid prototyping is that it enables the use of free form fabrication techniques that use toxic or potent compounds safely. These compounds can be safely incorporated in an excipient envelope, which reduces worker exposure.

[000147] A powder piston and build bed is provided. Powder includes any material (metal, plastic, etc.) that can be made into a powder or bonded with a liquid. The powder is rolled from a feeder source with a spreader onto a surface of a bed. The thickness of the layer is controlled by the computer. The print head then deposits a binder fluid onto the powder layer at a location where it is desired that the powder bind. Powder is again rolled into the build bed and the process is repeated, with the binding fluid deposition being controlled at each layer to correspond to the three-dimensional location of the device formation. For a further discussion of this process see, for example, U.S. Patent Publication No 2003/017365A1 to Monkhouse et al. published Sep. 18, 2003.

[000148] The rapid prototyping can use the two dimensional images obtained, as described above in Section 1, to determine each of the two-dimensional shapes for each of the layers of the prototyping machine. In this scenario, each two dimensional image slice would correspond to a two dimensional prototype slice. Alternatively, the three-dimensional shape of the defect can be determined, as described above, and then broken down into two dimensional slices for the rapid prototyping process. The advantage of using the three-dimensional model is that the two-dimensional slices used for the rapid prototyping machine

can be along the same plane as the two-dimensional images taken or along a different plane altogether.

[000149] Rapid prototyping can be combined or used in conjunction with casting techniques. For example, a shell or container with inner dimensions corresponding to an repair system can be made using rapid prototyping. Plastic or wax-like materials are typically used for this purpose. The inside of the container can subsequently be coated, for example with a ceramic, for subsequent casting. Using this process, personalized casts can be generated.

[000150] Rapid prototyping can be used for producing repair systems. Rapid prototyping can be performed at a manufacturing facility. Alternatively, it may be performed in the operating room after an intraoperative measurement has been performed.

6. Surgical Techniques

[000151] Prior to performing surgery on a patient, the surgeon can preoperatively make a determination of the alignment of the knee using, for example, an erect AP x-ray. In performing preoperative assessment any lateral and patella spurs that are present can be identified.

[000152] Using standard surgical techniques, the patient is anesthetized and an incision is made in order to provide access to the portion or portions of the knee joint to be repaired. A medial portal can be used initially to enable arthroscopy of the joint. Thereafter, the medial portal can be incorporated into the operative incision and/or standard lateral portals can be used.

[000153] Once an appropriate incision has been made, the exposed compartment is inspected for integrity, including the integrity of the ligament structures. If necessary, portions of the meniscus can be removed as well as any spurs or osteophytes that were identified in the AP x-ray or that may be present within the joint. In order to facilitate removal of osteophytes, the surgeon may flex the knee to gain exposure to additional medial and medial-posterior osteophytes. Additionally, osteophytes can be removed from the patella

during this process. If necessary, the medial and/or lateral meniscus can also be removed at this point, if desired, along with the rim of the meniscus.

[000154] As would be appreciated by those of skill in the art, evaluation of the medial cruciate ligament may be required to facilitate tibial osteophyte removal. Once the joint surfaces have been prepared, the desired repair system (e.g., implant(s) and/or implant component(s)) can be inserted into the joint.

EXAMPLE

[000155] This Example illustrates a process for designing and assessing three different bicompartamental knee implants or implant components. This Example also illustrates three different bicompartamental knee implants or implant components having patient-specific and/or engineered aspects or features.

[000156] Three different bicompartamental implants or implant components having anterior and posterior cuts were designed for a particular patient's right knee having a femur segment volume of 156.7 cm³. The three implants or implant components then were compared to a bicompartamental implant or implant component having only a posterior bone cut. FIG. 15A shows images of the particular patient's femur 1501 and patella 1502 and FIG. 15B illustrates the three different bicompartamental implants or implant components 1510-1520 ("Designs 1-3") and the bicompartamental implant or implant component having no bone cuts 1505 ("Baseline"). Table 1 includes a description of the resection volume, implant volume, and implant mass for each of the three implant designs and for the baseline implant.

Table 1 - Implant Designs

	Description	Resection volume (cm ³)	% Change from Baseline	Implant Volume (cm ³)	Implant Mass (g)	% Change from Baseline
Baseline	Single, posterior bone cut	1.6	-	12.9	107.1	-
Design 1	Posterior and anterior bone cuts; 2mm sub-basal anterior cut; 2mm PF joint relief and same angles	5.3	231%	17.0	141.1	32%

Design 2	Same as Design-1 but with patella implant optimized PF region	5.4	238%	17.8	147.7	38%
Design 3	Same as Design-2 but with flex angles adjusted for bone preservation	3.1	94%	14.8	122.8	15%

[000157] As shown in FIGS. 15C-15E, the baseline bicompartamental implant or implant component 1505 was designed to include only a single, posterior bone cut 1102, which differs by 12 degrees from the mechanical axis. The design also includes a small cut (also referred to as a dive in) 1104 on the anterior portion of the condyle (that is not covered by the implant) to allow for sinking the edge of the implant or implant component into this bone cut. The anterior flange is short to prevent closing of the “C” shape of the implant, which otherwise would prohibit fitting the implant onto the femur. In addition, the inner proximal edge of the anterior flange is flared for clearance. The pegs 1108 are set 15 degrees off the mechanical axis.

[000158] FIGS. 16A-16C illustrate the baseline bicompartamental implant or implant component 1505 in place on a model of a femur 1506. As shown in FIG. 16A, the implant or implant component offers limited anterior coverage 1110 of the PF region when the knee is in flexion. However, as shown in FIG. 16B, the baseline bicompartamental implant or implant component offers substantial posterior coverage 1112. The thickness of this implant in the posterior region was 8.5 mm. With this implant or implant component, the bone lost to resection was 1.6 cm³ (initial segment volume of 156.7 cm³ – final segment volume of 155.1 cm³).

[000159] As shown in FIGS. 17A-17C, the first bicompartamental implant or implant component design 1510 (“Design 1”) included both a posterior bone cut 1102 and an anterior bone cut 1114. The anterior bone cut was designed to be 2 mm below the basal point of the trochlear groove so that the PF region was relieved 2 mm evenly. The PF region 1116 of the implant or implant component also was designed to be patient specific, for example, so that one or more of the coronal and sagittal curvatures of the trochlear groove substantially

matched the patient's coronal and sagittal curvatures. The posterior cut 1102 and pegs 1108 are set at the same angle, and the anterior flange is 5 degrees divergent from the posterior cut and peg angle. In this design, a cement pocket 1118 was included and the proximal edge 1120 of the anterior flange 1121 was substantially straight.

[000160] FIGS. 18A-18C illustrate the first bicompartamental implant or implant component design 1510 ("Design 1") in place on a model of a femur 1511. As shown in FIG. 18A, the implant or implant component offers substantially more anterior coverage 1110 of the PF region when the knee is in flexion, as compared to the baseline design (see FIG. 16A). In addition, as shown in FIG. 18B, 1510 also offers substantial posterior coverage 1112. The thickness of this implant in the anterior region is 8.5 mm on the lateral side and 8.0 mm on the medial side. However, with this implant or implant component, the bone lost to resection was 5.3 cm³ (initial segment volume of 156.7 cm³ – final segment volume of 151.4 cm³).

[000161] As shown in FIGS. 19A-19C, the second bicompartamental implant or implant component design 1515 ("Design 2") included the posterior and anterior bone cuts as described with 1510, Design 1. Specifically, the anterior bone cut 1114 was designed to be 2 mm below the basal point. All other unaffected surfaces of the implant had about 4 mm thickness. In addition, the anterior flange cut 1121 and coverage and the posterior coverage for 1515, Design 2 were the same as described above for 1510, Design 1. However, dissimilarly to 1510, Design 1, the PF region 1116 of the implant or implant component of 1515, Design 2 was engineered to optimize the trochlear groove fit with a patellar implant component. The posterior cut 1102 and peg angles 1108 for 1515, Design 2 were as described above for 1510, Design 1.

[000162] FIGS. 20A-20C illustrate the second bicompartamental implant or implant component 1515 ("Design 2") in place on a model of a femur 1516. The thickness of this implant in the anterior region is 9.8 mm on the lateral side and 9.0 mm on the medial side. With this implant or implant component, the bone lost to resection was 5.4 cm³ (initial segment volume of 156.7 cm³ – final segment volume of 151.3 cm³).

[000163] As shown in FIGS. 21A-21C, the third bicompartamental implant or implant component design 1520 ("Design 3") included the posterior cut 1114 and anterior bone cuts

1102 as described with 1515, Design 2. In addition, the anterior flange cut 1121 and coverage for 1520, Design 3 was the similar as described above for 1515, Design 2. However, the flex of the cuts was altered to preserve bone. Specifically, the anterior cut was shifted to be 6 degrees off the mechanical axis and the posterior cut was shifted to be 1.5 degrees off the mechanical axis. Similar to 1515, Design 2, the PF region 1116 of the implant or implant component of 1520, Design 3 was engineered to optimize the trochlear groove fit with a patellar implant component. The peg angles 1108 for 1520, Design 3 were 7.6 degrees off the mechanical axis.

[000164] FIGS. 22A-22C illustrate the third bicompartamental implant or implant component 1520 (“Design 3”) in place on a model of a femur 1521. The thickness of this implant in the anterior region is 8 mm on the lateral side and 7.5 mm on the medial side. The posterior flange coverage was less than that for Design 2, due to the change in the flex angle. However, with this implant or implant component, the bone lost to resection was only 3.1 cm³ (initial segment volume of 156.7 cm³ – final segment volume of 153.6 cm³).

INCORPORATION BY REFERENCE

[000165] The entire disclosure of each of the publications, patent documents, and other references referred to herein is incorporated herein by reference in its entirety for all purposes to the same extent as if each individual source were individually denoted as being incorporated by reference.

EQUIVALENTS

[000166] The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The foregoing embodiments are therefore to be considered in all respects illustrative rather than limiting on the invention described herein. Scope of the invention is thus indicated by the appended claims rather than by the foregoing description, and all changes that come within the meaning and range of equivalency of the claims are intended to be embraced therein.

What is claimed is:

1. A patient-specific bicompartamental knee implant for implantation into a patient's joint, the implant comprising:

a body having a condylar portion and a trochlear portion, wherein the condylar portion has a shape generally resembling a surface of a condyle of the patient's knee and the trochlear portion having a shape generally resembling the surface of a trochlea of the patient's knee;

the condylar portion further having an articular surface wherein at least a portion of the articular surface is configured such that a curve of the at least a portion of the articular surface substantially matches a curve of a corresponding portion of an articular surface of the patient's condyle; and

the condylar portion further having a bone-facing surface opposite the articular surface, wherein at least a first portion of the bone-facing surface is planar and at least a second portion of the bone-facing surface substantially matches a corresponding portion of an articular surface of the patient's joint.

2. The implant of claim 1 wherein the planar portion of the bone-facing surface is located on a posterior of the condylar portion.

3. The implant of claim 1, wherein the condylar portion further comprises a third portion of the bone-facing surface is substantially planar.

4. The implant of claim 1, wherein the first and third portions are disposed at anterior and posterior ends of the implant and the second portion is disposed between the first and third portions.

5. The implant of claim 1, wherein the trochlear portion further comprises an articular surface wherein at least a portion of the articular surface is configured such that a curve of the at least a portion of the articular surface substantially matches a curve of a corresponding portion of an articular surface of a trochlea of the patient's joint.

6. The implant of claim 1, wherein the trochlear portion further comprises a bone-facing surface opposite the articular surface, wherein at least a portion of the bone-facing surface is planar.

7. A patient-specific bicompartamental knee implant for implantation into a patient's joint, the implant comprising:

a body having a condylar portion and a trochlear portion, wherein the condylar portion has a shape generally resembling a surface of a condyle of the patient's knee and the trochlear portion having a shape generally resembling the surface of a trochlea of the patient's knee;

the condylar portion further having an articular surface wherein at least a portion of the articular surface is configured such that a curve of the at least a portion of the articular surface substantially matches a curve of a corresponding portion of an articular surface of the patient's condyle; and

the trochlear portion having a bone-facing surface and an articular surface, wherein the bone-facing surface is generally opposite the articular surface and wherein at least a portion of the bone-facing surface is planar.

8. The implant of claim 7, wherein the condylar portion further comprises a bone-facing surface opposite the articular surface, wherein at least a portion of the bone-facing surface is planar.

9. The implant of claim 7, wherein the condylar portion further comprises a bone-facing surface opposite the articular surface, wherein at least a portion of the bone-facing surface substantially matches a corresponding portion of an articular surface of the patient's joint.

10. The implant of claim 7, wherein the condylar portion further comprises a bone-facing surface opposite the articular surface, wherein at least a portion of the bone-facing surface is planar and at least a second portion of the bone-facing surface substantially matches a corresponding portion of an articular surface of the patient's joint.

11. The implant of claim 10, wherein the planar portion of the bone-facing surface is located on a posterior of the condylar portion.
12. The implant of claim 7, wherein the condylar portion further comprises a bone-facing surface opposite the articular surface, wherein at least a first portion of the bone-facing surface is substantially planar, at least a second portion of the bone-facing surface substantially matches a corresponding portion of an articular surface of the patient's joint, and at least a third portion of the bone-facing surface is substantially planar.
13. The implant of claim 12, wherein the first and third portions are disposed at anterior and posterior ends of the implant and the second portion is disposed between the first and third portions.
14. The implant of claim 7, wherein at least a portion of the articular surface of the trochlear portion is configured such that a curve of the at least a portion of the articular surface substantially matches a curve of a corresponding portion of an articular surface of a trochlea of the patient's joint.
15. A patient-specific bicompartamental knee implant for implantation into a patient's joint, the implant comprising:
- a body having a condylar portion and a trochlear portion, wherein the condylar portion has a shape generally resembling a surface of a condyle of the patient's knee and the trochlear portion having a shape generally resembling the surface of a trochlea of the patient's knee;
 - the condylar portion further having a bone-facing surface and an articular surface, the bone-facing surface being generally opposite the articular surface, wherein at least a posterior portion of the bone-facing surface is planar and at least a second portion of the bone-facing surface substantially matches a corresponding portion of an articular surface of the patient's joint.
16. The implant of claim 15, wherein at least a portion of the articular surface of the condylar portion has a curve that substantially matches a curve of a corresponding portion of an articular surface of the patient's condyle.

17. The implant of claim 15, wherein the planar portion of the bone-facing surface is located on a posterior of the condylar portion.
18. The implant of claim 15, wherein the condylar portion further comprises a third portion of the bone-facing surface that is substantially planar.
19. The implant of claim 18, wherein the posterior and third portions are disposed at anterior and posterior ends of the implant and the second portion is disposed between the first and third portions.
20. The implant of claim 15, wherein the trochlear portion further comprises an articular surface wherein at least a portion of the articular surface is configured such that a curve of the at least a portion of the articular surface substantially matches a curve of a corresponding portion of an articular surface of a trochlea of the patient's joint.
21. The implant of claim 15, wherein the trochlear portion further comprises a bone-facing surface opposite the articular surface, wherein at least a portion of the bone-facing surface is planar.
22. A patient-specific bicompartamental knee implant for implantation into a patient's joint, the implant comprising:
- a body having a condylar portion and a trochlear portion, wherein the condylar portion has a shape generally resembling a surface of a condyle of the patient's knee and the trochlear portion having a shape generally resembling the surface of a trochlea of the patient's knee;
 - the condylar portion further having a bone-facing surface and an articular surface, the bone-facing surface being generally opposite the articular surface, wherein at least a portion of the bone-facing surface substantially matches a corresponding portion of an articular surface of the patient's joint; and
 - the trochlear portion further having a planar bone-facing surface.

23. The implant of claim 22, wherein at least a portion of the articular surface of the condylar portion has a curve that substantially matches a curve of a corresponding portion of an articular surface of the patient's condyle.

24. The implant of claim 22, wherein the trochlear portion further comprises an articular surface wherein at least a portion of the articular surface is configured such that a curve of the at least a portion of the articular surface substantially matches a curve of a corresponding portion of an articular surface of a trochlea of the patient's joint.

25. A patient-specific bicompartamental knee implant for implantation into a patient's joint, the implant comprising:

a body having a condylar portion and a trochlear portion, wherein the condylar portion has a shape generally resembling a surface of a condyle of the patient's knee and the trochlear portion having a shape generally resembling the surface of a trochlea of the patient's knee;

the condylar portion further having a bone-facing surface and an articular surface, the bone-facing surface being generally opposite the articular surface, wherein at least a portion of the bone-facing surface is substantially matches a corresponding portion of an articular surface of the patient's joint

the trochlear portion further having an articular surface wherein at least a portion of the articular surface is configured such that a curve of the at least a portion of the articular surface substantially matches a curve of a corresponding portion of an articular surface of a trochlea of the patient's joint;

the trochlear portion further having a planar bone-facing surface.

26. The implant of claim 25, wherein at least a portion of the articular surface of the condylar portion has a curve that substantially matches a curve of a corresponding portion of an articular surface of the patient's condyle.

27. The implant of claim 25, wherein the bone-facing surface opposite the articular surface further comprises a planar portion.

28. The implant of claim 25, wherein the planar portion of the bone-facing surface is located on a posterior of the condylar portion.

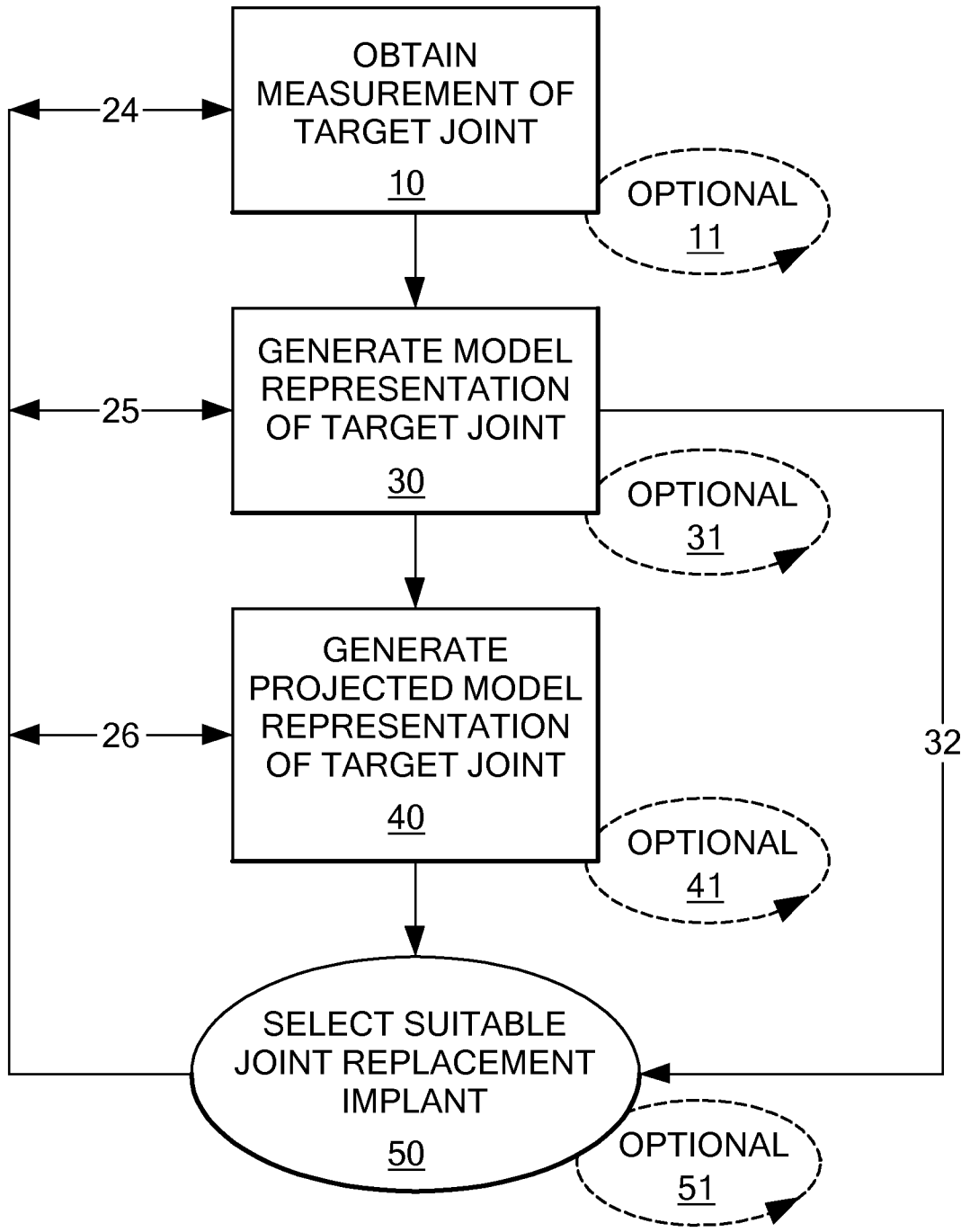


FIG. 1A

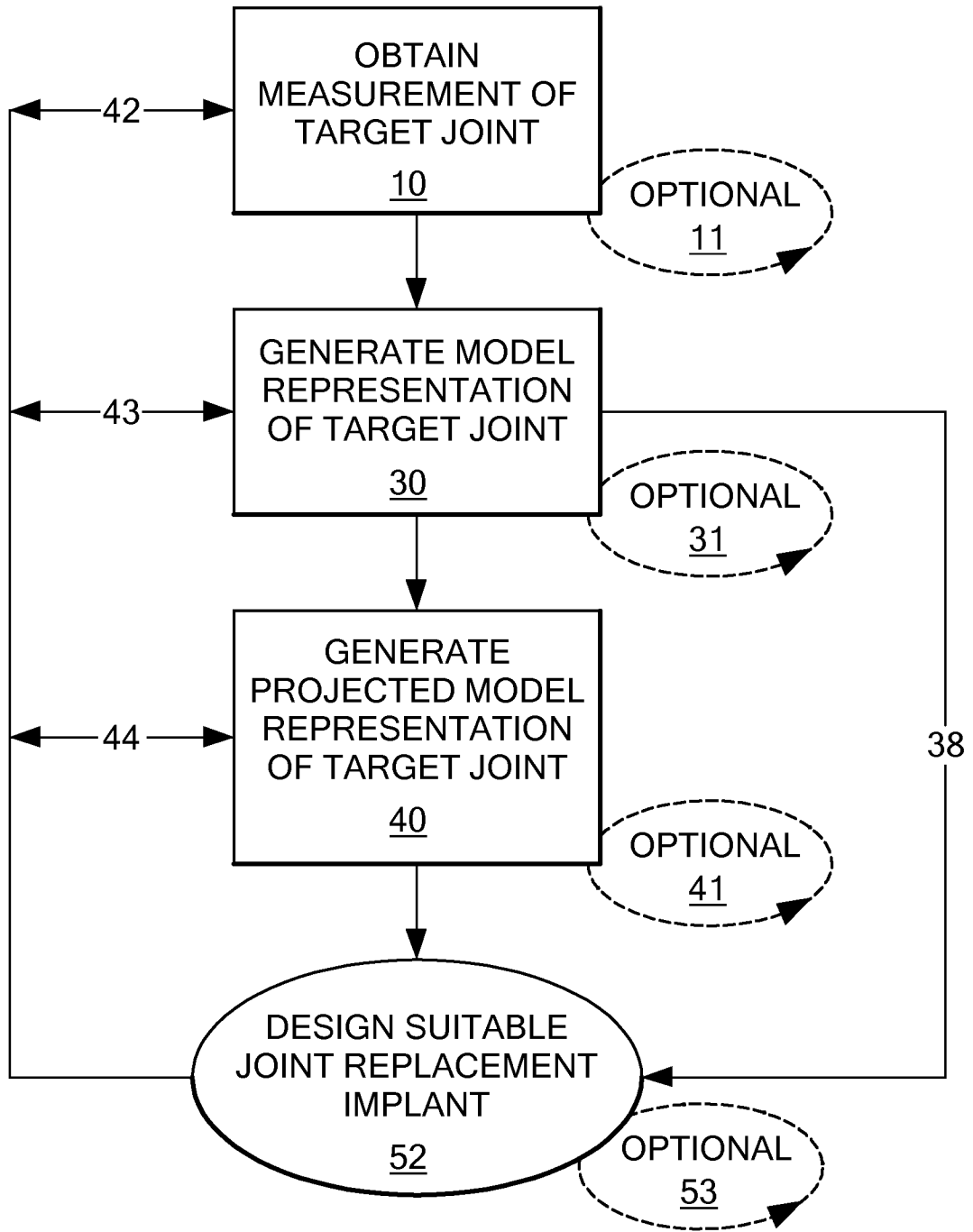


FIG. 1B

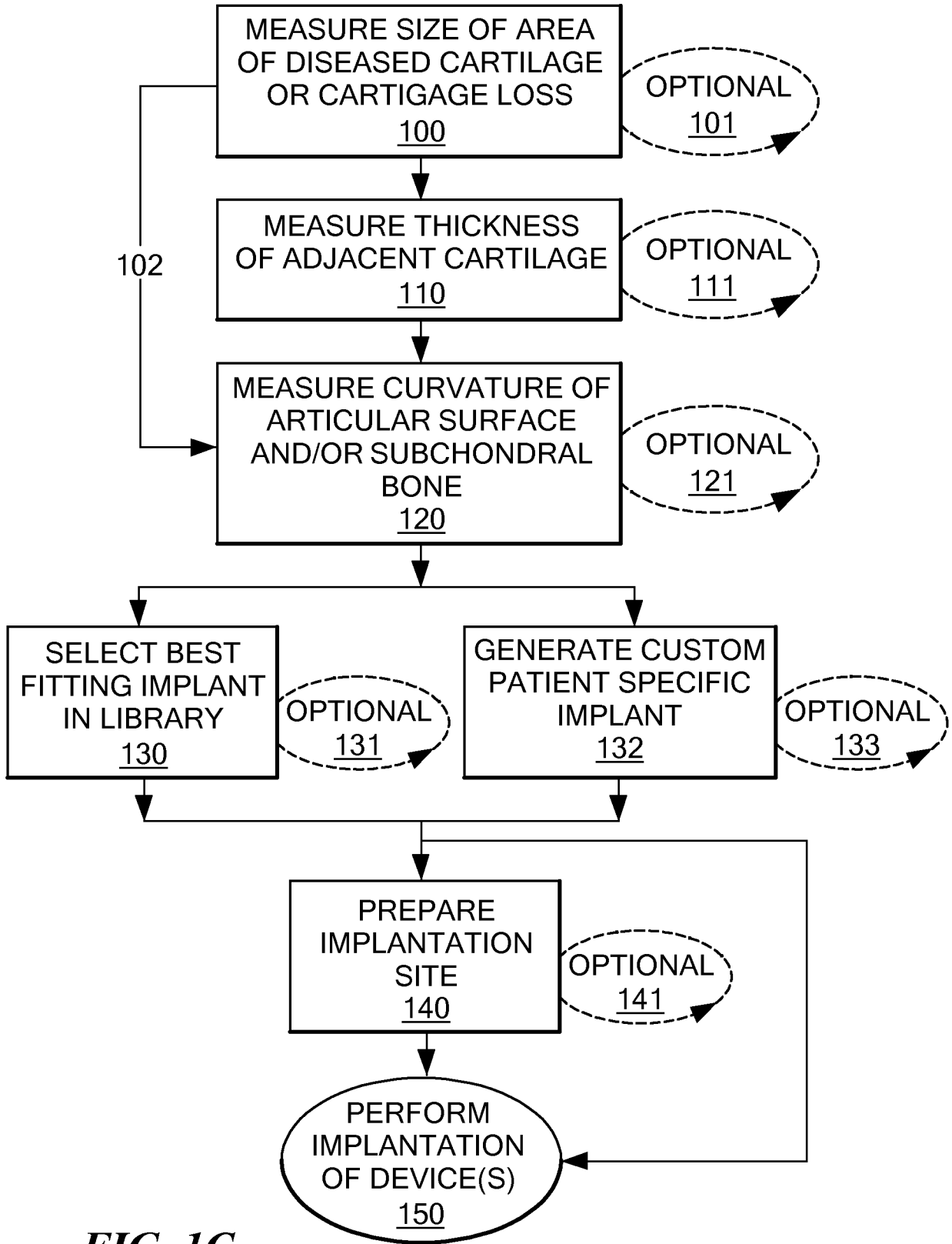


FIG. 1C

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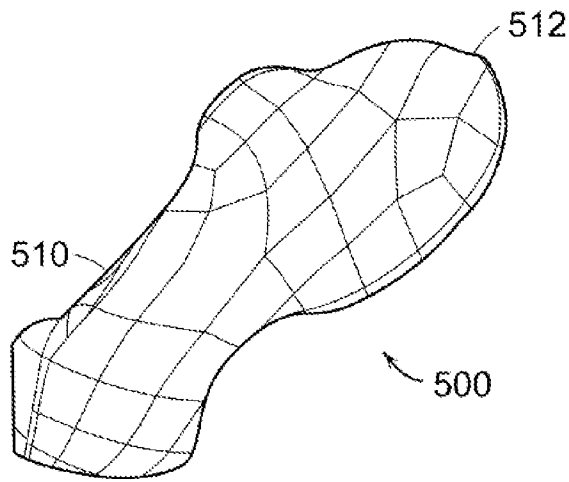


FIG. 2A

FIG. 2B

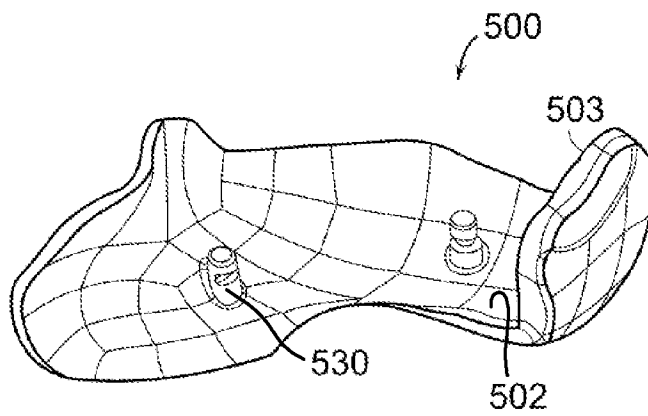
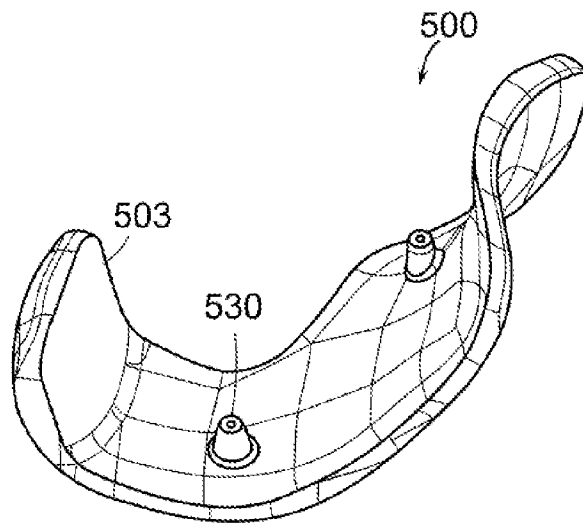


FIG. 2C

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FIG. 2D

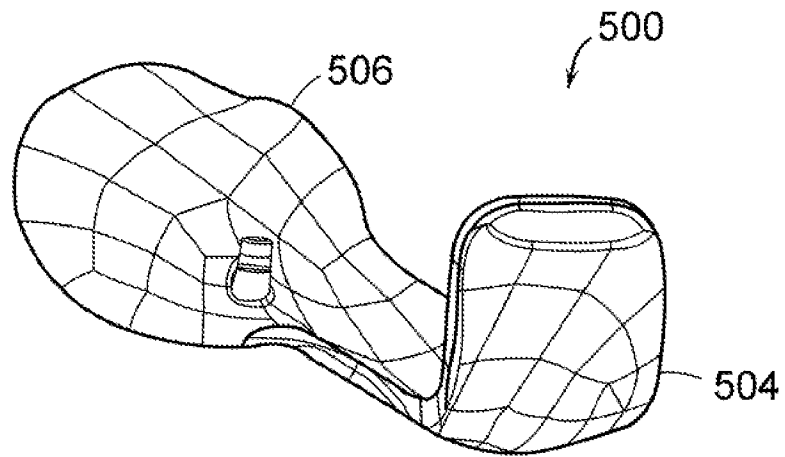


FIG. 2E

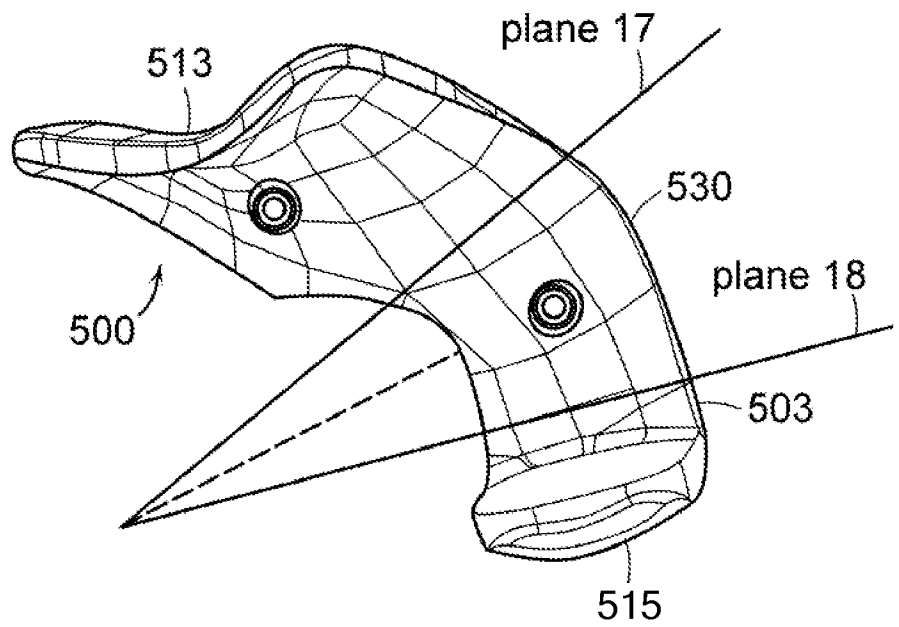
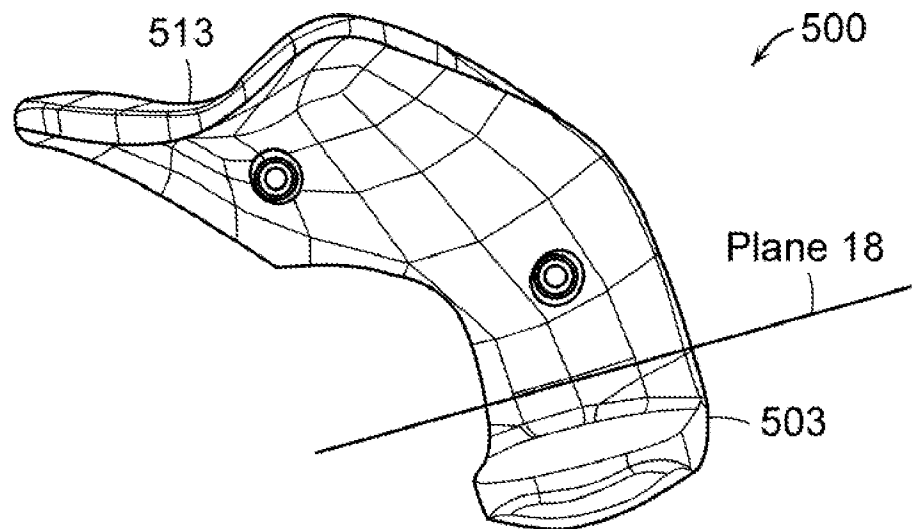


FIG. 2F



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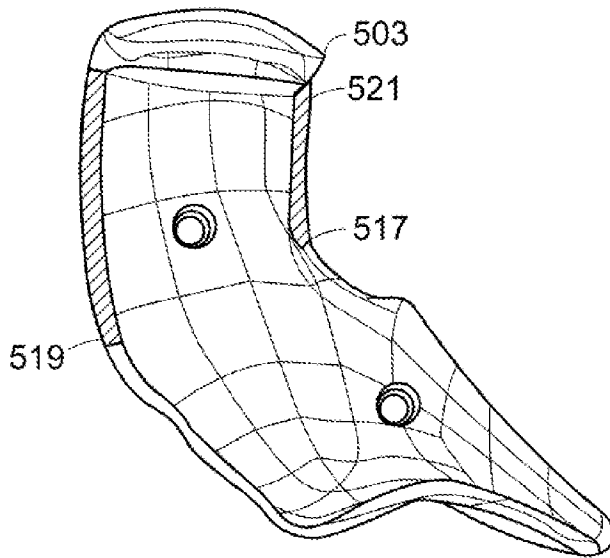


FIG. 2G

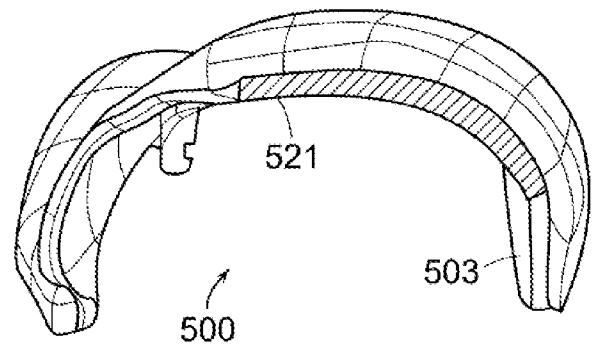


FIG. 2H

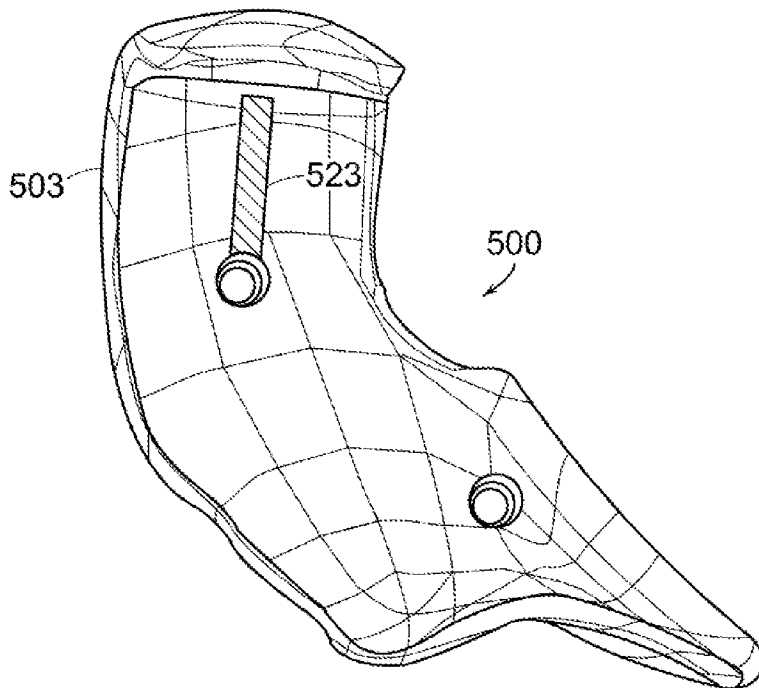


FIG. 2I

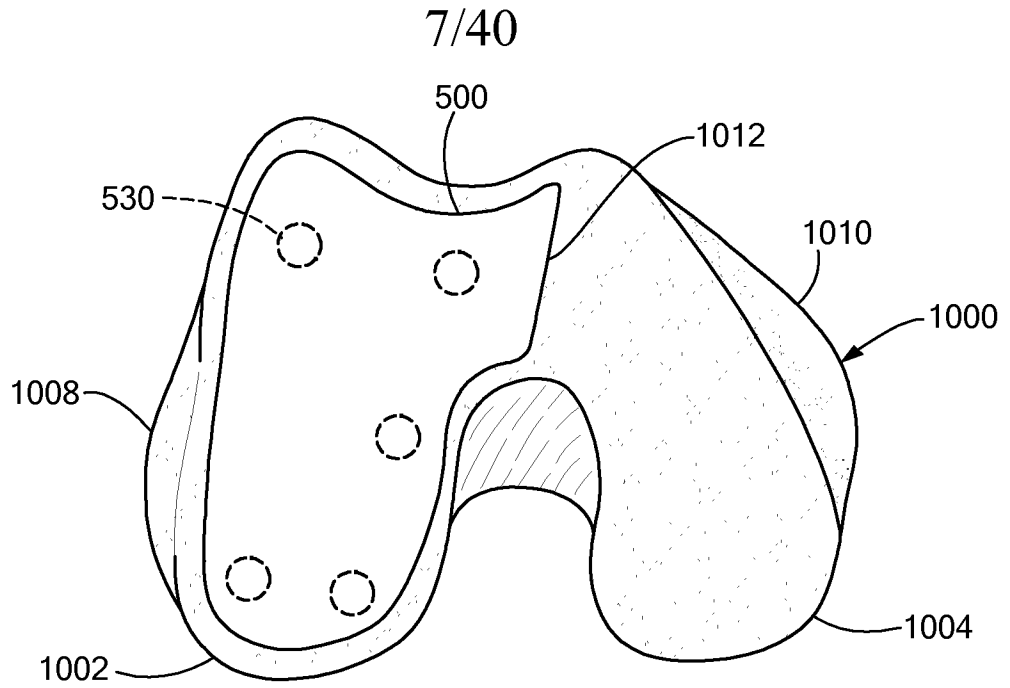


FIG. 2J

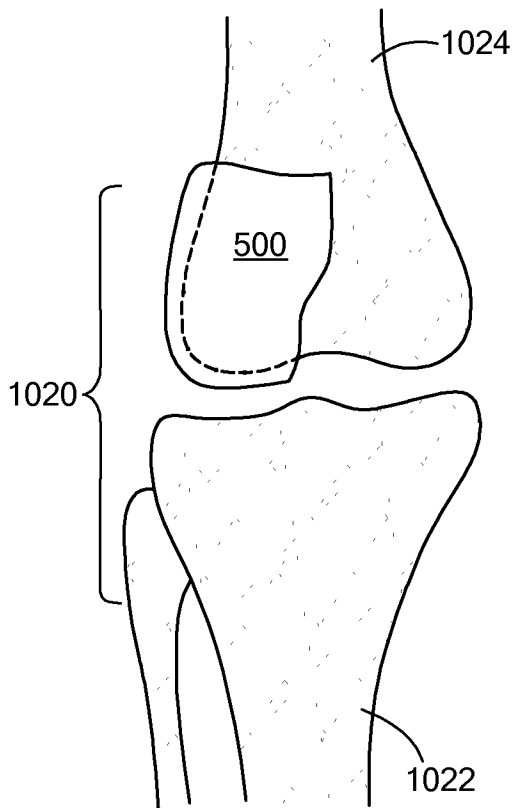


FIG. 2K

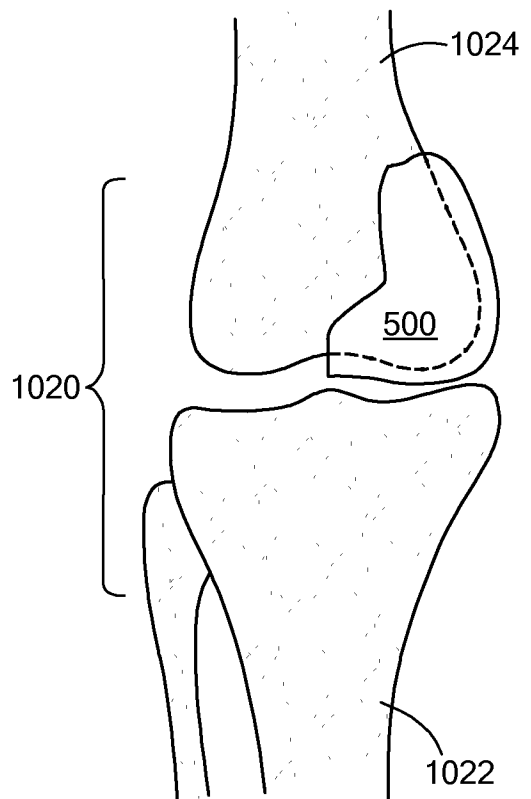


FIG. 2L

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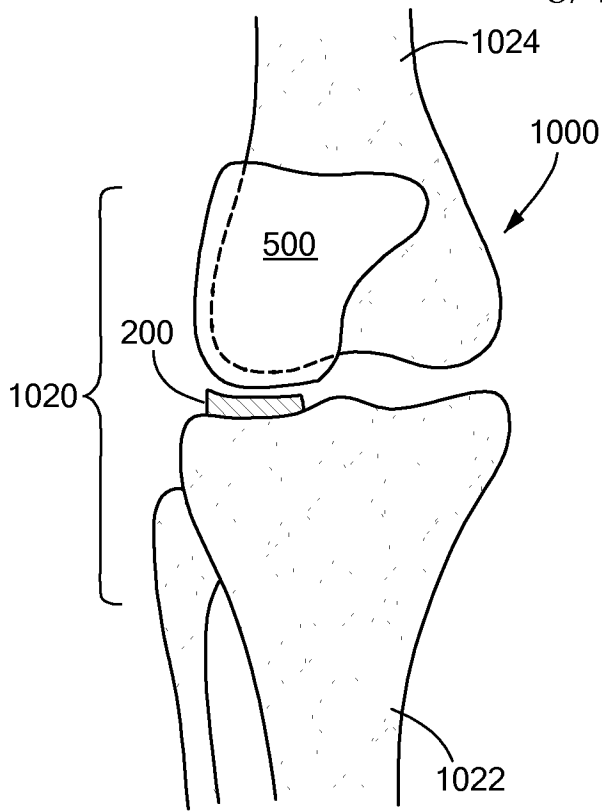


FIG. 2M

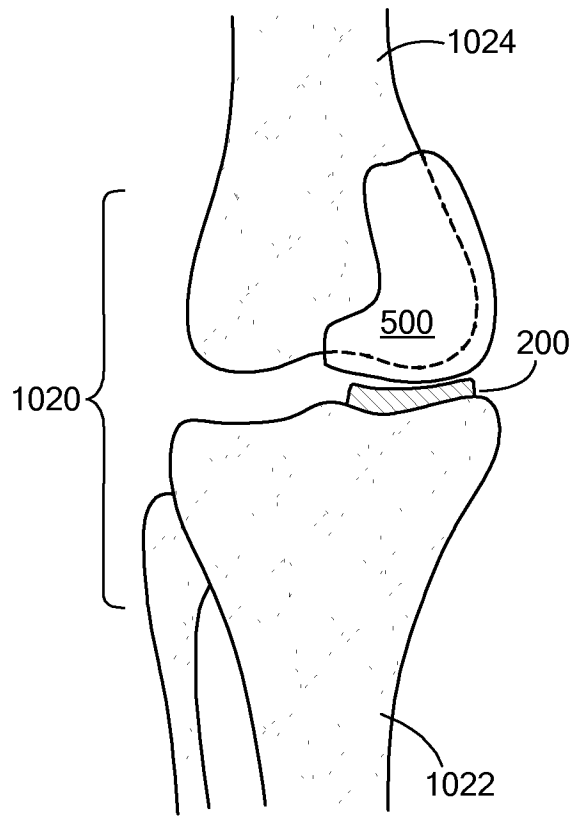


FIG. 2N

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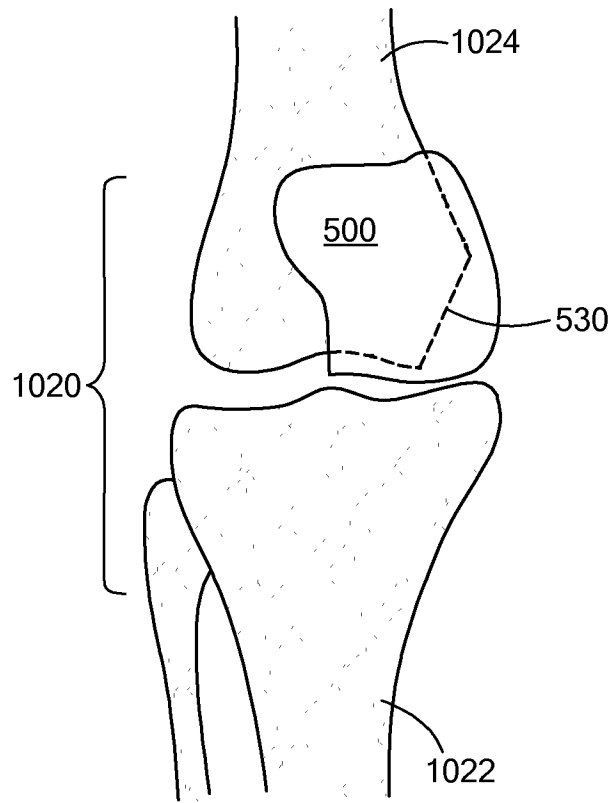


FIG. 20

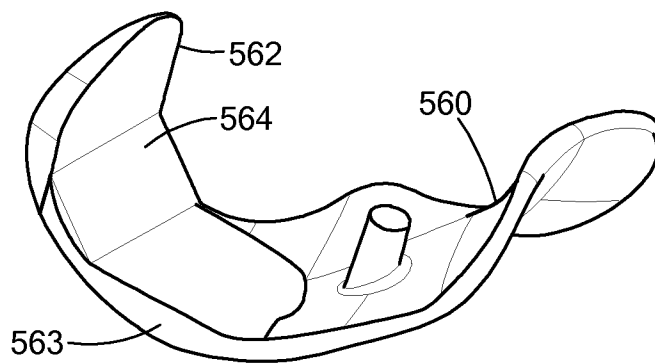


FIG. 2P

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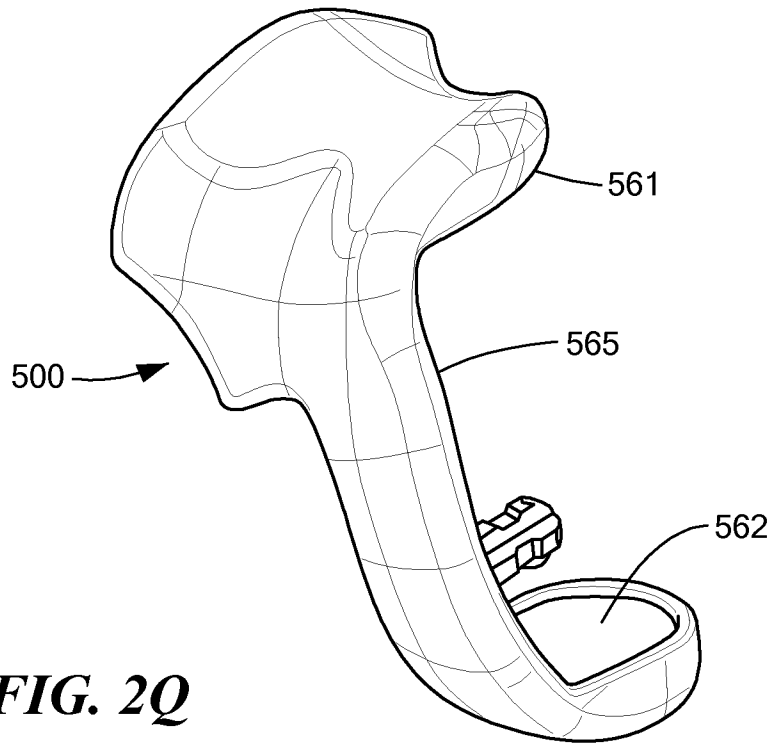


FIG. 2Q

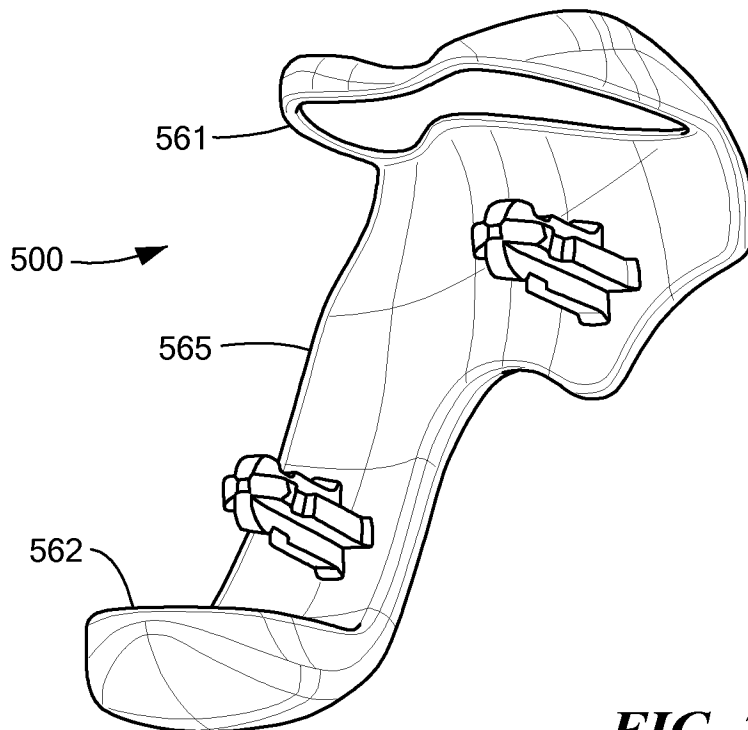


FIG. 2R

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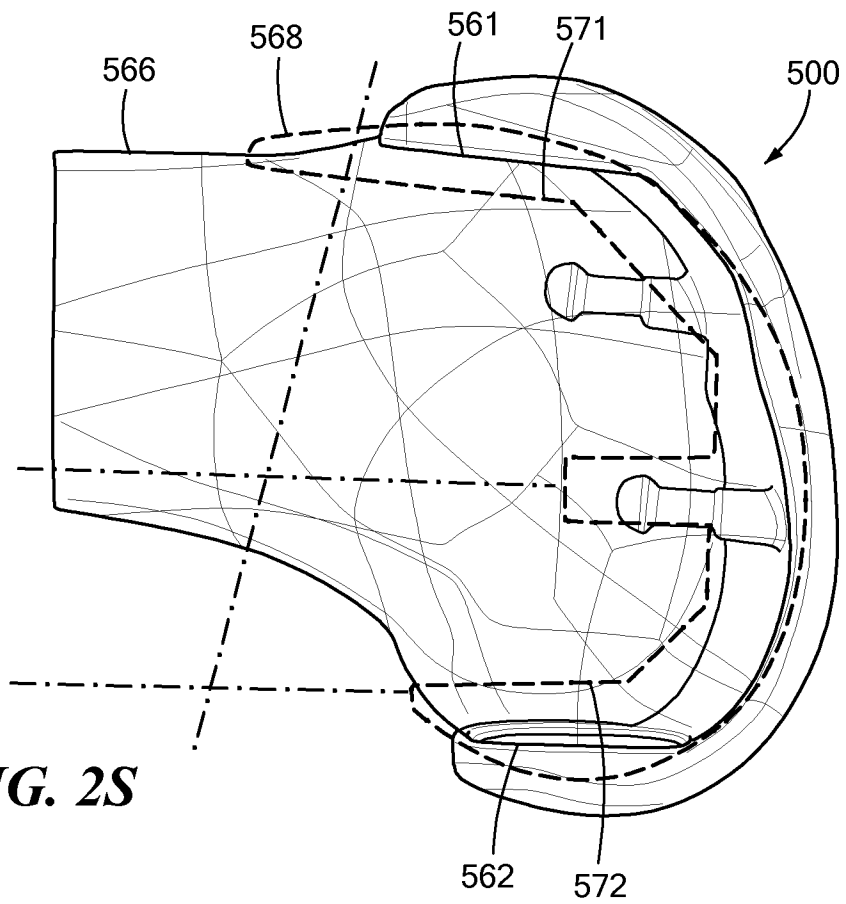


FIG. 2S

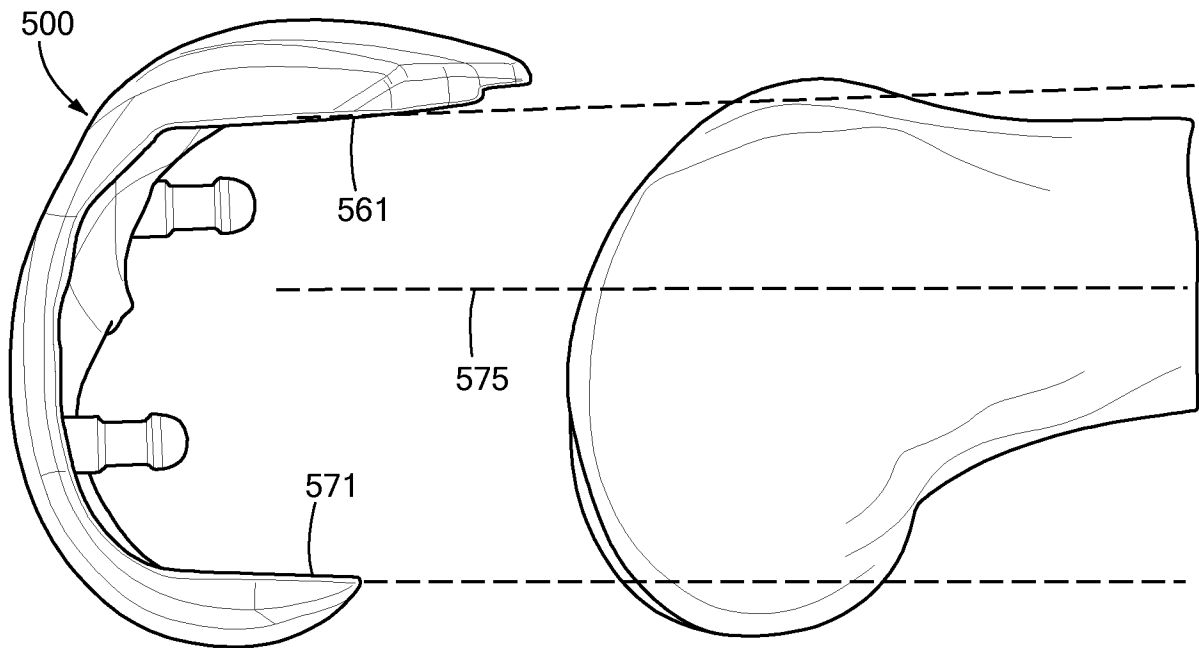


FIG. 3

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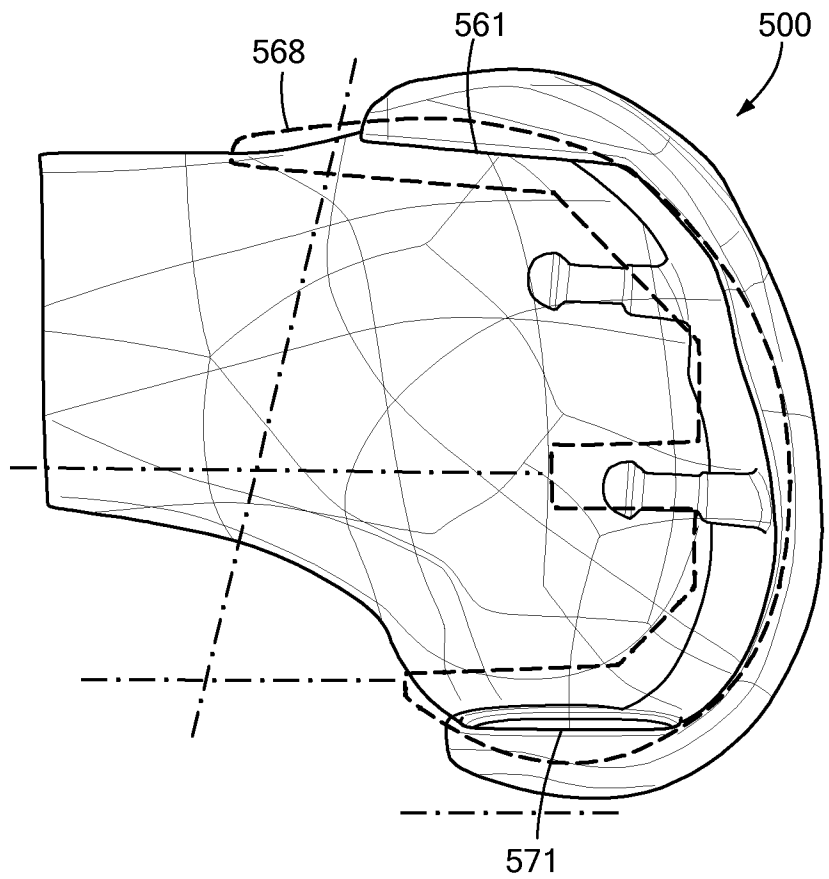


FIG. 4A

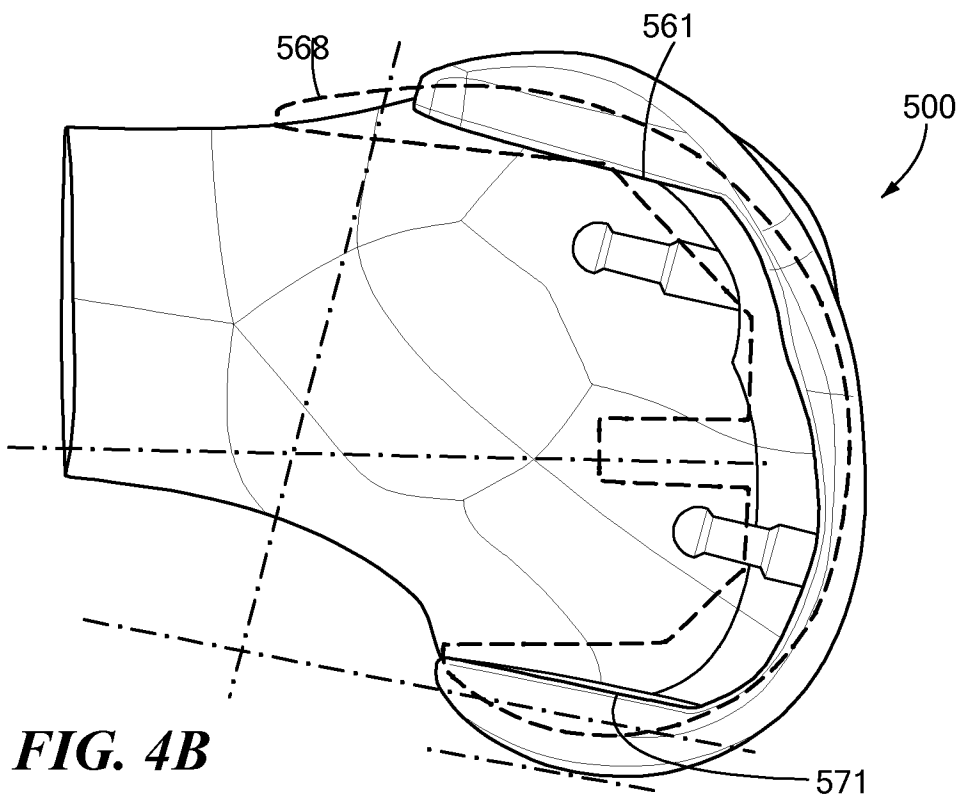


FIG. 4B

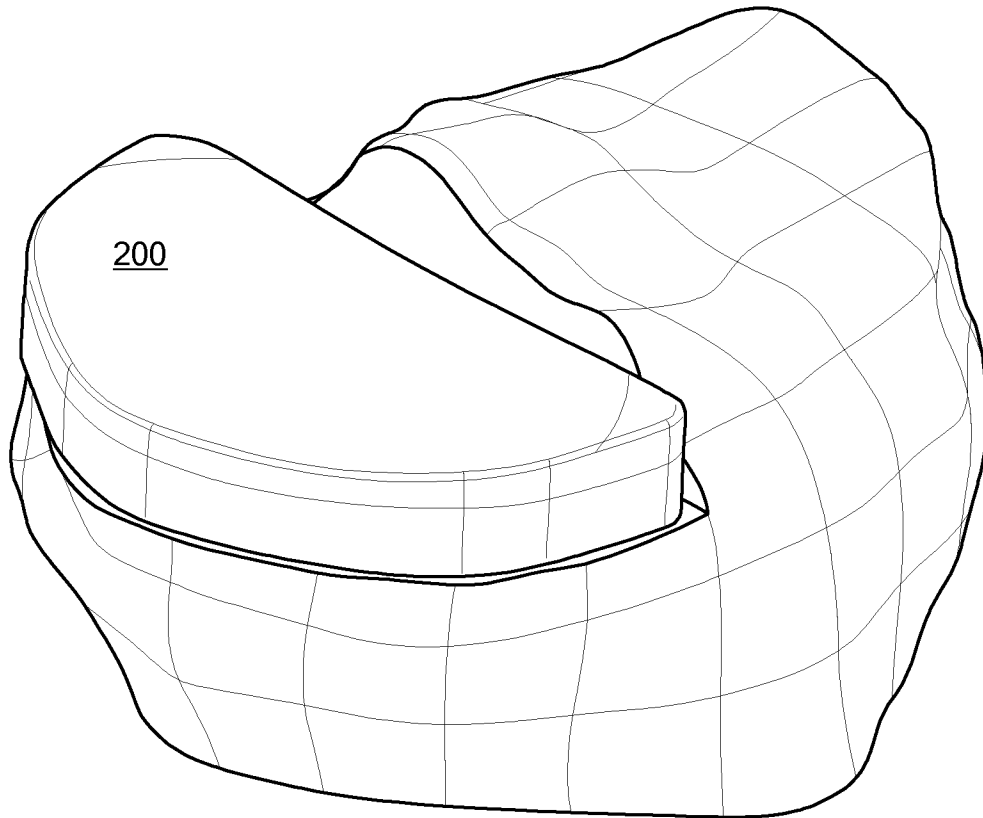


FIG. 5

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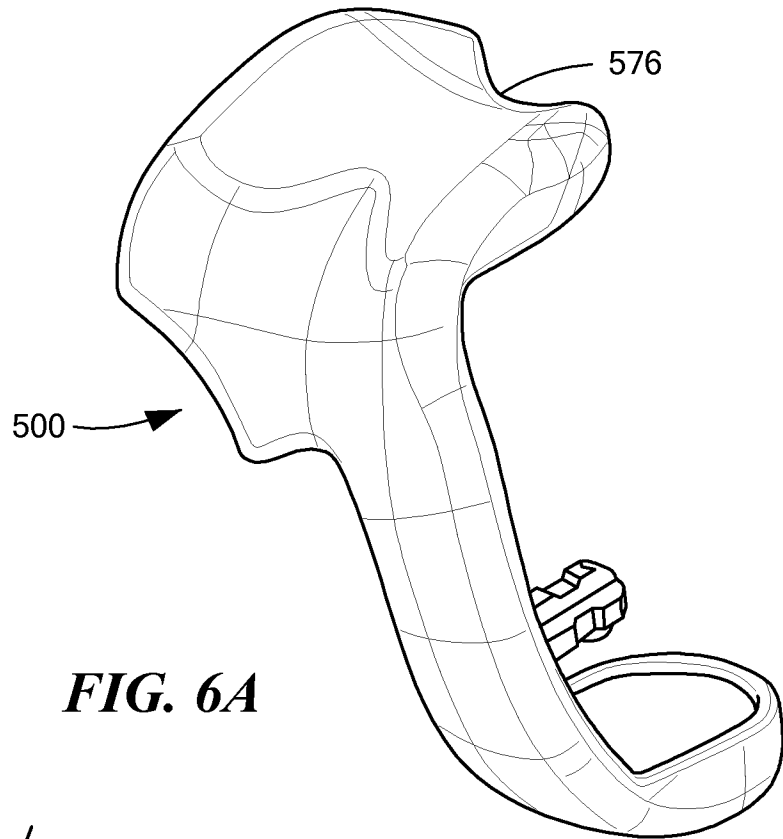


FIG. 6A

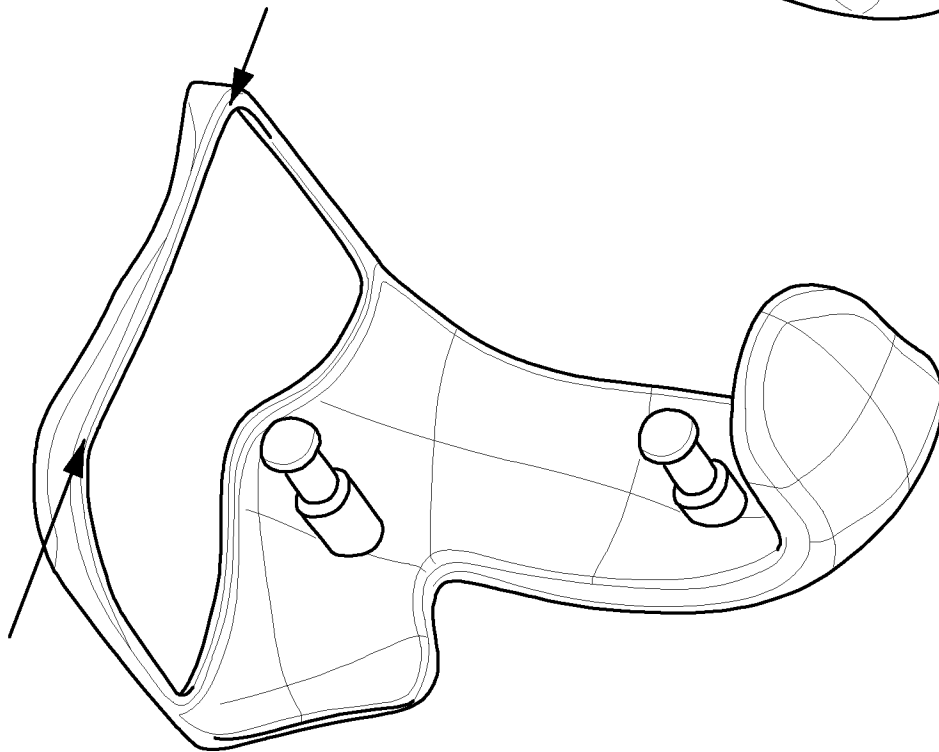


FIG. 6B

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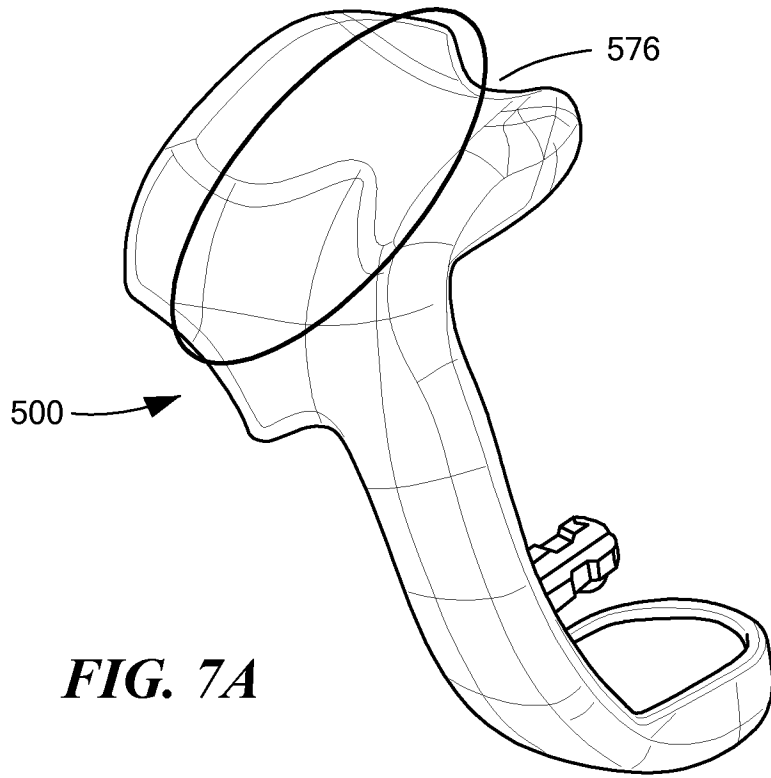


FIG. 7A

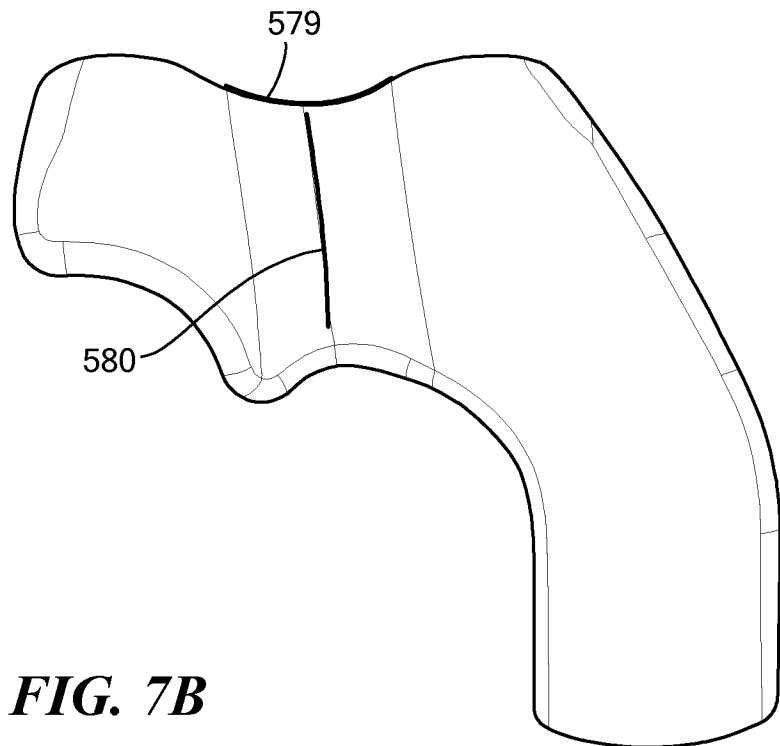


FIG. 7B

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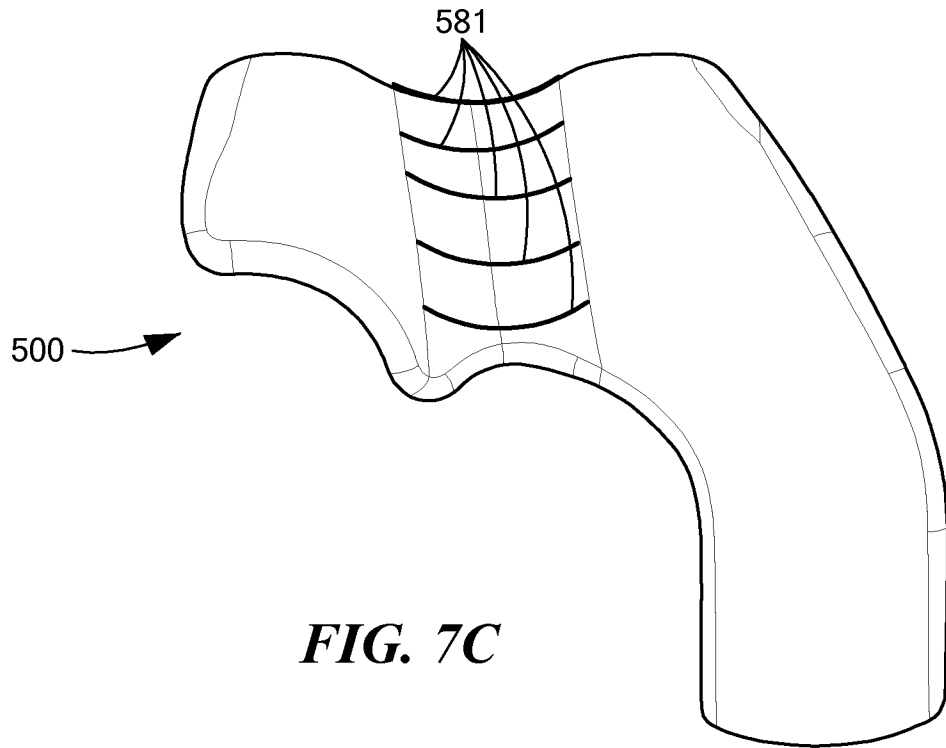


FIG. 7C

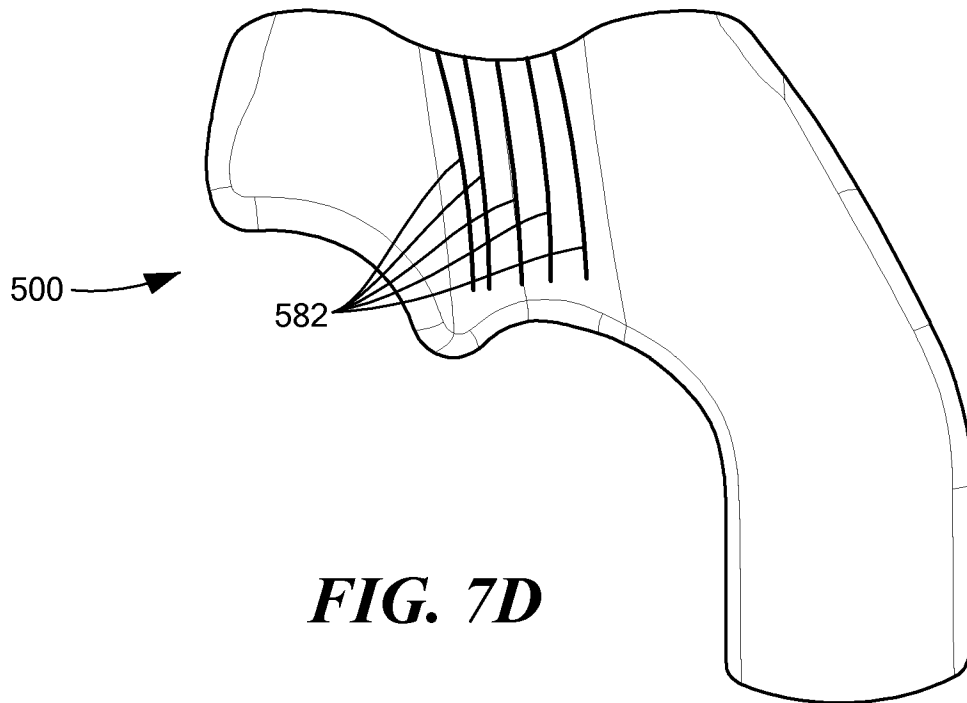


FIG. 7D

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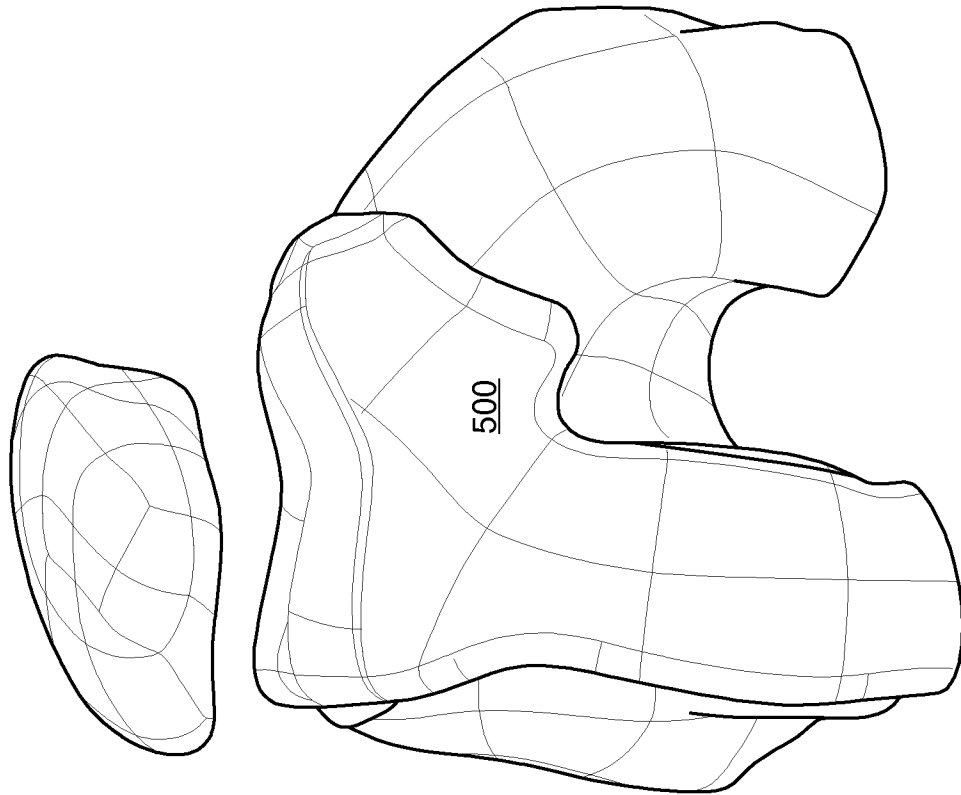


FIG. 7F

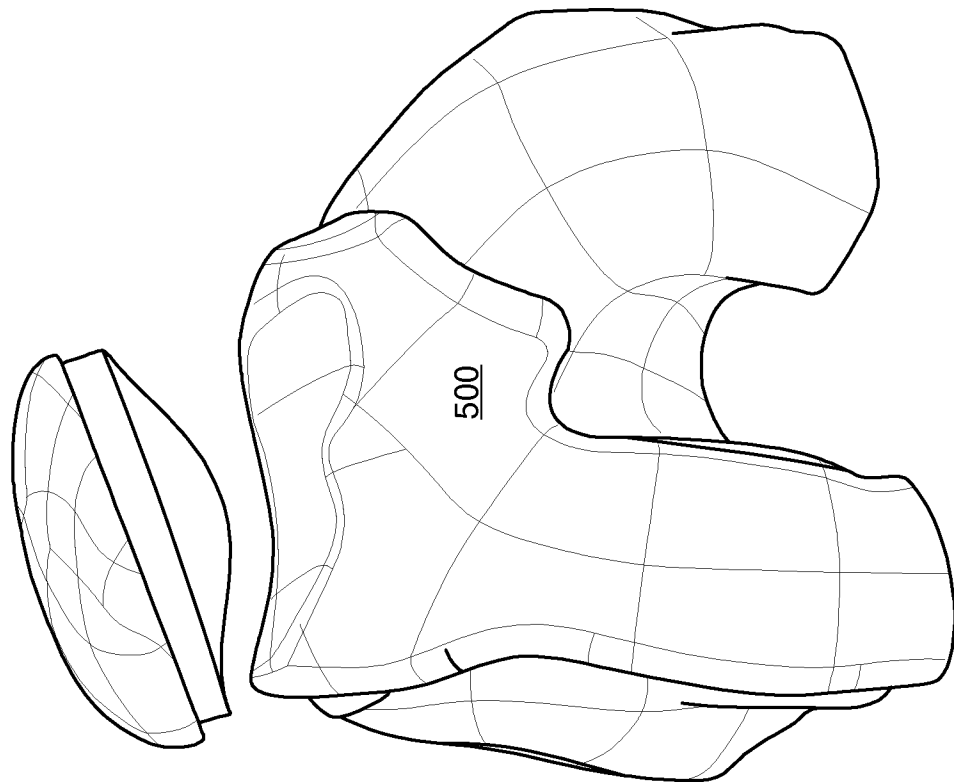


FIG. 7E

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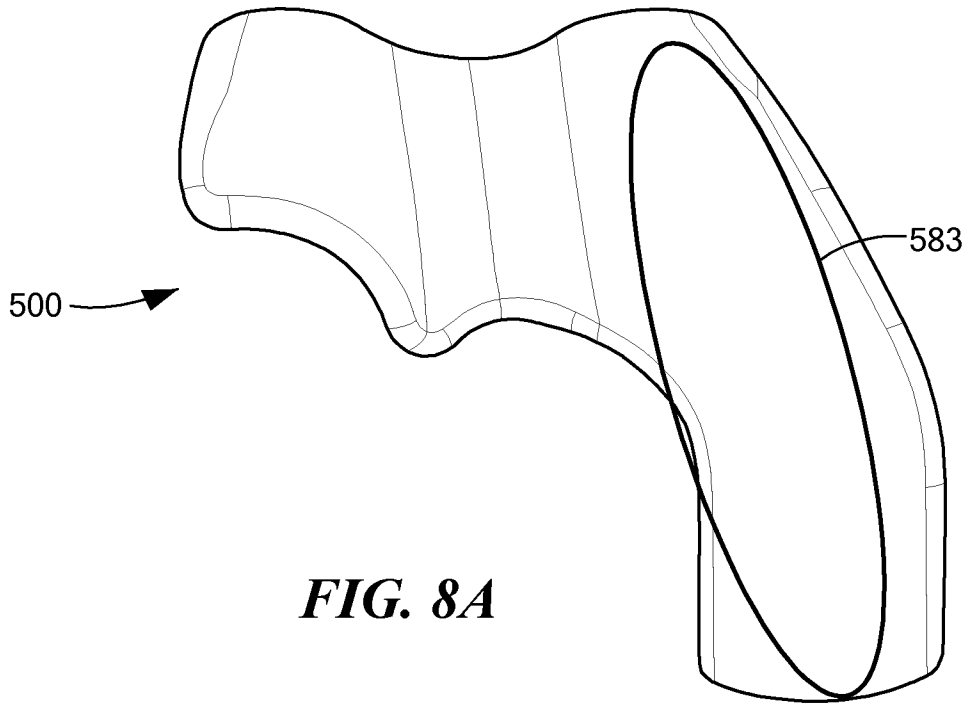


FIG. 8A

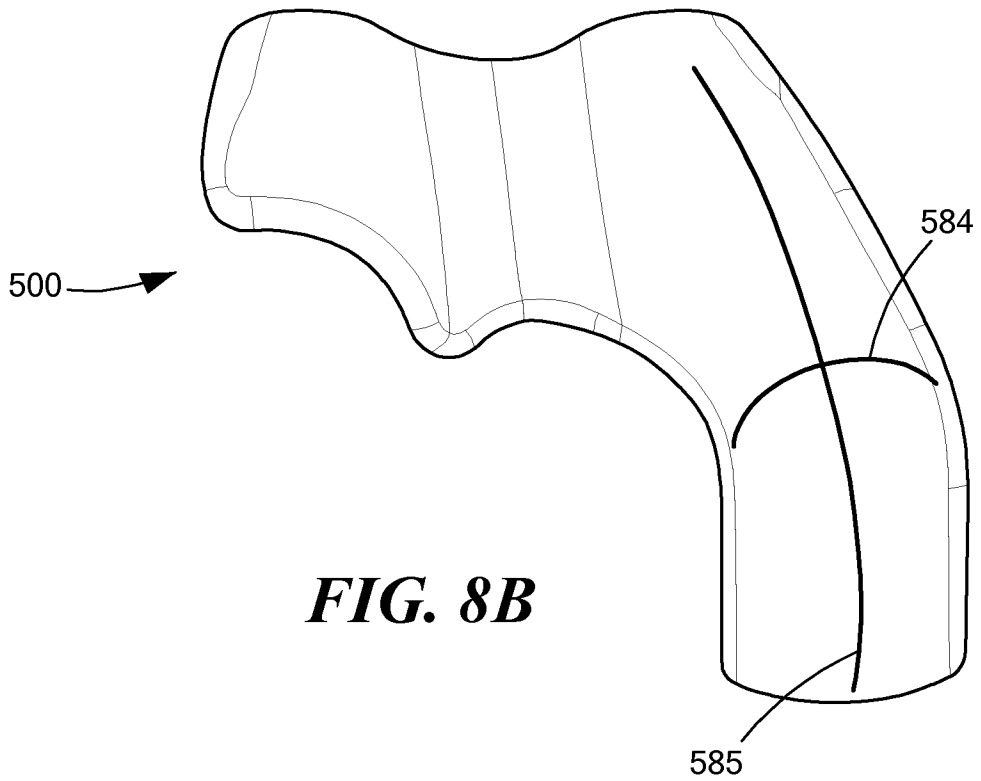


FIG. 8B

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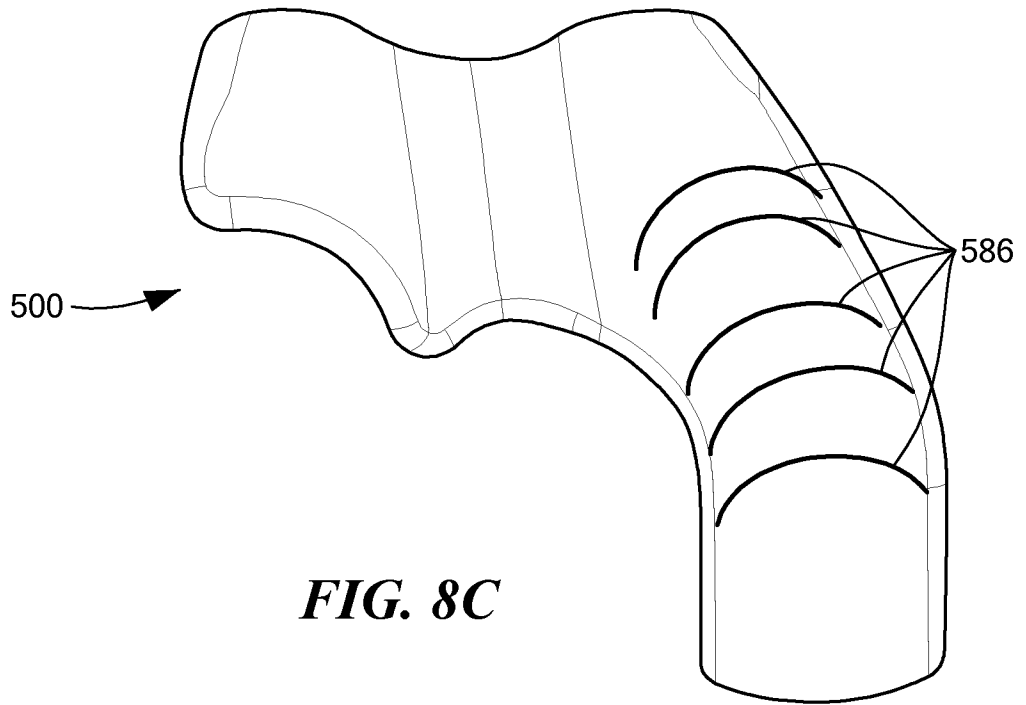


FIG. 8C

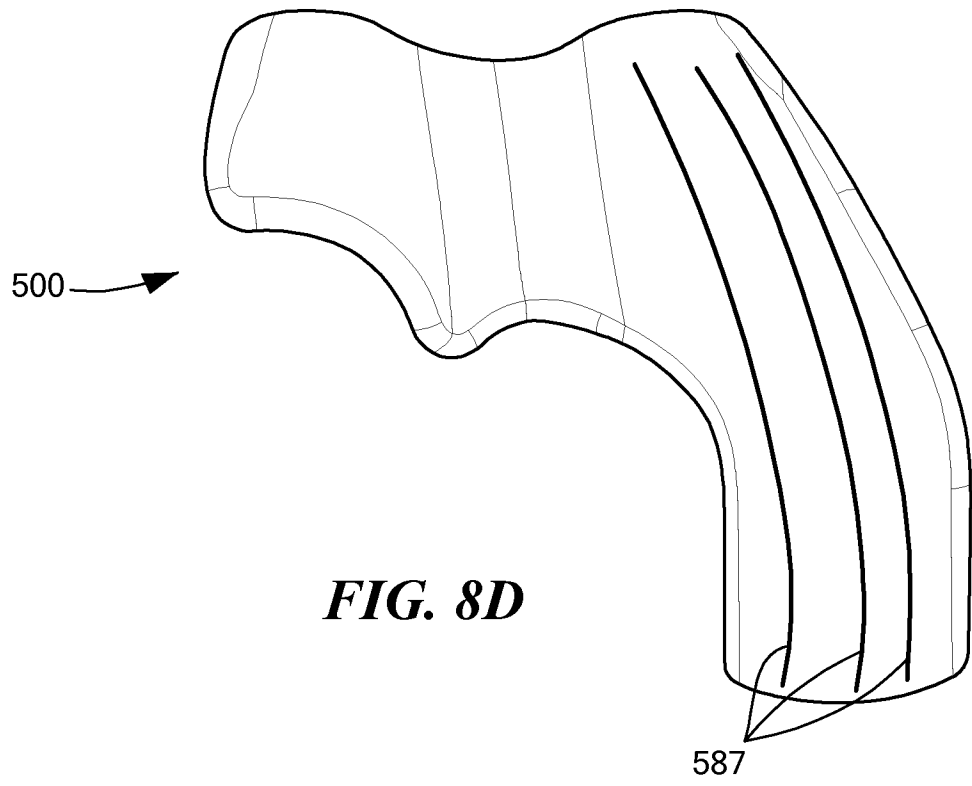


FIG. 8D

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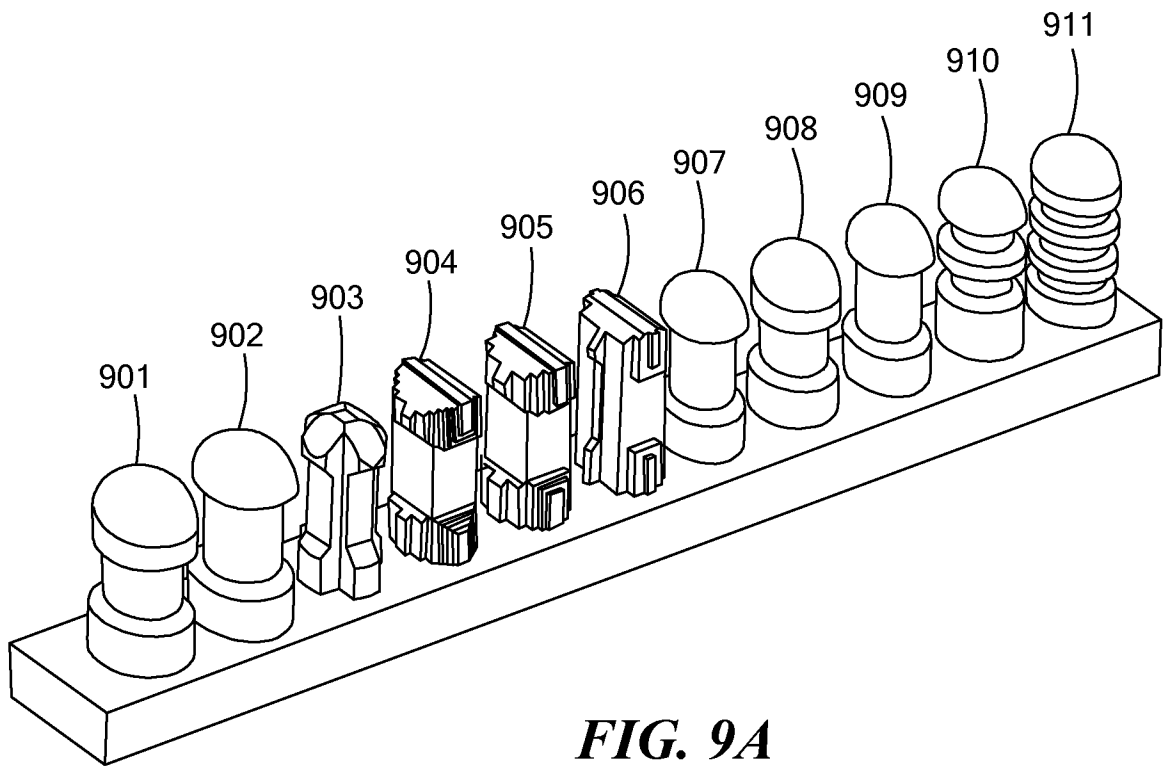


FIG. 9A

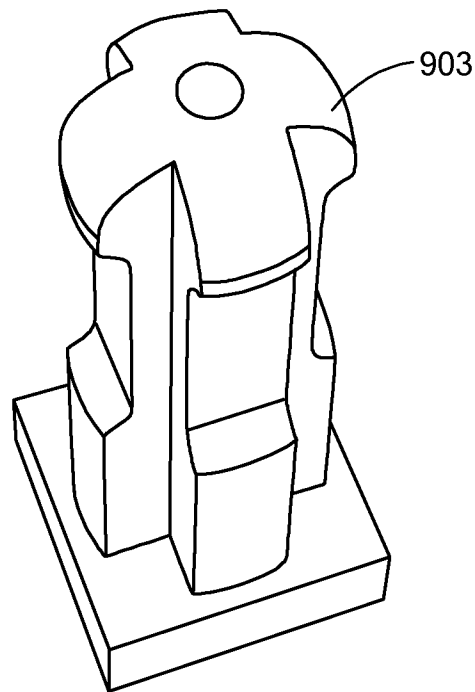


FIG. 9B

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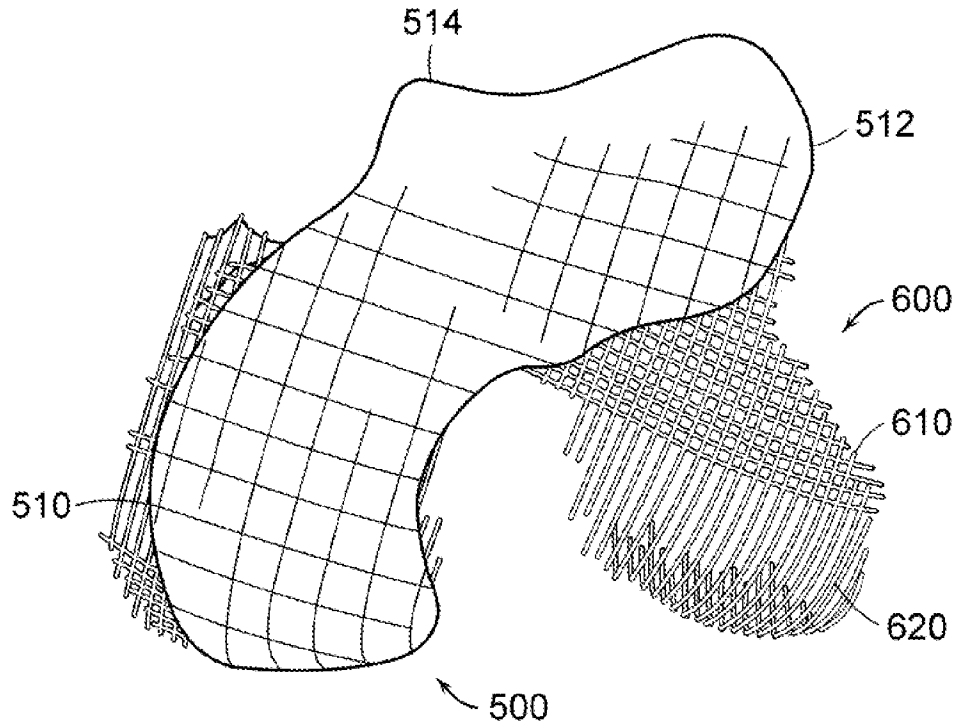


FIG. 10A

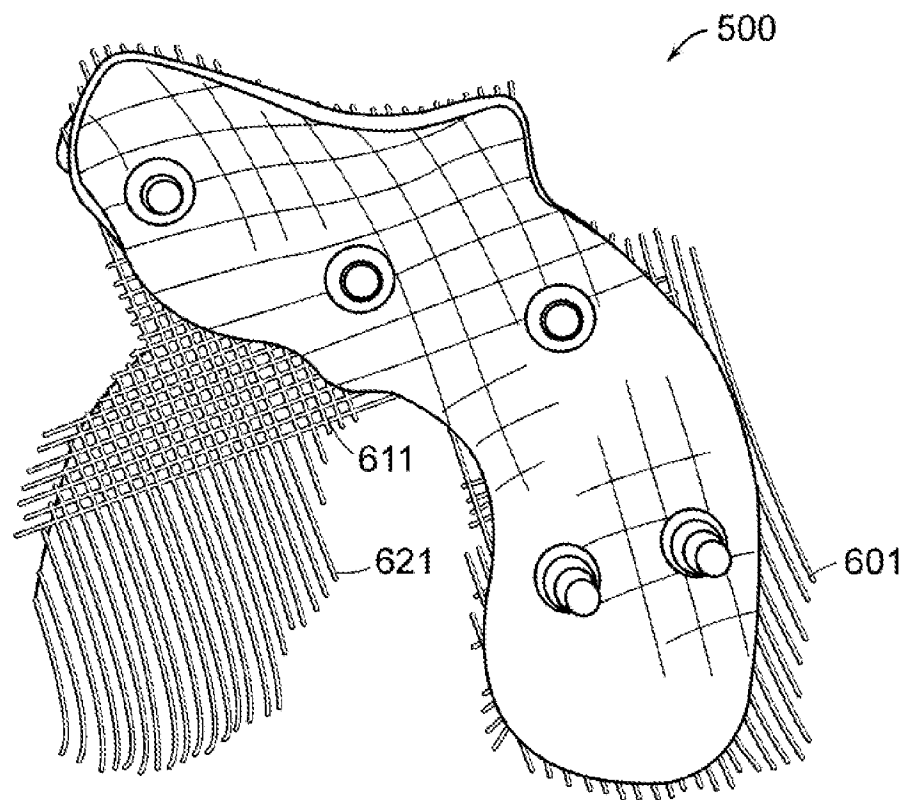


FIG. 10B

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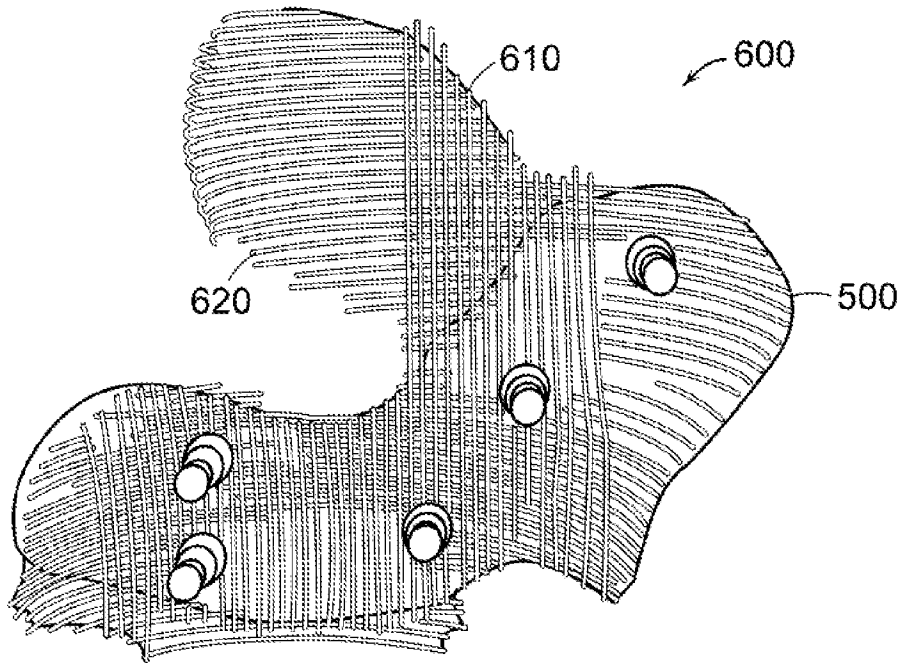


FIG. 10C

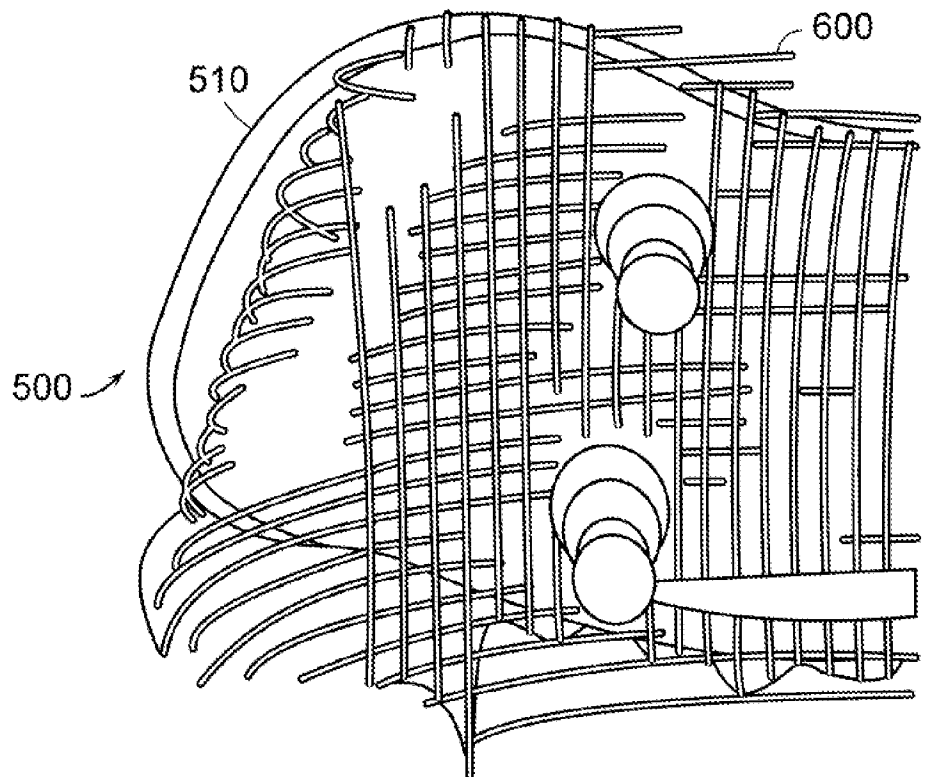


FIG. 10D

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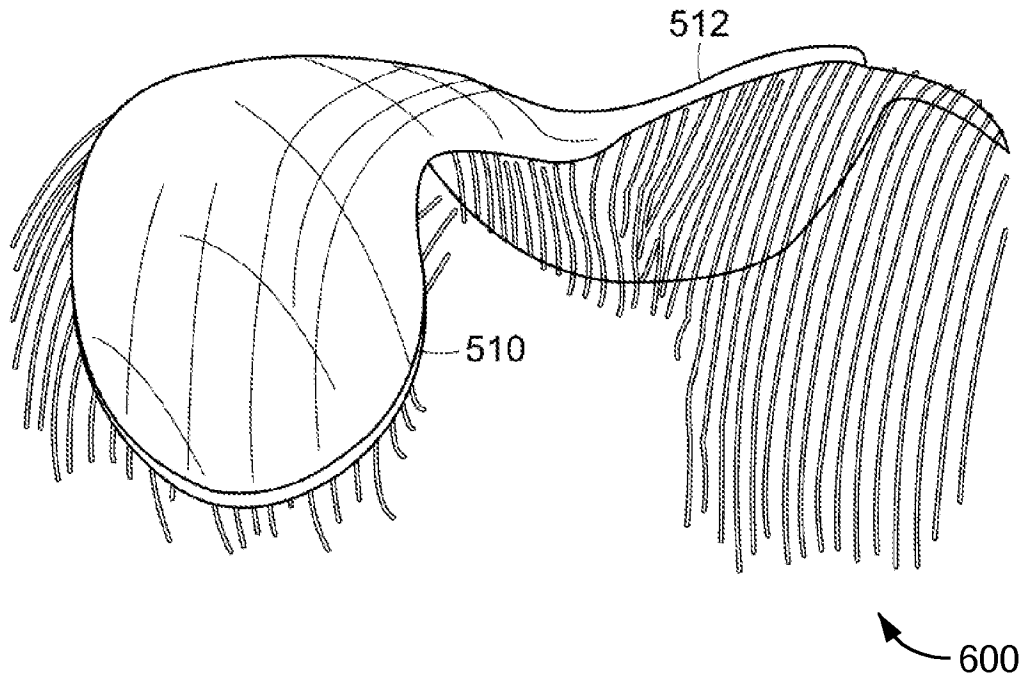


FIG. 10E

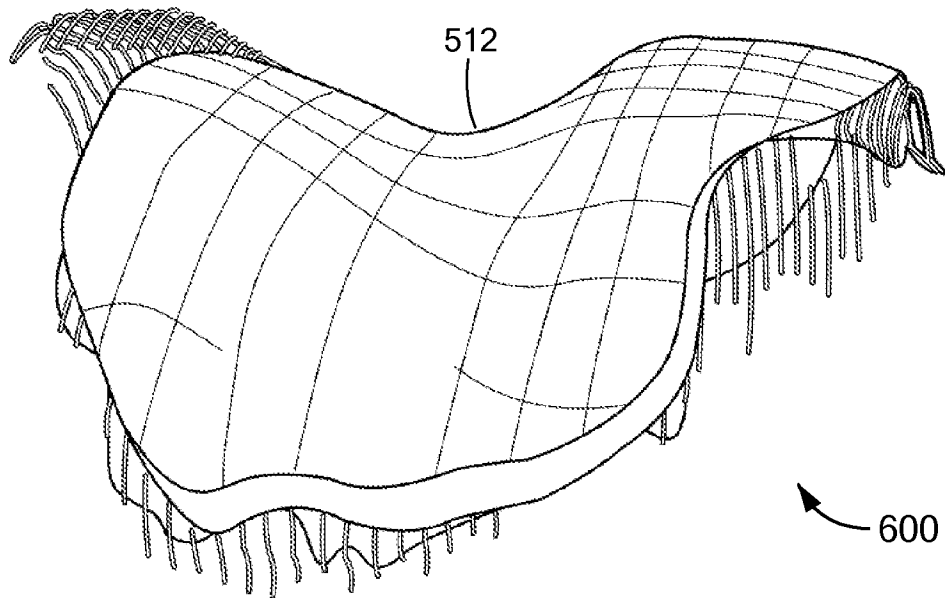


FIG. 10F

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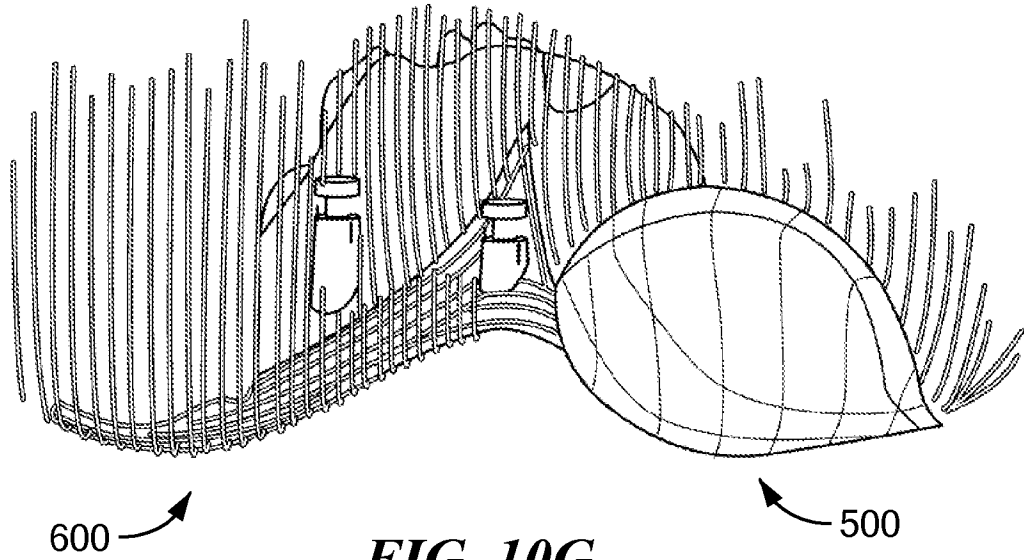


FIG. 10G

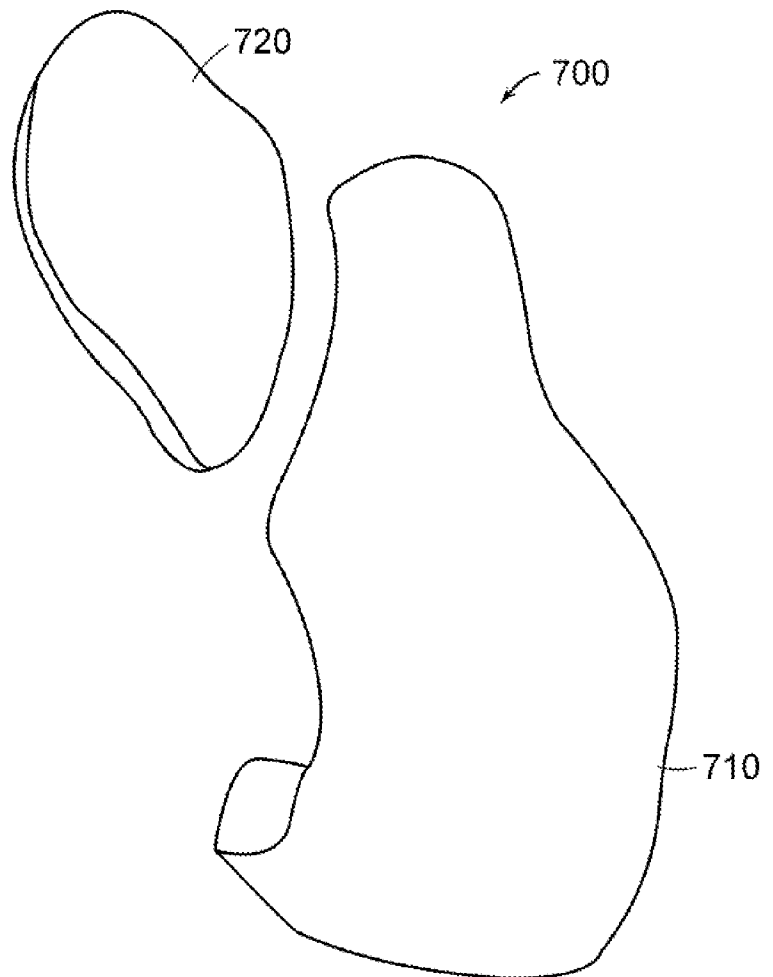


FIG. 11A

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FIG. 11B

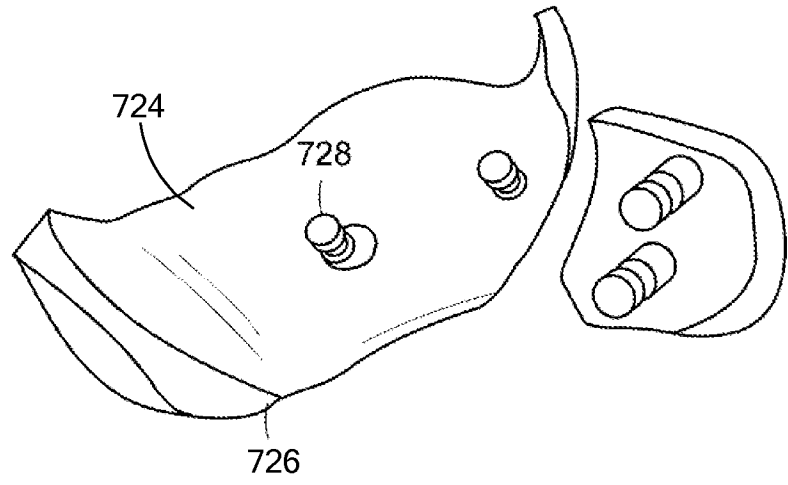
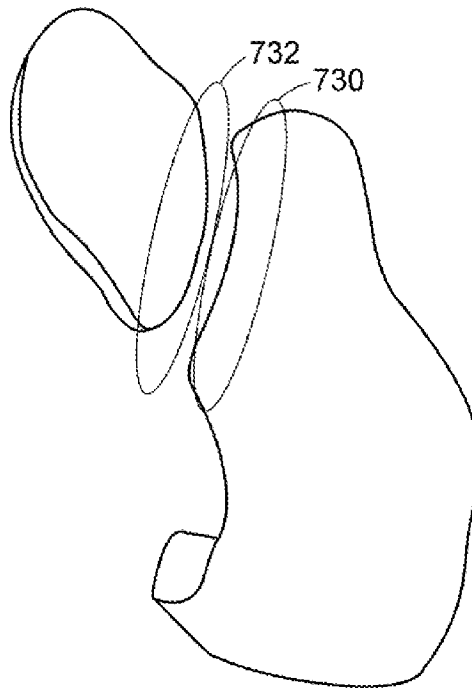


FIG. 11C



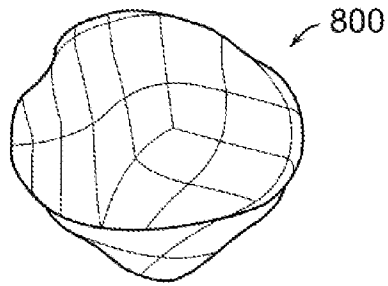


FIG. 12A

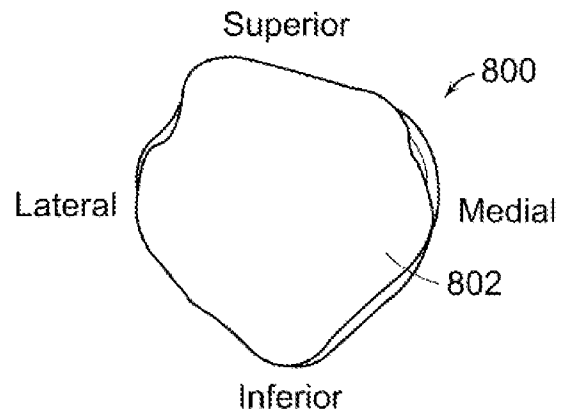


FIG. 12B

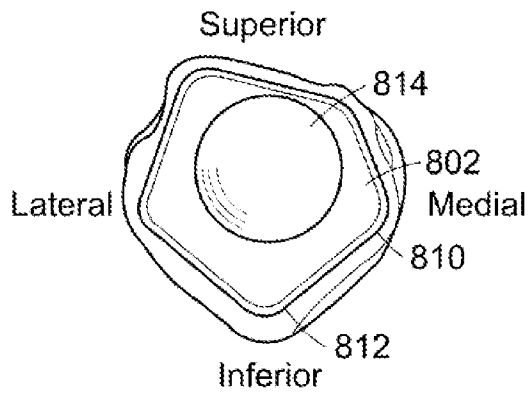


FIG. 12C

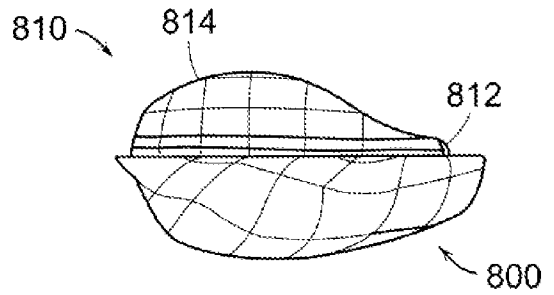


FIG. 12D

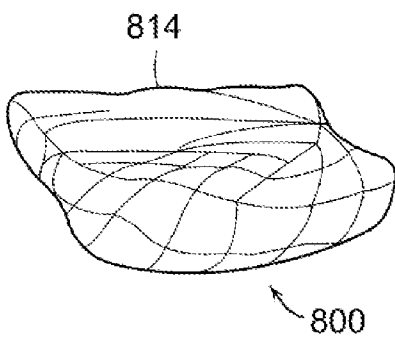


FIG. 12E

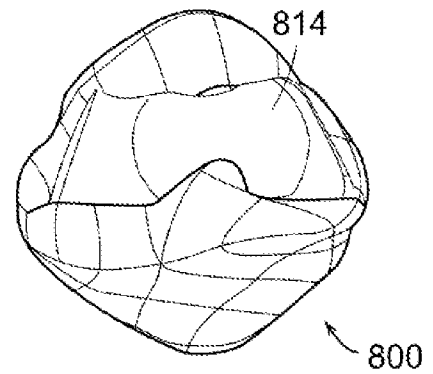


FIG. 12F

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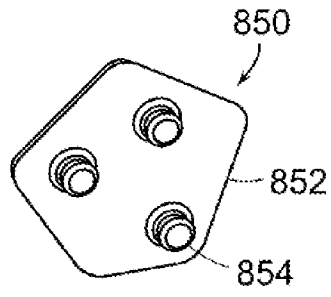


FIG. 12G

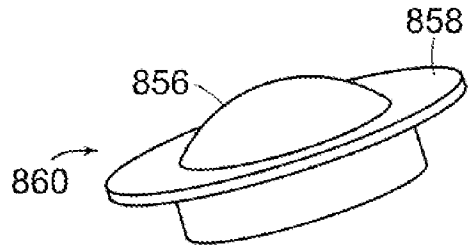


FIG. 12H

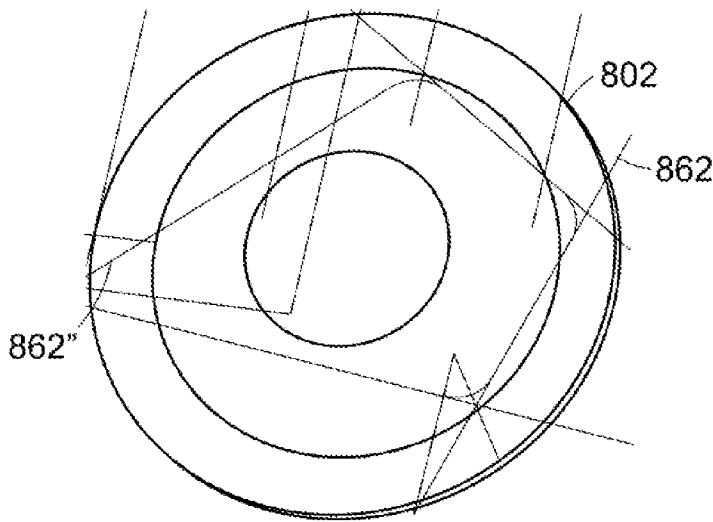


FIG. 12I

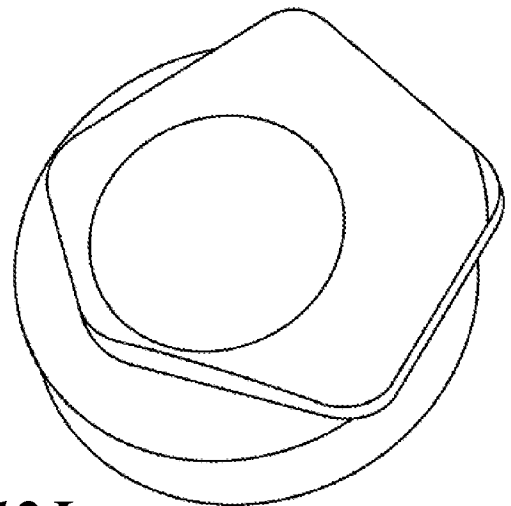


FIG. 12J

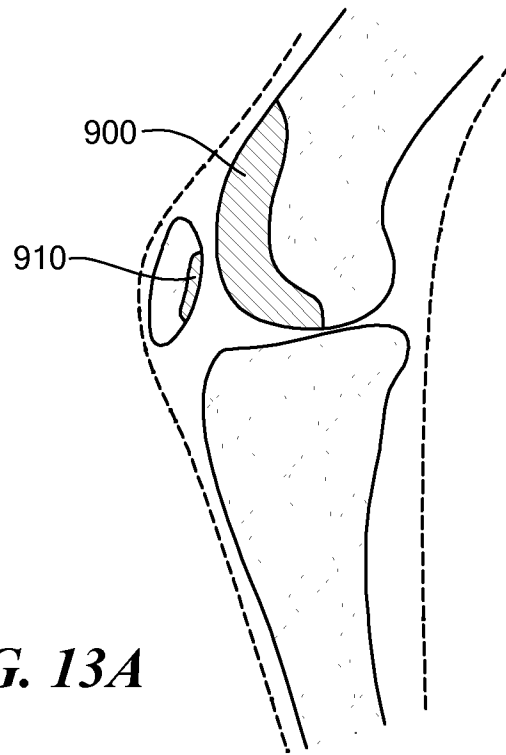


FIG. 13A

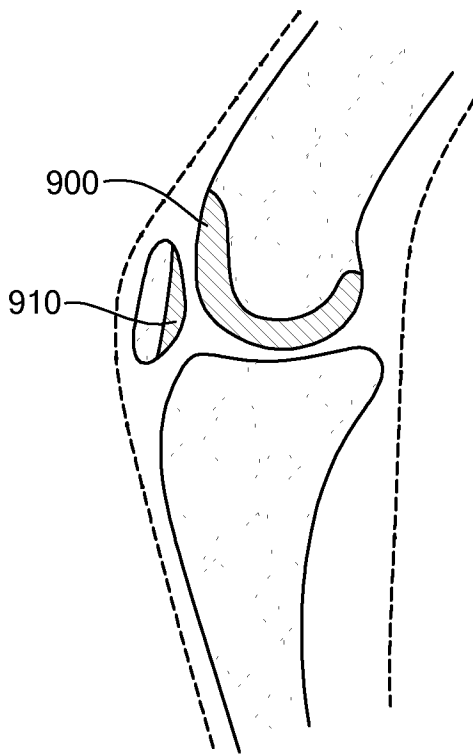


FIG. 13B

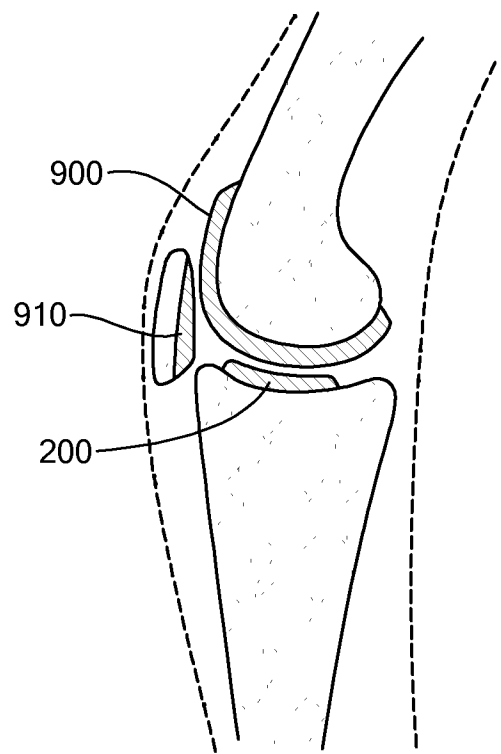


FIG. 13C

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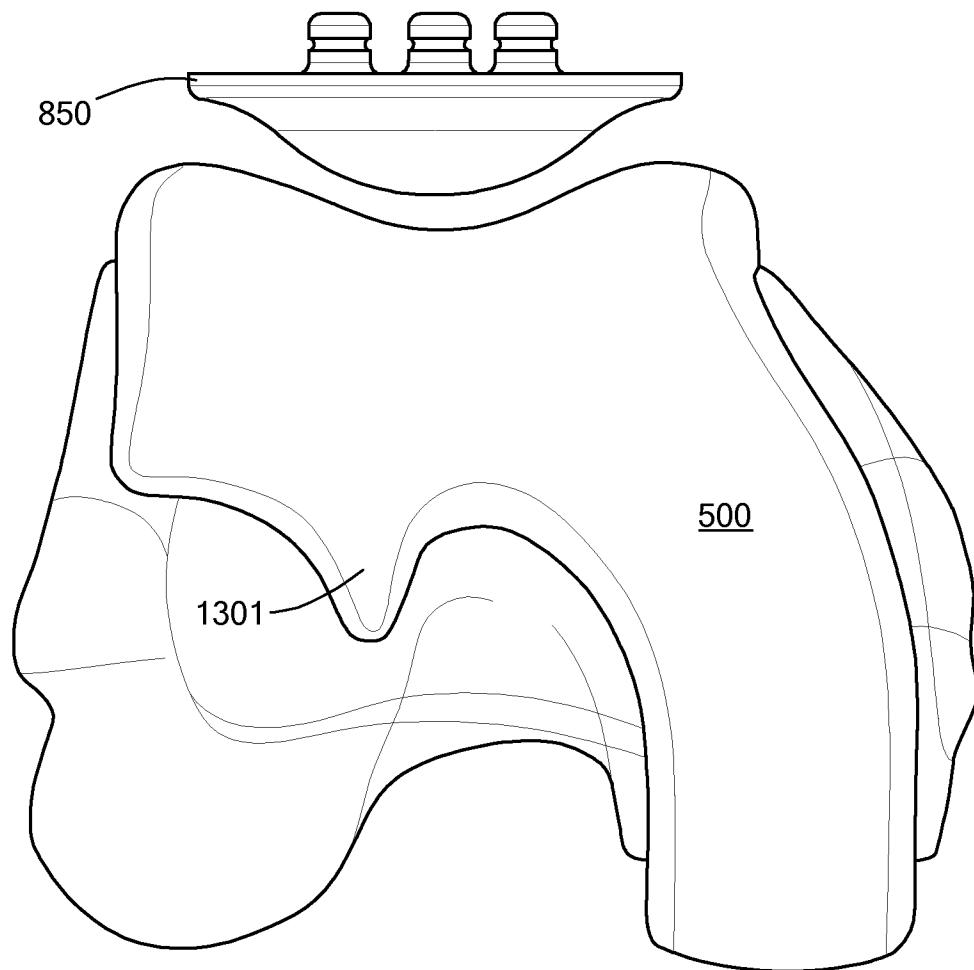


FIG. 13D

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FIG. 14A

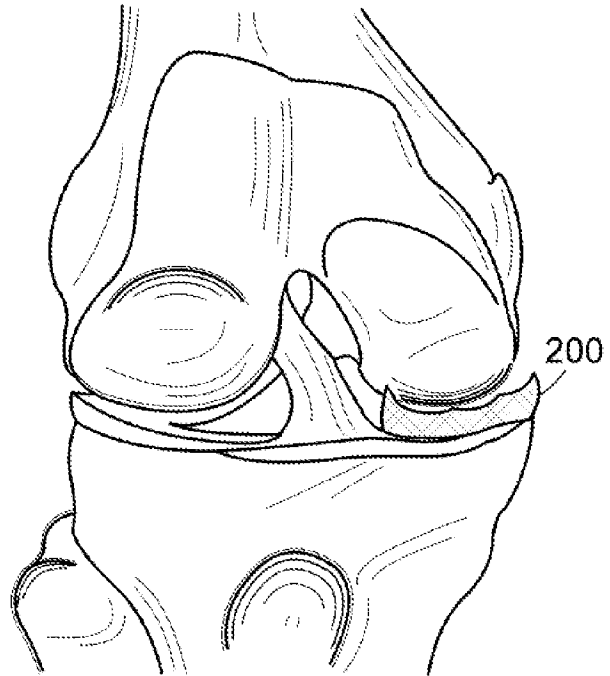
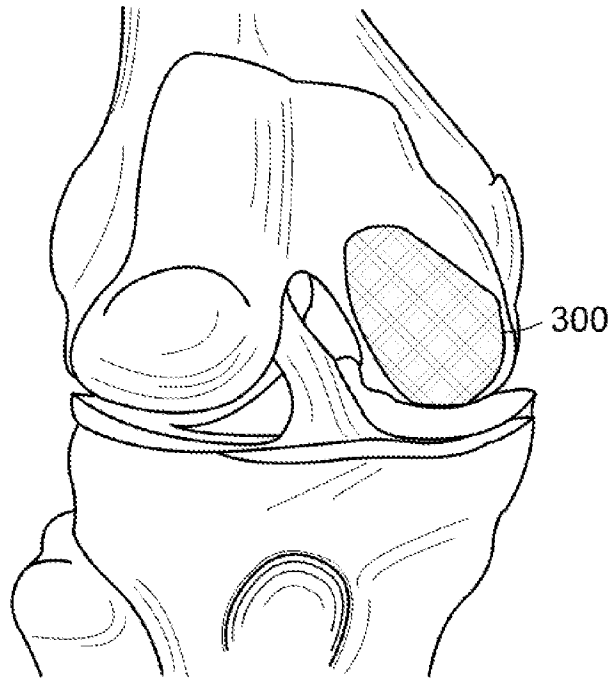


FIG. 14B



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FIG. 14C

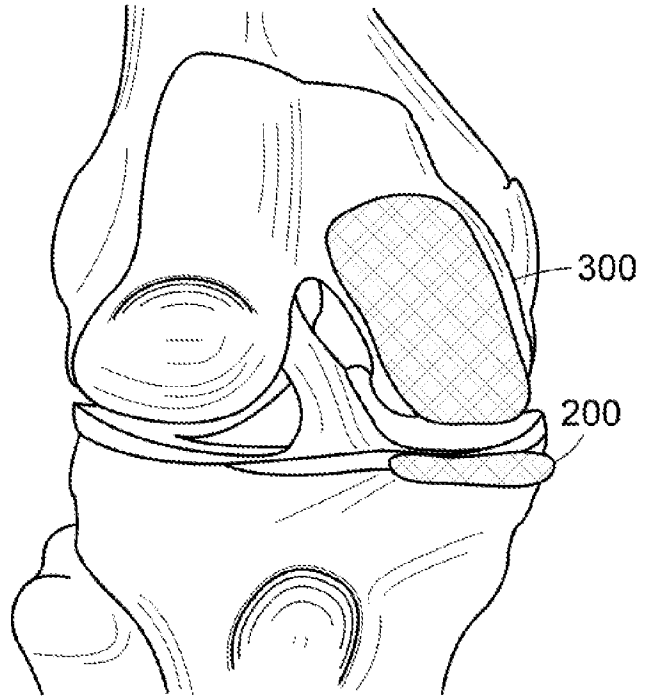
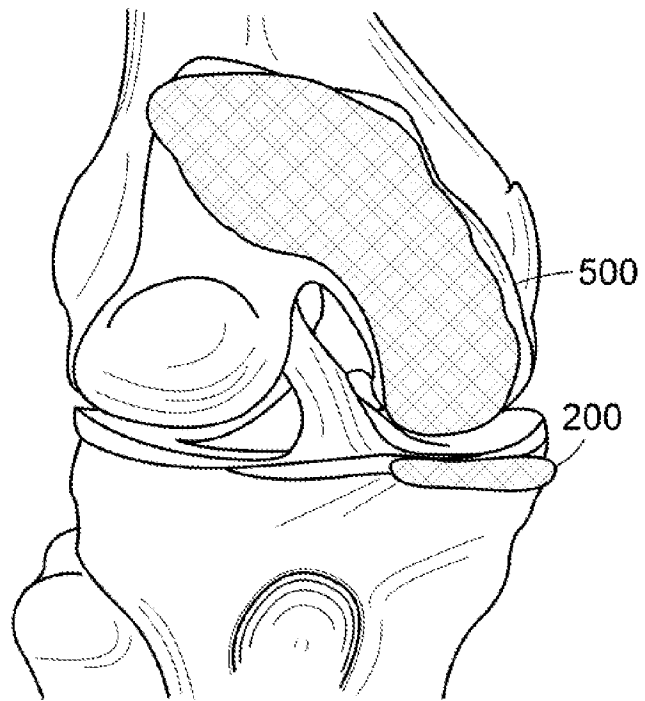


FIG. 14D



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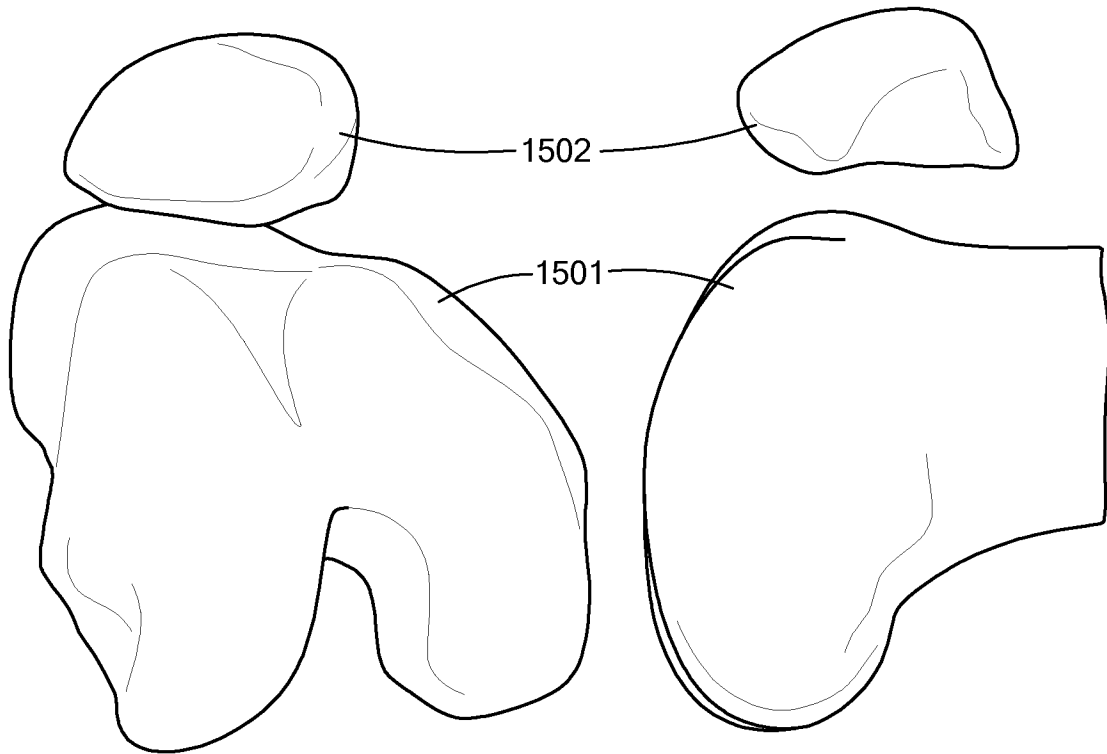


FIG. 15A

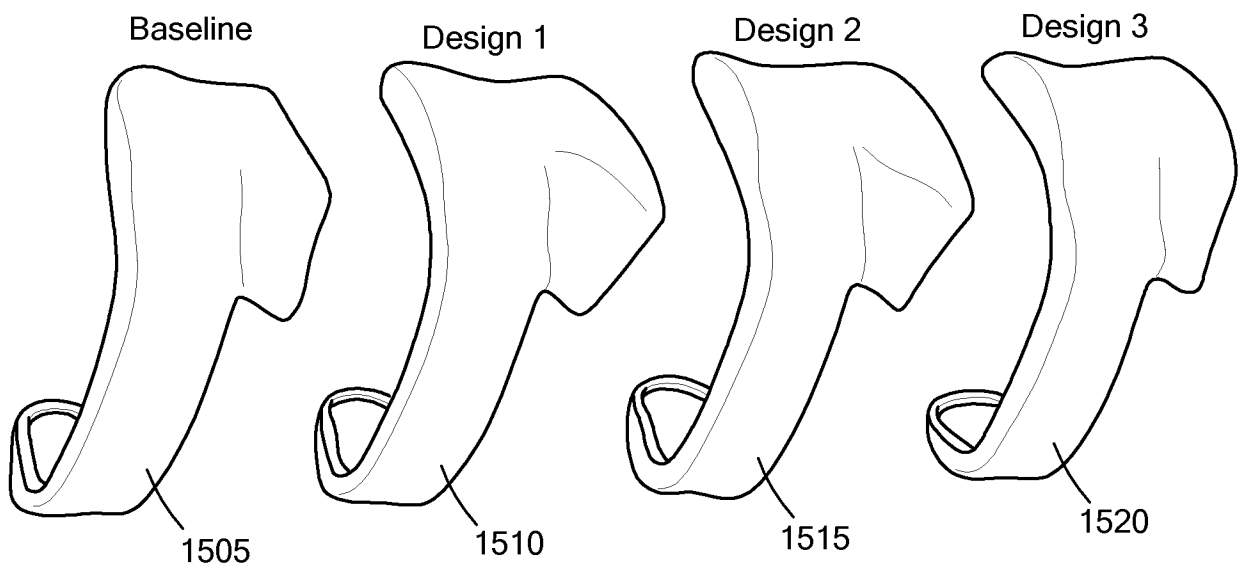


FIG. 15B

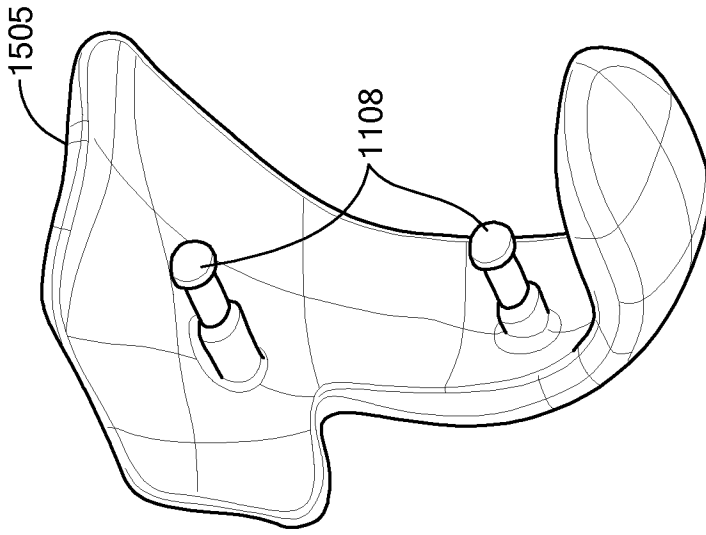


FIG. 15E

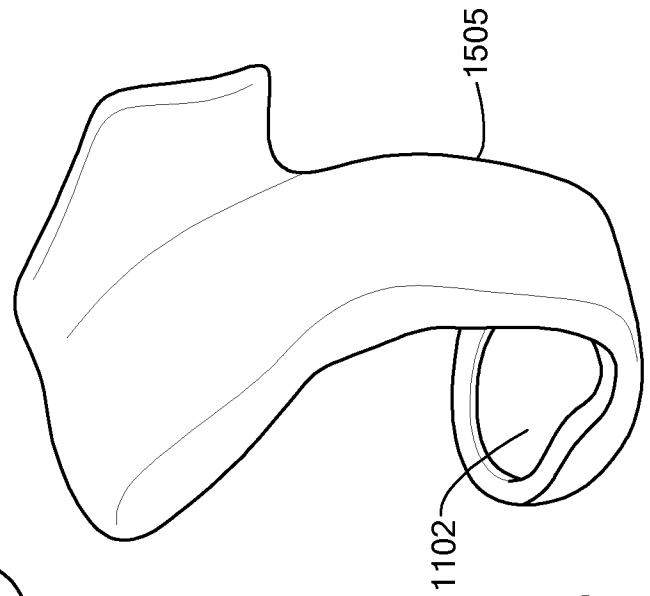


FIG. 15D

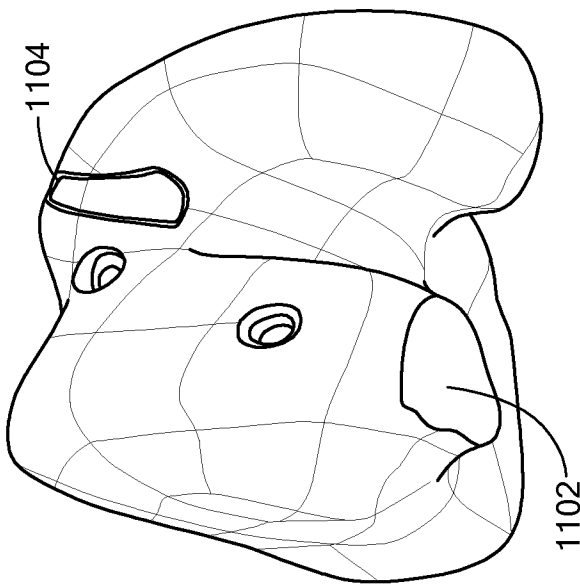


FIG. 15C

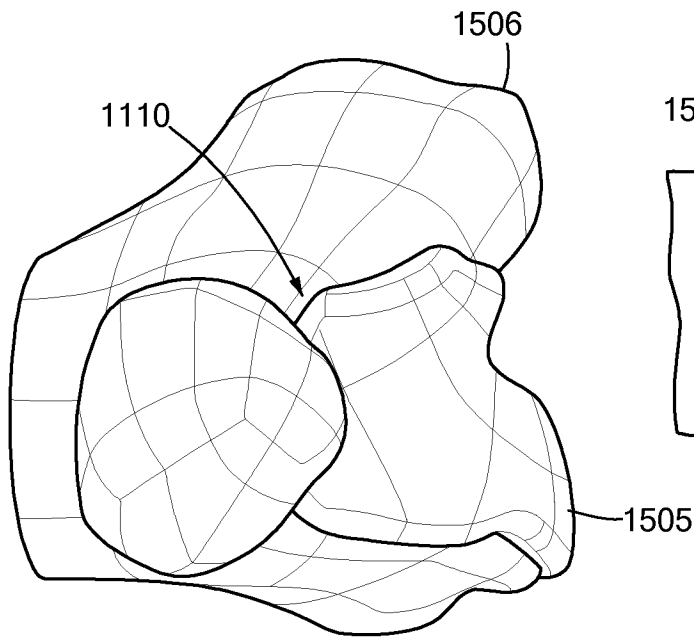


FIG. 16A

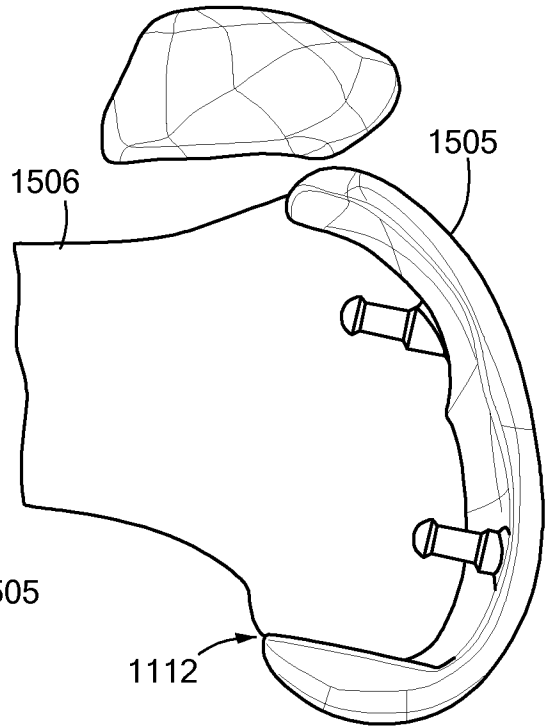


FIG. 16B

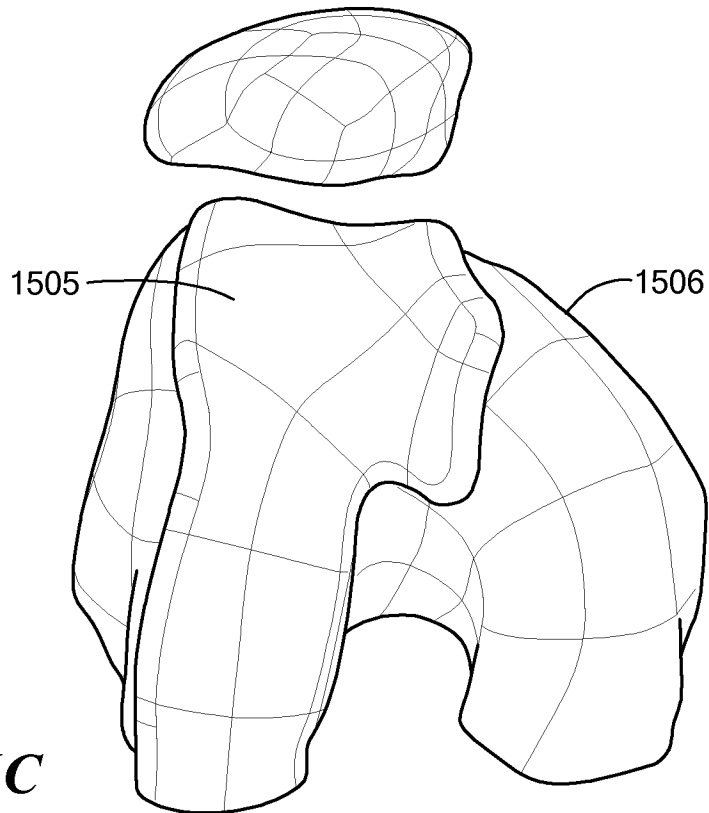


FIG. 16C

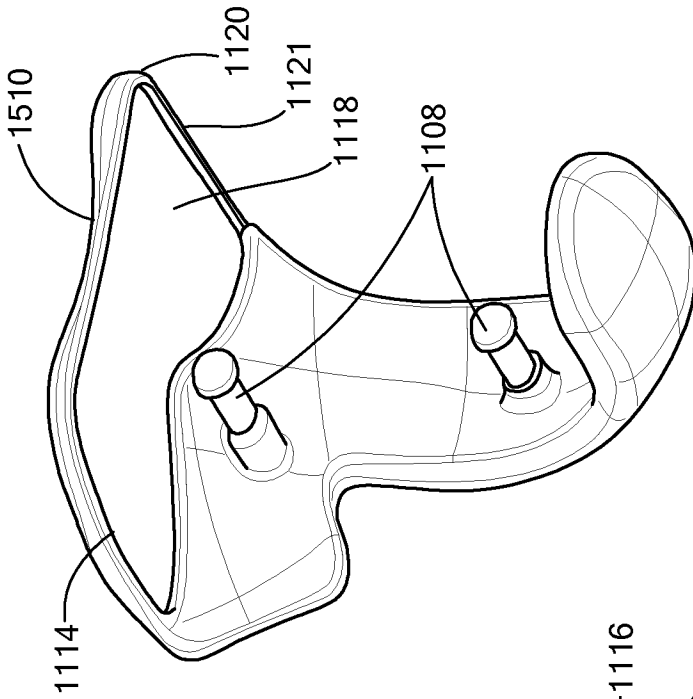


FIG. 17C

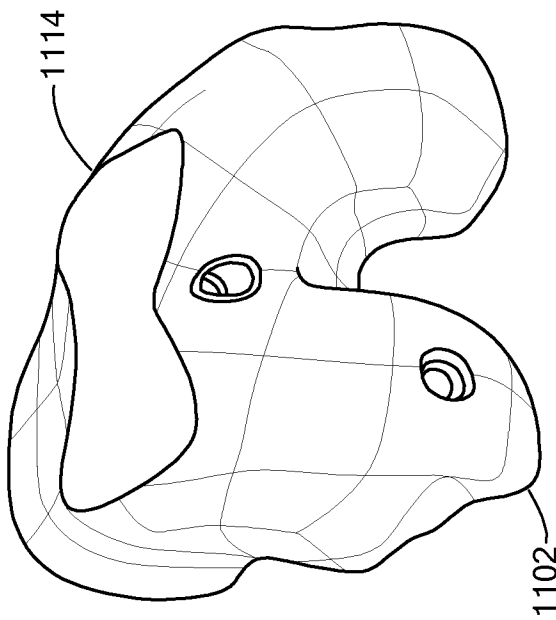


FIG. 17A

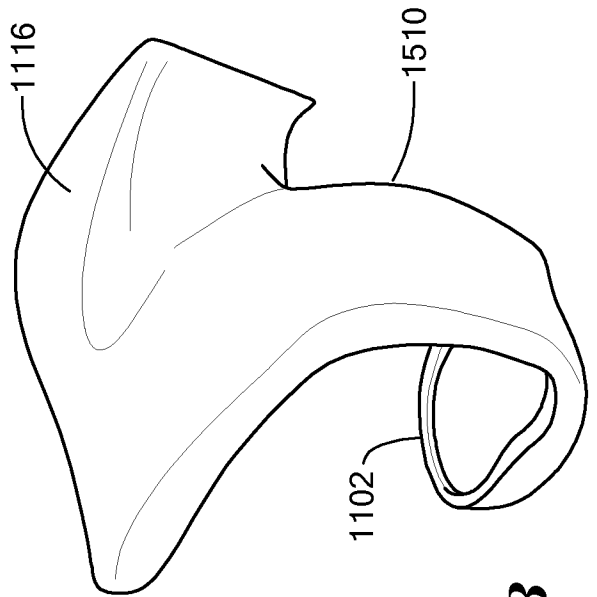


FIG. 17B

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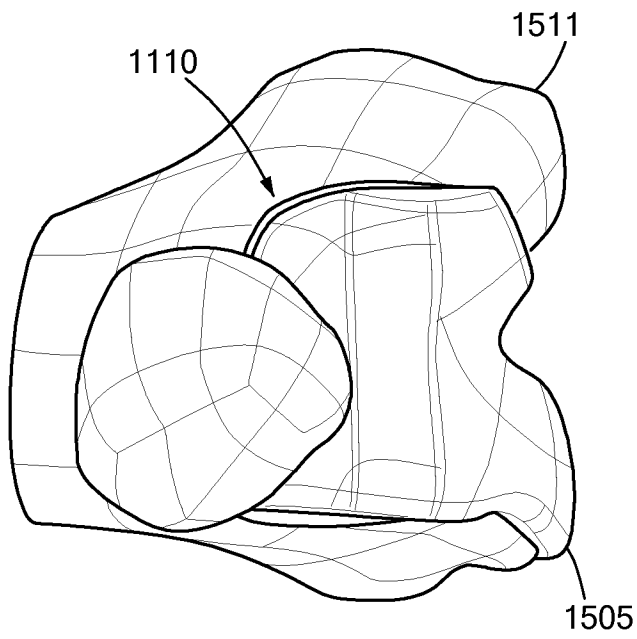


FIG. 18A

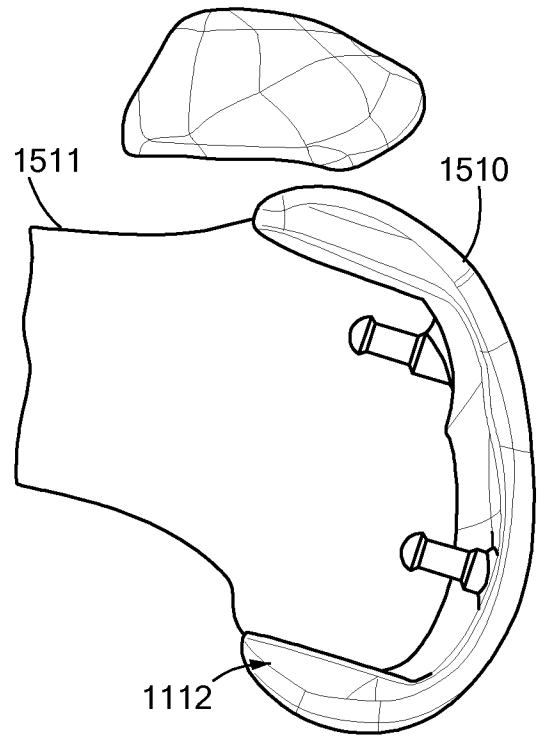


FIG. 18B

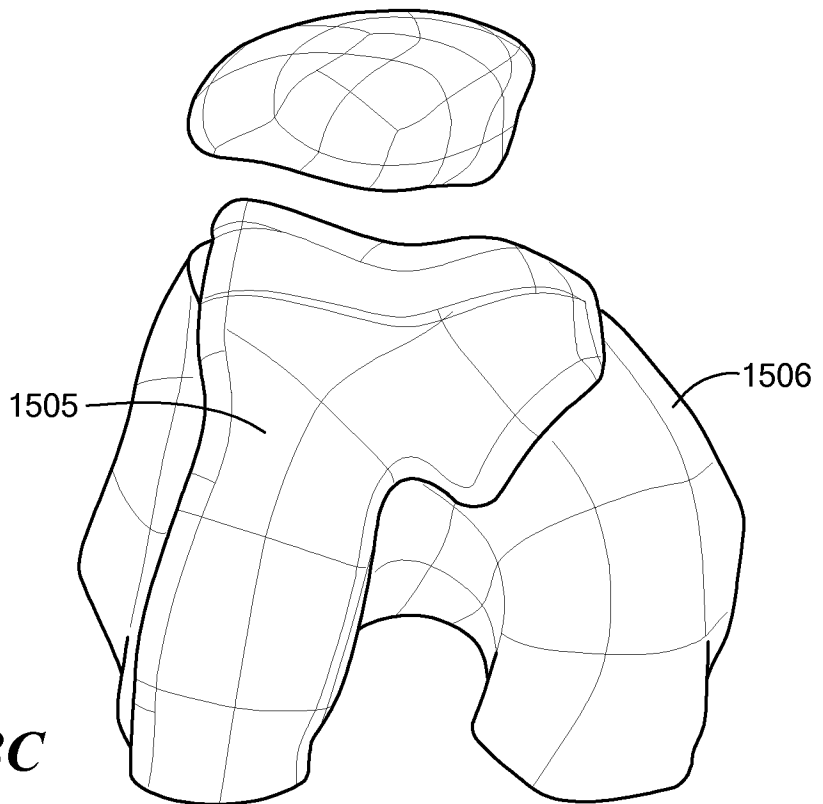


FIG. 18C

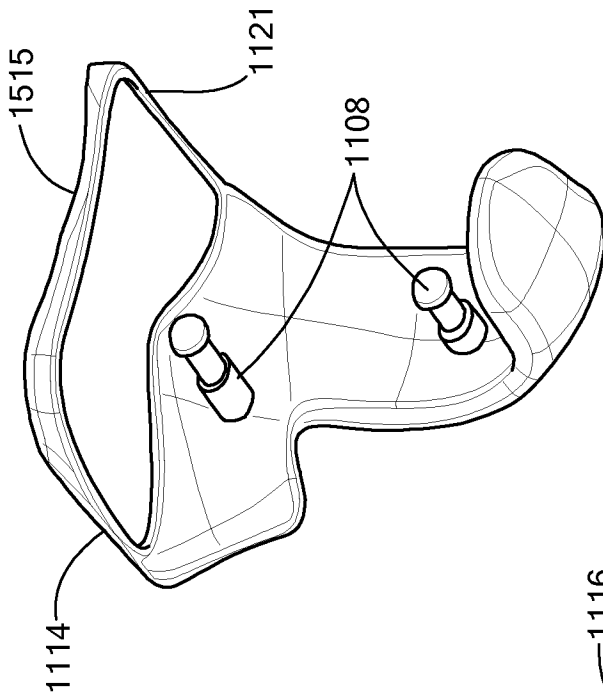


FIG. 19C

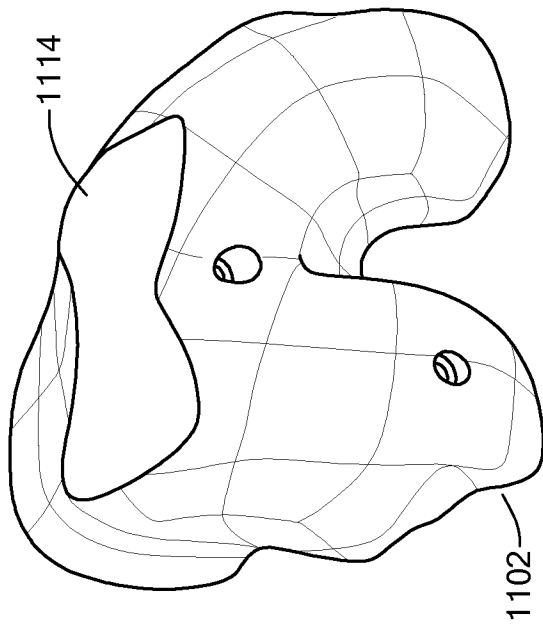


FIG. 19A

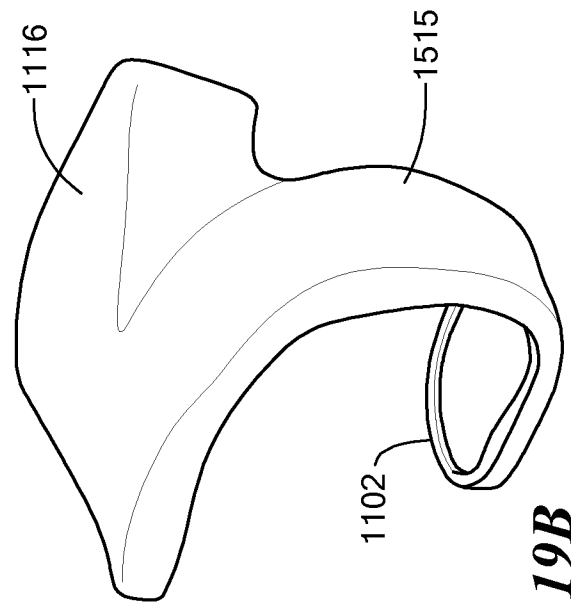


FIG. 19B

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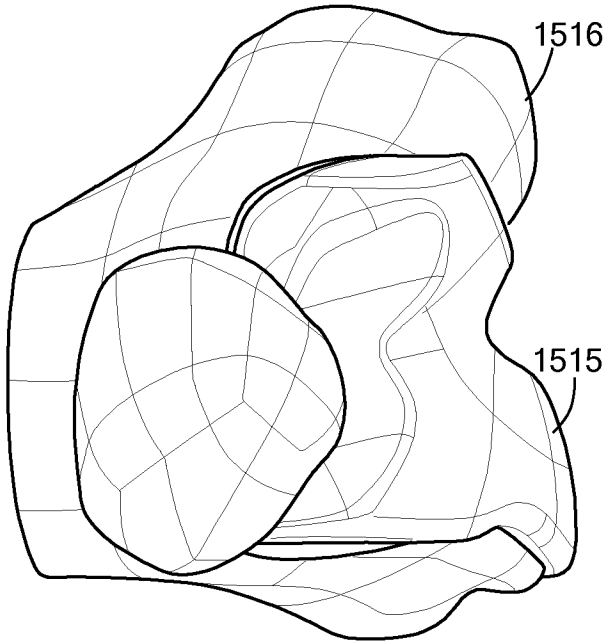


FIG. 20A

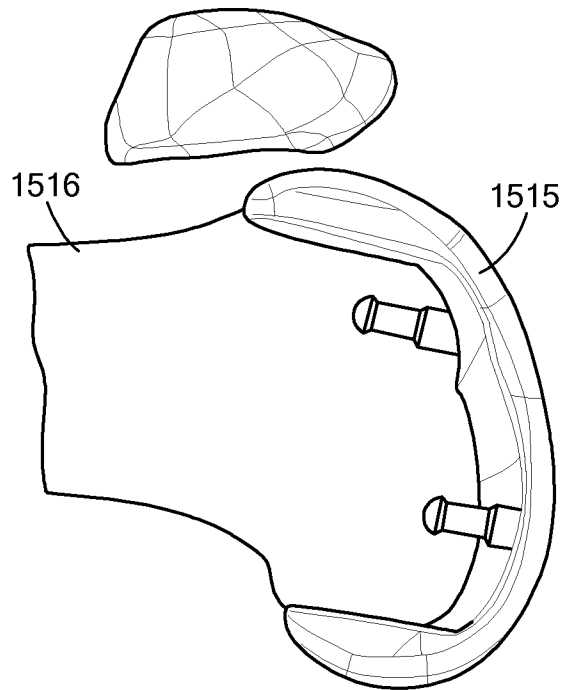


FIG. 20B

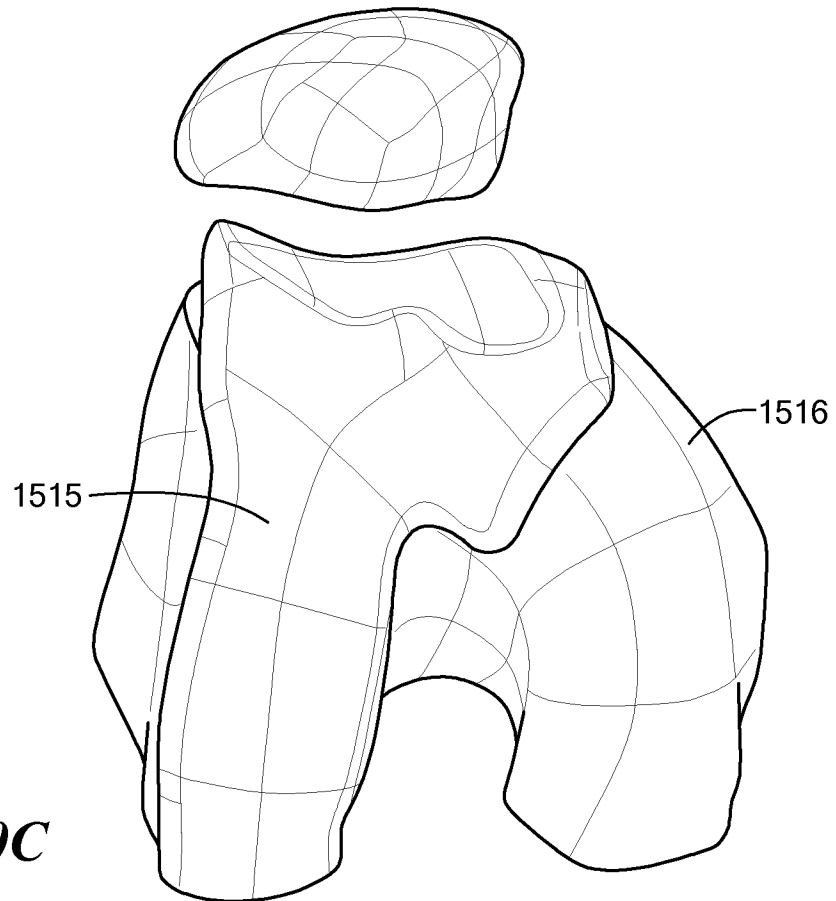


FIG. 20C

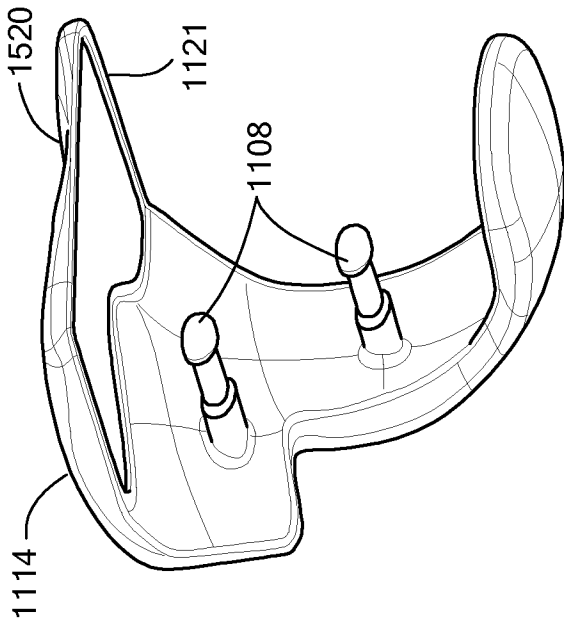


FIG. 21C

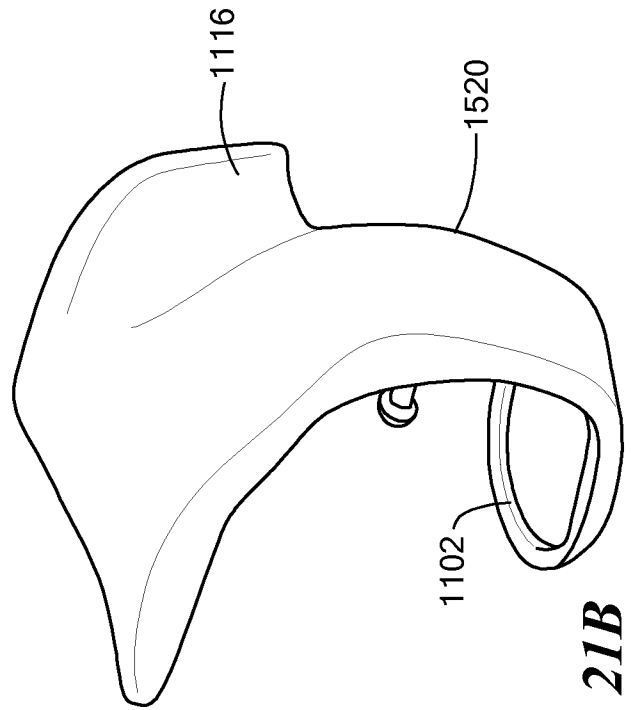


FIG. 21B

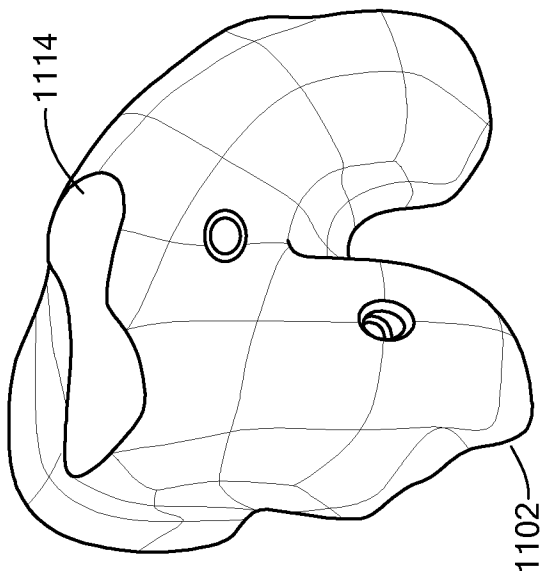


FIG. 21A

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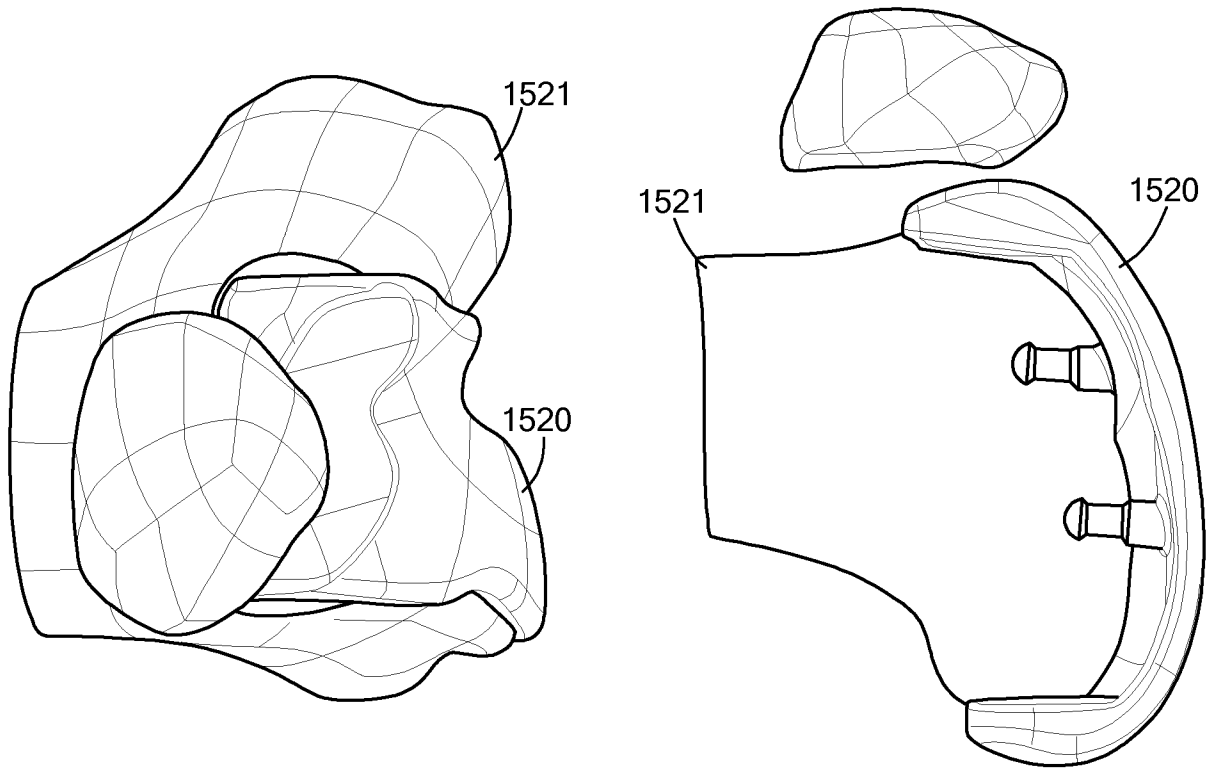


FIG. 22A

FIG. 22B

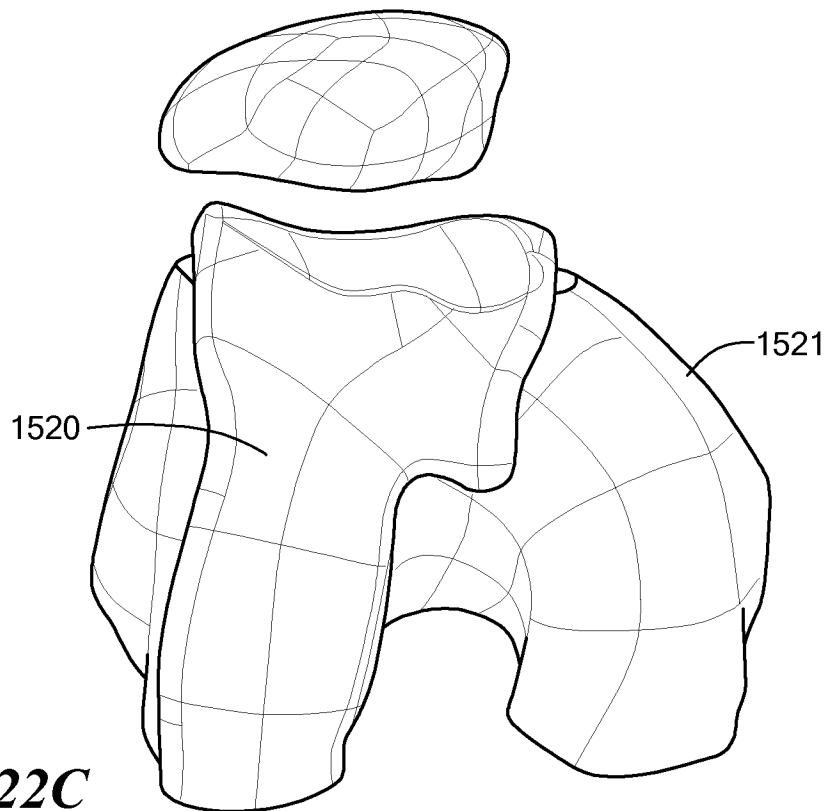


FIG. 22C