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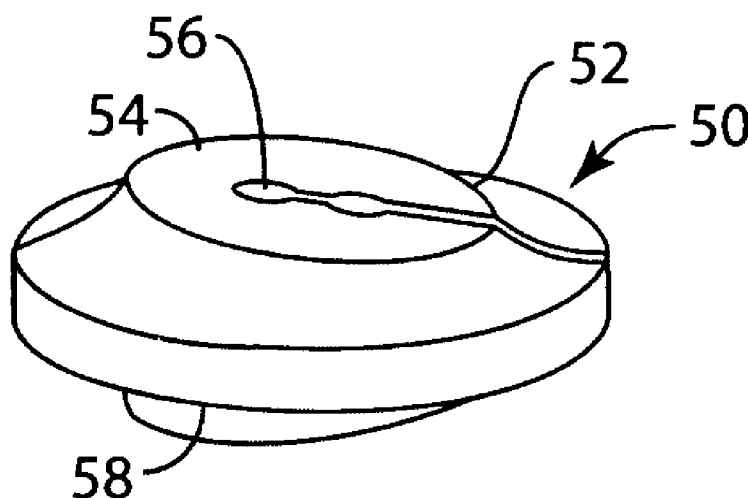


FIG. 4

(57) Abstract: The present invention provides an implantable joint prosthesis configured to replace a natural joint, and methods for implantation. The prosthesis may include a first component implantable in a first bone, having a first bearing surface, and a second component implantable in a second bone, having a second bearing surface which corresponds to the first bearing surface. Each bearing surface may include a flattened section such that when the bearing surfaces are placed in cooperation with one another in a preferred orientation, the flattened sections are aligned. Alternatively, the bearing surfaces may have an asymmetric configuration, with non-congruent surfaces that may enable correction of deformity. Several types of implantable joint prostheses are disclosed, including: carpometacarpal, metacarpophalangeal, metatarsophalangeal, distal interphalangeal, proximal interphalangeal, ankle, knee, shoulder, and hip.

JOINT PROSTHESES

TECHNICAL FIELD

[0009] The present invention relates to orthopedic medicine, and more specifically to methods and devices for the replacement of joints with artificial joint prostheses.

BACKGROUND OF THE INVENTION

[0010] Spinal arthroplasty is an emerging field that offers the promise of restoring and/or maintaining normal spinal motion. The goal of spinal arthroplasty is to reduce or eliminate adjacent segment disease (ASD) by maintaining the normal spinal biomechanics at the operative level. To accomplish this, an artificial cervical prosthesis must duplicate as closely as possible the natural spinal biomechanics, including maintaining the axial height of the disc as well as applying angular adjustment throughout the full range of motion of the natural spine.

[0011] The spine plays an integral role in neural protection, load bearing and motion. The vertebral column provides a strong, yet mobile central axis for the skeleton and is composed of twenty-four vertebral bodies with seventy-five stable articulations. The intervertebral disc is a fundamental component of the spinal motion segment, providing cushioning and flexibility. Adjacent vertebrae are linked together by three articulations: a) the vertebral bodies and disc, which transmit compressive and shear loads and provide flexibility, and b) by two facet joints, which protect the disc from translational shear stress and limit rotation. This "triple joint complex" allows for flexion, extension, lateral bending and rotation of the spine.

[0012] The intervertebral disc is composed of an inner gel-like matrix called the nucleus pulposus and an outer surrounding fibrous band called the annulus fibrosus. When compressive loads are placed on the spine, increased pressure in the nucleus pulposus is transmitted to the annulus, which bulges outwards. The degenerative cascade of the intervertebral disc initially involves desiccation of the nucleus pulposus. With decreased elasticity and dampening from the nucleus, increased loads are transmitted to the annulus and facets. The increased stress on the annulus can lead to fissures and radial tears in its collagen fibers. With further degeneration, this can lead to circumferential bulging of the disc, contained and uncontained disc herniations, and complete desiccation of the disc. This degenerative cascade can result in axial pain, by stimulating pain fibers in the annulus, or compression of spinal nerve roots and/or the spinal cord. This can manifest itself in motor weakness, pain and/or numbness in the arms or legs or both.

[0013] The structure and function of the discs may be altered by a variety of factors including repeated stress, trauma, infection, neoplasm, deformity, segmental instability and inflammatory conditions. Degeneration of the intervertebral disc is the most common etiology of clinical symptoms referable to the spine. Degeneration of the spine is a universal concomitant of human aging. In the cervical spine, neck and arm pain caused by nerve root compression has been estimated to affect 51% of the adult population. Spondylosis of the spine and aging are intimately related, with spondylosis increasing in both prevalence and severity with age. Fortunately, the majority of patients will improve without surgery. In approximately 10-15% of cases, spondylosis is associated with persistent nerve root and spinal cord compression and/or spinal pain, with a small percentage ultimately requiring surgery.

[0014] The most common type of surgery used in the United States for the treatment of degenerative disorders of the spine (spondylosis) is spinal fusion. In an interbody fusion, the diseased disc is removed and either a wedge of bone from the patient's hip, allograft or a metallic spacer is placed between the vertebrae where the disc was removed. This immobilizes the functional spinal unit. While this surgery has been successful in eliminating motion, there are disadvantages associated with it. By converting a mobile, functional spinal unit into a fixed, nonfunctional one, fusion results in increased strain patterns at levels adjacent to the fused segment. When a segment of the spine is fused, there is elimination of motion at the level of surgery. Therefore, the stresses that would normally be absorbed by the disc at the site of surgery are now transferred to adjacent segments. This can cause adjacent segment disease (ASD) to one or several spinal units adjacent to the affected level. ASD can be defined as a clinical syndrome of symptomatic degenerative changes occurring adjacent to a previously fused motion segment. Retrospective studies have estimated that ASD can occur in the cervical spine at a rate as high as 2.9% per year with a projected survivorship rate of 26% at 10 years (Hilibrand AS, Carlson GD, Palumbo M, Jones PK, Bohlman HH: Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. *J Bone Joint Surg (Am)* 81:519-528, 1999).

[0015] In the cervical spine, thousands of North Americans undergo surgery for cervical spondylosis each year. The majority of these procedures involve an anterior discectomy with decompression of the spinal cord and/or nerve root. The primary indication for surgery in the management of cervical spondylosis is radiculopathy, myelopathy and/or neck pain. Following the discectomy, an anterior interbody fusion is commonly performed. Autologous bone harvested from the iliac crest or cadaveric bone is most commonly used to fill the space created by the removal of the disc. A number of other solutions have been suggested, including metallic devices such as fusion cages or other types of spacers, xenografts such as bovine bone, and biological strategies such as the use of growth factors. The graft for the interbody fusion can be shaped to correct underlying deformity of the cervical spine. By contouring the graft one can restore lordosis to a straight or kyphotic spine.

[0016] A more recent alternative to spinal fusion is replacement of the damaged disc with a motion preservation device, which includes either a nucleus or total disc replacement (TDR). The rationale for the development of the artificial disc is to prevent adjacent segment disease. Artificial disc devices can be broadly divided into two categories, those that replace

the nucleus only, leaving the annulus and vertebral body end plates intact and those that involve replacement of the disc and addition of prosthetic end plates. Both strategies are directed at restoration of intervertebral disc function. Prosthetic nuclei are described, for example, in United States Patent Nos. 5,047,055 and 5,192,326. United States Patent application US2002/0183848 also discloses a prosthetic spinal disc nucleus that has a hydrogel core surrounded by a constraining jacket.

[0017] There are several different types of prosthetic devices for use in the cervical or lumbar segments of the spine designed for TDR. For example, the Prodisc™ and the Charite™ disc are composites of cobalt chromium end plates with a polyethylene core. The Prodisc™ is described in United States Patent No. 5,314,477 and the Charite™ disc is described in United States Patent Nos. 5,401,269 and 5,556,431. The Prestige™ disc is another type of artificial disc that comprises a metal on metal design with a ball and trough articulation. Another type of artificial disc that is gaining popularity in the cervical spine is the Bryan® disc, described in several United States Patent applications including 2004/0098131; 2004/00544411; and 2002/0 128715. The Bryan® disc is a composite artificial disc with a low friction, wear resistant, elastic nucleus that articulates with two circular metal plates.

[0018] Presently, there are at least four artificial cervical disc replacement systems undergoing clinical trials worldwide. These include unconstrained devices, such as the PCM cervical disc. These unconstrained devices do not have mechanical stops to limit their range of motion. The Bryan® Cervical disc, the Prodisc™ C and the Prestige™ LP cervical disc systems limit range of motion to varying degrees. These systems can be considered semi-constrained, in that there are mechanical stops outside the normal range of motion. Thus far, only the Charite™ disc has been approved for use in the United States.

[0019] Artificial spinal discs have been implanted for the management of degenerative disc disease producing radiculopathy, myelopathy and/or axial spinal pain. More recently, artificial discs have been adopted for the treatment of trauma. The aim of TDR is to reproduce the biomechanics of the natural disc. Early clinical and biomechanical studies with single and multi-level disc replacement have reported favorable clinical outcomes and preserved range of motion at the level of surgery. Preservation of range of motion, however, while an important feature of an artificial disc, is only a single measure of spinal biomechanics. The effect of the disc on angulation at the operative level, the average disc

space height, and overall spinal alignment (sagittal and coronal balance) also needs to be considered.

[0020] While the introduction of artificial discs has led to many successful surgeries, there are still problems associated with the current discs. For example, all of the current artificial cervical discs have a fixed height across the entire disc. The artificial discs presently available can have issues with focal kyphosis or kyphosis at adjacent segments of the spine after the patient post-operatively reassumes an upright position, supporting the weight of the head and body. For instance, with the Bryan® disc, the end plates are allowed to move freely about all axes of rotation, allowing the end plate to assume a position resulting from the forces exerted on the implant by the head and neck. At times, this position may be significantly different from the positioning of the disc intra-operatively. Several published studies with the Bryan® cervical disc replacement system have reported a tendency for the end plates of the prosthesis and the alignment of the cervical spine to develop kyphosis following surgery. [Pickett GE, Mitsis DK, Sekhon LH et al. Effects of a cervical disc prosthesis on segmental and cervical spine alignment. *Neurosurg Focus* 2004;17(E5):30-35; Johnson JP, Lauryssen C, Cambron HO, et al. Sagittal alignment and the Bryan® cervical disc. *Neurosurg Focus* 2004;17(E14):1-4; Sekhon LHS. Cervical arthroplasty in the management of spondylotic myelopathy: 18 month results. *Neurosurg Focus* 2004; 17(E8):55-61.] This kyphotic angulation of the prosthesis has been attributed to the passive (unconstrained motion with a mobile nucleus and variable instantaneous axis of rotation) design of the implant. None of the current TDR systems addresses this major complication.

[0021] A significant number of patients with spinal disc disease have a loss of sagittal alignment of the spine as a result of the degenerative process. In addition, varying degrees of coronal imbalance can also occur. None of the available artificial disc replacement systems are designed to restore normal alignment to a spine that is straight, which have focal/global kyphosis or coronal deformity. Existing artificial disc replacement systems that are inserted into either a straight, kyphotic or angulated segment are likely to take on the angle and local biomechanics determined by the facets, ligaments and muscle forces. As such, patients with a pre-operative straight spine may develop post-operative kyphosis, and patients with a pre-operative kyphosis may have a worsening of the deformity post-operatively. Kyphosis of the spine has been implicated in segmental instability and the development of clinically significant degenerative disease. Several clinical studies have described that a change in the

sagittal or coronal balance of the spine can result in clinically significant axial spinal pain as well the initiation and/or the acceleration of ASD. [Kawakami M, Tamaki T, Yoshida M, et al. Axial symptoms and cervical alignment after anterior spinal fusion for patients with cervical myelopathy. *J Spinal Disord* 1999;12:50-60; Harrison DD, Harrison DE, Janik TJ, et al. Modeling of the sagittal cervical spine as a method to discriminate hypolordosis: results of elliptical and circular modeling in 72 asymptomatic subjects, 52 acute neck pain subjects, and 70 chronic neck pain subjects. *Spine* 2004;29:2485-2492; Katsuura A, Hukuda S, Saruhashi Y, et al. Kyphotic malalignment after anterior cervical fusion is one of the factors promoting the degenerative process in adjacent intervertebral levels. *Eur Spine J* 2001;10:320-324; Ferch RD, Shad A, Cadoux-Hudson TA, Teddy PJ. Anterior correction of cervical kyphotic deformity: effects on myelopathy, neck pain, and sagittal alignment. *J Neurosurg* 2004; 100:S13-S19; Katsuura A, Hukuda S, Imanaka T, Miyamoto K, Kanemoto M. Anterior cervical plate used in degenerative disease can maintain cervical lordosis. *J Spinal Disord* 1996; 9:470-476.]

[0022] Attempting to provide a deformity correction by simply altering the end plate or the nucleus of an artificial disc, while still maintaining free movement about all axes of rotation, may not be sustainable as the forces exerted by the head and body on the artificial disc could counteract the desired correction. To provide a sustainable correction, some limitation on the axes of rotation is required. From a design perspective, the goal is to design an artificial disc that is able to correct deformity (coronal and sagittal), has mechanical stops outside the normal range of motion (semi-constrained), and preferably has variable instantaneous axis of rotation (IAR).

[0023] The limits on the axes of rotation can fall into two categories. One is to provide correction using a permanent rotation or translation of an axis to support the correction. This is accomplished using the geometries of the core and end plates themselves and is referred to the Geometric Constraint category. The second is to keep free range of motion about all axes but provide the correction using a material support. This type of design provides the correction by the imposition of a deformable material in the plane of correction for normal rotation in that plane. This is the Material Constraint category of designs.

[0024] Degenerative disc disease is a major source of morbidity in our society. It can lead to serious economic and emotional problems for those afflicted. Thus, there is a need for an

artificial disc that can alleviate both symptoms and correct deformity (sagittal or coronal or both) of the spine.

BRIEF SUMMARY OF THE INVENTION

[0025] There are a number of different strategies that can be used with disc replacements to address the need for alignment/deformity correction in the spine. With most of the available discs, the angle of disc insertion can significantly alter the orientation of the prosthesis. This is related to bone removal and end-plate preparation for the prosthesis. By changing the angle of insertion, the disc can be placed either in parallel or at an angle to the disc space. Unfortunately, by changing only the angle of insertion, one cannot correct an underlying deformity of the spine. Simply changing the angle of insertion is not adequate to compensate for a device that does not have sufficient off-center load bearing support or structure to maintain the correction of the deformity.

[0026] A strategy to correct lordosis in the lumbar spine has been utilized by the Link-Charite™ and Prodisc™ lumbar disc replacement systems by using wedge-shaped end plates. A wedge-shaped end plate has also been used in at least one case with the Bryan® cervical disc system. However, wedge-shaped end plates are not routinely available at the present time for cervical disc replacement systems. The strategy of using wedge-shaped end plate(s) involves forming a differential thickness across the end plate. The articulation between the ball and socket/trough or the nucleus and end plates is not altered, which is an advantage because the complex geometry of how the prosthesis provides motion is not altered. The disadvantage, however, is that this strategy is not forgiving if an error is made with either an overly corrected end plate or an end plate that is not corrected enough. The revision of the end plate can be difficult at the time of surgery and may even preclude the disc space from receiving a disc replacement. As most systems have a coating on the end plates that promote bony ingrowth, revision at a later date may be extremely difficult or even impossible. As there are two surfaces to the end plate, an outer surface that contacts the bone and an inner surface that articulates with the nucleus or core, it is conceivable that by changing the location or geometry of the inner surface, one could alter the center of rotation. This would be most applicable to prostheses that function as a "ball and socket" articulation. By changing the location of the "socket" or trough, this could alter how the prosthesis impacts alignment at the level of the disc.

[0027] An alternate method of achieving lordotic correction is by changing the nucleus or inner core. The biggest advantage of this approach is that the nucleus or core can be more easily interchanged or revised. Intra-operatively, instruments can be used to gage the need for and amount of correction and the appropriate nucleus can be inserted. By designing the correction into the nucleus, the surgeon is provided with flexibility and ease of insertion, and the ability for revision at a later date, which the other methods do not provide.

[0028] The invention includes a novel artificial disc that provides the normal range of motion of the natural intervertebral disc, along with the ability to correct deformity of the spine. The proposed disc allows for semi-constrained range of motion of the functional spinal unit. It will reproduce the kinematics of the pre-operative normal spine. It will possess maximum durability and biocompatibility, and a means for integrating itself into the spine bony structure for long-term stability. Its insertion will be safe, simple, and ideally not add significantly to surgical time compared with the current procedures. In contrast to the existing disc replacement systems, it will allow the surgeon to correct deformity while maintaining natural kinematics of the spine.

[0029] A major advantage of this system will be that the nucleus may be easily revisable. For instance, in most cases where the Bryan[®] disc needs revision, the entire disc, including the end plates, must be removed. In cases where the alignment of the spine changes with time, especially in children and young adults, this new disc replacement system will allow revision of the nucleus, if needed.

[0030] The present invention addresses the problems associated with the artificial discs of the prior art by providing an artificial disc that provides for correction of spinal alignment deformity.

[0031] The artificial disc of the present invention is useful for the treatment of degenerative disc disease including correcting spinal deformities such as kyphosis, lordosis, and scoliosis.

[0032] It is an object of one aspect of the invention to provide an improved artificial disc replacement that maintains motion at the operative level and reduces the incidence of adjacent segment disease.

[0033] In one aspect of the invention, the artificial disc incorporates an artificial nucleus having an asymmetrical maximum vertical axis. The present invention includes a non-

spherical nucleus with a maximum point of load-bearing and height in a non-central location (a differential in the anterior/posterior height of the nucleus).

[0034] In one embodiment, the nucleus is adapted to provide lordotic correction to a damaged spinal segment. In this case, the axis of greatest height is positioned in the anterior part of the nucleus.

[0035] In another embodiment, the nucleus is adapted to provide kyphotic adjustment. In this case, the maximum height axis is positioned in the posterior part of the nucleus.

[0036] In yet another embodiment, the asymmetrical nucleus can be used for the treatment of scoliosis. To achieve this, the axis of maximum height is lateral (parasagittal) to the middle of the disc.

[0037] According to another aspect of the present invention, an artificial nucleus, or core, is provided for use in an artificial disc. The nucleus comprises a body of biocompatible material, having the greatest vertical height either at the central vertical axis or at a vertical axis other than the central vertical axis.

[0038] In another embodiment, the body is spherical or ovoid (egg-shaped), having convex upper and lower surfaces and a non-central maximum height vertical axis. In an alternative embodiment, the nucleus is in the form of a truncated cylinder where the top is cut at a plane that is not parallel to the base. In another preferred embodiment, the disc is essentially circular.

[0039] It has been found that nucleus body designs with a completely rounded surface (not necessarily spherical) have issues with reliably maintaining correction when exposed to the variable forces of the head and neck. To address this issue, a segment or section that is flat or which has a contour different from the adjacent surface, can be formed in the central region of the nucleus body. This section will be referred to as a flattened section, which is meant to refer to any contour that is not the same as the adjacent surface(s) of the nucleus. Such a flattened surface can be planar or it can have other shapes such as a slight convex or concave shape with a radius of curvature different from the adjacent surface. Such a flattened surface could also be in the shape of a compound curve or other complex shape. In the example of providing a lordotic correction, the flattened segment can be angled relative to the superior end plate of the inferior vertebral body with the height of the anterior part being greater than the height of the posterior part. The overall shape of the nucleus body is still

asymmetric, but the flattened segment is incorporated to provide a reliable correction of the deformity. This flat segment provides stabilization of the correction by resisting misalignment moments acting through the nucleus. If the flattened segment is not of adequate size, there may be a tendency for the correction to disappear in the presence of an anterior load or for a hyper-lordotic over correction in the presence of a posterior load (during lordotic correction). An additional advantage of incorporating a flat segment in the nucleus is to provide surface contact over that area during small motions about the resting, neutral position of the device. This should help reduce wear on the device.

[0040] In another embodiment, the nucleus or core could be hemispherical in shape with a flattened inferior surface that fits in an opening or trough formed in the lower end plate. Alternatively, the nucleus is asymmetric in that it has a greater vertical dimension or thickness on the anterior aspect than on the posterior aspect in order to provide a lordotic correction. The superior surface of the nucleus can have a flattened portion. The flattened portion may incorporate a concave segment, but can have the other configurations as mentioned above. The shape of the trough can be such that it defines the outer limits of rotational or translational movement of the nucleus relative to the lower end plate. This design allows for greater ease of insertion of the nucleus without undue distraction of adjacent vertebrae because the trough could be open at one end to allow for the nucleus to be inserted, and then a stop could be inserted in the trough to maintain the nucleus in the trough.

[0041] In another embodiment, instead of ovoid shaped nucleus, an elongated or “sausage type” shape can be used, which has spherical or ovoid end sections and a flattened or cylindrical center section. When a nucleus of this shape mates with a cylindrical bearing surface on the upper end plate, both surface and line contact are provided during lateral bending as well as in flexion and extension. When this type of elongated nucleus is used, a corresponding end plate trough in the lower end plate can be provided that allows for axial rotation with stops beyond the limits of normal motion. This trough can have the shape of a “bow tie,” “dog bone” or the like. The trough can be slightly oversized compared with the nucleus to allow limited anterior/posterior and medial/lateral translation. Additionally, the bearing surface of the end plate trough can be curved upwardly at the outer limits of movement of the nucleus. This feature forces the nucleus to rise upwardly when it rotates and cause an axial distraction of the device that forces the adjacent vertebral bodies apart and loads the tissues between them, resulting in a gradual stop to the motion. The translation of

the core within the trough attempts to preserve the mobile instantaneous axis of rotation of the natural disc.

[0042] In another embodiment, an elongated or “sausage type” shape nucleus is shaped so that the superior surface of the nucleus possesses a depression or valley formed in the flattened section, which extends along the sagittal plane. This can be accomplished, for example, by removing material from the central region of the flattened segment of the nucleus, creating a valley between the side portions. The side portions are contiguous with the remaining elements of the nucleus, and do not protrude in the vertical plane. The side portions are preferably symmetrical about the sagittal plane.

[0043] Additionally, the trough can be open at the anterior end to allow for insertion of the nucleus without excessive distraction of the adjacent end plates. A locking mechanism can be provided to prevent the nucleus from being expelled from the trough after insertion of the nucleus.

[0044] In another aspect of the invention, a novel type of end plate is provided. Unlike other end plates, which require extensive preparation of the vertebral body surface, the present end plates have an essentially flat outer or vertebral-contacting surface that allows them to be easily inserted. In a preferred embodiment, the surface is a semi-round plate having at least one unidirectional keel for anchoring the plate in position. The outer surface of the end plate may be treated in a way that promotes bony ingrowth to enhance stability of the end plate *in situ*. In one embodiment, the outer (vertebral-contacting) surface and the inner (nucleus-contacting) surface are essentially parallel to each other. In another embodiment, the outer surface and the inner surface are non-parallel thereby giving the end plate an essentially wedge-like configuration. The orientation of the wide and narrow edges of the wedge can be adjusted to provide various types and degrees of spinal correction.

[0045] In another aspect of the invention the prosthesis comprises an artificial nucleus and at least one end plate. In this embodiment, the prosthesis comprises a superior end plate for attachment to an upper vertebral member, an inferior end plate for attachment to a lower vertebral member and a nucleus adapted to fit between the two end plates. The end plate of the invention has a generally flat surface on the bone contacting side and the appropriate geometric receptacle on the other side for articulating with the nucleus. A central keel can be formed in the center of the inner surface of the end plate to anchor the nucleus in position. The end plate can include a stop member to prevent the prosthesis from moving toward the

spinal canal. The nucleus may also have a maximum vertical axis that is not at the geometric center.

[0046] In another embodiment, the nucleus has an upper surface with an upper receptacle and a lower surface with a lower receptacle. The superior end plate has a downwardly projecting protrusion or anchor that engages the upper receptacle and the inferior end plate has an upwardly extending protrusion or anchor that engages the lower receptacle. The prosthesis maintains an appropriate spatial relationship between adjoining vertebrae and also permits normal range of motion of the spine. This embodiment can also include a receptacle that comprises a groove open at one end. The anchor on the end plate can include a central keel, which slides into position in the groove to secure the nucleus.

[0047] Another embodiment of the invention operates like a universal joint and incorporates three anatomical axes of rotation, two of which provide for flexion/extension and lateral bending motion, while the other one provides for axial rotation. These axes of rotation are accomplished by the use of a pair of two cylinders that can rotate relative to each other about a central post.

[0048] In another embodiment, one of the plates has a central post that engages the other plate, and an annular core positioned around the central post that is formed of a resilient material. The core can be asymmetrical and engage both plates to provide necessary deformity correction. The core can engage the end plates to provide the desired angle between the plates for deformity correction, with the central post engaging the other plate when the load exceeds a predetermined limit. Or, the post can engage the other plate with the core engaging the other plate to maintain the plates at the desired angle relative to each other when applied forces tend to change the relative angle of the plates. Alternatively, the core could be replaced by two or more discrete spacers for performing the same function.

[0049] In another aspect of the invention, the nucleus can utilize material deformation to accomplish the desired ranges of motion. The shape of the material can be used to provide a restoring force for deformity correction. In order to achieve these results, material can be removed from various parts of the core to change the modulus of elasticity of the core at selected locations, or material having variable elastic moduli could be used. In this way, different forces and motions can be provided through the design of the core.

[0050] The end plates can be provided with features that act as stops outside of the desired range of motion, which allow for anatomically-derived gradual stopping. This result

can be achieved by forming one or more camming surfaces in or on one of the end plates and providing a co-operating member on the other end plate for engaging the camming surface. The camming surface has a gradual curve on its inner surface. During relative movement between the end plates, the camming surface is engaged by the cooperating member, which results in an axial distraction of the end plates and provides a soft tissue assist to prevent a hard stop. Alternatively for rotational movement, cooperating camming surfaces can be provided so that distraction will occur when one end plate rotates relative to the other one.

[0051] In another embodiment, the nucleus has a tang or tab protruding in the posterior direction from the inferior aspect of the body of the nucleus (core). The tab interacts with the inferior endplate to resist “lift off” of the nucleus from the inferior endplate, thus preventing posterior migration (expulsion) of the nucleus into the spinal canal. In a more preferred embodiment, the underside of the tab is chamfered or beveled.

[0052] In another embodiment, the posterior superior surface of the nucleus is curved upward from the medial superior surface to provide an elevated posterior surface region relative to the center of the nucleus. In the full extension position of the prosthesis this configuration may reposition the instantaneous axis of rotation to a more superior location and allows the endplates to resist posterior shear. Posterior shear load is transmitted through the nucleus and into the inferior end plate rather than through the facet joints and related soft tissue structures.

[0053] In some embodiments, recesses on the anterior portion of the nucleus provide access for external instrumentation to facilitate placement and removal. These recesses are placed in an area such that they do not substantially interfere with the load carrying and transferring capabilities of the nucleus.

[0054] In some embodiments, a polymer is incorporated on one or more of the articulating surfaces. In one preferred embodiment, a component with an articulating surface is molded from the polymer. In a second preferred embodiment the polymer is incorporated by insert-molding as a part of the component. A preferred polymer for these embodiments is polyetheretherketone (PEEK). In another embodiment, ceramics or alternate materials such as zirconium oxide can be utilized.

[0055] The invention also includes a method for implanting spinal prostheses of the type described above, and instruments for performing such a method of implantation. The method includes the steps of distracting a pair of adjacent vertebral bodies to a specific disc space

height, maintaining the height between vertebral bodies with a first instrument that can operate to guide subsequent instruments for forming vertebral grooves on the adjacent vertebral bodies, forming vertebral grooves on the facing surfaces of the vertebral bodies that correspond with keels on the outer surfaces of the prosthesis by using the second instrument to guide drill bits; and inserting the prosthesis with the nucleus sandwiched between the end plates between the vertebral bodies with the keels being inserted into the vertebral grooves. The method also includes the steps of forming starter grooves with the second instrument and shaping the starter grooves into grooves with a third instrument, forming the grooves with a single instrument, and determining the size, shape and degree of lordosis to be accommodated before performing the step of forming grooves.

[0056] The set of instruments includes a first instrument with a pair of projections adapted to be inserted between a pair of adjacent vertebral bodies for maintaining the vertebral disc height, and a guide surface for guiding one or more other instruments into a predetermined position between the adjacent vertebral bodies. A second instrument includes a profile for engaging the guide surface of the first instrument for insertion between the vertebral bodies into a predetermined position, and a plurality of guide surfaces for guiding drill bits for forming grooves in the vertebral bodies that correspond with the keels formed on the outer surfaces of the end plates. The instruments can also include a set of trial instruments with a profile for engaging the guide surface of the first instrument for insertion between the vertebral bodies into a predetermined position, the trial instruments being sized and shaped for determining the size of the implant and the degree of lordosis to be accommodated. The instruments can include a set of trial instruments that are gauged to measure at least 0°, 3°, 6° and other varying degrees of lordosis.

[0057] A third instrument can be included that includes a profile for engaging the guide surface of the first instrument for insertion between the vertebral bodies into a predetermined position, and a plurality of cutting surfaces for shaping the grooves to correspond with the shapes of the keels when the third instrument is moved back-and-forth relative to the first instrument. The guide surfaces in the third instrument can be oblong for allowing the drill bit to move superior-inferior, medial-lateral relative to the axis of the grooves. A plurality of guide surfaces on the second instrument can be used for guiding drill bits for forming grooves in the vertebral bodies that correspond with the keels formed on the outer surfaces of the end

plates. The guide surfaces can be shaped to form an unequal number of grooves in the adjacent vertebral bodies.

[0058] Additional embodiments of the invention include implantable joint prostheses for the replacement of diseased or injured joints. Such prostheses may include, but are not limited to: a carpometacarpal joint prosthesis, a metatarsophalangeal joint prosthesis, a metacarpophalangeal joint prosthesis, a metatarsophalangeal joint prosthesis, a distal interphalangeal joint prosthesis, an ankle joint prosthesis, a knee joint prosthesis, a hip joint prosthesis, and a shoulder joint prosthesis. Each joint prosthesis may include corresponding flattened sections on opposing bearing surfaces, and the flattened sections may be asymmetrically positioned on the bearing surfaces. The flattened sections may provide for natural alignment of the joint when in the neutral position.

[0059] The foregoing has outlined rather broadly the features and technical advantages of the present invention in order that the detailed description of the invention that follows may be better understood. Additional features and advantages of the invention will be described hereinafter which form the subject of the claims of the invention. It should be appreciated by those skilled in the art that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present invention. It should also be realized by those skilled in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims. The novel features which are believed to be characteristic of the invention, both as to its organization and method of operation, together with further objects and advantages will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended as a definition of the limits of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0060] These and other features of the invention will become more apparent from the following description in which reference is made to the appended drawings wherein:

[0061] FIGURE 1A illustrates an spherical artificial disc nucleus with the maximum central axis in the geometric midline of the nucleus;

[0062] FIGURE 1B illustrates the nucleus of Figure 1A, with an offset maximum vertical axis that provides 3° of correction;

[0063] FIGURE 1C illustrates the nucleus of Figure 1A, with an offset maximum vertical axis that provides 6° of correction;

[0064] FIGURE 2A illustrates an asymmetrical artificial disc nucleus with the maximum central axis in the geometric midline of the nucleus;

[0065] FIGURE 2B illustrates the nucleus of Figure 2A with an offset maximum vertical axis that provides 3° of correction;

[0066] FIGURE 2C illustrates the nucleus of Figure 2A with an offset maximum vertical axis that provides 6° of correction;

[0067] FIGURE 3 is a top view of the embodiment of the artificial disc nucleus shown in Figure 1A;

[0068] FIGURE 4 is a perspective view of the embodiment of the artificial nucleus shown in Figure 1A;

[0069] FIGURE 5 is a perspective view of the embodiment of the artificial nucleus shown in Figure 2A;

[0070] FIGURE 6 is a perspective view of an outer surface of an end plate;

[0071] FIGURE 7 is a perspective view of an inner surface of an end plate;

[0072] FIGURE 8 is a front view of an end plate;

[0073] FIGURE 9 is a front view of a spinal disc device with the nucleus shown in Figure 1A;

[0074] FIGURE 10 is a side view of the spinal disc device of Figure 8;

[0075] FIGURE 11 is a front view of a spinal disc device with the nucleus shown in Figure 2A;

[0076] FIGURE 12 is a side view of the spinal disc device of Figure 8;

[0077] FIGURES 13A and 13B illustrate an embodiment of an artificial spinal disc prosthesis where the end plates may be adapted for lordotic correction;

[0078] FIGURES 14A, 14B, and 14C illustrate other embodiments where the end plates can be adapted for lordotic correction;

[0079] FIGURE 15 is a side view of another embodiment which provides for all directions of movement;

[0080] FIGURES 16A and 16B illustrate the two sections of the nucleus of the embodiment of Figure 15;

[0081] FIGURES 17 and 18 illustrate another embodiment of the invention in which the nucleus is formed of upper and lower sections with an intermediate section;

[0082] FIGURE 19 illustrates another embodiment of the invention in which the nucleus is cut in half and has a flat lower inferior surface;

[0083] FIGURE 20 is a schematic view of the nucleus of Figure 19;

[0084] FIGURE 21 illustrates a modification of the embodiment of Figure 19;

[0085] FIGURE 21A illustrates a nucleus with an asymmetric thickness and a concave superior surface that is designed to also provide a lordotic correction.

[0086] FIGURE 22 is a an underside view of the nucleus of Figure 21;

[0087] FIGURE 23 is a schematic view of the nucleus of Figure 21;

[0088] FIGURE 24 illustrates a modification of embodiment of Figure 19;

[0089] FIGURES 25-31 illustrate another embodiment of the invention in which the nucleus is elongated with a flattened section in the center;

[0090] FIGURES 32 and 33 illustrate another embodiment of the invention which utilizes a universal joint;

[0091] FIGURES 34-36 illustrate another embodiment of the invention in which a resilient ring and a post provide for relative motion between the end plates;

[0092] FIGURE 37 illustrates a modification of the embodiment of Figure 34;

[0093] FIGURES 38 and 39 illustrate another embodiment of the invention in which the nucleus is shaped to provide medial/lateral correction;

[0094] FIGURES 40-43 illustrate another embodiment of the invention in which the end plates are provided with stops outside the normal range of motion;

[0095] FIGURES 44A, 44B and 44C illustrates another embodiment of the invention in which the flattened segment of the nucleus contains a central depression;

[0096] FIGURES 45, 45A, 45B and 45C illustrate another embodiment of the invention in which the posterior superior surface of the nucleus has an elevated surface region;

[0097] FIGURES 46A, 46B, 46C and 46D illustrate another embodiment of the invention in which a modified keel configuration is shown;

[0098] FIGURES 47-53 are various views of instruments for implanting spinal prostheses of the type described above, and for illustrating a preferred method of implantation;

[0099] FIGURES 54, 55 and 56 illustrate another embodiment of the invention which is a two piece artificial spinal disc prosthesis;

[00100] FIGURE 57 is an anterior cross-sectional view of a carpometacarpal joint prosthesis implanted in a carpometacarpal joint;

[00101] FIGURE 58 is a perspective view of a metacarpal component and a trapezal component of the prosthesis of Figure 57;

[00102] FIGURE 59 is an lateral cross-sectional view of a metacarpophalangeal joint prosthesis implanted in a metacarpophalangeal joint;

[00103] FIGURE 60 is a lateral cross-sectional view of a distal interphalangeal joint prosthesis implanted in a distal interphalangeal joint;

[00104] FIGURE 61 is a perspective view of a distal phalange component and an intermediate phalange component of the prosthesis of Figure 60;

[00105] FIGURE 62 is a lateral cross-sectional view of a a first metatarsophalangeal joint prosthesis implanted in a first metatarsophalangeal joint;

[00106] FIGURE 63 is a perspective view of a metatarsal component and a phalange component of the prosthesis of Figure 62;

[00107] FIGURE 64 is a lateral cross-sectional view of an ankle joint prosthesis implanted an ankle joint;

[00108] FIGURE 65 is a posterior cross-sectional view of the ankle joint and ankle joint prosthesis of Figure 64;

[00109] FIGURE 66 is a lateral cross-sectional view of an alternative embodiment of an ankle joint prosthesis implanted in an ankle joint;

[00110] FIGURE 67 is a perspective view of the a tibial component and a talar component of the ankle joint prosthesis of Figure 66;

[00111] FIGURE 68A is a lateral cross-sectional view of a three-part ankle joint prosthesis;

[00112] FIGURE 68B is a posterior cross-sectional view of the three-part ankle joint prosthesis of Figure 68A;

[00113] FIGURE 69A is a lateral cross-sectional view of an alternative three-part ankle joint prosthesis;

[00114] FIGURE 69B is a posterior cross-sectional view of the three-part ankle joint prosthesis of Figure 69A;

[00115] FIGURE 70A is a lateral view of a talus with a groove cut into it in preparation for implantation of an ankle prosthesis;

[00116] FIGURE 70B is a lateral view of the talus of Figure 70A with a talar implant in the groove;

[00117] FIGURE 71 is a coronal view of a knee joint prosthesis;

[00118] FIGURE 72 is a perspective view of a femoral component and a tibial component of the knee joint prosthesis of Figure 71;

[00119] FIGURE 73 is an anterior cross-sectional view of a hip joint prosthesis implanted in a hip;

[00120] FIGURE 74 is a perspective view of a femoral component and an acetabular cup component of the hip joint prosthesis of Figure 73;

[00121] FIGURE 75 is an anterior cross-sectional view of a shoulder joint prosthesis implanted in a shoulder; and

[00122] FIGURE 76 is a perspective view of a humeral component and a glenoid component of the shoulder joint prosthesis of Figure 75.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00123] The present invention relates to systems and methods for partially or wholly replacing diseased or injured joints with artificial joint prostheses. Those of skill in the art will recognize that the following description is merely illustrative of the principles of the invention, which may be applied in various ways to provide many different alternative embodiments. This description is made for the purpose of illustrating the general principles of this invention and is not meant to limit the inventive concepts in the appended claims.

[00124] In its proper, healthy alignment, the spine follows natural curves, which promote proper sagittal and coronal balance (flexibility) and allow for balanced load sharing between the vertebrae. These curves include the cervical, thoracic, lumbar and sacral regions of the spine. Naturally, in order to accommodate a curve, there must be some variation in the angle of articulation between the functional spinal units and the height of an intradiscal space. The cervical and lumbar regions are naturally lordotic, or curved convexly in the anterior direction. At different segments along the spine, there are typically different heights for the vertebral bodies and the intradiscal space. In addition, the intradiscal space and vertebral body height may be different for different people.

[00125] Each intradiscal space has anterior and posterior regions. An artificial disc in the cervical, thoracic and lumbar regions that maintain the same height from the anterior to the posterior may promote an abnormal alignment, resulting in additional stress at the anterior or posterior portions of an adjacent disc. It may also result in an uneven load distribution across the device and cause an excessive amount of relative motion, wear debris and early failure.

[00126] As used herein, the terms, nucleus and core are used interchangeably to refer to an artificial intervertebral device that replaces a damaged natural spinal disc. The artificial core may be provided alone or in combination with a superior end plate for attachment to an upper vertebra or an inferior end plate for attachment to a lower vertebra or both.

[00127] The terms "upper" and "lower" are used herein to refer to the vertebrae on either side of the disc to be replaced, or a surface on a part in the position shown in the referenced drawing. A "superior" plate is affixed to an upper vertebra and an "inferior" plate is affixed to a lower vertebra of a functional spinal unit.

[00128] The terms vertical and horizontal are used herein relative to a standing human being in the anatomical position. The term "anterior" refers to the region towards the front and the term "posterior" refers to the region towards the back. The term "sagittal" refers to regions on either side of the central midline axis of a standing human being.

[00129] The term "asymmetrical" is used herein to refer to an axis of maximum height that is not placed centrally or to a nucleus or total disc replacement (TDR) not having its maximum vertical axis placed centrally. In other words, the maximum height is not situated or pivoted at a center line of symmetry so that the TDR comprises regions that are not exactly the same in shape or size as other regions on the other side of a line of symmetry. The location of maximal load bearing is located in a non-central location. The term may analogously apply to joint prostheses in which an axis of maximum height is not located centrally on a substantially convex bearing surface, or the axis of maximum depth of a depression is not placed centrally on a substantially concave bearing surface.

[00130] The term "normal alignment" is used herein to refer to the natural positioning of functional components of a healthy joint, relative to one another and/or the surrounding tissues. Normal alignment may refer to the static position of a joint at rest, wherein no stress or pressure is placed on the joint, and it may also refer to the dynamic position of a joint under natural mechanical stress such as during flexion or extension. Normal alignment may also be referred to as natural, healthy, or proper alignment. "Preferred" or "desired" alignment are used herein to refer to joint alignment that may be natural, or corrected, but places the joint components in a functional or desired position. The terms "preferred orientation" or "preferred relative orientation" used herein also refer to component alignment that may be natural, or corrected, in which the joint components are in a functional or desired position.

[00131] The phrase "preferred relative orientation" may refer to an orientation about a single axis, or about multiple axes. For example, an artificial disc implant may be designed to establish a preferred relative orientation about an axis extending medial-laterally to provide a preferred anterior-posterior angulation that mimics the appropriate lordosis or kyphosis of the joint motion segment. Alternatively, an artificial disc implant may be designed to establish a preferred relative orientation about an axis extending generally anterior-posteriorly to provide a preferred medial-lateral angulation that provides the desired degree of lateral bending. Such lateral bending may be zero degrees, reflecting the straightness of a healthy spine, or may be nonzero to the left or right to provide correction for various pathologies including scoliosis. As another alternative, an artificial disc implant may be designed to provide a preferred relative orientation about both of the medial-lateral and anterior-posterior axes to encourage proper lordosis or kyphosis while also encouraging the

desired lateral bending. A preferred relative orientation is a low energy point toward which the joint is naturally encouraged to come, in contrast to a point of resistance such as a motion stop.

[00132] An "orientation feature" is a feature present on one or more joint components that help the components establish a preferred relative orientation. For example, opposing bearing surfaces on joint components may include flattened sections, which are orientation features which cooperate to urge the components toward attaining a preferred relative orientation. Matching curved surfaces which align better in a preferred relative orientation may also be orientation features. Other configurations of orientation features may be possible in addition to flat and curved surfaces.

[00133] In one embodiment of the present invention, an artificial disc comprises a nucleus that is not geometrically symmetrical. The disc may have a maximum vertical axis that is not located at the geometric center of the disc. The maximum vertical axis may be located toward the front of the disc, the rear of the disc or on one side of the disc. The positioning of the maximum vertical height and load bearing capability is chosen depending on the type of deformity that needs to be corrected. The present invention also provides methods for the treatment of disc/vertebral body disease, lordosis, kyphosis and scoliosis using an asymmetric artificial disc.

[00134] One advantage of the present invention is that the "nucleus" or core may be interchanged and revised intra-operatively and post-operatively. Instruments can be used to gauge the need for and amount of correction and the appropriate implant can then be inserted. By introducing correction into the nucleus, the surgeon benefits from flexibility, ease of insertion and revisability that present systems do not provide.

[00135] Artificial discs of the present invention can be provided with various degrees of deformity correction. For this aspect of the invention, the surgeon can choose a disc having the appropriate correction for the patient. Thus, a method of treating a spinal deformity is provided. This method comprises preparing a spinal segment for implantation of an artificial disc, determining the desired angle of the intervertebral space, selecting an artificial nucleus having the desired dimensions, affixing a superior end plate to the upper vertebra, affixing an inferior end plate to the lower vertebra and inserting the selected nucleus between the superior and inferior end plates. Alternatively, and the assembled unit of end plate-nucleus-end plate may be inserted in unison. The configuration of the nucleus in this pre-assembled

construct can be determined by the intra-operative measurement tools, or with pre-operative calculations. Pre-operative planning techniques and instruments may also be able to determine the size and orientation of this device for insertion.

[00136] A major advantage of the present system is that the artificial disc can be more easily and rapidly inserted and the nucleus can be changed or revised in accordance with the magnitude of the deformity being corrected. This is especially useful in children and young adults where the alignment of the spine changes over time.

[00137] In one embodiment, an asymmetric nucleus adapted for lordotic correction of the cervical spine is provided. The surgeon can restore lordosis to the cervical spine while maintaining motion. The nucleus may be composed of a low friction elastomer such as polyurethane, polycarbonate-polyurethane, a polymer such as polyethylene (particularly ultra-high molecular weight polyethylene), a suitable ceramic, metals or metal alloys such as titanium or a titanium alloy, chrome-cobalt-molybdenum (CoCrMo), cobalt 28 chromium molybdenum, cobalt chrome, stainless steel, or other suitable materials. It has a generally circular geometric design, with varying degrees of lordosis incorporated into it by utilizing an axis of maximum height anterior to the geometric center of the nucleus. The anterior height of the nucleus varies, depending on the extent of lordotic correction needed. The nucleus is available in various lordotic angles, e.g. 0, 3° and 6°, as well as differing heights (e.g., 4, 6 and 8 mm). Before deciding on the final nucleus size, a set of instruments or other means can be used to gauge the need for lordotic correction.

[00138] The nucleus slides between a superior end plate and an inferior end plate. The nucleus can be maintained in position using various types of connectors. For example, in one embodiment, the convex surface of the nucleus has a midline groove to allow the nucleus to slide into place between the positioned end plates. A central keel on the concave surface of the end plate is received in the groove of the nucleus. It is apparent that other types of connections can be used to maintain the nucleus in position. For example, a tooth and lock system or a pop-in system could be used.

[00139] A number of embodiments of the nucleus and artificial disc of the present invention are illustrated in the appended drawings. In one aspect of the invention, correction of spinal segment alignment is provided by an artificial nucleus which has the shape of a truncated cylinder or which is generally spherical or ovoid in shape, wherein the two halves

on the arc on either side of a central axis are not symmetrical. In other words, the curvature is not geometrically parallel or symmetric.

[00140] In one embodiment, the implant consists of three pieces. The end plates will be made in differing sizes to accommodate differences in anatomy. These may be fabricated of titanium or a titanium alloy, chrome-cobalt-molybdenum (CoCrMo), cobalt 28 chromium molybdenum, cobalt chrome, stainless steel or other materials suitable for spinal prosthetic inserts.

[00141] The end plates can have two distinct surfaces. The flat surface of each end plate, which contacts the vertebral body end plate, is capable of accommodating bony ingrowth and incorporates a suitable coating, such as porous titanium, a calcium phosphate, or includes other types of known surfaces that promote bony ingrowth for long-term stability. The end plates can also have one or more parasagittal keels that provide immediate fixation. In one embodiment of the invention, a pair of parallel keels can be formed on the outer surface of one of the end plates, and a single, centrally-located keel can be formed on the outer surface of the other end plate. The other (inner) surface of the end plates can have a contour that corresponds with the geometric shape of the nucleus to form a bearing surface that allows for optimal articulation and wear characteristics with respect to the nucleus. In the middle of this bearing surface, there can be a single, central keel, which provides a constraint for the nucleus against excessive translation and range of motion. The nucleus can have a circular geometric design, with a midline groove to allow the nucleus to slide into place between the positioned end plates. A central keel on the concave surface of the end plate would fit into the groove of the nucleus. Before deciding on the final nucleus size, a set of instruments could be inserted to confirm the lordotic correction, but these may also be used as confirmation for other types of pre-surgical planning techniques and instrumentation. Alternatively, intra-operative instruments may be used as confirmation for other types of pre-surgical planning techniques and instrumentation.

[00142] Figures 1A to 1C illustrate various examples of artificial disc nuclei where the nucleus is symmetrical, with a maximum central axis in the geometric center 20 of a nucleus 10. The reference letters A and P illustrate the anterior and posterior orientation, respectively, of the nuclei 10, 14 and 18. The nucleus 10 is generally spherical in shape and is truncated with a flattened portion 22A on the upper side of the nucleus 10 and another

flattened surface 22B on the lower side. The nucleus also has upper and lower curved surfaces 24A and 24B, respectively, and a circumferential wall 26.

[00143] The flattened surfaces, as described above, can be advantageous because when the nucleus has a completely rounded surface, it cannot reliably maintain correction when exposed to the variable forces of the head and neck. A flattened surface incorporated into the central region of the nucleus can be used to solve this problem. The flattened surfaces have a contour different from the adjacent surface, and are formed in the nucleus body. The terms “flattened section” or “flattened surface” are used interchangeably and are meant to refer to any contour that is not the same as the adjacent surface(s) of the nucleus. Such a flattened surface can be planar or it be slightly convex or concave and have a radius of curvature different from the adjacent surface. Such a flattened surface could also be in the shape of a compound curve or other complex shape.

[00144] This flattened surface can be angled relative to the superior end plate of the inferior vertebral body (or vice versa, or both), with the height of the anterior end being greater than the height of the posterior end when lordotic correction is sought. The overall shape of the core can still be asymmetric, but the flattened surface can be incorporated to provide a reliable correction of the deformity. This flattened segment provides stabilization to resist the moments acting through the nucleus, i.e., if the flat is not of adequate size, there may be a tendency for the correction to disappear in the presence of an anterior load or for a hyper-lordotic over correction in the presence of a posterior load (during lordotic correction). Another advantage of the flattened segment is to provide surface contact over that area during small movements about the, neutral position of the device, which could help reduce wear on the device.

[00145] Figure 1A illustrates a nucleus 10 that has not been adapted for lordotic correction because the upper and lower surfaces 22A and 22B are parallel to each other. In this nucleus, the axis 20 of greatest height falls in the center of the disc. In Figure 1B, a nucleus 14 that provides 3° of correction is illustrated. This nucleus provides for lordotic correction. Figure 1C illustrates another artificial disc nucleus 18 having a greater degree of deformity correction. When deformity correction is provided as shown in Figures 1B and 1C, the geometric center of the nucleus may shift to a location that is offset from the axis 20.

[00146] If the anterior/posterior directions are reversed, it provides a kyphotic correction. If the nucleus is rotated 90 degrees, a scoliotic correction is provided. In the illustration in

Figure 1C, the maximum vertical axis 20 is positioned to provide a correction of 6°. It is apparent that the nucleus can be adjusted to provide various degrees of correction and, in certain cases, if no degree of correction is needed. Alternatively, only one of the halves of the nucleus 10 may have a flattened portion, with the other half having an outer surface that is curved.

[00147] In Figures 2A through 2C, asymmetrical ovoid embodiments of an artificial nucleus are shown. The nucleus comprises upper and lower surfaces 22A and 22B, which are “flattened” by virtue of the ovoid shape of the nucleus, upper and lower curved surfaces 24A and 24B, and a circumferential center portion 26. In the embodiments shown in Figures 2B and 2C, the maximum height axis 16 is asymmetrical with the geometric center 12 of the disc. In the nucleus shown in Figure 2A, where there is no correction, the maximum vertical height is at the central vertical axis 12. In the nucleus shown in Figure 2B, the maximum vertical axis 16 is positioned to provide an angle of correction of 3°. In the nucleus shown in Figure 2C, the maximum vertical axis 16 is positioned to provide an angle of correction of 6°.

[00148] Figure 3 is a top view of one example of a nucleus. This nucleus 40 comprises a central convex or flattened region 42, which includes a groove or slot 44. This groove or slot 44 enables the nucleus to slide onto the central keel or anchor of an end plate (not shown). While the nucleus 40 is shown as essentially circular, it is clearly apparent that it may take on other shapes such as an ovoid or ellipsoid shape. It is also clearly apparent that other types of anchor receiving means can be used. For example, the shape of the groove may vary or a snap-in or bayonet or dog-bone type of receptacle can be provided to anchor the nucleus in position. Those practiced in the art can provide additional locking methods including the addition of one or more parts to the core that provide an anchor.

[00149] For deformity correction, the nucleus may take the form of a truncated curved body as shown in Figure 4. For this embodiment, the nucleus 50 has an upper surface 52 that terminates in essentially flattened planar top 54. A slot 56 or a groove or opening of another appropriate shape, can be formed in upper surface 52 for receiving an anchor formed in the end plate. The lower surface 58 is typically an inverse of the upper surface. However, instead of being truncated with a flat surface as shown in Figure 4, the bottom surface could be asymmetrically spherical or ovoid in shape.

[00150] Alternatively, the nucleus may be circular, ovoid or egg-shaped having a non-central maximum vertical axis as shown in Fig 5. In another embodiment, the nucleus could be essentially circular or asymmetrically spherical.

[00151] Figure 5 illustrates an artificial nucleus 60 where the upper surface 62 is an asymmetric convex surface. Again, either the top or the bottom or both surfaces may be asymmetric.

[00152] For illustrative purposes, the nuclei in the figures have been shown adapted for lordotic correction. It is clearly apparent that the nucleus can have an asymmetric maximum height at the front (anterior), the rear (posterior) or the side (lateral). The asymmetrical nucleus of the present invention can be used to correct for various types of spinal misalignment including sagittal and coronal deformity.

[00153] The novel corrective nucleus of the present invention may be provided alone or it may be provided in combination with an upper end plate, a lower end plate or both an upper and a lower end plate.

[00154] Figures 6 through 8 illustrate an exemplary artificial end plate 70 that can be used in conjunction with the nucleus to provide a novel artificial disc unit. An artificial end plate according to the present invention comprises an inner surface with a concave bearing surface for receiving the convex surface of an artificial disc. The outer, or bone contacting, surface is essentially flat.

[00155] To accommodate some previously known end plates, it was necessary to spend a significant amount of surgical time to prepare the vertebrae to the appropriate shape to accommodate the artificial end plate. Figure 6 shows an end plate 70 with a flat outer surface 72 that enables the end plate to slide on the surface of the vertebra. One or more unidirectional keels 76 are formed on the outer surface 72 to provide for immediate fixation. The keels may be placed centrally or parasagittally. Fixation can be enhanced by incorporating onto the outer surface 72 a suitable coating 74, such as porous titanium, a calcium phosphate or the like, to promote bony ingrowth for long term stability.

[00156] A stop member 78 can be provided at the anterior edge 80 of the end plate. The stop member prevents the prosthesis from migrating posteriorly and possibly impinging on the spinal cord. An essentially semi-circular wall 82 joins the outer surface of the end plate to the inner surface. The thickness of 82 may vary with increased thickness anteriorly,

posteriorly or parasagittally, as discussed further below. The inner surface 84 is shown in greater detail in Figure 7.

[00157] The inner surface 84 of the end plate articulates with the nucleus. In the embodiment shown in Figure 7, this inner surface has a concave region 86, which receives the nucleus. An anchor 88 is provided in the center of the concave region 86 for positioning the nucleus and preventing it from migrating. The anchor 88 can be generally rectangular in shape with rounded edges, as shown, avoiding premature wear and cutting into the nucleus. Figure 8 illustrates a front view of the end plate showing the outer surface 72 having two parasagittal keels 76 and the inner surface 84 having a concave region 86 and a central anchor 88.

[00158] Figures 9-12 illustrate a nucleus and end plates described above assembled into a TDR implant. Figures 9 and 10 show the use of a nucleus 96 with a truncated cylinder shape and a flattened portion 97 on the superior side of the nucleus as described above, in conjunction with Figures 1A-1C, and Figures 11-12 show the same design with a nucleus 96 having an ovoid shape as shown in Figures 2A-2C. In these figures, a complete spinal disc prosthesis 90 comprising a superior end plate 92, an inferior end plate 94 and an artificial disc nucleus 96 is provided. The end plates and nucleus can be provided in different sizes to accommodate differences in anatomy. The end plates and various nuclei can be provided in a kit to the surgeon so that the appropriate sized components can be selected and used when the final size is determined. The end plates may be fabricated of titanium or titanium alloy, chrome-cobalt-molybdenum (CoCrMo), cobalt 28 chromium molybdenum, cobalt chrome, ceramics or other material suitable for spinal prosthetic implants.

[00159] The end plates have two distinct surfaces. The outer surface 98 is the surface that contacts the vertebral end plate. The outer surface is essentially flat enabling it to easily contact the surface of the natural vertebral end plate. The flat surface can be porous and incorporate a suitable treatment, such as porous titanium, a calcium phosphate or other types of known treatments such as coatings, plasma sprays, and structural changes to the surface, that promote bony ingrowth or ongrowth for long-term stability. At least one parasagittal keel 100 is formed on the outer surface of each end plate to provide immediate fixation.

[00160] As shown in Figs. 9-12, three parasagittal keels 100 are aligned with each other and located along both sides of the outer surface of the end plates. Alternatively, as shown Figure 9A a similar end plate design with an upper end plate 92 and a lower end plate 94

have an offset keel configuration with a pair of aligned parasagittal keels 100A formed on the outer surface of the upper end plate and a centrally-located row of aligned keels 100B formed on the outer surface of the lower end plate 94. This latter arrangement is believed to be advantageous because, with the upper and lower keels being offset from each other, the end plates should have greater stability and result in less stress on a vertebra where multiple implants are used.

[00161] Referring back to Figures 9-12, the inner surface 102 of each of the end plates has a concave region 103 or bearing surface that articulates with the nucleus. An anchoring protrusion 104 projects outwardly from the concave region, which provides an anchor for the nucleus and restricts posterior translation. Both the superior and the inferior end plates have flanges 106 for preventing the end plates from migrating into the spinal canal. The end plates can have holes 107 for allowing the end plates to be connected to the adjacent vertebrae through either metallic or bioabsorbable screws (not shown) that can be inserted through holes 107. Figures 9 and 11 illustrate front views of the prosthesis and Figures 10 and 12 illustrate side views.

[00162] In another aspect of the invention, shown in Figures 13A-13B and 14A-14C, spinal deformity can be addressed by providing an artificial spinal disc prosthesis where correction is provided in the end plates. Corrective end plates may be provided alone, in combination with a symmetrical artificial nucleus that has flattened surfaces as described above on both the top and bottom of the nucleus, as shown in Figures 13A-13B, or in combination with an asymmetrical nucleus that has flattened surfaces as described above on both the top and bottom of the nucleus, as shown in Figures 14A-14C.

[00163] Correctional end plates are shown in Figures 13A-13B and 14A-14C. The degree of correction can be achieved by altering the inner (nucleus-contacting) side of the end plate or the outer (vertebral-contacting) side of the end plate. As shown in Figures 13A-13B, the end plate 110 comprises an outer (bone-contacting) surface 112, an inner surface 114, and a perimeter wall 116 connecting the outer and inner surfaces. The height of the perimeter wall 116 may vary according to the degree and type of correction required. For example, Figure 13B illustrates an end plate adapted for a greater degree of correction than the end plate of Figure 13A. The positioning of the variable height can be adjusted to treat different conditions such as lordosis, kyphosis or scoliosis. The inner surface may be shaped to

receive the nucleus, and the height of the end plate can be adjusted according to the degree of correction required.

[00164] Alternatively, as shown in Figures 14A-14C, the outer surface 120 and the inner surface 122 may be essentially planar and the height is adjusted as the outer and inner surfaces become increasingly non-parallel as a result of variation in the height of the perimeter wall 124. Figures 14A through 14C illustrate increasing degrees of correction, respectively. An advantage of having an essentially planar outer, or vertebral-contacting, surface is that the device is easier to insert and requires less operating time to prepare the vertebral surface as compared to traditional artificial disc devices.

[00165] Figures 15, 16A and 16B illustrate another embodiment of the invention, which provides for all directions of movement, flexion/extension, lateral bending, and rotation about the symmetrical axis. In this design, the nucleus 130 is formed in two sections 130A and 130B. A post 132 is formed on the inner surface of one section 130A, and fits in an opening 134 that is formed on the inner surface of the other section 130B to provide for relative rotational movement between the two sections 130A and 130B. The post 132 and opening 134 can be formed on either section of the nucleus 130. The post and opening can be of any suitable size, and can be perpendicular to the opposing surfaces of the nucleus sections 130A and 130B, or be tilted at an angle off horizontal to orient the axis of axial rotation with the anatomically correct axis and provide a deformity correction.

[00166] In this configuration, the contact surfaces between the nucleus 130 and end plates 136 and 138, are designed to have the same corresponding asymmetrical contours at the preferred angle between them, as shown in Figure 15. Because there is only relative movement between the nucleus and the end plates in the anterior/posterior and medial/lateral directions, greater surface contact between the nucleus and the respective end plates is possible in order to transmit rotations of the end plates to the nucleus so that the two halves 130A and 130B, of the nucleus 130 will rotate with respect to each other, rather than having the end plates 136 and 138, rotate on the outer surface of the nucleus 130.

[00167] Figures 17 and 18 show another embodiment of the invention where instead of forming the nucleus 130 of a single piece of material, it can be formed of upper and lower sections 130A and 130B, with an intermediate section 140, that is either flat or wedge-shaped as shown in Figure 17, fixed to the upper and upper and lower sections. The intermediate section 140 can provide the nucleus with the appropriate degree of correction as shown in

Figure 18, instead of providing wedge-shaped end plates as discussed above. In a related embodiment of the invention, the nucleus 130 is essentially cut in half and has a flat inferior surface. This can be applied to the embodiment seen in Figures 17 and 18, where the section 130B is removed, leaving the inferior surface of intermediate section 140 articulating with the inferior end plate. By varying the configuration of the intermediate section 140, deformity correction can be achieved.

[00168] Figures 19 and 20 show another embodiment of the invention where the nucleus 130 is essentially cut in half and has a flat lower inferior surface. This shape can be used to resist expulsion of a nucleus with an ovoid/asymmetric shape, which could occur when the ovoid shape of the nucleus causes the end plates to tilt relative to each other to provide correction. As shown, the bottom surface of the nucleus 130 is flat and is formed with a circular opening 134 that is shaped and positioned to receive a post 136 formed on the opposing surface of the lower end plate 138 for allowing relative rotational movement between the nucleus 130 and the end plate 138. Alternatively, the nucleus could have the flat surface and opening 134 on its upper or superior surface, instead of being on the lower surface as shown. In this embodiment, the nucleus is preferably asymmetrical as shown in Figure 19.

[00169] A modification of the configuration in Figures 19 and 20, is shown in Figures 21 through 24, where the nucleus 130 is positioned in a slot or trough 142 formed in the upper surface of the lower end plate 138. As shown in Figure 21, the undersurface of the upper end plate 136 is contoured to match the nucleus. Alternatively, as shown in Figure 24, the undersurface of the end plate 136 can be flat and engage a flattened upper surface 144 of the nucleus 130.

[00170] In another embodiment, shown in Figure 21A, lordotic correction is achieved in a prosthesis that replicates the movement of natural vertebrae. A nucleus 130 is provided that has a concave configuration on its superior articulating surface 137, as discussed above. This concave articulating surface 137 may incorporate a flattened segment as shown above. The nucleus 130 is asymmetrical in that its superior surface 137 is formed with an anterior aspect 145a that has a greater vertical dimension, i.e., is thicker, than the posterior aspect 145b. The superior endplate 136 has an undersurface 147 that is similar in shape and articulates relative to the superior surface 137 of the nucleus 130. The corresponding articulating surfaces 137 and 147 can be rounded in the shape of a compound curve or other type of continuous curve,

so that they are essentially congruent through a full range of motion. The superior surface of the bottom end plate 138 is formed with a defined recess 139 that is highly polished, preferably to a mirror finish. The nucleus 130 is positioned for movement in the recess 139, with the elevated edges that form the recess limiting movement of the nucleus relative to the bottom end plate. The nucleus 130 can be sized and shaped to provide for controlled motion between the nucleus and the bottom end plate so that the nucleus 130 can slide in a gliding movement from side-to-side and/or from front-to-back relative to the superior surface 139 of the bottom end plate 138 to provide for relative translational movement in the medial-lateral and/or anterior-posterior directions as indicated by the arrows 146 and 148.

[00171] The trough can be larger than the nucleus in both the anterior/posterior and medial/lateral directions to allow for a desired amount of translation in those directions as shown by the arrows A and B in Figure 22. The trough can be open on the posterior or anterior end to allow the nucleus to be inserted simply by sliding it into the trough, as shown by the arrow A in Figure 21. In this way, the nucleus can be inserted without undue distraction of adjacent vertebrae. The nucleus can be prevented from moving out of the trough by providing a stop 144 of any suitable size and shape. Figure 23 is a schematic view of the nucleus 130 that is inserted in the trough in Figure 21.

[00172] Another embodiment of the invention is shown in Figures 25-31, where the nucleus 130 is elongated, with a flattened section 150 that is a partial cylinder with curved sections 152 and 154 on both sides of the flattened section. It is believed that this design, when mated with a cylindrical surface 156 on the interior of the upper end plate 136, shown in Figure 29, will provide better wear characteristics because it will have surface contact during medial/lateral bending and line contact during flexion/extension.

[00173] The elongated shape of the nucleus 130 is illustrated in Figures 25 and 26, which show that the nucleus has a round cross section with constant medial-lateral radius from anterior to posterior (A-P), with the flat section 150 in the middle being oriented to provide a correction angle as described above, for the flatted portions on the other embodiments of the nucleus. The interior surface 156 of the upper end plate 136 has a cylindrical shape with the same constant radius in the anterior/posterior direction as the nucleus.

[00174] In the neutral position, the cylindrical surface 156 mates with the flattened section 150 of the nucleus 130, and sits at an angle that provides a deformity correction as shown in Figure 31. In this position, there is surface contact between the end plate 136 and the

nucleus 130. During medial/lateral bending, there is also surface contact between the end plate and nucleus. During flexion/extension, with or without lateral bending, there is line contact between the end plate and nucleus. This configuration of core and end plate will always have line or surface contact, thus reducing the wear potential from point contact in some of the previous designs.

[00175] The elongated shape of the nucleus 130 allows for the end plate 138 to have a trough 157 in the shape of a “bow tie” as shown in Figures 27 and 28. This shape allows for axial rotation with stops beyond the limits of normal motion. The shape is oversized relative to the nucleus 130 by an appropriate amount to allow limited anterior/posterior and medial/lateral translation. Additionally, the bottom surface of the trough 157 can be rounded upwardly at the medial/lateral sides in Figure 30 (not shown), so that as the nucleus 130 rotates it is “cammed” up causing a distraction of the device that forces the vertebral bodies apart and loads the tissues between them resulting in a gradual stop to the motion. Translation of the nucleus 130 within the trough 157 will tend to preserve the mobile instantaneous axis of rotation of the natural disc.

[00176] Figures 32 and 33 show another embodiment of the invention, which utilizes a universal joint formed of a pair of cylinders 160 and 162 that rotate relative to each other about a central post 164 that projects from one of the cylinders 162 and engages an opening 166 in the other cylinder 160. The cylinders 160 and 162 are oriented perpendicular to each other and engage cylindrical surfaces 168 and 170, respectively, in the adjacent end plates 136 and 138. This design provides for three anatomical axes of rotation. Because of the independence of each axis of rotation, any correction provided by the shape of the nucleus that is formed of the two cylinders will result in rotation to compensate for the correction and a return to the uncorrected neutral position. Alternatively, the cylinders 160 and 162 may be shaped similarly to the elongated nucleus 130 shown in Figures 25-27, or another suitable shape with a flat inferior surface.

[00177] Another embodiment of the invention is shown in Figures 34-36, where a resilient ring 172 and a post 174 that has a rounded top portion 176 provide for relative motion between the end plates and for the desired angle of correction. The ring 172 is shown in detail in Figure 35. The ring 172 can be wedge shaped as shown in order to provide the desired amount of correction, or it can be flat (not shown) if no correction is desired. A projection 180 can be formed on the upper surface of the lower end plate 138 to mate with an

opening 182 in the ring 172 in order to prevent the ring 172 from moving relative to the lower end plate once the ring is in its desired position.

[00178] The upper end plate 136 has a cavity 178 that can be contoured to match the shape of the rounded top portion 176. The ring 172 is shaped so that the end plate 136 will ride on the ring 172 during “normal” ranges of motion, or through regular activities. However, when the normal ranges of motion are exceeded, then the ring 172 will compress and the upper end plate 136 will engage the post 174 causing the adjacent vertebrae to distract and thereby provide a gradual stopping motion or “anatomically-derived gradual stopping.” Alternatively, the post 174 could be designed to serve as the primary load carrying part of the articulation by riding in the cavity 178. In this design, the deformity correction force is only provided by compressing the ring 172. This design would have the advantage of reducing material stresses in the elastomer ring and creep.

[00179] As shown in Figure 37, instead providing the ring 176, the same result could be achieved by providing two or more stops 184A and 184B, formed of a resilient material, between the two end plates. The stops 184A and 184B can be mounted on the upper surface of the lower end plate 138. One of the stops 184A can project upwardly a greater distance than the other stop 184B in order to provide the desired correction.

[00180] Another embodiment of the invention is shown in Figures 38 and 39, where a nucleus 186 is provided that is formed of a resilient material that is shaped so that the nucleus provides medial/lateral rotation, but requires deformation of the material during flexion and extension. This is accomplished by providing a central portion 188 that is spherical or ovoid in shape and “flattened” adjacent end portions 190A and 190B that are cylindrical, which extend the flattened end portions around the circumference of the nucleus at both ends. The upper end plate has a cavity (not shown) that has a contour that is similar in shape to the nucleus 186. A trough (not shown) similar to the one in Figures 27 and 28 can be formed in the lower end plate 138.

[00181] For medial/lateral movement in the direction of the arrows A-A, the upper and lower end plates will rotate relative to each other through rotational movement of the upper end plate on the nucleus 186. However, flexion/extension in the direction of arrows B-B will occur only through deformation of the nucleus 186. Alternatively, the nucleus 186 can be rotated 90° on the lower end plate 138 so that so that the end plate 136 will rotate on the nucleus during flexion/extension and the nucleus will deform during medial/lateral

movement. The end portion 190A has a larger diameter than the end portion 190B to provide for the desired amount of correction. As shown, the nucleus has been shaped so the resilience of the nucleus varies over its length. However, the nucleus could be formed of materials having varying degrees of resiliency along its length to achieve the same results.

[00182] Figures 40–43 illustrate another embodiment of the invention where the end plates 136 and 138 are provided with stops outside of the normal range of motion, which also utilize the concept of “anatomically-derived gradual stopping” discussed above in conjunction with Figures 34 and 35. This type of stop can be added to any design that employs the use of end plates. This aspect of the invention is based on duplicating how the human body moves and then designing the cooperating surfaces to mimic those motions as closely as possible. As shown in Figure 40, the end plate 136 has a post 200 on its lower surface that engages pocket 202 formed in the upper surface of the lower end plate and 138. Preferably, a pair of posts and pockets are provided on opposite sides of the nucleus 130.

[00183] As shown in Figures 40-43, the pocket 202 has a slot 204 in it with a curved surface 206 that is engaged by the lower end 208 of the post 200. As the end plates 136 and 138 move in the anterior/posterior direction relative to each other during extension/flexion, the lower end 208 of the post rides along the curved surface 206. As the post reaches the outer limits of travel the lower end 208 will begin riding up the gradually curved section of the surface 208, which causes distraction between adjacent vertebrae as illustrated by the arrow A in Figure 43 and loads the tissues between them, resulting in a gradual stop to the motion.

[00184] Figures 44a, 44b and 44c illustrate another embodiment of the invention with a central depression or valley in the flattened segment on the superior surface of the core. In this embodiment the nucleus 130 has first and second flattened sections 150 and 151 that are formed between curved sections 152 and 154. A shallow depression or valley 330 is formed in the flattened sections 150 and 151 and the curved section 152 to provide an indentation with slightly elevated margins 310, 320 that are rounded and contiguous with the adjacent surfaces 150, 151 and 152. The depression 330 is elongated in the anterior/posterior direction, along the sagittal plane SP. The depression 330 and margins 310 and 320 are symmetric about the sagittal plane SP. A pair of transition zones 340 and 350 extend between the depression 330 and the surrounding surfaces. This configuration is designed to potentially improve load distribution as the superior endplate moves relative to the nucleus

because contact is distributed along the margins 310 and 320 instead being concentrated along the mid-sagittal plane or other portion of the nucleus.

[00185] Another embodiment of the invention is shown in Figures 45, 45a, 45b and 45c, where the posterior superior surface 360 of the nucleus 130 is formed to curve upwardly toward the superior end plate 136 relative to the superior surface 350 of the nucleus in order to provide a relatively elevated posterior surface region 360. The superior end plate 136 has a corresponding surface 370 contoured to fit the posterior superior surface 360 of the nucleus. This configuration is designed to enhance the stability of the prosthesis by allowing the endplates 136 and 138 to resist posterior shear when they are in a lordotic position. Figures 45b and 45c illustrate the relative positions of the components in Figure 45 as the spine moves in flexion and extension, respectively. The elevated surface region 360 and its corresponding surface on the end plate 136 causes shear loads to be transmitted through the nucleus and into the inferior endplate. Consequently, abnormal loads on facet joints of the natural spine and related soft tissue structures are prevented.

[00186] Figure 45b illustrates another feature of the invention where the nucleus 130 has a tang or tab 300 that extends posteriorly from the posterior-inferior aspect of the nucleus 130, which fits in an undercut portion or recess 302 of the bottom end plate 138. The tab 300 operates to resist posterior migration (i.e., expulsion) of the nucleus toward the spinal canal by preventing "lift off" of the nucleus from the inferior end plate and possible dislocation of the nucleus. As shown, the tab 300 can be rounded, chamfered or beveled in order to facilitate initial insertion and intra-operative or post-operative replacement of the nucleus.

[00187] As shown in Figs. 44a and 44c, a pair of shallow cavities or dimples 342 and 344, are formed on opposite sides of the anterior aspect of the nucleus in order to allow a retrieval/insertion instrument to engage the nucleus for insertion and removal. These cavities 342 and 344 are formed in a location where they do not interfere with the load carrying capabilities of the nucleus.

[00188] Figures 46a, 46b, 46c and 46d show another embodiment of the invention where a pair of keels 100a are formed in the outer surface of the top end plate 92, with a bony ingrowth surface 101a formed between the keels 100a. The lower surface of the bottom end plate 94 has a single keel 100b formed along its anterior/posterior centerline, or sagittal plane, with a bony ingrowth surface 101b formed on both sides of the keel 100b. The design of a pair of parasagittal keels on the superior endplate and a single central keel on the inferior

endplate, or vice versa, prevents “in line” sagittal cuts in the vertebral body that can increase the possibility of fracture of the body. Alternatively, a pair of keels could be formed on the inferior endplate and a single keel on the superior could be used with the same beneficial results. This and other combinations of keels with an unequal number and/or locations of keels on the superior and inferior endplates will prevent excessive stress in the vertebral bodies when multiple spinal levels undergo device implantation.

[00189] The keels 100a and 100b include a rail 400 attached to the respective end plates, with multiple teeth 402 in accordance with the size of the device, on each rail that projects in the anterior direction. The rails 400 can include a number of holes 404 to allow for bony ingrowth for anchoring the rails in place after implantation. The bony ingrowth surfaces can be any known type of surface that allows tissue to grow into or adhere to the upper end plate 92. Such a surface can include sintered beads, fibers, or other materials attached to the upper end plate, or the surface can be roughened or textured in a known way. The ingrowth surfaces 101a and 101b on the top and bottom plates are protected by slight elevations or lips, which surround the bony ingrowth surface (not shown). Tabs 406 can be provided to limit posterior migration and for tooling locations for insertion instruments. A pair of shallow cavities or dimples 408, 410, can be formed on opposite sides of the anterior aspect of the end plates 92, 94, respectively, in order to allow a retrieval/insertion instrument to engage the end plates for insertion and removal.

[00190] In another aspect of the invention, all of the articulating surfaces of the prosthesis can be formed of a polymer. As discussed above, the nucleus can be formed entirely of a polymer such as, for example, ultra-high molecular weight polyethylene (“UHMWPE”), a cross, linked UHMWPE, a ceramic, polyetheretherketone (“PEEK”) or other type of suitable polymer. The bony ingrowth surfaces can be made from plasma sprayed metals, hydroxyapatite or similar bone-like coatings, and can include a coating of bone growth factors. The articulating surfaces of the end plates can be formed with inserts of an appropriate polymer, ceramic or the like. The remaining exterior surfaces of the end plates that interface with bone can be formed with bony ingrowth surfaces of the type discussed above.

[00191] Figs. 47 and 48 illustrate a frame or scaffold 500 that is used to distract adjacent vertebral bodies 502 and 504 of the human spine, looking in the direction of the anterior surface of spine with the scaffold 500 in place. The scaffold 500 also operates as an

instrument guide for preparing adjacent bone surfaces on the vertebral bodies 502 and 504. The scaffold 500 is held in place by locking mechanisms 490 that attach to the vertebral bodies 502 and 504 through distracting pins 492 that are connected to the vertebral bodies 502 and 504.

[00192] The vertebral bodies 502 and 504 are distracted in a known way by means of a distracting instrument (not shown) that is connected between the distracting pins 492 that are connected to the vertebral bodies for distracting them or spreading them apart to create a space 509 between them after the natural nucleus (not shown) is removed.

[00193] As the scaffold 500 is inserted between the vertebral bodies 502 and 504, the locking mechanisms 490 are placed over the distracting pins 492 and screws 491 are tightened to hold the scaffold 500 in place. As shown in Figure 48, anchoring spikes 510 on the inner surface of the scaffold 500 on opposite sides of the space 509 engage the vertebral bodies 502 and 504 and provide additional support for anchoring the scaffold 500 to the vertebral bodies.

[00194] A pair of lateral projections 506 on the inner surface of the scaffold 500, extend posteriorly into the disc space 510, bilaterally, for maintaining the vertebral bodies 502 and 504 at a specific disc height. Grooves 514 are formed on the facing surfaces of the projections 506 for guiding instruments such as a trial, a drill guide and a keel shaper used during the implantation process, which are described in greater detail below.

[00195] Figure 49 shows one of a set of trial instruments 516 with a handle 516a, that can be inserted in the scaffold 500 or directly into the disc space to gauge AP/medial-lateral endplate coverage between the vertebral bodies 502 and 504 for determining the correct implant size that will be used. The side surfaces of the trial instruments 516 may have profiles 515 that are shaped to fit into the grooves 514 formed on the scaffold projections 506. The trial instruments also may have two or more stops 513a and 513b for preventing the instrument from being inserted too far posteriorly between the endplates 502 and 504. The set of trial instruments should be sized and shaped to at least have the capability of gauging various degrees of lordotic correction, preferably at least 0°, 3° and 6° of lordotic correction, and to determine the size of the anterior-posterior and medial-lateral dimensions of the endplates for the prosthesis.

[00196] Figure 50 shows a drill guide 518 with a handle 518a, and guide holes 520a, 520b and 520c formed in tabs 519a, 519b and 519c, respectively, for setting the trajectory for drill

bits (not shown) that are used to make starter holes in the vertebral body 502 and 504, for grooves that will ultimately receive keels formed on the endplates of the prosthesis that are described in greater detail above. The tabs 519a, 519b and 519c also operate as stops for preventing the drill guide from being inserted too far posteriorly into the disc space 509 between the vertebral bodies 502 and 504. The drill guide 518 has side surfaces with profiles 515 that are shaped to fit into the grooves 514 formed in the lateral projections 506 on the scaffold 500. The guide holes correspond to the location of the keels formed on outer surfaces of the upper and lower end plates of the prosthesis described above, and are used to guide drill bits (not shown) for forming starter holes (not shown) that open onto the facing surfaces of the vertebral bodies 502 and 504, so that they can be shaped to receive the keels by the instrument shown in Figure 52. Figure 51 shows the scaffold 500 positioned between the vertebral bodies 502 and 504, ready to have the holes drilled in direction of the arrows.

[00197] Once the starter holes are drilled, a keel cutting instrument 522 of the type shown in Figure 52 is inserted in the scaffold 500 for shaping the starter holes into grooves in the vertebral bodies 502 and 504. The keel cutting instrument 522 includes side surfaces with profiles 515 that are shaped to fit into the grooves 514 in the lateral projections 506 on the scaffold 500 so that the location and motion of the instrument can be precisely controlled. The keel cutting instrument also includes sharp cutting edges 524a, 524b and 524c that are used to shape the openings that were drilled into the vertebral bodies 502 and 504, with a simple back-and-forth movement of the instrument relative to the scaffold 500. In this way, grooves of the exact shape are formed in the vertebral bodies for receiving the keels on the prosthesis with minimal force being applied to the prosthesis. One or more stops 526a, 526b and 526c are provided on the instrument 515 for preventing the instrument from being inserted too far posteriorly between the vertebral bodies 502 and 504 as the grooves are formed.

[00198] As shown in Figure 52, described above, the keel cutting instrument 522 has one keel cutter 524a placed on one surface and two keel cutters 524b, 524c on the opposite surface, although other configurations can be used as long as there is a shape such that at least one keel is on one surface and at least two are on the other surface for providing maximum stabilization for the prosthesis and resisting torsional forces on the prosthesis. The instrument also has one or more stops 526a, 526b and 526c for preventing the instrument from being inserted too far between the endplates 502 and 504.

[00199] Alternatively, the drill guide 518 and keel cutter 522 can be replaced with a drill guide 600 of the type shown in Figs. 53A-53D. The drill guide 600 can include side surfaces with profiles 515 that are shaped to fit into the grooves 514 in the lateral projections 506 on the scaffold 500 so that the location and motion of the instrument can be precisely controlled. In another technique, the scaffold 500 is not used and the drill guide 600 is inserted into the disc space 509 with the aid of intra-operative fluoroscopy. The drill guide 600 also can have a collar 602 that includes three guide holes 604a, 604b and 604c for guiding drill bits 606 shown in Figs. 53A and 53B. The collar also operates as a stop to prevent the drill guide from moving to far posteriorly between the vertebral bodies 502 and 504. The guide holes are oblong in shape so that the drill bits can be moved in the guide holes to form not only starter holes, but also to form the grooves for the keels on the prosthesis. In this way, the keel cutter 522 described does not have to be used as the grooves for receiving the keels are formed solely through the use of the drill guide 600.

[00200] The final step of the process of implanting the prosthesis, after the grooves for the keels are formed, includes assembling the prosthesis of the selected size and degree of lordotic correction, with the nucleus sandwiched between the end plates. The physician uses an instrument that is designed to engage the shallow cavities or dimples 408 and 410 on the end plates of the prosthesis described above. After lining up the keels of the prosthesis with the grooves created in the vertebral bodies 502 and 504, the prosthesis is then gently tapped into place between the vertebral bodies 502 and 504. The grooves formed as discussed above minimize the amount of force needed to position the prosthesis in the proper location between the vertebral bodies 502 and 504.

[00201] In the event that a core with an incorrect size or shape is inserted, the disc space could be distracted by various means, including vertebral body distracting pins that are well known. An instrument with small pins that are designed to engage the small holes on the lateral aspect of the nucleus (as described previously) is used to remove the nucleus so that it can be replaced with one having the correct size and shape.

[00202] Another embodiment of the invention that is designed to correct lordosis in the spine is a 2-piece device of the type shown in Figs. 54, 55 and 56, that allows normal kinematics while at the same time has a wedge-shaped geometry. This design includes an elongated ball or "sausage shaped" articulating bearing surface, that is preferably located on the inferior endplate, that has its greatest diameter either anterior, posterior or lateral to the

mid-portion of the inferior endplate. This design would alter the articulation between the superior and inferior endplates to provide a deformity correction.

[00203] As shown in Figs. 54, 55 and 56, an elongated or “sausage type” shaped articulating surface 500 can be incorporated into the inferior endplate 502 such that the prosthesis has a 2-piece design, as opposed to the 3-piece design described in previous embodiments. The elongated articulating surface 500 includes a flattened segment 504 and mates with a bearing surface 506 on the superior endplate 508. As shown in Fig. 54, the flattened segment 504 is incorporated onto the inferior bearing surface to allow the resting configuration of the engaged endplates to be in a lordotic configuration in the shape of a truncated cone. With this design, the inferior endplate 502 will have a maximum vertical axis that is not located at the geometric center of the prosthesis, but is located either toward the front of the endplate, the rear of the endplate or on one side of the endplate. The positioning of the maximum vertical height and load bearing capability is chosen depending on the type of deformity that needs to be corrected. In Fig. 54, the geometric center is located toward the front of the endplate 502, which will provide lordotic correction.

[00204] The articulating bearing surface 500 of the inferior endplate 502 also includes curved sections 510 and 512 on opposite sides of the flattened segment 504 to provide the full range of motion and translation in the sagittal and coronal planes.

[00205] The superior endplate 508 attaches to an upper vertebral member (not shown), and the inferior end plate 502 attaches to a lower vertebral member (not shown). The endplates have an essentially flat outer or vertebral-contacting surface that allows them to be easily inserted. There can be keels or teeth 514, having the configuration discussed in detail above, to provide acute stability and anchoring of the device. The keels can be staggered to avoid stress concentration in the bone. There may be two parasagittal keels on the superior endplate and one midline keel on the inferior endplate or vice versa. The outer surface of the end plates 502 and 508 may be treated in a way that promotes bony ingrowth to enhance stability of the end plate *in situ*. The end plate can include a stop member 516 to prevent the prosthesis from moving toward the spinal canal.

[00206] The end plates can have two distinct surfaces. The flat surface of each end plate, which contacts the vertebral body end plate, is capable of accommodating bony ingrowth and incorporates a suitable coating, such as porous titanium, a calcium phosphate, or includes other types of known surfaces mentioned above that promote bony ingrowth for long-term

stability. The end plates can also have one or more parasagittal keels that provide immediate fixation.

[00207] The two pieces 502 and 508 may be composed of a low friction elastomer such as polyurethane, polycarbonate-polyurethane, a polymer such as polyethylene (particularly ultra-high molecular weight polyethylene), a suitable ceramic, metals or metal alloys such as titanium or a titanium alloy, chrome-cobalt-molybdenum (CoCrMo), cobalt 28, chromium molybdenum, cobalt chrome, stainless steel, PEEK or other suitable materials. The flattened segment 504 of the inferior endplate 502 has a generally cylindrical geometric design, with varying degrees of lordosis incorporated into it by utilizing an axis of maximum height anterior to the geometric center of the inferior endplate. The anterior height of the inferior endplate varies, depending on the extent of lordotic correction needed. The inferior endplate can be made available in various lordotic angles, e.g. 0, 3° and 6°, as well as differing heights (e.g., 4, 6 and 8 mm). Before deciding on the final device size, a set of instruments of the type described above or other means can be used to gauge the need for lordotic correction.

[00208] As mentioned above, the articulating bearing surface 500 of the inferior endplate 502 is elongated, with a flattened section that is either a partial cylinder or a partial cone, with curved sections 510 and 512 on both sides of the flattened section. This shape is designed so that when the articulating bearing surface 500 of the inferior endplate is mated with the cylindrical bearing surface 506 on the superior endplate 508, better wear characteristics will result because there will be surface contact during medial/lateral bending and line contact during flexion/extension.

[00209] In the neutral position, the bearing surface 506 mates with the flattened bearing surface 504 and sits at an angle that provides the desired deformity correction. In this position, there is surface contact between the superior end plate 502 and 508 and the inferior endplate. During medial/lateral bending, there will also be surface contact, but between the bearing surface 506 and one of the curved sections 510 and 512.

[00210] In Figures 57-76, various embodiments of joint replacing implants are depicted, including a carpometacarpal joint implant, a metatarsophalangeal joint implant, a metacarpophalangeal joint, a first metatarsophalangeal joint, a distal and a proximal interphalangeal joint implant, an ankle implant, a total knee implant, a hip implant, and a shoulder implant. The bearing surfaces of each implant may include an orientation feature such as a flattened section similar to those disclosed above. The flattened sections may be

contiguous with other portions of the bearing surfaces, meaning they are immediately adjacent to those portions.

[00211] Referring to Figure 57, a sagittal view of a carpometacarpal joint is shown, with a metacarpal component 610 of a carpometacarpal prosthesis 600 implanted in the metacarpal bone, and a trapezal component 650 of the prosthesis implanted in the trapezium and potentially extending to the scaphoid. The metacarpal component 610 has a stem portion 612 joined to a dome-like head portion 614. Positioned opposite the metacarpal component 610 is the trapezal component 650, comprising a cup-like receptacle portion 654 and a stem portion 652. The head portion 614 is configured to mate with and articulate within the receptacle portion 654, to replace the motion of the natural carpometacarpal joint. Alternatively the dome-like head could be positioned in the trapezium and the cup-like receptacle on the metacarpal bone.

[00212] Referring to Figure 58, a perspective view of the metacarpal component 610 and trapezal component 650 are shown. The stem portion 612 of the metacarpal component 610 has a generally cylindrical stem body 616, which extends from the head portion 614 to a tapered, pointed tip 618. The stem body 616 may have a constant diameter along its length or may taper from the head portion 614 to the tip 618. Threads 620 encircle the stem body 616 at its proximal end and continue onto the tip 618. In other embodiments of the invention, threads or grooves or porous and/or hydroxyapatite may be present along part or all of the stem body, or the stem body may be non-threaded. Additionally, it is appreciated that the stem body 616 may not be cylindrical in form with a round cross-sectional shape, but have different cross-sectional shapes such as a square, a rectangle, a triangle, a hexagon, or another shape.

[00213] Distal to the stem portion 612, the head portion 614 comprises a base 622 and a dome 624. The base 622 is a flat, circular element from which the dome 624 extends distally. The base 622 has a proximal-facing bone contacting surface 626 which is configured to be seated in the prepared metacarpal. The bone contacting surface 626 may be a porous or non-porous tissue ingrowth surface. A thickness of the base may vary from a thin, bone conserving profile to a thicker bone replacing profile. The dome 624 has a generally hemispherical configuration; however a central section of the dome, extending from one edge to the opposite edge is shaped as a portion of a cylinder having a constant radius, resulting in a flattened section 630. Alternatively the dome may have an asymmetric configuration with

the flattened section placed outside the central section of the dome. The flattened section 630 has a constant radius, and lies in an anterior-posterior orientation; however in other embodiments it may lie in a medial-lateral orientation. The flattened section may also be available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity. Alternatively the flattened section may be positioned to correct coronal or rotatory deformity. Contiguous to either side of flattened section 630 are rounded areas, a first rounded section 632 and a second rounded section 634. The rounded areas 632 and 634 may have the same or differing heights and configurations. A continuous substantially convex bearing surface 636 covers the rounded sections 632, 634 and the flattened section 630.

[00214] The introduction of the flattened section determines the alignment of the implant components and either introduces a preferred relative orientation for the articulation of the dome-like head and the cup-like receptacle or alternatively reduces a pre-operative deformity of the carpometacarpal joint. A prosthesis that allowed a preferred alignment or orientation of the carpocarpal, carpometacarpal and intermetacarpal joints would be of particular importance in the setting where the palmar and/or dorsal ligature are compromised. Any disease process that affected the static alignment of the joints in the anatomical position would require an active correction of the deformity by the implant.

[00215] The stem portion 652 of the trapezoid component 650 is configured similarly to the stem portion 612 set forth previously, with a stem body 656, a tip 658, and threads 660. In the embodiment depicted in Figures 57 and 58, the stem portion 652 is long enough to engage only the trapezium; however in alternative embodiments the trapezoid stem portion 652 may be longer than the metacarpal stem portion 612 in order to extend through the trapezium and anchor in the scaphoid. Joined to the stem portion 652 at its proximal end is the cup-shaped receptacle portion 654. The receptacle 654 has a distal-facing bone contacting surface 676 which is configured to be seated in the proximal side of the trapezium. The bone contacting surface 676 may be a porous or non-porous tissue ingrowth surface. The inside of the receptacle portion 654 is a substantially concave bearing surface 678 configured to mate concentrically and articulate with the dome 624, and has a flattened section 680 which extends from one edge of the cup to the other in an anterior-posterior orientation. The flattened section 680 may be centered along the antero-posterior axis; alternately it may offset from the center in an asymmetrical orientation. In another embodiment, the flattened

section 680 may be oriented along the medial-lateral axis. The flattened section receptacle portion is available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity. Contiguous with the flattened section 680 is a first rounded cup section 682, and a second rounded cup section 684.

[00216] The carpometacarpal prosthesis 600 is configured to be implanted in the metacarpal and trapezium bones such that the dome 624 articulates inside the cup 654 in a preferred relative orientation. The dome 624 may rotate partially within the cup 654, limited by the flexion/extension and medial/lateral movements of the surrounding muscles and ligaments. It may act in an unconstrained or a semi-constrained manner. As the thumb is moved medial-laterally, the cup 654 will slide over the dome 624. At a neutral medial-lateral position, the flattened section 680 of the cup will be in alignment with the flattened section 630 of the dome.

[00217] As the thumb flexes and extends, along the dorso-palmar axis, if the flattened sections 630, 680 are aligned the movement will be smooth, since the curvature of the flattened section 680 of the cup corresponds to the curvature of the flattened section 630 of the dome. If the posterior-anterior movement is canted slightly medially or laterally, the flattened sections 630, 680 will not be aligned.

[00218] When a joint such as the carpometacarpal joint is diseased or injured, and the joint replaced, some surrounding soft tissues are usually irreplaceably lost due to the disease or injury, and the replacement procedure. Loss of the soft tissues can result in the loss of the natural alignment of the bones in the joint; as tissues provide natural support and constraint to the bones. Providing the mateable flattened surfaces 630, 680 may replace some of the natural joint alignment formerly provided by the soft tissues. Fixed deformity of the carpometacarpal joint is associated with longstanding osteoarthritis, rheumatoid arthritis, inflammatory and non-inflammatory arthritis and post traumatic arthritis. The mateable flattened surfaces are able to address preoperative deformity in the varus and valgus plane and preoperative deformity in all planes.

[00219] Referring to Figure 59, a lateral view of a metacarpophalangeal joint prosthesis 700 implanted in a metacarpal bone and a phalangeal bone is shown. The metacarpophalangeal prosthesis 700 may be generally similar to the carpometacarpal prosthesis 600, however it may be sized and shaped slightly differently to match the

particular geometry of the joint. The metacarpophalangeal joint prosthesis 700 comprises a domed metacarpal component 710 and a cup-like phalangeal component 750. Alternatively the dome-like head component could be positioned in the phalangeal component and the cup-like receptacle component in the metacarpal bone.

[00220] The metacarpal component 710 has a stem 712, a base 714, and a substantially convex head 716. A flattened section 730 extends medial-laterally across the head 716. Alternatively the flattened section 730 may extend in an antero-posterior orientation across the head 716. The phalangeal component 750 comprises a stem 752 and a substantially concave receptacle 754. A flattened section 760, shaped to correspond to the flattened section 730, extends medial-laterally across the receptacle 754. When the components are implanted, the convex head 716 articulates inside the concave receptacle 754. At a neutral position, the corresponding flattened sections 730, 760 align. In this preferred relative orientation, medial-lateral movement of the joint is smooth. Alternatively the head 716 may have an asymmetric configuration with the flattened section placed outside the central section of the head.

[00221] Referring to Figure 60, a lateral view depicts a distal interphalangeal joint prosthesis 800 implanted in an intermediate phalange and a distal phalange. The distal interphalangeal prosthesis 800 comprises an intermediate phalange component 810 which is shaped to be implanted in the distal end of an intermediate phalange, and a distal phalange component 850 which is shaped to be implanted in the proximal end of a distal phalange. Alternatively the dome-like head 810 could be positioned in the distal phalangeal component and the cup-like receptacle 850 in the intermediate phalangeal bone.

[00222] The distal interphalangeal joint prosthesis may be similar to the carpometacarpal and metacarpophalangeal prosthesis, but sized differently to accommodate the smaller distal interphalangeal joint. It is appreciated that a substantially comparable prosthesis could be made for the proximal interphalangeal joint.

[00223] Referring to Figure 61, the intermediate phalange component 810 and the distal phalange component 850 are shown in an enlarged perspective view. The intermediate phalange component 810 has a stem 812, a base 814, and a substantially convex head 816. A flattened section 830 extends antero-posteriorly across a portion of the head 816, and a substantially convex bearing surface 832 extends across the distal side of the head, including the flattened section 830. In another embodiment of the invention, the flattened section could extend medial-laterally across the head, or with another orientation. Alternatively the dome

may have an asymmetric configuration with the flattened section placed outside the central section of the dome. The flattened section is also available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity.

[00224] The distal phalangeal component 850 comprises a stem 852 and a concave receptacle 854. A flattened section 860, shaped to correspond to the flattened section 830, extends antero-posteriorly across a portion of the receptacle 854, and a substantially concave bearing surface 862 extends across the proximal side of the receptacle 854. When the components are implanted, the convex head 816 fits inside the concave receptacle 854 and the bearing surfaces 832, 862 articulate. At a neutral position, the corresponding flattened sections 830, 860 align. In this preferred relative orientation, antero-posterior extension and flexion of the joint is smooth.

[00225] Fixed deformity of the proximal interphalangeal joint is associated with longstanding osteoarthritis, rheumatoid arthritis, inflammatory and non inflammatory arthritis and post traumatic arthritis. Conditions such as swan neck and boutonnière deformities of the interphalangeal joint also require addressing associated soft tissue contractures at the metacarpal phalangeal joint. The mateable flattened surfaces are able to address preoperative deformity in the varus and valgus plane and preoperative deformity in the flexion and extension plane.

[00226] Referring to Figure 62, a lateral view of a “great toe” or first metatarsophalangeal joint implant 900 is shown. The first metatarsophalangeal implant 900 has a metatarsal component 910 and a phalangeal component 950. When implanted in opposing metatarsal and phalangeal bones, the metatarsal 910 and phalangeal 950 components may engage and articulate with one another to replace the function of a natural metatarsophalangeal joint.

[00227] Figure 63 displays enlarged perspective views of the metatarsal 910 and phalangeal 950 components. The metatarsal component 910 has a plurality of short spikes 912, which protrude proximally from a substantially circular base 914. Alternatively, a single stem may take the place of the spikes. Either spikes or stem may have threads, grooves or other features to enhance fixation of the component in the bone. The proximal side of the base 914 is a metatarsal bone-contacting surface 918. The bone-contacting surface 918, spikes 912, and/or stem may comprise a porous or non-porous tissue ingrowth surface.

[00228] A rounded head 916 extends distally from the base 914. One aspect of the head 916, such as the dorsal aspect, may be built up as a wedge to provide an angled bearing surface, to mimic the natural configuration of the first metatarsophalangeal joint and/or accommodate deformities of the articular cartilage of the first metatarsal. The outer surface of the head 916 is a substantially convex bearing surface 920. Extending from the dorsal edge of the head 916 to the opposite anterior edge and forming part of the bearing surface 920 is a flattened section 930. The flattened section 930 is substantially shaped as a portion of a cylinder; however, since one side of the head may be built up to form an angled bearing surface, the radius of the cylinder may not be constant and the flattened section may therefore be asymmetrical. The flattened section is also available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity. A first curved section 932 curves from one side of the flattened section 930 to the edge of the head 916, and a second curved section 934 curves from the opposite side of the flattened section 930 to the opposite edge of the head 916.

[00229] The phalangeal component comprises a distally extending stem 952, and a cup-like receptacle 954 shaped to cooperate with the rounded head 916. The distal side of the receptacle 954 is a phalangeal bone-contacting surface 956, and it and the stem may comprise a porous or non-porous tissue ingrowth surface. The proximal side of the receptacle 954 has a cup-like depression contoured to correspond to the shape of the rounded head 916. A substantially concave bearing surface 960 covers the proximal side of the receptacle 954, and a flattened section 970 extends from the dorsal side of the receptacle 954 to the opposite anterior side. Adjacent to the flattened section 970 on one side is a first cup section 972, and a second cup section 974 extends from the opposite side of the flattened section 974. The flattened section receptacle portion is also available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity.

[00230] The metatarsal 910 and phalangeal 950 components may optimally be implanted so that their flattened sections 930, 970 are aligned when in the neutral position. When aligned in a preferred relative orientation, flexion/extension of the joint may be smooth as the flattened sections 930, 970 slide along one another. As the phalange is moved laterally to either side, the flattened sections may no longer align precisely, as the head flattened section 930 encounters a lateral cup section 972, 974, and the receptacle flattened section 970

encounters the opposite curved sections 932 or 934. Fixed deformity of the metatarsal phalangeal joint is associated with longstanding osteoarthritis, rheumatoid arthritis, inflammatory and non inflammatory arthritis and post traumatic arthritis. The mateable flattened surfaces are able to address preoperative deformity in the varus and valgus plane and preoperative deformity in the flexion and extension plane.

[00231] Figure 64 is a lateral view of an ankle with an implanted ankle joint prosthesis 1000 according to one embodiment of the invention. The ankle prosthesis 1000 has a tibial component 1010 configured to be implanted in the distal end of the tibia, and a talar component 1050 configured to be implanted on the talus. Figure 65 is a posterior view of the implanted ankle joint prosthesis.

[00232] Returning to Figure 64, the tibial component 1010 has a proximally extending stem 1012 which may be fixed with bone cement in the prepared tibia. Threads, grooves or other features (not visible in Figure 64) may be present on the stem to assist in securing the implantation of the component 1010. Distal to the stem 1012 is the receptacle 1016, which is cup-like in shape with a generally centrally located depression 1020. The cup opens distally or downward when the component is implanted in the tibia. The proximally facing underside of the cup is a tibial bone-contacting surface 1018. The tibial bone-contacting surface 1018, the stem 1012 and the threads 1014 may comprise a porous or non-porous tissue ingrowth surface.

[00233] The depression 1020 may be symmetrical, or may be asymmetrical in depth and orientation. That is, the deepest part of the depression 1020 may be located not at the center of the receptacle 1016, but removed somewhat anteriorly, posteriorly, medially or laterally from the center. A substantially concave bearing surface 1022 lines the depression 1020. An orientation feature which is a flattened section 1030 extends antero-posteriorly across the bearing surface 1022. Within the flattened section 1030, the surface 1022 is flat across its medial-lateral dimension, although it may curve antero-posteriorly. Medially adjacent to the flattened section 1030 is a medial cup section 1032, and laterally adjacent to the flattened section 1030 is a lateral cup section 1034 (not visible in Figure 64).

[00234] Turning to Figure 65, the talar component 1050 is sized and configured to correspond to the tibial component 1010, such that the tibial component 1010 can fit over and articulate with the talar component 1050 to approximate the motion of the natural ankle joint. The talar component 1050 has a plurality of spikes 1052 which protrude distally from a base

1054. Generally flat and plate-like, the base 1054 has a distal facing talar bone-contacting surface 1056 from which the spikes 1052 extend. The spikes 1052 and talar bone-contacting surface 1056 may comprise a porous or non-porous bone ingrowth surface. In this embodiment of the invention, the talar bone-contacting surface 1056 is flat, configured to be implanted upon a substantially resected section of the talus.

[00235] From the proximal side of the base 1054 rises a dome portion 1058, the outer surface of which is a substantially convex bearing surface 1060. The dome portion 1058 may not be radially symmetrical as in a true hemisphere but may be asymmetrical to match the depression of the tibial component. In the embodiment pictured in Figure 64, the highest portion of the dome is shifted anteriorly from the center, although centered medial-laterally. This configuration allows the talar component to more closely match the morphology of the natural talus. The height and shape of the dome 1058 are designed to mate with the shape of the depression 1020 in the receptacle 1010, and to functionally replace the resected section of the talus.

[00236] An orientation feature in the form of a flattened section 1070 extends antero-posteriorly across the convex bearing surface 1060. Within the flattened section 1070, the surface 1060 is flat across its medial-lateral dimension, although it may curve antero-posteriorly. Medially adjacent to the flattened section 1070 is a medial curved section 1072, and laterally adjacent to the flattened section 1070 is a lateral curved section 1074. The flattened section 1070 is also available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity. The flattened section on the tibial component is also available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity.

[00237] Once the talar 1050 and tibial 1100 components are implanted and allowed to cooperate, the concave bearing surface 1022 comes in contact with the convex bearing surface 1060. When the bearing surfaces are aligned at a neutral, low energy position or preferred relative orientation, the tibial flattened section 1030 will correspond to the talar flattened section 1070. From this position, antero-posterior flexion and extension of the joint will be smooth. As the ankle is rotated medial-laterally, the flattened sections may move out of alignment as the talar flattened section 1070 encounters a cup section 1032 or 1034, and the tibial flattened section 1030 encounters the opposite curved sections 1072 or 1074. Fixed

deformity of the ankle joint is associated with longstanding osteoarthritis, rheumatoid arthritis, inflammatory and non inflammatory arthritis and post traumatic arthritis. The mateable flattened surfaces are able to address preoperative deformity in the varus and valgus plane and preoperative deformity in the flexion and extension plane. Additional corrective procedures at the level of the subtalar joint may be required to address varus and valgus deformities.

[00238] Referring to Figure 66, an alternative embodiment of an ankle prosthesis 1100 is shown, implanted in the tibia and talus. Ankle prosthesis 1100 is designed to be less bulky and to be used when a minimally invasive procedure is preferred. The prosthesis 1100 comprises a tibial component 1110 and a talar component 1150. The talar component 1150 may be implanted on the existing talus or alternatively a reamer may be used to create a perfect groove for the talar component 1150 such that once seated, component 1150 lies flush with the surrounding bone.

[00239] Referring to Figure 67, an enlarged perspective view of the ankle prosthesis 1100 is shown. The talar component 1150 comprises a curved bearing portion 1152, from which a plurality of spikes 1154 protrude distally. The curved bearing portion 1152 is shaped to fit over a minimally resected section of the talus. Therefore, curved bearing portion 1152 does not have a flat base and a dome which varies in thickness to substitute for the missing resected bone; instead the curved bearing portion 1152 is curved to fit over or into the conserved talus. Alternatively, the talar component 1150 may sit in a groove created within the talus with a suitable reamer. A flattened section 1170 extends antero-posteriorly across a substantially convex bearing surface 1160 of the talar component 1150. The flattened section 1170 is available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity. Within the flattened section 1170, the bearing surface 1160 is flat across its medial-lateral dimension, although it may curve antero-posteriorly. Medially adjacent to the flattened section 1170 is a medial curved section 1172, and laterally adjacent to the flattened section 1170 is a lateral curved section 1174. Alternatively the talar component 1150 may not have a flattened section and purely have a cylindrical configuration with a corresponding geometry in the tibial component 1110.

[00240] The tibial component 1110 may have many of the same characteristics and features as the tibial component 1010, especially with regards to the stem and tibial bone

contacting surface. However the specific morphology of the cup-like depression 1120 may differ, to conform to the morphology of the trimmer talar component 1150. A substantially concave bearing surface 1122 lines the depression 1120, and is shaped to articulate with the convex bearing surface 1160 of the talar component. A flattened section 1130 extends antero-posteriorly across the bearing surface 1122. Within the flattened section 1130, the surface 1122 is flat across its medial-lateral dimension, although it may curve antero-posteriorly. Medially adjacent to the flattened section 1130 is a medial cup section 1132, and laterally adjacent to the flattened section 1130 is a lateral cup section 1134. The flattened section 1130 is also available in varus and valgus and flexion and extension angled implants in order to correct preoperative varus and/or valgus deformity and flexion and/or extension deformity. Fixed deformity of the ankle joint is associated with longstanding osteoarthritis, rheumatoid arthritis, inflammatory and non inflammatory arthritis and post traumatic arthritis. The mateable flattened surfaces are able to address preoperative deformity in the varus and valgus plane and preoperative deformity in the flexion and extension plane. Additional corrective procedures at the level of the subtalar joint may be required to address varus and valgus deformities.

[00241] Referring to Figures 68A and 68B, lateral and posterior cross-sectional views of another embodiment of an ankle implant are presented. Three-part ankle implant 1500 includes a superior tibial endplate 1510, an inferior talar endplate 1530, and a bearing insert 1550. The tibial and talar endplate may be formed of a biocompatible metal or metal alloy, while the bearing insert may be formed of a biocompatible polymer. This embodiment provides flattened sections extending both antero-posteriorly and medial-laterally in the same implant. The height of the bearing insert may vary and the selection of a particular height may depend on the type and severity of deformity.

[00242] Referring to Figure 68A, tibial endplate 1510 has a superior bone-facing side 1512 with at least one spike 1514 or other feature for securing the endplate to a prepared tibia. An inferior bearing side 1516 includes a post 1518 or other feature for securing the endplate to the bearing insert 1550, which extends caudally toward the talar implant 1530. The talar endplate 1530 has an inferior bone-facing side 1532 with one or a plurality of spikes 1534 for securing the endplate to a prepared talus. A superior bearing side 1536 is on the opposite cephalad side of the endplate 1530.

[00243] As seen best in Figure 68B, the bearing insert 1550 includes a superior bearing surface 1552, which may be substantially convex, and may be shaped to articulate with the inferior bearing side 1516 of the tibial endplate 1510. A pocket 1554 in the superior articulating surface 1552 is positioned to receive the post 1518 when the implant is assembled. In other embodiments of the invention another type of anchoring device other than the post and pocket may be included. The superior bearing surface 1552 includes a superior flattened section 1560 which is oriented antero-posteriorly across the surface, flanked on each side by a curved section 1562. The curved sections allow eversion and inversion of the ankle. The superior bearing surface 1552 may be asymmetrical; preferably an anterior portion of the superior bearing surface may be higher than a posterior portion, although alternatively it may be lower.

[00244] As seen best in Figure 68A an inferior bearing surface 1568, which may be substantially convex, is shaped to articulate with the superior bearing side 1536 of the talar endplate 1530. The bearing surface 1568 includes an inferior flattened portion 1570 which is oriented medial-laterally across the surface, flanked anteriorly and posteriorly by a curved section 1572. The curved sections 1572 allow dorsiflexion and planterflexion of the ankle. Alternatively the flat may be introduced into only the antero-posterior orientation or only the medial-lateral orientation depending on the desired deformity correction. The flattened sections 1560, 1570 may not have identical sizes of flat segments, depending on the desired deformity correction.

[00245] Figures 69A and 69B represent lateral and antero-posterior cross-sectional views of an alternative three-part ankle implant 1600. Ankle implant 1600 includes a superior tibial endplate 1610, inferior talar endplate 1630, and bearing insert 1650. Ankle implant 1600 differs from three-part ankle implant 1500 in that the orientations of the flattened sections are reversed: on the bearing insert a superior flattened section is oriented medial-laterally and an inferior flattened section is oriented antero-posteriorly. In addition, the bearing insert 1650 is free floating between the endplates 1610, 1630, with no anchoring device. The talar and/or tibial endplate may include a depression to match the curvature of the facing bearing surface and which may contribute to retention of the bearing insert.

[00246] Referring to Figure 69A, bearing insert 1650 has a substantially convex superior bearing surface 1652 which articulates with the superior tibial endplate 1610. A flattened section 1660 extends across the bearing surface medial-laterally. Flanking the flattened

section 1660 anteriorly and posteriorly is a curved section 1662. The curved sections 1662 allow dorsiflexion and plantarflexion of the joint. The bearing insert 1650 may be asymmetrical in that a height of the bearing insert may be higher in the anterior portion as seen in Figure 69A. Alternatively the height of the bearing insert may be constant or thinner in the anterior portion, depending upon the deformity to be corrected. Similarly, the height of the bearing insert can vary medial-laterally, again depending upon the deformity to be corrected.

[00247] Referring to Figure 69B, the bearing insert 1650 has a substantially convex inferior bearing surface 1668 which articulates with the inferior talar endplate 1630. The inferior bearing surface 1668 has a flattened section 1670 which extends antero-posteriorly across the insert, flanked on each side by a curved portion 1672. The curved sections 1672 allow eversion and inversion of the ankle.

[00248] Referring to Figures 70A and 70B, an alternative method for implanting any of the ankle implants previously described is shown. A reamer, rasp, or another suitable tool or combination of tools, is used to prepare a groove 1702 in the talus, as seen in Figure 70A. The groove 1702 is a recess in the bone shaped to receive a talar implant 1704, and may be deep enough so that the top surface of the implant is substantially flush with the surrounding bone when implanted in the groove, as shown in Figure 70B. The talar implant 1704 may be shaped to mimic the height and general shape of the removed bone surface. Alternatively, any of the talar implants described above, or a similar implant may be implanted in the groove. By implanting the talar implant in the groove 1702, the total cephalad-caudal height of the implanted prosthesis is reduced, since the implant does not extend significantly above the surrounding bone surface. A similar groove may be prepared in the tibia to receive any of the tibial implants previously presented, or grooves may be prepared in both the tibia and talus, further reducing the total height of the joint replacement.

[00249] During an implantation procedure for any of the prostheses described herein, a reamer or other suitable tool may be used to prepare a recessed area in the bone into which the prosthesis will be implanted. A procedure similar to that described above for an implantable ankle prosthesis may also be implemented for other prostheses, including but not limited to, thumb, finger, toe, knee, shoulder and hip prostheses. Creating a recessed groove into which a component may be implanted may conserve space between joint components and reduce the overall height of a joint replacement.

[00250] Referring to Figure 71, a coronal view of a knee implant 1200 comprising a femoral component 1210 and tibial component 1250 is shown. The femoral component 1210 may have three major portions: a stem 1212, a split condylar portion 1214 and a patellar portion 1216. A stem 1252, tibial tray 1254 and a meniscal portion 1256 make up the tibial component 1250.

[00251] Referring to Figure 72, an enlarged perspective view of the femoral component 1210 and tibial component 1250 is shown. The stem 1212 extends from a proximal end 1220 to a distal end 1222, where it is fixed in a base 1224 which is perpendicular to the stem 1212. Curving around the base 1224 posteriorly to anteriorly is the condylar portion 1214. The condylar portion 1214 is split into two condyles, the medial condyle 1226 and a lateral condyle 1228. Each condyle 1226, 1228 has a substantially convex bearing surface 1230, 1232, each of which may curve antero-posteriorly and medial-laterally, to substantially match the original geometry of the resected knee. Each convex bearing surface 1230, 1232 may further have a flattened section 1234, 1236. Within the flattened sections 1234, 1236, the bearing surfaces 1230, 1232 may not curve antero-posteriorly or medial-laterally, but may be flat. Alternatively the flat may be introduced into only the antero-posterior orientation or only the medial-lateral orientation depending on the desired deformity correction. The flattened sections 1234, 1236 may not have identical sizes of flat segments, depending on the desired deformity correction. These flattened sections 1234, 1236 are positioned so that when the knee is in extension, the flattened sections 1234, 1236 are oriented distally and rest upon the bearing portion 1256.

[00252] The stem 1252 of the tibial component 1250 extends from a distal end 1258 to a proximal end 1260 which is joined to the distal side of the tibial tray 1254. On the proximal side of the tibial tray is the meniscal portion 1256. The meniscal portion 1256 may be a separate insert or may be formed monolithically with the tibial tray 1254. Two concavities extend antero-posteriorly across the meniscal portion 1256, a medial concavity 1262 and a lateral concavity 1264. The concavities are positioned so that when both components are implanted, the medial condyle 1226 contacts and articulates with the medial concavity 1262, and the lateral condyle 1228 contacts and articulates with the lateral concavity 1264. Each concavity 1262, 1264 has a substantially concave bearing surface 1266, 1268. A medial flattened section 1270 may be located on the medial bearing surface 1266, and a lateral flattened section 1272 on the lateral bearing surface 1268. Within the flattened sections 1270,

1272, the bearing surface 1266, 1268 are not concave, but flat, configured to correspond to the flattened sections 1234, 1236 of the femoral components.

[00253] When the knee is in extension the flattened sections of the femoral and tibial components are aligned, as the femoral component rests upon the tibial component. As the knee is flexed, the femoral component 1210 will rotate posteriorly with respect to the tibial component 1250, and the flattened sections 1234, 1236 will move anteriorly so that they are no longer in alignment with the medial 1270 and lateral 1272 flattened sections on the meniscal portion 1256. As they move out of alignment, the posterior edges of the flattened sections 1234, 1236 will encounter the concave portions of the concavities 1262, 1264.

[00254] Referring to Figure 73, a cross-sectional view of a hip prosthesis 1300 is shown. The hip prosthesis 1300 comprises an acetabular cup component 1310 and a femoral component 1350.

[00255] Referring to Figure 74, a perspective view of the hip prosthesis components 1310, 1350 is presented. The acetabular cup component 1310 is cup-like in shape, with a convex bone-contacting surface 1312 which may be a porous or non-porous bone ingrowth surface. Lining the inside of the component is a substantially concave bearing surface 1314, which may be made of a biocompatible metal, plastic or ceramic. Generally centrally positioned on the concave bearing surface 1314 is a flattened section 1316, which may be circular in shape. Contiguously encircling the flattened section 1316 is a concave ring section 1318. The flattened section 1316 may be symmetrically positioned on the concave bearing surface as in Figure 74; alternatively it may be asymmetrically placed.

[00256] The femoral component 1350 includes a stem 1352, a neck 1354, and a head 1356. The stem 1352 may have a porous or non-porous bone ingrowth surface, and is shaped to be implanted in the resected proximal end of the femur. The neck 1354 may be generally perpendicular to the stem 1352, but can be aligned at a non-perpendicular angle if required, to match the particular geometry of the patient's hip. The head 1356 is mounted to or contiguous with the proximal end of the neck. The head 1356 is generally spherical in shape, and is configured to articulate with the acetabular cup component 1310. A substantially convex bearing surface 1358 covers the outer spherical surface of the head. A section of the convex bearing surface 1358 may be a flattened section 1360, which is configured to potentially incorporate a planar surface. The flattened section 1360 may be located so that it corresponds concentrically to the flattened surface 1316 of the acetabular cup component

1310, when the components 1310, 1350 are implanted and mated together. As with the flattened section 1316 on the acetabular cup, the flattened section 1360 of the femoral component may be symmetrically or asymmetrically located on the bearing surface.

[00257] Referring to Figure 75, a cross-sectional view of a shoulder prosthesis 1400 is shown. The shoulder prosthesis 1400 comprises a humeral component 1410 configured to be implanted in the proximal end of a resected humerus, and a glenoid component 1450 configured to be implanted into the glenoid cavity of the scapula.

[00258] Referring to Figure 76, a perspective view of the shoulder prosthesis components 1410, 1450 is presented. The glenoid component 1450 depicted comprises a small stem 1452, a base 1454, and a socket 1456. In other embodiments of the invention, there may be a plurality of stems, or no stem. The stem 1452 is joined to a bone-contacting side 1458 of the base 1454. Both the stem 1452 and the bone-contacting side 1458 of the base may comprise a porous or non-porous bone ingrowth surface. The concave socket 1456 is joined to the base 1454 on the opposite side from the stem 1452. A substantially concave bearing surface 1462 lines the inside of the socket 1456. A flattened section 1460 is generally centrally located on the concave bearing surface 1458, forming a substantially circular flat area on the surface 1458. Contiguously encircling the flattened section 1460 is a concave ring section 1464.

[00259] The humeral component 1410 comprises a stem 1412 and a head 1414. The stem 1412 is long, slender and generally cylindrical in shape, and is shaped to be inserted into the proximal end of a resected humerus, as seen in Figure 75. A neck 1416 extends from the proximal end of the stem 1412 and connects the head 1414 to the stem. The head 1414 is generally hemispherical in shape, with a flat, distally oriented bone-facing side 1418 and a rounded, proximally oriented substantially convex bearing surface 1420. A flattened section 1430 occupies a portion of the convex bearing surface 1420, forming a substantially circular planar segment on the surface.

[00260] When the humeral 1410 and glenoid 1450 components are implanted and the joint is in a neutral position or preferred relative orientation, the flattened sections 1430, 1460 are aligned, opposing one another in a concentric correspondence. The flattened segment may provide a desired alignment that may be particularly relevant in revision or tumor surgery where the surrounding soft-tissue structures have been affected. The flattened sections 1430, 1460 may be located generally centrally on the humeral and glenoid components as shown, or may be asymmetrically offset to if necessary correct a deformity.

[00261] Many of joint replacement implants described above may also include a third component designed to cooperate with the first and second components to create a universal joint with two axes of rotation. The third component may have two bearing surfaces, one configured to cooperate with the first component and a second configured to cooperate with the second component. The bearing surfaces on the third component may have flattened sections configured to cooperate with the flattened sections on the first and second components. For example, a first bearing surface on the third component may have a flattened section configured to cooperate with a flattened section on the first component to provide a flexion/extension axis of rotation, while the second bearing surface on the third component may have a flattened section configured to cooperate with a flattened section on the second component to provide a varus/valgus axis of rotation.

[00262] The joint replacement implants depicted in Figures 57-76 may be formed of biocompatible materials such as bio-compatible metals or other suitable strong materials. An implant may be formed of one biocompatible material while the bearing surface comprises another biocompatible material.

[00263] The implant components may be formed wholly or partially of any biocompatible metal, such as stainless steel, Titanium, Titanium alloys, Cobalt Chrome, CCM (Cobalt Chrome Molybdenum), Aluminum, Zirconium, Nickel Titanium (NiTi / Nitinol), shape memory metals, superelastic metals, metal matrix composites such as Titanium Carbide, Tungsten Carbide, Tantalum, or Chromium, among others. The implant components can be formed wholly or partially of a biocompatible ceramic material such as alumina, zirconia, alumina-zirconia blends, or other ceramic composites. The implant components can be formed wholly or partially of a biocompatible polymer such as PEEK, carbon or glass-fiber reinforced polymers, ABS, polycarbonate, polyethylenes, ultra high molecular weight polyethylene (UHMWPE), nylons, polymer composites, acetals, polyesters, polypropylene, PTFE, ePTFE, absorbable polymers such as poly l-lactic acid (PLLA), polylactic acid (PLA), polyglycolic acid (PGA), TCP, glycolides, lactides, hydrogels, elastomers such as silicone, nitrile, butyl, thermoplastic elastomers (TPE's), or ethylene vinyl acetate (EVA), among others.

[00264] The implant components can be can be formed wholly or partially of another biocompatible material including diamond or dia mond-like materials, carbon, hyrdogels, pyrocarbon, pyrolitic carbon, allograft bone, demineralized bone, collagen, cartilage,

tricalcium phosphate, calcium phosphate, hydroxyapatite, PMMA – bone cement, proteins, amino acids, nucleic acids, or sugars, among others.

[00265] The implant components may also be coated wholly or partially with specialized coatings such as Titanium Nitride, Titanium Boride, Titanium Carbide, ion-based coatings, ceramic coatings, oxide coatings, plasma, PTFE coatings, low-friction coatings, hydrophobic or hydrophilic coatings, or vapor deposition coatings, among others. Bone-contacting portions of implant components may comprise porous or non-porous bone ingrowth surfaces.

[00266] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. For example, above are described various alternative examples of joint prostheses. It is appreciated that various features of the above-described examples can be mixed and matched to form a variety of other alternatives, each of which may have a different bearing surface configuration or preferred relative orientation according to the invention. As such, the described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

[00267] Although the present invention and its advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the invention as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present invention. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

CLAIMS

1. An implantable joint prosthesis, the prosthesis comprising:
 - a first component having a first bearing surface; and
 - a second component having a second bearing surface shaped to articulate with the first bearing surface;

wherein the first bearing surface has, in at least one cross section, a first flattened section positioned between and contiguous with first and second curved sections of the first bearing surface, and the second bearing surface has, in at least one cross section, a second flattened section positioned between and contiguous with third and fourth curved sections of the second bearing surface;

wherein the second flattened section is configured to rest against the first flattened section in a preferred relative orientation of the first and second components.
2. The implantable joint prosthesis of claim 1, wherein the first flattened section is not positioned centrally on the first bearing surface, and wherein the second flattened section is not positioned centrally on the second bearing surface.
3. The implantable joint prosthesis of claim 1, wherein the first bearing surface is substantially convex and the second bearing surface is substantially concave.
4. The implantable joint prosthesis of claim 1, wherein the prosthesis is selected from the group consisting of an artificial disc replacement, an artificial disc nucleus, a carpometacarpal joint prosthesis, a metacarpophalangeal joint prosthesis, a metatarsophalangeal joint prosthesis, a distal interphalangeal joint prosthesis, a proximal interphalangeal joint prosthesis, an ankle joint prosthesis, a knee joint prosthesis, a hip joint prosthesis, and a shoulder joint prosthesis.
5. The implantable joint prosthesis of claim 1, further comprising:
 - a third component, the third component having a third bearing surface with a third flattened section, wherein the third bearing surface is configured to articulate with a fourth bearing surface of the second component;

wherein the fourth bearing surface comprises a fourth flattened section;

wherein the second flattened section is configured to rest against the first flattened section in one relative orientation of the first and second components.

6. The implantable joint prosthesis of claim 1, wherein the first component further comprises a first bone-contacting surface and the second component further comprises a second bone-contacting surface, wherein the first and second bone-contacting surfaces comprise tissue ingrowth surfaces.

7. The implantable joint prosthesis of claim 1, wherein the first bearing surface has an axis of maximum height that is not located centrally on the first bearing surface, wherein the second bearing surface has an axis of maximum depth that is not located centrally on the second bearing surface.

8. The implantable joint prosthesis of claim 1, wherein the first flattened section is shaped as a portion of a cylinder to provide the preferred relative orientation about a single axis.

9. The implantable joint prosthesis of claim 1, wherein the first flattened section is generally circular in shape, wherein the first and second curved sections cooperate to define a semispherical shape surrounding the first flattened section to provide the preferred relative orientation about two orthogonal axes.

10. An implantable joint prosthesis, the prosthesis comprising:

a first component having a first bearing surface with a first curved section and a first orientation feature; and

a second component having a second bearing surface with a second curved section and a second orientation feature, wherein the second bearing surface is shaped to articulate with the first bearing surface;

wherein the first and second orientation features are configured to cooperate to urge the first and second components toward a preferred relative orientation.

11. The implantable joint prosthesis of claim 10, wherein the first orientation feature comprises a first flattened section and the second orientation feature comprises a second flattened section.

12. The implantable joint prosthesis of claim 10, further comprising:

a third component, the third component having a third bearing surface with a third orientation feature, wherein the third bearing surface is configured to articulate with a fourth bearing surface of the second component;

wherein the fourth bearing surface comprises a fourth orientation feature;

wherein the second orientation feature is configured to rest against the first orientation feature in one relative orientation of the first and second components.

13. The implantable joint prosthesis of claim 10, wherein the prosthesis is selected from the group consisting of an artificial disc replacement, an artificial disc nucleus, a carpometacarpal joint prosthesis, a metacarpophalangeal joint prosthesis, a metatarsophalangeal joint prosthesis, a distal interphalangeal joint prosthesis, a proximal interphalangeal joint prosthesis, an ankle joint prosthesis, a knee joint prosthesis, a hip joint prosthesis and a shoulder joint prosthesis.

14. The implantable joint prosthesis of claim 10, wherein the first orientation feature is not centrally located on the first bearing surface, and the second orientation feature is not centrally located on the second bearing surface.

15. The implantable joint prosthesis of claim 10, wherein the first bearing surface has an axis of maximum height that is not located centrally on the first bearing surface, wherein the second bearing surface has an axis of maximum depth that is not located centrally on the second bearing surface.

16. The implantable joint prosthesis of claim 10, wherein the first orientation feature is shaped as a portion of a cylinder to provide the preferred relative orientation about a single axis.

17. The implantable joint prosthesis of claim 10, wherein the first orientation feature is generally circular in shape, wherein the first curved section is contiguous with the first orientation feature to define a semispherical shape surrounding the first orientation feature to provide the preferred relative orientation about two orthogonal axes.

18. A method for replacing a natural joint with an implantable joint prosthesis, the method comprising:

securing a first component to a first bone, the first component having a first bearing surface with a first flattened section positioned between and contiguous with first and second curved sections of the first bearing surface;

securing a second component to a second bone, the second component having a second bearing surface with a second flattened section positioned between and contiguous with first and second curved sections of the second bearing surface; and

positioning the first bearing surface to articulate with the second bearing surface such that the second flattened section rests against the first flattened section in a preferred relative orientation of the first and second components.

19. The method of claim 18, wherein the first flattened section is not positioned centrally on the first bearing surface, and wherein the second flattened section is not positioned centrally on the second bearing surface.

20. The method of claim 18, wherein the first bearing surface is substantially convex and the second bearing surface is substantially concave.

21. The method of claim 18, wherein the prosthesis is selected from the group consisting of an artificial disc replacement, an artificial disc nucleus, a carpometacarpal joint prosthesis, a metacarpophalangeal joint prosthesis, a metatarsophalangeal joint prosthesis, a distal interphalangeal joint prosthesis, a proximal interphalangeal joint prosthesis, an ankle joint prosthesis, a knee joint prosthesis, a hip joint prosthesis, and a shoulder joint prosthesis.

22. The method of claim 18, wherein the first component further comprises a first bone-contacting surface and the second component further comprises a second bone-contacting surface, wherein the first and second bone-contacting surfaces comprise tissue ingrowth surfaces.

23. The method of claim 18, wherein the first bearing surface has an axis of maximum height that is not located centrally on the first bearing surface, wherein the second bearing surface has an axis of maximum depth that is not located centrally on the second bearing surface.

24. The method of claim 18, wherein the first flattened section is shaped as a portion of a cylinder to provide the preferred relative orientation about a single axis.

25. The method of claim 18, wherein the first flattened section is generally circular in shape, wherein the first and second curved sections cooperate to define a semispherical shape surrounding the first flattened section to provide the preferred relative orientation about two orthogonal axes.

26. A method for replacing a natural joint with an implantable joint prosthesis, the method comprising:

securing a first component to a first bone, the first component having a first bearing surface with a first curved section and a first orientation feature;

securing a second component to a second bone, the second component having a second bearing surface with a second curved section and a second orientation feature; and

positioning the first bearing surface to articulate with the second bearing surface such that the first and second orientation features cooperate to urge the first and second components toward a preferred relative orientation.

27. The method of claim 26, wherein the first orientation feature comprises a first flattened section and the second orientation feature comprises a second flattened section.

28. The method of claim 26, wherein the prosthesis is selected from the group consisting of an artificial disc replacement, an artificial disc nucleus, a carpometacarpal joint prosthesis, a metacarpophalangeal joint prosthesis, a metatarsophalangeal joint prosthesis, a distal interphalangeal joint prosthesis, a proximal interphalangeal joint prosthesis, an ankle joint prosthesis, a knee joint prosthesis, a hip joint prosthesis and a shoulder joint prosthesis.

29. The method of claim 26, wherein the first orientation feature is not centrally located on the first bearing surface and the second orientation feature is not centrally located on the second bearing surface.

30. The method of claim 26, wherein the first bearing surface has an axis of maximum height that is not located centrally on the first bearing surface, wherein the second bearing surface has an axis of maximum depth that is not located centrally on the second bearing surface.

31. The method of claim 26, wherein the first orientation feature is shaped as a portion of a cylinder to provide the preferred relative orientation about a single axis.

32. The method of claim 26, wherein the first orientation feature is generally circular in shape, wherein the first curved section is contiguous with the first orientation feature to define a semispherical shape surrounding the first orientation feature to provide the preferred relative orientation about two orthogonal axes.

33. A method for replacing a natural joint with an implantable joint prosthesis, the method comprising:

securing a first component to a first bone, the first component having a first bearing surface with a first curved section and a first orientation feature;

securing a second component to a second bone, the second component having a second bearing surface with a second curved section and a second orientation feature;

positioning a third component having a third bearing surface with a third orientation feature to articulate with the third bearing surface such that the first and third orientation features cooperate to urge the first and third components toward a preferred relative orientation.

34. The method of claim 33, wherein the first orientation feature comprises a first flattened section and the second orientation feature comprises a second flattened section.

35. The method of claim 33, wherein the prosthesis is selected from the group consisting of an artificial disc replacement, an artificial disc nucleus, a carpometacarpal joint prosthesis, a metacarpophalangeal joint prosthesis, a metatarsophalangeal joint prosthesis, a distal interphalangeal joint prosthesis, a proximal interphalangeal joint prosthesis, an ankle joint prosthesis, a knee joint prosthesis, a hip joint prosthesis and a shoulder joint prosthesis.

36. The method of claim 33, wherein the first orientation feature is not centrally located on the first bearing surface, and the second orientation feature is not centrally located on the second bearing surface.

37. The method of claim 33, wherein the third orientation feature is not centrally located on the third bearing surface.

38. The method of claim 33, wherein the first bearing surface is substantially concave, the second bearing surface is substantially concave, and the third bearing surface is substantially convex.

39. The method of claim 33, wherein the third orientation feature is shaped as a portion of a cylinder to provide the preferred relative orientation about a single axis.

40. The method of claim 33, wherein the third component further comprises a fourth bearing surface with a fourth orientation feature, further comprising positioning the second bearing surface to articulate with the fourth bearing surface such that the second and fourth

orientation features cooperate to urge the second and third components toward a preferred relative orientation.

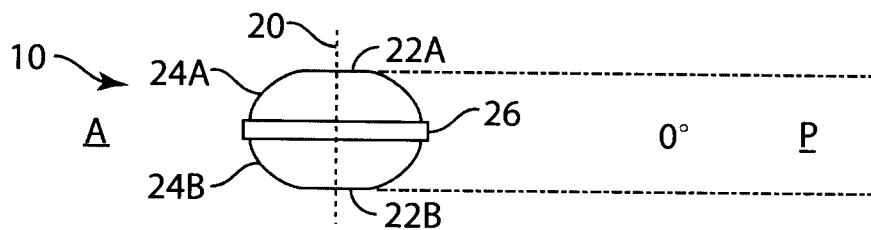


FIG.1A

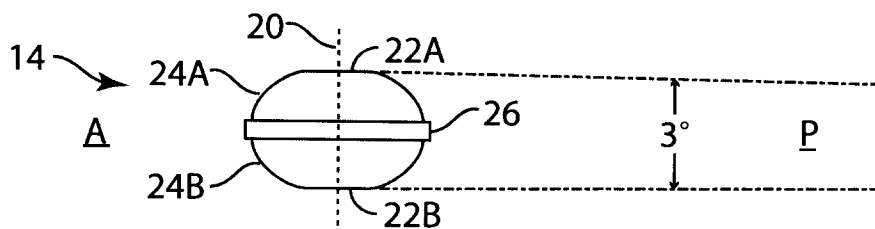


FIG. 1B

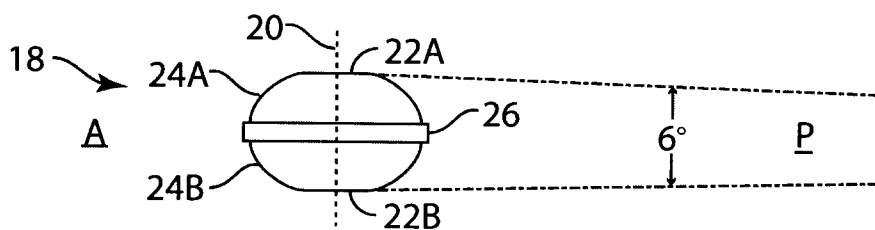


FIG. 1C

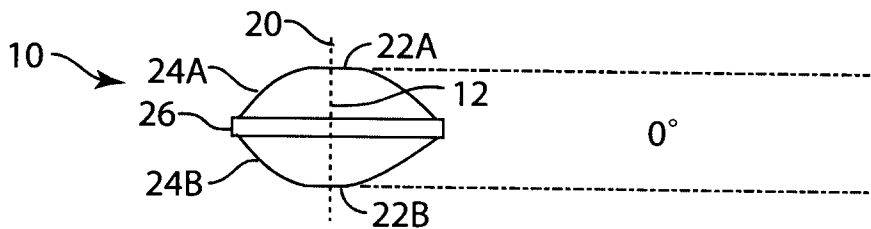


FIG.2A

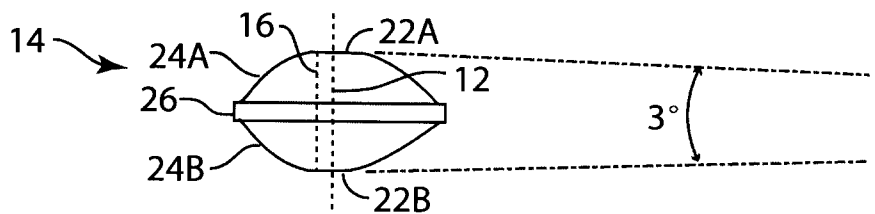


FIG. 2B

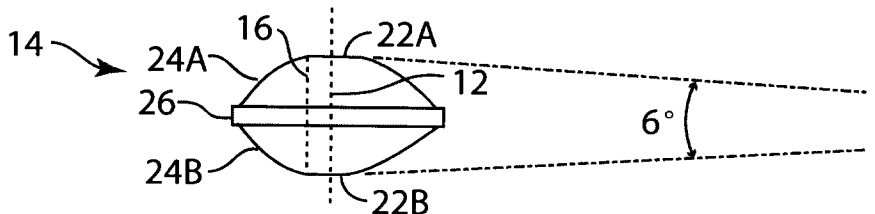


FIG.2C

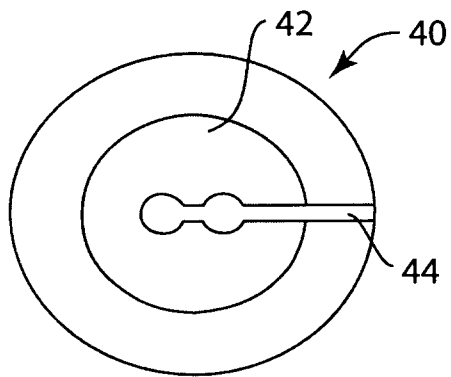


FIG. 3

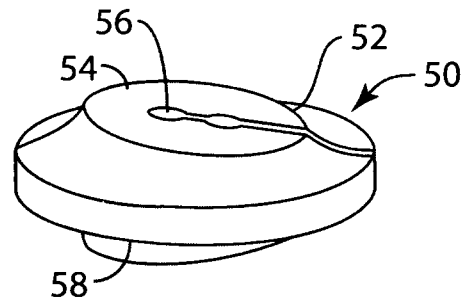


FIG. 4

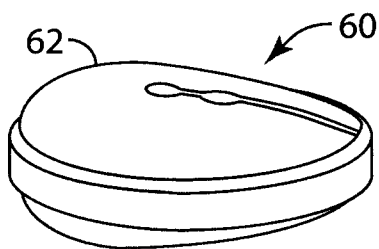


FIG. 5

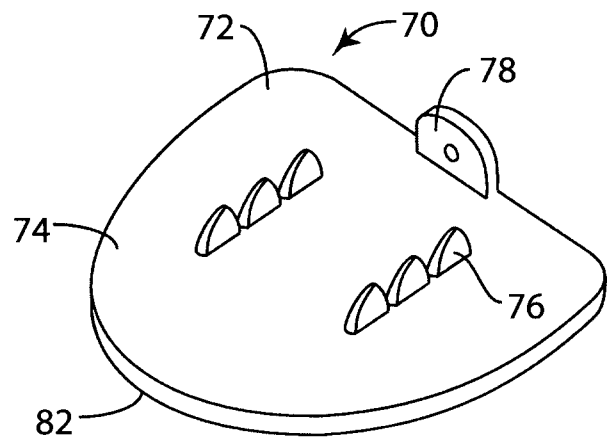


FIG. 6

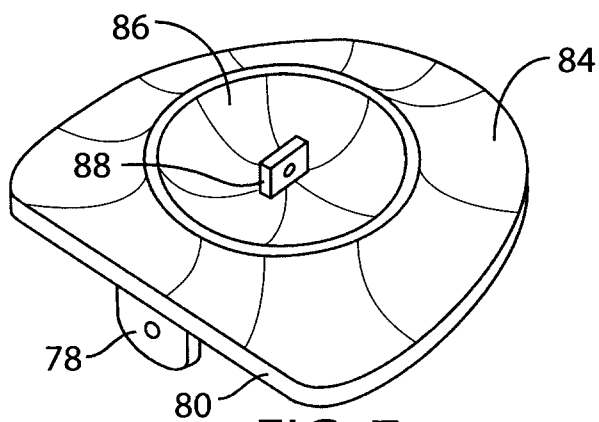


FIG. 7

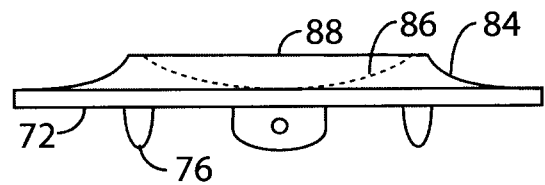


FIG. 8

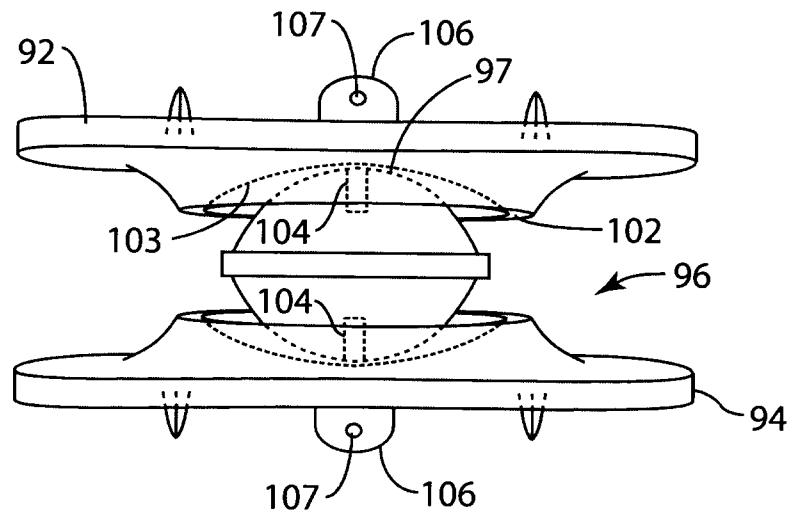


Fig. 9

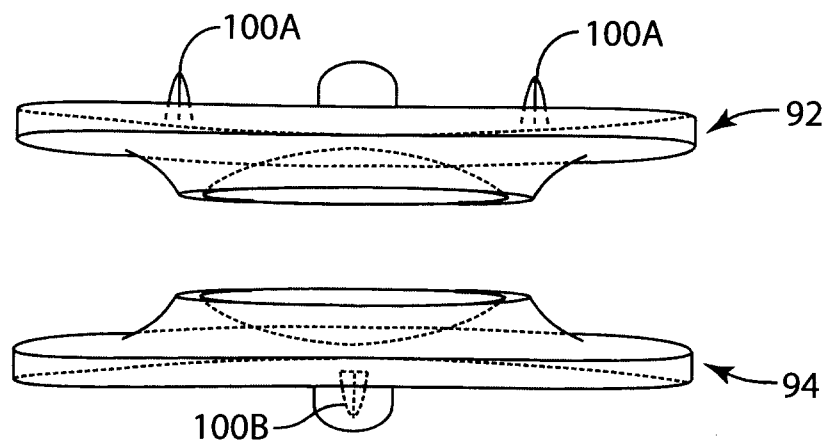


FIG. 9A

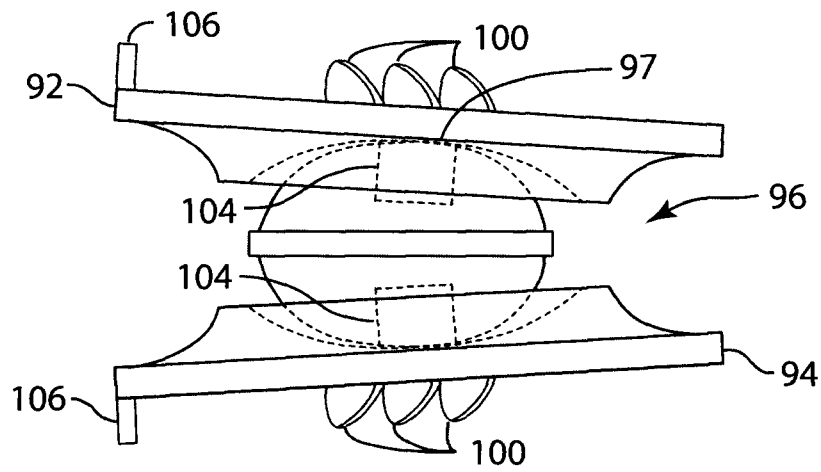


FIG. 10

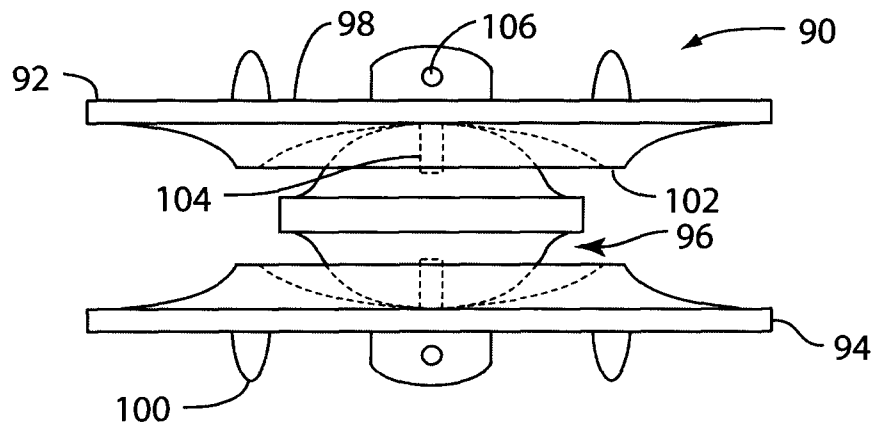


FIG. 11

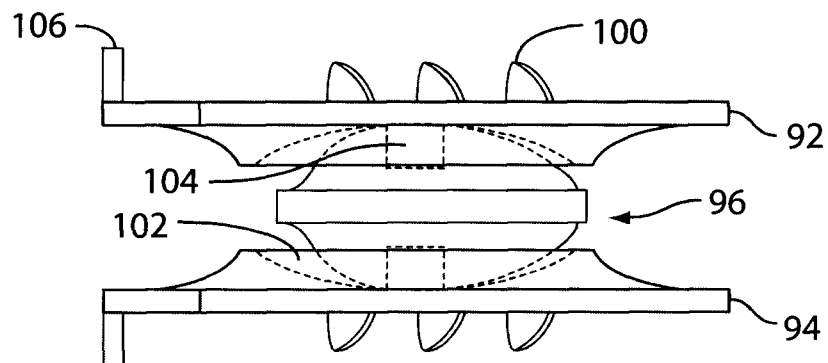


FIG. 12

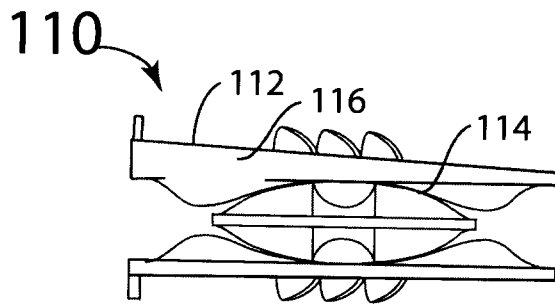


FIG. 13A

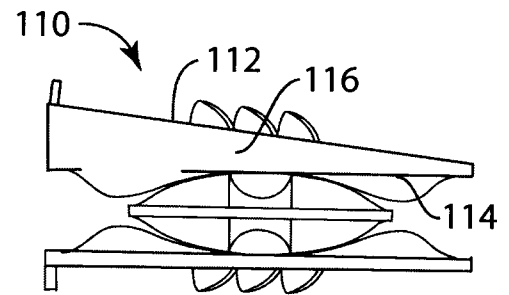


FIG. 13B

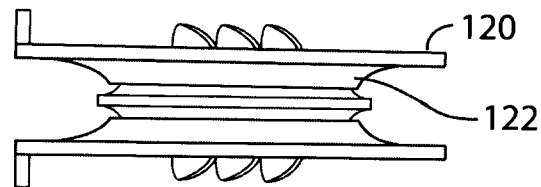


FIG. 14A

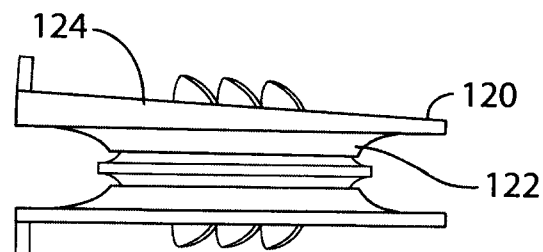


FIG. 14B

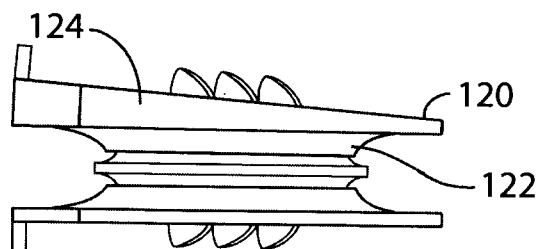


FIG. 14C

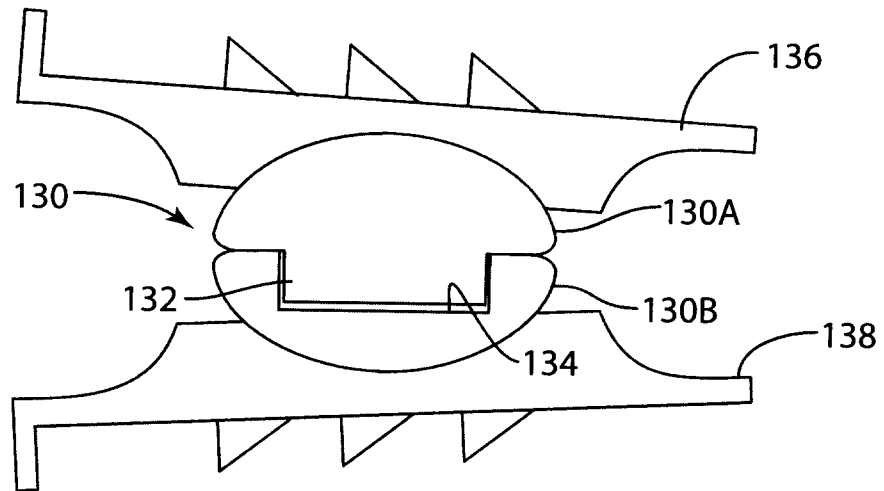


FIG. 15

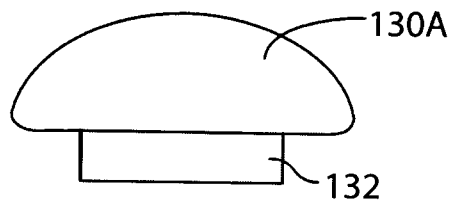


FIG. 16A

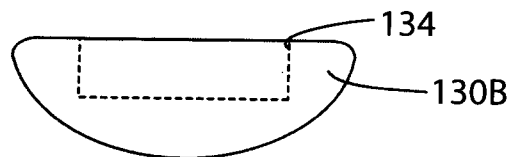


FIG. 16B

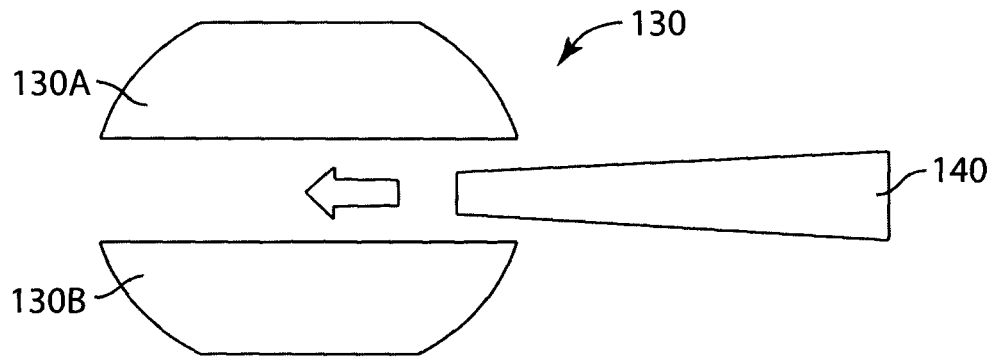


FIG. 17

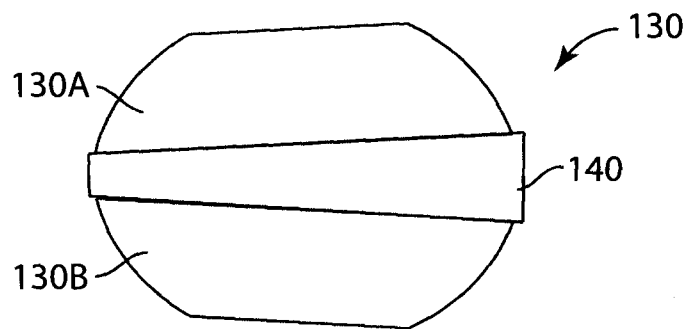


FIG. 18

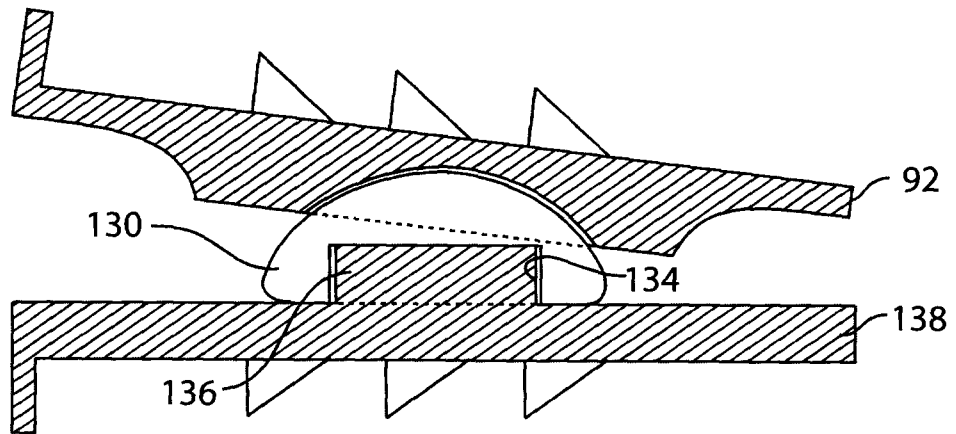


FIG. 19

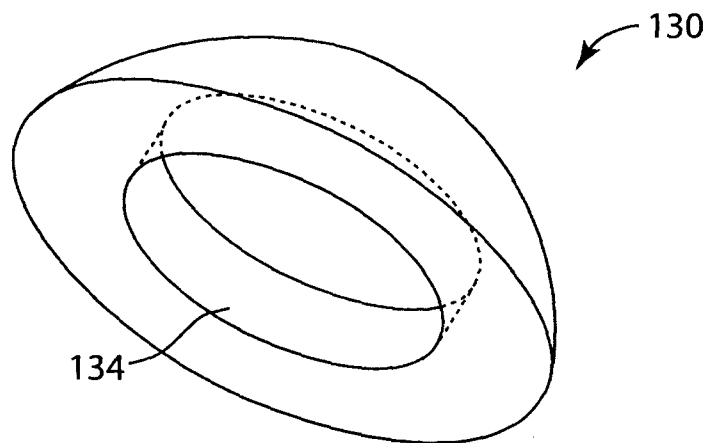


FIG. 20

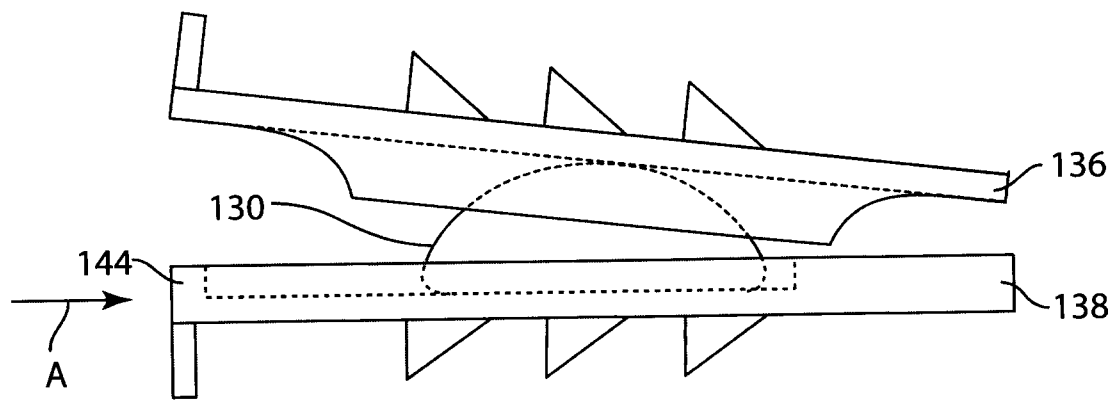


FIG. 21

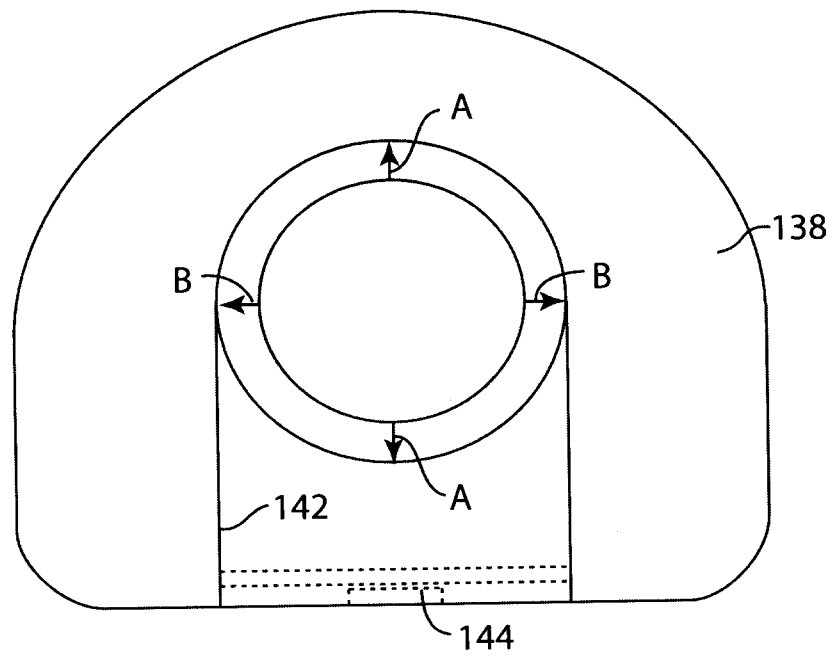


FIG. 22

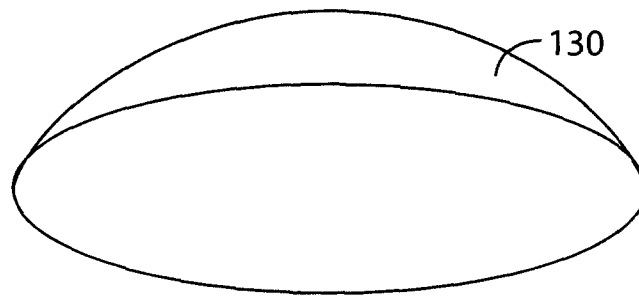


FIG. 23

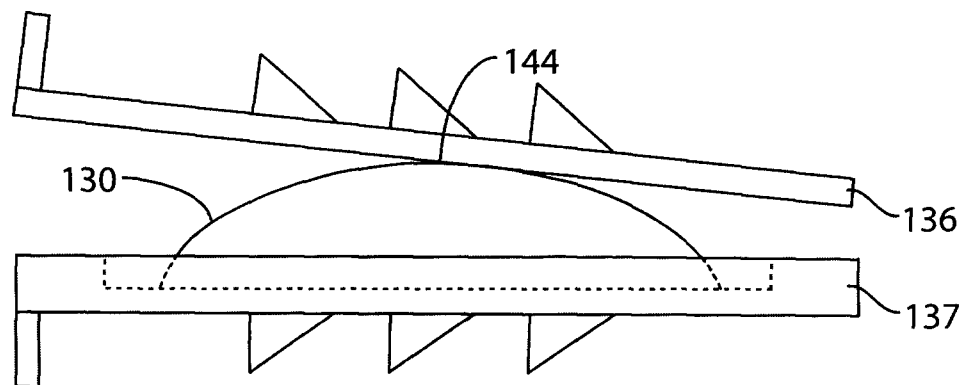


FIG. 24

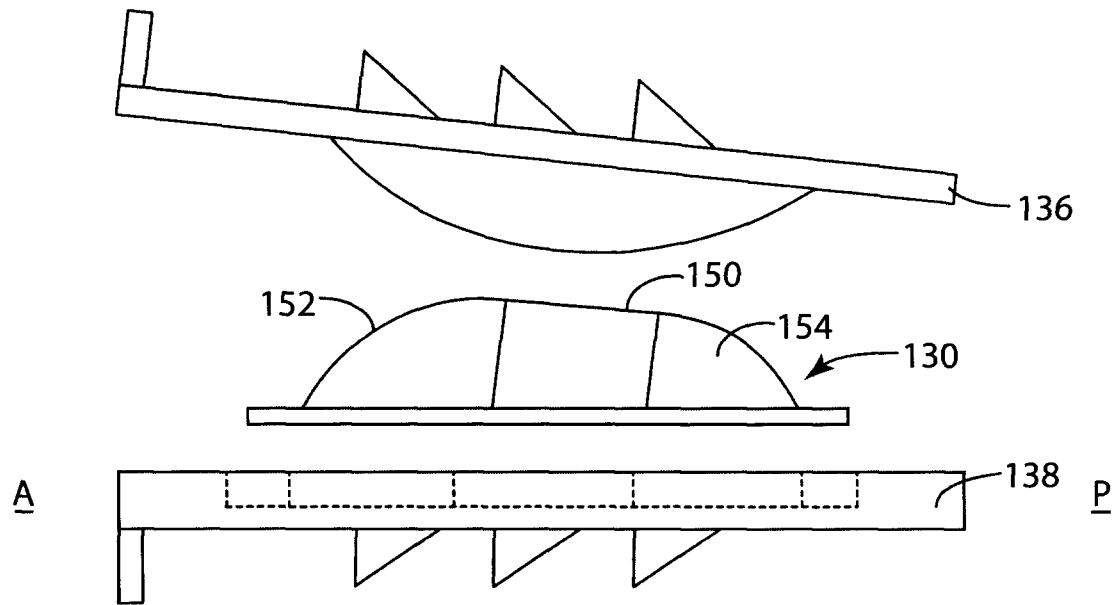


FIG. 25

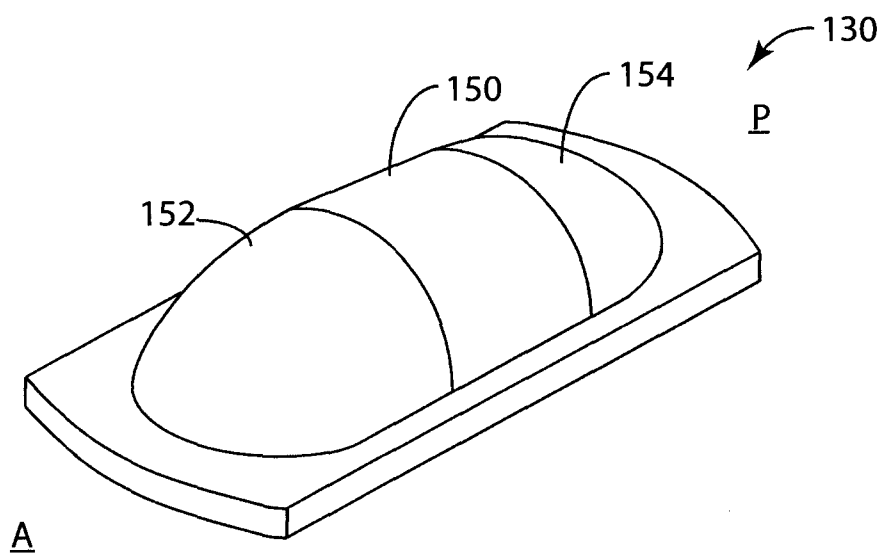


FIG. 26

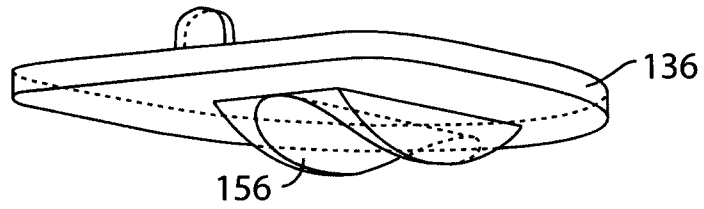


FIG. 29

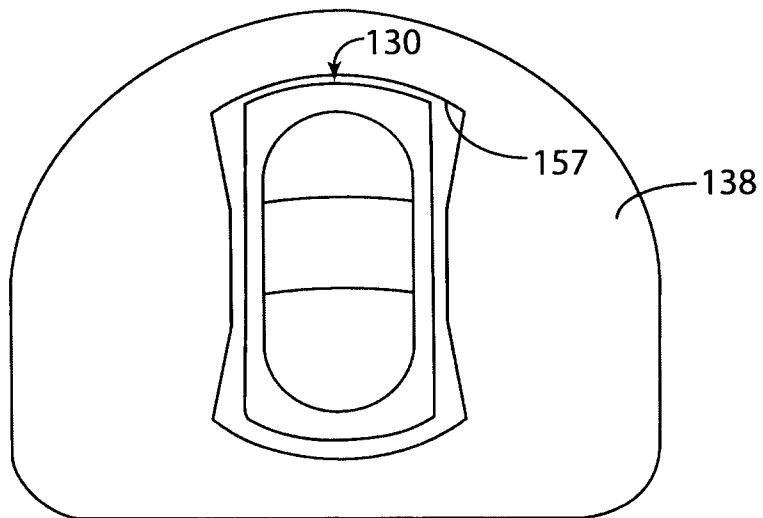


FIG. 28

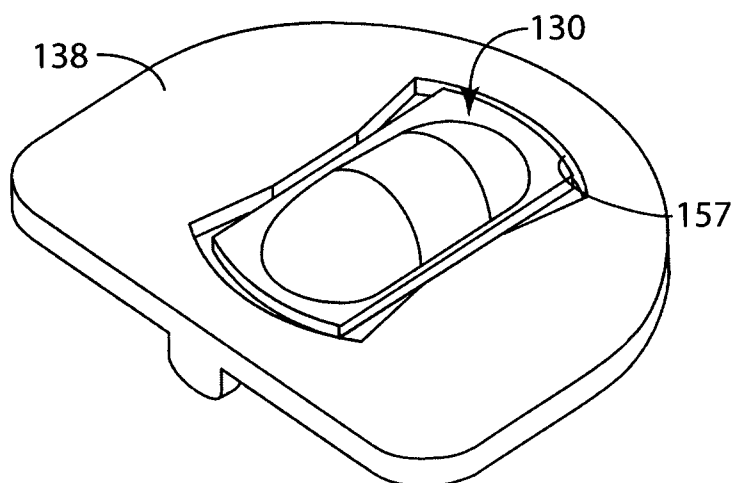


FIG. 27

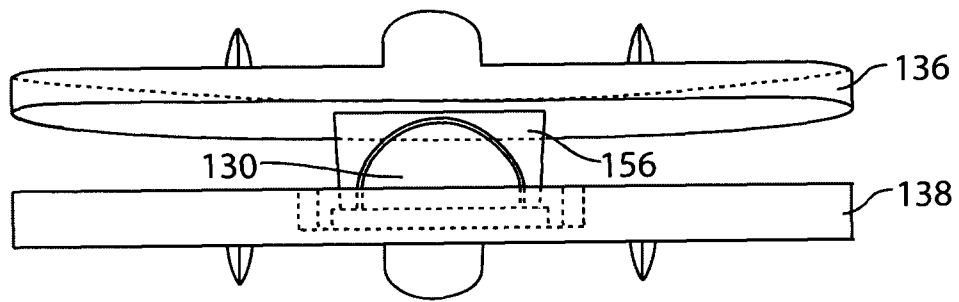


FIG. 30

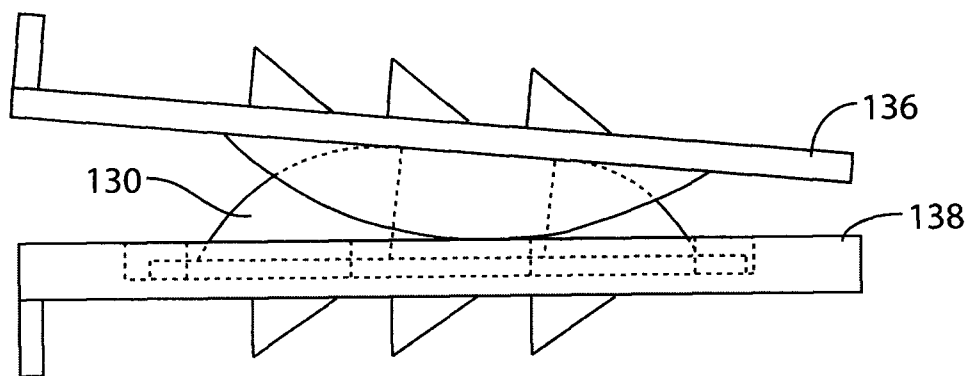


FIG. 31

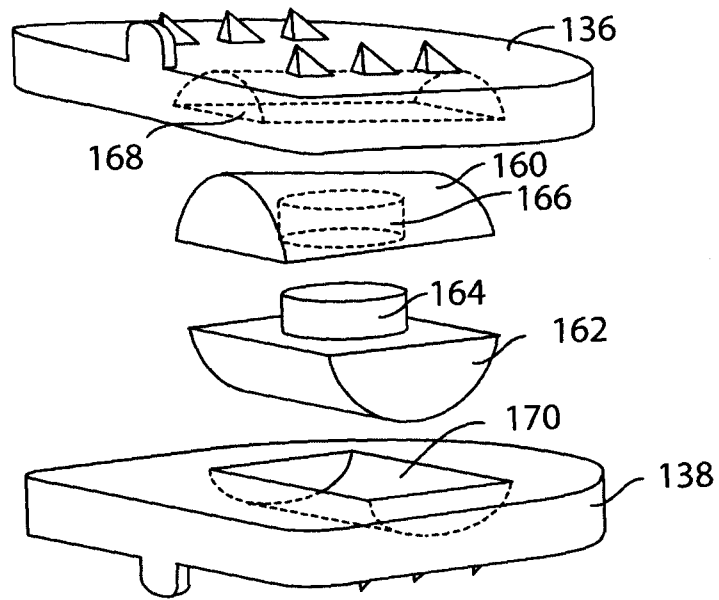


FIG. 32

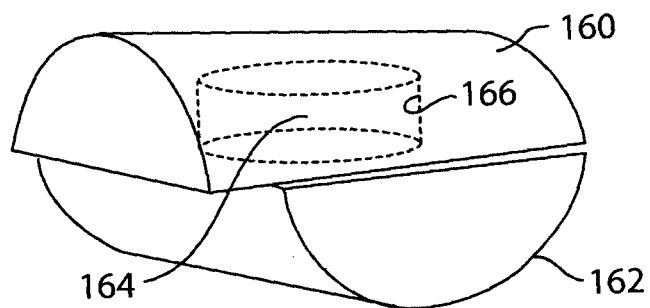


FIG. 33

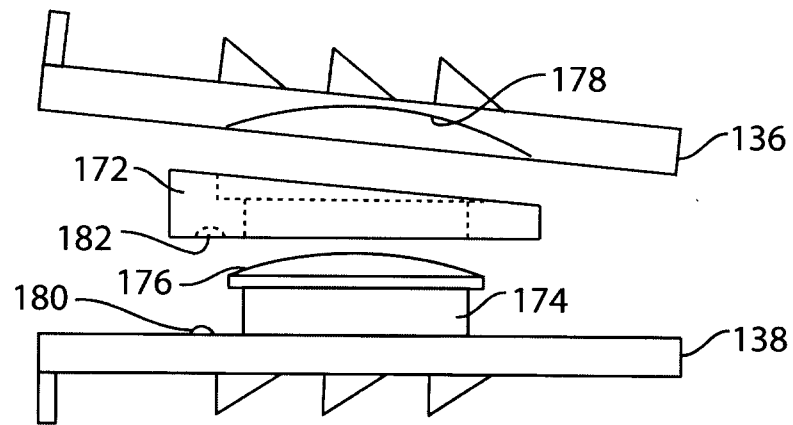


FIG. 34

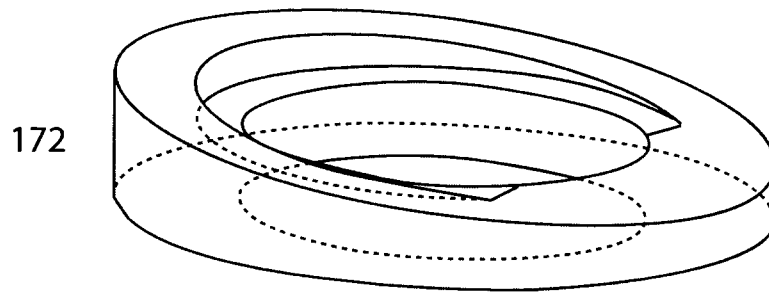


FIG. 35

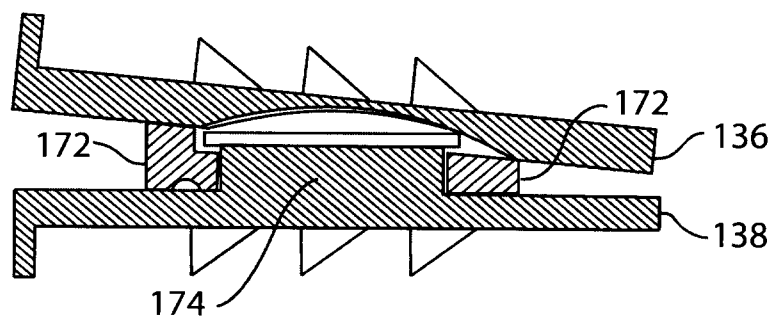


FIG. 36

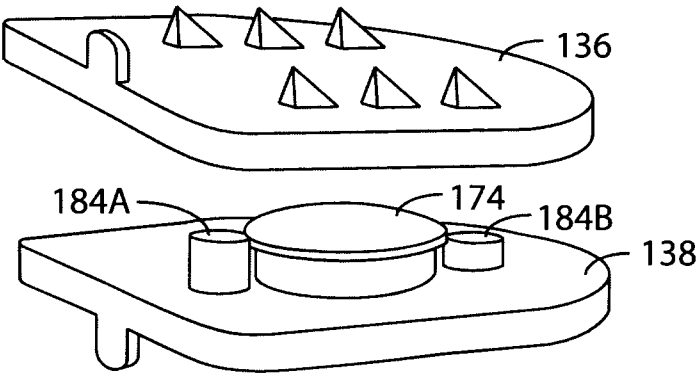


FIG. 37

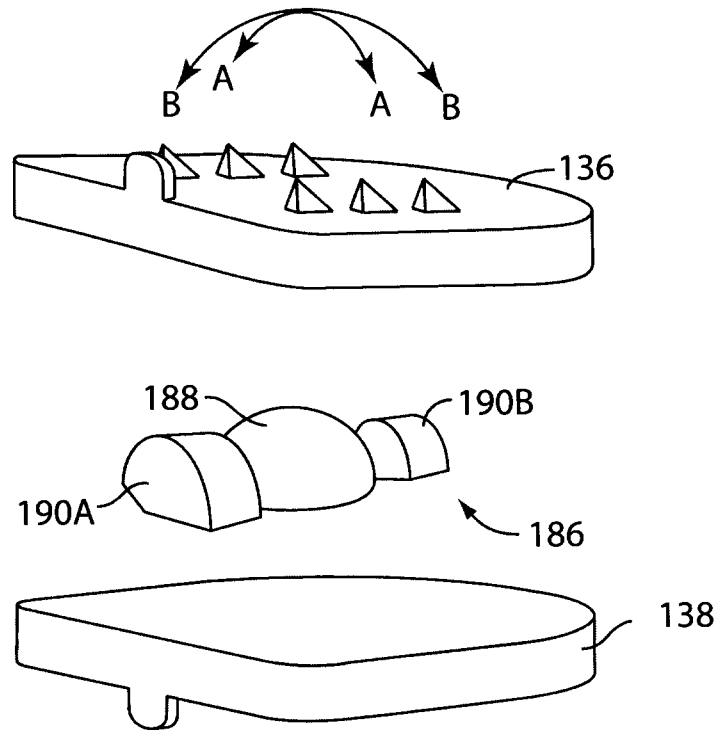


FIG. 38

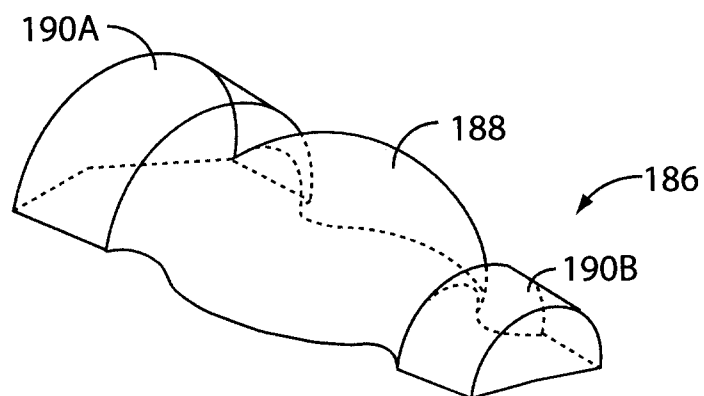


FIG. 39

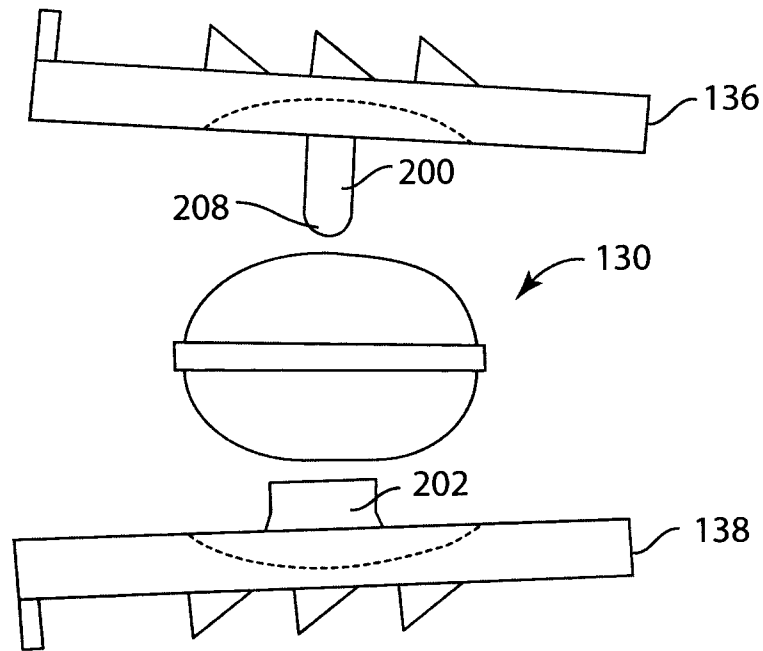


FIG. 40

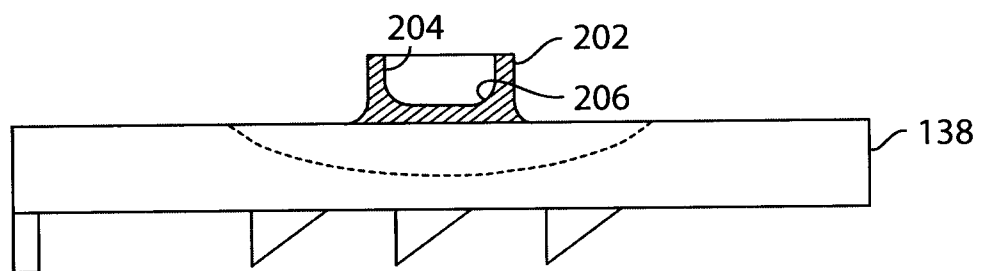


FIG. 41

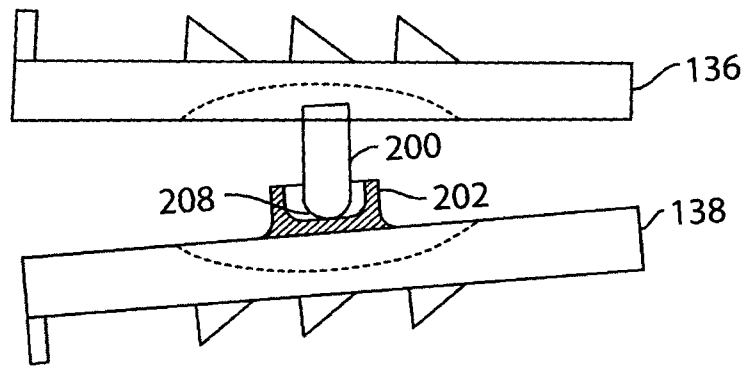


FIG. 42

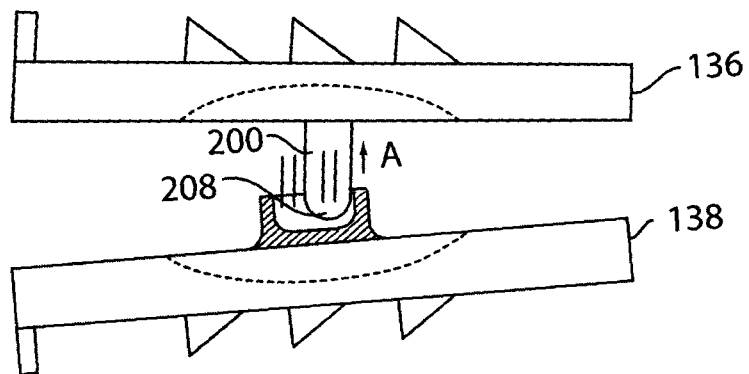


FIG. 43

FIG. 21A

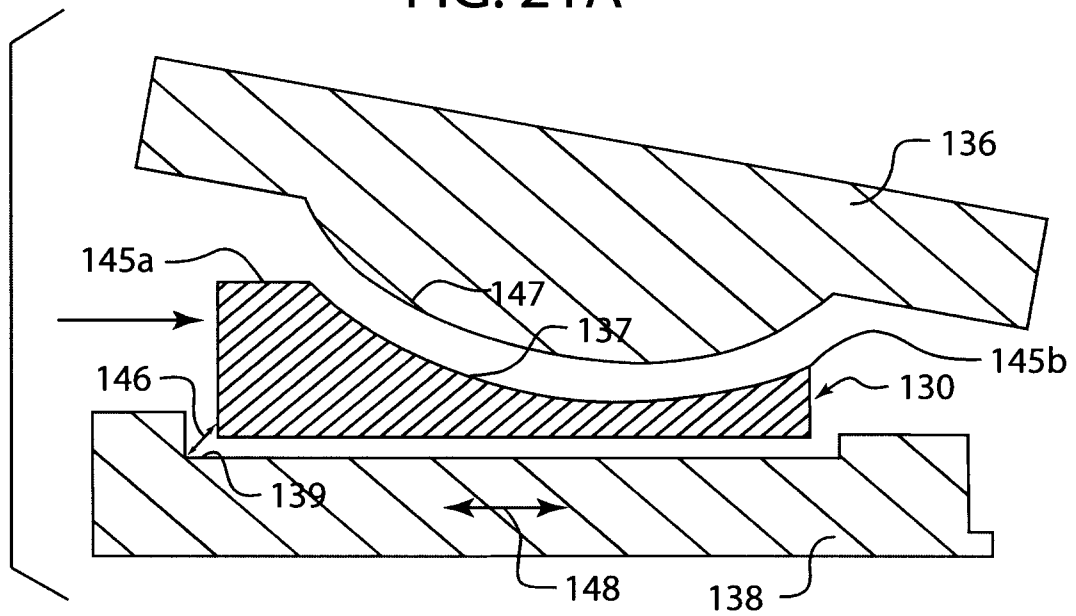


FIG. 44A

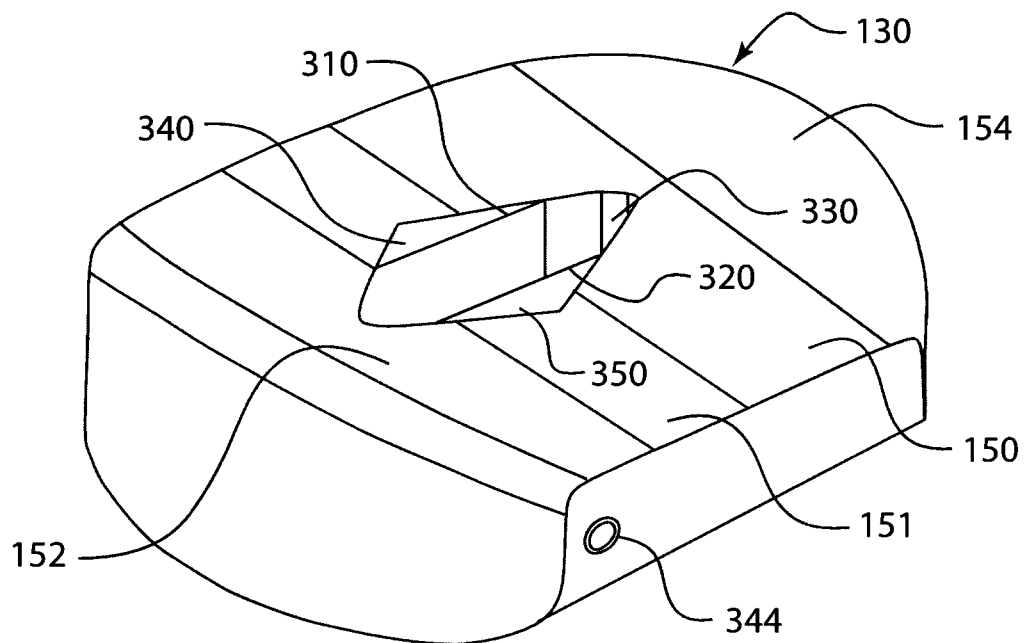


Fig. 44B

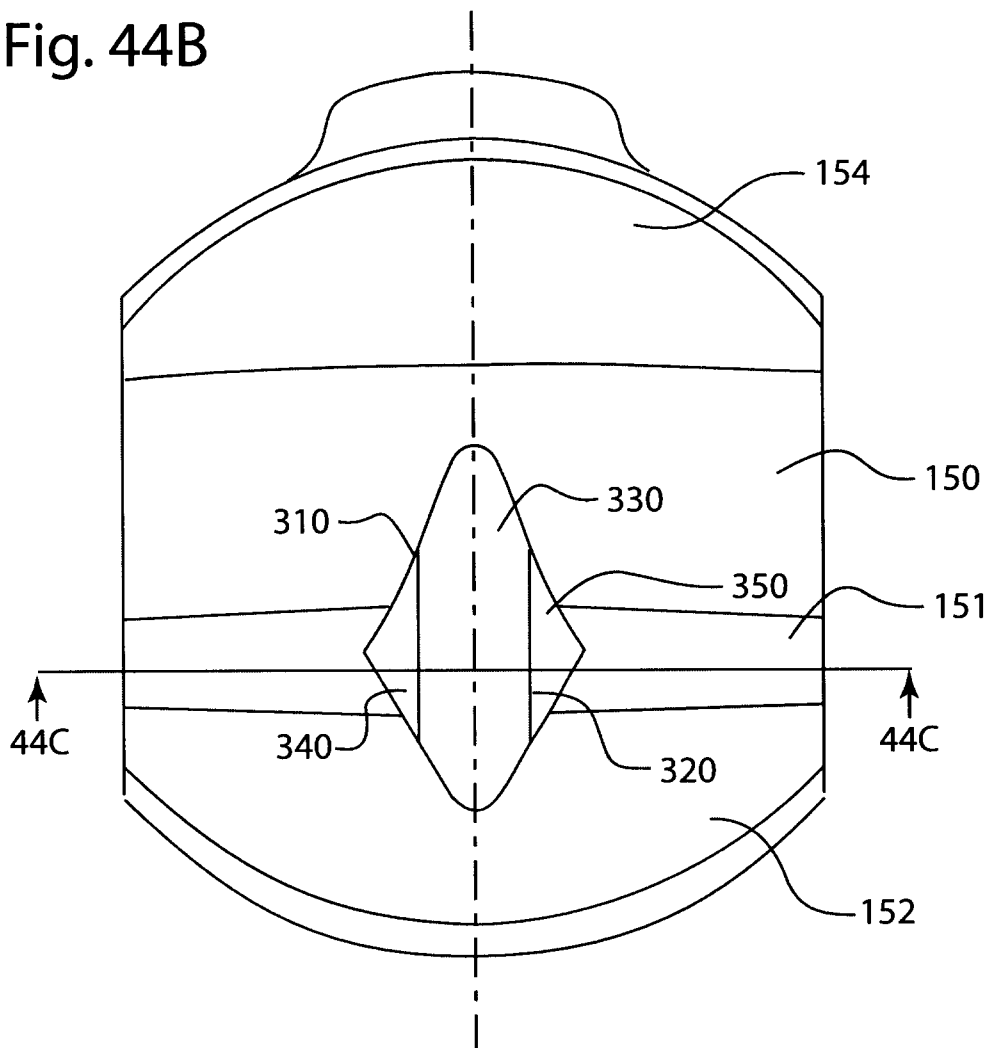


FIG. 44C

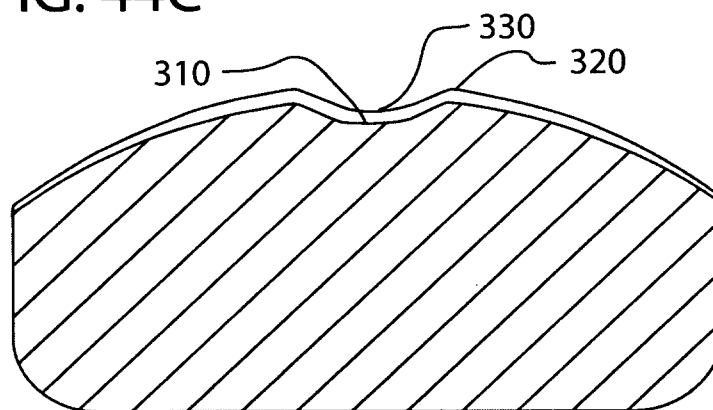


FIG. 45

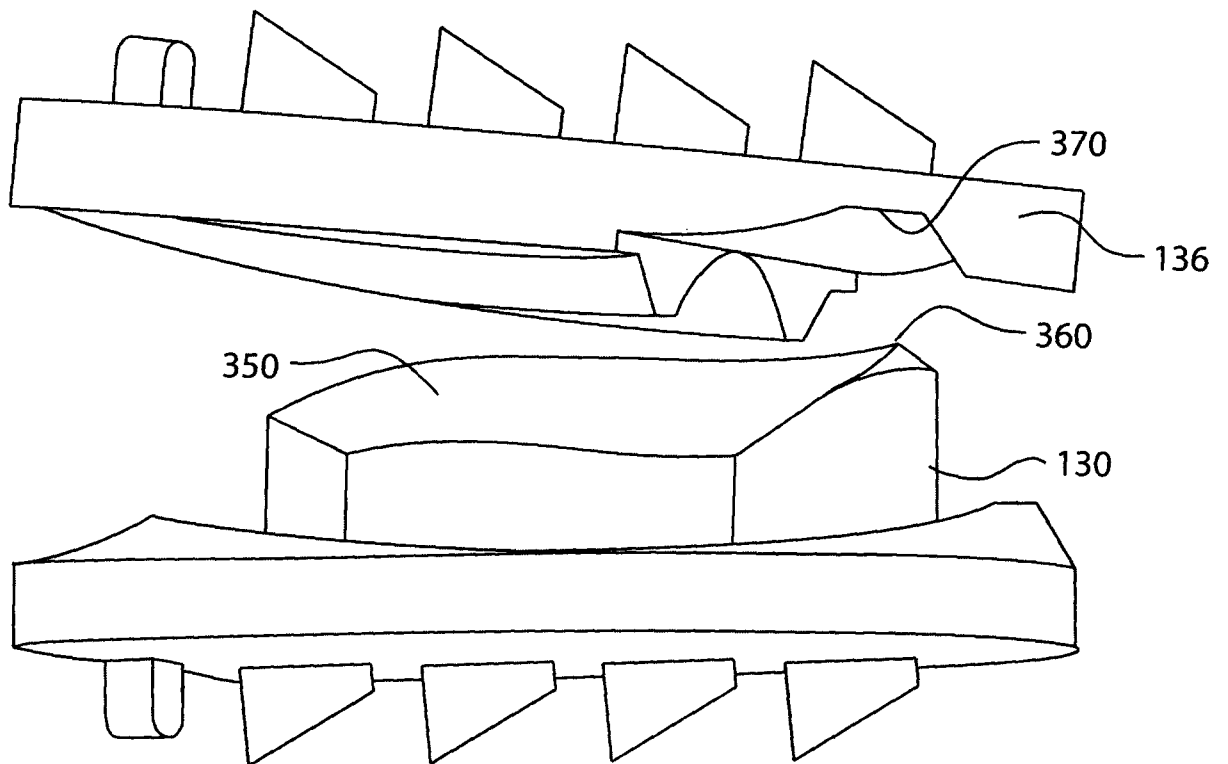


FIG. 45A

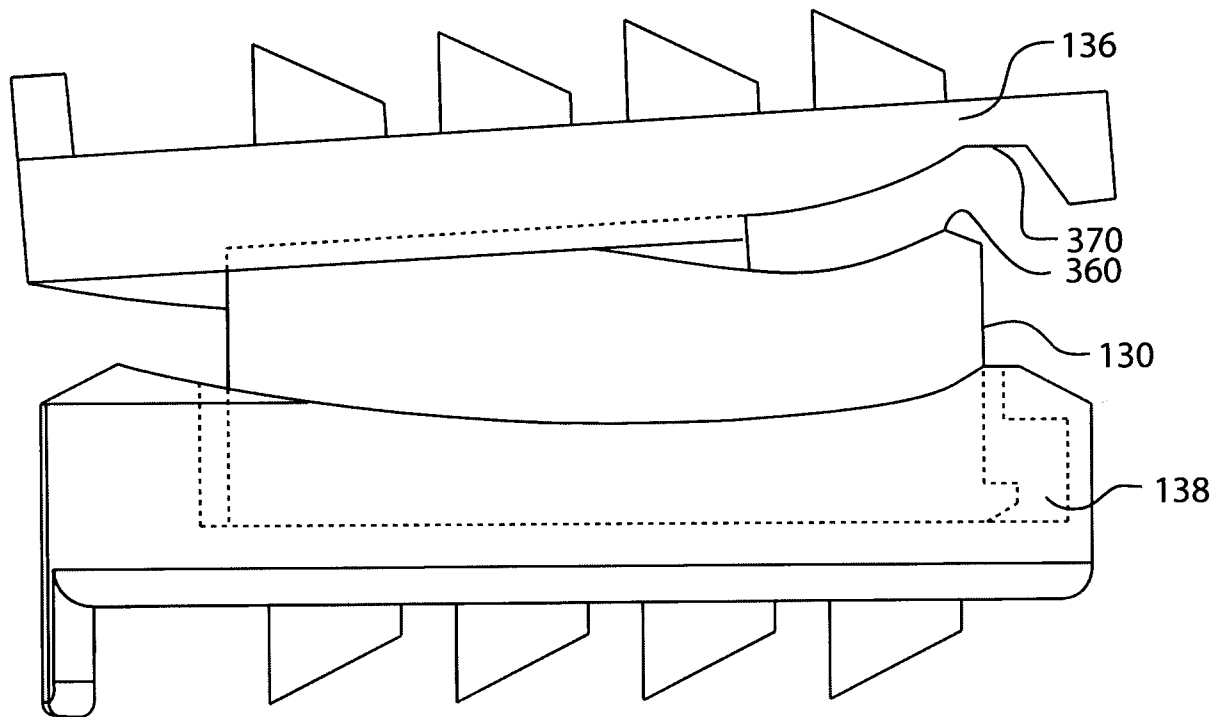


FIG. 45B

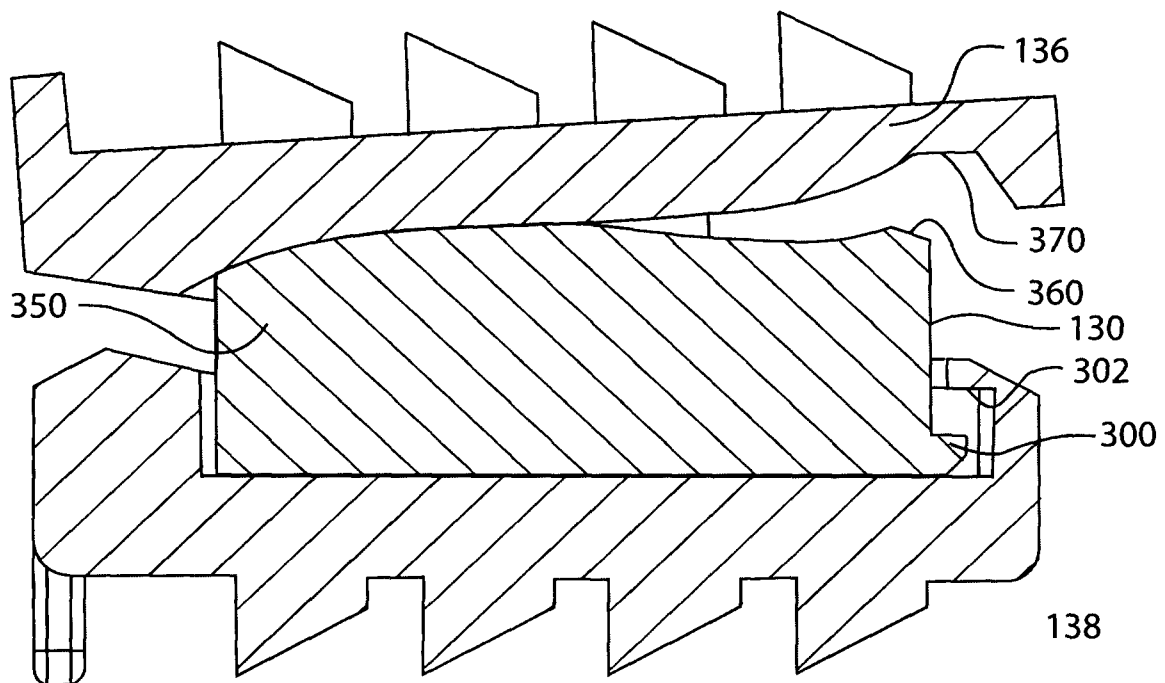


FIG. 45C

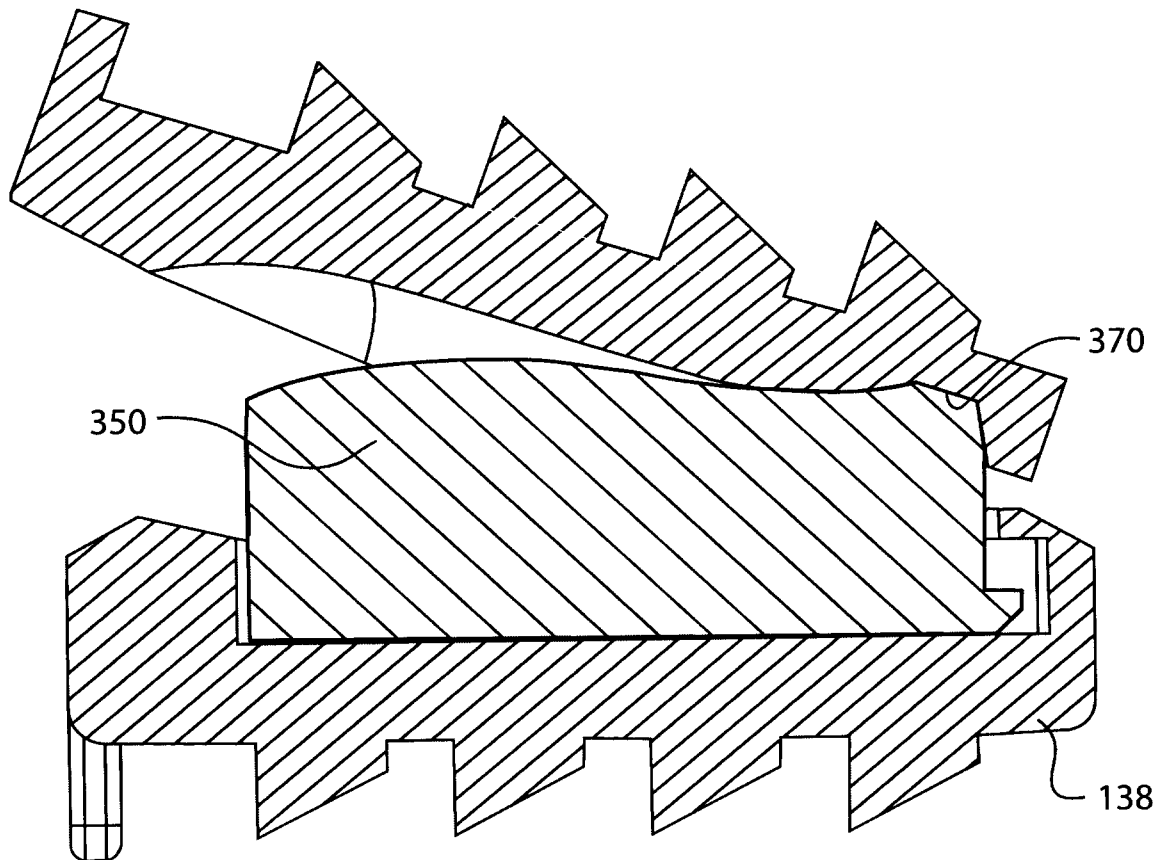


FIG. 46A

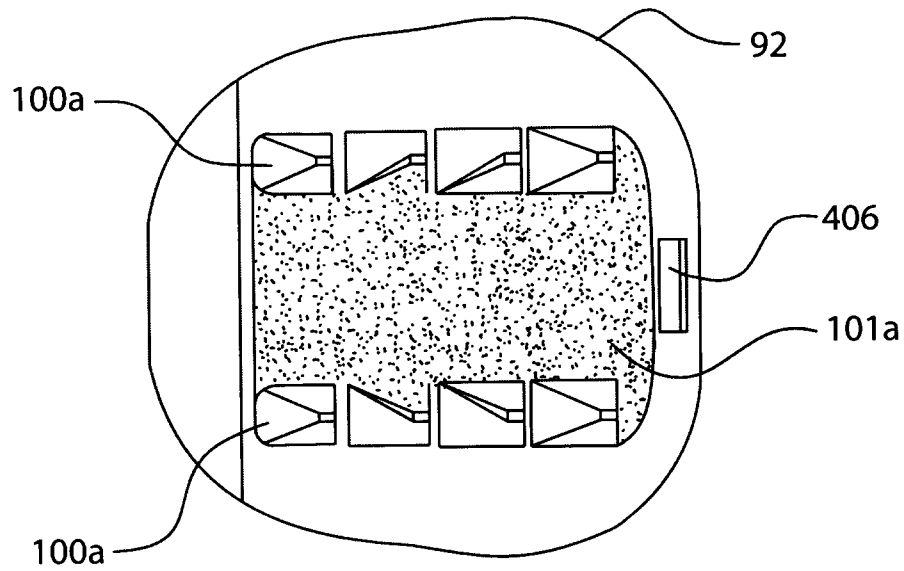


FIG. 46B

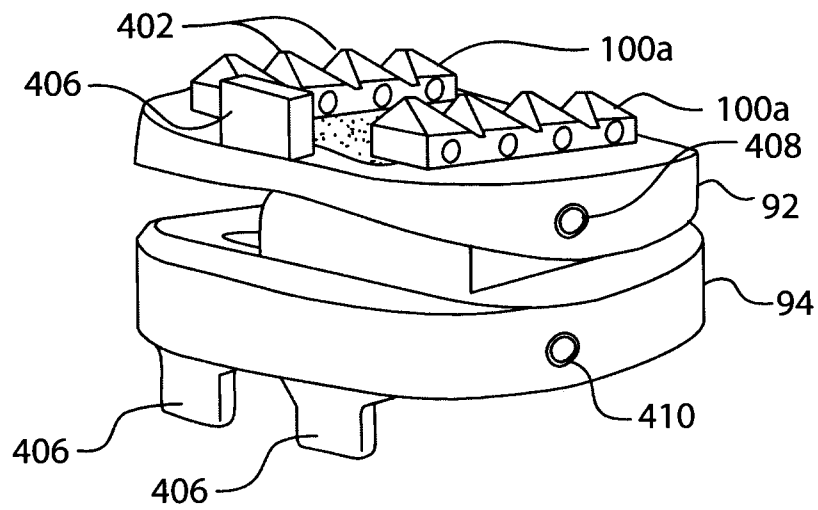


FIG. 46C

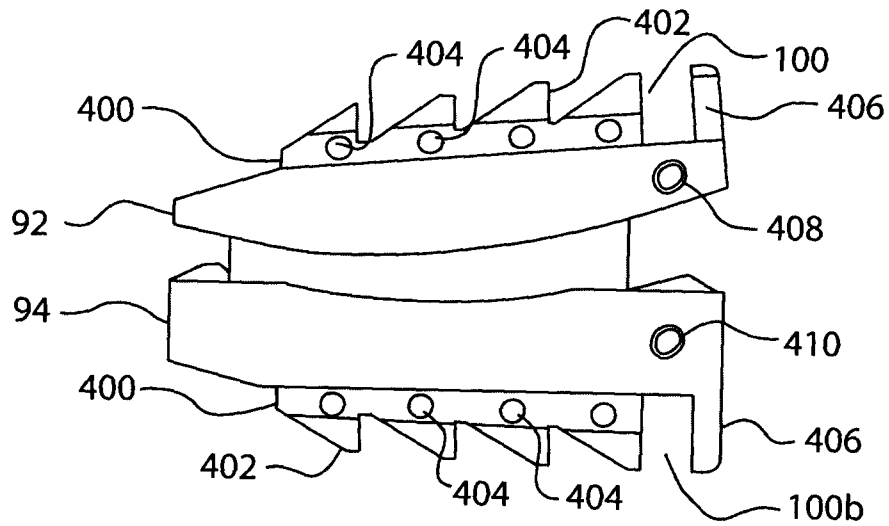
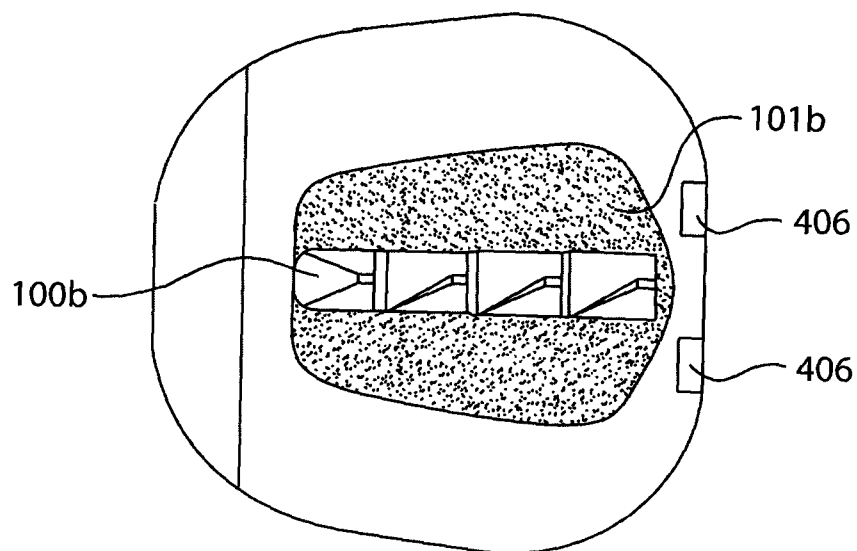
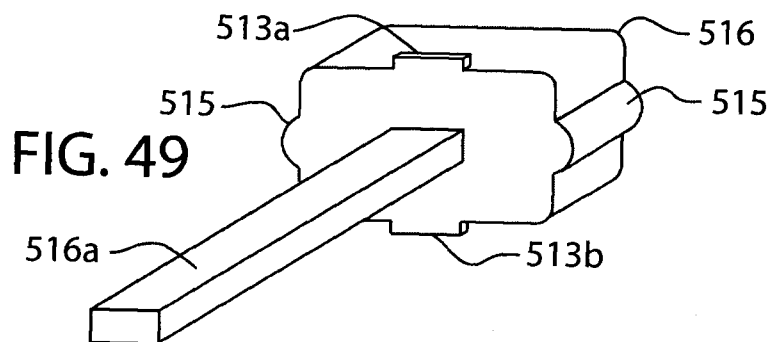
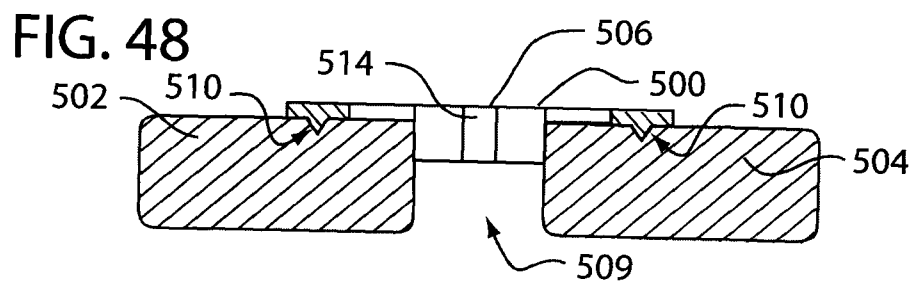
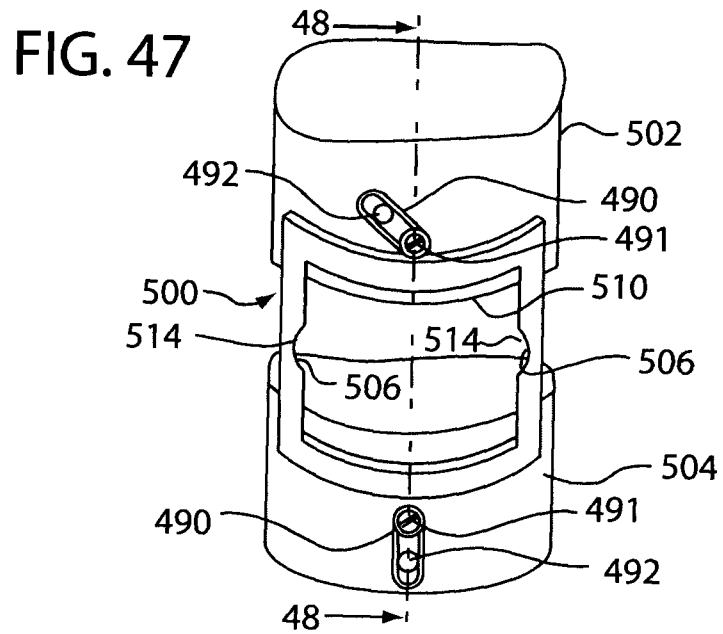


FIG. 46D





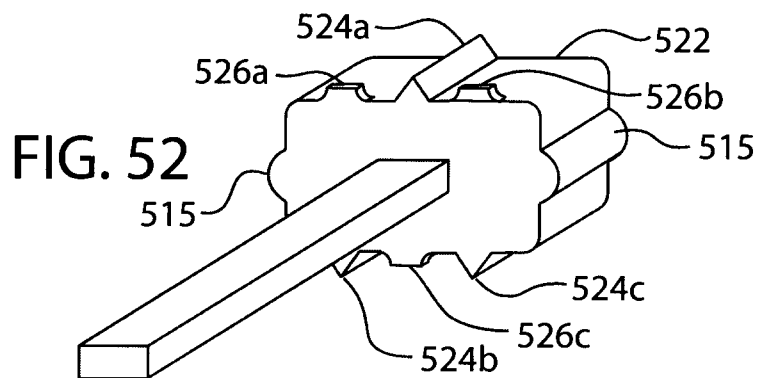
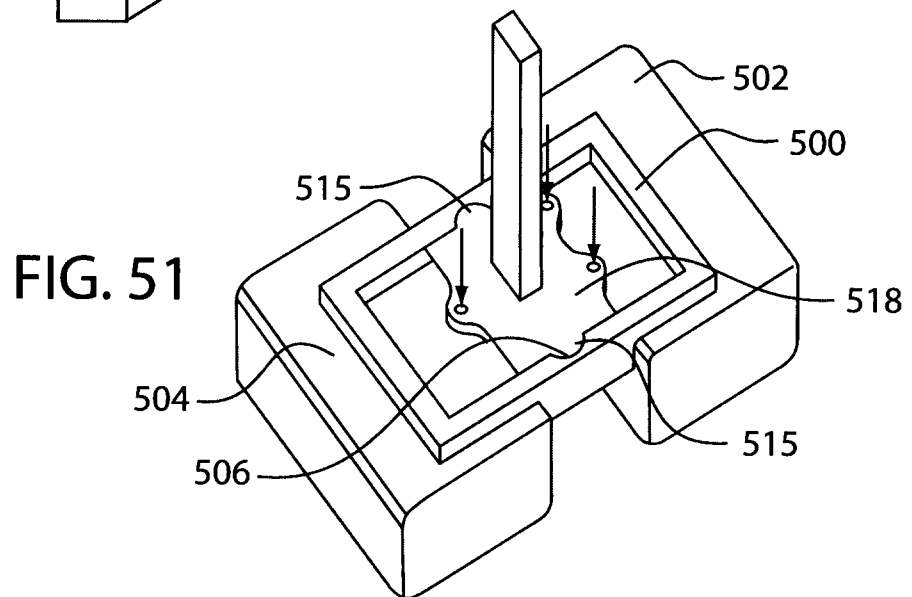
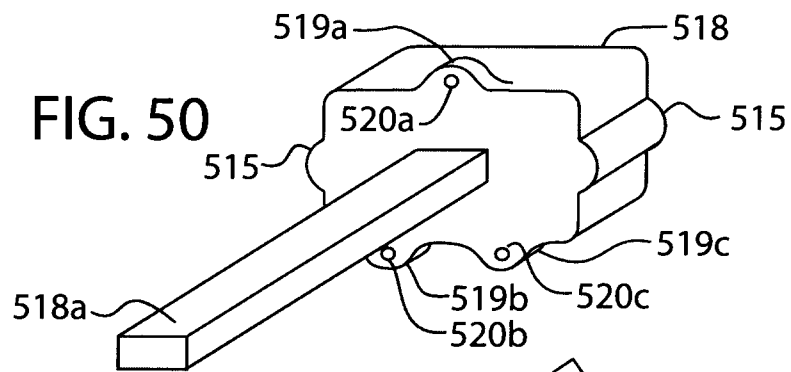


FIG. 53A

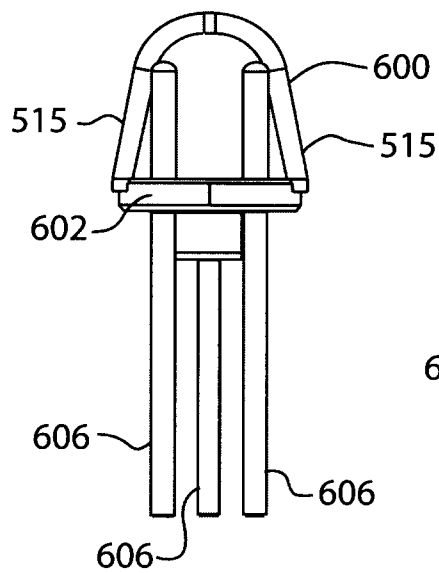


FIG. 53B

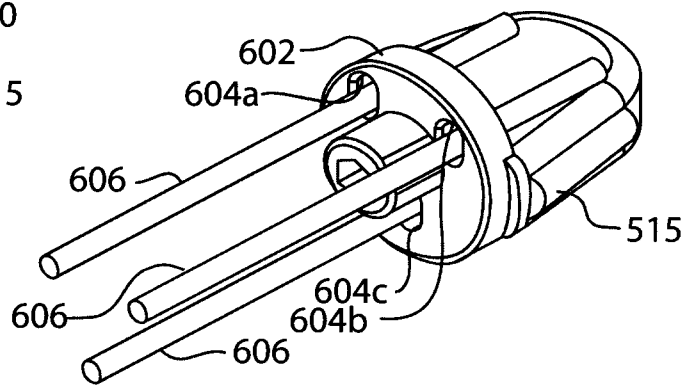


FIG. 53C

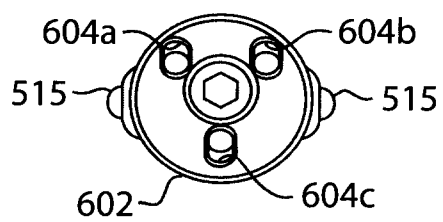
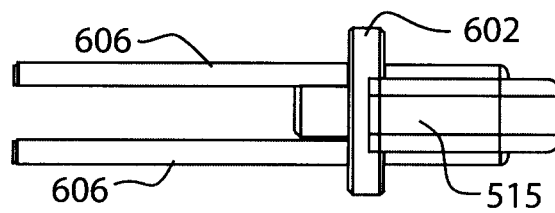


FIG. 53D



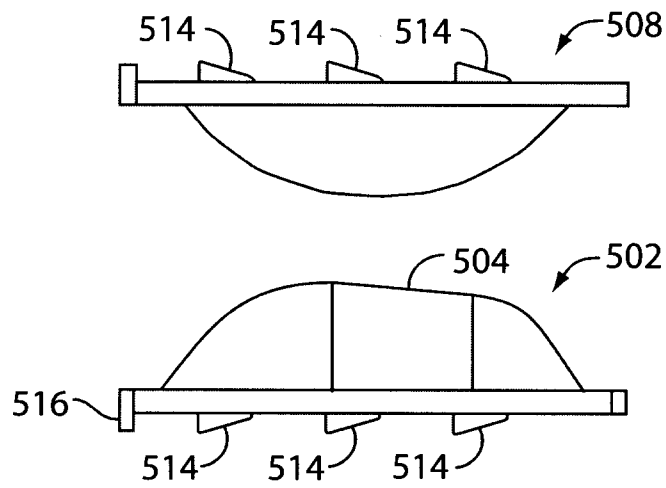


FIG. 54

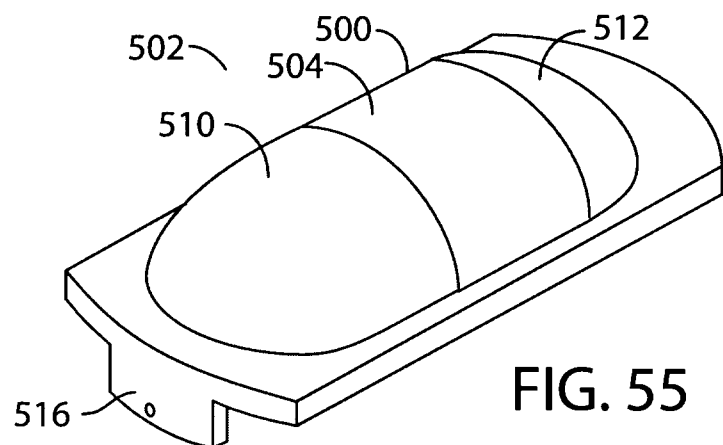


FIG. 55

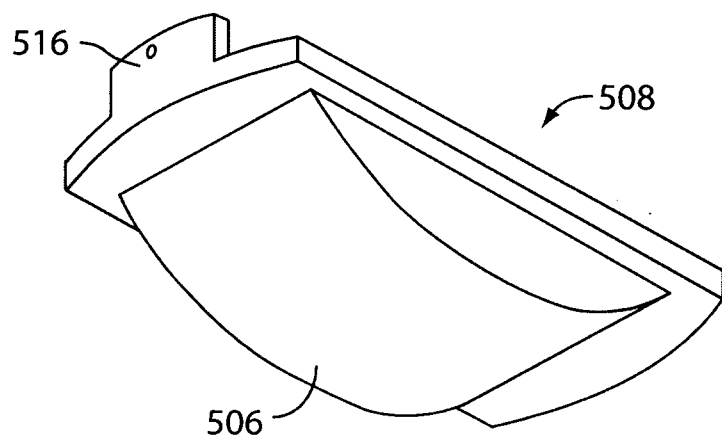


FIG. 56

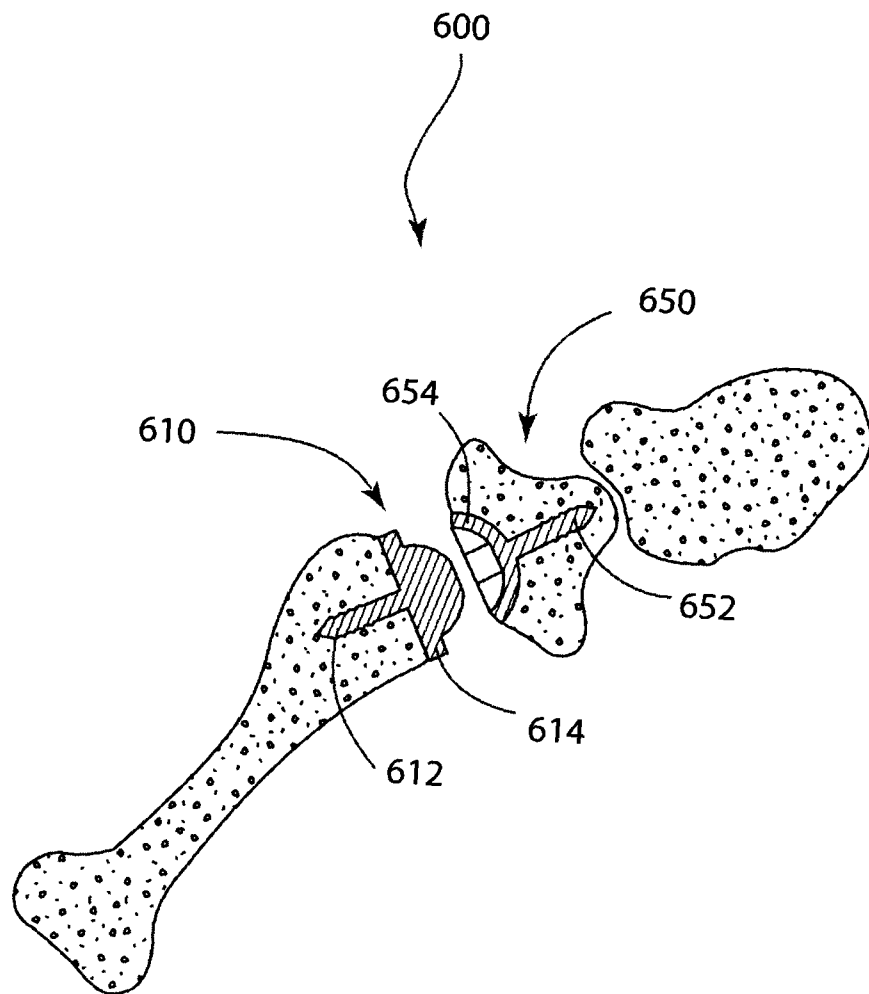


Fig. 57

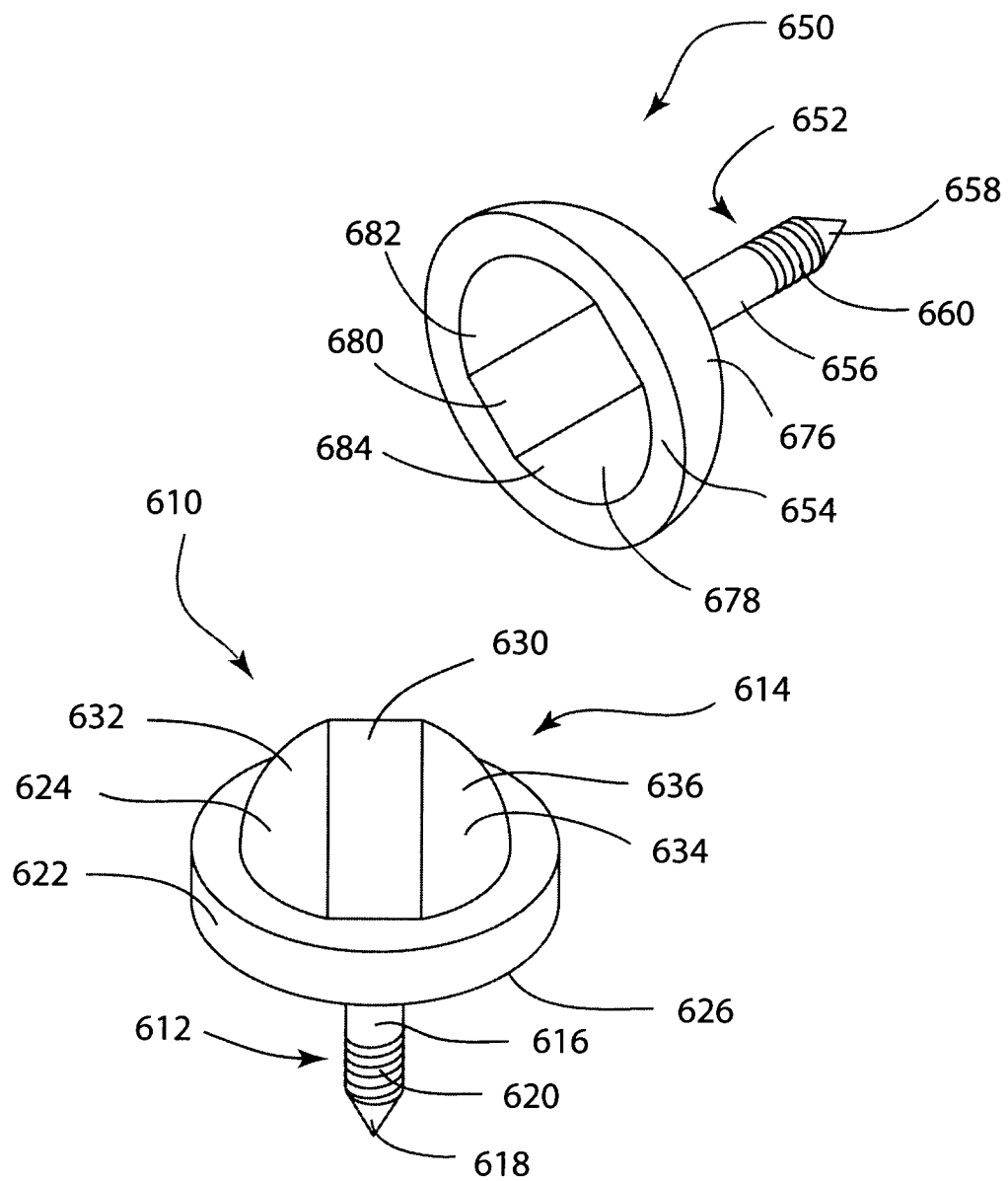


Fig. 58

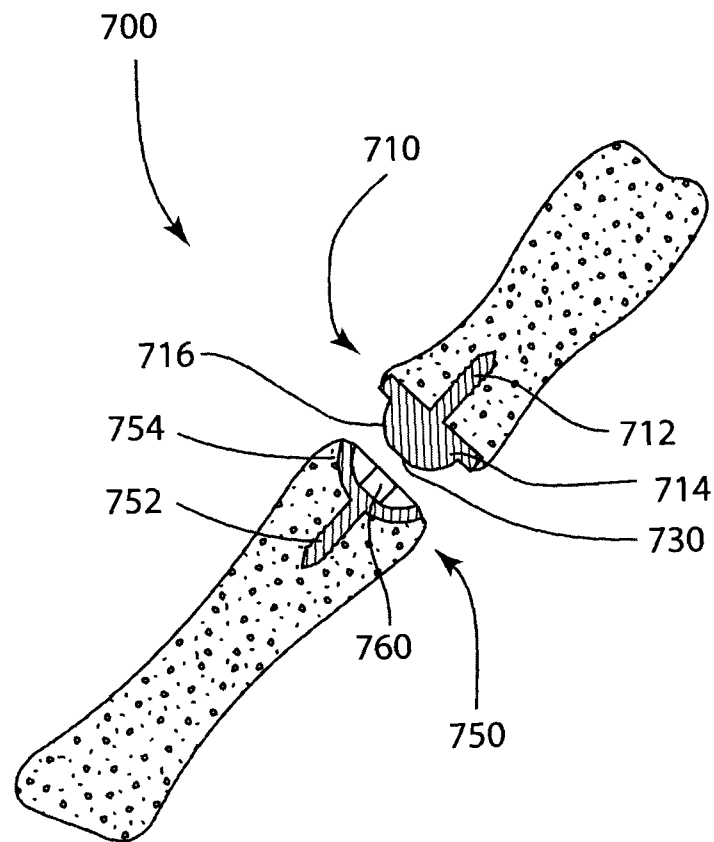


Fig. 59

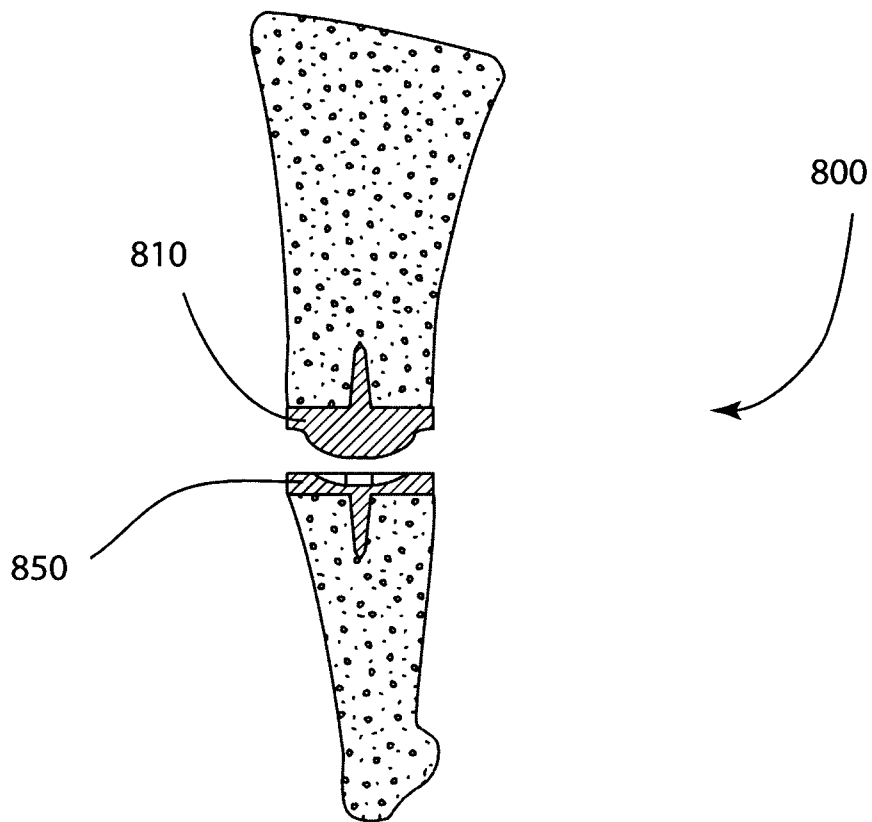


Fig. 60

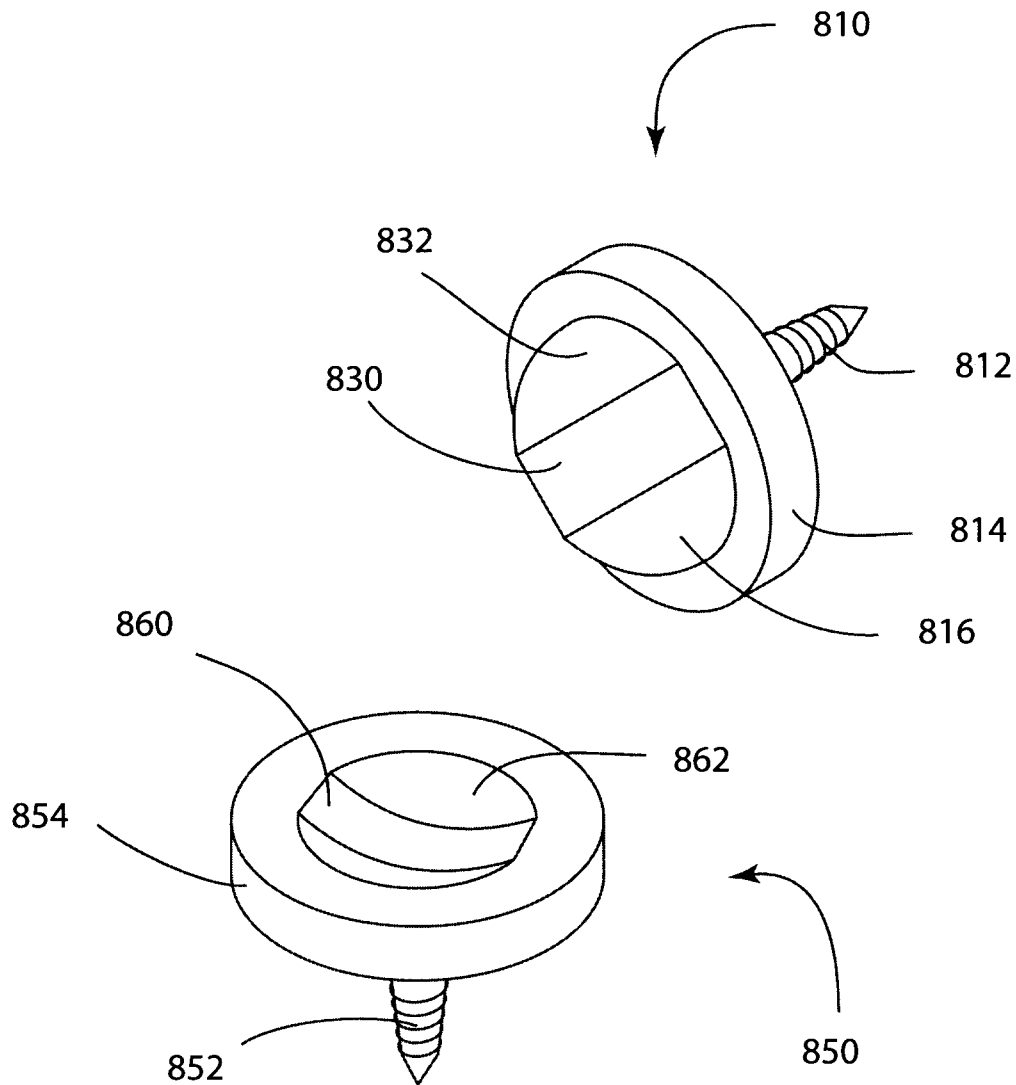


Fig. 61

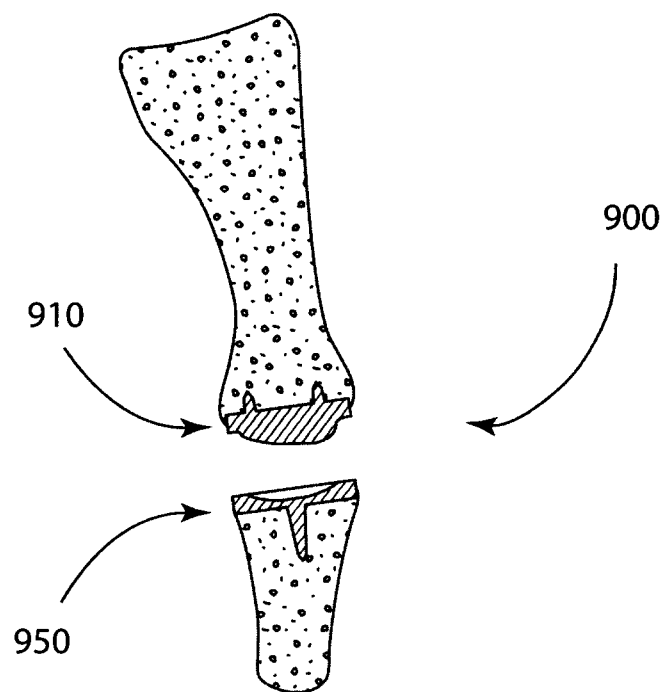


Fig.62

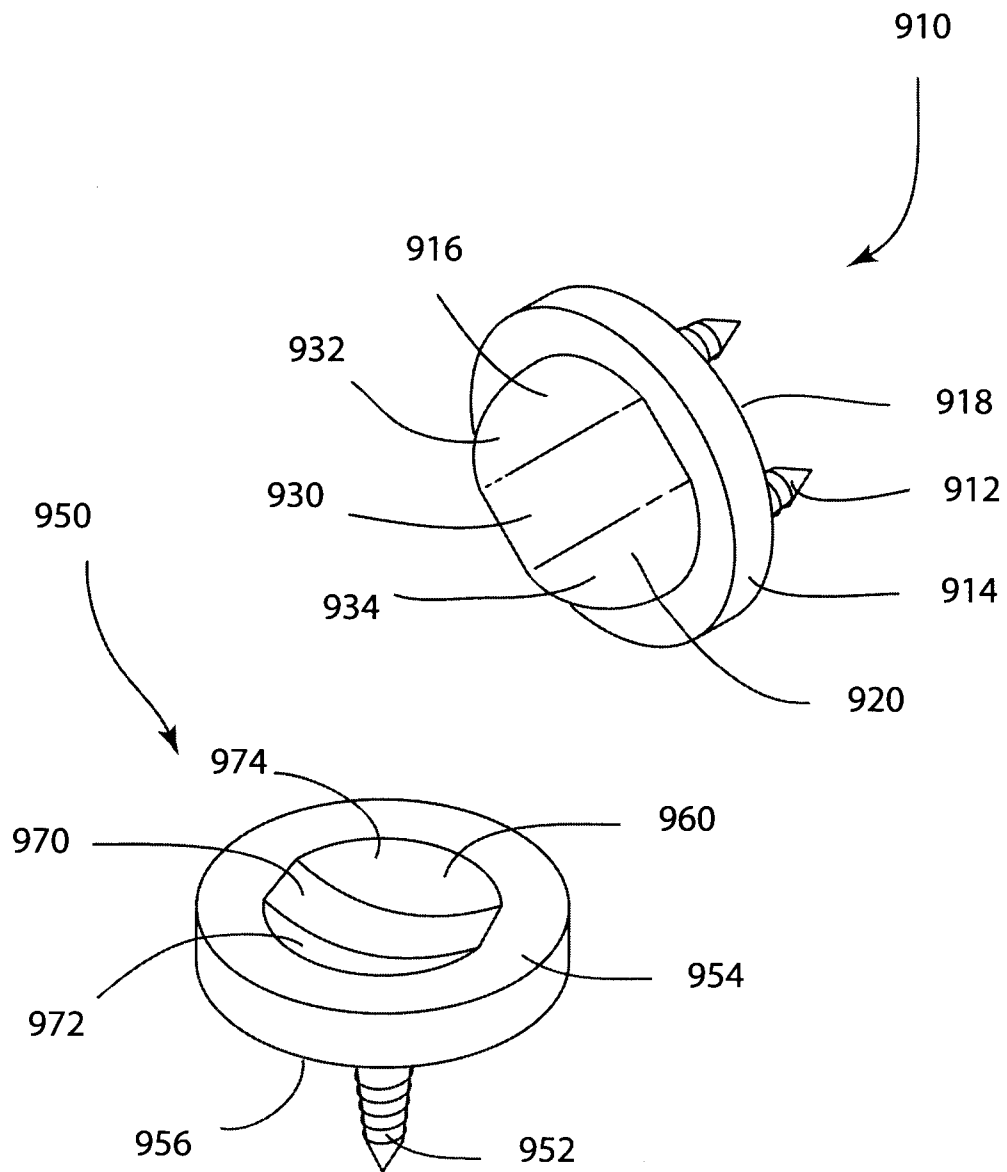


Fig. 63

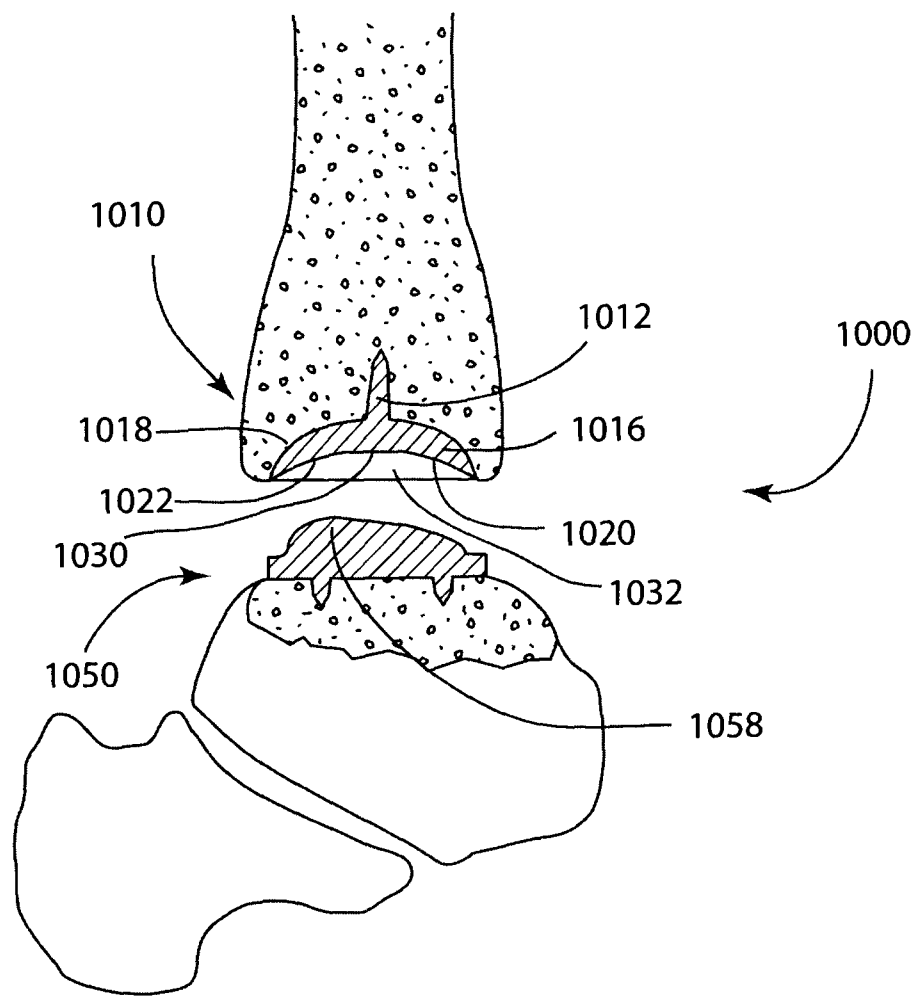


Fig. 64

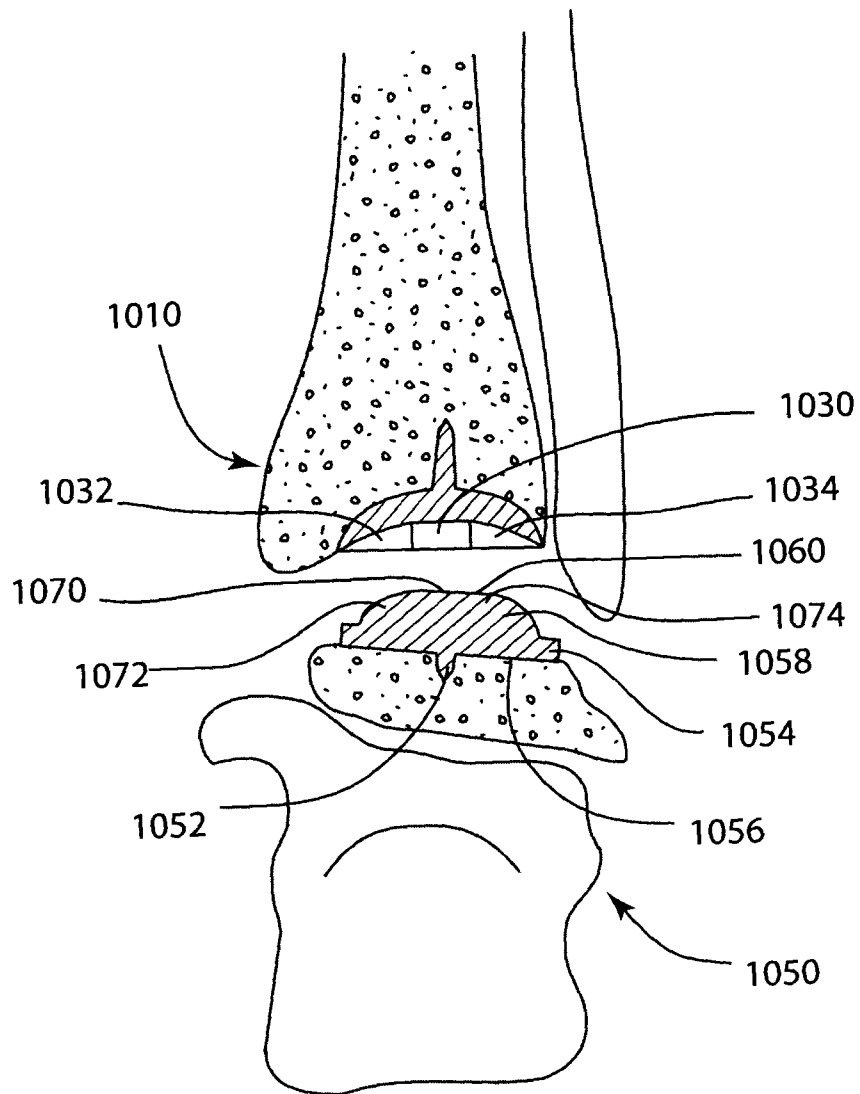


Fig. 65

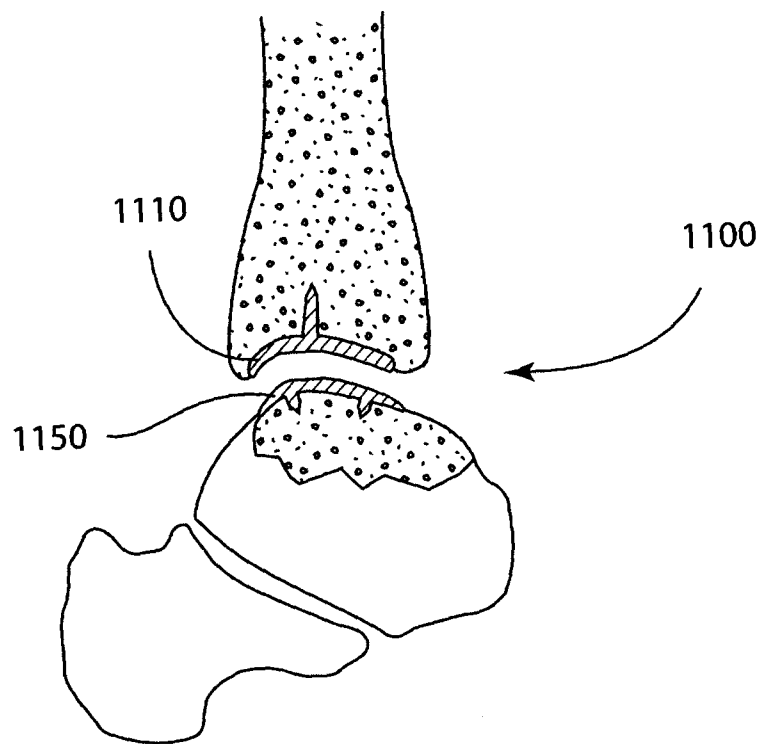


Fig. 66

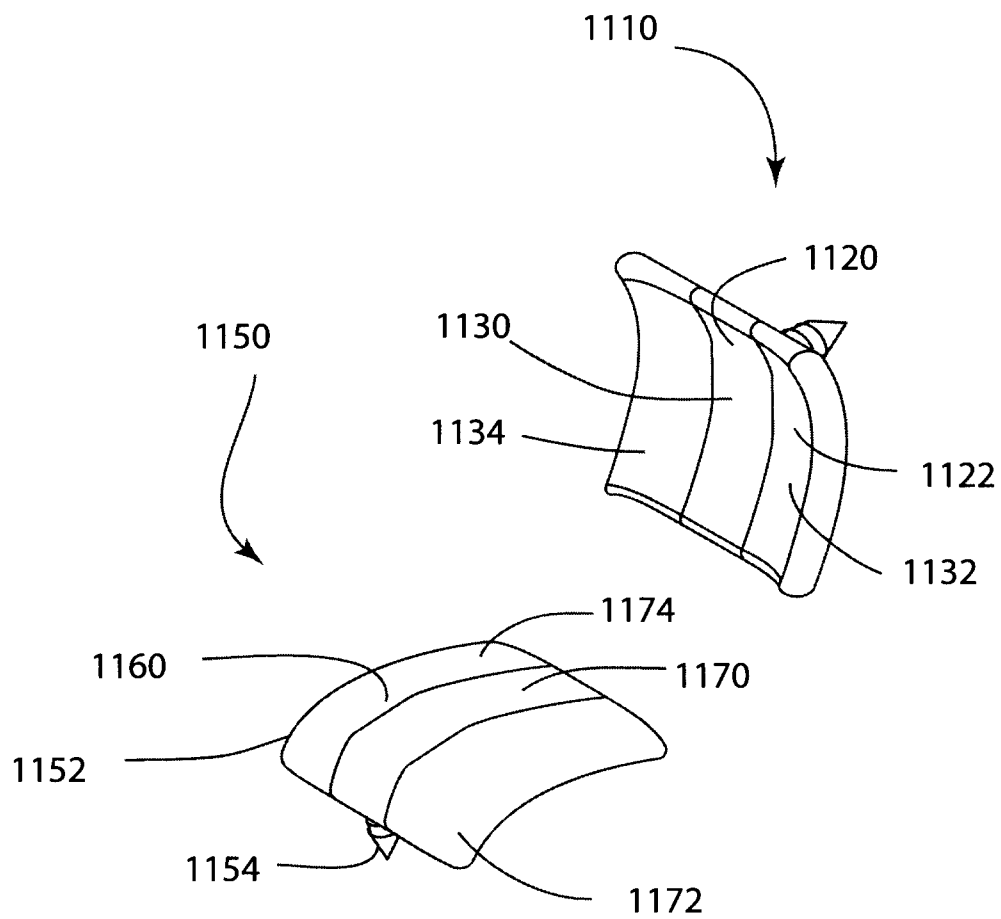


Fig. 67

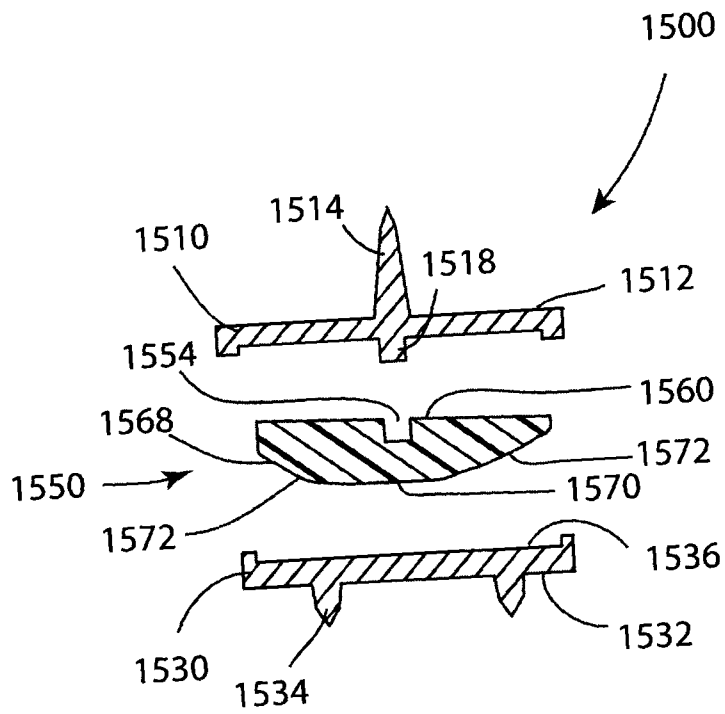


Fig. 68A

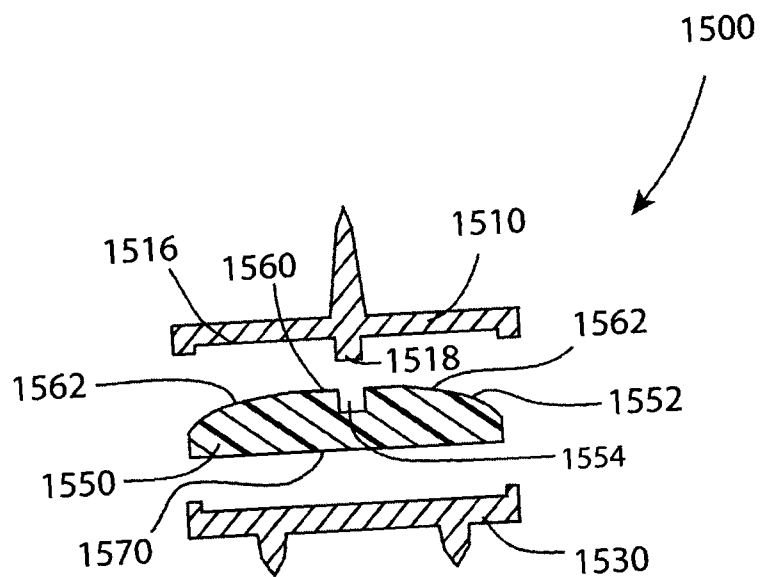


Fig. 68B

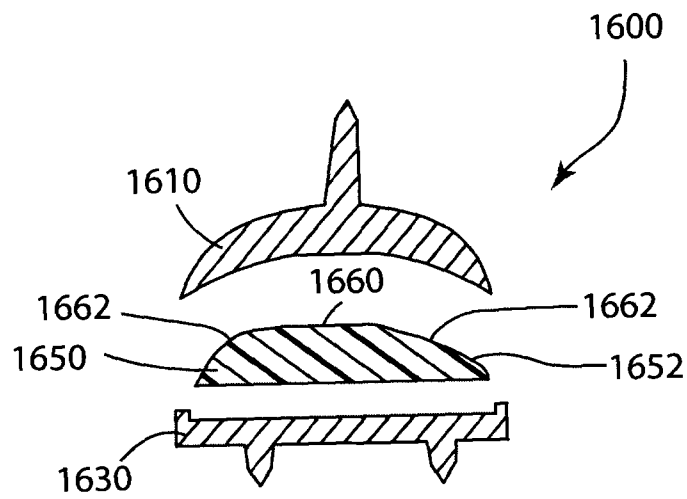


Fig. 69A

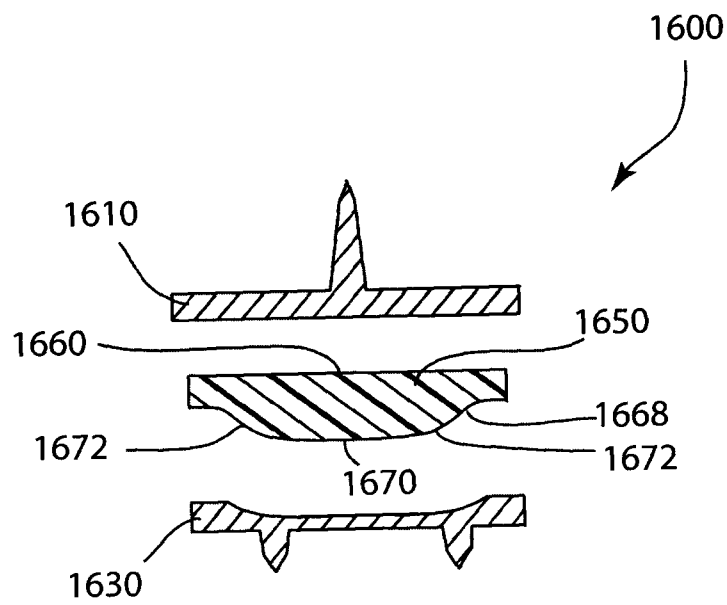


Fig. 69B

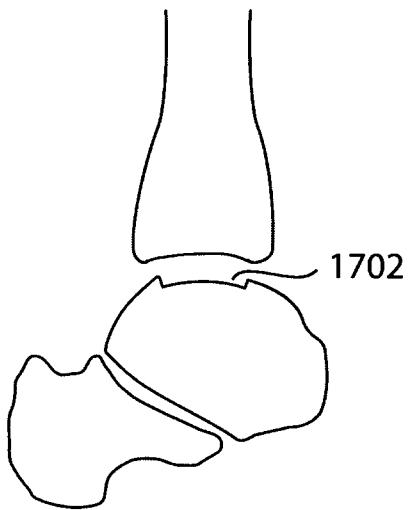


Fig. 70A

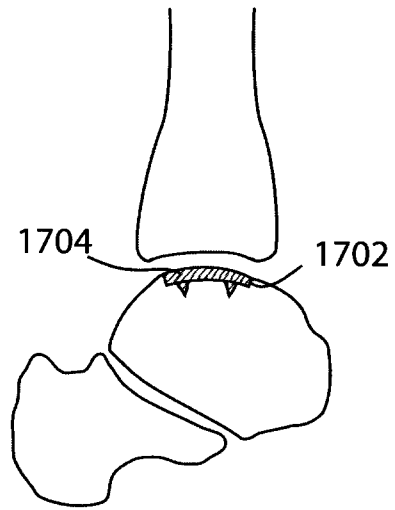


Fig. 70B

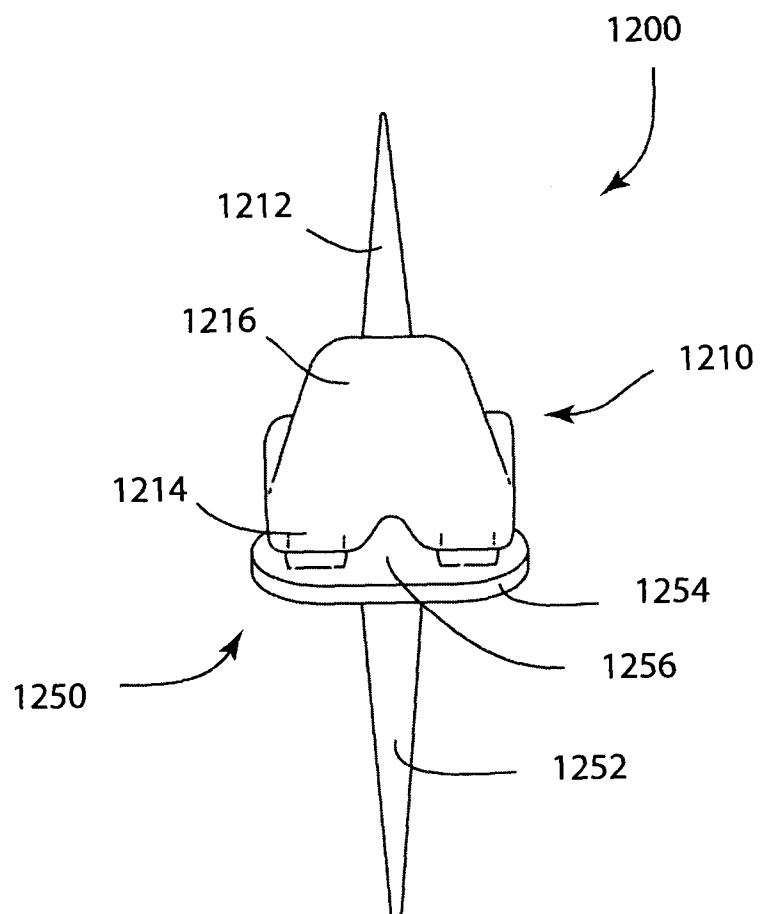


Fig. 71

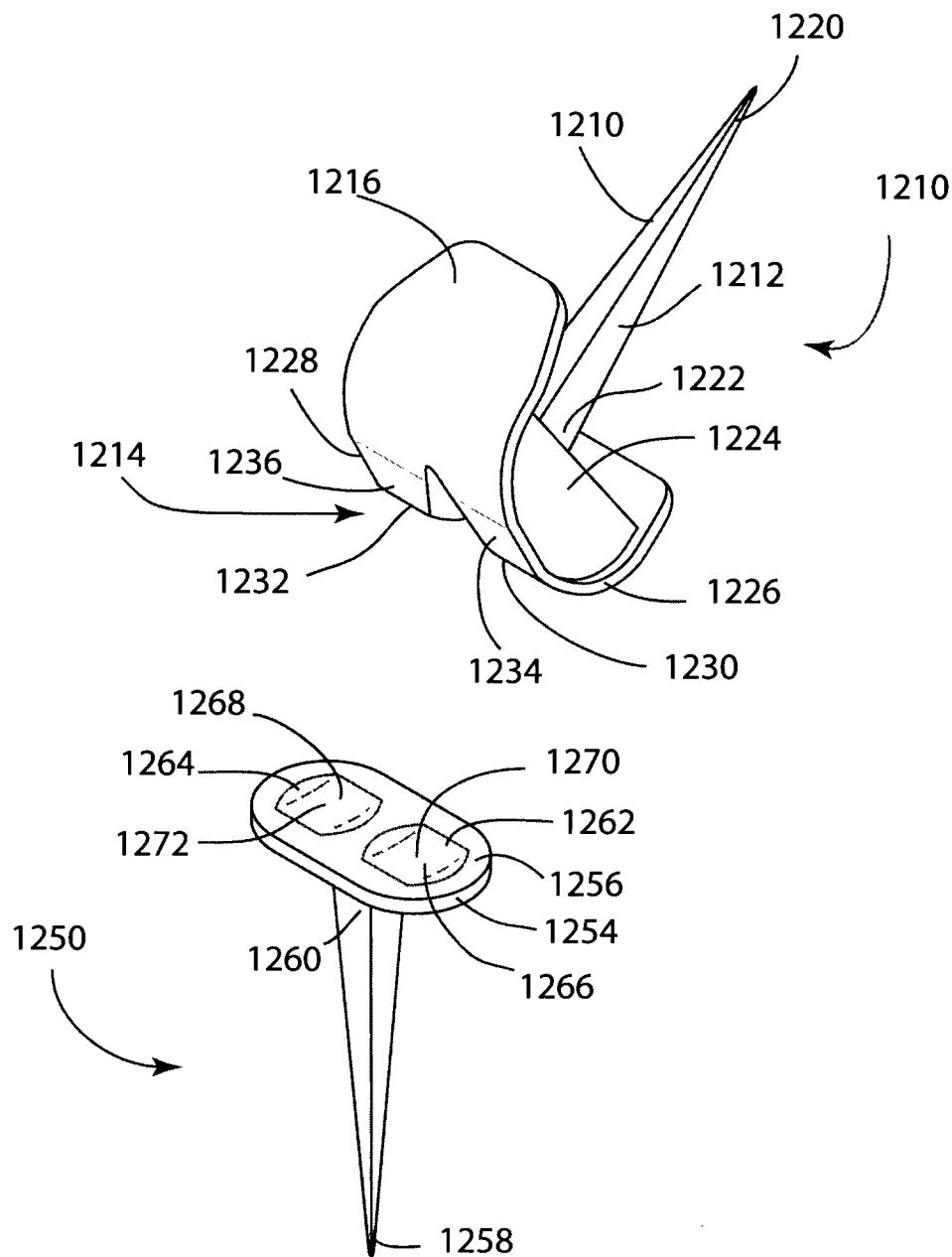


Fig. 72

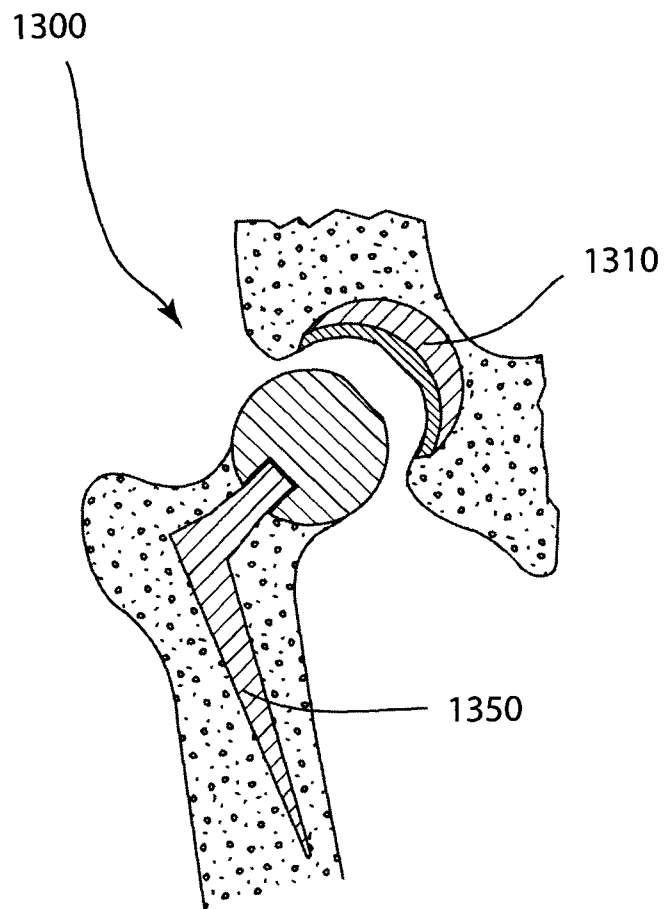


Fig. 73

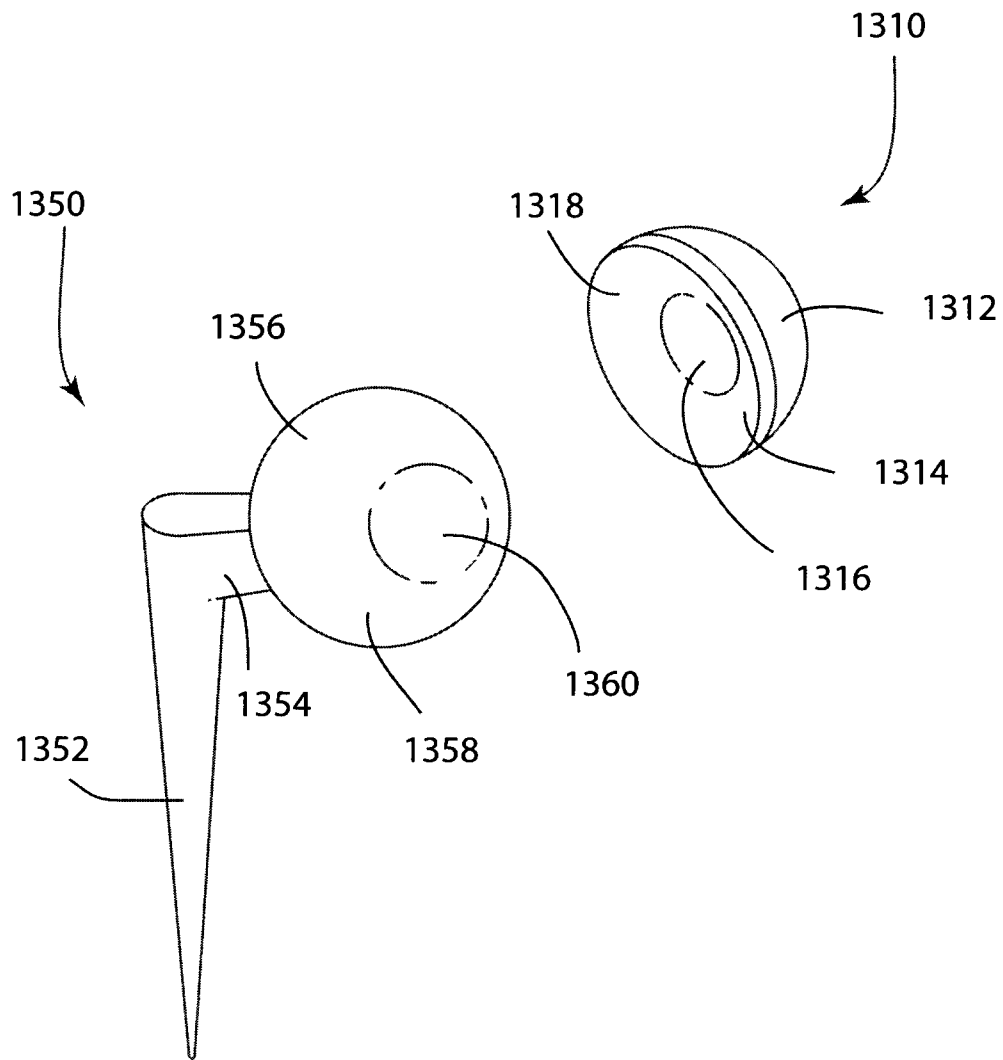


Fig. 74

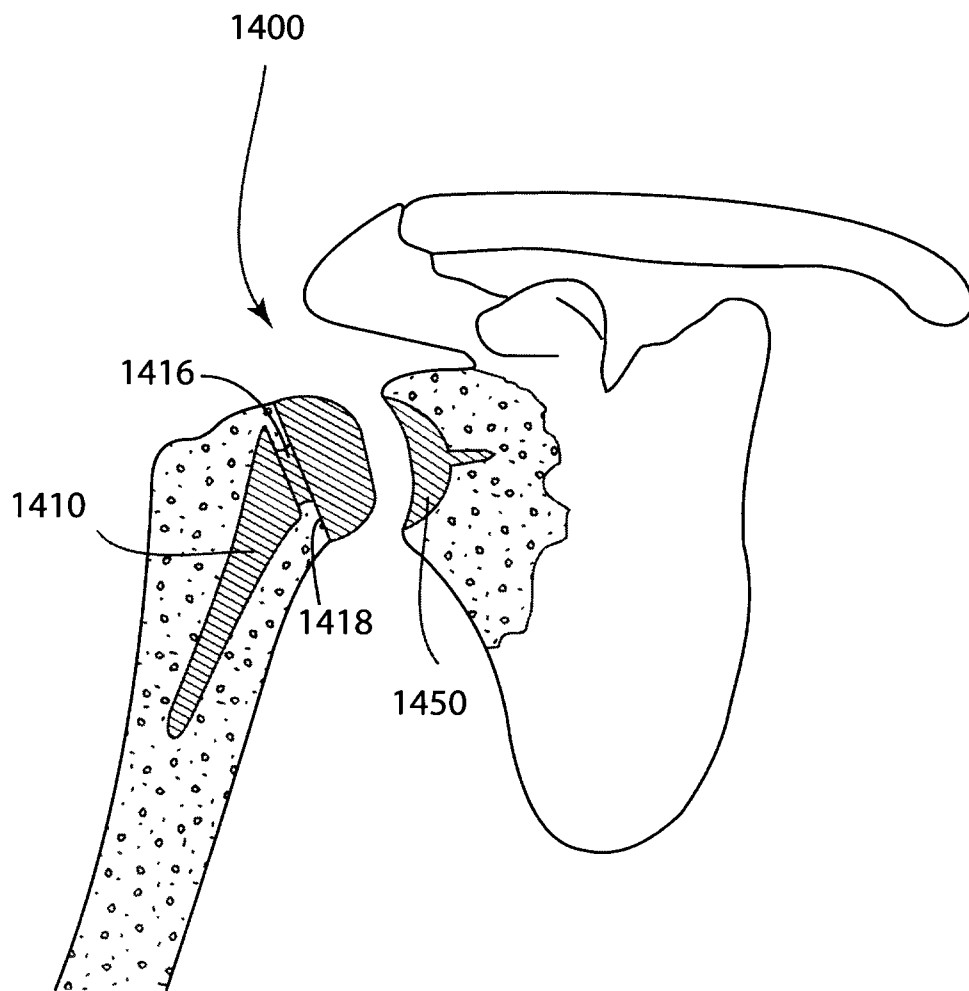


Fig. 75

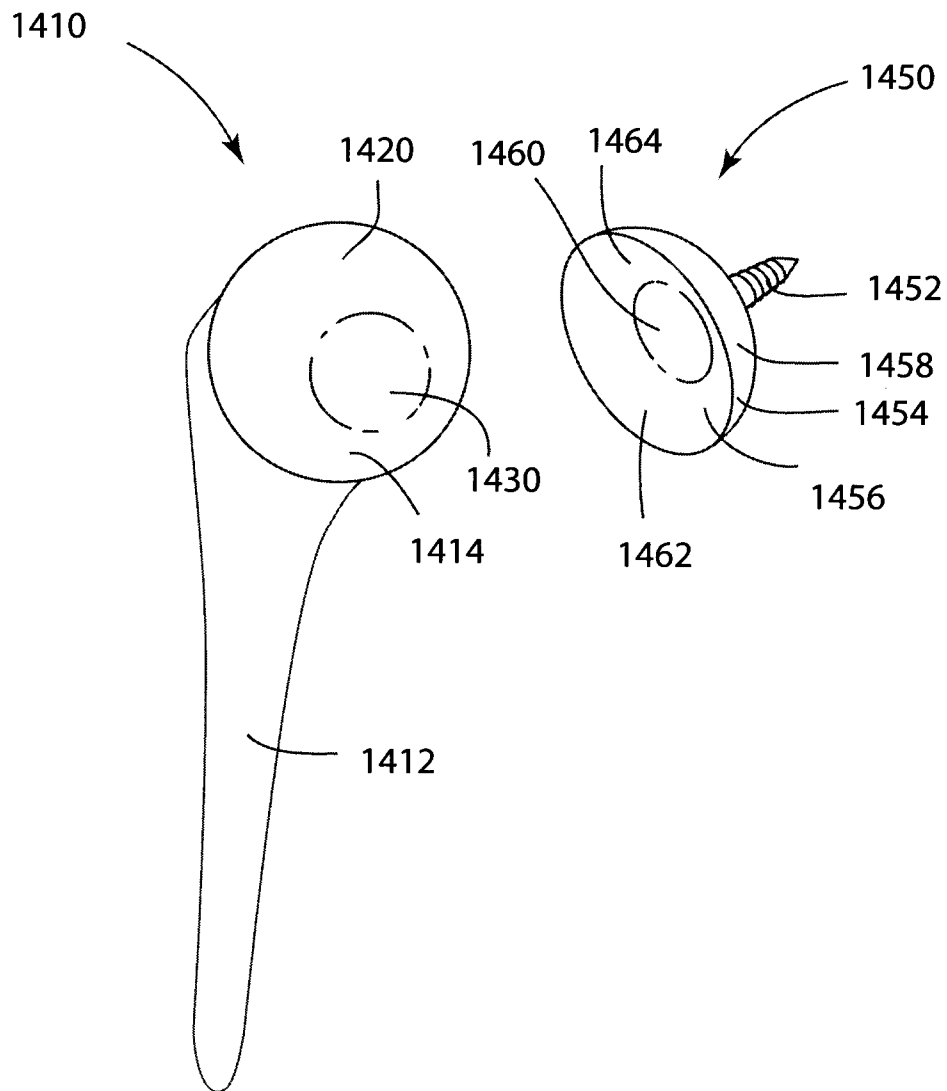


Fig. 76

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2009/000268

A. CLASSIFICATION OF SUBJECT MATTER IPC: A61F 2/30 (2006.01) , A61F 2/32 (2006.01) , A61F 2/38 (2006.01) , A61F 2/40 (2006.01) , A61F 2/42 (2006.01) , A61F 2/44 (2006.01) , A61F 2/46 (2006.01) According to International Patent Classification (IPC) or to both national classification and IPC														
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC8: A61F 2*, A61F 2/44, A61F 2/30, 32, 38, 40, 42 USPC: 623/17.16, 623/17.15, 623*, 606/71 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used) Delphion, Canadian Patent Database, Esp@cenet Keywords: joint, implant, prosthesis, prosthetic, spine, spinal, disc, nucleus, implant, flat, flattened														
C. DOCUMENTS CONSIDERED TO BE RELEVANT <table border="1"> <thead> <tr> <th>Category*</th> <th>Citation of document, with indication, where appropriate, of the relevant passages</th> <th>Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td>X, &</td> <td>WO 2006/004848 A1 (DUGGAL, N. et al.) 12 January 2006 (12-01-2006) *Paras. [0093]-[0108]; Para. [0111]; Claims; Figures*</td> <td>1-17</td> </tr> <tr> <td>X</td> <td>WO 2007/041375 A2 (LANG, P. et al.) 12 April 2007 (12-04-2007) *Paras. [00161]-[00164]; Para. [00169]; Para. [00169]; Para. [00178]; Figures 16E, 147D, 18D*</td> <td>1-7, 10-15</td> </tr> <tr> <td>X</td> <td>US 2008/0033563 A1 (KHANDKAR, A. et al.) 07 February 2008 (07-02-2008) *Paras. [0046]-[0052]; Para. [0072] - [0073]; Para. [0079] - [0080]; Figures*</td> <td>1, 3-6, 8, 10-13, 16</td> </tr> </tbody> </table>			Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	X, &	WO 2006/004848 A1 (DUGGAL, N. et al.) 12 January 2006 (12-01-2006) *Paras. [0093]-[0108]; Para. [0111]; Claims; Figures*	1-17	X	WO 2007/041375 A2 (LANG, P. et al.) 12 April 2007 (12-04-2007) *Paras. [00161]-[00164]; Para. [00169]; Para. [00169]; Para. [00178]; Figures 16E, 147D, 18D*	1-7, 10-15	X	US 2008/0033563 A1 (KHANDKAR, A. et al.) 07 February 2008 (07-02-2008) *Paras. [0046]-[0052]; Para. [0072] - [0073]; Para. [0079] - [0080]; Figures*	1, 3-6, 8, 10-13, 16
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.												
X, &	WO 2006/004848 A1 (DUGGAL, N. et al.) 12 January 2006 (12-01-2006) *Paras. [0093]-[0108]; Para. [0111]; Claims; Figures*	1-17												
X	WO 2007/041375 A2 (LANG, P. et al.) 12 April 2007 (12-04-2007) *Paras. [00161]-[00164]; Para. [00169]; Para. [00169]; Para. [00178]; Figures 16E, 147D, 18D*	1-7, 10-15												
X	US 2008/0033563 A1 (KHANDKAR, A. et al.) 07 February 2008 (07-02-2008) *Paras. [0046]-[0052]; Para. [0072] - [0073]; Para. [0079] - [0080]; Figures*	1, 3-6, 8, 10-13, 16												
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex. <table border="1"> <tbody> <tr> <td>* Special categories of cited documents :</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td></td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </tbody> </table>			* Special categories of cited documents :	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family	"O" document referring to an oral disclosure, use, exhibition or other means		"P" document published prior to the international filing date but later than the priority date claimed	
* Special categories of cited documents :	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention													
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone													
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art													
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family													
"O" document referring to an oral disclosure, use, exhibition or other means														
"P" document published prior to the international filing date but later than the priority date claimed														
Date of the actual completion of the international search 20 May 2009 (20-05-2009)		Date of mailing of the international search report 23 June 2009 (23-06-2009)												
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476		Authorized officer Robilyn Vanos 819- 934-4260												

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/CA2009/000268**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)**

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

1. ☒ Claim Nos. : 18-40
because they relate to subject matter not required to be searched by this Authority, namely :

Claims 18-40 are considered to be directed to a method of medical treatment, which the International Search Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(v).
2. ☐ Claim Nos. :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :
3. ☐ Claim Nos. :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. :

Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2009/000268

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO 2006004848A1	12-01-2006	AU 2005260554A1	12-01-2006
		BR PI0512736A	08-04-2008
		CA 2570192A1	12-01-2006
		CN 101022770A	22-08-2007
		EP 1773256A1	18-04-2007
		JP 2008504892T	21-02-2008
		KR 20070056049A	31-05-2007
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