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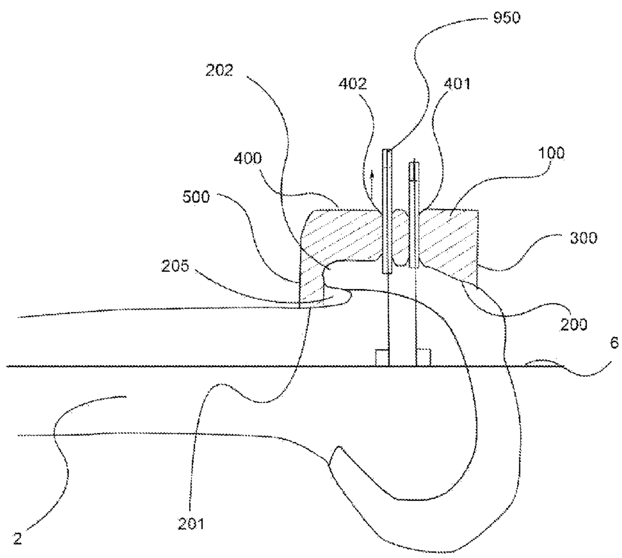
(54) Title: ANATOMICALLY MATCHED PATIENT ALIGNMENT BLOCKS

Fig. 3



(57) Abstract: The present invention relates to systems and methods for design and manufacturing anatomically matched patient alignment blocks (100, 1000) for referencing and aligning during an arthroplasty procedure. More specifically, the present invention relates to improved anatomically matched patient alignment blocks for use in arthroplasty procedure, a novel system for design and manufacturing of these blocks based upon patient's anatomy. The present invention also relates to the method of positioning the improved anatomically matched patient alignment blocks during arthroplasty procedure.

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Anatomically matched patient alignment blocks

FIELD OF INVENTION

The present invention relates to systems and methods for design and manufacturing anatomically matched patient alignment block for referencing and aligning during an arthroplasty procedure. More specifically, the present invention relates to improved anatomically matched patient alignment blocks for use in arthroplasty procedure, a novel system for design and manufacturing of these anatomically matched patient alignment blocks based upon patient's anatomy. The present invention also relates to the method of positioning the improved anatomically matched patient alignment blocks during an arthroplasty procedure.

BACKGROUND OF THE INVENTION

Over time and through repeated use, bones and joints can become damaged or worn. For example, repetitive strain on bones and joints (e.g., through athletic activity), traumatic events, and certain diseases (e.g., osteoarthritis) can cause cartilage in joint areas, which normally provides a cushioning effect, to wear down or get damaged. This condition results in pain, stiffness, and decreased mobility for the patient.

Arthroplasty procedure is commonly used to replace the joint with an artificial joint. During a typical arthroplasty procedure, an arthritic or otherwise dysfunctional joint is reshaped and / or realigned, and an implant system is accurately positioned into the damaged region. Arthroplasty procedures may take place on any of the joints in different regions of the body including knee, hip, shoulder and elbow.

There are a number of arthroplasty procedures one of which is a total knee arthroplasty ("TKA"), in which a damaged knee joint is replaced with prosthetic implant system. The knee joint may have been damaged by arthritis such as in severe osteoarthritis or degenerative arthritis, trauma, or a rare destructive joint disease. During a TKA procedure, a damaged portion in the distal region of the femur may be removed and replaced with a metal implant, and a damaged portion in the proximal region of the tibia may be removed and replaced with a channeled piece of plastic having a metal stem.

Implants that are implanted into a damaged region may provide support and structure to the damaged region, and may help to restore the damaged region, thereby enhancing joints functionality. Prior to implantation of an implant in a damaged region, the damaged region may be prepared to receive the implant. For example, in a knee arthroplasty procedure, one or more of the bones in the knee area, such as the femur and/or the tibia, may be treated (e.g., cut, drilled, reamed, and/or resurfaced) to provide one or more surfaces that can align with the implant components and thereby accommodate the implant system.

Typically, in arthroplasty procedure, there are multiple surgical steps to accurately place the implant system. The longevity of implant in a patient depends on the accuracy with which these surgical steps are performed. For example, in TKA, accuracy of implant alignment is an important factor to the success of the procedure. A few millimeter translational misalignment, or few degree rotational misalignment, may result in an imbalanced joint, and may thereby significantly affect the outcome of the TKA procedure. For example, implant misalignment may result in intolerable post-surgery pain, poor gait, faster implant wear and many a times a need for revision of a surgery adding cost and pain to the patient.

To achieve accurate implant alignment, while treating any region of a bone with surgical steps such as cutting, drilling, reaming, and/or resurfacing, it is important to correctly determine the location at which the treatment will take place and how these cutting & drilling instruments are positioned with respect to the patient. Many a times, set of complex instruments with literature study is used as a guide for accurate alignment. The accuracy of such system is limited to surgeon's assumptions and expertise. Also, every patient has unique joint issues.

Indian Patent Application No. 4479/KOLNP/2009 discloses Patient specific surgical instruments, and in particular cutting guides, and methods of use and manufacture.

Indian Patent Application No. 2317/KOLNP/2010 discloses a method of computer generating a three-dimensional surface model of an arthroplasty target region of a bone forming a joint. The method may include: generating two-dimensional images of at least a portion of the bone; generating an open-loop contour line along the arthroplasty target region in at least some of the two-dimensional images; and generating the three-dimensional model of the arthroplasty target region from the open-loop contour lines.

Indian Patent application no. 2980/KOLNP/2010 discloses a method for producing a customised surgical instrument or prosthesis for a specific patient using x-ray images. A computer implemented method for generating the patient specific model of the body part is also described.

US Patent 8,092,465 and US Patent 8,070,752 disclose a method of preparing a joint for a prosthesis in a patient. The method includes obtaining scan data associated with the joint of the patient, preparing a three-dimensional image of the joint based on the scan data, preparing an interactive initial surgical plan based on the scan data, sending the surgical plan to a surgeon, receiving a finalized surgical plan from the surgeon, and preparing an image of a patient-specific alignment guide. However, this method does not take into account the soft tissues such as cartilage, patella tendon in the preparation of the patient-specific alignment guide. Also, the guide does not have a reference surface for a surgeon to reference the cut before actually making the same, nor does it have any additional features to accommodate a variety of surgical instruments.

In some methods, a patient specific positioning block designed from patients imaging data (CT Scan, MRI Scan) may be used to accurately position and orient a finishing instrument, such as a cutting, drilling, reaming, or resurfacing instrument on the regions of the bone. The arthroplasty jig may, for example, include one or more apertures and/or slots that are configured to accept such an instrument. The limitation of such arthroplasty blocks is its limited intra-operative flexibility.

Further, the arthroplasty blocks available presently do not provide a flat surface to allow the surgeon to double check the cut to be made or allow the surgeon to change the position of the cut if required. Also, the conventional TKA surgery requires drilling of a Intra medullary canal hole, which results in loss of bone marrow of the patient and increases the patient recovery time.

Further, in the existing scenario the process of manufacturing of patient specific arthroplasty blocks is a long-drawn, tedious and costly proposition. Moreover, due to the complex shape of patient specific arthroplasty jigs, manufacturing method has been limited to additive manufacturing also known as rapid prototyping resulting in a significant increase in the cost. Therefore, there is a need for an optimized design to enable intra-operative flexibility as well as cost effective way of manufacturing these patient specific blocks so that they can be afforded by the masses.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide an improved anatomically matched patient alignment block for use in arthroplasty procedure.

It is another object of the present invention to provide an improved anatomically matched patient alignment block that increases surgical accuracy of the bone cuts made by a surgeon and provide an osteophyte and soft tissue friendly system.

It is another object of the present invention to provide an improved anatomically matched patient alignment block that support anterior referencing techniques for arthroplasty in addition to the posterior referencing techniques.

It is another object of the present invention to provide an improved anatomically matched patient alignment block that is capable of being used for making multiple bone cuts during an arthroplasty procedure.

It is another object of the present invention to an improved anatomically matched patient alignment block such that the block is removable during an arthroplasty procedure without removal of pins.

It is another object of the present invention to provide improved anatomically matched patient alignment blocks that provide a reduction in the surgical steps required during arthroplastic surgery.

It is another object of the present invention to provide improved anatomically matched patient alignment blocks that allow a reduction in the number of surgical instruments used during an arthroplasty procedure

It is another object of the present invention to provide improved anatomically matched patient alignment blocks that eliminate the need for removal of osteophytes during arthroplastic surgery.

It is another object of the present invention to provide improved anatomically matched patient alignment blocks that provide a soft tissue friendly system thereby reducing the risk of injury to the soft tissues of a patient during arthroplastic surgery.

It is another object of the present invention to provide improved anatomically matched patient alignment blocks that reduces the post surgical patient recovery time.

It is another object of the present invention to provide improved anatomically matched patient alignment blocks that are easy to manufacture and adapted to be used with various standard surgical instruments.

It is another object of the present invention to provide a process for manufacturing improved anatomically matched patient alignment blocks that is cost effective and reduces manufacturing time.

It is another object of the present invention to provide a process for manufacturing improved anatomically matched patient alignment blocks that is capable of being reproduced on a small scale.

It is another object of the present invention to provide a method of positioning the improved anatomically matched patient alignment blocks wherein the method provides intra-operative flexibility during arthroplasty procedure.

SUMMARY OF THE INVENTION

The present invention relates to systems and methods for design and manufacturing improved anatomically matched patient alignment blocks based upon patients anatomy, along with surgeons clinical input.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A shows a side view of the femur and tibia bones of a patient.

Fig. 1B is a front view of the femur and tibia bones of a patient.

Fig. 2 is an isometric view of the patient specific surface of a anatomically matched patient alignment block for femur according to the present invention.

Fig. 3 is a sagittal section view of an anatomically matched patient alignment block for femur according to the present invention.

Fig. 4 is an isometric view of an embodiment of an anatomically matched patient alignment block for femur according to the present invention.

Fig. 5 is an isometric view of an anatomically matched patient alignment block for femur according to the present invention.

Fig. 6 is an isometric view of the proximal side of an anatomically matched patient alignment block for femur according to the present invention.

Fig. 7A and 7B are the isometric and saggital views respectively of another embodiment of anatomically matched patient alignment block for femur according to the present invention.

Fig. 8 is a distal view of another embodiment of an anatomically matched patient alignment block for femur according to the present invention.

Fig. 9A, 9B and 9C are isometric views of another embodiment of a anatomically matched patient alignment block for femur according to the present invention.

Fig. 10 is a distal view of an embodiment of an anatomically matched patient alignment block for femur according to the present invention.

Fig. 11A, 11B, 11C are an isometric views of another embodiment of a anatomically matched patient alignment block for femur according to the present invention.

Fig. 12 is another isometric view of another embodiment of a anatomically matched patient alignment block for femur according to the present invention.

Fig. 13A & 13B are isometric views of yet another embodiment of a anatomically matched patient alignment block for femur according to the present invention.

Fig. 14 is an isometric view of an anatomically matched patient alignment block for tibia according to the present invention.

Fig. 15 is an isometric view of the patient specific surface of an anatomically matched patient alignment block for tibia according to the present invention.

Fig. 16 is a sagittal sectional view of an anatomically matched patient alignment block for tibia according to the present invention.

Fig. 17 is an isometric view of proximal side of an anatomically matched patient alignment block for tibia according to the present invention.

Fig. 18 is a flowchart showing an embodiment of the process

DETAILED DESCRIPTION OF THE INVENTION

The present invention obviates the aforesaid problems and provides anatomically matched patient alignment blocks to be used for joint replacements at a lower cost with higher intra-operative flexibility. The present invention also provides a process for making the anatomically matched patient alignment blocks and method of positioning the said anatomically matched patient alignment blocks.

The patient anatomy information is transferred to the surface of the anatomically matched patient alignment blocks. The said blocks use pin holes/slots which act as a holding pins as well as a reference pins once the block is taken out. These reference pin holes/ slots provide accurate references for the use of standard surgical instruments. These blocks may also contain flat surface that can be used as a reference for cutting the bone. The blocks may also have reference features (Such as grove, slot, arrow, line, etc.)

to confirm the surgical results intra-operatively. Such reference features or design of blocks can also be such that it is easily recognized via computer assisted surgery intra-operatively. The blocks can also be part of computer assisted surgery system, where the active or passive camera system can dynamically recognize these blocks in surgery and provide dynamic input intra-operatively for optimal outcome of surgery.

The design and type of raw material used for making the anatomically matched patient alignment blocks is also optimized thereby bringing down the manufacturing cost considerably and making the block affordable to common people. In various embodiments, the blocks can be manufactured using plastic, metal or any other biocompatible material sheet, rod, blocks which are then cut into required size. These anatomically matched patient alignment blocks can also be made out of pre-molded (via for example, injection molding) blocks from bio-compatible resin according to the present invention. Machining is a preferred method to transfer the patient anatomy information onto these raw material blocks. The blocks can also be manufactured using any material (non-biocompatible material such as wood, plastic etc.) and can be post processed by providing bio-compatible coating. This coating can also act as for example, anti-microbial, low friction, coating to improve the performance.

As used herein the term "Arthroplasty procedure" refers to an operative procedure of orthopedic surgery, in which an arthritic or otherwise dysfunctional joint is reshaped and / or realigned, and optionally an implant system is positioned into the damaged region. Arthroplasty procedures may take place on any of the joints in different regions of the body including knee, hip, ankle, shoulder, elbow etc. For example, in the context of knee replacement surgery, the present invention provides blocks that provide holes for locating the pins. The anatomically matched patient alignment blocks can be, but not limited to, made of two piece set. For example for a Total knee arthroplasty (TKA), the present invention provides one anatomically matched patient alignment block for femur which can be placed at the distal end to identify the location of pins for making a distal femoral cut using conventional surgical instruments and another anatomically matched patient alignment block for Tibia to identify the location of pins that can be used for making a proximal tibia cut using conventional surgical instruments. The anatomically matched patient alignment block may have a provision to double check alignments cuts before pinning and/or cutting.

Also, as used herein the term "bone" includes any bone or surrounding tissues such as cortical bone, cartilage, tendon, ligament, muscles which is intended for arthroplasty procedure.

Each patient has a unique surface geometry, the anatomically matched patient alignment blocks of the present invention captures this geometry at the contact surface to accurately place them onto the patient bone anatomy. The three dimensional (3D) information may come from any scanning modality, for example, computerized tomography (CT) scans, magnetic resonance imaging (MRI), multiple X-rays or Ultrasound etc. In a preferred embodiment, CT scans are used to obtain the images of the joints of a patient as it is cost effective way to capture 3D information. Using the scanned images, an anatomically matched patient alignment block is manufactured according to the present invention to match the bone specifications of a patient. Various existing image segmentation, 3D reconstruction and machining technologies can be used for modeling the 3D of patient's anatomy and transferring image on to the block. Prior to designing of such blocks, a surgeon may also view the surgical plan and provide necessary input to optimize the surgery. This 3D plan can be viewed in a mobile application or internet with web page having capabilities to show 3D models which can be modified, cut, rotated, repositioned dynamically and real time onto a digital display screen.

The number of such anatomically matched patient alignment blocks for an arthroplasty may vary, each pin hole set providing reference to one surgical step. The shape of the block can be as simple as a rectangular or square block for ease of manufacturability. The blocks may have round edges to mitigate any risk associated in surgery with sharp edges. The block has at least one flat surface to identify and provide visual to surgeon for cutting / pinning. The blocks may have complete contact surface or partial bone contact and designed such that it preferably does not contact specific area such as cartilage, patella tendon or other soft tissues that are identifiable depending on the scanning modality. For example, when CT scans are used, the block may only contact bone and osteophyte region to accurately position the blocks and may stay away from the regions where there is cartilage. This can enhance accuracy of positioning the blocks.

The blocks of the present invention are provided with slots for one or more holding pins and/or one or more reference pins. The holding pins are used to keep the blocks in a steady position while the reference pins define the position of the metal cutting block. The position of holding pins could be such that it anchors the bone with the block resulting in a sturdy and accurate positioning of the block with reference to the bone. For example, the holding pins can be placed in "X" shape such that they are not intercepting. The placement of the slot for the reference pins is based upon the 3D data generated from scan image, location information derived from metal cutting blocks, and the input provided by surgeon for desired outcome of the surgery.

The block can be configured with additional extended features such as lip to provide a more locking/snuggly position as well as avoid the blocks to slide further down from its position. The patient specific blocks of the instant invention can be made out of medical grade plastic such as Polyoxymethylene (also known as Celcon, Delrin), High Density Polyethylene, Polyether Ether Ketone (PEEK), Polyamides, Nylon, Polyurethane. The blocks can also be made of any medical grade metal such as stainless steel, Titanium allow or a combination of metal and plastic. The block can be made as a single piece made out of one material or as an assembly of multiple components that are made from different material or a combination.

The anatomically matched patient alignment blocks of the present invention may be cleaned using any of the cleaning techniques like water rinsing, Ultrasonic cleaning etc. There can be a finishing operation on the blocks to remove burrs and sharp edges. These blocks can have patient specific information like name, unique identification number etc. which can be engraved using laser etching technique or any other machining technique.

In another embodiment the present invention also provides the process for making the anatomically matched patient alignment blocks wherein a surgeon identifies a patient needing a Total Knee Replacement; the patient is sent to a CT Scan center for a leg scan (Including Hip, Knee & Ankle); based on the information from the CT scan, a 3D model of the area intended for arthroplasty including bone anatomy information, osteophyte information (via Segmentation process) is created using a generic software; a Surgical pre-operative plan for that patient is created using the said 3D models and is sent to surgeon for approval (via 3D PDF, Dynamic group images, word document); the surgeon evaluates the plan and gives necessary changes / inputs which are then used to create a anatomically matched patient alignment block set. The femur and a tibia block is designed in such a way that the blocks do not interfere with the neighboring soft tissues; the blocks are manufactured using machining on a pre-molded medical grade plastic blocks (alternatively Rapid Prototyping). After cleaning and packaging the blocks gets shipped (in a sterile or non-sterile state) to the hospital/dealer. Alternatively, manufacturing and cleaning process can happen at the hospital. Thus, the process for manufacturing improved anatomically matched patient alignment blocks according to the present invention is capable of being reproduced on a small scale.

At the time of surgery, the surgeon places these blocks which are fitting the anatomical surface of the patient's bone and osteophytes. The pins are then drilled into the bone and blocks are removed without removing the pins (due to undercut release built in for osteophytes support). The standard resection blocks are placed on these pins and surgeon performs the distal femoral cut and proximal tibia cut.

Thus, the present invention delivers necessary patient surgical planning via simple blocks, namely anatomically matched patient alignment blocks that can be easily manufactured in a cost effective way. The present invention removes the high cost and complexity involved in conventional total knee arthroplasty (TKA) by supporting pin positioning of distal femur cut and proximal tibia cuts also providing greater intra-operative flexibility to surgeon.

The present invention provides improved anatomically matched patient alignment blocks that increase surgical accuracy of the bone cuts made by a surgeon and provide an osteophyte and soft tissue friendly system. Using the improved anatomically matched patient alignment blocks of the present invention, the total number of surgical steps is reduced while the surgical accuracy is increased. Further, during Total Knee Arthroplasty (TKA), the need for creating Intra-Medullary canal in the femur is eliminated by using these blocks of the present invention and thereby reducing infection risk as well as facilitating faster surgery and recovery time.

The improved anatomically matched patient alignment blocks of the present invention also provide a reference surface to allow a surgeon to take a decision to make the cut during surgery. The improved anatomically matched patient alignment blocks of the present invention provide an osteophyte and soft tissue friendly system and also eliminate the need for removing osteophytes from the patient's bones as opposed to the conventional or currently available arthroplastic surgical procedures. The improved anatomically matched patient alignment blocks of the present invention also provide a soft tissue friendly system by providing undercut releases for soft tissues such as cartilage, patella tendon etc. thereby providing a unique fit and diminishing the risk of injury to the soft tissues of the patient. The improved anatomically matched patient alignment blocks are easy to manufacture and adapted to be used with various standard surgical instruments.

The improved anatomically matched patient alignment blocks of the present invention increases surgical accuracy of the bone cuts made by a surgeon and provide an osteophyte and soft tissue friendly system. The alignment blocks of the present invention anterior referencing surgical techniques for arthroplasty in addition to the posterior referencing techniques which allows greater intra-operative flexibility to a surgeon. Further, the alignment blocks of the present invention can be used for making multiple bone cuts during an arthroplasty procedure. The alignment blocks of the present invention allow a significant reduction (upto about 15-20%) in the number of surgical steps required during arthroplastic procedures as compared to conventional arthroplasty procedures.

The structure of the anatomically matched patient alignment block is such that each block has a curved three dimensional (3D) surface that is a fully or partially presenting the patient's anatomy information that is derived from the 3D model of the that patients bone generated from scans of a patient's bone. The scans include CT scan, MRI scan, X-ray scans or ultrasound or a combination of these. The anatomy information includes the 3D bone information, the osteophyte information and information on the soft tissues present in and around the contact area of the block. For example, for a total knee arthroplasty, this information is derived from 3D model generated from the CT or MRI scans of the patient's knee. The shape of this Curved 3D surface is such that it fits snuggly to the bone and has only one unique position where it fits snuggly. This curved 3d surface on the block may have additional gap to accommodate soft tissues such as cartilage or any other soft tissue, the information of which is not very accurately be determined from Scans. By providing these gaps around the cartilage and other soft tissue, the present invention eliminates the need of using expensive modality such as MRI for accurate 3D reconstruction of soft tissue. This 3D curved surface may also have a window slot opening to visually check the fit at the time of surgery to ensure that the contact of the block on to the patient surface is accurate. This window slot may also help the surgeon accurately position the block in the right direction and thereby helping to position the blocks quickly.

The surface adjacent to the patient specific curved 3D surface may be curved or chamfered so as to have easy insertion of the blocks of the present invention and can accommodate these soft tissues including but not limited to medial collateral ligament, and patella tendon and avoid any damage to the soft tissues around the knee area of the patient.

The anatomically matched patient alignment block according to the present invention may have additional features such as lip to provide a more locking/snuggly position as well as avoid the blocks to slide further down. One side of this lip surface may also be a curved 3d surface that is generated from patient's 3D model, including any releases from soft tissues. The anatomically matched patient alignment block may also additionally comprise one or more rough surface generated so as to provide a better grip of the block especially when it is held in a clinical environment in the slippery fluidy gloves on the hands of a surgeon.

Fig. 1A and 1B illustrates the various aspects of a patient's femur and tibia bones that are important for making the distal femoral cut and the proximal tibia cut during total knee arthroplasty. The femur 1 comprises of a proximal femur end 3, a distal femur end 2, a femoral head 4, a knee femur center 5, an anterior distal femur surface 8 where the patient specific blocks of the present invention are placed, and intra medullary canal 9. A femur mechanical axis 6 is also shown. During a conventional total Knee arthroplasty procedure multiple sets of instrumentation are used to accurately recreate patient knee joint via positioning the implant system in alignment with these Femur and tibia axes. To accurately find mechanical axis of the individual bones, at times an intra-medullary canal is created especially in femur bone. This additional surgical step requires removal of critical bone marrow as well as could increase the risk of side effects such as fat embolism. The present invention provides the benefit of not having to create additional canals, such as the intra-medullary canal, in the bones resulting in faster recovery, lower surgical risks and reduce side effects. The tibia 50 comprises a proximal end of tibia 51, a distal end of tibia 52, a tibia center 53, a tibia mechanical axis 54 and the anterior proximal tibia surface 55 on which the anatomically matched patient alignment blocks of the present invention are placed during Total Knee arthroplasty. Also shown are the osteophytes 16 on the distal end of femur 2 and the osteophytes 56 on the proximal end of tibia 52.

Fig. 2 shows an anatomically matched patient alignment block for femur block 100 with a curved 3D surface 200 that partially matches the anatomy information of the patient's anterior distal femur surface 8. The anatomy information includes the 3D bone information of the femur, the osteophyte information and information on the soft tissues present in and around the contact area of the block 100. This information is derived from the 3D model generated from CT or MRI scans of the patient's knee. The curved 3D surface 200 comprises of a bone contact surface 201 to be in contact with the anterior distal femur surface 8, an osteophyte contact surface 202 to be in contact with the osteophytes 16, a cartilage release 203 such that the block 100 does not contact or rupture the cartilage present around the proximal end of the femur 3, a window opening 204 to allow the surgeon to visually check the contact of the block 100 with the patient's bone surface i.e. the anterior distal femur surface 8 at the time of surgery to ensure correct positioning of the anatomically matched patient alignment blocks, and an undercut release 205. Also shown is a flat distal femur reference cut surface 300, an anterior surface 400 which lies opposite to the curved 3D surface 200, a side surface 600 that lies to the right of the anterior surface 400 and a second side surface 700 that lies to the left of the anterior surface 400. These side surfaces 600 and 700 may be flat or chamfered and may also contain features to facilitate the holding of the block 100.

Fig. 3 is a cross sectional view of the anatomically matched patient alignment block for femur 100 positioned on the distal end of the femur 2 with respect to the femur mechanical axis 6. The curved 3D surface 200 is in contact with the femur bone surface and has partially matching contour surface with respect to the anterior distal femur surface 8 and osteophytes corresponding to the bone contact surface 201 and the osteophyte contact surface 202 respectively. A pair of headless pins 950 is driven through the holes 401 or 402 from the anterior surface 400, into the femur. The undercut release 205 on the curved 3D surface 200 allows the blocks to come out easily in the direction of the pin insertion without any tissues interfering or locking this block removal without needing to remove the pins. Also shown are the proximal femur bone surface 500 and the flat distal femur reference cut surface.

Fig. 4 shows the another view of an exemplary anatomically matched patient alignment block for use on femur with an anterior surface 400 which lies opposite to the curved 3D surface 200 and is also parallel to the Trans Epicondyler Axis 7 shown in Fig. 1. The anterior surface 400 comprises pairs of holes 401 and 402 which correspond to standard instruments used in TKA. There may also be present a feature 404 for aligning a conventional alignment rod on the anterior surface. The feature 404 may be in the form of a slot or a scribe line or a laser marking on the anterior surface of the block which may present a mechanical axis or anatomical axis parallel to the Intra medullary canal that passes through the center of the bone. Also shown in Fig. 4 is a flat distal femur reference cut surface 300 which may be used by the surgeon during the surgery to double check the position for making the distal femoral cut. Also shown in Fig. 4 is the window slot opening 204 present on the curved 3D surface 200, side surfaces 600 and 700 and the proximal femur block surface 500.

Fig. 5 is another view of the anatomically matched patient alignment block for femur 100 showing its application on the anterior distal femur surface 8 of the distal end of femur 2. The flat distal femur reference cut surface 300 is located only on one side, the side of the femur bone that will be eventually be resected to make the distal femoral cut. This flat surface provides 300 reference cut surface so that at the time of surgery, the surgeon may put a blade runner 12 or any other flat ruler like instrument and double check if the cut the surgeon will eventually make is in line with what surgeon would like before actually making the cut.

Fig. 6 shows another view of an anatomically matched patient alignment block for femur 100 showing the flat distal femur reference cut surface 300 wherein the surface 300 also comprises a feature 301 for supporting computer assisted surgery such that during surgery the surgeon can double check the accuracy of these blocks with respect to bone using computer assisted surgery.

Fig. 7A is another view of the anatomically matched patient alignment block 100 for use on femur wherein the proximal femur block surface 500 also contains the hole 302 allowing the surgeon to reconfirm the alignment with the femur mechanical axis 6 during surgery by passing a laser / light beam through the hole 302 using a laser pointer or torch 13, as shown in Fig. 7B.

Fig. 8 shows an anatomically matched patient alignment block 100 for femur wherein the flat distal femur reference cut surface 300 additionally comprises lips 303 for femoral rotation reference. The length of the lips is such that it creates a hypothetical reference line representing the trans-epicondyler axis 7 of the patient. This hypothetical reference line corresponding to the Trans Epicondyler Axis 7 can be used as a reference for femoral rotation. The length of the lips can be determined using landmarks that are observed in the 3D models generated from CT / MRI scans of that patient.

Fig. 9A shows the anterior surface 400 of the anatomically matched patient alignment block 100 for femur comprising the sets of holes 401, 402 which go all the way to the curved 3D surface 200 such that they allow set of headless pins 950 to be inserted into the bone. There can be one or more such set of holes present on the block, each set representing a standard instrument that can be used. As there can be multiple different instruments that are present, having multiple set of holes can provide flexibility in the surgery depending on which instrument is available at the time of surgery. The block 100 may also have one or more threaded hole 403 to accommodate alignment rod 10 of an alignment handle 11, such as the one shown in Fig. 9B, allowing a surgeon to double check the alignment of the distal femoral cut using a standard instrument before actually making the distal femoral cut. The use of the block 100 in combination with the alignment handle is illustrated in Fig. 9C.

Fig. 10 is another view of the anatomically matched patient alignment block 100 for femur showing the trans-epicondyler axis for femur 7 and the anterior surface 400 which is parallel to the trans-epicondyler axis 7. This anterior surface 400 provides a reference during the surgery to set the rotation angle of the femoral component which should be close to or parallel to this surface.

Fig. 11B illustrates a distal femur resection guide 900 which is a standard instrument used during total knee arthroplasty. Fig. 11A illustrates the use of the distal femur resection guide 900 in combination with the anatomically matched patient alignment femur block 100. Fig. 11C illustrates another embodiment of a patient specific arthroplasty femur block 100 wherein the anterior surface 400 contains a slot 405 for seating for the distal femur resection guide 900 such that the surgeon can make cuts from the resection guides without removing the anatomically matched patient alignment block 100. In such cases the holes on the surface may be replaced with an opening 406, which may be circular or rectangular, to accommodate the headless pins 950 coming through the distal femur resection guide 900. Such slot 405 may be present on any surface of the alignment blocks to accommodate any conventional surgical instrument that is employed during arthroplasty.

Fig. 12 illustrates other embodiments of the anatomically matched patient alignment 100 of the present invention having additional features. Figure 12 illustrates an embodiment of the invention wherein the anatomically matched patient alignment block 100 for femur has additional protrusions and or islands such that it provides easy gripping of the block. The recess 800 provides finger grip feature to the block while the recess 801 provides a feature for thumb grip in the anatomically matched patient alignment block 100. The surfaces could be of the shape that provides good seating of thumb and fingers. The position of these recesses/impressions can be located anywhere in the block so as to provide pressure in unique direction for better fitment and rigid fit of the blocks.

Fig. 13A illustrates another embodiment of the present invention wherein the anatomically matched patient alignment block 100 for femur is configured with stubs 407 to rest an anterior resection guide 14 that is connected to a femoral alignment guide 15 which is connected to the anterior resection guide 14 as shown in Figure 13B. One or multiple surface of these stubs 407 will contact the anterior resection guide 14 such that the cutting slot in anterior resection guide 14 gets accurately positioned to make an anterior skim cut. This anterior skim cut is an another important cut for the preparation of femur so that a femoral component of the Total Knee Arthroplasty (TKA) can be fitted. This allows the anatomically matched patient alignment blocks of the present invention to support anterior referencing surgical techniques in addition to posterior referencing surgical techniques.

In addition to the anatomically matched patient alignment block 100 for femur as described above, there can be additional such alignment blocks that can used in preparation of femur. These blocks may provide instead of distal cut, reference for other such cuts that are necessary to prepare the femur so that a femoral component of the Total Knee Arthroplasty (TKA) can be fitted.

Yet another embodiment of the present invention provides anatomically matched patient alignment blocks for tibia for the preparation of the tibia during Total Knee arthroplasty.

Fig. 14 illustrates an exemplary anatomically matched patient alignment block 1000 for use on the tibia during total knee arthroplasty having two extended lip shapes 3030 protruding outwards from the flat Proximal tibia reference cut surface 3000; a curved 3D surface 2000 that partially matches the patient bone anatomy information derived from the scans of a patient; and a Window opening for tibial tuberosity 2040; side surfaces 6000 and 7000; an anterior surface 4000 lying opposite to the curved 3D surface 2000 containing sets of holes 4010, 4020 and a distal tibia block surface 5000. The side surfaces may be chamfered to provide surfaces 6010 and 7010 for soft tissue release while the anterior surface 4000 may also be configured with a slot 4030 to position the alignment rod. The extended lip shapes 3030 lock the position of the block 1000 so that it does not move further down during surgery and also provide additional support on the anterior proximal tibia surface 55 (as shown in Fig. 1) for providing a unique snuggly fit. The window opening 2040 for the tibia tuberosity provides an easy release of the block such that it does not hit the tibial tuberosity or any soft tissues around that area, and also provides a reference slot 4030 in the middle of the tibia for alignment check by the surgeon. The Flat Proximal tibia reference cut surface 3000 provides a reference surface for making a cut during surgery so that the surgeon may put a blade runner and double check the cut before making the same. The holes 4010, 4020 on the anterior a surface 4000 correspond to standard instruments used during total knee arthroplasty. The side surfaces 6000 and 7000 helps to provide a better grip to hold the blocks and provide proper pressure to snuggly fit to the bone.

The structure of the patient specific tibia block is such that each block has a curved 3D surface 2000 that is a fully or partially presenting the patient's bone and osteophytes anatomy shape that is derived from the 3D model of the that patients tibia generated from CT/MRI scans. The shape of this 3D Curved surface 2000 is such that it fits snuggly to the bone and has only one unique fitting position.

Fig. 15 is another view of a anatomically matched patient alignment block 1000 for use on the tibia. The curved 3D surface 2000 comprises a window opening for tibia tuberosity 2040 for tibial tuberosity release, a patella tendon release surface 2030 created to provide space to accommodate Patella tendon near where it gets attached to the tibial tuberosity, an osteophyte contact surface 2020 matching the osteophytes present on the tibia bone of the patient; a bone contact surface 2010 matching the patient's bone on the tibia and an undercut release surface 2050. The flat proximal tibia reference cut surface 3000 provides a final cut surface for surgeon confirmation and chamfers 6010, 7010 are provided to avoid pinching of soft tissues around the tibia bone. Also shown is the anterior surface 4000 containing the sets of holes 4010 and 4020, and the distal tibia block surface 5000.

The patella tendon release 2030 on the 3D curved surface 2000 accommodates soft tissues such as but not limited to Patella Tendon, Lateral Collateral ligament, medial collateral ligament, Anterior Cruciate Ligament, Posterior cruciate ligament or any other soft tissue, the information of which is determined from 3D model generated out of CT/MRI Scans of the patient. The window opening 2040 around the tibial tuberosity provides a release so that it does not hit the patient's tibial tuberosity and the patella tendon attachment at that location. This window opening 2040 may also act as a reference opening in the middle of the Tibia indicating the direction and alignment of tibia mechanical axis 54 (as shown in Fig. 1B).

The flat proximal tibia reference cut surface 3000 is located only on one side, the side of the bone that will be eventually be resected to make the proximal tibia cut. This proximal tibia reference cut flat surface 3000 provides reference cut surface so that at the time of surgery, the surgeon can put a blade runner or any other flat ruler like instrument and double check if the resection cut they will eventually make is in line with what they would like before actually making the cut.

Fig. 16 illustrates the application of the anatomically matched patient alignment tibia block 1000 during total knee arthroplasty wherein the headless pins 950 are driven through the block 1000 into the proximal end of tibia before making the proximal tibial cut in a manner such that the pins 950 remain accurately positioned with respect to the tibia mechanical axis 54 as determined from the pre-operative planning by the surgeon.

Fig. 17 presents another view of the anatomically matched patient alignment tibia block 1000 placed on the tibia 51 of the patient during total knee arthroplasty.

In another embodiment the present invention also provides a process for manufacturing the anatomically matched patient alignment blocks of the present invention. Fig. 18 illustrates one such process for the manufacturing the anatomically matched patient alignment block of the present invention. The process begins with a surgeon identifying a patient that is suitable for this technology. The surgeon asks the patient to visit a pre-qualified scan centre and get the required scans done. Such scans must include but not limited to the Hip region around the femoral head, complete bony landmarks around Knee joint approximately 100 mm on both the sides of the knee joint line, as well as ankle joint to accurately create patients required axis. The scans may preferably be CT scans or MRI scans, most preferably CT scans. This Scan data is then sent in a DICOM format or any other lossless compression format to the manufacturer. The data can be sent via CD/DVD or any other memory storage media through a pre-address envelop or uploaded directly to the servers via internet.

A 3D model of that patient's bone and desired soft tissue area is created using standard segmentation tools or 3D modeling software available in the market. These 3D models in is then imported into a designing software where appropriate landmarks are selected. A default surgical plan is then created showing the tentative resection / cuts of the femur and tibia, namely Distal Femoral Cut and Proximal tibia cut. This plan showing the default values is then sent to surgeon for confirmation. This plan can be sent via method such as but not limited to Email, web based, Mobile phone application, Fax, etc. When sending this file electronically, the format of such planning file can have either 2D images showing a specific view of the 3D files or it can be multiple 2D images showing in a group so that they look like 3D or it can be actual 3D representation of patient's geometry. The surgeon may provide feedback on changes if any to this plan. This feedback will be received by the manufacturer and the anatomically matched patient alignment blocks will be designed accordingly. The design of the blocks can be done using any standard design computer software where all the necessary structural features discussed are incorporated. Once this design is ready, special code may be generated to convert the design information into machining code. This block can then be manufactured using 3 axis, 4 axis or 5 axis machine. For easy identification of each block, each block may have unique identification number and / bar code marked using but not limited to laser etching, laser engraving, marker laser printer etc. This marking process may happen before or after the machining operation. Machining operation may happen on all the above mentioned surfaces or may only happen around patient specific 3D Curved surface, wherein for the later case, a premolded / premachined blocks are kept ready in batches and only the patient specific surface is machined. The blocks may go through cleaning, shipping and sterilization prior to being used on the patient.

The anatomically matched patient alignment blocks described above may be employed for making distal femoral cut and proximal tibia cut in a total knee arthroplasty. Such blocks can be used to position standard metal cutting blocks or resection guides. The anatomically matched patient alignment blocks of the present invention can also be used to make one or multiple surgical cuts. One block can be used for one or multiple such positions with different surface referencing or cutting a specific area for the arthroplasty procedure.

Further explanations are made in combination of Figs. 1 to 18 where the inter reference will be made to the various drawings.

In an embodiment the present invention provides an improved anatomically matched patient alignment block (100, 1000) for referencing and aligning during an arthroplasty procedure, said alignment block comprising: a curved surface (200, 2000) adapted to match with a patient's bone anatomy said curved surface being configured with at least a release gap around surrounding soft tissues or bones or both and an undercut release (205,2050) for easy removal of said alignment block; an anterior surface (400, 4000) opposite to said curved surface wherein said anterior surface comprises at least an aperture (401, 4010) to receive at least two pins (950) for pinning said alignment block (100, 1000) to a bone of a patient during an arthroplasty procedure such that said alignment block (100, 1000) is removable without removing said pins; and at least a flat surface (300, 3000) for providing a reference surface for checking the location of a cut to be performed during the arthroplasty procedure.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said aperture (401, 4010) on the anterior surface (400, 4000) is selected from a group comprising of a slot, a hole, a pair of holes and combinations thereof.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said anterior surface (400, 4000) is adapted for use with surgical instruments used during arthroplasty procedure. Various surgical instrumentation typically used during conventional arthroplasty procedures include but are not limited to resection guide(s), alignment rod(s), metal cutting guide(s) etc.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said anterior surface is flat, curved, stepped or circular.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein the patient's bone anatomy is determined from a three dimensional model generated from atleast one scan of the area intended for arthroplasty procedure.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said scan is selected from a group comprising of Computer Tomography (CT) scan, Magnetic Resonance Imaging (MRI) scan, X-ray scan, Ultrasound and combinations thereof.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein information relating to said patient bone anatomy includes bone anatomy information, osteophyte information (16, 56), soft tissue information and combinations thereof.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said flat surface (300, 3000) is positioned adjacent to or opposite to said curved surface (200, 2000).

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said alignment block is substantially rectangular or substantially square in shape.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said alignment block is configured with at least a feature to facilitate the handling and use of various instrumentation to be employed during arthroplasty procedure.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said feature includes one or more of extended lips (303, 3030), protrusions, stubs (407), recessions or slots (204, 404, 405, 406, 403, 4030) provided on any of the surfaces of said alignment block (100, 1000).

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said feature is a slot (403, 4030) that allows for the insertion of an alignment rod for checking alignment during arthroplasty procedure.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said arthroplasty procedure includes knee arthroplasty, hip arthroplasty, shoulder arthroplasty, wrist arthroplasty, ankle arthroplasty, spinal surgeries, and Osteotomies.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said alignment block is adapted for use on distal femur (2) or proximal tibia (51) during knee arthroplasty.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said alignment block is made from a material selected from the group comprising of a biocompatible material, a non-biocompatible material coated with a biocompatible material, a metal in combination with a biocompatible material, a surgically approved alloy, a surgically approved metal, and combinations thereof.

In another embodiment the present invention provides the anatomically matched patient alignment block (100, 1000) wherein said biocompatible material is selected from the group consisting of polyoxymethylene, high density polyethylene, polyether ether ketone, polyamides, polyurethane and combinations thereof.

Still another embodiment of the present invention provides a process for making the anatomically matched patient alignment block (100, 1000), said process comprising the steps of: obtaining atleast a scan of an area intended for performing arthroplasty procedure on a patient; identifying bone and anatomy information of the patient from said scan; creating a three dimensional model of said area based on the information from said scan; plotting a surgical cut on a three dimensional modeling software; creating a design of the shape of said alignment block on said three dimensional modeling software; and manufacturing said alignment block (100, 1000) for use in arthroplastic surgery of the patient based on the design created on the three dimensional modeling software.

Still another embodiment of the present invention provides a process for making the anatomically matched patient alignment block (100, 1000) further comprising a step of consulting with a surgeon to obtain his instructions prior to the step of creating a design of the said alignment block.

Still another embodiment of the present invention provides a process for making the anatomically matched patient alignment block (100, 1000), wherein the said scan is selected from the group comprising of Computer Tomography (CT) scan, Magnetic Resonance Imaging (MRI) scan, X-ray scan, Ultrasound, and combinations thereof.

Still another embodiment of the present invention provides a process for making the anatomically matched patient alignment block (100, 1000) wherein said alignment blocks are manufactured by conventional methods including machining, rapid prototyping and combinations thereof.

Still another embodiment of the present invention provides a process for making the anatomically matched patient alignment block (100, 1000) wherein the process performed on a small scale such as in a hospital.

Yet another embodiment of the present invention provides a method of positioning an anatomically matched patient alignment block (100, 1000), said method comprising: placing said alignment block (100, 1000) on the bone of a patient; positioning a surgical instrument for making a cut on the bone of a patient; and making the cut on the bone using the surgical instrument.

Yet another embodiment of the present invention provides a method of positioning an anatomically matched patient alignment block (100, 1000) optionally comprising a step of driving atleast two pins (950) through said alignment block (100, 1000).

Yet another embodiment of the present invention provides a method of positioning an anatomically matched patient alignment block (100, 1000) optionally comprising a step of removing the anatomically matched patient alignment block (100, 1000) before positioning the surgical instrument.

Yet another embodiment of the present invention provides a method of positioning an anatomically matched patient alignment block (100, 1000) optionally comprising a step of checking the alignment of the cut to be made.

Yet another embodiment of the present invention provides a method of positioning an anatomically matched patient alignment block (100, 1000), further comprising: placing the said alignment block (100, 1000) more than one time on the bone of the patient; and aligning and positioning an another surgical instrument for use during arthroplasty procedure.

Yet another embodiment of the present invention provides a method of positioning an anatomically matched patient alignment block (100, 1000) wherein the surgical instrument is a resection guide.

Yet another embodiment of the present invention provides a method of positioning an anatomically matched patient alignment block (100, 1000), wherein the bone is a part of a knee, elbow, hip, shoulder, wrist, ankle or spine.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, although the embodiments described hereinabove describe only Total Knee arthroplasty, similar anatomically matched patient alignment blocks can also be used for any surgical operation related to bone, including but not limited to hip arthroplasty, knee arthroplasty, shoulder arthroplasty, spinal surgeries, Osteotomies, trauma cases etc. Additionally other combinations, omissions, substitutions, and modifications will be apparent to the skilled artisan in view of the disclosure herein. It is contemplated that various aspects and features of the invention described can be practiced separately, combined together, or substituted for one another, and a variety of combination and subcombinations of the features and aspects can be made and still fall within the scope of the invention. Accordingly, the present invention is not intended to be limited by the recitation of the preferred embodiments but is to be defined by reference to the appended claims.

We claim:

1. An improved anatomically matched patient alignment block (100, 1000) for referencing and aligning during an arthroplasty procedure, said alignment block comprising:

   a curved surface (200, 2000) adapted to match with a patient's bone anatomy said curved surface being configured with at least a release gap (203, 2030, 2040) around surrounding soft tissues or bones or both and an undercut release (205, 2050) for easy removal of said alignment block (100, 1000);

   an anterior surface (400, 4000) opposite to said curved surface wherein said anterior surface comprises at least an aperture (401, 4010) to receive at least two pins (950) for pinning said alignment block (100, 1000) to a bone of a patient during an arthroplasty procedure such that said alignment block (100, 1000) is removable without removing said pins; and

   at least a flat surface (300, 3000) for providing a reference surface for checking the location of a cut to be performed during the arthroplasty procedure.

2. The alignment block (100, 1000) as claimed in claim 1, wherein said aperture (401, 4010) on the anterior surface (400, 4000) is selected from a group comprising of a slot, a hole, a pair of holes and combinations thereof.

3. The alignment block (100, 1000) as claimed in claim 1, wherein said anterior surface (400, 4000) is adapted for use with surgical instruments used during arthroplasty procedure.

4. The alignment block (100, 1000) as claimed in claim 3, wherein said anterior surface (400, 4000) is flat, curved, stepped or circular.

5. The alignment block (100, 1000) as claimed in claim 1, wherein the patient's bone anatomy is determined from a three dimensional model generated from atleast one scan of the area intended for arthroplasty procedure.

6. The alignment block (100, 1000) as claimed in claim 5, wherein said scan is selected from a group comprising of Computer Tomography (CT) scan, Magnetic Resonance Imaging (MRI) scan, X-ray scan, Ultrasound and combinations thereof.

7. The alignment block (100, 1000) as claimed in claim 1, wherein information relating to said patient bone anatomy includes bone anatomy information, osteophyte information (16, 56) soft tissue information and combinations thereof.

8. The alignment block (100, 1000) as claimed in claim 1, wherein said flat surface (300, 3000) is positioned adjacent or opposite to said curved surface (200, 2000).

9. The alignment block (100, 1000) as claimed in claim 1, wherein said alignment block (100, 1000) is substantially rectangular or substantially square in shape.

10. The alignment block (100, 1000) as claimed in claim 1, wherein said alignment block is configured with at least a feature to facilitate the handling and use of instrumentation to be employed during arthroplasty procedure.

11. The alignment block (100, 1000) as claimed in claim 10, wherein said feature includes one or more of extended lips (303, 3030), protrusions, stubs (407), recessions or slots (204, 404, 405, 406, 403, 4030) provided on any of the surfaces of said alignment block (100, 1000).

12. The alignment block (100, 1000) as claimed in claim 10, wherein said feature is a slot (403, 4030) that allows for the insertion of an alignment rod (10) for checking alignment during arthroplasty procedure.

13. The alignment block (100, 1000) as claimed in claim 1, wherein said arthroplasty procedure includes knee arthroplasty, hip arthroplasty, shoulder arthroplasty, wrist arthroplasty, ankle arthroplasty, spinal surgeries, and Osteotomies.

14. The alignment block (100, 1000) as claimed in claim 1, wherein said alignment block is adapted for use on distal femur (2) during knee arthroplasty.

15. The alignment block (100, 1000) as claimed in claim 1, wherein said alignment block is adapted for use on proximal tibia (51) during knee arthroplasty.

16. The alignment block (100, 1000) as claimed in claim 1, wherein said alignment block is made from a material selected from the group comprising of a biocompatible material, a non-biocompatible material coated with a biocompatible material, a metal in combination with a biocompatible material, a surgically approved alloy, a surgically approved metal, and combinations thereof.

17. The alignment block (100, 1000) as claimed in claim 16, wherein said biocompatible material is selected from the group consisting of polyoxymethylene, high density polyethylene, polyether ether ketone, polyamides, polyurethane and combinations thereof.

18. A process for making the - alignment block (100, 1000) as claimed in claims 1 to 17, said process comprising the steps of:

obtaining atleast a scan of an area intended for performing arthroplasty procedure on a patient;

identifying bone and anatomy information of the patient from said scan;

creating a three dimensional model of said area based on the information from said scan;

plotting a surgical cut on a three dimensional modeling software;

creating a design of the shape of said alignment block on said three dimensional modeling software; and

manufacturing said alignment block (100, 1000) for use in arthroplastic surgery of the patient based on the design created on the three dimensional modeling software.

19. The process as claimed in claim 18, further comprising a step of consulting with a surgeon to obtain his instructions prior to the step of creating a design of the said alignment block.

20. The process as claimed in claim 18, wherein the said scan is selected from the group comprising of Computer Tomography (CT) scan, Magnetic Resonance Imaging (MRI) scan, X-ray scan, Ultrasound, and combinations thereof.

21. The process as claimed in claim 18, wherein said alignment blocks (100, 1000) is manufactured by conventional methods including machining, rapid prototyping and combinations thereof.

22. The process as claimed in claim 18, wherein the process performed on a small scale such as in a hospital.

23. A method of positioning an anatomically matched patient alignment block (100, 1000) as claimed in claims 1 to 17, said method comprising:

placing said alignment block (100, 1000) on the bone of a patient;

positioning a surgical instrument for making a cut on the bone of a patient; and

making the cut on the bone using the surgical instrument.

24. The method as claimed in claim 23, optionally comprising a step of driving atleast two pins (950) through said alignment block (100, 1000).

25. The method as claimed in claim 23, optionally comprising a step of removing the alignment block (100, 1000) before positioning the surgical instrument.

26. The method as claimed in claim 23, optionally comprising a step of checking the alignment of the cut to be made.

27. The method as claimed in claim 23, further comprising:

placing said alignment block (100, 1000) more than one time on the bone of the patient; and

aligning and positioning an another surgical instrument for use during arthroplasty procedure.

28. The method as claimed in claim 23, wherein the surgical instrument is a resection guide.

29. The method as claimed in claim 23, wherein the bone is a part of a knee, elbow, hip, shoulder, wrist, ankle or spine.

Fig. 1A

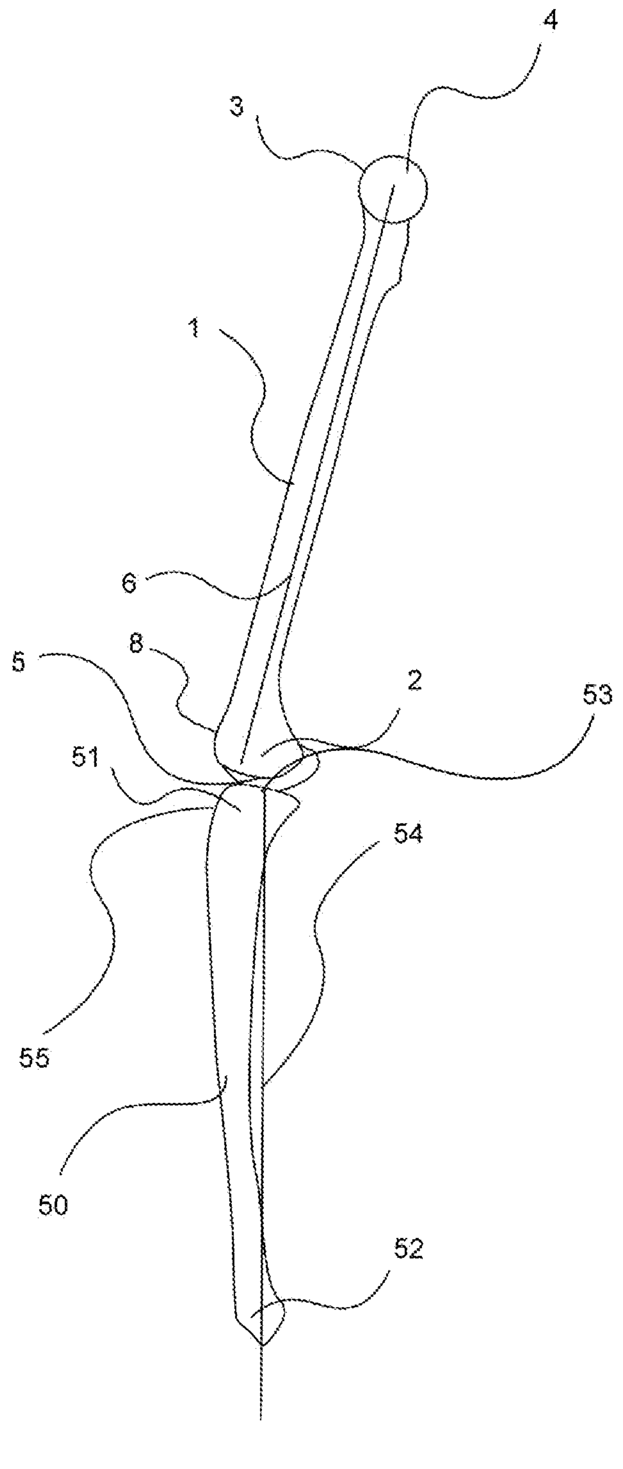


Fig. 1B

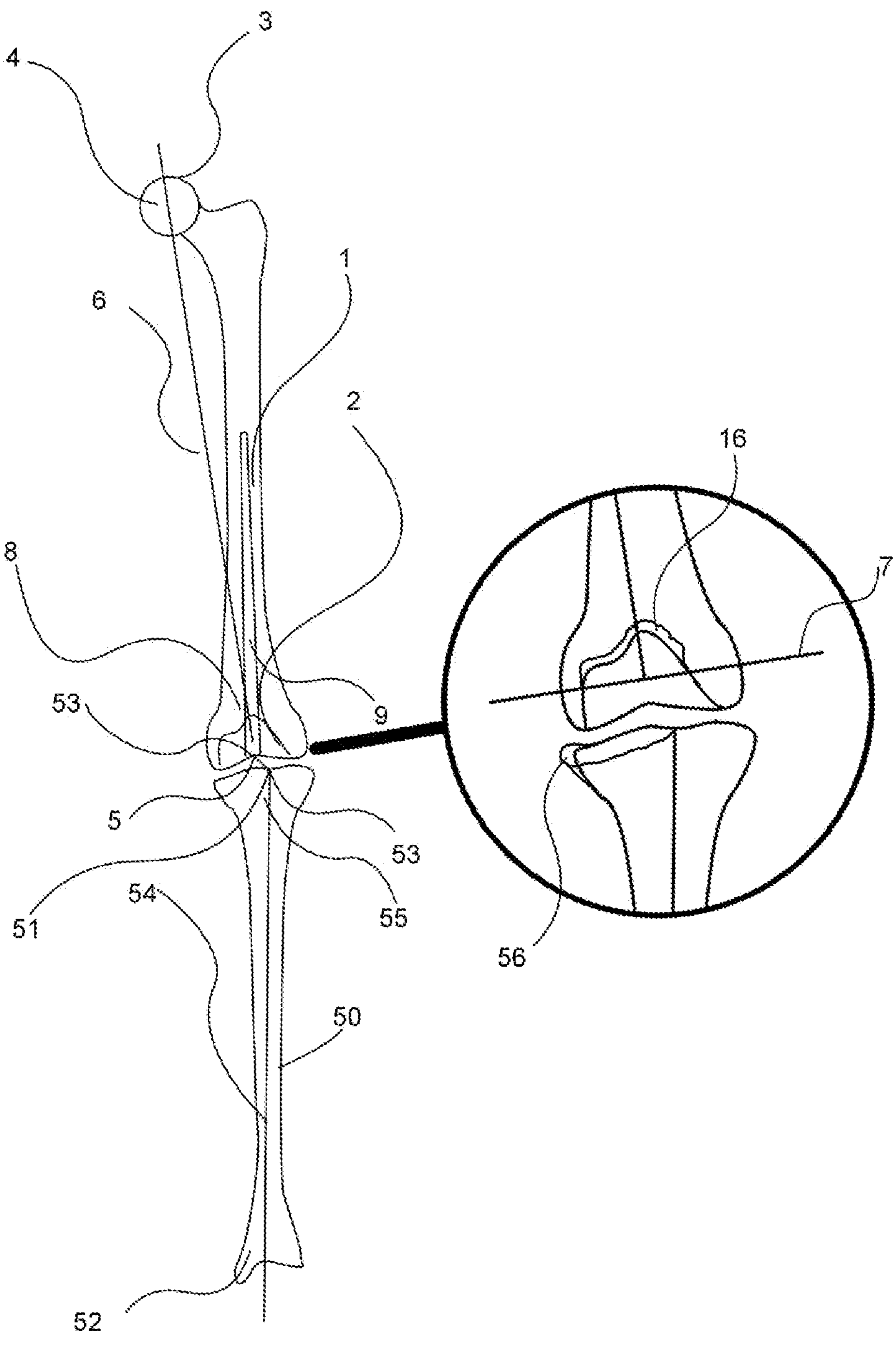


Fig. 2

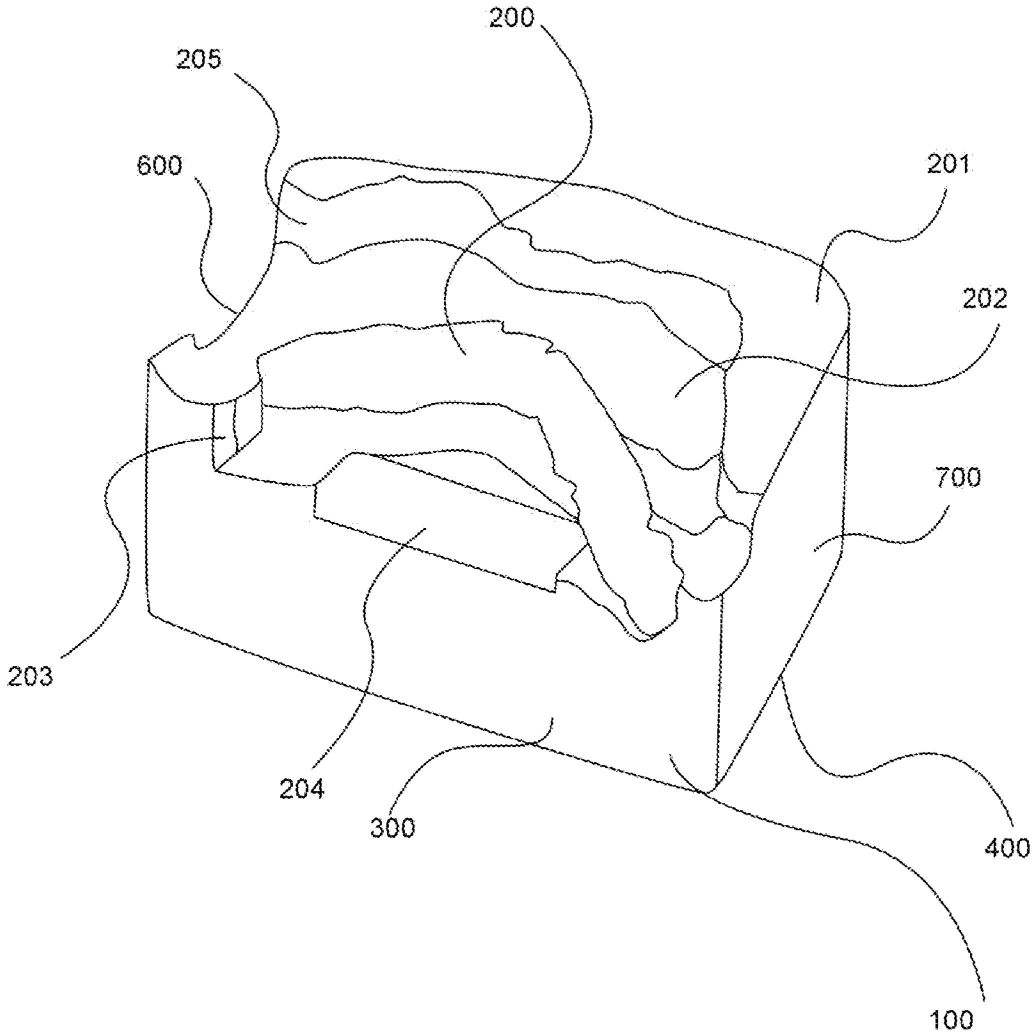


Fig. 3

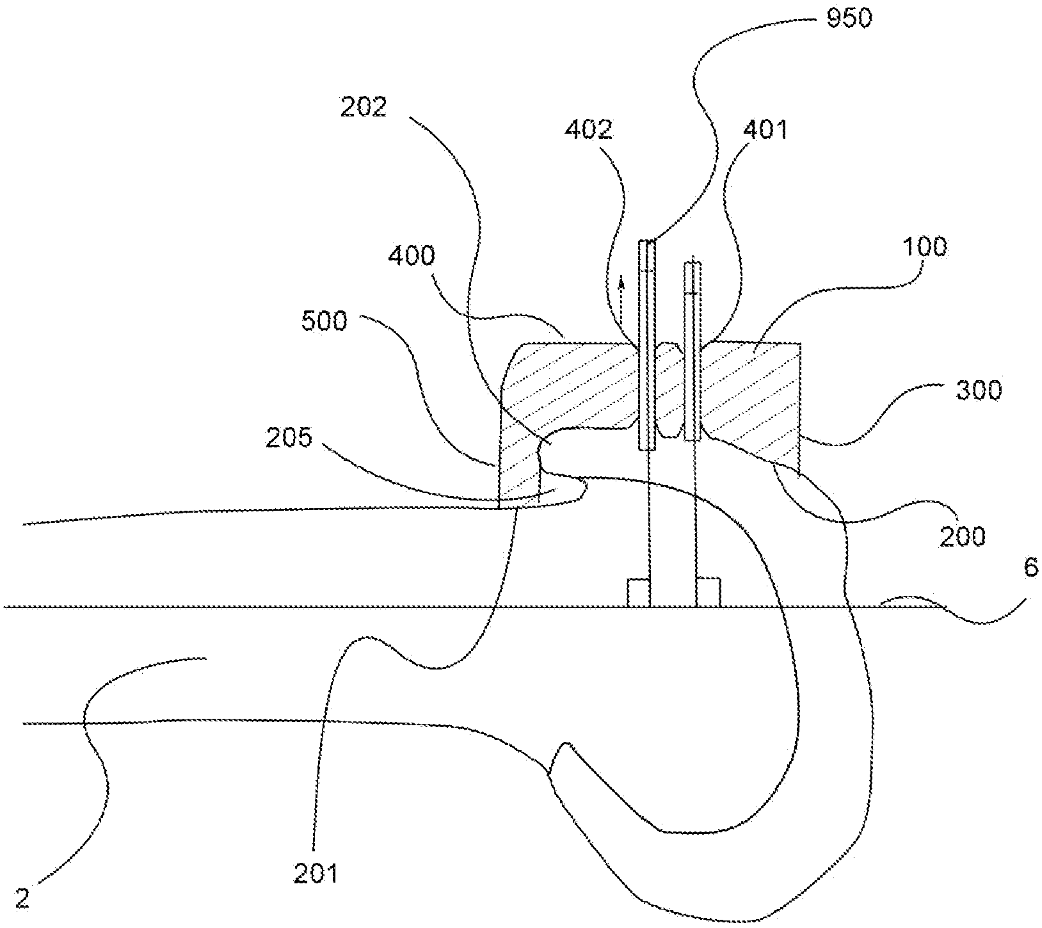


Fig. 4

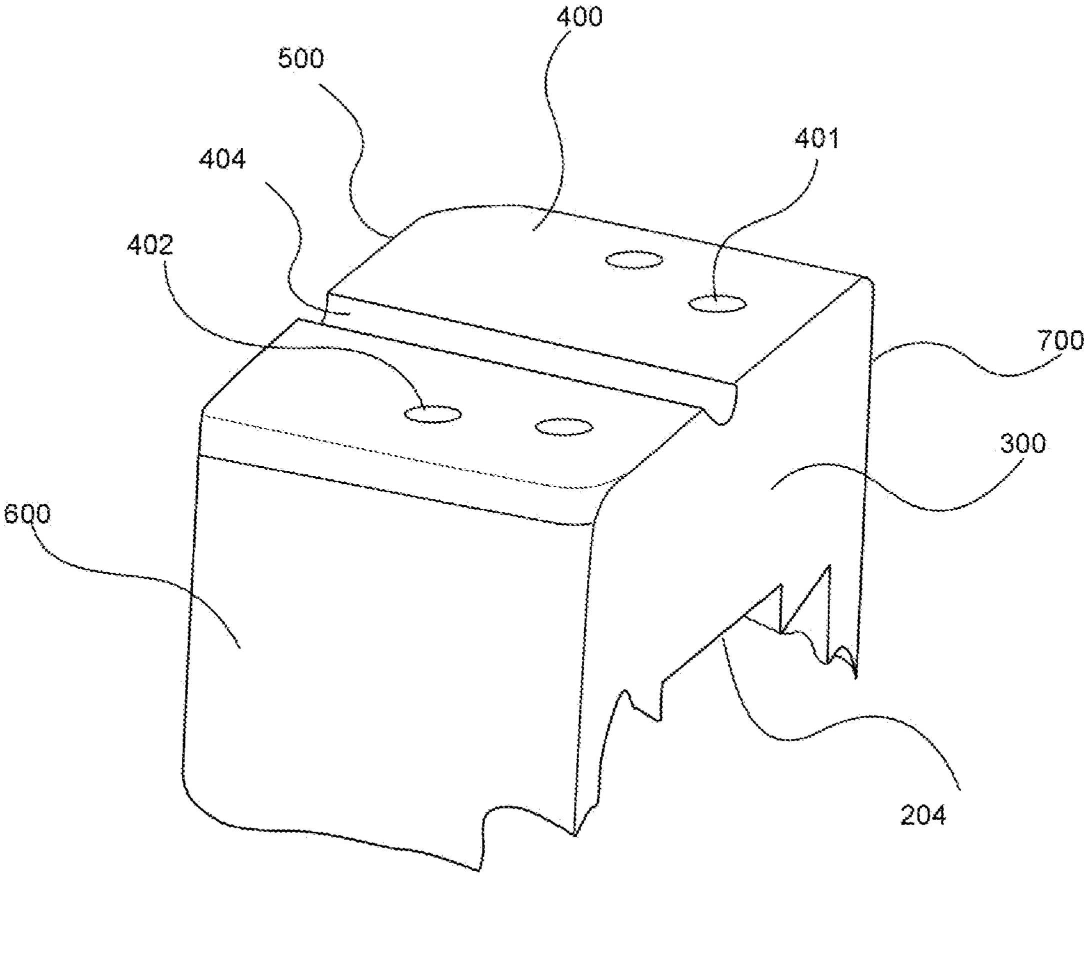


Fig. 5

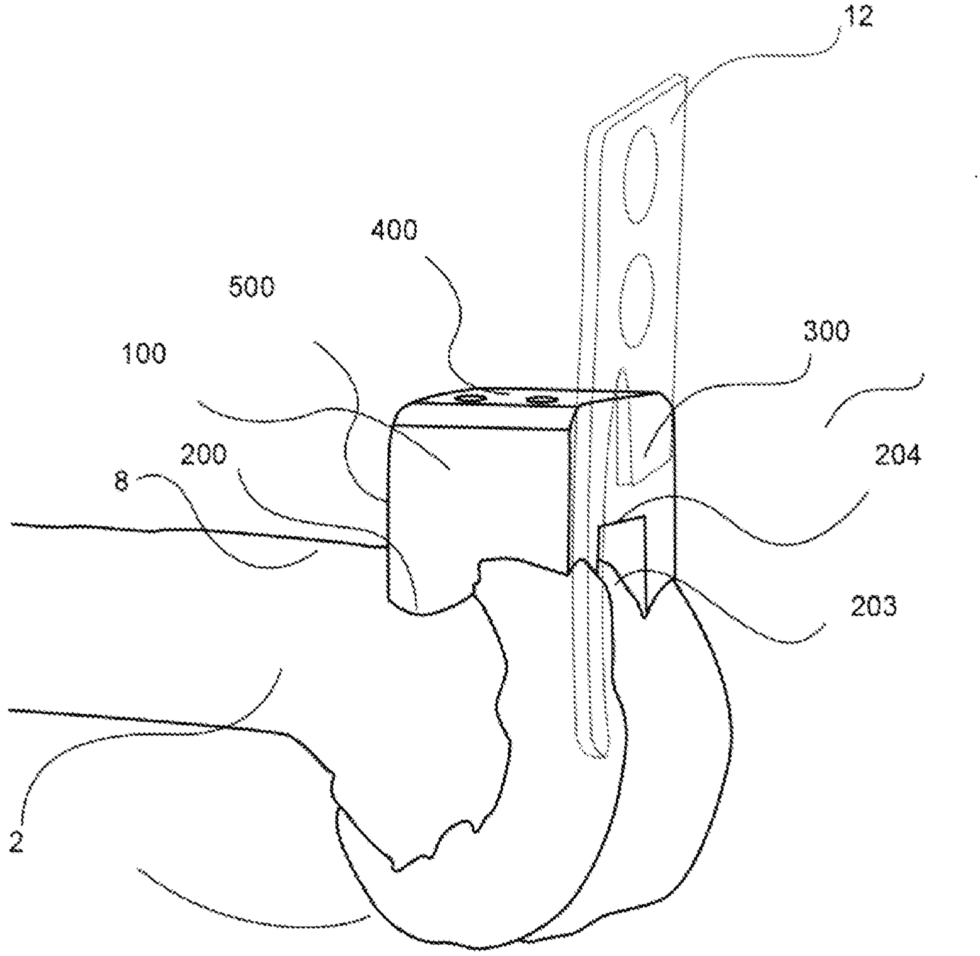


Fig. 6

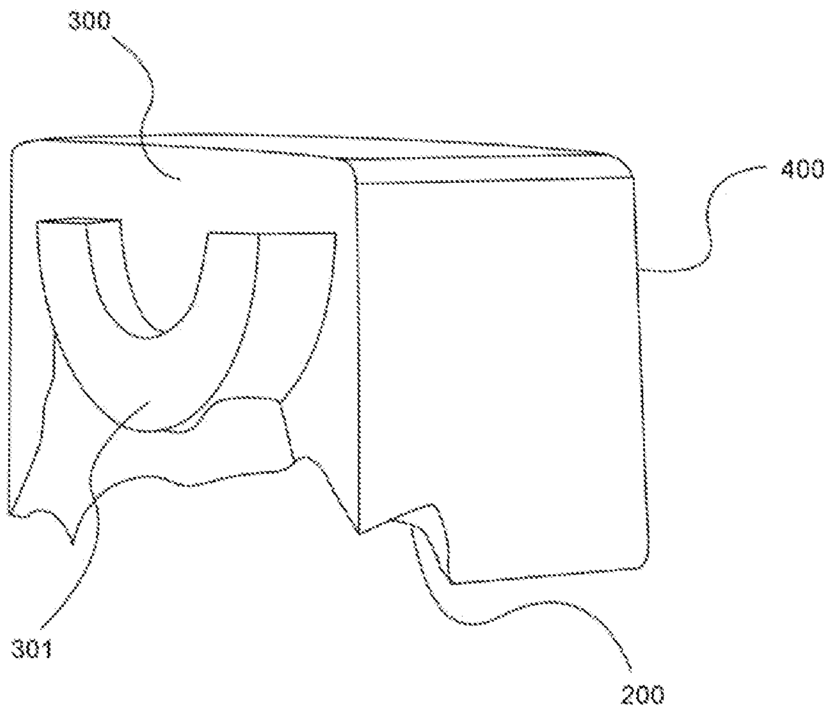


Fig. 7A

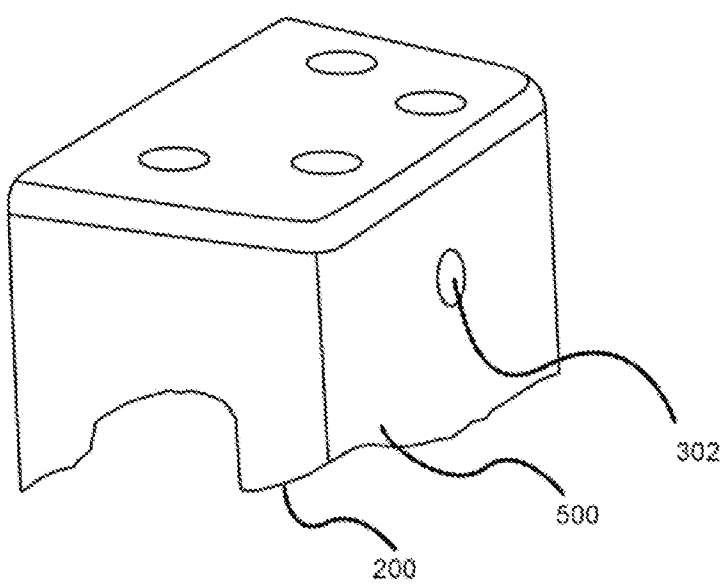


Fig. 7B

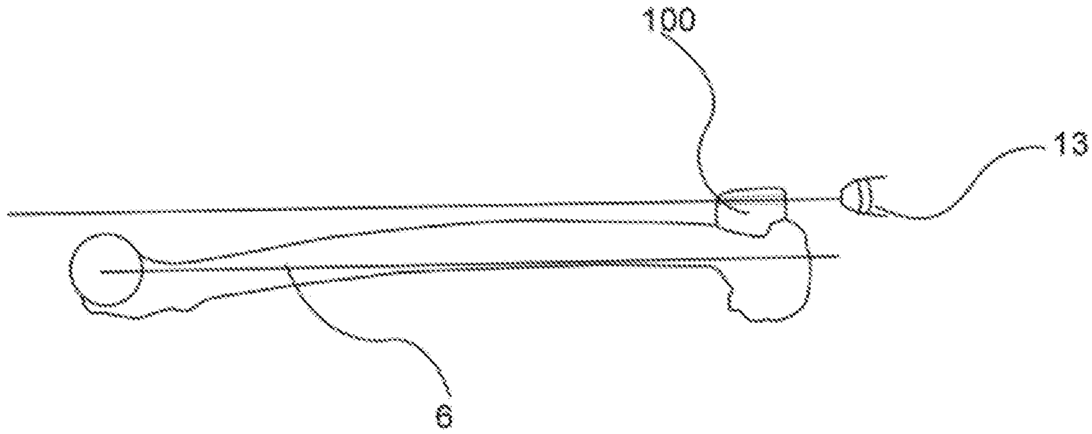


Fig. 8

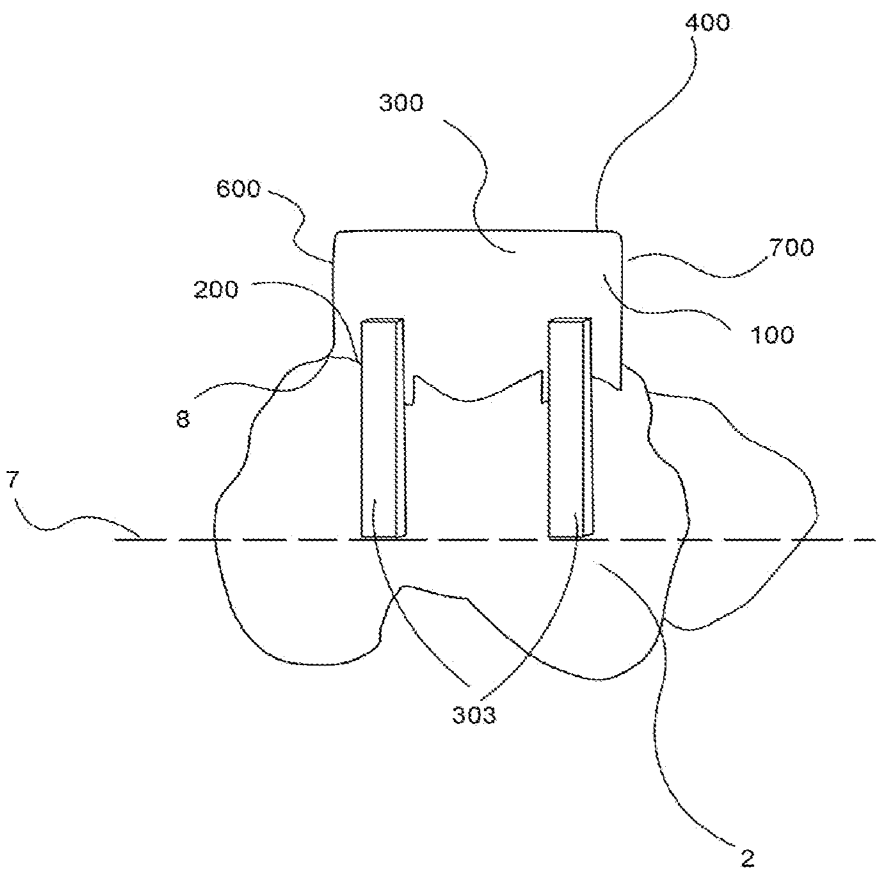


Fig. 9A Fig. 9B

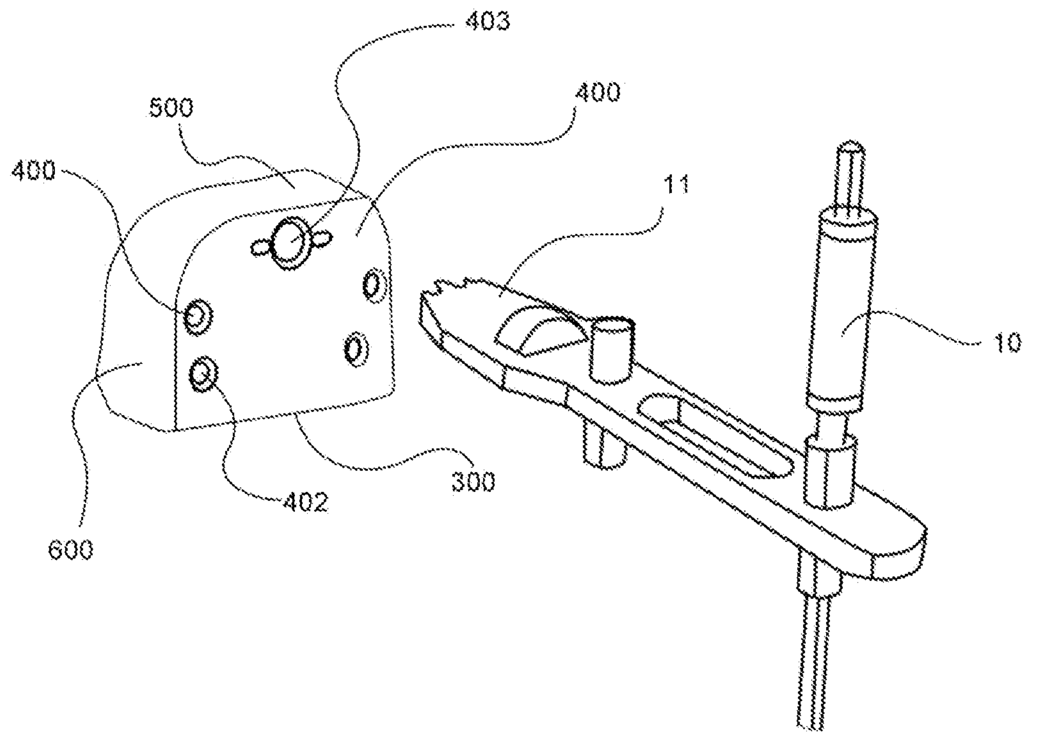


Fig. 9C

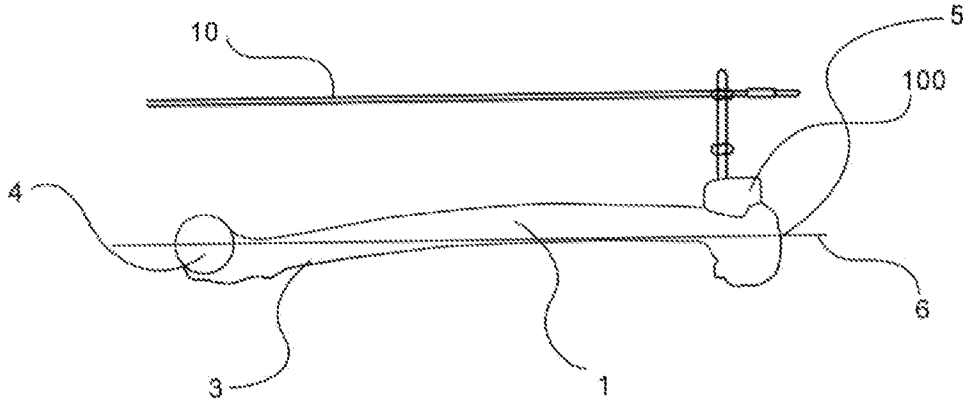


Fig. 10

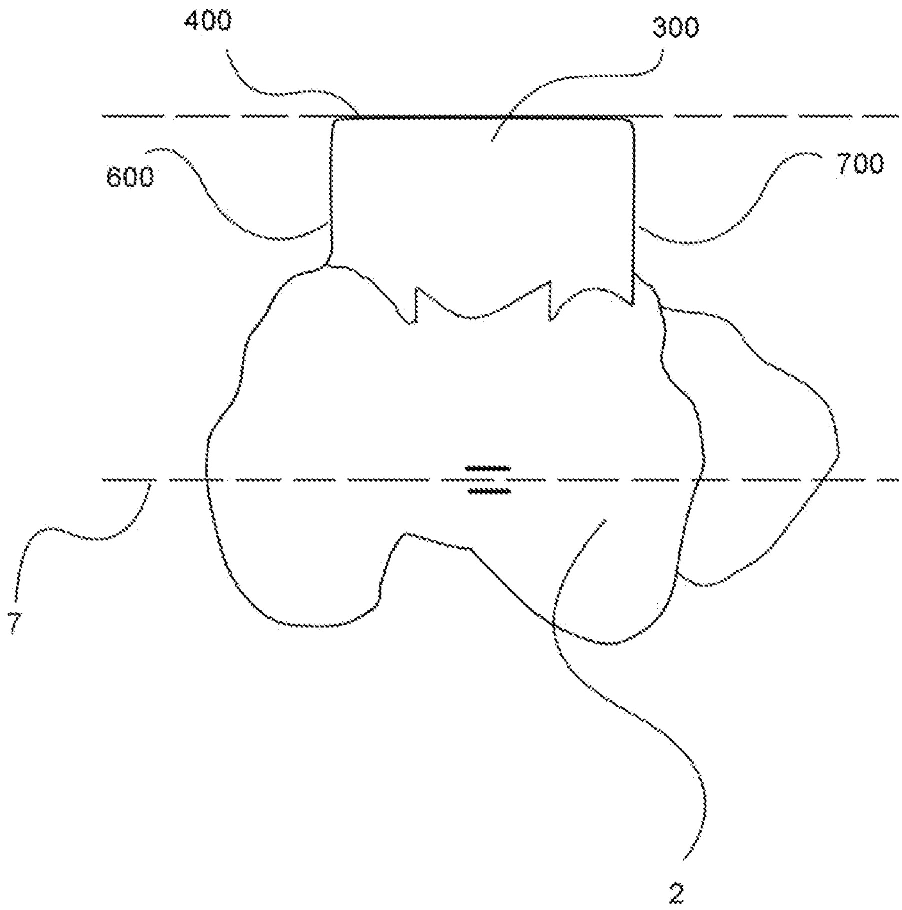


Fig. 11A

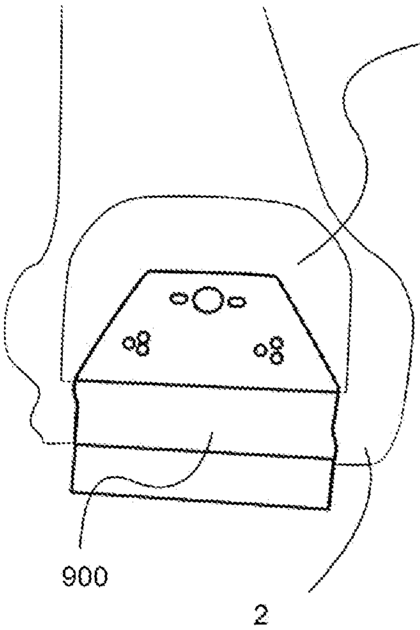
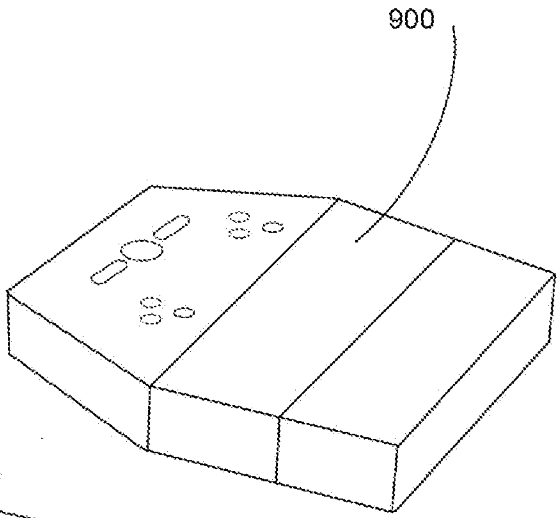


Fig. 11B



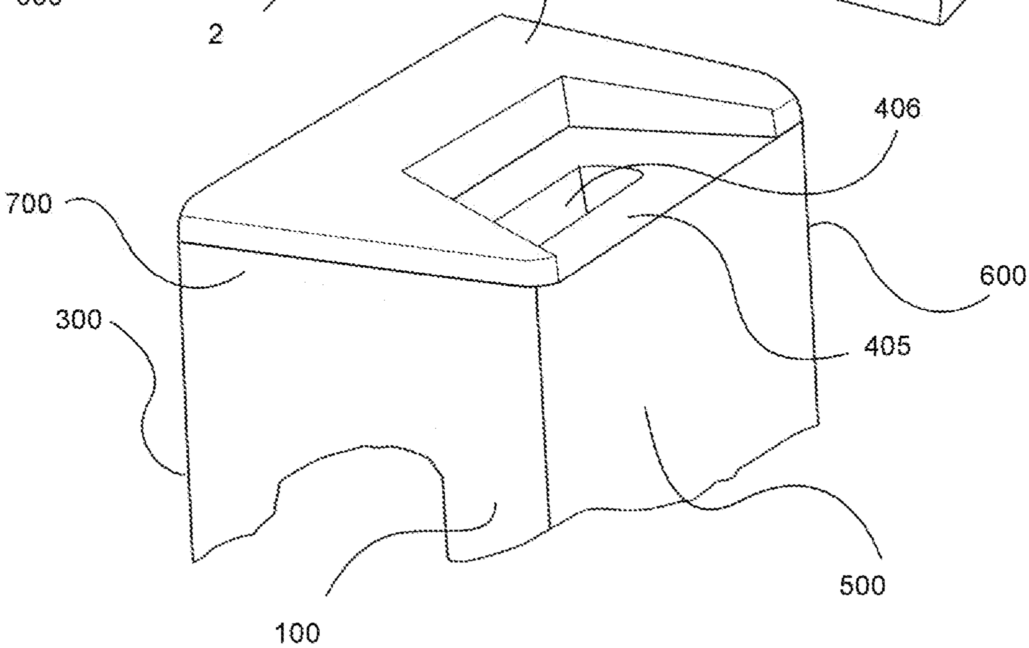


Fig. 11C

Fig. 12

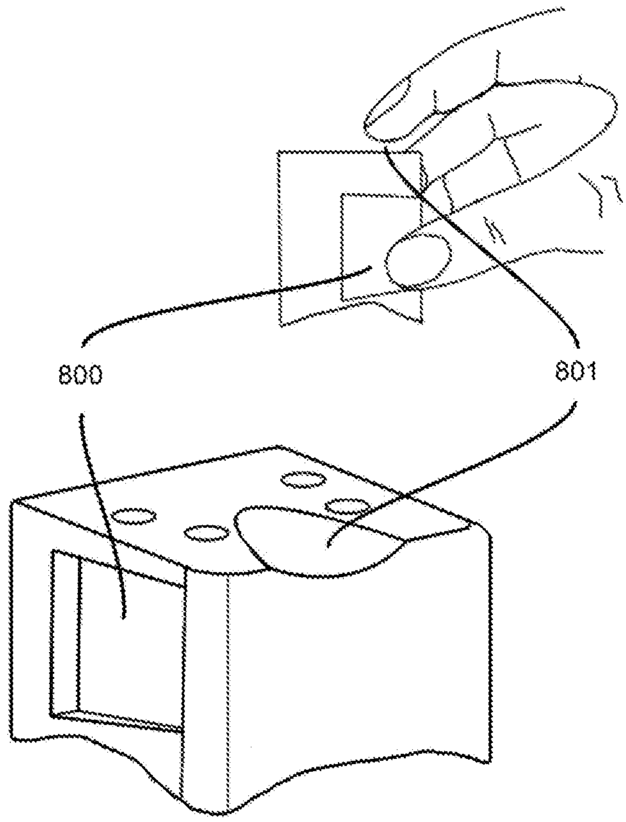
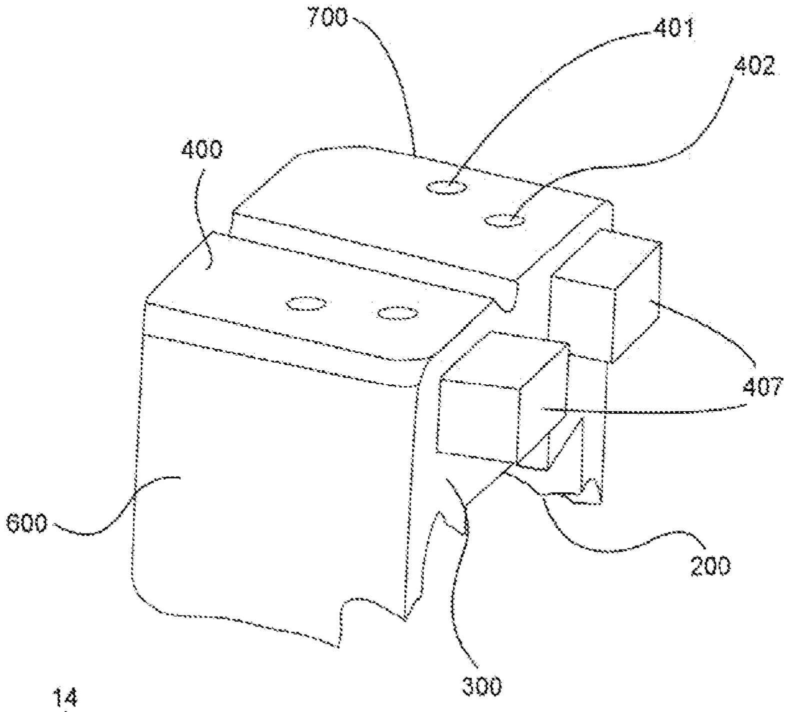


Fig. 13A



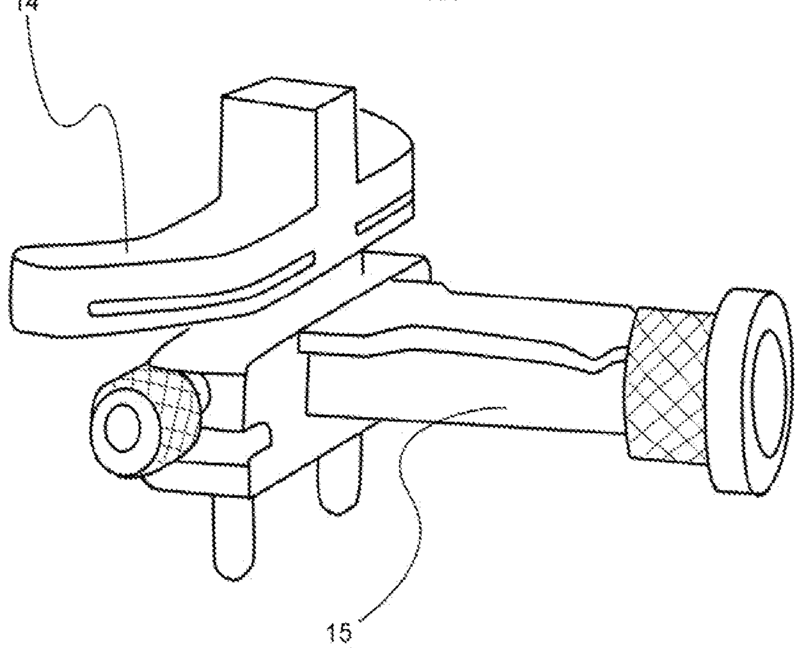
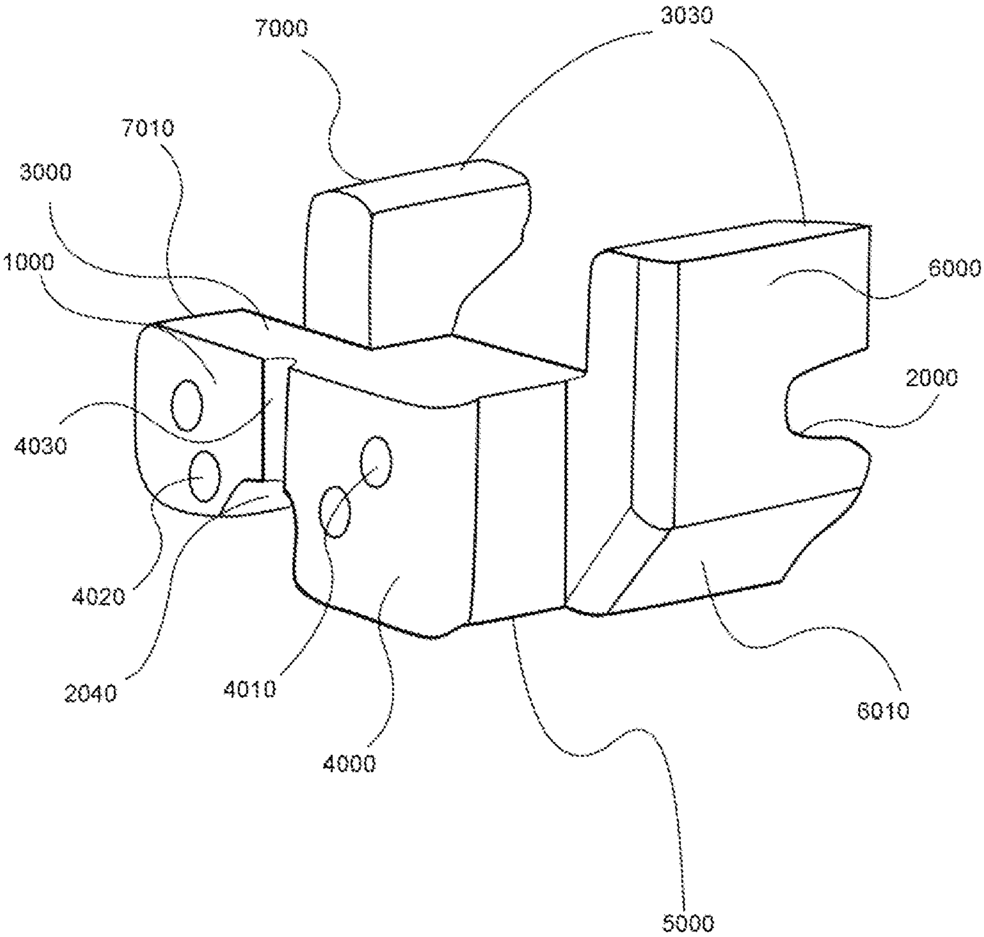


Fig. 13 B

Fig. 14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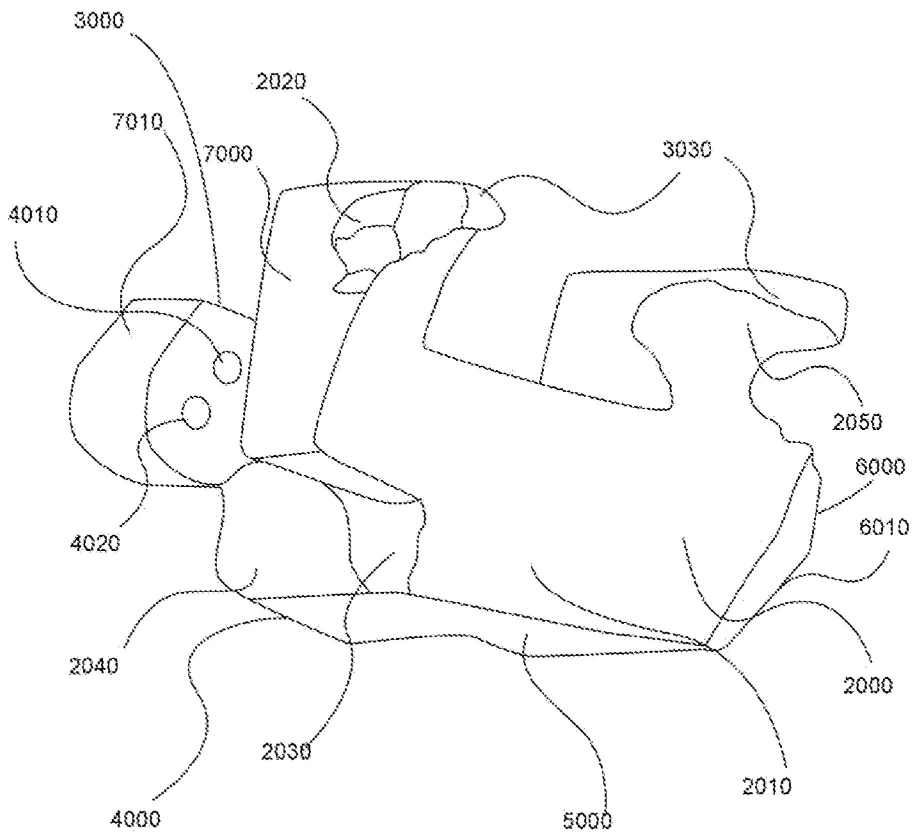
3030
7010
3000
1000
6000
2000
4030
4020
2040
4010
4000
6010
5000

Fig. 15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2020
7010
7000
3030
4010
2050
6000
6010
4020
2040
2000
2030
2010
4000
5000

Fig. 16

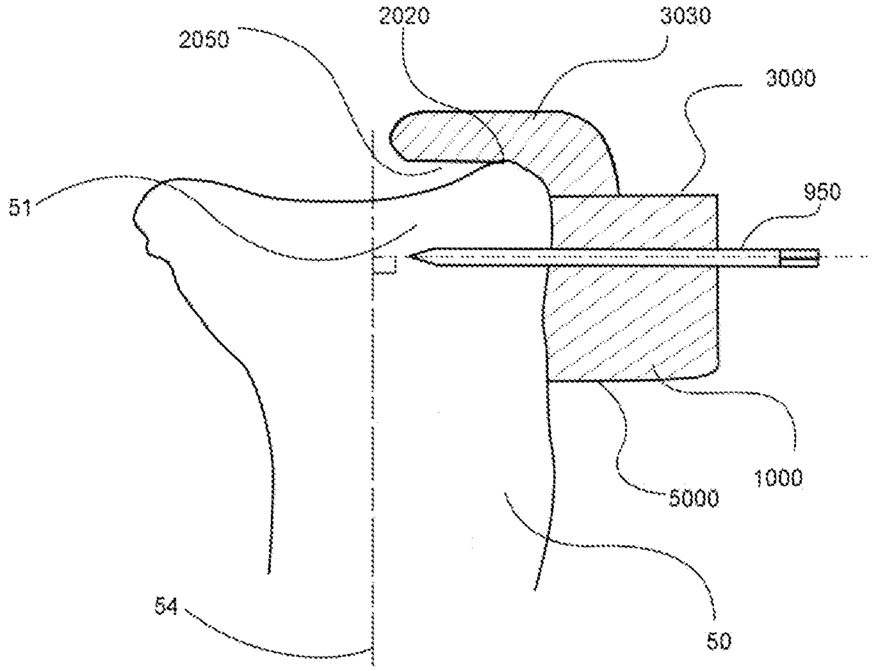


Fig. 17

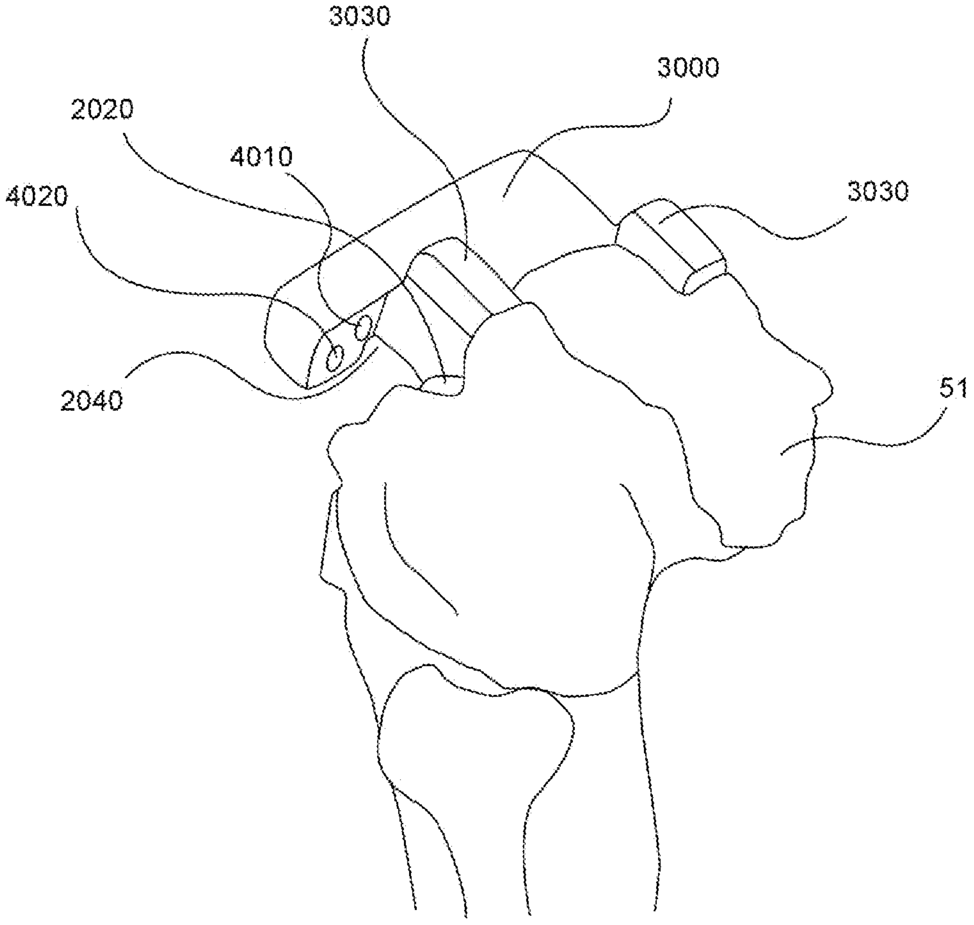
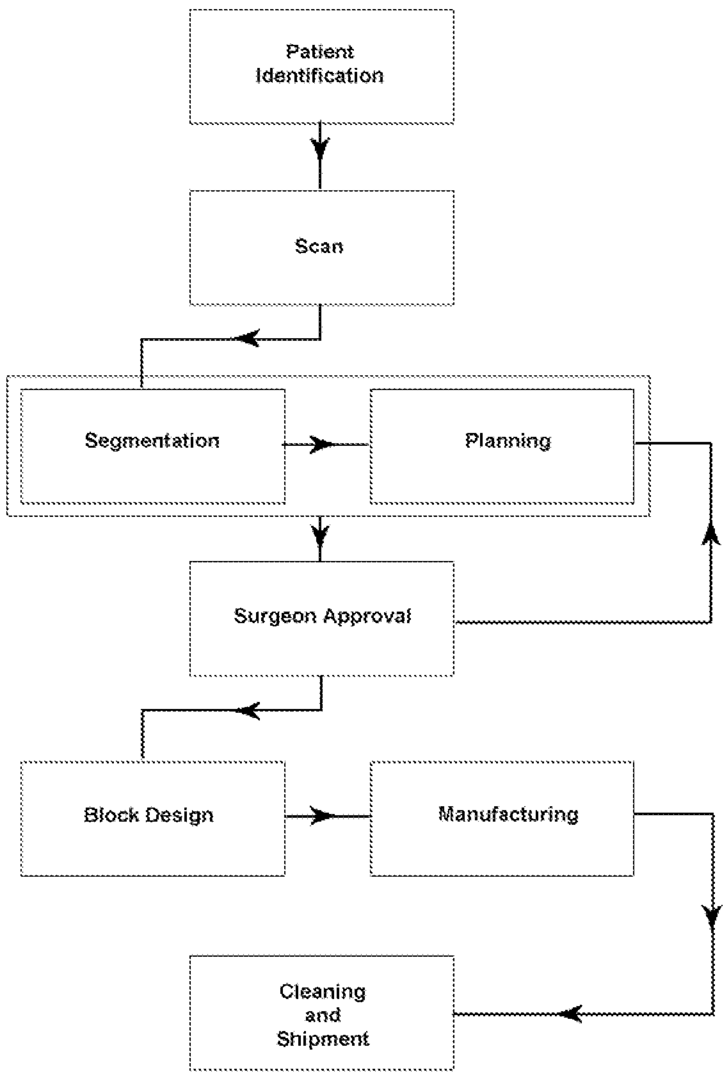


Fig. 18


Patient Identification
Scan
Segmentation
Planning
Surgeon Approval
Block Design
Manufacturing
Cleaning and Shipment

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2012/052169

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/15
ADD.

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

B. FIELDS SEARCHED

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

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 447 702 A (UNIV LEEDS [GB]) 24 September 2008 (2008-09-24) page 3, line 3 - line 5 page 19, line 19 - page 25, line 25 page 41, line 14 - line 30 figures 1,2,3 -----	1-7, 9-18,20, 21
X	US 2009/087276 A1 (ROSE BRYAN [US]) 2 April 2009 (2009-04-02) paragraph [0245] paragraph [0273] - paragraph [0274] paragraph [0286] - paragraph [0291] figures 1,19-25,124 -----	1-11, 13-16, 18-22
	-/--	

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 September 2012	02/10/2012

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

International application No.
PCT/IB2012/052169

INTERNATIONAL SEARCH REPORT

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

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

1. [X] Claims Nos.: 23-29
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

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

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

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

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2012/052169

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/001083 A1 (DEPUY INT LTD [GB]; DEPUY ORTHOPAEDIE GMBH [DE]; DEPUY ORTHOPAEDIC INC) 31 December 2008 (2008-12-31) page 8, line 16 - page 11, line 16 page 14, line 24 - page 15, line 5 figures 1,2A-2E -----	1-11, 13-18, 20,21
X	US 2010/212138 A1 (CARROLL MICHAEL [US] ET AL) 26 August 2010 (2010-08-26) paragraph [0036] - paragraph [0044] paragraph [0047] figures 8-18 -----	1-11, 13-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2012/052169

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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			US 2009099567	A1	16-04-2009
			US 2009131942	A1	21-05-2009
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