(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 January 2016 (14.01.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/004993 A1

(51) International Patent Classification:
A61B 17/17 (2006.01) *A61F 2/30* (2006.01)
A61B 19/00 (2006.01) *A61F 2/46* (2006.01)

(21) International Application Number:
PCT/EP2014/064765

(22) International Filing Date:
9 July 2014 (09.07.2014)

(25) Filing Language: English

(26) Publication Language: English

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) **Title**: DESIGN METHOD OF A RIG

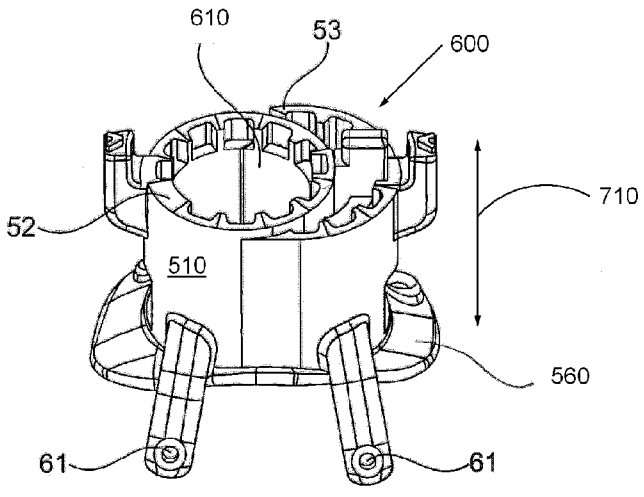

Fig. 13

(57) **Abstract**: A design method for design of an individually customized rig (600), said rig (600) having a hollow tubular shell (510) open at both ends, characterized in that the interior of said shell defines at least first and second intersecting circular cylinders and wherein the design method for said rig (600) comprises the steps; A first damage identification step (101) comprising identifying a bone and or cartilage area (4) in a patient comprising a bone and or cartilage damage (5) and presentation of a 3D view (9) of said identified area using a software program A second virtual model making step (14) comprising making a 3D model of a virtual rig comprising a step of virtually placing in said 3D view (9) at least two circular shapes (303), wherein each circular shape (303) partly overlaps at least one other circular shape (303'), and wherein the combined area (20) of the circular shapes covers or partly covers said identified bone and or cartilage damage (5) and wherein positioning data is used to create the position and interior of said hollow tubular rig shell (510) of the virtual rig which is open at both ends and wherein selection of at least first and second intersecting circular cylinder rig is based on the selected sizes of the circular shapes (303), or slightly larger, and wherein a positioning surface (560) of the virtual rig is created which is a bone and or cartilage-engaging end of said hollow tubular shell (510) and wherein said positioning surface (560) is adapted to face and align to the surface structure surrounding the hollow circular shapes of the rig when the rig is placed in a virtual model of the joint A third production step (34) comprising producing a rig (600) according to the virtually created rig which is adapted to mimic the volume and shape according to said created virtual model of the rig as well as the rig as such, a method for placement of the rig in a joint and a tool for placing the rig.

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Design method of a rig

Field of the invention

This invention relates in general to the field of orthopedic surgery and to cartilage and or bone resurfacing. The present invention relates to a rig intended for guiding replacement of a part of a bone and or cartilage portion and to a design method of such a rig. Further this invention also relates to a design method of an implant, surgery kits, kits of tools and a method for replacing a portion of an articular surface of a joint.

Background

In the surgical operation of implanting small implants it is critical that the implant is positioned in a precise manner. If the implant is offset from its intended position it may cause increased wear or load on the joint. For example, if the implant is tilted this may result in an edge that projects above the cartilage surface and causes wear on the opposing cartilage in the joint. Another example is when the implant is placed in a position with the surface of the implant projecting above the surface of the cartilage causing the joint to articulate in an uneven manner and increasing the load on an opposing point of the joint. For the patient, also small misplacements or deviations from an ideal position may result in pain, longer time for convalescence or even a surgical operation being done in vain and making it more difficult to repair the damage in the joint. A large burden is therefore placed on the surgeon not to misplace or misfit the implant. There is a need for a guide or rig which can guide the surgeon to place the implant in a precise manner and also which can guide the removal of damaged tissue. Further there is a need for a rig which is designed to fit various damages and still give reproducible and precise placement each time even if the placement of the damage varies.

Prior art

Examples of prior art disclosing implants and tools for replacement of damaged cartilage are:

EP 2 389 905 shows a design method for designing an implant and a tool kit.

WO2008098061 and US20120271417 disclose an implant for replacing a portion of an articular surface, wherein the implant comprises a first, second and third segment, wherein said first and said second segment partially overlap and said third and said second segment partially overlap. The implant is inserted by a guide system wherein reaming of the articulate

surface is guided by using a guide pin. A drill guide may be used to establish the axes of the guide pin with respect to the articular surface.

US8062302 discloses a guide comprising a block having a patient-specific surface and first and second drilling holes.

US20110152869 discloses a trochlea repair system having two working axes displaced from each other, wherein the two working axes are used to create two partially overlapping sockets.

WO2010099357 discloses a system for repair of a defect in an articulate surface, comprising a guide block which may comprise an opening configured to allow the cutter to pass through the guide block.

Object of the Invention

The general object of the invention is to solve the problem of providing a design method (2) for a rig which enables precision in the insertion and positioning of an implant (1) at an articular surface of a joint. The object of the invention is also to provide a rig and an implant and a design method of an implant.

There is a need for a tool or rig that is designed to give precise guidance and support to the surgeon during the implant surgery of small implants. Further there is a need of a flexible design method for such a rig.

The invention further seeks to solve the partial problems of:

Providing a method for cartilage replacement wherein an implant is firmly attached in the joint and is well integrated into the surface structure of the joint, in order to generate optimal repair of damaged tissue and cause minimum damage to the surrounding tissue.

Providing a design method for a rig to be used for positioning of an implant to be implanted in the joint, improving the positioning of the implant in order to generate optimal repair of damaged tissue and cause minimum damage to the surrounding tissue and aiding the surgeon in that positioning.

Providing an individual design of a rig.

By using the design method according to the invention the surgeon can get a precise way to place an implant in the joint using the design method of the rig and using the rig according to the invention. The system according to the invention wherein rig channel shapes may be built individually depending on cartilage damage and location of damage in the joint and by

selecting from different sizes of circular shapes (303) or substantially circular shapes, partly overlapping each other in combinations which may be individually selected for one patient, allows the surgeon to choose an implant which fits the size and shape of the bone and or cartilage damage or defect and gives the surgeon an easy to use design method and a tool set for making the excisions needed.

The design method according to the invention allows for producing a rig and an implant which is easy to fit to an individual damage and an individual patient. The design build up in this method, comprising choosing size and at least two circular shapes and choosing thickness, surface shape, articular surface etc for each implant, makes this solution unique and easy to individualize but still suitable for large scale industrial manufacturing. The circular shape build-up of the rig channels makes the rig also easy to use and gives an exact fit of each implant in every patient.

Advantages of the invention

The area of the joint damage may not be easily covered by a single circular implant if the damaged area is elongate or is irregular or large in shape. Instead of using a number of separate implants or an implant requiring complicated bone removal techniques, using several different drills and tools, the design method of the surgical implant and the rig according to the present invention provides an exceptionally simple solution which also utilizes a single rig anchored in place for the entire pre-drilling and drilling operation.

In one embodiment the same double-drill, the same pre drilling guide socket and the same depth adjustment socket is used for all drillings, This is made possible by a rig which permits shifting of the guide socket or adjustment socket from one side to the other side (or the other sides) of the hollow shell interior between drillings. In one embodiment a movable interior arcuate wall insert can also be inserted in each position to provide a complete circular cylinder for holding the pre-drilling guide socket for each drilling. The socket may also be adjustable. In another embodiment the movable insert is not arcuate but is a cylinder. In another embodiment no insert at all is used. Other similar embodiments are of course also possible.

According to one embodiment, this will simply create two identical peg holes and an exactly excavated cavity to fit an implant in the form of two intersecting circles of the same diameter. Merely removing the insert wall in the cylindrical interior then creates a shell, already securely rigged in location, for a rig for the oblong implant (1) with two pegs (23 and (23´). A handled gauge in the shape of the implant is inserted after drilling to check that the proper drilling depth has been reached. After all drillings have been made and depth checked, the drilling rig is removed.

Summary of the invention

The invention is directed to a design method for design of an individually customized rig (600), said rig (600) having a hollow tubular shell (510) open at both ends, wherein the interior of said shell defines at least first and second intersecting circular cylinders and wherein the design method for said rig (600) comprises the steps;

-A first damage identification step (101) comprising identifying a bone and or cartilage area (4) in a patient comprising a bone and or cartilage damage (5) and presentation of a 3D view (9) of said identified area using a software program

-A second virtual model making step (14) comprising making a 3D model of a virtual rig comprising a step of virtually placing in said 3D view (9) at least two circular shapes (303), wherein each circular shape (303) partly overlaps at least one other circular shape (303'), and wherein the combined area (20) of the circular shapes covers or partly covers said identified bone and or cartilage damage (5) and wherein positioning data is used to create the position and interior of said hollow tubular rig shell (510) of the virtual rig which is open at both ends and wherein selection of at least first and second intersecting circular cylinder rig is based on the selected sizes of the circular shapes (303), or slightly larger, and wherein a positioning surface (560) of the virtual rig is created which is a bone and or cartilage-engaging end of said hollow tubular shell (510) and wherein said positioning surface (560) is adapted to face and align to the surface structure surrounding the hollow circular shapes of the rig when the rig is placed in a virtual model of the joint.

-A third production step (34) comprising producing a rig (600) according to the virtually created rig which is adapted to mimic the volume and shape according to said created virtual model of the rig .

A design method for design of an individually customized rig (600) wherein the the interior of said shell defines first, second intersecting circular cylinders of equal diameter.

A design method for design of an individually customized rig (600) wherein the interior of said shell defines first, second and third intersecting circular cylinders of equal diameter.

A design method for designing an individually customized rig(600) to any of wherein a design step is added designing an arcuate wall which is adapted to be selectively insertable into said shell interior to complete the full circumference as desired.

A design method , wherein the movable insert is not arcuate but is a cylinder.

A design method for design of an individually customized rig (600), wherein the positioning surface (560) of said rig (600) is provided with multiple holes (61, 161) for pins anchoring the rig securely in place on the surface to be repaired.

A design method for design of an individually customized rig (600) wherein a first selection step further comprises;

-placing at least two points (19) each from where an axis (15) will origin from, the points (19) are placed on the bone surface (50) in the 3D view (9) of the joint in or nearby the area of the bone and or cartilage damage (5) or the points (19) are placed on a simulated bone surface which is a virtually created surface in or nearby the area of the bone and or cartilage damage (5)
-selecting axe-distance (53)
-selecting diameter of circular shapes, the diameter (302) of the circular shapes (303) are selected between 10-30mm or for example 15-25mm
-selecting coverage of the implant area (20) over the cartilage and or bone damage (5), wherein the coverage may be between 50-100%
and wherein a second selection step comprises;
-Selection of the angles (25) of the axes (15) which originate from a point (19) of said simulated bone surface (51) and wherein the axes (15) and (15') have an angle (25) 0-40 degrees in relation to a bone-axis (60) which is normal in relation to a tangential plane (28) of the simulated bone surface in that point (19).

A design method (2) for design of an individually customized rig (600), wherein each circular shape (303) comprises an axis (15) and wherein the overlap (301) of the circular shapes (303) depends on selection of diameter (302) of the circular shapes (303) in combination of selection of closeness of an axis (15) of one circular shape (303) in relation to another axis (15') of another circular shape (303) in combination with selection of desired coverage for the implant of the cartilage and / or bone damage (5).

A design method (2) for design of an individually customized rig (600), wherein each circular shape (303) comprises an axis (15) and wherein the overlap (301) of the circular shapes (303) depends on selection of diameter (302) of between 1-3cm of the circular shapes (303) in combination of selection axe-distance (53) of between 6mm to 32 mm of one axis (15) of one circular shape (303) in relation to another axis (15') of another circular shape (303') in combination with selection of 50-100% of coverage for the implant body over the cartilage and / or bone damage (5).

A design method (2) for design of an individually customized rig (600) , wherein identifying a cartilage and or bone area (4) in a patient is performed by taking CT, CBCT, MRI images or the like of a joint of a patient and using these images to create a 3D view (9) of the bone and or cartilage area (4) and the bone and or cartilage damage (5) using for example a software program useful for virtual 3D animation.

A design method (2) for design of an individually customized rig (600) , wherein at least three circular shapes (303) are placed partly overlapping, covering or partly covering said cartilage and or bone damage (5).

A design method (2) for design of an individually customized rig (600), wherein said circular shapes (303) are in the size having a diameter of between 0.5-4cm.

A design method (2)for design of an individually customized rig (600) , wherein 2-5 circular shapes (303) are placed partly overlapping, covering said bone and or cartilage damage (5).

A design method (2) for design of an individually customized rig (600), wherein creating a virtual model of a rig) further comprises creating a simulated bone surface (53) in the 3D view (9), which mimics a non-damaged bone surface in a healthy patient and using said simulated bone surface (51) as a base when creating the virtual model of said rig.

A design method (2) for design of an individually customized rig (600) , wherein virtually placing at least two circular shapes (303) in the second step (14) of the method according to the invention comprises virtually placing at least two points (19) each from where an axis (15) will origin from, the points (19) are placed on the bone surface (50) of the joint in or nearby the area of the bone and or cartilage damage (5) or the points (19) are placed on a simulated bone surface which is a virtually created surface in or nearby the area of the bone and or cartilage damage (5), and wherein the simulated bone surface (51) is a surface which preferably corresponds to a three dimensional (3D) image of a bone surface in a healthy joint and wherein the points (19) are in the center of the circular shapes (303), and wherein the circular shapes (303), partly overlapping each other, and wherein the axes (15) are placed so that the combined area spread (20) of the circular shapes (303) covers or partly covers said identified bone and or cartilage damage (5).

A design method (2) for design of an individually customized rig (600), wherein virtually placing at least two circular shapes (303) is performed by placing the virtual circular shapes (303) comprising axes (15) in a predetermined angle in relation to each other.

A design method (2) for design of an individually customized rig (600), wherein each circular shape has an axis which is 90° in relation to the surface (451) of the circular shape (303).

A design method (2) for design of an individually customized rig (600), wherein the area of the placed circular shapes (303) including a surrounding area for letting an adjustment socket be inserted will comprise the created hollow space in the rig (600).

A design method (2) for design of an individually customized rig (600), comprising virtually placing at least three circular shapes (303) in a row or other symmetry wherein at least one circular shape overlaps with at least two other circular shapes (303).

A design method (2) for design of an individually customized rig (600) , comprises virtually placing two circular shapes (303) wherein the two circular shapes overlap each other.

A design method (2) for design of an individually customized rig (600), wherein each circular shape (303) has an axis (15) at a point (19) and wherein said axis (15) is 90° in relation to the normal of a tangent in a point (19) on the virtual bone contact surface (51).

A rig (600) designed according to the design method (2) mentioned above.

A method for placement of an implant in a bone and or cartilage area in a joint using the rig described in the specification.

A tool module system for replacing a portion of an articular surface (6) of a joint wherein said tool module system comprises a rig (600) with at least a first and a second guide channel and an insert guide stop wherein the insert guide stop is adapted to support instruments used in one of the guide channels of the guide tool and configured to fit inside a part of the volume inside at least one of said guide channels.

A guide tool of the guide system according to the invention comprising at least two guide holes or guide channels or openings to allow an in insert tool, for example a cutter or drill or rotary cutter, to pass through.

Brief description of the figures

Embodiments of the invention will now be described in more detail with reference to the appended drawings. Please note that the exemplified embodiments of the invention disclosed in the figures is not to be interpreted limiting the scope of the invention.

Figure 1, is an exemplified embodiment according to the invention, not limiting of the scope of the present invention, disclosing a view of a 3D view of a patients' knee joint comprising a cartilage damage, said 3D view is created from MR data images or the like.

Figure 2 is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and shows different examples of placement of the circular shapes in the first step of the design method in relation to each other.

Figure 3 is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and shows an virtual implant placed in a knee.

Figure 4a shows a pre-drilling guide socket.

Figure 4b shows a drilling depth adjustment socket.

Figure 5 is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and shows an example where the circular shapes have varying diameters.

Figure 6 is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and showing a view after placement of the circular shapes and design of circular shapes with non-parallel axes.

Figure 7 is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and shows two circular shapes covering the bone and or cartilage damage.

Figures 8a and 8b is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and showing the virtual model of the implant placed at the implantation site and comprising a simulated cartilage surface (6) of the implant (1) which simulates the cartilage surface before the cartilage damage. Fig 8a is a view from one side and figure 8b is virtual implant from above.

Figure 9 is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and showing a bone and cartilage damage wherein a simulated repair surface (16) is created which is a surface which preferably corresponds to a three dimensional (3D) image of a simulated healthy cartilage surface.

Figure 10 is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and showing a design method according to the present invention comprising three general steps.

Figure 11A is an exemplified embodiment according to the invention, not limiting of the scope of the present invention and showing placement of axes of two circular shapes in a joint with a cartilage and bone damage.

Figure 11B is an exemplified embodiment according to the invention, not limiting of the scope showing the placement of the axes in relation to each other with an axe-distance and in relation to a simulated bone surface wherein the axes originate from a point of said simulated bone surface. Alternatively, it is also possible to use a simulated cartilage surface for placement of the axes.

Figure 12 shows a two-pegged implant.

Figure 13 shows a rig according to one embodiment of the invention for a two peg-implant. The rig is mounted in place.

Figure 14a shows one embodiment of a three-pegged implant having the form of three identical intersecting circles.

Figure 14b shows one embodiment of a rig with wall insert for a three-peg implant, seen from above.

Figure 15 shows an example of a double drill for use with the drilling rig according to the invention.

Detailed description of the invention

Introduction

The present invention relates to a design method (2) for design of an individually customized rig(600) The rig (600)designed by the method (2) according to the invention is to be used for cartilage repair in a joint of a human or animal.

The design method (2) for design of an individually customized rig according to the present invention is described below.

The design method for design of an individually customized rig (600), said rig (600) having a hollow tubular shell (510) open at both ends, characterized in that the interior of said shell

defines at least first and second intersecting circular cylinders and wherein the design method for said rig (600) comprises the steps;

-A first damage identification step (101) comprising identifying a bone and or cartilage area (4) in a patient comprising a bone and or cartilage damage (5) and presentation of a 3D view (9) of said identified area using a software program

-A second virtual model making step (14) comprising making a 3D model of a virtual rig comprising a step of virtually placing in said 3D view (9) at least two circular shapes (303), wherein each circular shape (303) partly overlapping at least one other circular shape (303'), and wherein the combined area (20) of the circular shapes cover or partly cover said identified bone and or cartilage damage (5) and wherein these positioning data is used to create the position and interior of said hollow tubular rig shell (510) of the virtual rig which is open at both ends and wherein selection of least first and second intersecting circular cylinders rig is based on the selected sizes of the circular shapes (303), or slightly larger, and wherein a positioning surface (560) of the virtual rig is created which is a bone and or cartilage-engaging end of said hollow tubular shell (510) and wherein said positioning surface (560) is adapted to face and align to the surface structure surrounding the hollow circular shapes of the rig when the rig is placed in a virtual model of the joint.

-A third production step (34) comprising producing a rig (600) according to the created virtually created rig which is adapted to mimic the volume and shape according to said created virtual model of the rig.

Figure 10 shows the design method (2) according to the present invention comprising three general steps; A first damage identification step (101), a second virtual model making step (14), a third production step (34).

The design method according to the invention allows for producing a rig which is easy to fit to repair an individual damage in a patient.

The design building up of this method comprising choosing size and at least two circular shapes and choosing overlap, thickness, articular surface etc for each rig makes this solution unique and easy to individualize, but still suitable for large scale industrial manufacturing.

The circular shape build-up of the implant makes the rig also easy to place by drilling and or reaming giving an exact fit of each implant in every patient.

A first damage identification step (101)

A first damage identification step (101) comprises identifying a bone and or cartilage area (4) in a joint of a patient comprising a bone and or cartilage damage (5) and presentation of a 3D

view (9) of said identified area using a software program. The first damage identification step (101) in the design method (2) according to the invention is to identify the bone and or cartilage area (4) in a joint of a specific patient whom is in need of bone and or cartilage repair. This is done from 2D images such as MR images. A 3D view (9) of a joint comprising a bone and or cartilage area (4) and or comprising the bone and or cartilage damage (5) is created by taking 2D images of the joint and converting them into a 3D view (9). The bone and or cartilage damage (5) can for example be identified in the 2D images which then are converted into a 3D view (9).

Useful imaging techniques are for example Computed Tomography (CT), Cone Beam Computed Tomography (CBCT), Magnetic resonance imaging (MRI) or other suitable techniques such as delayed Gadolinium-enhanced MRI of cartilage (dGEMRIC) techniques or the like). The taken 2D images of the joint are used to create a 3D model or view (9) of the patient's bone and or cartilage and using for example a software program, for example a CAD animation program for example a radiography software program or the like is useful for 3D animation.

A joint representation-CAD animation model is created which is a 3D view (9) comprising the bone and or cartilage area (4) based on images from the joint. This model is further comprising the bone and or cartilage damage (5).

A damage-representation CAD animation model which shows the bone and or cartilage damage (5) may be created manually from 2D images by manually marking out damaged area pixels in each 2D image and from that create a 3D view (9) or the damage-representation CAD animation model may be a combination of the marked up 2D images.

In an automated process a computer program, for example a radiography software program, could be adapted to scan the images for predetermined characteristics of an area and or spread, curvature and or a location of bone and or cartilage damage (2) in the image data and combine the automatically marked 2D images into a 3D view (9) also called the damage representation CAD animation model .The size of the area which is of interest to map or to create a 3D view (9) of is usually not depending of the size of the cartilage damage and the type of joint or bone part which is to be repaired, usually the surgeon does not know where in the joint the damage is located before taking images of the patients joint, therefore usually, images of the whole bone and or cartilage area (4) of the joint are used to create a virtual 3D view (9). A virtual 3D view (9) is a joint representation CAD animation model which can be selected to show the bone and or cartilage area (4), the bone and or cartilage damage (5), placement of virtual rig or virtual implant etc.

In one embodiment according to the invention a first damage identification step (101) of the design method (2) according to the invention comprises identifying a bone and or cartilage area (4) in a patient by taking images of the injury or damage in the joint of a patient and then use these images of the individual patient's bone and or cartilage area (4) to create a joint representation CAD animation model .

See for example figure 1, not limiting for the scope of the present invention, for one view of a 3D view (9) of a patient's knee joint and a cartilage and or bone area (4) comprising a bone and or cartilage damage (5) which is created from MR images or the like. Figure 1 shows a 3D view (9) of a patient's knee joint comprising a bone and or cartilage damage (5) wherein the borders around the bone and or cartilage damage (18) are marked-up.

Joints in a human or animal which may be repaired by using the rig designed according to the design method (2) according to the present invention can be selected from for example any of a knee, hip, shoulder, toe or finger joint.

Figure 9 shows a 3D view (9) wherein a bone and or cartilage damage is marked (5) and wherein a simulated cartilage repair surface (16) is marked out and wherein a simulated bone surface (51) is marked out and wherein the figure further comprises surrounding cartilage surface (36) and surrounding bone (35).

A second virtual model making step (14)

The second step (14) in the method according to the invention comprises a first step of selecting a surface comprising at least two circular shapes (301) which decides upon how much the combined area (20) of the circular shapes (301) cover or partly cover said identified bone and or cartilage damage (5). This positioning data of the circular shapes (301) is used to create the position and interior of said hollow tubular rig shell (510) of the virtual rig which is open at both ends and wherein selection of at least first and second intersecting circular cylinders rig is based on the selected sizes of the circular shapes (303), or slightly larger, and wherein a positioning surface (560) of the virtual rig is created which is a bone and or cartilage-engaging end of said hollow tubular shell (510) and wherein said positioning surface (560) is adapted to face and align to the surface structure surrounding the hollow circular shapes of the rig when the rig is placed in a virtual model of the joint.

In one embodiment, the second step (14) in the method according to the invention comprises virtually placing at least two points (19) each from where an axis (15) will origin, the points (19) are placed on the bone surface (50) of the joint in or nearby the area of the bone and or cartilage damage (5) or the points (19) are placed on a simulated bone surface (51) which is a virtually created surface and covering the area of the bone and or cartilage damage (5). The

simulated bone surface (51) is a surface which preferably corresponds to a three dimensional (3D) image of a bone surface in a healthy joint. The points (19) are surrounded by selected circular shapes (303). The points (19) are centered in the circular shapes (301), the circular shapes (303), partly overlapping each other, and wherein the points (19) with the axes (15) are placed so that the combined area spread (20) of the circular shapes (303) covers or partly covers said identified bone and or cartilage damage (5).

The axes (15) are placed with a selected axe-distance (53) from each other.

In one embodiment of the invention the second step (14) in the method according to the invention comprises a first selection of diameters (302) of the circular shapes (303), selection of how much the circular shapes (303) should cover of the bone and or cartilage damage (5), selection of placement of axes (15) by selection of points (19) of intersection of the axes (15) on a simulated bone surface (51) or placement directly on a bone surface (50) in a 3D view of a joint. I another embodiment the diameter (302) of the circular shapes are selected simultaneously as the placement of the points (19) are made.

Different types of selections may be comprised in the second virtual model making step (14) and are in one embodiment according to the design method (2) according to the invention selected in the following order. In other embodiments the first, second and third selections can be made in any order or can be made simultaneously;

First selections;

These first selections made in the second virtual model making step (14) according to the invention can be made in any order or can be made simultaneously;

-placing at least two points (19) each from where an axis (15) will origin from, the points (19) are placed on the bone surface (50) of the joint in or nearby the area of the bone and or cartilage damage (5) or the points (19) are placed on a simulated bone surface (51) which is a virtually created surface and covering the area of the bone and or cartilage damage (5)

-selecting diameter of circular shapes, the diameter (302) of the circular shapes (303) are selected between 10-30mm or for example 15-25mm

- wherein the axe-distance (53) between the points (19) is for example between 6-32mm or 7-20 mm or 7-12mm

-selecting coverage of the implant area (7) over the cartilage and or bone damage (5). The coverage is preferably 100% but may be between 50-100%.

Second selections;

-Selection of the angles (25) of the axes (15). Angles (25) in relation to simulated bone surface (51) or (50) and in relation to other axes.

Figure 11A shows an exemplified embodiment according to the invention, not limiting for the scope of the present invention, showing placement of axes of two circular shapes in a joint with a cartilage and bone damage, the placement of the axes (15) and (15') is shown in relation to each other with an axe-distance (53) See figure 11B and in relation to a simulated bone surface (51) wherein the axes (15) and (15') originate from a point (19) of said simulated bone surface (51) and wherein the axes (15) and (15') have an angle (25, 25') in relation to an bone-axis (60) which is normal in relation to an tangential plane (28, 28') of the simulated bone surface in the point (19). Figures 11 A and B further comprises cartilage (36), bone (35), bone surface (50).

Third selections;

-In the third selection step of the second step (14) the height (710) of the hollow tubular rig shell (510) of the virtual rig is decided. The height of the hollow tubular shell (510) is selected depending on surrounding tissue and place of cartilage damage in order for ease of placement of the rig (600) during surgery and in order to have to make as little surgical intervention as possible. The height might be decided depending on where the implant is being placed. The height may vary depending on whether the implant is on for example the condylea or trochlea of a knee, being at least between 20-30 mm on the first and between at least 25-45 mm on the second. However a total variation of the height (710) between 10-90mm is foreseen.

-In the third selection step of the second step (14) the spread of an individually customized positioning surface (560) is also selected. The positioning surface (560) of the virtual rig is created which is a bone and or cartilage-engaging end of said hollow tubular shell (510) and wherein said positioning surface (560) is adapted to face and align to the surface structure surrounding the hollow circular shapes of the rig when the rig is placed in a virtual model of the joint. The spread of the positioning surface (560) is selected depending on surrounding tissue and place of cartilage damage in order for ease of placement of the rig (600) during surgery and in order to have to make as little surgical intervention as possible. In one embodiment the spread is selected to cover an area in the joint with a curvature to guide the surgeon so that the rig (600) only can be placed in one way in the joint and thereby

minimizing non-correct placement. The positioning surface (560) protrudes around the hollow tubular shell (510) so that the positioning surface gives the rig support during usage.

-The hollow tubular rig shell (510) of the virtually created rig should preferably have a height (710) of in between 10-90mm , especially 20-30mm for condylea and 25-45 mm for trochlea of a knee.

-In one embodiment the height of the hollow tubular rig shell (510) is decided upon by using the surfaces of the circular shapes (303) placed on a simulated bone surface (51) to create a cylindrical sphere presenting an elongation of a virtual view of the side wall of the circular shapes.

Different types of first and or second and or third selections in second virtual model making step (14) which is combinable according to the method of the invention:

In one embodiment according to the invention the axe-distance (53) is between 6-32 or for example 7-20 or for example 7-12 mm.

In one embodiment according to the invention the axe-distance (53) is larger than 8mm.

In one embodiment according to the invention the axe-distance (53) is 8mm.

The placements of the points (19) and/or axes (15) and/ or the selection of diameters (302) of the circular shapes (303) are done manually by an operator using a software program or automatically by a software program.

In one embodiment at least two axes (15) are parallel in relation to each other. However even if the two axes are parallel the angle between the surface of the cartilage and the axes is in this embodiment not 90 grades because of the curvature of the cartilage. In other embodiments the axes (15) have different angles in relation to each other and also in relation to a simulated bone surface (51). See for example figure 6 for an example according to the invention wherein two circular shapes (303) are placed on a bone surface, with an overlap (301) and with non-parallel axes (15) and (15') and also showing the surface (301) of the circular shapes (303) and (303´).

In one embodiment the design method (2) for design of an individually customized rig (600) according to any preceding claims, comprises virtually placing at least two circular shapes (303) is performed by placing two circular shapes (303) so that the diameter of the circular shapes (303) has a 20-90% or 40-70% overlap (301) in relation to the diameter of each circle

The second virtual model making step (14) in the method according to one embodiment of the invention comprises virtually placing at least two circular shapes (303), partly overlapping, covering or partly covering said identified bone and or cartilage damage (5).

Figure 7 illustrates an example according to the invention of the second virtual model making step (14) and comprises two virtually placed circular shapes (303) spread out over an implant area (20) covering said identified cartilage and or bone damage (5) in a 3D view (9).

In one embodiment the second virtual model making step (14) in the design method (2) according to the invention comprises;

-virtually placing at least two circular shapes (303), partly overlapping, covering or partly covering said identified cartilage and or bone damage (5) and

-virtually creating at least two directions of at least two circular shapes (303) in relation to the identified cartilage and or bone area (4).

In one embodiment of the invention the different directions of the axes, for the angle of axis (15) and (15') is described. Axis (15) has an angle (25) of 0-40 degrees in relation to a bone-axis (60) which is normal in relation to a tangential plane (28) of the simulated bone surface (51) or in relation to the bone surface (51) in the point (19). Axis (15') has an angle (25') of 0-40 degrees in relation to a bone-axis (60') which is normal in relation to a tangential plane (28) of the simulated bone surface (51) in the point (19') in a 3D view (9) of a virtually repaired articulate cartilage surface.

In one embodiment the different axes (15) and (15´) of the circular shapes (303) have directions that are parallel to each other. In one embodiment the different axes (15) of the circular shapes (303) have different directions in relation to each other.

In one embodiment, the second step (14) in the method according to the invention comprises of virtually placing at least two circular shapes (303), partly overlapping, covering said identified bone and or cartilage damage (5).

In one embodiment, the second step (14) in the method according to the invention (2) comprises of virtually placing at least two circular shapes (303), partly overlapping, covering said identified bone and or cartilage damage (5) and wherein all the circular shapes (303) have identical or approximately the same diameter.

In one embodiment, the second virtual model making step (14)_in the method according to the invention comprises of virtually placing at least two circular shapes (303), partly overlapping, covering said identified bone and or cartilage damage (5) and wherein the

different circular shapes (303) have diameters in varying sizes, for example one with smaller diameter than another. See for example figure 5 wherein one circular shape (303) has one diameter (302) and another circular shape (303') has a smaller diameter (302') and wherein the both circular shapes has an overlap (301).

In one embodiment the second virtual model making step (14) in the method according to the invention comprises of virtually placing at least two circular shapes (303), partly overlapping, covering a part or covering the complete bone and or cartilage damage (5) identified in images and presented in the 3D model of the bone and or cartilage area (4) in the joint identified in the first step (101) of the design method (2) according to the invention.

The combined area (20) of the overlapping circular shapes (303) together with a surrounding area giving space to the drilling socket will together define the area (20) of the implant body (30) to be produced. In other words the area or cross section of the inside of the hollow tubular shell (510) means the sum of the spread of the shapes of the circular shapes (303).

The placement of the circular shapes (303) in relation to each other may be placement in a row or in symmetric groups or for example in an asymmetric order. For different examples of placement patterns of the circular shapes (303) see figure 2.

The placement pattern is selected depending on for example the placement of the bone and or cartilage damage (5), and or the size of the bone and or cartilage damage (5) and or the spread of the bone and or cartilage damage (5) and or the depth of the bone and or cartilage damage (5).

The overlap (301) of the circular shapes (303) is in one embodiment of the invention performed so that the diameter of the circular shapes (303) has a 20-90% overlap (301) or for example 30-80% or for example 40-70% in relation to the diameter (302) of each overlapping circle.

The overlap (301) of the circular shapes (303) is in one embodiment of the invention performed so that the diameter of the circular shapes (303) has at least 40% overlap (301) in relation to the diameter of each overlapping circle.

The diameters of the circular shapes (303) (303) according to the invention are between 5-30mm or between 10-25 mm or for example between 15-25 mm.

Figure 3 shows one exemplified embodiment of the invention. Figure 3 shows a virtual implant (42) placed in a knee and wherein the virtual implant (42) comprises two circular shapes (303) placed so that they have an overlap and further the axes (15, 15') of the circular

shapes (303, 303') of the implant is parallel in this example. This implant is placed with help of the rig designed by the design method (2) according to the present invention.

Figures 8a and 8b shown exemplified embodiment according to the invention, not limiting for the scope of the present invention, showing the virtual model of the implant (42) placed at the implantation site and comprising a simulated cartilage surface (41) of the virtual model of the implant (42) which mimics the cartilage surface before a cartilage damage. Further the virtual implant model (42) in the example in Figure 8a comprises a virtual implant body (30) and two extending post (23), see figure 8a.

Fig 8a is a view from one side and figure 8b is a view of a virtual model of the implant (42) from above and wherein the area (20) of the implant to be produced is shown.

The rig according to the invention may further comprise a wall insert (610). The guide tool of the guide system according to the invention comprises at least two guide holes or guide channels or openings to allow a in insert tool, for example a cutter or drill or rotary cutter, to pass through. The design of the wall insert (610) is in one embodiment a part of the design method according to the invention. The wall insert (610) is used in order to support the insert tools so that the channel inside the hollow tubular shell (510) of the rig (600) supports the insert tools during usage of the rig.

The insert tools are in one embodiment supported by parts of the walls of the guide channel inside the hollow tubular shell (510) in combination with a part of the sidewall of an wall insert (610). The wall insert (610) is a module which fits inside the guide channels by mimicking parts of the pattern of the guide channel inside area of the rig. The combination of parts of inside guide channel walls and part of sidewall of a wall insert (610) forms a round or cylindrical shaped guide hole, hereby called the active guide hole or guide channel. The active guide channel is a guide channel that may be used for insertion of insert tools at that time. The active guide channel is changed by moving around the wall insert (610) in the inside area of the guide channels. By moving around the wall insert (610) to guide or support another guide channel in the guide tool, new active guide channels are formed. It is also possible to use several inserts of different sizes in parallel instead of adjusting the insert during the work.

In another embodiment the movable insert is not arcuate but is a cylinder.

In another further embodiment no insert at all is used. Other similar embodiments are of course also possible.

The wall insert (610) when placed in the rig channel, efficiently blocks guide channels not in use and the wall insert (610) forms, together with the inside walls of the active guide channel, a cylinder shaped wall around an active guide channel of the rig (600).

The present invention may comprise a design method for a rig and a wall insert (610) which together make the surgeon drill or cutter used inside the guide forming excision sites which correspond to an implant structure. The guide channels in the guide are adapted so that the formed excision sites are partially overlapping each other.

By using a guide tool according to the invention the surgeon can get a precise way to make the excisions needed to place an implant in the joint. The system according to the invention wherein implant shapes may be build selecting from different sizes of circular shapes (303) partly overlapping each other in combinations allows the surgeon to choose an implant which fits the size and shape of the cartilage damage or defect and gives the surgeon easy to use tool set for making the excisions needed.

A third production step (34)

The design method according to the invention involves a third production step (34) of producing a rig (600).

The third production step (34) according to the invention comprises producing a rig (600) having the shape and volume as the virtual rig planned and created in first damage identification step (101) and the second virtual model making step (14).

Polyamide rigs produced with selective laser sintering (SLS) are especially useful. Other production techniques and other materials are also possible. Other similar polymers such as polypropylene, polyethylene, polystyrene, poly-methylmetaacrylate(PMMA), acrylonitrile butadiene styrene (ABS) and similar compounds can be used. The rig can also comprise any metal or metal alloy used for structural applications in the human or animal body, such as stainless steel, cobalt-based alloys, chrome-based alloys, titanium-based alloys, pure titanium, zirconium-based alloys, tantalum, niobium and precious metals and their alloys. If a ceramic is used, it can be a biocompatible ceramic such as aluminium oxide, silicon nitride or yttria-stabilized zirconia. The rig may contain parts that are made of other materials as well.

Use method of the rig (600) according to the invention

Figure 13 shows an example of one embodiment of a rig according to the present invention which is used for all of the hole preparation. The rig comprises an elongated hollow shell 510 having the form of two intersecting (overlapping) circular cylinders 52, 53 of the same diameter and the hollow tubular rig shell (510) has a height (710) between 10-90mm. The rig (600) can be formed to conform to the shape of the bone and cartilage area of the patient to be repaired or can be a standard rig. The rig is held securely in place on the condylar surface in this case by individually customized the positioning surface (560) and with pins (not shown) driven in through holes 61, to hold the rig securely in place throughout the entire drilling process.

After the pins have been driven in, the cutting and drilling process can begin, with a wall insert (610) inserted in one end of the hollow shell, leaving an entire first circular cylinder (52) at one end of the hollow tubular shell. At this time the surgeon may insert into the first circular cylinder a depth adjustment socket (505) (Figure 4b) and then a sharp cylindrical hand knife, sized exactly to the interior of the adjustment socket (505), makes a preliminary circular sharp edged cut through the cartilage down to the bone. A circular bare bone area is left after this cartilage removal.

In one embodiment, the surgeon uses a 17/4 mm double drill as shown schematically in Figure 15. It has a central narrow 4 mm diameter bit (401), and a wider 17 mm diameter cutting bit (402). The outer lateral surface (403) of the double drill conforms to the circular cylinder, which securely holds the double drill to drill, in the same operation, a central 4 mm hole for the first peg (23) and a much shallower surrounding bore 17 mm in diameter in this example. A pre-drilling of the initial part of the peg hole in the bone can according to one embodiment be made using a guide socket (501) (Figure 4a). This improves the exact placement of the simultaneous drilling of the peg hole and the circular bare-bone area with the double drill (Figure 15). After removing the drill, and flushing out organic matter, the surgeon then slides the wall insert (610) out and inserts it in on the other side of the hollow shell, creating a complete circular cylindrical guide hole on the opposite side of the hollow shell.

The surgeon then inserts the adjustment socket and uses the same cylindrical knife in the newly created guide hole, to make a circular excision of the cartilage (not a complete circle since the intersecting portion has already been removed in the previous step). The in this embodiment 17/4 mm double drill is then used again first with the guide socket(501) to pre-drill the peg hole and then with the adjustment socket(505) to double-drill the peg hole to its

full depth and create the bare-bone circle , i.e. the 4 mm hole for the second peg and a second surrounding shallow bore which is of course also 17 mm in diameter.

These two drilling operations have created 4 mm peg holes and a space in the bone to exactly accommodate in this case a 17+17 implant of the invention. The wall insert (610) is then completely removed. A handle-equipped gauge corresponding to the intersecting circular forms making up the implant, is used to make sure that the holes have been drilled to the proper depth in the bone. The rig is then removed and the implant pegs or extending posts (23) are inserted into their holes. For the cap of the implant to lodge exactly in the in this case 17+17 shallow cavity removed from the surface of the bone it is usually necessary to carefully tap the cap, preferably on top of the first peg, with interference fit, with a hammer via a special mandrel. The first, slightly thicker peg, is tapped down into its hole while the second peg, slightly narrower, slides easily into its hole. The larger diameter part of the 17/4 mm drill in this example has a rim to excavate a peripheral slot slightly deeper than the 17 mm shallow cavity, to accommodate the peripheral ridge (47) of the implant, helping to hold the implant securely in place during healing and subsequent loading during use.

Thus the rig, which can be form-fitted to the shape of the individual patient´s cartilage surface in this example, is placed over the damaged area of the condyle and is anchored securely in place, in this particular non-limiting example, by driving in four pins (not shown) into holes (61) in the condyle shaped lower end of the rig (600). It is now securely in place for the entire drilling operation, which be simplified greatly and made much more exact and less dependent on the artistry of the surgeon, which may vary from day to day.

After drilling of the holes, the pins are pulled out and the rig is removed from the site, for implantation of the implant and reconstitution of the joint with the new implant.

It will be understood by the person skilled in the art that the rig as claimed can be supplemented with an insert sleeve to make one of the circular cylinders of a small diameter, e.g. from 17 to 15 mm in diameter, to accommodate an implant having the form of two intersecting circles of slightly different diameters, for example 15 + 17 millimeters. Of course also rigs with a specific predecided fixed diameter may be prepared.

It will of course also be possible, within the scope of the invention to create an implant in the form of three, or more, intersecting circles, to cover bone damage of more irregular shape. One such three-circle implant 101 is shown from below in Figure 14a showing three pegs (148),(149) and (150). In this example peg (148) has an interference fit diameter in relation to the common nominal diameter of all three pegs and the other two pegs(149) and (150) have clearance fit diameters in relation to the common nominal diameter.

The rig for this three-circle implant is shown from above in Figure 14b. The rig is held in place on the bone by pins (not shown) inserted through holes (161). The wall insert (610), completes the first circular cylinder (152) covering the remaining portions of the other two circular cylinders. When the first circular drilling has been made the wall insert(610) is pulled out, rotated 120 degrees and is inserted again to provide a drill guide for the next circle drilling with the same double drill, which in one embodiment can be the same 17/4 drill used together with the two-circle rig. After rotation 120 degrees again and drilling, a three pegged implant is inserted. As stated above, this insert has one peg which is of interference fit dimension in relation to its nominal diameter (in this case 4 mm) and the other two pegs are of clearance fit.

Figure 15 shows an exemplary 4/17 double drill for use with the multiple circle rigs described above (or with a previously known single circle rig). The double drill has a 4 mm central bit (401) for creating the hole for the peg and a wider cutting surface (402) for creating the 17 mm shallow hole. One of the advantages of the invention is that the same double drill can be used for single, double or triple (or more) intersecting circle shaped implants, used twice or three times as the case may be for the two embodiments shown here. According to the example in figure 17 the hole is more shallow then the peg. According to other examples it could also be deeper than the peg.

Figure 12 shows an exemplified embodiment of an implant (1) according to the invention, having two circular shapes, having two extending posts (23, 23') or pegs and a protruding edge (47) surrounding the implant body (30). This example is directed to an example wherein the two circular shapes have the same diameters.

Claims

1. A design method for design of an individually customized rig (600), said rig (600) having a hollow tubular shell (510) open at both ends, characterized in that the interior of said shell defines at least first and second intersecting circular cylinders and wherein the design method for said rig (600) comprises the steps;
-A first damage identification step (101) comprising identifying a bone and or cartilage area (4) in a patient comprising a bone and or cartilage damage (5) and presentation of a 3D view (9) of said identified area using a software program
- A second virtual model making step (14) comprising making a 3D model of a virtual rig comprising a step of virtually placing in said 3D view (9) at least two circular shapes (303), wherein each circular shape (303) partly overlaps at least one other circular shape (303'), and wherein the combined area (20) of the circular shapes covers or partly covers said identified bone and or cartilage damage (5) and wherein positioning data is used to create the position and interior of said hollow tubular rig shell (510) of the virtual rig which is open at both ends and wherein selection of at least first and second intersecting circular cylinder rig is based on the selected sizes of the circular shapes (303), or slightly larger, and wherein a positioning surface (560) of the virtual rig is created which is a bone and or cartilage-engaging end of said hollow tubular shell (510) and wherein said positioning surface (560) is adapted to face and align to the surface structure surrounding the hollow circular shapes of the rig when the rig is placed in a virtual model of the joint.
-A third production step (34) comprising producing a rig (600) according to the virtually created rig which is adapted to mimic the volume and shape according to said created virtual model of the rig.

2. Design method for design of an individually customized rig (600) according to Claim 1 characterized in that the interior of said shell defines first, second intersecting circular cylinders of equal diameter.

3. Design method for design of an individually customized rig (600) according to Claim 1, characterized in that the interior of said shell defines first, second and third intersecting circular cylinders of equal diameter.

4. A design method for designing an individually customized rig (600) according to any of the preceding claims, characterized by an addition a design step designing an arcuate wall which is adapted to be selectively insertable into said shell interior to

complete the full circumference as desired.

5. A design method according to claim 4 wherein the movable insert is not arcuate but is a cylinder.

6. A design method for design of an individually customized rig (600) according to any of the preceding claims, characterized in that the positioning surface (560) of said rig (600) is provided with multiple holes (61, 161) for pins anchoring the rig securely in place on the surface to be repaired.

7. A design method for design of an individually customized rig (600) according to any of the preceding claims and wherein a first selection step further comprises;
-placing at least two points (19) each from where an axis (15) will origin from, the points (19) are placed on the bone surface (50) in the 3D view (9) of the joint in or nearby the area of the bone and or cartilage damage (5) or the points (19) are placed on a simulated bone surface which is a virtually created surface in or nearby the area of the bone and or cartilage damage (5)
-selecting axe-distance (53)
-selecting diameter of circular shapes, the diameter (302) of the circular shapes (303) are selected between 10-30mm or for example 15-25mm
-selecting coverage of the implant area (20) over the cartilage and or bone damage (5), wherein the coverage may be between 50-100%
and wherein a second selection step comprises;
-Selection of the angles (25) of the axes (15) which originate from a point (19) of said simulated bone surface (51) and wherein the axes (15) and (15') have an angle (25) 0-40 degrees in relation to a bone-axis (60) which is normal in relation to a tangential plane (28) of the simulated bone surface in that point (19).

8. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, wherein each circular shape (303) comprises an axis (15) and wherein the overlap (301) of the circular shapes (303) depends on selection of diameter (302) of the circular shapes (303) in combination of selection of closeness of an axis (15) of one circular shape (303) in relation to another axis (15') of another circular shape (303) in combination with selection of desired coverage for the implant of the cartilage and / or bone damage (5).

9. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, wherein each circular shape (303) comprises an axis (15) and wherein the overlap (301) of the circular shapes (303) depends on selection of diameter (302) of between 1-3cm of the circular shapes (303) in combination of selection axe-distance (53) of between 6mm to 32 mm of one axis (15) of one circular shape (303) in relation to another axis (15') of another circular shape (303') in combination with selection of 50-100% of coverage for the implant body over the cartilage and / or bone damage (5).

10. A design method (2) for design of an individually customized rig (600) according to any preceding claims, wherein identifying a cartilage and or bone area (4) in a patient is performed by taking CT, CBCT, MRI images or the like of a joint of a patient and using these images to create a 3D view (9) of the bone and or cartilage area (4) and the bone and or cartilage damage (5) using for example a software program useful for virtual 3D animation.

11. A design method (2) for design of an individually customized rig (600) according to any preceding claims, wherein at least three circular shapes (303) are placed partly overlapping, covering or partly covering said cartilage and or bone damage (5).

12. A design method (2) for design of an individually customized rig (600) according to any preceding claims, wherein said circular shapes (303) are in the size having a diameter of between 0.5-4cm.

13. A design method (2)for design of an individually customized rig (600) according to any preceding claims, wherein 2-5 circular shapes (303) are placed partly overlapping, covering said bone and or cartilage damage (5).

14. A design method (2) for design of an individually customized rig (600) according to any preceding claims, wherein creating a virtual model of a rig) further comprises creating a simulated bone surface (53) in the 3D view (9), which mimics a non-damaged bone surface in a healthy patient and using said simulated bone surface (51) as a base when creating the virtual model of said rig.

15. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, wherein virtually placing at least two circular shapes (303) in the second step (14) of the method according to the invention comprises

virtually placing at least two points (19) each from where an axis (15) will origin from, the points (19) are placed on the bone surface (50) of the joint in or nearby the area of the bone and or cartilage damage (5) or the points (19) are placed on a simulated bone surface which is a virtually created surface in or nearby the area of the bone and or cartilage damage (5), and wherein the simulated bone surface (51) is a surface which preferably corresponds to a three dimensional (3D) image of a bone surface in a healthy joint and wherein the points (19) are in the center of the circular shapes (303), and wherein the circular shapes (303), partly overlapping each other, and wherein the axes (15) are placed so that the combined area spread (20) of the circular shapes (303) covers or partly covers said identified bone and or cartilage damage (5).

16. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, wherein virtually placing at least two circular shapes (303) is performed by placing the virtual circular shapes (303) comprising axes (15) in a predetermined angle in relation to each other.

17. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, wherein each circular shape has an axis which is 90° in relation to the surface (451) of the circular shape (303).

18. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, wherein the area of the placed circular shapes (303) including a surrounding area for letting an adjustment socket be inserted will comprise the created hollow space in the rig (600).

19. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, comprising virtually placing at least three circular shapes (303) in a row or other symmetry wherein at least one circular shape overlaps with at least two other circular shapes (303).

20. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, comprises virtually placing two circular shapes (303) wherein the two circular shapes overlap each other.

21. A design method (2) for design of an individually customized rig (600) according to any of the preceding claims, wherein each circular shape (303) has an axis (15) at a point (19) and wherein said axis (15) is 90° in relation to the normal of a tangent in a

point (19) on the virtual bone contact surface (51).

22. A rig (600) designed according to the design method (2) in any of the preceding claims.

23. A method for placement of an implant in a bone and or cartilage area in a joint using the rig according to any of the preceding claims.

24. A tool module system for replacing a portion of an articular surface (6) of a joint wherein said tool module system comprises a rig (600) with at least a first and a second guide channel and an insert guide stop which is **characterized in** that said insert guide stop is adapted to support instruments used in one of the guide channels of the guide tool and configured to fit inside a part of the volume inside at least one of said guide channels.

25. A guide tool of the guide system according to the invention comprising at least two guide holes or guide channels or openings to allow an in insert tool, for example a cutter or drill or rotary cutter, to pass through.

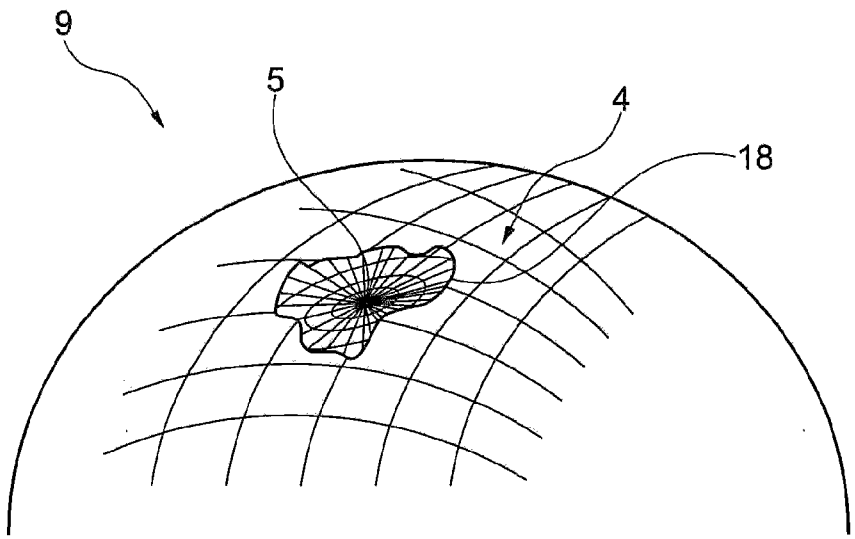

Fig. 1

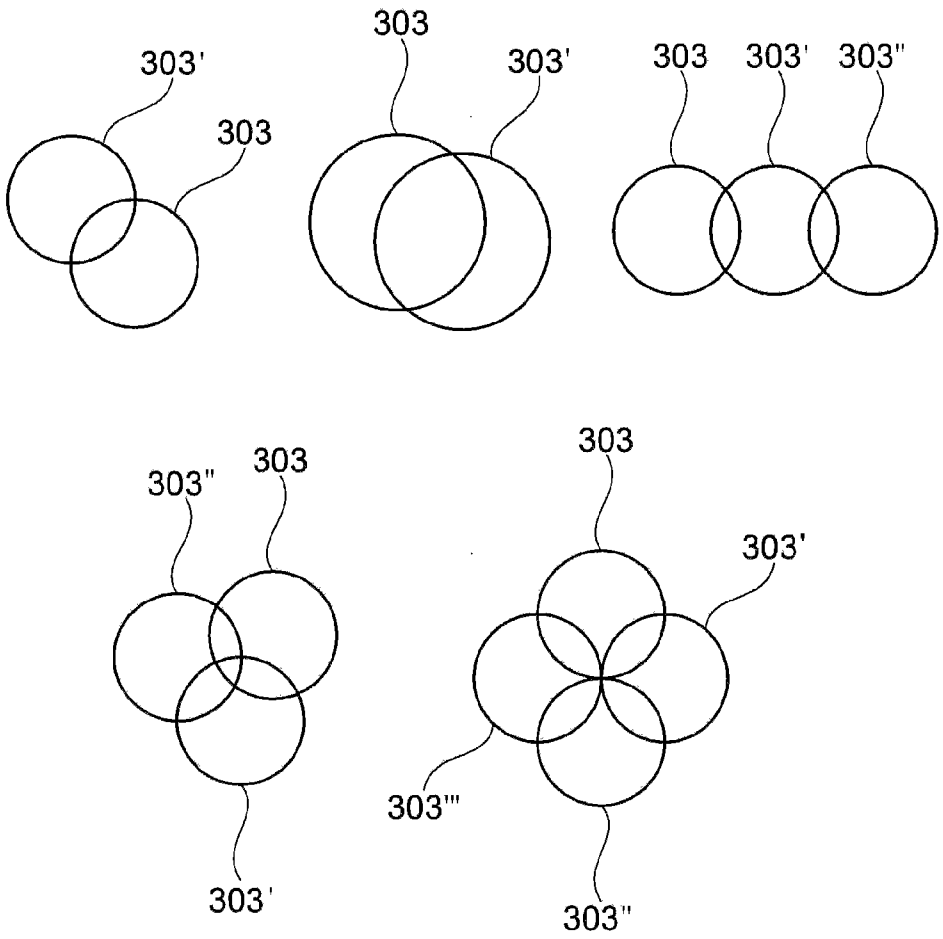

Fig. 2

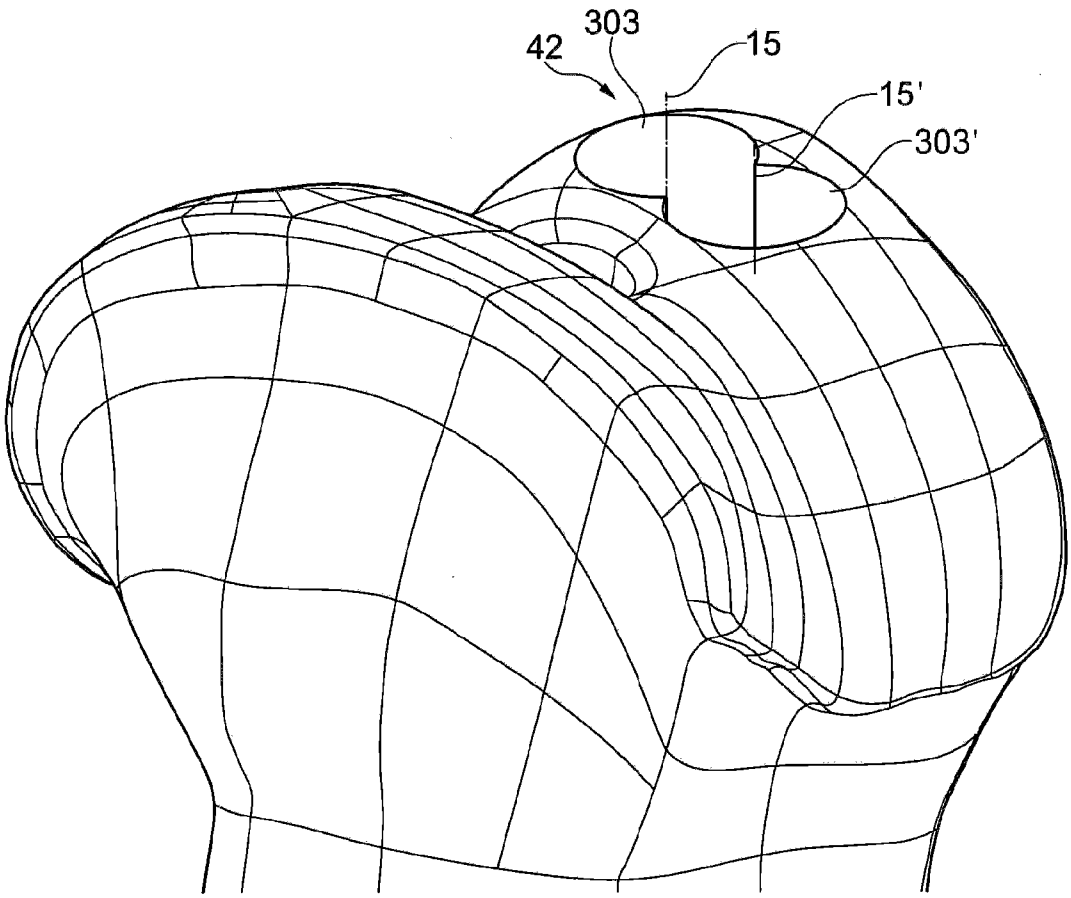

Fig. 3

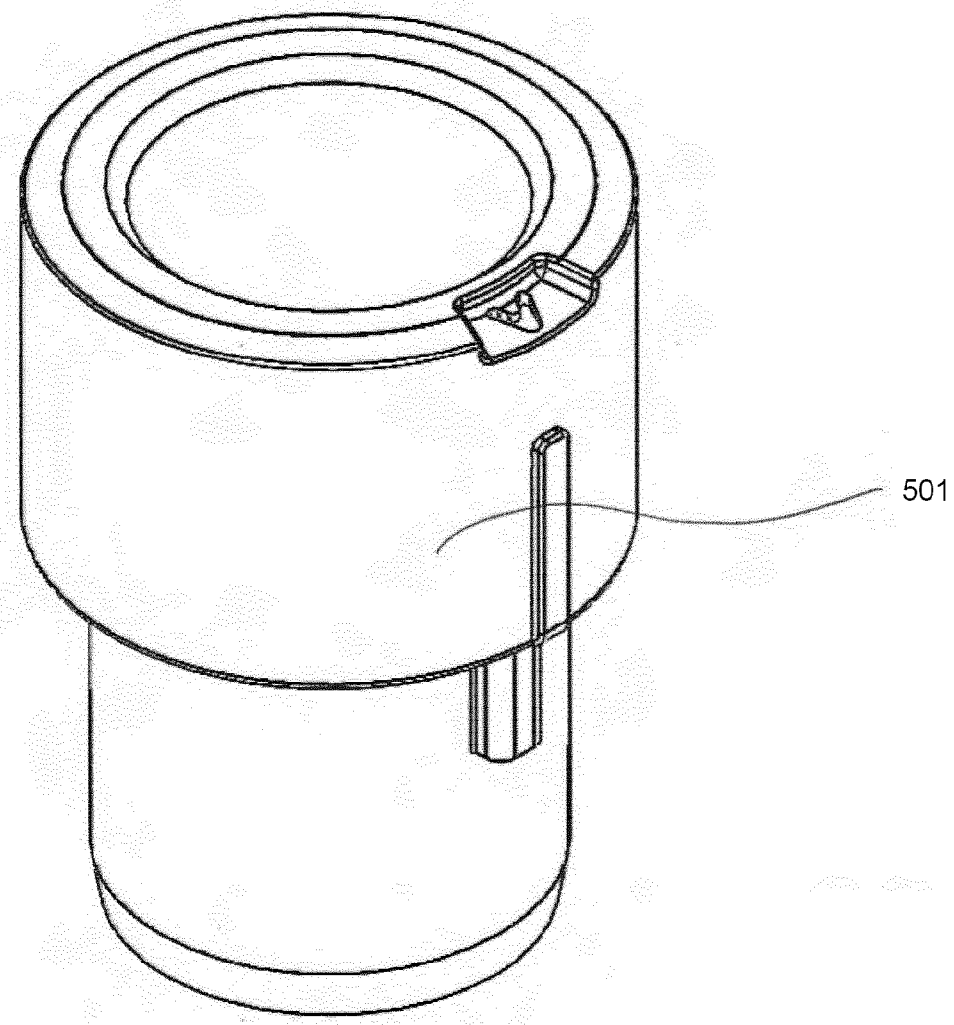

Fig. 4a

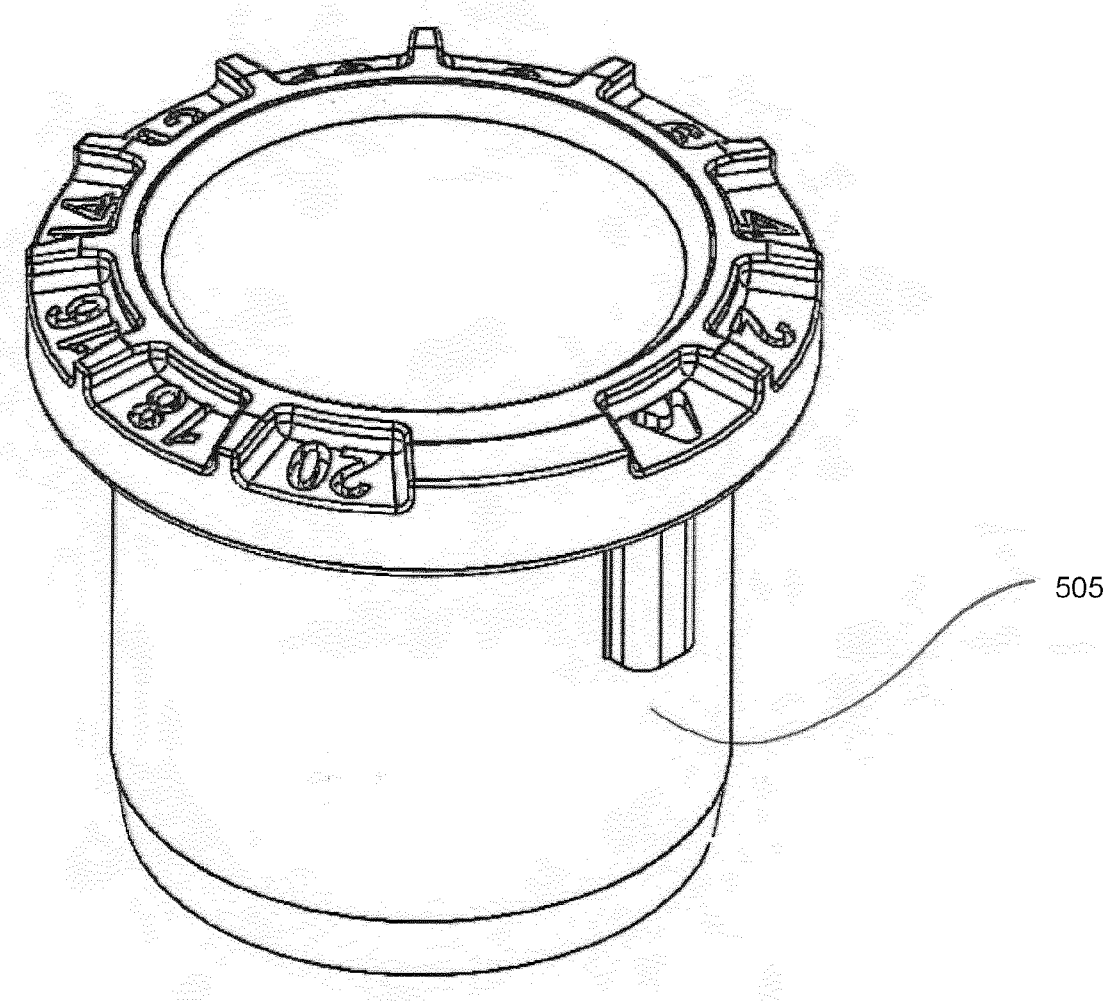

Fig. 4b

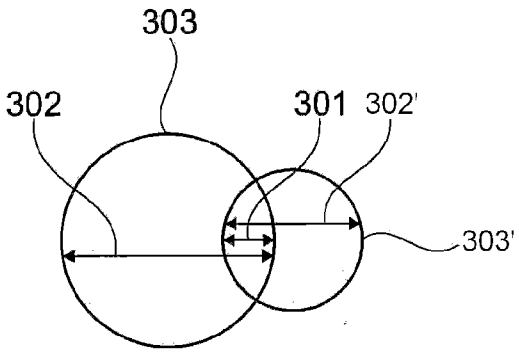

Fig. 5

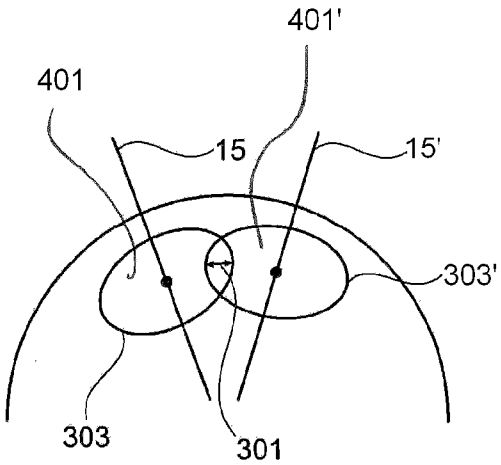

Fig. 6

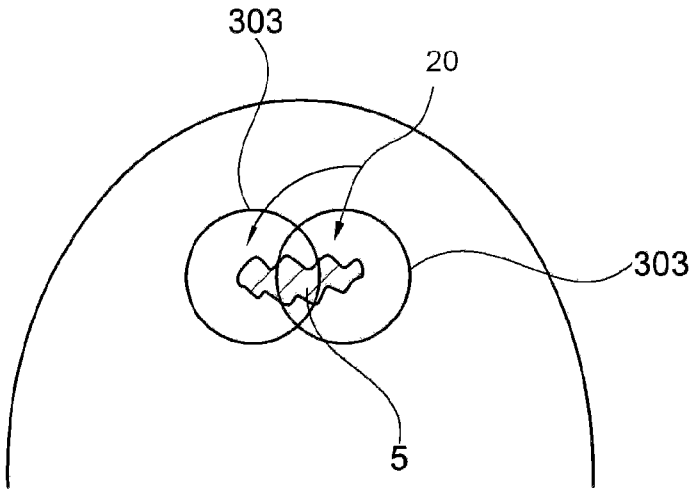

Fig. 7

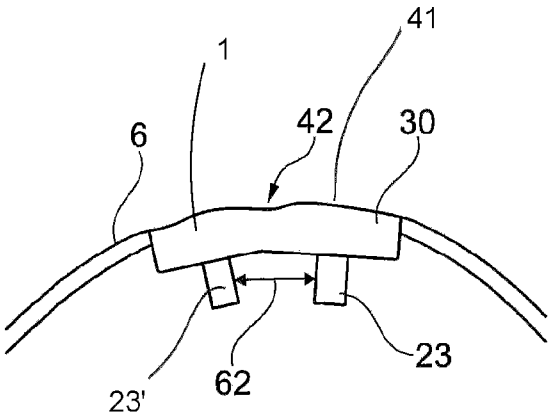

Fig. 8a

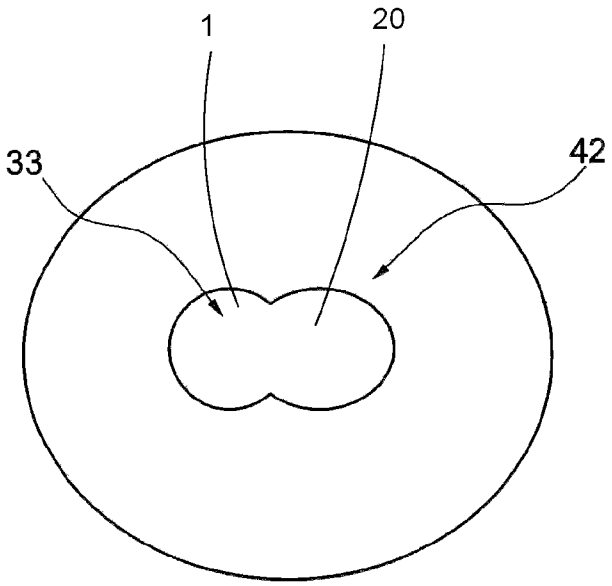

Fig. 8b

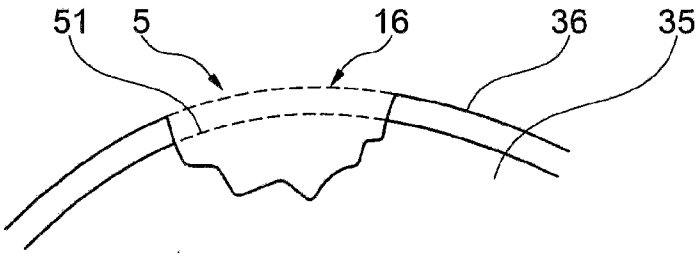

Fig. 9

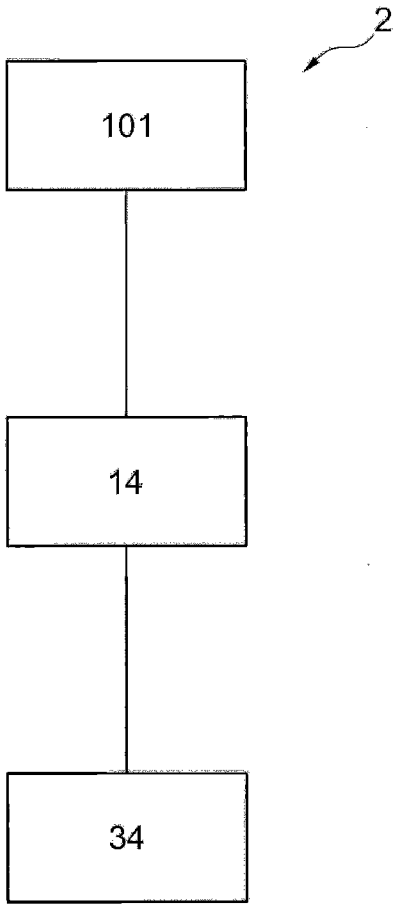

Fig. 10

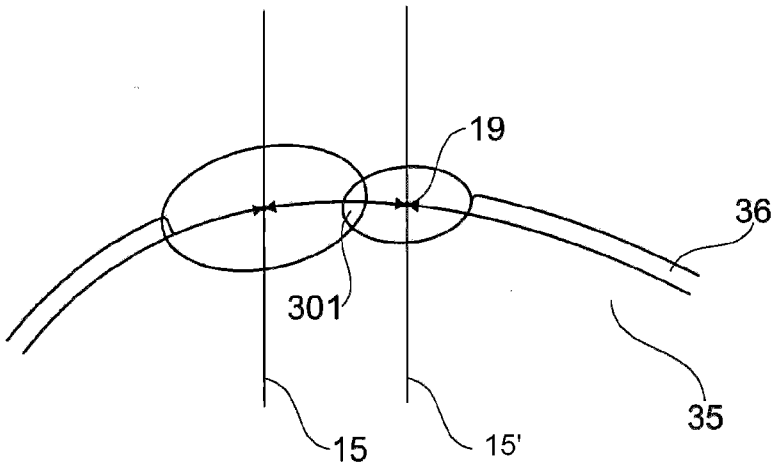

Fig. 11a

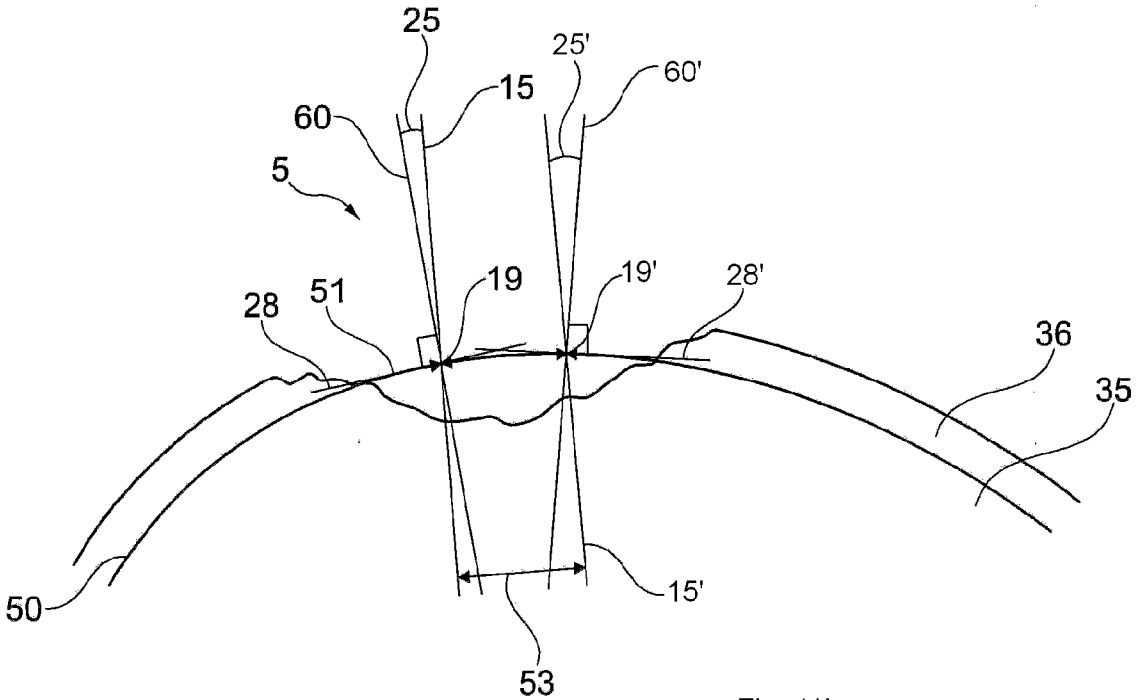

Fig. 11b

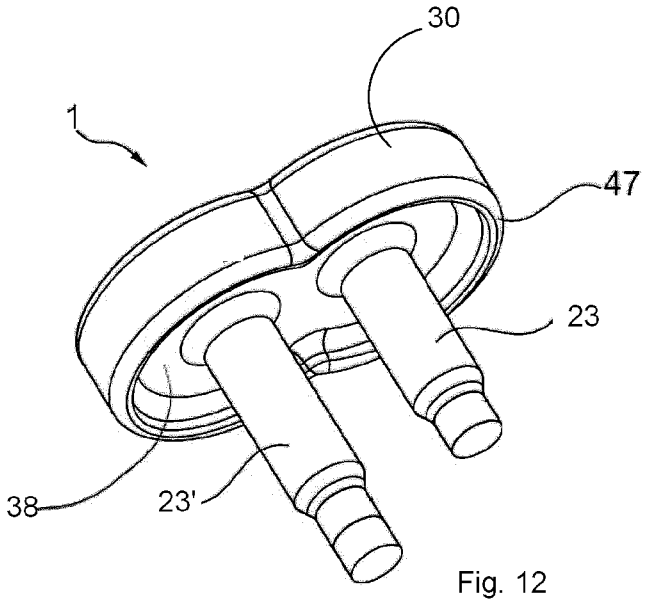

Fig. 12

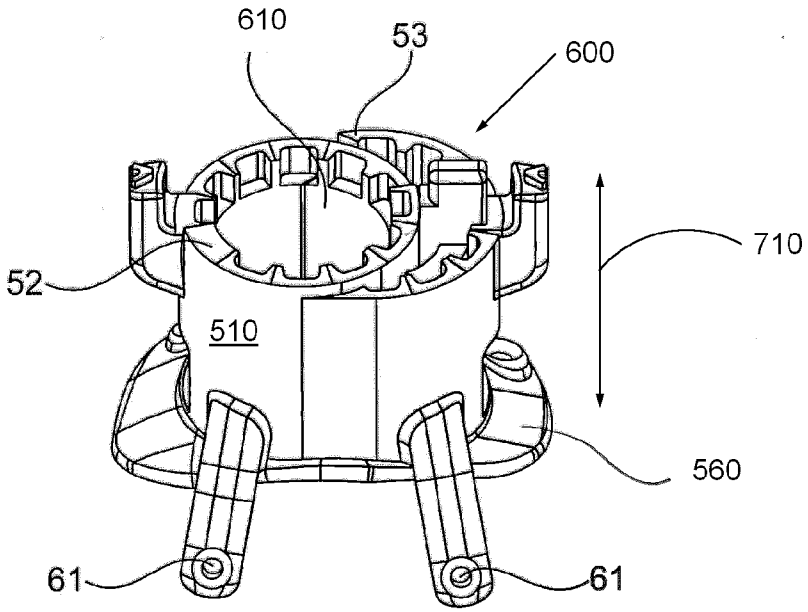

Fig. 13

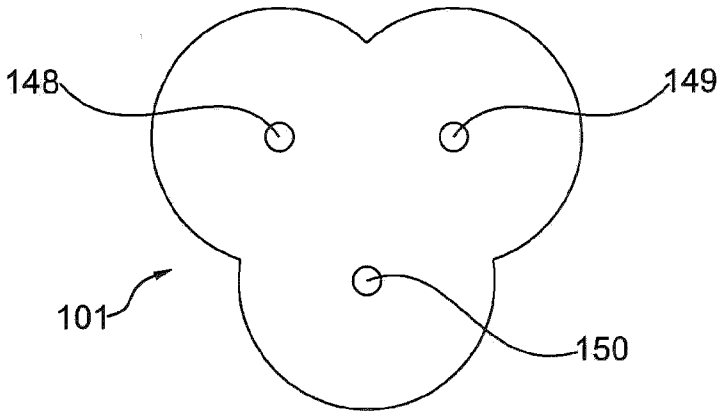

Fig. 14a

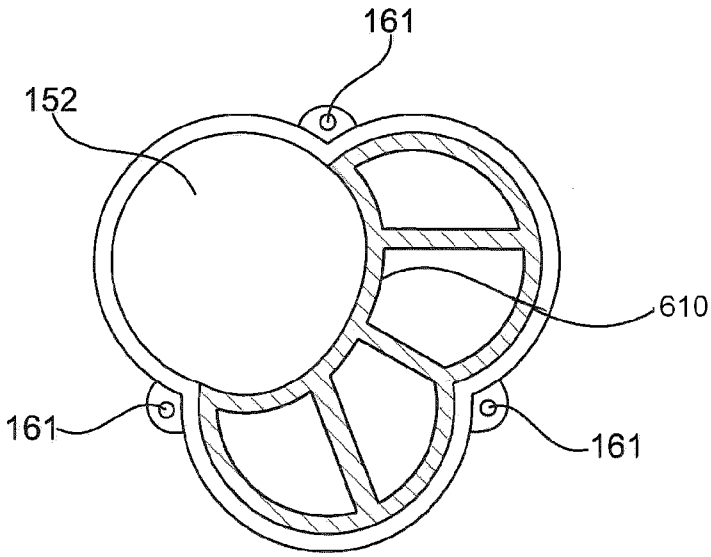

Fig. 14b

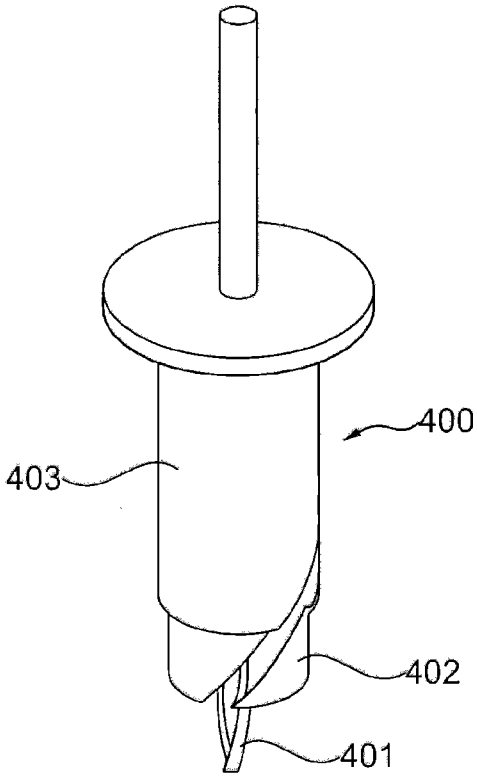

Fig. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2014/064765

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
because they relate to subject matter not required to be searched by this Authority, namely:

Claim 23 relates to subject-matter covered by the provisions of Rule 39.1(iv) PCT (Method for treatment of the human or animal body by surgery). Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim which is also not searched.

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:

see additional sheet

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. [X] 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.:

1-22, 24

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.

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/064765

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/17 A61B19/00 A61F2/30 A61F2/46
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 A61F

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	US 2012/209278 A1 (RIES MICHAEL [US] ET AL) 16 August 2012 (2012-08-16)	22
A	paragraphs [0042], [0068] - [0071]; figures 5-6D,12	1
A	EP 2 389 905 A1 (EPISURF MEDICAL AB [SE]) 30 November 2011 (2011-11-30) paragraphs [0012] - [0015], [0034] - [0036]; figures 1,4a,4b,11	1
X	WO 94/09730 A1 (SMITH & NEPHEW RICHARDS INC [US]) 11 May 1994 (1994-05-11)	22,24
A	page 7, line 13 - page 8, line 11; figures 1-4	1

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 February 2015	05/03/2015

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	Fourcade, Olivier

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2014/064765

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2009/108591 A1 (SCHWARTZ BIOMEDICAL LLC [US]; SCHWARTZ HERBERT E [US]; PROCH FRANCIS S) 3 September 2009 (2009-09-03) paragraphs [0094] - [0098]; figures 17-32 -----	1
X	EP 2 514 373 A1 (EPISURF MEDICAL AB [SE] EPISURF IP MAN AB [SE]) 24 October 2012 (2012-10-24) paragraphs [0036], [0048], [0049]; figures 1-3,7,8 -----	24

2

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2014/064765

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012209278 A1	16-08-2012	AU 2012218086 A1	11-07-2013
		CA 2824616 A1	23-08-2012
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		WO 2009108591 A1	03-09-2009
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		EP 2699172 A1	26-02-2014
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		US 2014142643 A1	22-05-2014
		WO 2012143531 A1	26-10-2012

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-22

   Design method for designing an individually customized rig having first and second intersecting cylinders, and rig designed according to said method.

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2. claim: 24

   Tool system comprising a rig having first and second guide channels

   ---

3. claim: 25

   Guide tool comprising two guide channels
