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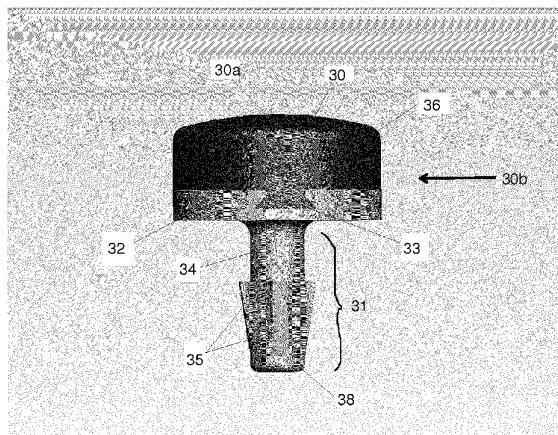


FIG. 2

(57) Abstract: A partial resurfacing implant (30b) for use in repairing an articular cartilage defect site (29) that includes a top articulating portion (30) having a top surface (30a) that is configured with at least one radius of curvature to approximate the surface contour of the articular cartilage surrounding the defect site. The implant also includes a supporting plate (32) that has a top surface and a bottom surface. The top surface is attached to the top articulating portion by a locking mechanism (33). The bottom surface of the supporting plate is constructed to facilitate the insertion of the implant into the defect site. Extending from the bottom surface of the supporting plate is at least one implant fixation portion (31). The at least one implant fixation portion is integrally connected to and is oriented about normal relative to the bottom surface. A method of repairing an articular cartilage defect with the partial joint resurfacing implant is also disclosed.

PARTIAL JOINT RESURFACING IMPLANT, INSTRUMENTATION, AND METHOD

Cross-Reference to Related Application

[0001] This application claims priority to U.S. Provisional Application No. 61/032,141 filed February 28, 2008, the disclosure of which is herein incorporated by reference in its entirety.

Technical Field

[0002] The present invention relates generally to surgical devices for use in partial resurfacing of damaged or diseased articular cartilage of the joints and to surgical methods using such devices.

Background of the Invention

[0003] Articular cartilage, or hyaline type cartilage, is a unique tissue providing a smooth, lubricious, hydrophilic, load bearing covering on the ends of bones in diarthroidal joints, in particular the knee, hip, shoulder, to name a few. This tissue is susceptible to damage or deterioration caused by excessive loading resulting in inflammation, pain, swelling, and joint dysfunction. As a result many methods have been developed to clinically treat patients when cartilage degeneration occurs.

[0004] Articular cartilage, or hyaline type cartilage, is a unique tissue providing a smooth, lubricious, hydrophilic, load bearing covering on the ends of bones in diarthroidal joints, in particular the knee, hip, shoulder, to name a few. This tissue is susceptible to damage or deterioration caused by excessive loading resulting in inflammation, pain, swelling, and joint dysfunction. As a result many methods have been developed to clinically treat articular cartilage defects.

[0005] For smaller cartilage defects surgical techniques have been used to stimulate an intrinsic repair process. These include drilling, abrasion and microfracture of the subchondral bone which induces bleeding resulting in the formation of a new fibrocartilage covering. Unfortunately the biomechanical properties of this tissue is not equivalent to the original hyaline cartilage, and over time the repair tissue is prone to wear, many times resulting in osteoarthritis.

[0006] Alternatively, an osteo-articular transfer system (OATS) procedure may be done, especially as the defect size increases. This technique involves coring a plug of cartilage and subchondral bone from a non weight bearing area of the bone and implanting it to a prepared hole in the defect area. One or multiple plugs can be used to fill the defect area. This procedure is technically difficult as the cored bone/cartilage plugs must be accurately placed to create the new contiguous articulating surface. Leaving the surface of the plugs too high or low can significantly compromise the surgical outcome. Due to the multiple drilling locations and angles needed, this procedure is typically done with an open surgical technique followed by a lengthy rehabilitation schedule.

[0007] Autologus chondrocyte implantation is a transfer type system where cartilage cells are harvested in one surgical procedure, expanded in a laboratory, and then injected into the prepared defect site in a second surgery. While clinical outcomes are reported to be similar to the above described techniques this procedure is extremely expensive, requires two surgeries (one of which is a challenging open procedure), and similar long rehabilitation schedule.

[0008] Other biological attempts have been made to treat larger cartilage defects with tissue engineered bioabsorbable scaffold systems. Unfortunately they have not shown clinical outcomes advantageous to the above described techniques.

[0009] For many larger defects in the knee the only option available is to treat these defects nonoperatively in an endeavor to control symptoms until a unicompartamental knee replacement (UKR) or total knee replacement (TKR) is accomplished. With these devices both articulating bone ends are removed and replaced with metal and an ultrahigh molecular weight polyethylene insert (with or without a metal backing) is placed between the two metallic pieces. In a UKR both bone ends of the medial or lateral half of the knee are replaced whereas with a TKR both halves (and patella) are replaced. These prosthetic devices require an invasive, technically demanding implantation procedure and a long, involved, and painful rehabilitation period. Further, these devices are often larger than the defective tissue that needs to be replaced, so healthy bone and cartilage are sacrificed to accommodate the implants. Albeit that modern UKR and TKR devices are much improved from early hinged knee prostheses, there is still a loss of joint kinematics as this normal

tissue is removed. Additionally, the lifetime of TKRs is limited by a variety of implant and patient-related factors resulting in many patients outliving their primary prosthetic device, thus requiring a more difficult revision TKR surgery. To avoid this eventual revision surgery many younger patients will endure the pain and limited use these defects cause in order to put off the TKR procedure as long as possible. It should be noted that the same events occur in the hip and shoulder joints as well.

[0010] Implants constructed using measurements obtained from a defect have also been used. The installed implant thus attempts to closely match the shape of the defective area and articulate directly with the opposing native cartilage surface. This device has operative advantages over traditional knee prostheses; however, the opposing articular cartilage is prone to damage due to the large differences in material properties and is further exacerbated by any contour mismatching.

[0011] Similarly, metals, usually cobalt-chromium or titanium alloys, have been used for the surface of hip hemiarthroplasties. These prosthetic devices replace only the femoral side of the hip joint and articulate against the facing cartilage of the acetabulum. These metal implants have exhibited adverse effects on the cartilage against which they articulate causing erosion of the facing cartilage in several clinical studies. Thus, merely matching the anatomical shape of the cartilage that is resurfaced is not enough to prevent damage of the facing cartilage by a metallic counterface.

[0012] Several researchers have tried using lower modulus polymeric materials, such as high density or ultra high molecular weight polyethylene (UHMWPE), for the surface of hemiarthroplasty implants on the theory that a material with mechanical properties more closely matched to those of cartilage would cause less cartilage damage. These implants also caused erosion of the facing cartilage *in vivo* likely due to a mismatch in surface chemistry properties, (i.e. UHMWPE is hydrophobic and cartilage is hydrophilic). Thus, lower modulus implants alone are not enough to prevent damage of the facing cartilage.

[0013] Accordingly there is a need for an improved cartilage replacement system that would be effective in restoring a smooth, lubricious, and hydrophilic load bearing surface, with a modulus less than traditional metals, that can be easily implanted with

minimal normal tissue removal, and requires a less involved rehabilitation schedule ultimately restoring joint kinematics while avoiding damage to the opposing cartilage surface.

Summary of the Invention

[0014] Advancement of the state of surgical repair of damaged or diseased articular cartilage of joints is desirable. The present invention satisfies the need for improvements to implants and corresponding surgical instruments used to insert such implants in patients who have either diseased or damaged articular cartilage by providing a partial resurfacing implant and instrument system that allows the operating surgeon to accurately insert, with accuracy, an implant that maximizes defect coverage while minimizing host bone and cartilage removal.

[0015] The present invention provides in one aspect, an implant for repairing an articular cartilage defect site. The implant includes a top articulating portion and a supporting plate. The supporting plate has a top surface and a bottom surface with the top surface of the supporting plate being attached to the top articulating portion. The bottom surface of the supporting plate is constructed to assist with the insertion of the implant into the articular cartilage defect site.

[0016] The present invention provides in another aspect, a partial resurfacing implant for repairing a cartilage defect site. The implant includes a top articulating portion that has a top surface which is shaped with at least one radius of curvature to approximate the surface contour of the adjacent cartilage surrounding the defect site. The implant also has a supporting plate that includes a top surface and a bottom surface. The top surface of the supporting plate is attached to the top articulating portion with the bottom surface of the supporting plate being constructed to assist with the insertion of the implant into the cartilage defect site.

[0017] The present invention provides in yet another aspect, a surgical method for repairing an articular cartilage defect site. The method generally includes the step of surgically creating an opening in the articular cartilage defect site. The method may include the step of using a partial resurfacing implant in the defect site. The implant includes a top articulating portion and supporting plate. The supporting plate generally includes a top surface and a bottom surface. The top surface of the

supporting plate is attached in some manner to the top articulating portion with the bottom surface of the supporting plate being constructed to assist in the insertion of the implant into the articular cartilage defect site. The method may also include the step of implanting the partial resurfacing implant into the defect site opening. Usually, when upon inserting the implant into the defect site, the top articulating portion and adjacent articular cartilage will be positioned tangential to each other which allows for unrestricted motion over the defect site.

[0018] Further, additional features, benefits and advantages of the present invention will become apparent from the drawings and descriptions contained therein. Other embodiments and aspects of the invention are described in detail herein and are considered a part of the claimed invention.

Brief Description of the Drawings

[0019] The subject matter which is regarded as the invention is particularly pointed out and distinctly claimed in the claims at the conclusion of the specification. The foregoing and other objects, features and advantages of the invention are apparent from the following detailed description taken in conjunction with the accompanying drawings in which:

[0020] FIG. 1 is a perspective view of a distal condyle of a human femur with a cartilage defect, in accordance with an aspect of the present invention;

[0021] FIG. 2 is a perspective side view of one embodiment of a cartilage resurfacing implant, in accordance with an aspect of the present invention;

[0022] FIG. 3 is a perspective side view of a second embodiment of a cartilage resurfacing implant with a single implant fixation portion, in accordance with an aspect of the present invention;

[0023] FIG. 4 is a perspective side view of the second embodiment of a cartilage resurfacing implant of FIG. 3 with multiple implant fixation portions, in accordance with an aspect of the present invention;

[0024] FIG. 5 is a distal view of one embodiment of multiple cartilage resurfacing implants positioned adjacent to each other, in accordance with an aspect of the present invention;

[0025] FIG. 6 is a perspective view of one embodiment of an anatomical drill guide, in accordance with an aspect of the present invention;

[0026] FIG. 7 is a perspective view of one embodiment of a pronged anatomical drill guide, in accordance with an aspect of the present invention;

[0027] FIG. 8 is a perspective view of one embodiment of a multi-axis anatomical drill guide, in accordance with an aspect of the present invention;

[0028] FIG. 9 is a side view of one embodiment of an anatomical drill guide positioned on the distal aspect of a femoral condyle, in accordance with an aspect of the present invention;

[0029] FIG. 10 is a side sectional view of a cartilage cutting instrument, in accordance with an aspect of the present invention;

[0030] FIG. 11 is an enlarged side sectional view of the distal end of the cartilage cutting instrument of FIG. 10 positioned adjacent to the femoral condyle, in accordance with an aspect of the present invention;

[0031] FIG. 12 is a sectional side view of a prepared defect site at the distal aspect of the femoral condyle, in accordance with an aspect of the present invention;

[0032] FIG. 13 is a perspective view of a trial implant before insertion into a prepared defect site, in accordance with an aspect of the present invention;

[0033] FIG. 14 is a perspective view of an implant insertion instrument, in accordance with an aspect of the present invention;

[0034] FIG. 15 is a perspective view of the resurfacing implant of FIG. 2 seated within the prepared defect side in the distal aspect of the femoral condyle, in accordance with an aspect of the present invention;

[0035] FIG. 16 is a top view of the cartilage resurfacing implant of FIG. 4, in accordance with an aspect of the present invention;

[0036] FIG. 17 is a perspective view of the distal aspect of a femur with an attached dual hole drill guide, in accordance with an aspect of the present invention;

[0037] FIG. 18 is a perspective view of the distal aspect of a femur with dual pilot drills positioned within the drill guide of FIG. 15, in accordance with an aspect of the present invention;

[0038] FIG. 19 is a perspective view of the distal aspect of a femur with dual pilot drills positioned within the drill guide of FIG. 15, in accordance with an aspect of the present invention;

[0039] FIG. 20 is a perspective view of the distal aspect of a femur with one of the dual pilot drills remaining following removal of the second pilot drill, in accordance with an aspect of the present invention;

[0040] FIG. 21 is a perspective view of the distal aspect of a femur with a cutting cannula assembly placed over the single pilot drill, in accordance with an aspect of the present invention;

[0041] FIG. 22 is a perspective view of an inner support member being removed from the cutting cannula of FIG. 21, in accordance with an aspect of the present invention;

[0042] FIG. 23 is a perspective view of a cannulated reamer being placed over a single pilot drill, in accordance with an aspect of the present invention;

[0043] FIG. 24 is a perspective view of the distal femur being reamed with the cannulated reamer of FIG. 23, in accordance with an aspect of the present invention;

[0044] FIG. 25 is a perspective view of the re-insertion of a second pilot drill into the posterior hole and placement of a cutting tube guide, in accordance with an aspect of the present invention;

[0045] FIG. 26 is a perspective view of the cutting cannula inserted over the second pilot drill and abutting cutting tube guide, in accordance with an aspect of the present invention;

[0046] FIG. 27 is a perspective view of an inner support member being removed from the cutting cannula of FIG. 26, in accordance with an aspect of the present invention;

[0047] FIG. 28 is a perspective view of the cannulated reamer being placed over the second pilot drill, in accordance with an aspect of the present invention;

[0048] FIG. 29 is a perspective view of the cannulated reamer removing bone from the distal femur, in accordance with an aspect of the present invention;

[0049] FIG. 30 is a perspective view of the prepared defect site in the distal femur, in accordance with an aspect of the present invention;

[0050] FIG. 31 is a superior view of a third embodiment of a cartilage replacement implant, in accordance with an aspect of the present invention;

[0051] FIG. 32 is a perspective view of the prepared defect site in the distal femur following the removal of the cartilage flaps, in accordance with an aspect of the present invention;

[0052] FIG. 33 is a perspective view of the insertion of a trial sizing instrument inserted into the prepared defect site of FIG. 32, in accordance with an aspect of the present invention;

[0053] FIG. 34 is a perspective view of the insertion of the cartilage replacement implant of FIG. 4 prior to final implantation into the distal femur, in accordance with an aspect of the present invention;

[0054] FIG. 35 is a perspective view of the insertion of a trial-drill guide for the cartilage resurfacing implant of FIG. 3, in accordance with an aspect of the present invention;

[0055] FIG. 36 is a perspective view of the prepare defect site after the removal of the trial-drill guide of FIG. 35, in accordance with an aspect of the present invention; and

[0056] FIG. 37 is a perspective view of the insertion of the cartilage replacement implant of FIG. 3 prior to final implantation into the distal femur, in accordance with an aspect of the present invention.

Detailed Description for Carrying Out the Invention

[0057] For the purposes of promoting an understanding of the principles of the partial joint resurfacing implant, corresponding surgical instruments and surgical method for inserting the resurfacing implant, reference will now be made to the embodiments, or examples, illustrated in the drawings and specific language will be used to describe these. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations and further modifications in the described embodiments, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the multi-functional surgical instrument invention relates.

[0058] In this detailed description and the following claims, the words proximal, distal, anterior, posterior, medial, lateral, superior and inferior are defined by their standard usage for indicating a particular part of a bone, prosthesis or surgical instrument according to the relative disposition of the surgical instrument or directional terms of reference. For example, "proximal" means the portion of an implant or instrument positioned nearest the torso, while "distal" indicates the part of the implant or instrument farthest from the torso. As for directional terms, "anterior" is a direction towards the front side of the body, "posterior" means a direction towards the back side of the body, "medial" means towards the midline of the body, "lateral" is a direction towards the sides or away from the midline of the body, "superior" means a direction above and "inferior" means a direction below another object or structure.

[0059] As used herein, the terms "partial joint resurfacing implant", "surfacing implant" and "implant" may be used interchangeably as they essentially describe the same type of implantable device.

[0060] Referring to FIG. 1, cartilage defects 29 in the knee, and more specifically within the femoral condyle 5a and other joints, occur as a result of wear and/or mechanical overloading. They occur in varying sizes and shapes and tend to progress

to larger defects if left untreated. To reduce or eliminate the pain caused by these defects and to decrease or eliminate the progression of the joint deterioration, the damaged cartilage with a portion of underlying bone is removed and replaced with a device providing a new articulating surface and an anchor into the bone.

[0061] Referring to FIG. 2, a generally cylindrical implant 30b of the present invention is shown for example purposes only. The top articulating portion 30 is made from a material that has a lower modulus of elasticity than traditional metal implants. In this embodiment, top articulating portion 30 consists of a polymeric smooth, lubricious, and hydrophilic top surface 30a fabricated from a polysaccharide-treated thermoplastic polymer material capable of withstanding *in vivo* loading. This articulating surface material is more fully described in patent Application Serial number 10/283,760 that is herein incorporated by reference. It should be noted that other biocompatible materials may be used to fabricate top articulating portion 30, that include, but are not limited to: polysaccharide treated thermoplastic polymers including polysaccharides such as hyaluronic acid, chitosan, thermoplastic polymers such as UHMWPE and other aliphatic polymers like polypropylene, polybutylene, polyethylene-butylene rubber. Also other thermoplastic polymers such as polyurethanes, polysiloxanes, polyesters, are contemplated for use. Additional other materials to fabricate top articulating portion 30 may include polyesters such as PET (polyethylene terephthalate); perfluorinated hydrocarbons [e.g. teflon]; acrylates [e.g. PMMA (polymethyl methacrylate), polyacrylonitrile, polyacrylamide]; polyamides (e.g. nylon); polycarbonate; epoxy resins; PEEK (polyether ether ketone); ceramics; polysiloxanes (e.g. silicone resins); metals (e.g. cobalt chrome, titanium and titanium alloys, stainless steel); and hydrogels (e.g. polyvinyl alcohol).

[0062] The implant fixation portion 31 of the implant can be constructed of metal, polymer, composite or other biocompatible resorbable or non-resorbable material including, but not limited to, Co-Cr, Ti Alloy, PEEK, UHMWPE or alternatively, entirely from the same material that makes up top articulating portion 30.

[0063] As shown in FIG. 2, implant 30b further includes supporting plate 32 that has a locking mechanism 33 to securely couple top articulating portion 30.

[0064] The bone interfacing portion of implant fixation portion 31 that extends from supporting plate 32 can be treated or contains features to permit bony ingrowth from the bone bed in which it is implanted. It is contemplated that implant fixation portion 31 may include a lower stem 34 portion containing fixation barbs 35, threads or fins (not shown) to lock implant 30b into bone. Although not shown, other bone fixation members that project from the undersurface of supporting plate 32 are contemplated and may include tapered stems, straight pegs or a plurality of pegs. It is contemplated that implant fixation portion 31 and the bottom surface of supporting plate 32 could also have a coating or finish to assist with bone integration, such as HA, TCP or BMP coating, titanium plasma spray, grit blasting, or any other operation that roughens the surface of the structure. It is understood that the construct of implant 30b as shown in FIG. 2 will minimize the amount of resected bone which is advantageous for reducing trauma to the remaining healthy surrounding bone, reducing healing time, and will permit later removal without compromising total joint arthroplasty efficacy at that time. It is further understood by one skilled in the art that implant 30b may be constructed without implant fixation portion 31. It is contemplated that for such a construct the bottom surface of supporting plate 32 may be coated or finished using the above-named techniques to enhance or assist with bone integration. An embodiment constructed without implant fixation portion 31 may be used in various clinical situations when a projecting structure is deemed unnecessary.

[0065] Top articulating portion 30 of implant 30b is commonly fabricated using direct compression molding techniques to overmold supporting plate 32 resulting in a final construct where top articulating portion 30 is securely adhered to supporting plate 32 via locking mechanism 33.

[0066] As described previously, top portion 30 is attached to supporting plate 32 via locking mechanism 33 which for example purposes is configured as an undercut dovetail locking arrangement. The angle of the two vertical walls of the dovetail locking arrangement are generally less than 90 degrees, which provides resistance against top articulating portion 30 from dislodging superiorly. The nature of the dovetail feature may also prevent top articulating portion 30 from rotating relative to the supporting plate 32. Additionally, locking mechanism 33 may include two

dovetail cuts perpendicular to each other, resulting in a cross-shaped arrangement if viewed from a superior perspective. Having multiple directional cuts helps to ensure that there is no translational or sliding movement of top articulating portion 30 relative to supporting plate 32. Alternative modes of fixing top articulating portion 30 to supporting plate 32 may also include a snap-fit mechanism, an adhesive material or an alternative locking channel.

[0067] The bottom aspect of implant 30b is generally a one-piece construct that is made up of two different constructs, supporting plate 32 that holds and supports top articulating portion 30, and implant fixation portion 31 that functions to provide stability and fixation within the host bone. Supporting plate 32 includes a generally flat bottom surface to which implant fixation portion 31 is integrally connected. The top surface of supporting plate 32 may also be generally flat as well, notwithstanding locking mechanism 33 that is disposed thereon. Implant fixation portion 31 includes a generally cylindrical lower stem 34 part that includes a proximal cylindrical section and a distal bone fixation section that includes multiple tapered barbs 35 projecting away from the central axis of lower stem 34. Due to the nature of the barb design as shown in FIG. 2, rotation is also prevented post implantation in the bone. The various numbers of barbs 35 that may be employed will range from two to six depending upon their shape and size and quality of bone seen during implantation. The bottom tip 38 of implant fixation portion 31 is generally tapered to allow for ease of insertion into the pilot hole during the surgical procedure.

[0068] Top surface 30a of implant 30b can be molded or machined with various radii to create a contour that closely matches the curvature of the adjacent normal articulating cartilage surface of the subject joint when implanted. Alternatively, top surface 30a may be made substantially planar to avoid being proud relative to the adjacent normal joint surface and assist in reducing the likelihood of damaging the opposing articular cartilage surface. Additionally, the peripheral edge of top articulating portion 30 may have a generous radius 36 around the entire circumference. This helps to ensure that there are no transitional edges that could potential wear down opposing cartilage over time. It also makes a smooth transition from the adjacent normal cartilage surface to implant 30b. In the event radius 36 or top articulating portion 30 is absent, the user may trim or cut the surrounding edge

during the implantation procedure to ensure a seamless transition and matching geometry between implant 30b and the surrounding native cartilage.

[0069] Referring to FIGS. 3, 4, 5 and 16, implant 30b can be provided in various cross-sectional geometries or circumferential shapes, including but not limited to, elliptical, rectangular, oval, oblong and also include features like scallops or flat edges that allow for the placing of multiple implants in close proximity to each other to more closely match and fill the host cartilage defect shape. As shown in FIG. 5 for example purposes only, multiple implants 30b have been aligned serially to provide coverage over a wide cartilage defect that a single implant would not be able to cover. For this purpose, implant 30b may be interlocked or joined in some manner to ensure bone fixation and continuity of the multiple respective top articulating portions.

[0070] An example of alternative shape of implant 30b includes an oblong configuration with a single implant fixation portion as seen in FIGS. 3 and 16. The oblong, or “racetrack” shaped implant 40b is configured such that it might more closely match cartilage defects that are longer, yet narrower, than just a circular defect. Such an implant is similar to implant 30b in that it has two components, a top articulating portion 40, and a supporting plate 42. Supporting plate 42 may further include a centralized implant fixation portion 41 that has a lower stem 44 part and fixation barbs 45 that extend away from the distal aspect of lower stem 44. Implant 40b shown in FIG. 3 has a single implant fixation portion 41 although multiple implant portions 41 are contemplated like the embodiment shown in FIG. 4.

[0071] Similar to implant 30b, implant 40b will utilize a locking mechanism similar to the previously described dovetail undercut (not shown), that connects top articulating portion 40 to supporting plate 42. Top articulating portion 40 could also be attached to supporting plate 42 via a snap-fit mechanism or adhesive material. Similar to implant 30b, the articulating surface curvature of the implant 40b is such that it matches the curvature of the adjacent native cartilage on the femur. In a normal femur, there are usually two different curvature geometries – one in the anterior-posterior (AP) direction, and one in the medial-lateral (ML) direction, implant 40b could have a different radius of curvature in the AP direction as compared to the ML direction in order to accommodate the natural shape of the native femur. Because of this, implant 40b has the potential to better fit the geometry of the femur because the

dual directional radiuses as opposed to only uni-directional radius as use for implant 30b.

[0072] The present invention also discloses a surgical method for the insertion of implant 30b into the distal femoral condyle.

[0073] The first step is typically to assess the size of the defect. The surgeon will measure the size of the cartilage defect and cartilage thickness. The size and thickness is used to determine the appropriate implant size. The thickness measurement is used to determine the drilling depth of the surface preparation drills and reamers.

[0074] Referring to FIG. 6, an anatomical drill guide 4a is shown. In order to ensure that the first hole drilled is normal to the native articulating cartilage surface, the surgical method utilizes a drill guide that references the geometry of the host articulating cartilage surface. Guide 4a will reference a femoral condyle in the knee. However, guide 4a could also be designed to reference the geometry of other anatomy in the knee, hip, shoulder, ankle, hand, wrist, spine, etc. The premise would be the same for each anatomic position in that guide 4a, whose geometry matches the surface geometry of the native articulating cartilage surface, is able to pilot the guide hole so that it is drilled normal to the surface.

[0075] Typically, a joint will have two or more radius of curvatures – one will be in the Anterior/Posterior plane (AP curve), and the other will be in the Medial/Lateral plane (ML curve). Guide 4a can be marked so that the user can place guide 4a in the correct orientation with respect to the articulating cartilage surface. The typical geometry of the anatomy will be used to construct under surface 1, 2 of guide 4a so that it matches the cartilage/bone surface. Therefore, guide 4a will have a curve in the AP plane, and ML plane, which will allow guide 4a to sit flush on a femoral condyle. If needed, various sized drill guides can be constructed to accommodate variations in anatomical size and shape. Further, in some instances the diseased articulating cartilage surface might have only one radius of curvature, such as the femoral head in the hip and humeral head in the shoulder, where the shape is more spherical in nature. In this instance, drill guide 4a would be shaped appropriately to match either the AP and ML curves with each being equal.

[0076] In another instance, the diseased articulating surface may be flat or nearly flat, such as areas of the trochlear groove. In this instance, the AP and ML “curves” would be flat planes with infinite radii. Drill guide 4a underlying surfaces would need to replicate the planar arrangement to ensure the pilot hole is drilled normal to the flat surface.

[0077] Further, drill guide 4a contains a geometrical section 4 which allows the user to easily manipulate and place the anatomical drill guide. Drill guide also has a thru hole 3 that is sized appropriately for a pilot drill bit 11 (see FIG. 11) to be inserted. As a result of drill guide 4a being normal to the articular surface, the pilot drill bit 11 (see FIG. 11) will also be normal to the articular surface.

[0078] Referring to FIG. 7, an anatomical drill guide 4b is shown in an alternative embodiment. Drill guide 4b has three prongs 22 that are equal in length. By having three prongs with equal lengths, one can find the normal axis on a curved surface by ensuring three points of contact. Prongs 22 are all smooth and rounded on the end 24 to prevent scuffing or damaging of the cartilage during placement of guide 4b. Additionally, guide 4b can also have a center hole 23 which serves as a guide for the pilot drill bit. Center hole 23 will ensure that the pilot drill bit 11 (see FIG. 11) will be placed normal to the surface of the diseased articular cartilage.

[0079] Referring to FIG. 8, a multi-axis anatomical drill guide 4c is depicted. In many instances, a defect site will not be circular in shape, and, thus, a standard circular implant will not fully cover the affected area. As a result, multiple implants may be needed to be implanted into the defect site. In order to address such a presented clinical situation where standard circular implants are not adequate, multiple holes could be drilled normal to the articular cartilage surface. The present invention describes drill guide 4c that allows the user to drill multiple (e.g. three) holes. Drill guide 4c will reference the AP radius of curvature 25 as well as the ML radius of curvature 28 such that it will lay flush against the diseased articular cartilage surface. Multiple holes 27 are present in drill guide 4c which are each normal to the curves at their respective locations. Holes 27 are used as guides for inserting a pilot drill 11 (not shown), which will ensure that all three holes 27 are drilled normal to the articular cartilage surface. Additionally, drill guide 4c has a cannulated geometrical piece 26 attached that allows for manipulation and placement of the drill guide 4c.

[0080] Referring to FIG. 9, it is shown for the next step of the surgical method that the placement of guide 4a must be so that the interface 5 of drill guide 4a and the femoral condyle 5a is such that guide 4a is flush with the articular cartilage surface 5b.

[0081] Once guide 4a is in place, the surgical method provides for using an appropriate sized drill bit to create the hole for accommodating implant 30b. The drill bit is used until the etch line on the drill bit lines up with the back surface of drill guide 4a. This allows a set depth to be drilled.

[0082] A further step is to keep drill guide 4a in place, remove the drill bit and insert a separate insertion rod into the pilot hole that was made in the bone. An alternate to this step would be to unchuck the drill bit from the drill and just remove the drill guide leaving the drill bit intact. As a result, one could now use the drill bit instead of a separate insertion rod. Following this step, drill guide 4a may be removed by sliding it over insertion rod (or drill bit, if alternative method is used).

[0083] Referring to FIG. 10, a cartilage cutting instrument assembly 21 is shown. Instrument 21 comprises a sharp cutting edge 6 that is used to sever the cartilage. By severing the cartilage, a nice clean cut is created at the defect site, which enables better cartilage interface with implant 30b. The cutting tube 10a is attached to an ergonomic handle 7 to allow the user to easily grasp and manipulate the instrument. Another component of instrument 21 is the intermediate support tube 8, which is attached to another ergonomic handle 10 to allow for the user to remove support tube 8 from instrument 21 when needed. Intermediate support tube 8 is cannulated 9 such that it fits over the pilot drill bit 11 (see FIG. 11) or alternatively, an insertion rod (see FIG. 11) that was inserted following pilot hole generation.

[0084] The next step of the surgical method may include sliding instrument 21 over insertion rod (or pilot drill bit) until sharp cutting edge 6 touches articular surface 5b. The user will gently twist and push instrument 21 until the layer of cartilage is cut and the cutting edge 6 is touching the subchondral bone.

[0085] As seen in FIG. 11, instrument 21 is positioned adjacent to femoral condyle articular cartilage surface 5b prior to cutting the cartilage 12. Intermediate support tube 8 fits over pilot drill bit 11 that was placed using anatomical drill guide

4a. Cutting edge 6 is twisted, rotated, pushed or struck as required to cut and sever cartilage 12. Cutting edge 6 is not intended to significantly cut into the underlying subchondral bone. Once cartilage 12 is severed, intermediate support tube 8 is removed. This leaves only pilot drill bit 11 and cutting tube 10a in place.

[0086] Because intermediate support tube 8 is removed, a next step for the surgical method would be to insert a cannulated reamer (not shown) that fits into and through cutting tube 10a and over pilot drill bit 11. This is done to ensure that the larger hole is also oriented normal to the femoral surface. An etch mark on the reamer will reference the back of handle 10 (see FIG. 10) or, alternatively, an adjustable stop (not shown) could be used on the reamer to set the depth to be reamed which corresponds to the height of implant 30b. Additionally, cutting tube 10a acts as a protection barrier to keep the adjacent outer cartilage which is not to be removed from making contact, and thus being damaged, with the reamer. This will likely ensure that the clean-cut surface from the cartilage remains intact, which will assist in creating and maintaining a favorable interface between the native cartilage and implant 30b.

[0087] The next step of the surgical method will usually be to remove drill bit 11 (or insertion rod) and cutting tube 10a. The site is now prepared to receive implant 30b. Alternatively, the cutting tube 10a can be left in place to provide a barrier to prevent cartilage edge damage and fluid entrapment in the defect site.

[0088] Referring to FIG. 12, the resultant stepped implant preparation hole 14a in femoral condyle 12 is shown after the preceding drilling and reaming operations are completed. The smaller hole 13 is a result of pilot drill bit 11 (see FIG. 11). The larger hole 14 is a result of using a cannulated reamer to ream to the correct depth. Smaller hole 13 houses lower stem 34 of implant 30b and more generally, implant fixation portion 31, while larger hole 14 houses the recessed top articulating portion 30.

[0089] The surgical method further provides for the insertion of appropriate-sized trial implants. This will ensure that the proper fit and orientation is achieved prior to inserting implant 30b. As shown in FIG. 13, trial component 16a is used to verify a proper fit between implant 30b and stepped implant preparation hole 14a. Trial

component 16a contains a cylindrical piece 15 that has the same diameter (or slightly smaller) and height as the proposed implant 30b (see FIG. 2). In the preferred embodiment, the trial component 16a can have a stem 16 that is attached to the cylindrical piece 15 to allow for easier manipulation of the trial. By inserting trial 16a into prepared hole 14a, one can test the fit of implant 30b and stepped implant preparation hole 14a prior to the insertion of implant 30b. Specifically, important feedback given by trial component 16a is whether implant 30b will be proud, recessed, or oblique relative to the native articulating cartilage surface 5b which could all potentially adversely affect the post-operative functioning of implant 30b. If after inserting of cylindrical piece 15 it is found that implant 30b may be proud, one can either ream deeper into the bone or select an implant with a smaller height if available. Conversely, if cylindrical piece 15 is found to be recessed, one can select an implant with a larger or thicker height.

[0090] Referring to FIG. 14, an implant insertion instrument 17a is shown. Instrument 17a contains a soft (e.g. silicone-coated) tip 17 that is placed on a sturdy or rigid tube 21 that is preferably, but not necessarily metallic. Tip 17a can also be manufactured from any other soft or pliant material that will not damage top articulating portion 30 or top surface 30a upon insertion. It serves as a cushion and protects implant 30b from any harmful impact forces. In this embodiment, instrument 17a has a back portion 20 that can be interfaced with a suction hose. This suction keeps implant 30b in close proximity to silicone tip 17 until proper positioning is achieved. The suction can be easily controlled by the user via a small communication hole 19 that can be covered and uncovered as necessary with one's hand or finger to control the suction. Additionally, the handle portion 18 can be tapped on to ensure implant 30b is seated flush in the bone.

[0091] Referring to FIG. 15, implant 30b is seated in femoral condyle 5a replacing cartilage defect 29. Special care is taken to make sure to line up implant fixation portion 31 in smaller hole 13 and to ensure that implant 30b is flush with the inner shoulder of large hole 14, and articular cartilage surface 5b.

[0092] Referring collectively to FIGS. 17-37, the present invention also discloses a further surgical method for inserting an oblong or "racetrack" shaped implant 40b

(see FIG. 16) that includes either a single implant fixation portion 41 (see FIG. 3) or dual implant fixation portions (see FIG. 4).

[0093] As discussed previously, many defects found in the knee are not perfect circles and tend to be longer in the Anterior-Posterior (AP) plane than the Medial-Lateral (ML) plane. Therefore, having an implant that more closely matches the shape of defects typically seen will be advantageous in that the defect can be more easily covered than with a circular-shaped implant similar to implant 30b.

[0094] The surgical method for inserting implant 40b includes, as seen in FIG. 17, the step of using an anatomic drill guide 100 whose curvature closely matches that of the femur 50, and placing it on the femoral condyle over the defect. Instead of a single pilot hole (as done when preparing defect site for implant 30b), there are two pilot holes drilled. These holes represent the two axis of implant 40b (see FIG. 16) and the corresponding two implant fixation portions.

[0095] The surgical method provides further as shown in FIG. 18, the step of inserting two pilot drills 101 into each hole on drill guide 100 and drilling to the proper depth. The depth can be set via a mark on drill bits 101 that line up with the back of drill guide 100. Once both pilot drills 101 are inserted, drill guide 100 is removed as shown in FIG. 19.

[0096] The surgical method may include the step of removing one of the pilot drills 101 and leaving the posterior hole 51 exposed (see FIG. 20). A cutting cannula assembly 102, 103 is then slid down pilot drill 101 (see FIG. 21). Twisting motion to assembly 102, 103 will cause the sharp tip of the assembly to sever the targeted diseased cartilage.

[0097] Once the cartilage is severed, the surgical method will provide for the step of removing the inner support piece 103 while keeping the outer cannula 102 and pilot drill 101 in place (see FIG. 22). A cannulated bone reamer 104 is then placed over pilot drill 101 (see FIG. 23) and the bone is reamed to a set depth (see FIG. 24). Again, the depth of the bone cut can be determined via a mark or collar on reamer 104 that references the back of cutting cannula 102.

[0098] The surgical method provides further for the step of cutting the cartilage for the second axis as determined by the second drill bit. Specifically, using a similar method to cut the cartilage as for the first axis described above, cutting cannula 102 and pilot drill 101 from the first axis are removed, pilot drill 101 is reinserted into posterior hole 51 that replicates the second axis. Also, a cutting tube guide 200 is inserted into the adjacent the hole that has been previously drilled (see FIG. 25). Guide 200 has a cutout such that the outer diameter of cutting tube 102 fits snugly into it. The purpose of guide 200 is to ensure that when cutting the cartilage along the second axis, cutting cannula 102 is forced along a certain path. Without guide 200, there is a possibility that cutting cannula 102 will slide slightly inwards (anteriorly) towards the first pilot hole, thus making the defect slightly smaller than desired. Using the same method as the first axis, cutting cannula 102 is then slid down pilot drill 101 and into guide 200 allowing for the cartilage to be severed (see FIG. 26).

[0099] The surgical method may then include the step of reaming the bone out from the second axis. This is accomplished by removing inner-support piece 103 while keeping cutting cannula tube 102 in place (see FIG. 27). Cannulated bone reamer 104 is then placed over pilot drill 101 (see FIG. 28), and the bone is then reamed to a set depth as shown in FIG. 29. Again, the depth of the bone cut can be determined via a mark or collar on reamer 104 that references the back of cutting cannula 102.

[00100] Following the drilling over the second axis, the resulting shape of the prepared defect site resembles a “figure 8” as shown in FIG. 30. It is contemplated that an alternative implant could have an outer configuration of a “figure 8” 50b (see FIG. 31), such that it fits without having to do additional defect site preparation. However, typically the shape of the implant is more of a “racetrack” or oblong as seen in FIGS. 3, 4 and 16, such that it gets maximum coverage. Therefore, in order to accommodate the oblong shape, the flaps of cartilage are removed via an osteotome, drill, burr, or other sharp cutting instrument resulting in the final defect site shape as seen in FIG. 32.

[00101] The surgical method may have the further step of inserting a trial 300 to assess how the fit of the implant will be (see FIG. 33). Trial 300 geometry matches the geometry of the actual implant. This will allow the user to visualize how the

implant fits into the defect site. If the implant is too proud, recessed, or not perpendicular, trial 300 will enable the user to correct the sizing prior to inserting the actual implant.

[00102] The surgical method will generally then provide for the step of inserting the implant into the defect site. The two implant fixation portions 41 of implant 40b are lined up with the two pilot holes (see FIG. 34). Implant 40b is then tapped into place until it is flush with the surrounding cartilaginous surface.

[00103] In the event implant 40b has only a single implant fixation portion 41 (see FIG. 3), the surgical method steps outlined above would be the same. However, since the implant has one implant fixation portion 41 that is located at the center of the oval, another pilot hole must be created. In order to do this, one would also use trial 300 as a drill guide to drill the center hole (see FIG. 35). Once the center hole 54 is created, the defect now has a total of three holes (see FIG. 36). Single implant fixation portion 41 of implant 40b is then lined up with third, center hole 54 (see FIG. 37) and is tapped into place.

[00104] While embodiments of the invention have been illustrated and described in detail in the disclosure, the disclosure is to be considered as illustrative and not restrictive in character. All changes and modifications that come within the spirit of the invention are to be considered within the scope of the disclosure.

Claims

What is claimed is:

1. An implant for repairing an articular cartilage defect site, the implant comprising:

a top articulating portion; and

a supporting plate, the supporting plate comprising a top surface and a bottom surface, wherein the top surface of the supporting plate is coupled to the top articulating portion and the bottom surface of the supporting plate being configured to facilitate insertion into the articular cartilage defect site.

2. The implant of claim 1, wherein the top articulating portion further comprises a top surface, the top surface having a first radius of curvature with the first radius of curvature being selected to approximate the surface contour of the articular cartilage surrounding the defect site.

3. The implant of claim 1, wherein the top articulating portion further comprises a top surface, the top surface being planar to approximate the surface contour of the articular cartilage surrounding the defect site.

4. The implant of claim 1, wherein the top articulating portion is fabricated from a lubricious and hydrophilic polymer.

5. The implant of claim 4, wherein the lubricious and hydrophilic polymer is a polysaccharide treated thermoplastic polymer.

6. The implant of claim 1, wherein the top articulating portion is fabricated from a polymer selected from the group consisting of polyesters, perfluorinated hydrocarbons, acrylates, polyamides, polycarbonates PEEK, epoxy resins, polysiloxanes and hydrogels.

7. The implant of claim 2, wherein the top surface further comprises a second radius of curvature, wherein the first radius of curvature is greater than or equal to the second radius of curvature, with the first and second radius of curvatures

being selected to approximate the surface contour of the articular cartilage surrounding the defect site.

8. The implant of claim 1, wherein the implant further comprises a locking mechanism to mechanically interlock the top articulating portion to the supporting plate.

9. The implant of claim 8, wherein the locking mechanism comprising at least one of a channel disposed on the top surface of the supporting plate, a snap-fit interlock between the top articulating portion and the top surface of the supporting plate and a durable adhesive disposed between the top surface of the supporting plate and the top articulating portion.

10. The implant of claim 9, wherein the at least one channel is configured as at least one of a dovetail and a key-lock slot.

11. The implant of claim 1, wherein the implant has a cross-sectional shape, the cross-sectional shape being one of a circle, an oval, a rectangle, an oblong or a polygonal shape, wherein the cross-sectional shape of the implant is configured to fit within the articular cartilage defect site.

12. The implant of claim 1, wherein the supporting plate further comprises at least one implant fixation portion, the at least one implant fixation portion being integrally connected to and extending away from the bottom surface of the supporting plate.

13. The implant of claim 12, wherein the at least one implant fixation portion comprises a lower stem, the lower stem being configured as at least one of a cylindrical post, a tapered post, a peg and a polygonal dowel to facilitate insertion into the articular cartilage defect site.

14. The implant of claim 13, wherein the lower stem further comprises a proximal cylindrical section and distal bone fixation section, wherein at least two barbs project away from an outer surface of the distal bone fixation section, the barbs being configured to inhibit motion of the implant following implantation in the articular cartilage defect site.

15. The implant of claim 12, wherein the bottom surface of the supporting plate and the at least one implant fixation portion is coated with a material for facilitating bio-ingrowth between the implant and the articular cartilage defect site.

16. The implant of claim 15, wherein the material is at least one of hydroxyapatite, calcium phosphates, calcium sulfates, BMP, and a growth factor.

17. A partial resurfacing implant for repairing a cartilage defect site, the implant comprising:

a top articulating portion having a top surface being configured with at least one radius of curvature to approximate the surface contour of the cartilage surrounding the defect site; and

a supporting plate, the supporting plate comprising a top surface and a bottom surface, wherein the top surface of the supporting plate is coupled to the top articulating portion and the bottom surface of the supporting plate being configured to facilitate insertion into the cartilage defect site.

18. The partial resurfacing implant of claim 17, wherein the top articulating portion is fabricated from a hydrophilic polymer.

19. The partial resurfacing implant of claim 18, wherein the hydrophilic polymer is a polysaccharide treated thermoplastic polymer.

20. The partial resurfacing implant of claim 17, wherein the top articulating portion is fabricated from a polymer selected from the group consisting of polyesters, perfluorinated hydrocarbons, acrylates, polyamides, polycarbonates PEEK, epoxy resins, polysiloxanes and hydrogels.

21. The partial resurfacing implant of claim 17, wherein the implant further comprises a locking mechanism to couple the top articulating portion to the supporting plate.

22. The partial resurfacing implant of claim 21, wherein the locking mechanism comprising at least one of a channel disposed on the top surface of the supporting plate, a snap-fit mechanical lock between the top articulating portion and the top surface of the supporting plate and a durable adhesive disposed between the top surface of the supporting plate and the top articulating portion.

23. The partial resurfacing implant of claim 22, wherein the at least one channel is configured as at least one of a dovetail and a key-lock slot.

24. The partial resurfacing implant of claim 17 wherein the implant has a cross-sectional shape, the cross-sectional shape being one of a circle, an oval, a rectangle, an oblong or a polygonal shape, wherein the cross-sectional shape of the implant is configured to fit within the cartilage defect site.

25. The partial resurfacing implant of claim 17, wherein the supporting plate further comprises at least one implant fixation portion, the at least one implant fixation portion being integrally connected to the bottom surface of the supporting plate.

26. The partial resurfacing implant of claim 25, wherein the at least one implant fixation portion extends in a perpendicular direction from the bottom surface of the supporting plate.

27. The partial resurfacing implant of claim 25, wherein the at least one implant fixation portion comprises a lower stem, the lower stem being configured as at least one of a cylindrical post, a tapered post, a peg and a polygonal dowel to facilitate insertion into the cartilage defect site.

28. The partial resurfacing implant of claim 27, wherein the lower stem comprises a proximal cylindrical section and distal bone fixation section, wherein at least two barbs project away from an outer surface of the distal bone fixation section, the barbs being configured to inhibit motion of the implant following implantation in the cartilage defect site.

29. The partial resurfacing implant of claim 25, wherein the bottom surface of the supporting plate and the at least one implant fixation portion is coated

with a material for facilitating bio-ingrowth between the implant and the cartilage defect site, the material is at least one of hydroxyapatite, calcium phosphates, calcium sulfates, BMP, and a growth factor.

30. A method of repairing an articular cartilage defect site, the method comprising:

surgically creating an opening in the articular cartilage defect site;

employing a partial resurfacing implant, the implant comprising:

a top articulating portion; and

a supporting plate, the supporting plate comprising a top surface and a bottom surface, wherein the top surface of the supporting plate is coupled to the top articulating portion and the bottom surface of the supporting plate being configured to facilitate insertion into the articular cartilage defect site; and

implanting the partial resurfacing implant into the opening, wherein the supporting plate is inserted into the opening with the top articulating portion and adjacent articular cartilage being positioned tangential to each other to facilitate motion over the defect site.

31. The method of claim 30, wherein the surgically creating an opening further comprises employing a drill guide to form a pilot hole in the defect site, the pilot hole being oriented substantially normal to the articular cartilage defect site.

32. The method of claim 30, wherein the surgically creating an opening further comprises cutting damaged articular cartilage from the articular cartilage defect site.

33. The method of claim 30, wherein the surgically creating an opening further comprises enlarging the pilot hole to accommodate the implant.

34. The method of claim 30, further comprising the step of inserting a trial implant within the articular cartilage defect site to confirm the sizing and final positioning of the partial resurfacing implant.

* * * * *

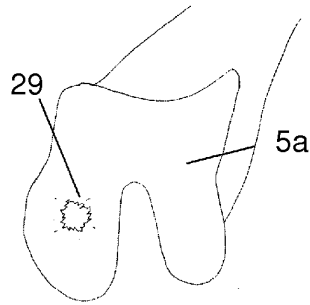


FIG. 1

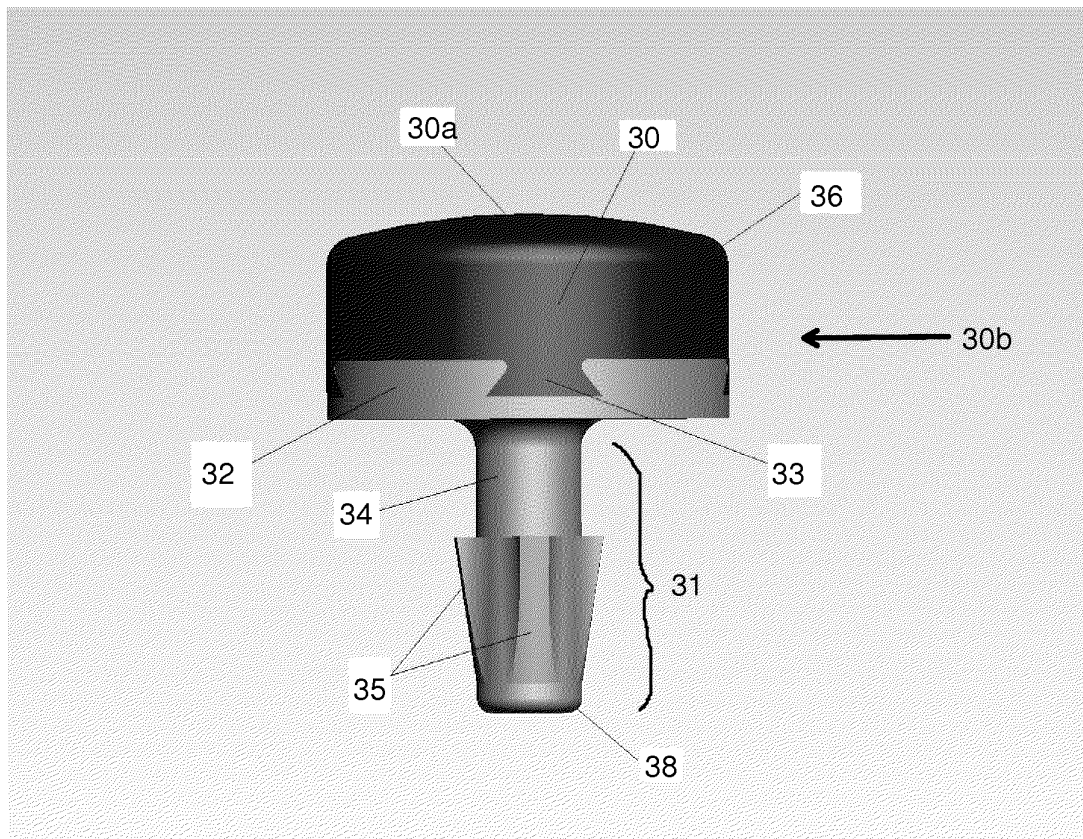


FIG. 2

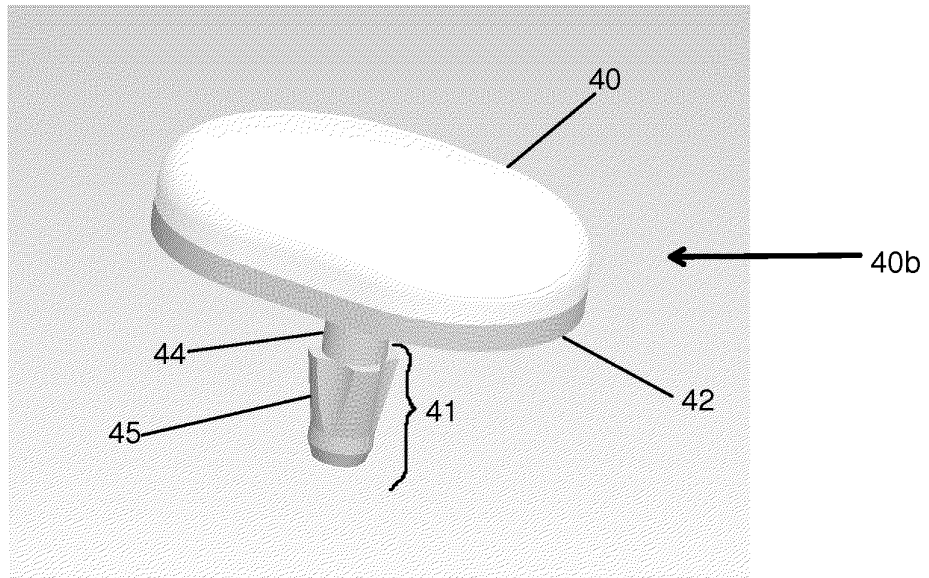


FIG. 3

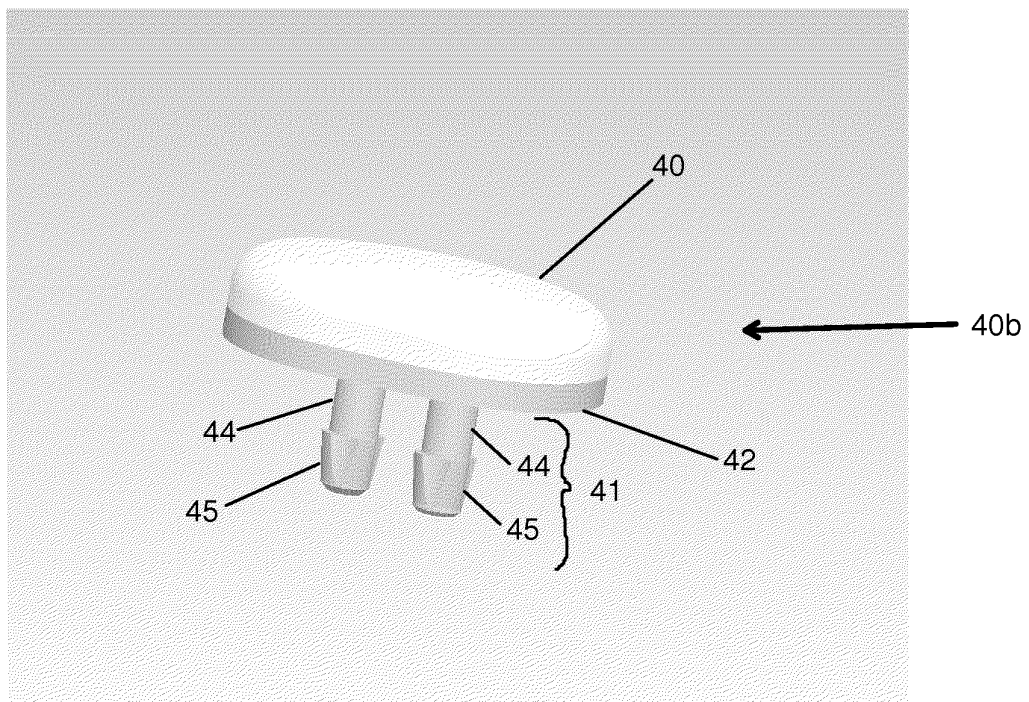


FIG. 4

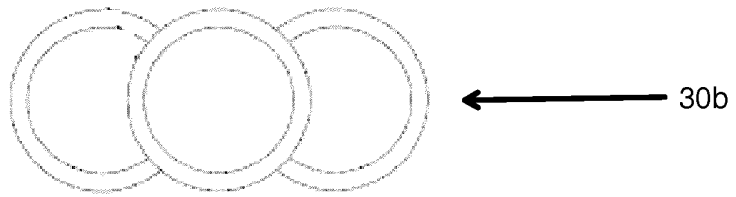


FIG. 5

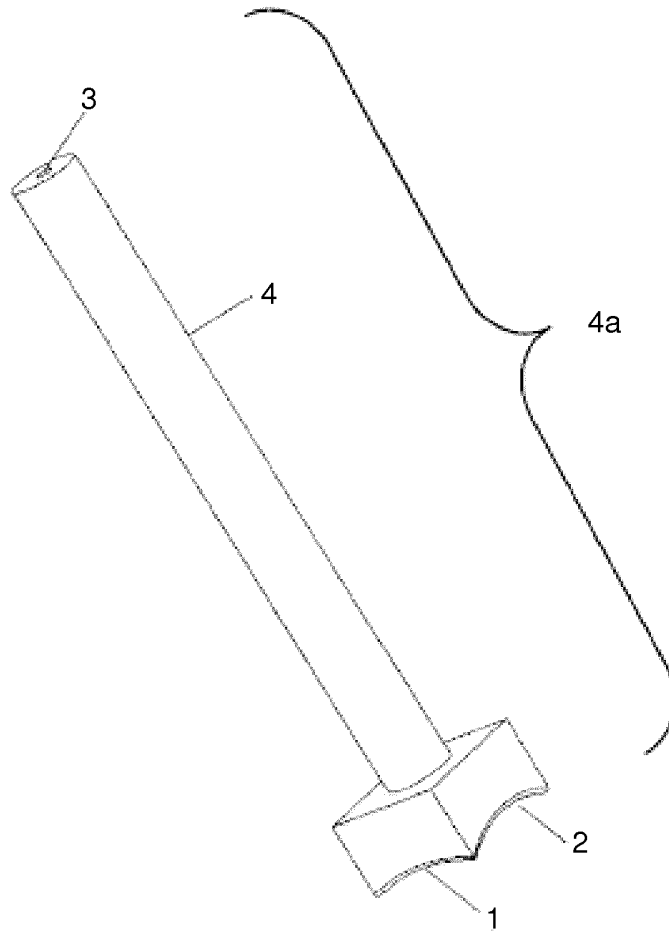


FIG. 6

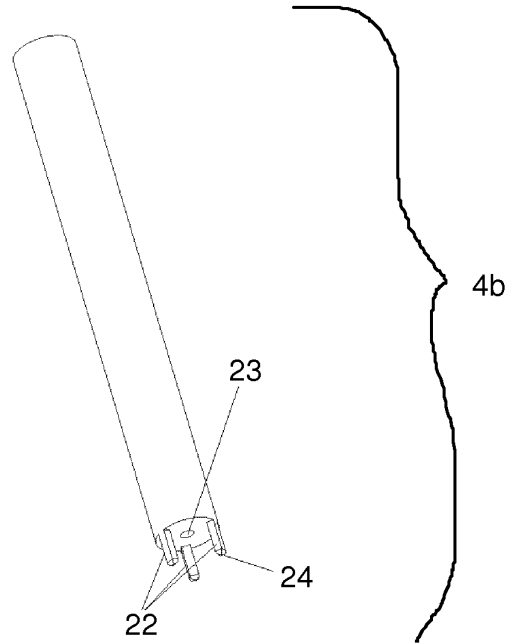


FIG. 7

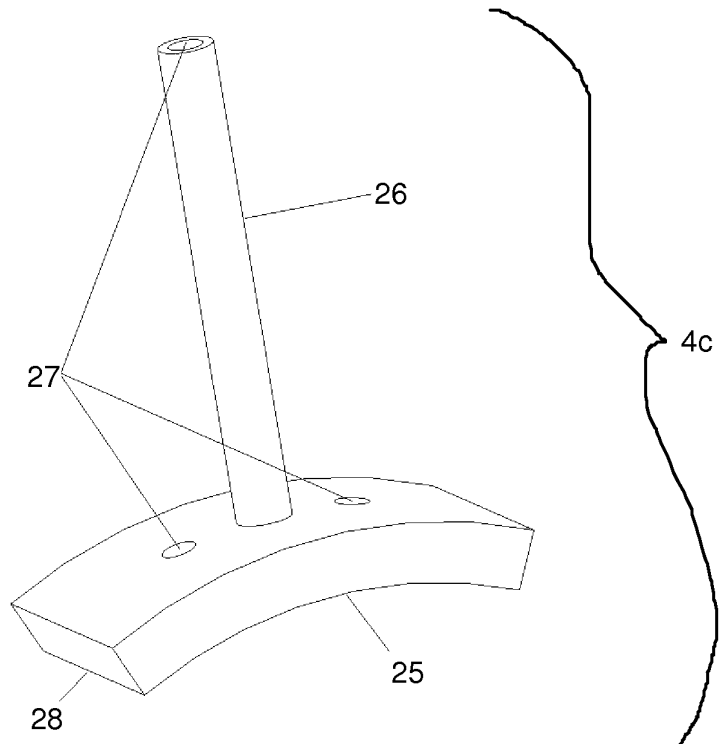


FIG. 8

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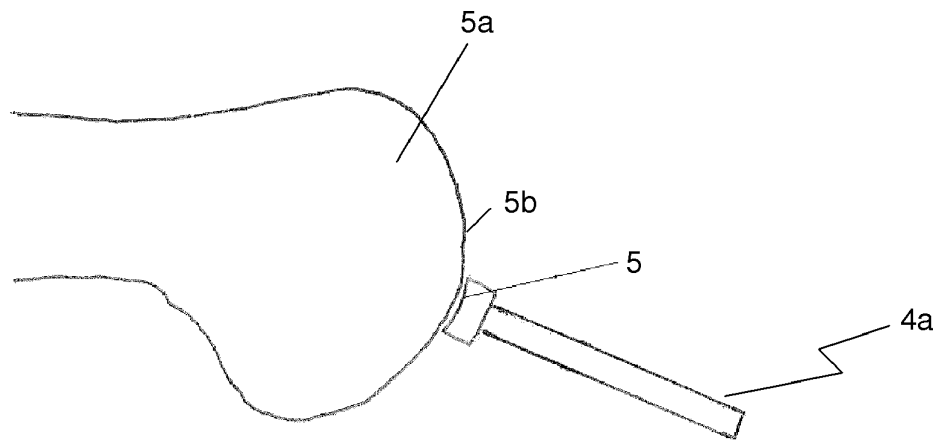


FIG. 9

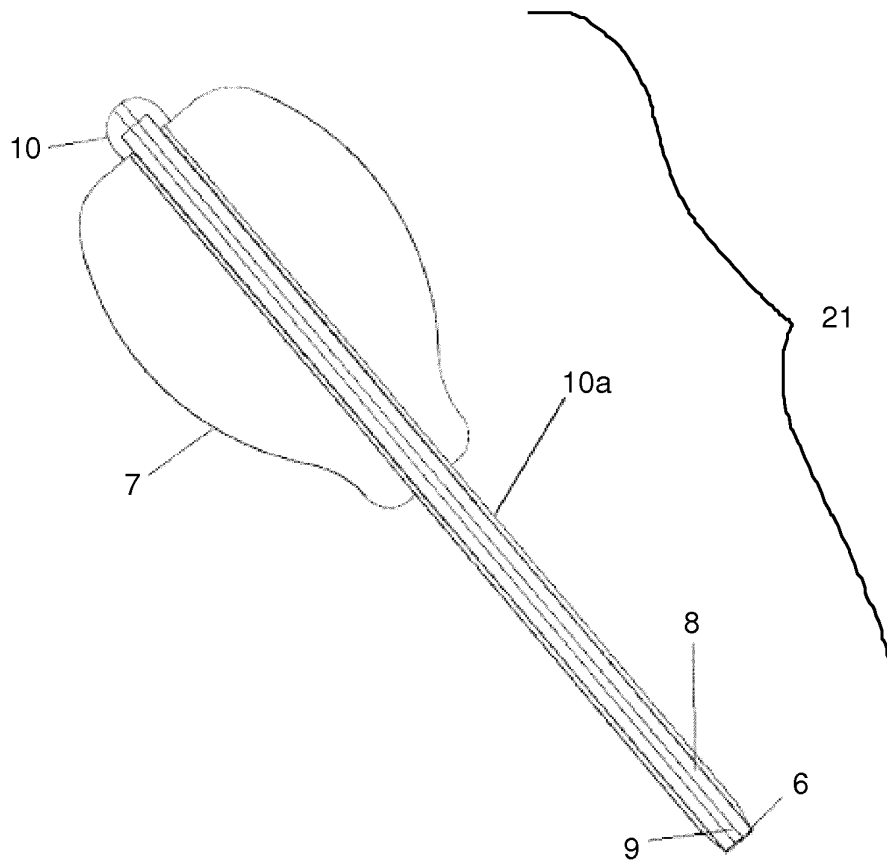


FIG. 10

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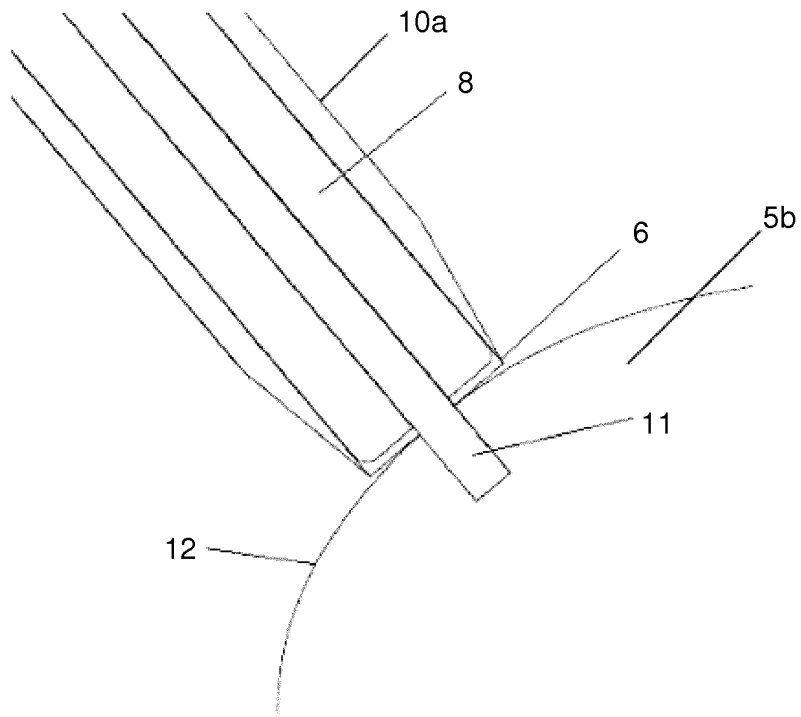


FIG. 11

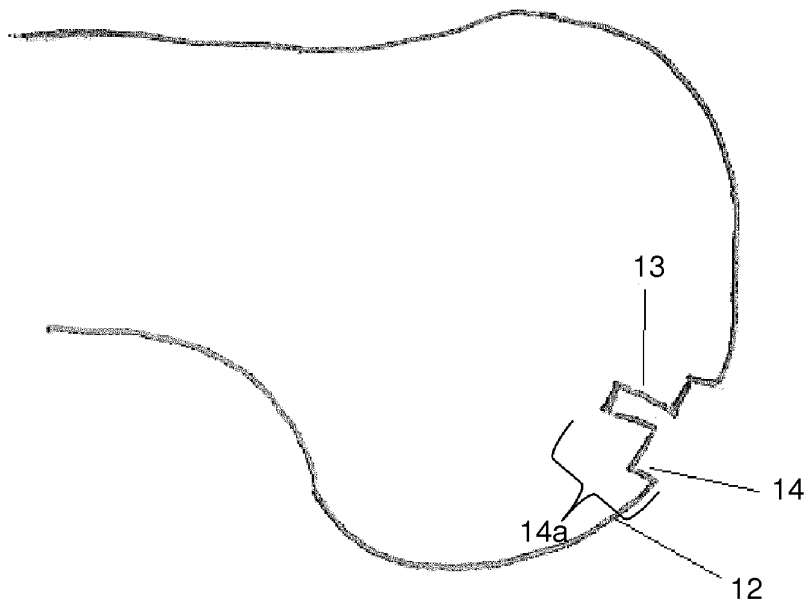


FIG. 12

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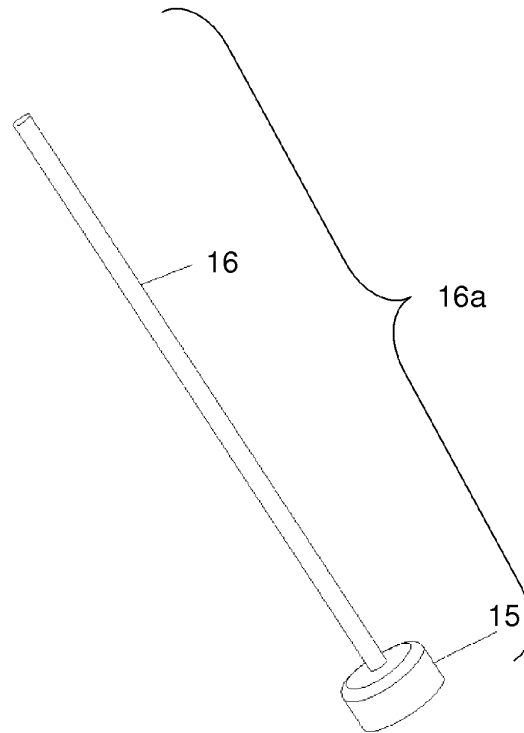


FIG. 13

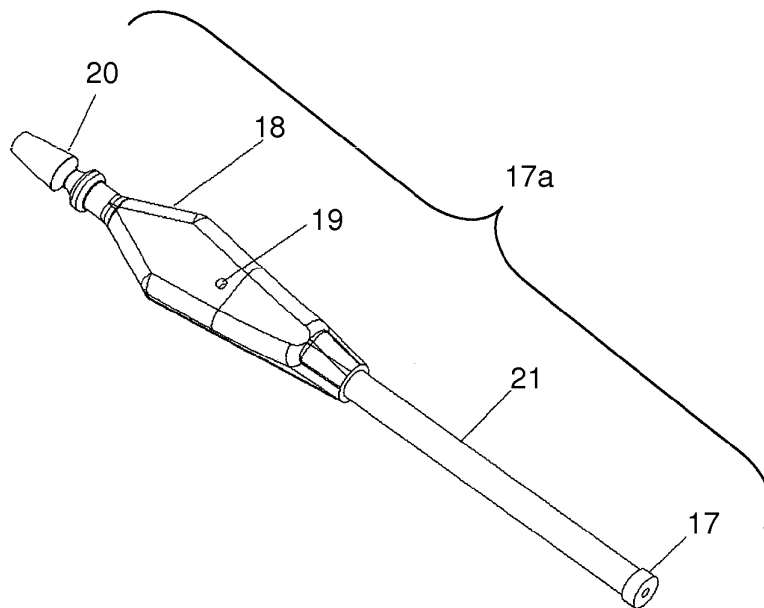


FIG. 14

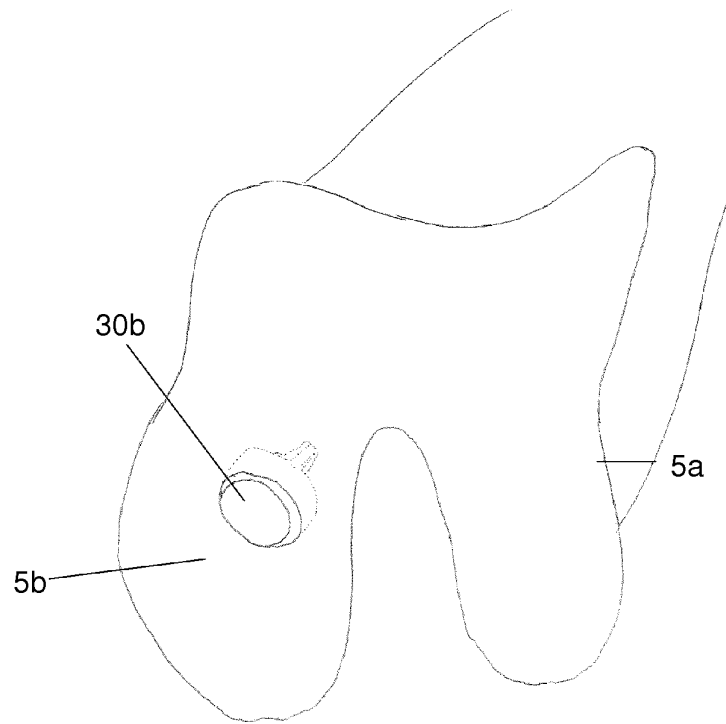


FIG. 15

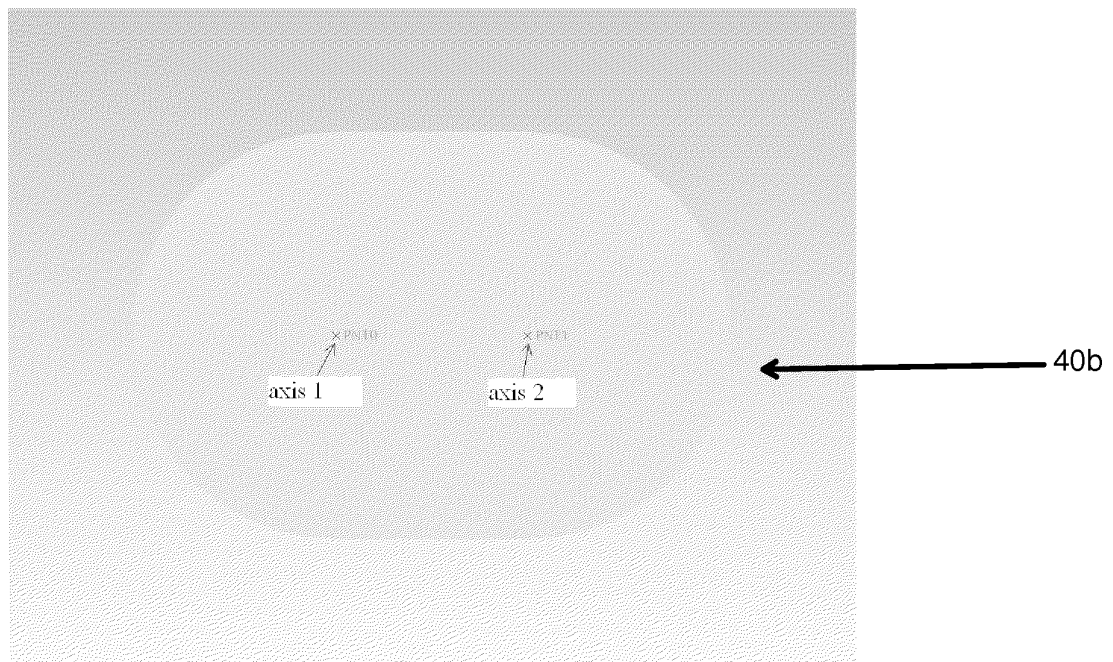


FIG. 16

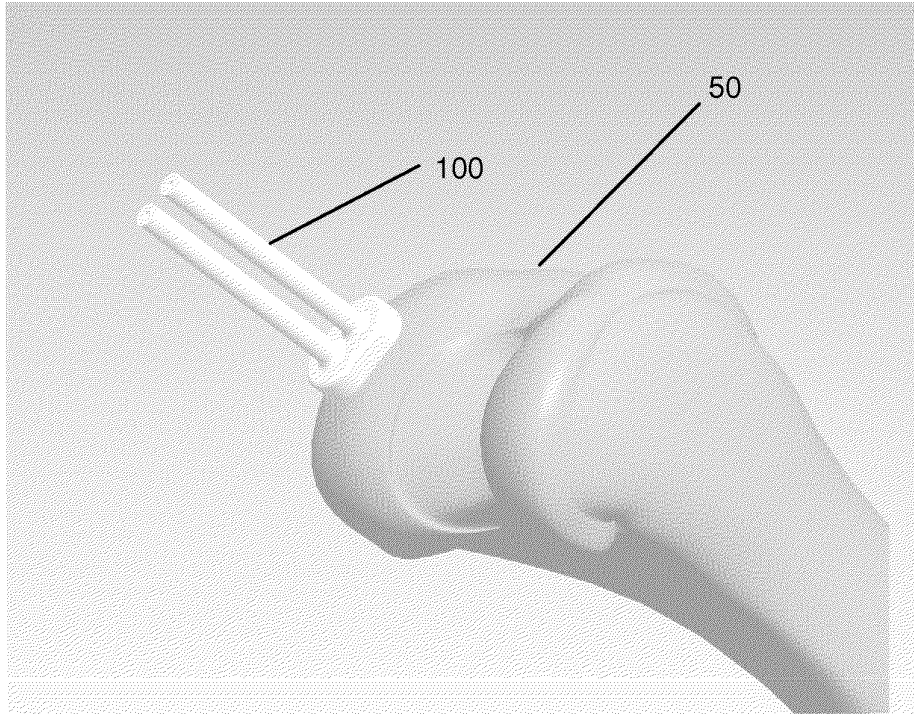


FIG. 17

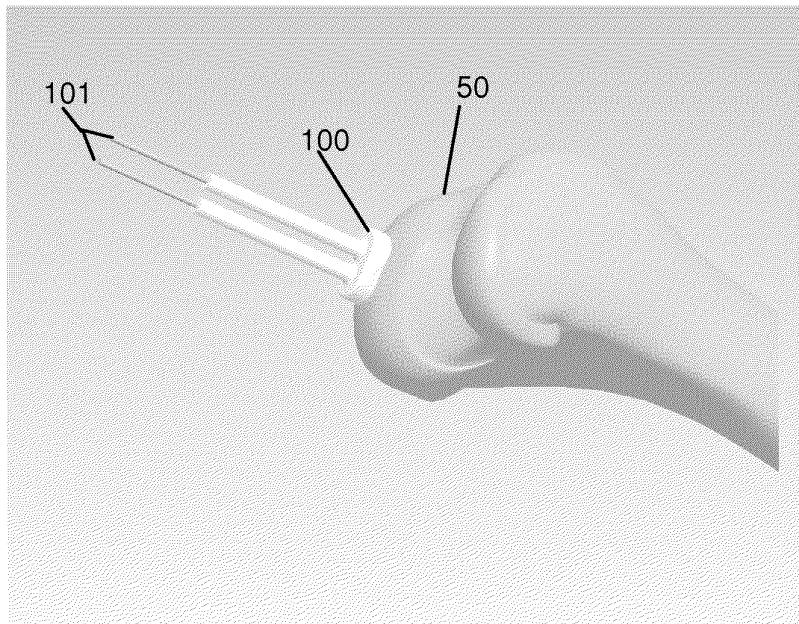


FIG. 18

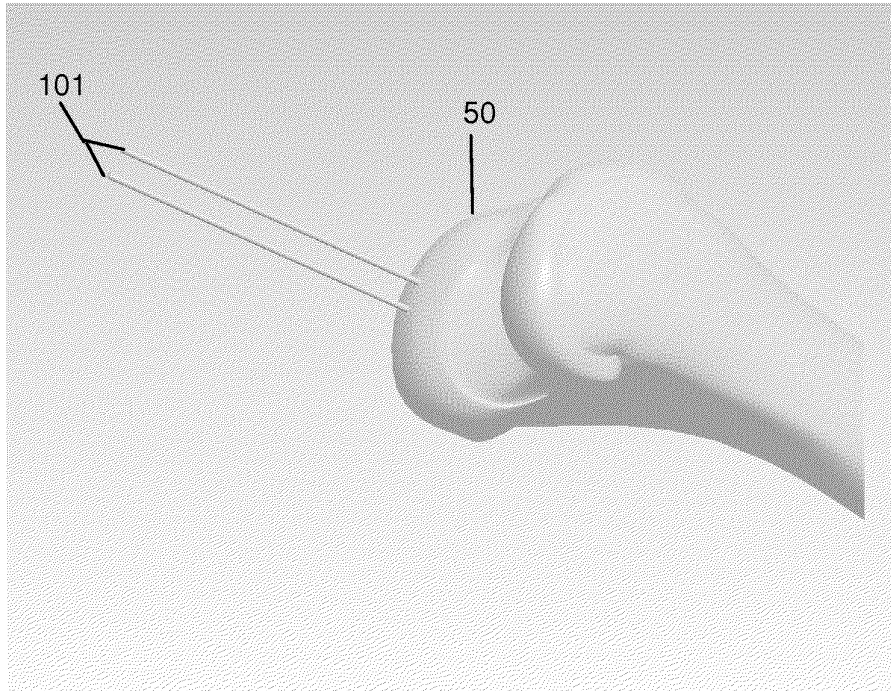


FIG. 19

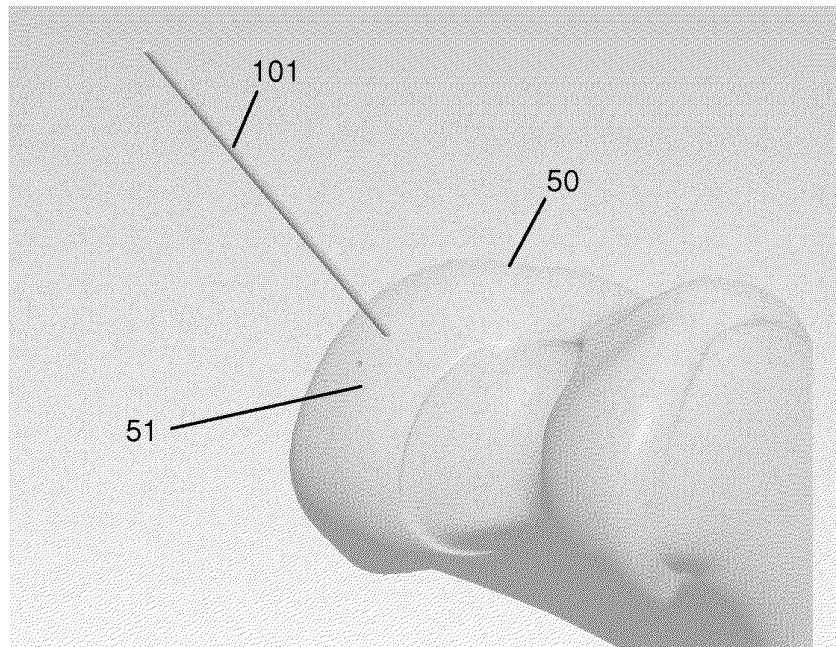


FIG. 20

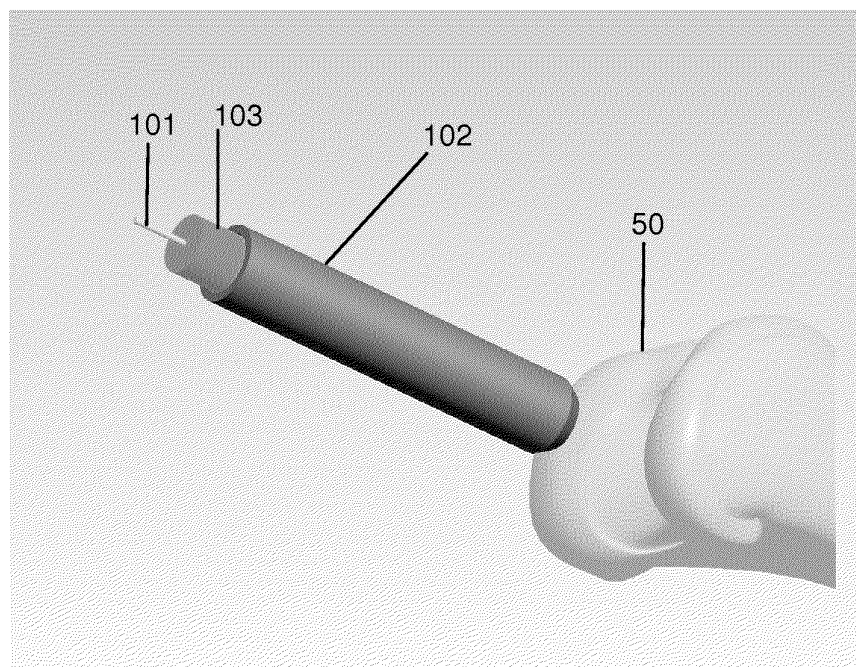


FIG. 21

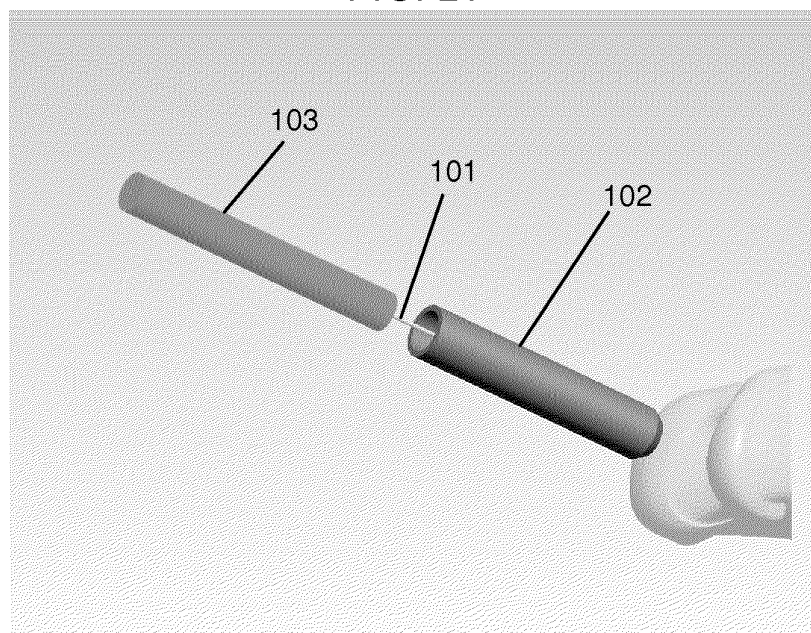
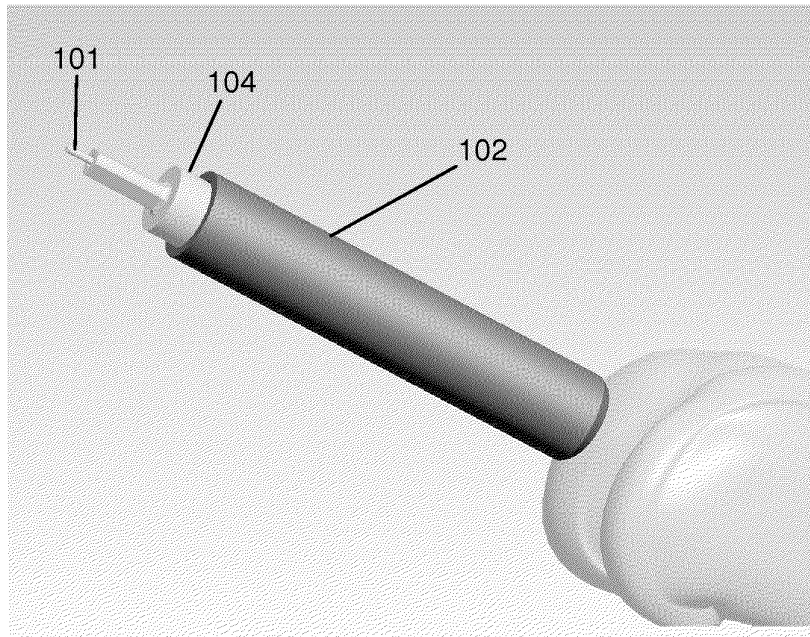
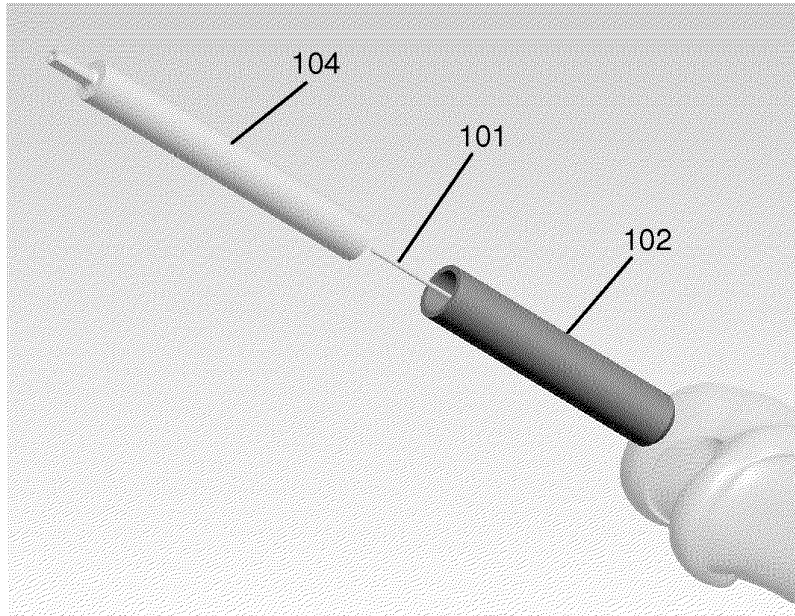


FIG. 22



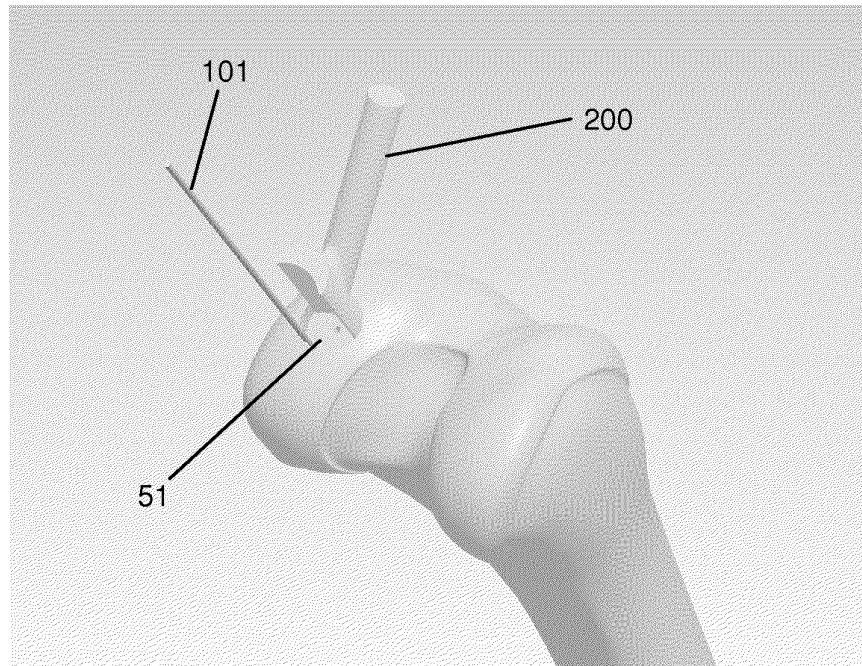


FIG. 25

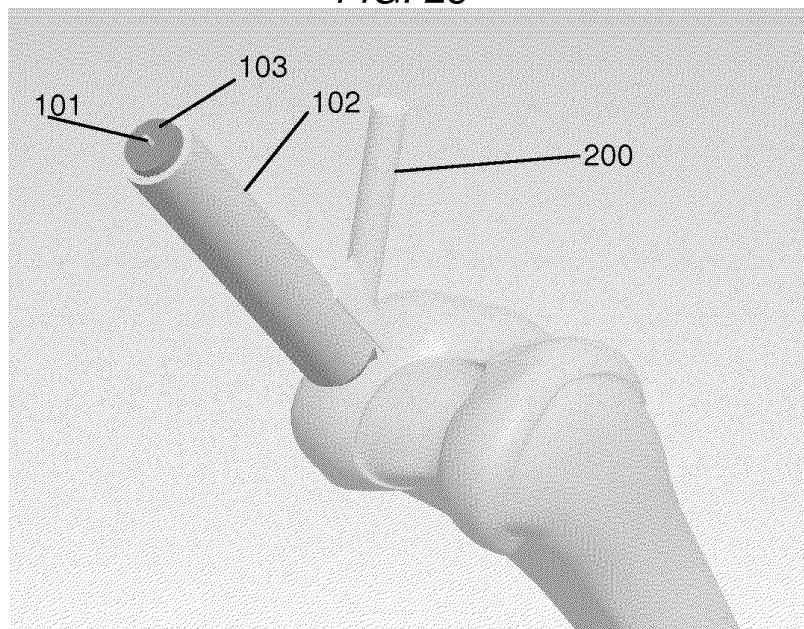


FIG. 26

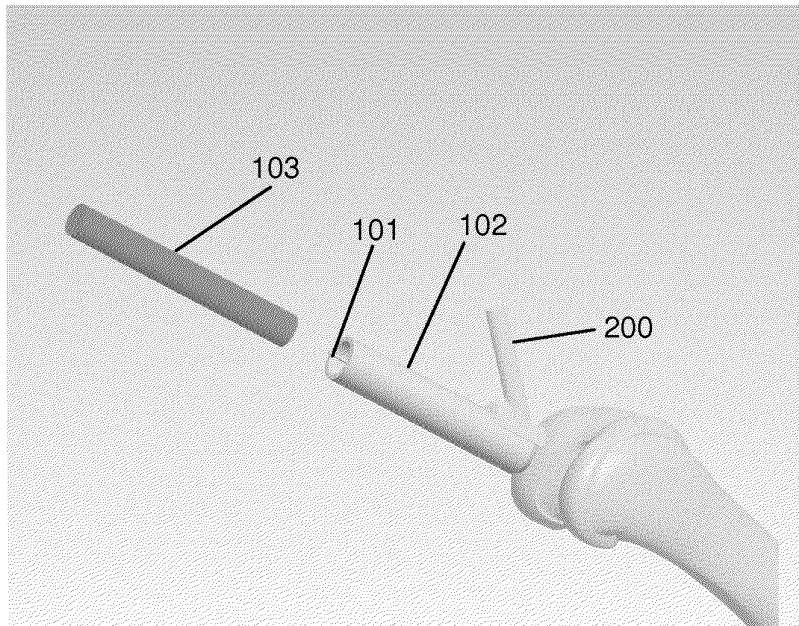


FIG. 27

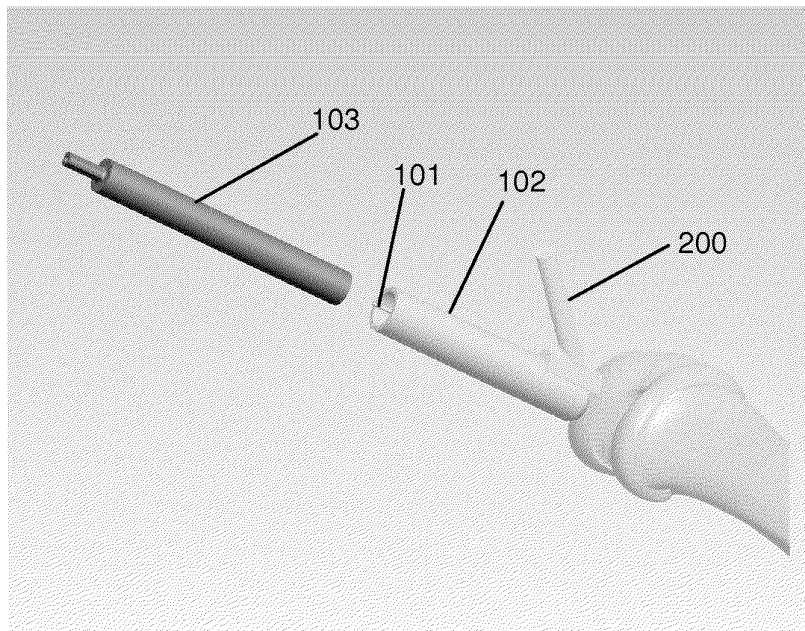


FIG. 28

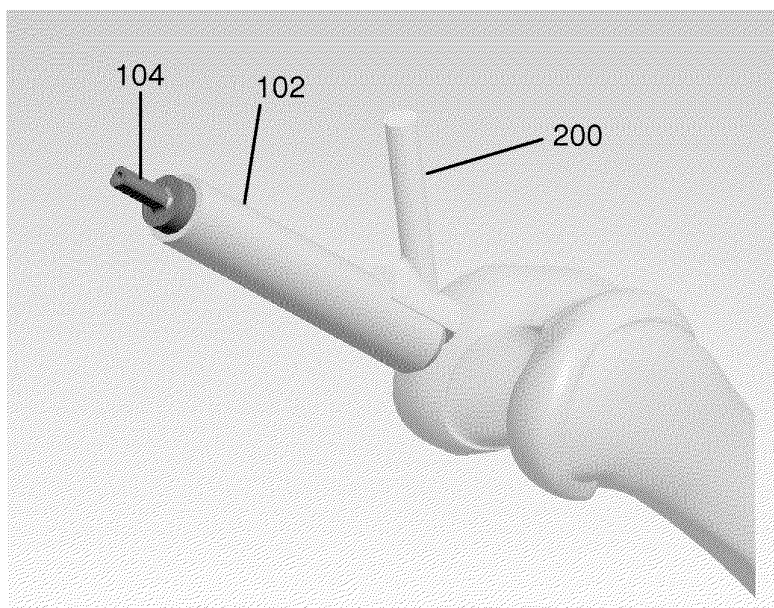


FIG. 29

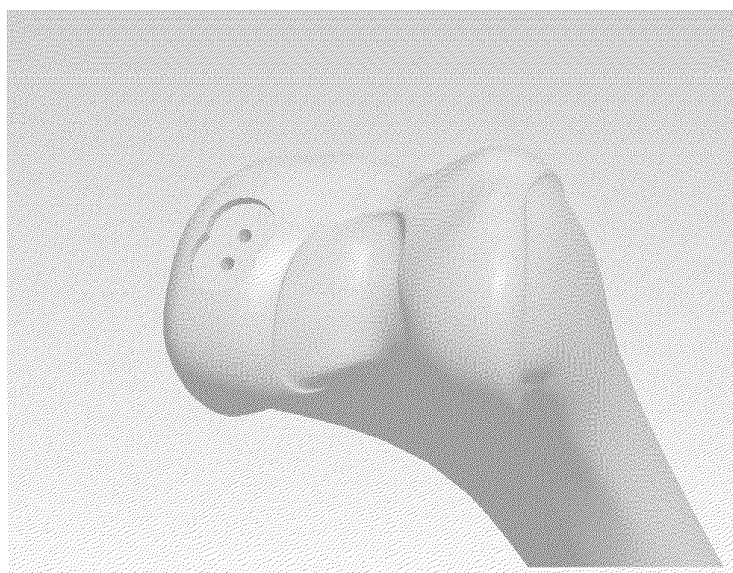


FIG. 30

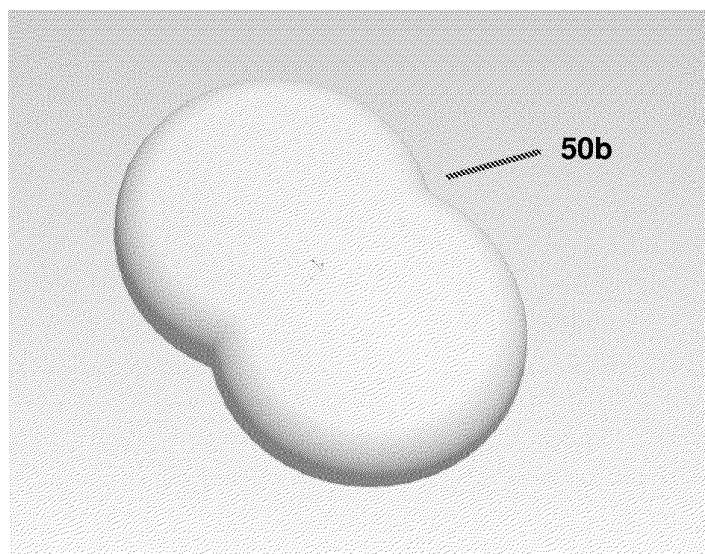


FIG. 31

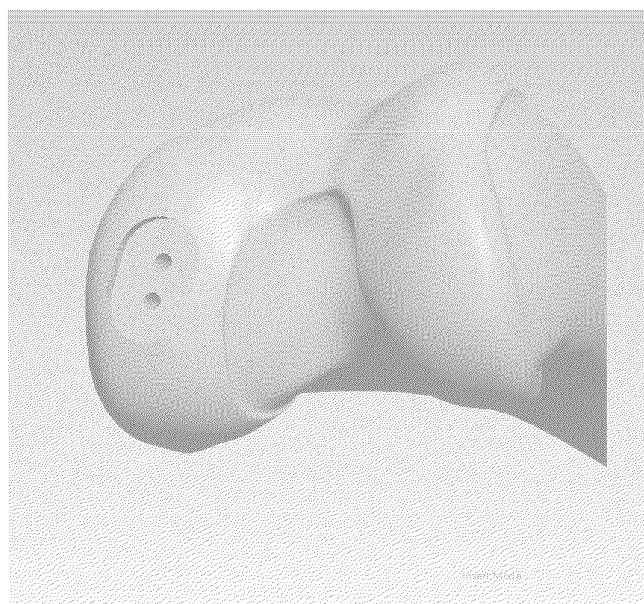


FIG. 32

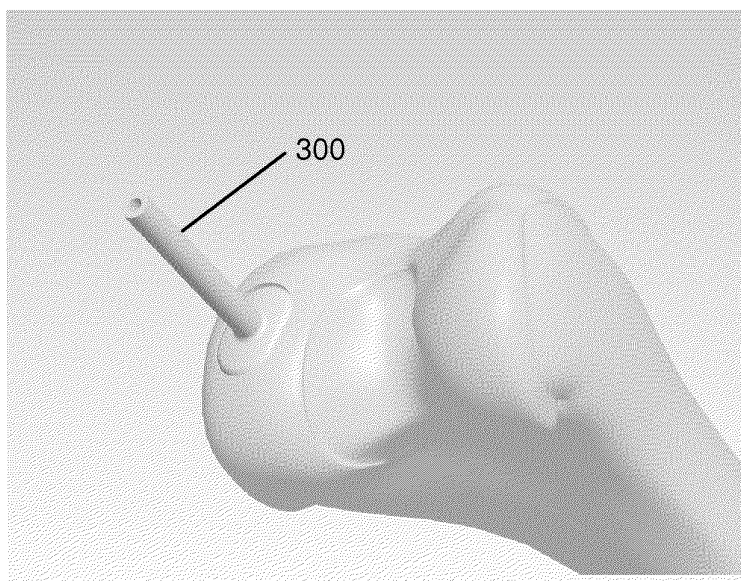


FIG. 33

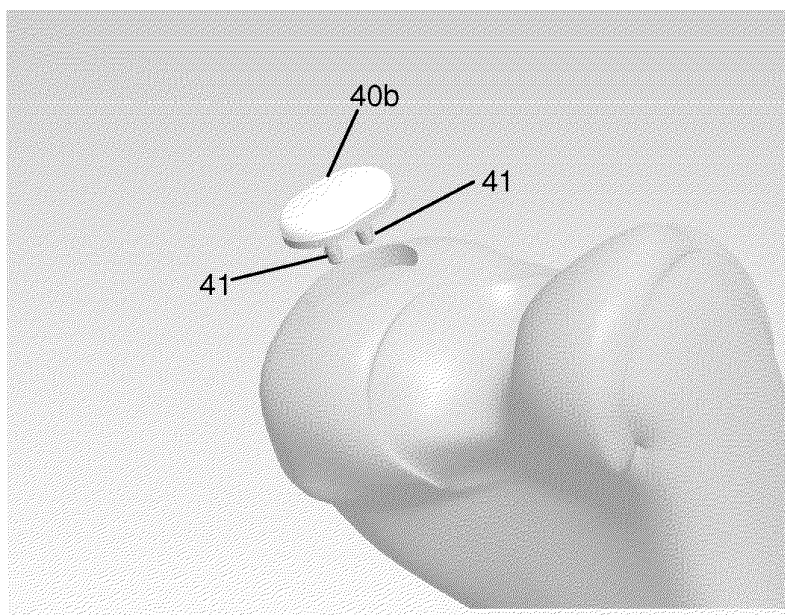


FIG. 34

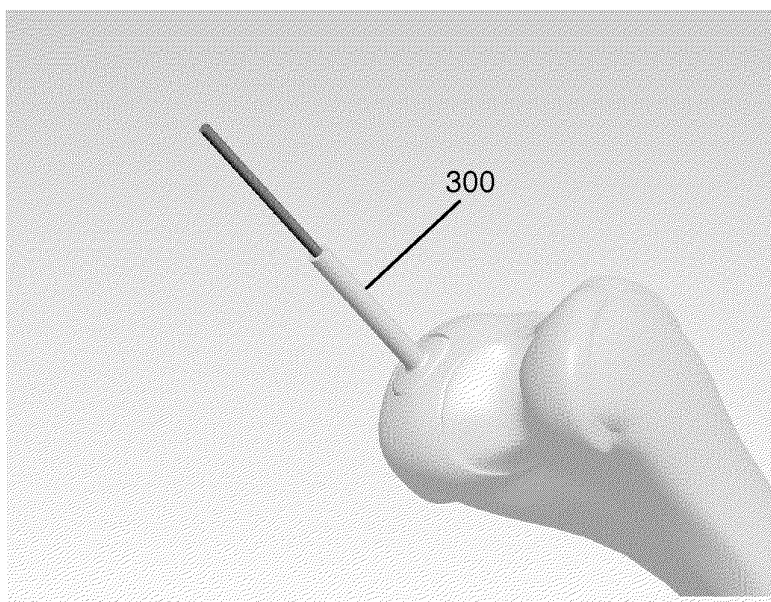


FIG. 35

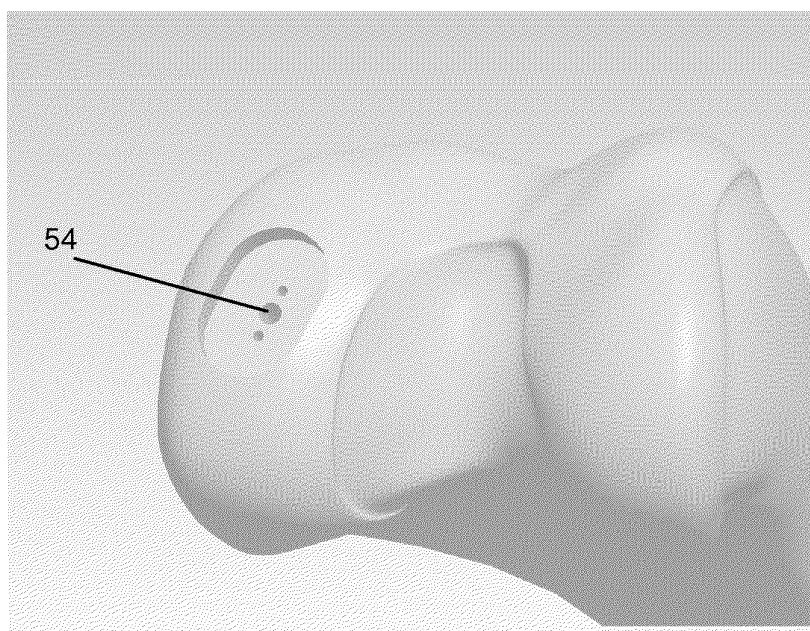


FIG. 36

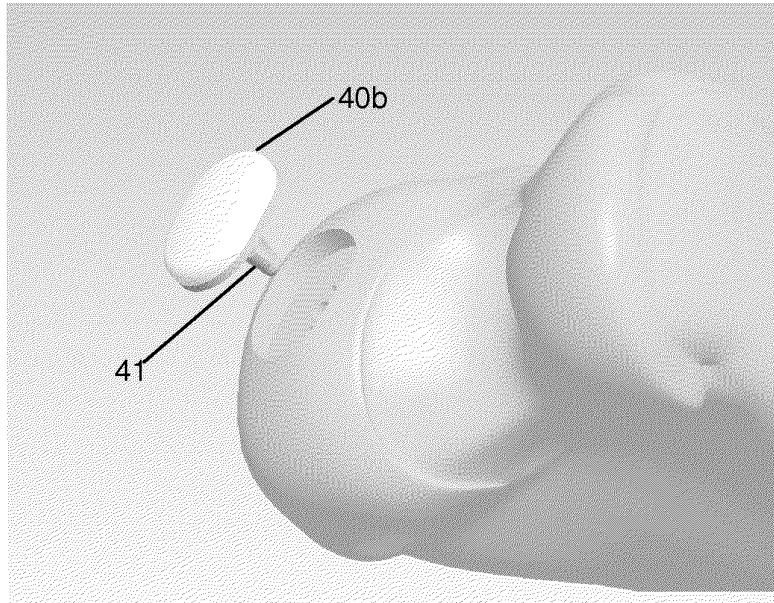


FIG. 37