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(54) Title: METHOD AND APPARATUS FOR USE IN THE PRODUCTION OF A SURGICAL GUIDE

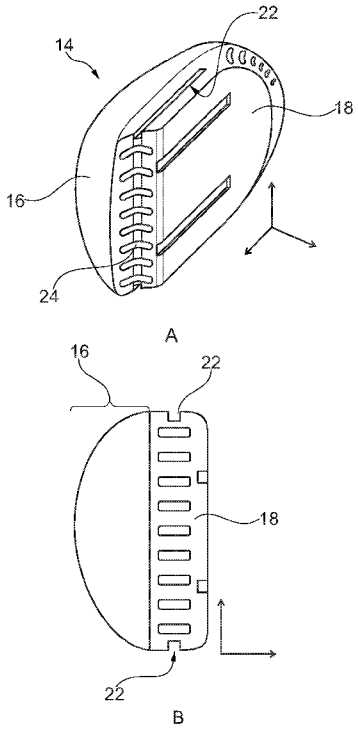

Fig. 2

(57) Abstract: Method and Apparatus for use in the Production of a Surgical Guide A method of producing a modification plan for producing a surgical guide from an impression element (16) includes: obtaining surface data representing a configuration of a surface of an impression element(16) providing an impression of a surgical site; obtaining image data of a patient's anatomy; obtaining surgical plan data providing a surgical plan with respect to features in the image data representing anatomical features of the patient's anatomy; registering the impression element (16) using the surface data and the image data with anatomical features of the patient's anatomy; producing a modification plan from the surgical plan data using the registration of the impression element (16) with anatomical features of the patient's anatomy, the modification plan being a plan for modifying the impression element.

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Method and Apparatus for use in the Production of a Surgical Guide

The present invention relates to a method and apparatus for use in the production of a surgical guide, for example in the intraoperative production of a surgical guide. EP2649951 discloses patient selectable joint arthroplasty devices and surgical tools. US2007/172506 discloses an osteochondral implant procedure. US2008/114368 discloses a method and apparatus for osteochondral autograft transplantation.US2012/179147 discloses an adaptable therapeutic, diagnostic or surgical guide. US2013/119579 and US2013/236874 disclose a method and system for producing at least one patient-specific surgical aid.

Accurate placement is important to the success of many surgical implants and prostheses and guidance devices for use in surgery to overcome this problem have been developed. These systems often take the form of large and bulky robotic guides or navigation systems that must be registered to the patient's anatomy and the pre-operative imaging data. These systems are costly, significantly interrupt the surgeons work flow, require extensive set-up time, extra trained staff and are inconvenient to operate in limited space of the modern operating theatre. These systems require lengthy cleaning procedures and are often complicated to set up with the added risk that their digital nature makes them susceptible to errors whilst guiding the procedure.

Rapid manufacturing/prototyping techniques have been used effectively to produce simple bespoke guides that may be sterilised and brought into the surgical field. Such patient specific instrumentation is used in many surgical specialities such as dentistry, maxillofacial surgery and orthopaedics in particular. These guides have been shown to be useful in many different procedures as their bespoke nature allows them to be created to fit specifically onto a particular piece of anatomy in a similar manner to a jigsaw piece fitting a specific location. These guides, may, for example, be produced with holes or cutting slots to facilitate the guidance of surgical tools such as a drill during the procedure.

The present invention seeks to provide an improved method and apparatus for use in the production of a surgical guide.

According to an aspect of the invention, there is provided a method of producing a modification plan for producing a surgical guide from an impression element, the method including:

obtaining surface data representing a configuration of a surface of an impression element providing an impression of a surgical site;

obtaining image data of a patient's anatomy;

obtaining surgical plan data providing a surgical plan with respect to features in the image data representing anatomical features of the patient's anatomy;

registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy;

producing a modification plan from the surgical plan data using the registration of the impression element with anatomical features of the patient's anatomy, the modification plan being a plan for modifying the impression element. In embodiments, the modification plan is in accordance with the surgical plan data, that is to say that the modification plan is derived from the surgical plan data to enable a guide produced with the modification plan to guide surgery in accordance with the surgical plan.

In embodiments, the surgical site may be an operatively exposed surgical site. The modification plan is a plan of how to modify the impression element to produce a surgical guide. In embodiments, the modification plan is a structural modification plan of how to structurally modify the impression element. In embodiments, the modification plan is a tooling plan, a tooling plan being a plan of how to tool the impression element. However, in other embodiments, the modification plan is a plan of how to mark the impression element for example with guiding marks for subsequent cutting by hand. Tooling can include cutting or any

other method of creating an opening, such as a gap or a hole, in the impression element, such as by cutting, drilling, milling etc.

In embodiments, the image data of the patient's anatomy includes image data of anatomical features in the vicinity of the surgical site. Generally, the image data is captured before the surgical site is exposed and therefore does not include image data directly relating to the exposure of the surgical site. The image data generally does not include the entirety of the patient's anatomy.

In embodiments, the surgical plan is an electronic plan made, with reference to features of the image data which represent anatomical features of the patient's anatomy, defining how surgical interventions are to be made.

As will be understood by one skilled in the art, registering two elements together includes calibrating how the features of one relate to the features of the other, for example by determining the configuration of both elements within a common coordinate system or frame of reference. For physical elements this is in general done by correlating data representing each element. Registration can be considered to provide a relative position.

In embodiments, the impression element is registered directly with anatomical features, meaning it is not necessary for a reference marker to be inserted before the image data is captured.

In embodiments, registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy includes identifying, for a plurality of points on the surface of the impression element, a corresponding plurality of points on anatomical features of the patient, wherein a corresponding plurality of points on anatomical features of the patient are the plurality of points of the surgical site adjacent to the plurality of points on the impression element when the impression element is in place at the surgical site.

In embodiments, registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy includes registering the surface data with features in the image data which represent anatomical features of the patient's anatomy.

In embodiments, registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy includes identifying, for a plurality of points in the surface data representing points on the surface of the impression element, a plurality of points in the image data which represent corresponding points on anatomical features of the patient.

In embodiments, a registration of an impression element with another object can include a determination of a relative position of a plurality of points on the surface of the impression element with respect to the other object.

In embodiments, the impression element is a moulded element, preferably moulded by being placed against the surgical site.

In some embodiments, the modification plan includes instructions for operating a production apparatus to modify or to guide modification of the impression element.

In some embodiments, the instructions can be for presentation to a user to allow the user to operate the production apparatus.

In embodiments, producing the modification plan includes producing a plan defined with respect to features of the surface data, representing features of the impression element. In other words, in such embodiments, the surgical plan defined with respect to features of the image data is converted to a plan defined with respect to features of the surface data using the registration of the surface

data with features in the image data. This plan can be used to produce the instructions.

The instructions can be modification instructions, or they can be instructions to position a modification guide to guide an external modification tool.

In some embodiments, the method includes registering the impression element with the production apparatus using the surface data, the production apparatus including a modification tool for modifying the impression element or a modification guide for guiding a modification tool;

wherein producing instructions includes producing instructions based on a calibrated position of the modification tool or modification guide and the registration of the impression element with the production apparatus.

In embodiments, by registering the impression element with the production apparatus, the position of the impression element with respect to the production apparatus, for example in a receptor assembly, is calibrated. Therefore, desired modifications defined with respect to the impression element can be converted into modifications defined with respect to the production apparatus. By having the position of the modification tool or modification guide of the production apparatus calibrated, these modifications defined with respect to the production apparatus can be converted into instructions for the production apparatus, for example operation instructions defining how to operate the modification tool to make the desired modifications to the impression element, or instructions defining how to position the modification guide to enable such desired modifications to be made.

In embodiments, registering the impression element with the production apparatus includes registering the surface data with data representing a structure of the production apparatus. Producing instructions can include converting a plan defined with respect to features of the surface data into a plan defined with respect to data representing a structure of the production apparatus by using the registration of

the surface data with data representing a structure of the production apparatus. Using the calibration of the position of the modification tool or modification guide, this can be converted into instructions for use of the modification tool or modification guide, such as operation instructions governing the operation of the modification tool or modification guide.

In some embodiments, registering the impression element with the production apparatus uses data representing a relative position of a surface configuration recorder with respect to the production apparatus. In other embodiments, this registration can use a predetermined relative position with respect to the production apparatus of a feature in the surface data, for example surface data representing a reference element of a carrier.

The instructions can include instructions concerning how to move the impression element and/or modification guide and/or how to operate the modification tool.

The instructions provide how to modify the impression element, or how to guide modification of the impression element, to produce a guide to guide surgery according to the surgical plan.

In some embodiments, the method includes registering the impression element with a carrier carrying the impression element using the surface data.

In embodiments, registering the impression element with a carrier includes using a calibration of a position of the carrier during the recording of the surface data for example with respect to the production apparatus. In some embodiments, the production apparatus can include a receptor assembly configured to hold the carrier in a predetermined relative position during the recording of the surface data and during modification of the impression element. In other embodiments, the surface data can include data representing a reference element of the carrier.

The carrier can have a predetermined configuration.

In embodiments, registering the impression element with a carrier includes registering the surface data with data representing a structure or configuration of the carrier.

In some embodiments, obtaining surface data includes operating a scanner to scan the surface of the impression element.

In other embodiments the surface data can be obtained by touching a digitiser arm against a plurality of points on the surface of the impression element.

Where the surface data is obtained from a scanner, the surface data can include data representing distance from the scanner to a plurality of points on the surface of the impression element.

Preferably, the scanner is an optical scanner since this is a very precise way of scanning, and offers considerably greater precision than for example CT scans.

According to an aspect of the invention, there is provided a method of producing a surgical guide, including:

producing a modification plan as above, wherein obtaining surface data includes operating a surface configuration recorder to obtain the surface data; and

modifying the impression element in accordance with the modification plan.

Preferably, the surface configuration recorder is a scanner.

Preferably, modifying the impression element in accordance with the modification plan includes operating a production apparatus to modify the impression element, or to guide modification of the impression element, in accordance with the modification plan to produce the surgical guide.

In embodiments, operating the production apparatus is in accordance with the instructions discussed above.

Preferably, operating the production apparatus includes operating a modification tool of the production apparatus, operating a modification tool preferably including one or more of cutting, drilling and milling.

In other embodiments, operating the production apparatus can include operating a modification guide.

The method preferably includes placing a mouldable element against the surgical site to form the impression element.

According to an aspect of the invention, there is provided a mouldable element for use in surgery, including:

mouldable material for being placed against a surgical site to form an impression of that site; and

a reference element coupled to the mouldable material for allowing a configuration of a surface of the mouldable material to be recorded with respect to a known point of reference.

The mouldable element preferably includes a carrier for carrying the mouldable material, the carrier including the reference element.

The reference element preferably includes a coupling element for coupling the carrier to a production apparatus in a predetermined position.

The carrier can include an identification element, the identification element optionally identifying a particular patient or a particular surgical procedure with which the mouldable element is to be used.

In some embodiments, the carrier includes a body and at least one registration arm extending from the body, the at least one registration arm being fixed with respect to the body, the at least one registration arm being operable to register contact with bone whereby to assist registration of the mouldable element with anatomical features of a patient by providing information relating to a position of bone with respect to the body of the carrier when the carrier is in place at a surgical site.

In some embodiments, the carrier includes a coupling element for coupling to a guiding element for guiding a surgical component to interact with a surgical site.

In some embodiments, the carrier includes a guiding element for guiding a surgical component to interact with a surgical site.

In some embodiments, the carrier includes a body and the guiding element is provided on an arm extending from the body.

In some embodiments, the guiding element is fixed with respect to the body.

The guiding element is preferably selectively configurable.

In some embodiments, the guiding element can be selectively configured into any one of a plurality of different configurations, for example the guiding element can be or can include a component which can be aligned in any one of a plurality of orientations, and/or positioned in any one of a plurality of positions.

Preferably, the guiding element includes a surgical tool for being guided by the respective guiding element.

In some embodiments, the guiding element includes a screw guide for guiding a screw to be screwed into a surgical site, the screw guide enabling registration of a screw screwed into a surgical site with anatomical features of a patient.

In some embodiments, the mouldable material includes a first surface designed to receive an impression of a surgical site and to be scanned, and wherein the reference element includes a projection projecting laterally beyond a side of the first surface whereby to be included in a scan of the first surface.

In some embodiments, the reference element can include one or more arms extending from the carrier. Having both the first surface and the reference element recorded means that the configuration of the first surface can be determined with respect to the reference element.

In some embodiments, the mouldable material includes an outer layer of thermoplastic material and an inner layer of permanently deformable material.

The thermoplastic material preferably has a transition temperature below a tissue damaging threshold.

According to an aspect of the invention, there is provided a surgical guide or jig including a mouldable element as above having been moulded to form an impression of a surgical site to provide a tissue fitting surface, and modified, preferably cut, drilled, or prepared, to provide a guide for a surgical tool.

According to an aspect of the invention, there is provided an impression element holder, including:

a first coupling element for coupling the holder into a production apparatus in a predetermined position;

a second coupling element for coupling an impression element into the holder in a predetermined position;

a receiving zone for receiving an impression element coupled to the second coupling element without contact with a production apparatus coupled to the first coupling element.

The impression element holder preferably includes an open side to allow an impression element held within the holder to be optically scanned.

According to an aspect of the invention, there is provided a production apparatus for the production of a surgical guide, including:

a receptor assembly having received therein an impression element conforming to a shape of a surgical site; and

a modification tool for modifying the impression element or a modification guide for guiding a modification tool; wherein the modification tool or modification guide and the impression element are positionable in a plurality of predetermined relative positions to allow the impression element to be modified in accordance with a modification plan, wherein a modification plan is a plan for modifying the impression element and is derived from a surgical plan and a registration of the impression element with anatomical features of a patient's anatomy.

According to an aspect of the invention, there is provided a production apparatus for the production of a surgical guide, including:

a receptor assembly for receiving an impression element conforming to a shape of a surgical site;

a surface configuration recorder for recording a configuration of a surface of an impression element received by the receptor assembly to produce surface data for registering that impression element with anatomical features of a patient's anatomy and with the production apparatus; and

a modification tool for modifying an impression element received by the receptor assembly or a modification guide for guiding a modification tool; wherein the modification tool or modification guide and an impression element received by the receptor assembly are positionable in a plurality of predetermined relative

positions to allow an impression element received by the receptor assembly to be modified in accordance with a modification plan, wherein a modification plan is a plan for modifying an impression element and is derived from a surgical plan and a registration of that impression element with anatomical features of a respective patient's anatomy.

Preferably, the surface configuration recorder is a scanner, preferably an optical scanner.

Preferably, the modification tool includes one or more of a cutter for cutting an impression element, a drill for drilling an impression element, a milling component for milling an impression element, a slot saw for sawing, and a marker for marking an impression element.

The apparatus preferably includes:

a processor for determining, from a modification plan and a registration of the apparatus with an impression element received by the receptor assembly, a desired relative position of the modification tool or modification guide with respect to that impression element to enable that impression element to be modified in accordance with that modification plan.

In some embodiments, the processor is operable to obtain a modification plan from an external computing device.

In some embodiments, the processor is operable to obtain patient registration data providing a registration of an impression element received by the receptor assembly with anatomical features of a respective patient's anatomy, wherein the processor is operable to obtain a surgical plan, and wherein the processor is operable to calculate a modification plan from the patient registration data and the surgical plan.

In embodiments, a registration of an impression element with anatomical features of a patient's anatomy includes a registration of surface data representing a configuration of a surface of that impression element with features of image data representing anatomical features of a patient's anatomy. This can include an identification, for a plurality of points in the surface data representing points on the surface of the impression element, with a plurality of points in the image data which represent corresponding points on anatomical features of the patient.

Preferably, the processor is operable to determine how to modify an impression element in accordance with the surgical plan by using the patient registration data to determine how a respective impression element will align with a surgical site, and thereby determining how to modify an impression element in order to provide a configuration at a surgical site that is in accordance with the surgical plan.

Preferably, the processor is operable to determine patient registration data from image data of a patient's anatomy and surface data from the surface configuration recorder.

In some embodiments, the processor is operable to register an impression element received in the receptor assembly with the production apparatus, preferably with the receptor assembly, using surface data from the surface configuration recorder.

The processor can be calibrated with a relative position of the surface configuration recorder, and the modification tool or modification guide.

The processor can be operable to adapt its calibration in response to movement of the surface configuration recorder and/or modification tool and/or modification guide.

The apparatus can include a control unit operable to adjust a relative position of the modification tool or modification guide with respect to an impression element received by the receptor assembly in order to place them in a desired relative position.

The relative position of the modification tool or modification guide with respect to an impression element received by the receptor assembly can be adjusted by adjusting the relative position of the modification tool or modification guide with respect to the receptor assembly, which can include adjusting the position of the modification tool or modification guide and/or the receptor assembly.

The control unit can include the processor. The processor and/or control unit can be configured to perform the method above.

In some embodiments, the control unit is operable to adjust a position of the receptor assembly and/or the modification tool or modification guide to enable modification in accordance with a modification plan.

In some embodiments, the control unit is operable to control the modification tool to modify an impression element received by the receptor assembly in accordance with a respective modification plan.

In some embodiments, the control unit is calibrated with relative positions of the surface configuration recorder and of the modification tool or modification guide and optionally of the receptor assembly.

In some embodiments, the control unit is operable to adapt its calibration in response to movement of the surface configuration recorder and/or receptor assembly and/or modification tool and/or modification guide.

Preferably, the control unit is operable to obtain spatial registration data providing a registration of an impression element received by the receptor assembly with the apparatus, and wherein the control unit is operable to control the modification tool to modify a received impression element in accordance with a modification plan using the spatial registration data.

Preferably, the receptor assembly includes a coupling or attachment element to cooperate with a corresponding coupling or attachment element on an impression element.

Preferably, the receptor assembly is configured to receive an impression element holder for holding an impression element without contact with the apparatus to prevent contamination of a received impression element or the apparatus.

In embodiments, the modification tool can releasably hold a tool element to enable a used tool element to be substituted for a new sterile tool element.

The tool element can for example be a cutting element for a cutter, a drill bit for a drill, a milling component head for a milling component, a marker element for a marker, or a saw element for a saw.

The apparatus can include a motor for moving the modification tool or modification guide.

The apparatus can include a motor for moving the receptor assembly.

According to an aspect of the invention, there is provided a method including:

obtaining from a surface configuration recorder surface data representing a configuration of a surface of an impression element providing an impression of a surgical site;

obtaining data relating to a relative position of a location for the guiding element with respect to the surface;

obtaining image data of a patient's anatomy;

registering the impression element with the location for the guiding element using the surface data and the data relating to the relative position of the location for the guiding element with respect to the surface;

registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy;

registering the guiding element with anatomical features of the patient's anatomy using the registration of the impression element with anatomical features of the patient's anatomy and the registration of the impression element with the location for the guiding element.

The guiding element can be at the location for the guiding element during recordal, or the guiding element may have been removed before recordal of the surface data.

The data relating to a relative position of the location for the guiding element with respect to the surface can include data relating to a relative position of the location for the guiding element with respect to the surface configuration recorder.

The data relating to a relative position of the location for the guiding element with respect to the surface can include data identifying features in the surface data representing the location of the guiding element or it can include data identifying features in the surface data representing a reference marker and data providing a relative position of the location for the guiding element with respect to the reference marker. In other words, obtaining data relating to a relative position of the location for the guiding element with respect to the surface can include determining from the surface data a relative position of a reference marker and/or the location of the guiding element with respect to the surface.

In some embodiments, the data relating to a relative position of the location for the guiding element with respect to the surface includes data relating to a relative position, during the recordal of the surface data, of the surface and a carrier carrying the impression element, wherein the carrier includes or can receive the guiding element; and wherein registering the impression element with the guiding element includes registering the impression element with the carrier using the surface data and the data relating to the relative position of the surface and the carrier.

In some embodiments, obtaining data relating to a relative position of the surface and the carrier includes determining from the surface data a relative position of a reference element of the carrier with respect to the surface.

In some embodiments, the guiding element is configurable, and the method includes:

obtaining surgical plan data providing a surgical plan with respect to features in the image data representing anatomical features of the patient's anatomy;

determining a configuration for the guiding element from the surgical plan data using the registration of the location for the guiding element with anatomical features of the patient's anatomy.

In some embodiments, registering the guiding element with anatomical features of the patient's anatomy includes registering data relating to each of the plurality of configurations of the guiding element with features in the image data representing anatomical features.

The method can include configuring the guiding element in accordance with the determined configuration.

The method can include guiding the surgical component using the guiding element to perform a surgical interaction with the patient.

According to an aspect of the invention, there is provided a method of registering a guiding element with a patient's anatomy, the method including:

obtaining from a surface configuration recorder surface data representing a configuration of a surface of an impression element providing an impression of a surgical site;

obtaining data relating to a relative position during the recordal of the surface data of the surface configuration recorder and a carrier carrying the impression element, wherein the carrier includes or can receive a guiding element for guiding a surgical component;

obtaining image data of a patient's anatomy;

registering the impression element with the carrier using the surface data and the data relating to the relative position of the surface configuration recorder and the carrier;

registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy;

registering the guiding element with anatomical features of the patient's anatomy using the registration of the impression element with anatomical features of the patient's anatomy and the registration of the impression element with the carrier.

In embodiments, registering the impression element with the carrier includes registering the surface data with data relating to a structure or configuration of the carrier.

In some embodiments, registering the guiding element with anatomical features of the patient's anatomy uses data relating to a position of the guiding element, for example with respect to the carrier.

In embodiments, registering the guiding element with anatomical features of the patient's anatomy includes registering data relating to a structure of the guiding element with features of the image data representing anatomical features.

Preferably, the guiding element is configurable, and the method includes:

obtaining surgical plan data providing a surgical plan with respect to features in the image data representing anatomical features of the patient's anatomy;

determining a configuration for the guiding element from the surgical plan data using the registration of the impression element with anatomical features of the patient's anatomy.

In some embodiments, registering the guiding element with anatomical features of the patient's anatomy uses data relating to a position with respect to the carrier when the guiding element is coupled to the carrier of those parts of the guiding element that are fixed with respect to the carrier when the guiding element is coupled to the carrier.

In other embodiments, registering the guiding element with anatomical features of the patient's anatomy uses data relating to each of the plurality of configurations of the guiding element with respect to the carrier when the guiding element is coupled to the carrier.

The method can include configuring the guiding element in accordance with the determined configuration.

In embodiments, the configuration for the guiding element is determined in accordance with the surgical plan data, that is to say that the configuration is derived from the surgical plan data to enable the guiding element to guide surgery in accordance with the surgical plan.

In some embodiments, the surgical component can be a surgical tool and the guiding element can include the surgical tool that the guiding element is configured to guide to enable surgery to be carried out in accordance with the surgical plan.

In embodiments, obtaining data relating to a relative position during the recordal of the surface data of the surface configuration recorder and the carrier includes determining from the surface data a relative position of a reference element of the carrier with respect to the surface or surface configuration recorder.

In embodiments, the reference element has a known position with respect to the carrier as a whole, and the position of the carrier with respect to the surface or surface configuration recorder can thereby be determined.

The method can include guiding the surgical component using the guiding element to perform a surgical interaction with the patient.

In one embodiment, a surgical screw or other marker can be attached to the patient's anatomy using the guiding element, and that marker will be registered to anatomical features of the patient's anatomy, thereby enabling that marker to be used as a reference point for surgical navigation or guidance.

According to an aspect of the invention, there is provided a registration apparatus for use in the registration of a guiding element with a patient's anatomy, including:

a receptor assembly including a coupling element for coupling to a coupling element on a carrier for an impression element whereby to hold a carrier for an impression element in a predetermined position; and

a surface configuration recorder for recording a configuration on a surface of an impression element carried by a carrier received by the receptor assembly to produce surface data for registering that impression element with anatomical features of a patient's anatomy and with that carrier and thereby for registering that carrier with anatomical features of a patient's anatomy.

According to an aspect of the invention, there is provided a kit for producing a surgical guide, including:

an apparatus as above; and

at least one impression element being a mouldable element as above.

According to an aspect of the invention, there is provided a kit for producing a surgical guide, including:

an apparatus as above; and

mouldable material for placing against a surgical site to form an impression element.

The kit preferably includes at least one carrier for being attached to the or a part of the mouldable material to carry the mouldable material.

According to an aspect of the invention, there is provided a computer program for performing the method above when executed on a computing device.

According to an aspect of the invention, there is provided a programmable guiding element for guiding a surgical intervention, including:

a coupling element for coupling the guiding element to a carrier for an impression element; and

a tool guide selectively configurable in any one of a plurality of configurations for guiding a tool to make a surgical intervention, wherein each of the plurality of configurations provides the tool guide in a different predetermined position with respect to the coupling element.

The guiding element can include a surgical tool to be guided by the tool guide.

According to an aspect of the invention, there is provided a method including:

obtaining surface data representing a configuration of a surface of an impression element providing an impression of a surgical site;

obtaining image data of a patient's anatomy; and

registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy.

In some embodiments, the carrier may be used to temporarily attach the impression element to other surgical tools such that the impression element may be moulded to surgical anatomy in difficult to reach places for example.

In some embodiments, a mouldable material can be placed in a surgical site in order to form an impression of that site. The material can then be placed in an apparatus which can scan the impressed surface of the mouldable material. The apparatus is calibrated so that it can spatially register the scan with the apparatus. For example, the mouldable material can be attached to a carrier component and the material can be placed in the apparatus by connecting an attachment element on the carrier component to a corresponding element in the apparatus so that the material is in a precalibrated location within the apparatus. The scanner can also be in a predetermined calibrated position within the apparatus enabling a determination from the scan of the position of the material with respect to carrier component and hence with respect to the rest of the apparatus. Using the fact that the material is known to fit against a surgical site, the scanned material can be spatially registered with image data of the patient. A surgical plan which dictates how surgery at the surgical site should proceed can then be converted into a plan as to how to modify, for example cut, the material to form a guide to guide the surgery. The apparatus can either serve as a marker to mark or guide modification, for example cutting, of the material, or it can itself modify the material in accordance with the modification plan. The modified material, when placed back into the surgical site, will thus act as a surgical guide.

It is to be appreciated that certain embodiments of the invention as discussed herein may be incorporated as code (e.g., a software algorithm or program) residing in firmware and/or on computer useable medium having control logic for enabling execution on a computer system having a computer processor. Such a computer system typically includes memory storage configured to provide output from execution of the code which configures a processor in accordance with the execution. The code can be arranged as firmware or software, and can be organized as a set of modules such as discrete code modules, function calls, procedure calls or objects in an object-oriented programming environment. If implemented using modules, the code can comprise a single module or a plurality of modules that operate in cooperation with one another.

Previously, guides produced by rapid manufacturing/prototyping techniques have been time consuming to produce with long manufacturing times and logistics chains, often needing post production processing. Commercial 3D printing equipment is expensive and each printed guide had to be individually sterilised. The guides had to be produced in advance of the surgery and thus were unable to be modified once the operation had commenced if they were found to be problematic or the parameters of the operation were changed.

In contrast, in preferred embodiments of the invention, guides can be produced intraoperatively directly from an impression of the surgical site, thereby minimising manufacturing time and logistics chains, removing the expense of 3D printing equipment, and enabling custom guides to be manufactured or modified during surgery in accordance with the desired procedure.

Preferred embodiments use a surgical navigation registration technique and associated apparatus for the intraoperative manufacture of a bespoke guide to facilitate the placement, operation or use, of a surgical tool, implant or accessory. Embodiments of the invention herein described can provide a cost effective system capable of producing patient specific surgical guides with minimal

production time. Bespoke guides may be produced intraoperatively without extended set up time, cleaning or interruption to the surgical workflow.

Embodiments of the invention are described below, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a diagram showing a planned placement for a guide wire in a scapula;
Figure 2A and 2B are, respectively, a perspective and side view of a guide blank according to an embodiment of the invention;

Figure 3 is a perspective view of a production apparatus according to an embodiment of the invention;

Figure 4 is a perspective view of a receptor assembly and modification tool for the production apparatus of Figure 3;

Figure 5 is an exploded view showing the insertion of the guide blank of Figure 2 into the production apparatus of Figure 3;

Figure 6 is a diagrammatic flow chart showing the use of the guide blank of Figure 2 to take an impression of a surgical site;

Figure 7 is a side view showing a guide made from the guide blank of Figure 2;

Figure 8 shows a guide blank according to another embodiment of the invention being placed against a surgical site;

Figure 9A shows a guide blank according to an embodiment of the invention;

Figure 9B shows the guide blank of Figure 9A subject to a deforming force;

Figure 10 shows the production of a guide blank according to another embodiment of the invention;

Figure 11 shows a surgical plan being constructed;

Figure 12 shows a guide blank holder and a carrier according to an embodiment of the invention;

Figure 13 shows a production apparatus according to an embodiment of the invention;

Figure 14 shows an internal view of the production apparatus of Figure 13;

Figure 15 shows the carrier of Figure 12 with a mouldable element in place on a model of a scapula;

Figure 16 shows the guide blank holder and carrier of Figure 12 in the receptor assembly of the production apparatus of Figures 13 to 15;

Figure 17 shows another view of the arrangement of Figure 16;

Figure 18 shows a carrier according to an embodiment of the invention;

Figure 19 shows a guiding element according to an embodiment of the invention; and

Figure 20 shows a guiding element according to an embodiment of the invention.

It is to be noted that the drawings are schematic only and not to scale.

Embodiments are described below within the framework of the total shoulder arthroplasty procedure, with specific focus on a method for orientating the glenoid component of the prosthesis within the glenoid cavity of the scapula 10 as shown in Figure 1. However, embodiments of the invention can also be used for other surgical procedures, for example for different parts of the human body including dental surgery, or for the body of a different animal, and/or with different guiding structures, as described in more detail below.

As commonly practiced in many surgical fields; once preoperative imaging data such as an MRI or CT scan has been obtained, a surgeon may pre-operatively digitally plan the procedure to be performed using software planning tools. Such software will produce a prescription for the procedure. For the purposes of this description, it is assumed that such a prescription in the form of a suitable digital plan (**DP**) defines the placement of a guide wire 12 into the glenoid cavity of the scapula 10. However, as mentioned above, in other embodiments, a digital plan may define various other surgical interventions to be made. The digital plan defines a surgical procedure with respect to features in the pre-operative imaging data representing anatomical features of the patient.

In total shoulder arthroplasty, the guide wire is a commonly used piece of hardware that is drilled into bone to define the axis and location of a hole that will be drilled into the glenoid in order to affix the glenoid component of the joint prosthesis into place. Once in position, the guide wire is drilled over with a cannulated drill bit and removed to create the hole for the implant stalk. In this way the axis and position of the implant stalk is consequentially defined.

In the embodiment of Figures 2 to 7, a guide blank 14 is provided including a modifiable or mouldable element 16, and a rigid carrier 18 for carrying the mouldable element 16.

The guide blank 14 can also be referred to as a registration tool since, as described below, it is registered to a production apparatus and anatomical features of a patient.

As described below, the guide blank 14 is later on in the workflow inserted into and adapted by a production apparatus 20 (shown for example in Fig 3) which is able to modify the guide blank to rapidly form a bespoke guide to facilitate the placement of the aforementioned guide wire 12.

The mouldable element 16 can be a temporarily mouldable element made up, for example, of a material that, once activated, is initially pliable and will eventually harden over time or in the presence of a catalyst or other setting initiator such as a bright light of particular wavelength or exposure to atmospheric air. In other embodiments, the mouldable element can be a non-hardening mouldable material, although this is not preferred since there may be a risk of the mouldable element being undesirably deformed during further processing.

As described above, the mouldable material is contained, retained, and incorporated within the carrier.

The mouldable element can be moulded by being pressed into a surgical site, after which it can be considered to be an impression element, as it will provide an impression of the surgical site.

The carrier 18 includes a coupling arrangement by which the guide blank 14 can be coupled into the production apparatus 20 in a predetermined position.
In the embodiment of Figures 2 to 7, the coupling arrangement includes guides in the form of channels 22 which can receive counterpart guides in the form of ridges in order to couple the guide blank 14 to the production apparatus 20 as described below. In other embodiments, the coupling arrangement can include a clip or other attachment mechanism.

In the embodiment of Figures 2 to 7, the carrier 18 is a standardised component that has features that are compatible with features of the production apparatus 20. By providing the carrier 18 as a standardised component, it can be easy to ensure that it easily fits into a receptor assembly of a production apparatus in a known predetermined position.

The carrier 18 may incorporate additional features such as finger rests, grips 24, or fixings for additional associated instrumentation.

In some embodiments, a variety of sterile pre-packaged guide blanks may be offered, compatible with and reflecting the various sizes of surgical sites that a surgeon may face. For the embodiment of Figures 2 to 7, a guide blank of the appropriate size and shape for the purpose of a shoulder replacement will be selected. In this case, one that is roughly the shape of the average human glenoid cavity.

In the embodiment of Figures 2 to 7, the production apparatus 20 includes the following elements as shown in Figures 3 and 4:

A scanner 26 to create a detailed 3D surface scan of an object. This can for example be an optical 3D scanner.

1. A receptor assembly 28 capable of receiving the guide blank 14.
2. An adjustment mechanism 30 operable to manipulate and orientate the position of the receptor assembly 28 (and thereby also a guide blank received in the receptor assembly) with respect to a modification tool 32.
3. A modification tool 32 capable of independent movement with respect to the receptor assembly 28 (and thereby also with respect to a guide blank received in the receptor assembly) and operable to modify the guide blank 14 when received in the receptor assembly.

4. A control unit 34, such as a microprocessor control unit, designed, suitably connected and powered such that it may control the functioning of the production apparatus 20.
5. A communication element 36, for example with wireless connection capabilities, such that the production apparatus may be given external commands by an operator and obtain data.

However, it is not necessary in all embodiments to have an adjustment mechanism 30; in some embodiments the modification tool can provide the necessary relative movement.

The scanner 26 is arranged to face the receptor assembly 28 thereby to be able to scan the impression element 16 of a guide blank 14 received therein.

The adjustment mechanism is configured to manipulate and orientate the position of the receptor assembly 28 (and thereby also a guide blank received in the receptor assembly) with respect to the scanner 26 to enable the scanner 26 to scan the entire surface of the impression element 16 and in some embodiments to scan at least a part of the carrier 18.

The control unit 34 is calibrated with the relative position of the scanner with respect to at least one reference point. In this embodiment, the receptor assembly provides a reference point although reference points can be provided by any or all parts of the production apparatus. In some embodiments, the receptor assembly does not provide a reference point but is itself calibrated with respect to the one or more reference points.

The control unit 34 can therefore determine from a scan by the scanner the position of the impression element of a guide blank in the receptor assembly with respect to the one or more reference points of the production apparatus, thereby registering the impression element to the production apparatus. In the

embodiment of Figures 2 to 7, because the carrier 18 is a standardised component, that is to say it has a predetermined configuration, and is received only in a predetermined position in the receptor assembly, the entire guide blank, including the carrier, is effectively registered to the production apparatus.

As described above, the control unit 34 is operable to control the position of the receptor assembly 28 using the adjustment mechanism 30, for example to enable the whole of the impression element to be scanned. The control unit is configured to compensate for such movements of the receptor assembly when registering the impression element with the production apparatus.

The control unit is also calibrated with the relative position of the modification tool with respect to the one or more reference points and thereby with respect to the production apparatus. Once the impression element has been registered to the production apparatus, the control unit can therefore also determine the position of the modification tool with respect to the impression element, enabling the control unit to manipulate the modification tool and the adjustment mechanism to make a desired modification to a guide blank.

In some embodiments, as components within the production apparatus move relative to each other, for example as a result of movement of the modification tool or operation of the adjustment mechanism, the control unit 34 is configured to adjust its calibration.

As described above, the modification tool is movable with respect to the receptor assembly. The modification tool can be moved to come into contact with a guide blank in the receptor assembly whereby to modify the guide blank in a controlled manner.

The modification tool can for example include a CNC drill, cutting device or other modifier, depending on the type of modification to be made to the guide blank. In

some embodiments, the modification tool does not structurally modify the guide blank, but simply marks it. In such embodiments, the modification tool can include a marker to mark the guide blank to show where structural modifications should be made, and these structural modifications can be made subsequently by hand. The production apparatus 20 is a sealed self-contained, reusable unit. For this reason, any part of the production apparatus that comes into contact with any material that will touch any human tissue must be easily disposed of and replaced in order to maintain sterility.

As described above, the production apparatus includes the receptor assembly 20 into which the guide blank 14 is able to be attached once it has received an impression of a surgical site as described herein. In this embodiment, the receptor assembly 20 is located centrally within the production apparatus, although other positions are possible.

Once the patient's anatomy has been suitably dissected in the usual fashion to expose the surgical site, in this case the glenoid cavity as shown in Figure 1, the guide blank is used to begin the guidance process.

The aforementioned deformable area of the guide blank 14 – the mouldable element 16 – is suitably activated whilst the guide blank 14 is firmly pressed into the glenoid cavity allowing the deformable surface to mould to the shape and form an impression of the glenoid cavity and any exposed edges. This process can be seen in Figure 6. Position 100 shows the guide blank 14 being pressed into the surgical site to form an impression. As explained below, it is preferable for as much contact as possible between the mouldable area of the guide blank and any bony anatomy that may be safely exposed.

Once the mouldable element 16 has set and become a firm impression element, the guide blank with integral mouldable element, having been moulded to the

shape of the glenoid, may be removed from the surgical field and the next stage of the process may begin.

In order to aid later relocation of the guide blank, provision may be made for screwing or pinning of the guide blank into place, perhaps at the time that the mouldable material is setting.

A guide blank holder 38, which in some embodiments can be referred to as an enclosure lining, is then inserted into the receptor assembly 28 of the production apparatus. The guide blank holder 38 is single use and sterile and includes a guide blank coupling element 40 to couple a guide blank into the guide blank holder 38 in a predetermined relative position so that the guide blank is received in a receiving zone 41 without contact with the production apparatus. In the embodiment of Figures 2 to 7, the guide blank coupling element includes a channel 43 including first and second ridges 42 for coupling to first and second channels on the carrier 18 of a guide blank 14, although other coupling or attachment mechanisms can be used in other embodiments.

The guide blank holder also includes at least one receptor assembly coupling arrangement for coupling the guide blank holder into a holder coupling arrangement of the receptor assembly so that the guide blank holder is held in a predetermined relative position without the guide blank contacting the production apparatus. In the embodiment of Figures 2 to 7, the at least one receptor assembly coupling arrangement includes first and second flanges 44 for being received in a holder coupling arrangement including first and second channels 46 of the receptor assembly.

In the embodiment of Figures 2 to 7, the guide blank holder 38 is a standardised component and the control unit 34 is calibrated with dimensions of the guide blank holder 38 and carrier 18 whereby the control unit 34 is calibrated with the relative position of the carrier 18 and holder 38 with respect to the one or more reference

points, and thereby to the production apparatus, when inserted into the receptor assembly.

The guide blank 14 is inserted into the receptor assembly 28 of the production apparatus 20, in particular into the guide blank holder 38, itself separate from, in the sense of non-integral with and removable from, the production apparatus assembly.

The guide blank 14 is fastened into place in a fixed predetermined position with respect to the receptor assembly as defined by the standardised construction of both the receptor assembly and the guide blank holder. In other words, when inserted into the guide blank holder, the carrier of the guide blank is in a predetermined position with respect to the receptor assembly.

Whilst the surfaces of the receptor assembly are not sterile, the guide blank holder is placed into the aperture by a sterile agent such that when it is affixed within the production apparatus, the surfaces of the guide blank holder not in contact with the production apparatus remain sterile. The guide blank 14 may now be inserted into its corresponding coupling element 40 in the guide blank holder and also remain sterile as shown in Figure 5.

Once the prepared guide blank has been affixed in the above way, the assembly including the production apparatus, guide blank holder and guide blank is now initiated.

The microprocessor control unit 34 of the production apparatus now may wirelessly or otherwise connect via the communication element 36 with one or more computers including the digital plan and the medical imaging data relating to the particular patient such as CT scan data. For example, this may be the computer used by the surgeon to plan the procedure they wish to undertake. The

digital plan or prescription for the operation may be downloaded into the control unit 34 of the production apparatus.

The guide blank 14 is anchored in place within the guide blank holder 38 in the receptor assembly 28 such that the impression element 16 faces towards the aforementioned 3D surface scanner 26 within the production apparatus.
The 3D surface scanner is mounted in a fixed position thus the microprocessor is programmed with an inherent knowledge of the spatial relation between the surface scanner and the position of the receptor assembly containing the guide blank holder and the guide blank.

The surface scanner scans in the direction of the impression element 16 of the guide blank 14, thus forming a 3D surface model of the impression element 16. If required, the receptor assembly may manipulate the guide blank 14 in several axes, with the use of integrated servo motors or otherwise, for example using the adjustment mechanism 30, to maximally expose all surfaces of the impression element to the scanner.

Because the control unit 34 is calibrated with the relative positions of the scanner and the one or more reference points, the control unit 34 can determine the relative position of the impression element with respect to the one or more reference points and can thereby co-register the 3D surface topography of the impression element with the production apparatus. Because in this embodiment the carrier 18 and guide blank holder are standardised components, the control unit 34 can register the impression element with the carrier and with the guide blank holder. The control unit can also register the impression element with the receptor assembly within the production apparatus.

This co-registration is facilitated by the interposition of 3D data from the scanner alongside the pre-determined geometry of the carrier, guide blank holder and production apparatus assembly with respect to the 3D scanner. This process may

be further explained if the impression element were to be removed from the guide blank such that only the carrier 18 were to remain affixed within the guide blank holder within the production apparatus; the scanner would produce 3D data identical to its pre-programmed 'knowledge' of the geometry within the production apparatus regardless of the spatial configuration of the assembly. If the impression element is now added, the scan will produce data with a 'body' – the impression element, obscuring the aforementioned 'standard geometry picture' that would have been seen from the point of view of the 3D scanner. The distance from the scanner surface to all points of the impression element surface will inherently be calculable thus this data may be used to produce a virtual model 'within' the production apparatus processor, of the position and shape of the impression element surface with respect to the carrier of the guide blank, the guide blank holder and the production apparatus aperture assembly; thus spatially registering all geometry.

To be surgically useful, all components must now be co-registered with anatomical features of patient anatomy as defined by pre-operative image data. A computer program is executed either on an associated computer or the inbuilt processor within the production apparatus. This program analyses the 3D scan data of the impression element and compares it to the imported CT scan data in the following way. It is given that the majority of the impression element will be the impression caused by pressing the impression element to the native bony anatomy within the surgical field; in the case of this embodiment, that of the glenoid cavity (Fig 1) surface. An individual's bony anatomy is unique is shape, in addition to this, wear and tear has often removed the majority of the cartilage from the surface of the joint and osteoarthritis has deformed the surface into a topographically unique geometry. In the case of the total shoulder arthroplasty (TSA), the glenoid labrum is also removed and the anterior rotator cuff muscles are released, thus exposing the distinct anterior edge of the glenoid. With appropriate commonplace medical imaging software, it is possible to isolate only the bony anatomy from the pre-operative imaging data and produce a virtual 3D model. The program then runs an

algorithm that matches the scanned surface of the impression element, with the corresponding anatomy obtained from the processed pre-operative imaging data. Advantageously, the initial pre-operative imaging of the patient can be done before the surgery begins, possibly days or weeks before. Some portion of any impression on the impression element caused by bony anatomy from the surgical field will have a matching topographical area on the pre-operative imaging data. The algorithm identifies these matching sites over as large an area as possible. For the purposes of this embodiment, it is assumed that this process may be externally assisted if, for example, the operator virtually 'colours-in', or otherwise indicates, specific areas on the virtual bony anatomy model, from which they will plan the case, that they are sure will form at least a part of the impression element surface. For example, at the time of surgery, the surgeon may roughly colour in these corresponding areas on the moulded surface of the impression element with a sterile marker pen. This will assist the algorithm as it will roughly highlight areas that should be near-by each other if it is imagined that the impression element could be brought together with 'virtual' 3D model of the patient's anatomy. 'Registration' algorithms used to co-register data representing a surface configuration with preoperative imaging data are within the ability of the skilled person and extensively described in the art.

Due to the moulding procedure of the mouldable element**,** the guide blank may only be fitted back into the surgical field in the same position at which it was first moulded as a result of its unique fixed topography. The above algorithm co-registers the impression element with the unique area of anatomy onto which it fits. Through the aforementioned process the impression element has also been co-registered with the carrier, with the guide blank holder, and with the production apparatus. Thus, the guide blank is now precisely positionally defined with respect to the patient anatomy **and** within the production apparatus. Of course, the positional definition of the impression element or guide blank with respect to the patient anatomy defines the position if the impression element were to be placed back at the surgical site, whereas the position definition with respect to the

production apparatus defines the position in the receptor assembly. Put another way, the carrier of the guide blank has been spatially registered with the scanned surface of the impression element but at the same time the impression element has now been registered with the patient anatomy from which it was moulded. The result of this process ensures that if, at this point, the guide blank is placed back into the surgical field in the identical position from whence it was moulded; the software will 'understand' the spatial orientation and position of the carrier and the impression element with respect to the patient anatomy and be able to generate a 3D 'virtual' model of the guide blank in situ on the bony anatomy as illustrated in Figure 6.

Guide creation:

In this embodiment, the above elements have been set up for the purpose of guiding the orientation and position of the axis through which to place a guide wire 12 (Fig 1) to facilitate the correct positioning of the glenoid component of the total shoulder replacement. As previously described, the production apparatus also houses a modification tool, in this embodiment a CNC drill 32 (Fig 3 & Fig 4) situated on the opposite end of the receptor assembly 28 to the 3D scanner assembly 26. The CNC drill 32 may, however, be positioned in any convenient position within the production apparatus. This drilling assembly 32 includes a motor 50 capable of powering a rotating sterile drill bit 48, and apparatus to orientate the position of the drill assembly with respect to the guide blank once the guide blank has been mounted within the guide blank holder within the receptor assembly 28.

The motor assembly 50 is provided with an aperture into which may be fitted the sterile drill bit 48, the sterile drill bit 48 being of diameter just larger then the diameter of the selected guide wire 12. The drill may for example be provided with a quick release assembly. As previously established, the guide blank should remain sterile as it will eventually be placed back into the surgical field. For this reason, every time the apparatus is used on a new patient, a newly sterilised drill

bit 48 is placed into the drilling apparatus 32 of the production apparatus before use. The working shaft of the drill bit 48 remains sterile as it will not come into contact with any other structures other than the sterile guide blank mounted above it.

In this embodiment, the drill assembly 32 is capable of translation in the x and y and Z axis of the plane of the scanner 26 whilst the adjustment mechanism 30 is capable, using a second motor, of rotating the affixed guide blank in the X and Y axis. The herein described method for the movement of the guide blank and modification tool may be substituted for any method of movement used on existing or future devices such as CNC devices. Both the translational movements of the CNC drill 32 and rotation of the receptor assembly 28 may be unpowered in a different embodiment. As an alternative to computer controlled positioning, movement may be controlled via the turning of, for example, a graduated dial in order to position and lock a particular axis into a position specified by a computer. The axis and position through which the surgeon would like to drill into the glenoid cavity to facilitate placement of the glenoid component guide wire is previously specified by the surgeon in the preoperative digital operative prescription or digital plan.

The control unit 34 is configured to use the co-registration of the impression element with anatomical features at the surgical site to convert the digital plan into a plan for the impression element. Effectively, the co-registration of the impression element with anatomical features at the surgical site allows the impression element and anatomical features at the surgical site, and therefore the digital plan, to be expressed in the same frame of reference as if the impression element were in place at the surgical site, and thereby allows the digital plan to be converted into a plan for the impression element. The plan for the impression element indicates how the impression element should be modified to form a guide to comply with the digital plan, so that the guide can guide the surgery according to the digital plan when the guide has been placed back into the surgical site from which the original

impression was taken. For example, in the embodiment of Figures 2 to 7, the plan for the impression element is a plan for a hole 52 through the impression element to accommodate the guide wire 12, as shown in Figure 7.

The control unit is also configured to convert the plan for the impression element into modification instructions, the modification instructions being instructions for the adjustment mechanism 30 and the modification tool 32 in order to modify the guide blank in accordance with the plan for the impression element. The control unit is configured to convert the plan for the impression element into modification instructions using the registration of the impression element with respect to the production apparatus. The control unit can express the impression element, and therefore the plan for the impression element, in the same frame of reference as the production apparatus and can thereby determine modification instructions of how to operate the production apparatus to follow the plan.

The modification instructions provide control instructions to the production apparatus to operate the drilling apparatus and manipulate the position of the guide blank with respect to the drilling apparatus such that a guiding hole may be drilled through the guide blank that satisfies the positional and axial constraints specified in the operative prescription. The aforementioned registration steps ensure that the hole drilled is positionally and axially equivalent to the position of the virtual guide wire with respect to the glenoid from the post-operative plan. Once the control unit has determined the modification and/or control instructions, it operates the production apparatus in accordance with those instructions to modify the guide blank held in the receptor assembly. The guide blank is now a guide and may be removed from the guide blank holder within the production apparatus cavity and placed back into the glenoid cavity in its fixed position as defined by the now solid impression element. If need be, the guide may be secured in place with some accessory pins, alternatively it may be held in place with applied pressure by the surgeon or an assistant. The surgeon may now drill the guide wire 12 through the hole created in the guide as shown in Figure 7, with the knowledge that the

position and orientation at which the guide wire will pass into the glenoid surface will be identical to the pre-operative virtual plan previously specified. Clean passage of the guide wire or surgical drill may be facilitated by previously inserting a suitable sleeve through the prepared hole. Any swarf remaining after the drilling procedure may be washed away before use, alternatively the CNC drill apparatus may be provided with a suction or washer system capable of ensuring no swarf remains at the drilling site.

Once the guide wire insertion process has been completed, the drill may be removed from the end of the fixated guide wire and the guide 14 may be slid off the wire, leaving the guide wire 12 in place, satisfying the pre-determined positional constraints previously laid out by the surgeon in the operative prescription. At this juncture the procedure may now continue as normal, with the knowledge that the glenoid component will be affixed in the optimal orientation possible as defined by the guide wire 12.

Figure 12 shows a guide blank holder 1038 and a carrier 1018 according to an embodiment of the invention.

As can be seen, in this embodiment, the carrier 1018 includes a plateau 1019 which in this embodiment includes a narrow region 1020 and a wide region 1021, with sides of the plateau 1019 tapering from the wide region 1021 to the narrow region 1020, the plateau 1019 having rounded edges.

The plateau 1019 includes a plurality of spikes for receiving and coupling a carrier 1018 to mouldable material.

The carrier 1018 includes a first foot 1023 mounted on the plateau 1019 on the opposite surface from the spikes 1022 in the region of the narrow region 1020, and second and third feet 1024, 1025 mounted on the opposite surface of the plateau 1019 from the spikes 1022 in the region of the wide region 1021.

The first, second and third feet are mounted to legs which depend from the plateau. The first foot 1023 includes a capture element including first and second protrusions joined by a wall 1026 which extends only part the way along the protrusions, so that the protrusions for part of their length are joined by the wall 1026, and for part of their length have a gap between them.

The guide blank holder 1038 includes a perimeter wall 1039 which extends substantially straight along lateral walls and includes a curved front wall 1040 but has an open back, top, and bottom. A lip 1041 extends outwardly from a base of the perimeter wall 1039.

A first retaining element 1042 is attached to the perimeter wall adjacent to the front wall 1040. The first retaining element 1042 includes a recess 1043 into which the first and second protrusions of the first foot 1023 of the carrier 1018 can be placed and an obstruction element 1044 arranged adjacent to the recess 1043 to obstruct the wall 1026 of the carrier 1018 when the foot 1023 of the carrier 1018 is in the recess 1043. The recess 1043 is bordered by a wall. This wall has an opening facing the obstruction element 1044.

The guide blank holder 1038 also includes first and second food rests 1045 disposed so that the second and third feet 1024, 1025 of the carrier 1018 can rest upon them when the first foot 1023 of the carrier 1018 is coupled with the retaining element 1042. The first and second foot rests 1045 are positioned adjacent to the open back end of the guide blank holder 1038.

When the carrier 1018 is to be inserted into the guide blank holder 1038, the first foot 1023 is placed into the retaining element 1042 so that the first and second protrusions are disposed in the recess 1043 and retained therein on three sides by the wall of the recess. The carrier 1018 is prevented from leaving the recess 1043

via the opening in the recess owing to the obstruction of movement of the wall 1026 by the obstruction element 1044.

The second and third feet of the carrier 1018 rest upon the foot rests 1045. The carrier is then held in a receiving zone 1050 in the guide blank holder, protected by the perimeter wall 1039.

When placed into a production apparatus 1020 such as shown in Figure 13, the lip1041 of the guide blank holder 1038 couples with a channel in a receptor assembly 1028 of the production apparatus in a predetermined position without the carrier coming into contact with the production apparatus.

Figure 14 shows a modification tool 1032 in the production apparatus 1020.

The embodiment of Figure 12 is particularly advantageous as the carrier can be clipped into the guide blank holder with one hand.

The skilled person will appreciate that any or all of the processing or software described herein, such as the registration of elements, and the calculation of modification instructions, can be performed by the control unit 34 itself or can be performed by an external computer.

The above described embodiments provide a method specifically for the placement of a guide wire into the glenoid cavity during the TSA procedure.

Other embodiments can be used for other surgical procedures. Embodiments of the aforementioned guide may be produced such that they are specifically designed for certain procedures. An example might be a guide designed to facilitate the positioning and orientation of the acetabular component in total hip arthroplasty surgery as shown in Figure 8. In this embodiment, the impression element 16' of the guide 14' is produced such that it is bulbous in structure similar

to that of the femoral head, so as to support the mouldable material, and to minimise the amount of material needed.

A range of sterile, pre-packaged guide blanks can be provided reflecting the various sizes of acetabulum that may be presented.

Once the mouldable element 16' has been activated, the guide blank may be pressed into the acetabulum 60, ensuring that the mouldable element 16' conforms to the unique topography of the intraoperatively exposed bone. Once the mouldable element 16' has been modified in this way, the process may continue in the manner described in the previous embodiment in order to produce a guide.

The production apparatus may be designed such that it will accommodate guide blanks of differing types reflecting the different types of operation in which they might be used. All guide blanks might have an identical standardised carrier where practical. The mouldable element will vary in initial design and size to accommodate differing applications.

Embedded RFID tags, bar, or QR codes may identify various aspects of the patient and procedure, such as patient name, operation side, digital plan, and component sizing to the software.

The following describes one design for the mouldable element of the guide blank, although other designs and materials can be used in other embodiments. The mouldable element includes 2 constituent parts and is shown in figure 9A. An outer layer 62 that will come into contact with patient anatomy includes a low temperature thermoplastic. A layer 64 immediately below the outer layer 62 is formed from a permanently deformable material with a consistency suitable to provide mechanical support to the outermost thermoplastic layer 62. This material is pre-formed in a configuration such that that it may fit the general shape of the anatomical area to which the guide blank is designed to be moulded. This dictates

the general shape of the as yet unformed thermoplastic layer 62. The mouldable element 16 is mounted on the carrier 18 of the guide blank 14.

To activate the guide blank 14, an infrared heated receptacle may be provided associated with or as part of the production apparatus. The selected guide blank may be placed into the aforementioned receptacle and the thermoplastic surface heated to its transition temperature. At this point, the production apparatus may set itself up to shortly receive the moulded guide blank, for example, by selecting the correct tool from an internal library that it will need for the imminent modification of the prepared guide blank. The thermoplastic that is selected for the outer layer 62 has a transition temperature lower than that of the tissue damaging threshold. Once sufficiently heated The guide blank is held by the carrier and the mouldable element is pressed onto the anatomical area of interest thus allowing the thermoplastic layer 62, supported by the deformable material layer 64 underneath, to take the shape of the underlying anatomy before, once again, becoming solid as shown in Figure 9B.

In another embodiment, the mouldable element 16'' and carrier 18'' begin the process as separate entities as shown in Figure 10. A sterile biocompatible, rapid setting polymer 70 is provided in a sterile syringe 72. The carrier 18'' has features 22 as described above that allow it to be slotted into the aforementioned guide blank holder and on its reverse surface, it possess barbed members 74 that generate adhesive forces if the member is pressed into the rapid setting polymer 70. The surgeon injects the polymer 70 onto the surface of the dissected joint or bony anatomy and may roughly shape it into a globular body. A sterile carrier 18'' is then pressed into the globular body as it sets hard such that the barbed surface of the carrier 18'' will end up solidly held in the body of the polymer so that the globular body forms the mouldable element 16''. The guide blank holder interfacing surface of the carrier remains exposed. In this way, once fully set, this guide blank may be removed from the surgical field and will include a body of solid polymer that has been moulded to the topography of the chosen bony anatomy

and a carrier geometrically fixed in position with respect to the moulded surface. From this point, the process may now continue in the same manner as has been previously described.

In a further embodiment, the guide blank may consist solely of a body of mouldable material without any sort of carrier. The mouldable material in such an embodiment is sterile and able to 'set' to become hardened. A sterile guide blank holder is provided with, for example, spiked hinged members such that the now set body of mouldable material is able to be securely fastened into the guide blank holder. As there is no carrier in this case the body is affixed into the guide blank holder such that its moulded face is in view of the scanner. The body is now fixed with respect to the guide blank holder which is itself geometrically fixed with respect to the rest of the production apparatus. The scanner now scans the surface of the body thus geometrically registering it with both the preoperative CT scan and the production apparatus. The body may now be modified in the above described manner and placed back into the patient to act as a guide.

The guide blank may be modified such that it is capable of guiding a multitude of different surgical processes. Modifications might include holes for guide wires as described above, but may include other guidance or navigational structures. Options might include slots to cut grooves or section pieces of bone in operations such as the total knee replacement or to dictate angle and position for the removal of the proximal humeral head in TSA surgery.

Another embodiment is shown in Figures 18 and 19. Figure 18 shows a guide blank 2014 corresponding in many respects to the guide blank described in respect of Figures 2 to 7. A carrier 2018 includes a coupling arrangement including guides in the form of channels 2022 similar to that described in respect of the embodiment of Figures 2-7. In this embodiment, the channels 2022 are provided on first and second rails 2023 which are proud of the surface of the carrier 2018.

However, the channels 2022 work in substantially the same way as the channels 22 described above.

The carrier 2018 has a predetermined configuration and is rigid so as to maintain that predetermined configuration during moulding of the mouldable element and scanning.

In this embodiment, the carrier 2018 includes a reference element or fiducial marker 2100 in the form of a T-shaped lateral projection from the carrier 2018. As with other embodiments, in this embodiment, the carrier 2018 is arranged opposite a surface of the mouldable element 2016 which will be scanned. The fiducial element 2100 is configured to project laterally beyond the mouldable element 2016 so that a scan of the surface of the mouldable element opposite the carrier 2018 will include a scan of the fiducial element 2100. With knowledge of the configuration and position of the fiducial element with respect to a body 2015 of the carrier, the position of the carrier 2018 as a whole with respect to the mouldable element 2016 can be obtained from the relative position in the scan of the fiducial element 2100.

In this embodiment, the carrier 2018 includes a guiding element coupling arrangement for coupling the carrier 2018 to a guiding element. In this embodiment, the guiding element is a sterile programmable tool 2200 as shown in Figure 19. However, in other embodiments, the guiding element can be any element for guiding a surgical component to interact with a patient.

In this embodiment, the guiding element coupling arrangement includes a plurality of recesses 2102 for receiving respective feet 2202 of the guiding element 2200. In this embodiment, there are four recesses for four feet of the guiding element as this provides a stable coupling. However, a different number can be included in other embodiments.

Each of the recesses 2102 includes an alignment block 2104 to be received in an alignment recess 2204 of the respective guiding element foot in order to maintain the guiding element, or at least those parts of the guiding element that are fixed with respect to the feet 2202, in a desired predetermined position with respect to the carrier 2018. As is described below, some components of the guiding element may be movable for example to allow the guiding element to be placed into one of a plurality of different configurations.

As shown in Figure 19, the guiding element 2200 includes four feet 2202 to couple with the four recesses 2102 on the carrier 2018. Each of the feet 2202 is coupled to a leg 2206 which depends from a body 2208 of the guiding element 2200. In this embodiment, the body and feet are fixed with respect to each other. The body of the guiding element includes a tool guide 2210 which can be positioned in any one of a plurality of configurations. In other words, it is programmable. In this embodiment, a tool guide 2210 is a drill guidance tube which passes through the body 2208 of the guiding element 2200. However, in other embodiments, the tool guide 2210 can be a guide for different types of tools, for example can include a reconfigurable slot through which a cutting tool can operate.

In this embodiment, the guiding element 2200 includes first and second dials 2212 to orientate the tool guide 2210 in two mutually perpendicular axes in order to position the tool guide 2210 in a desired one of the plurality of possible configurations. These dials 2212 are designed to be adjusted by the surgeon by hand. However, in other embodiments, the tool guide 2210 can be automatically reconfigured.

In some embodiments, the guiding element 2200 can include a surgical tool to be guided by the tool guide 2210 and in other embodiments the tool guide 2210 can be for guiding a separate tool.

In operation, the mouldable element 2016 becomes an impression element providing an impression of a surgical site in the same manner as described above. The impression element is scanned and registered with anatomical features of the patient's anatomy by software, again as described above. However, in this embodiment, because of the guiding element 2200 it is not necessary to modify the impression element and carrier in order to form a surgical guide. In this embodiment, the impression element 2016 is registered with the carrier 2018 using the presence of the fiducial element 2100 in the scan of the impression element 2016. As described above, from the position of the fiducial element 2100 in the scan, the position of the entire carrier 2018 with respect to the scan can be determined, and the carrier 2018 as a whole can be registered to the impression element 2016. It is therefore not necessary in this embodiment for the carrier to be clipped into a production or registration apparatus, since the registration is all performed from one scan. A surgeon or a surgeon's assistant simply needs to scan the impression element and fiducial element, for example by a handheld 3D optical scanner.

On an electronic level, what is happening is that data representing the configuration of the carrier 2018 is registered with surface data from the scan representing the surface configuration of the impression element 2016.

Once the carrier 2018 has been registered with the impression element 2016, the guiding element 2200 can be registered with the impression element 2016. In other words, data representing the structure of the guiding element can be registered with the surface data representing the configuration of the surface of the impression element 2016. The data representing the structure of the guiding element may include data representing a predetermined configuration with respect to the carrier 2018 of those parts of the guiding element 2200 which are fixed with respect to the carrier after coupling and data representing the configurability of the reconfigurable parts of the guiding element. In other embodiments, the data representing the structure of the guiding element may include data representing

each of the possible configurations of the guiding element with respect to the carrier after coupling. The data representing the structure of the guiding element can be registered with the surface data using the registration of the carrier 2018 with the impression element 2016.

The guiding element 2200 can then be registered with anatomical features of the patient's anatomy. In other words, the data representing the structure of the guiding element 2200 can be registered with features of image data representing features of the patient's anatomy, for example from pre-operative imaging data. This can be done using the registration of the guiding element 2200 with the impression element 2016, and the registration of the impression element 2016 with the anatomical features of the patient.

With the guiding element 2200 registered with anatomical features of the patient, the software determines a desired configuration of the tool guide 2210 in order to guide a tool to form a surgical interaction with a patient which is in accordance with the surgical plan.

In this embodiment, the body 2208 of the programmable tool is inherently registered with the carrier 2018 as it is only able to be clipped in in one way. The impression element 2016 is registered to patient anatomy in the manner discussed above. The impression element is then registered to the carrier element 2018 using the fiducial marker. The impression element 2016 is now inherently registered with the body 2208 of the programmable tool by virtue of the fact they are both registered to the carrier 2018. As described above, once anatomical registration has been carried out, the digital plan may now be expressed in the frame of reference of the impression element 2016 and the carrier 2018 and, as previously, be used to create a modification plan. In this embodiment, the programmable tool body 2208 is registered with respect to the impression element and the carrier so the digital plan may now be expressed in the same frame of reference as the programmable tool body 2208. The computer software is pre-

programmed with an inherent 'knowledge' of the dynamics of the tool guide 2210 with respect to the tool body 2208 as facilitated by the programming dials 2212, thus, the software may now calculate an appropriate configuration or transformation such that the tool guide 2210 axis and position is identical to the axis and position of the axis of the digital plan. It is to be noted that this axis may also be described with respect to the impression element or carrier 2018 as once anatomical registration has been carried out the coordinates describing the geometry of the digital plan with respect to the patient anatomy may also be described with respect to the impression element and carrier.

The software now converts this configuration or transformation into the required numerical values to which the programmable tool control dials 2212 must be rotated such that the tool guide 2210 matches the axis and placement of the appropriate drilling axis in the real wold. A surgeon or assistant may now rotate the dials to the appropriate value, ensure the programmable tool is clipped onto the carrier 2018 in the appropriate recessions 2102, and drill through the tool guide 2210 into the patient anatomy (in this embodiment passing through the carrier and impression element) thus placing a guide wire or pin in the identical geometrical configuration as defined by the plan.

This embodiment therefore has the advantage that it does not require a production apparatus, and does not require direct modification of the impression element, but can use a standardised programmable tool and register all the components together using a simple handheld scanner.

The embodiment of Figures 18 and 19 can be provided without the fiducial element 2100, and the registration can be performed in a registration apparatus that corresponds in many respects to the production apparatus described above; however, the production apparatus in such an embodiment does not need a modification tool.

In embodiments, the guide element 2200 can be an integral part of the carrier 2018. Furthermore, the guide element does not need to be programmable, but can be provided in a fixed predetermined location with respect to the carrier 2018 to allow a reference marker to be attached to a patient's anatomy for guidance or navigation for further surgery. For example, in Figure 8, the carrier can include holes 80 in arms 84 or other extending members for the placement and registration of guide pins or screws 82 that may, themselves, orientate other surgical equipment. The carrier 14' is registered with anatomical features of the patient in the manner described above. Since the holes 80 and arms 84 are in a predetermined position with respect to the body of the carrier, they are therefore also registered with the anatomical features of the patient. The standard hole in the carrier 80 defines the axial position of the screw or pin and an associated flanged screw driver 86 can drive the screw into the bone until the flange 88 comes into contact with the top of the guidance hole 80, thus limiting the distance that the screw or pin may be driven into the bone. Once these guide pins 82 are in place, separate apparatus may be placed over the pins such that it will also be inherently registered to patient anatomy and the original guide may be discarded. This process allows the joint surface to be fully exposed whilst intraoperative guidance may still be used as the fixed members screwed into nearby bone will be registered to patient anatomy. In this manner, standardised surgical guides may be positioned in a patient specific manner thus allowing the precise placement of standardised cuts or holes in, for example, a knee replacement procedure.

Figure 20 shows an example of such separate apparatus that may be placed over the pins so that it will be inherently registered to anatomical features of the patient's anatomy.

Figure 20 shows a programmable guiding element 3000 including a pin sleeve 3002 and a tool guide 3004. The tool guide 3004 can be positioned in any one of a plurality of positions with respect to the pin sleeve 3002. In this embodiment, the

tool guide 3004 is a drill guide, however in other embodiments other tool guides may be provided.

In this embodiment, the tool guide 3004 is mounted on a stalk which is coupled to the pin sleeve 3002 by a ratcheted pivot mechanism 3006 which allows the stalk 3005 to be positioned at any one of a plurality of angles with respect to the pivot 3006. In this embodiment the ratcheted pivot 3006 includes a dial 3008 marked with positions such as angles so that the surgeon may position the stalk 3005 at the desired angle.

The ratcheted pivot 3006 does not need to be ratcheted in every embodiment, but it is provided with a means to hold the stalk in a desired position.

In addition, the pin sleeve 3002 includes first and second mutually twistable components and markings to show the extent of twist. Accordingly, in this embodiment, by appropriate twisting of the pin sleeve and movement of the stalk, the tool guide 3004 can be placed in a plurality of different configurations, each configuration providing the tool guide in a different position with respect to a pin in the pin sleeve.

The pin sleeve 3002 includes an internal passage 3010 for receiving a pin such as the pin 3012 shown in Figure 20. In this embodiment, the passage 3010 and pin 3012 are asymmetric so that the pin sleeve 3012 will only fit over the pin 3012 in one orientation, thereby ensuring that the guiding element 3000 is positioned on the pin 3012 in a known predetermined manner. In this embodiment, this is achieved by the pin 3012 including a flange 3014 and the passage 3010 including a corresponding channel 3016 for receiving the flange 3014. However, in another embodiment, a carrier may be designed similar to the depiction in figure 8 however it will guide the placement of 2 planar pins. In this way, flanged pins need not be used as a programmable object possessing 2 pin sleeves may be used and slid over both pins thus locking the body both positionally and axially.

In use, once the carrier and impression element of Figure 8 have been used to position a pin such as the pin 3012 in a known position and configuration with respect to anatomical features of the patient's anatomy, the pin sleeve 3002 of the guiding element 3000 is positioned over the pin 3012. Owing to the predetermined structure and adjustability of the guiding element 3000, or the pre-calibrated possible configurations of the guiding element 3000, the guiding element 3000 can thereby be registered to the anatomical features of the patient's anatomy using the registration of the pin 3012 to the anatomical features of the patient's anatomy. The guiding element 3000 can therefore be expressed in the same frame of reference as anatomical features of the patient's anatomy and therefore the same frame of reference as the surgical plan. The desired configuration of the guiding element 3000, that is to say the desired position of the tool guide 3004, or in this embodiment the desired settings for the ratcheted pivot and mutually twistable components in order to enable a surgical interaction with a patient in accordance with the surgical plan can thereby be determined.

The software outputs the desired configuration following the anatomical registration of the impression element and carrier 14' that has allowed the placement of a pin(s) into known locations on patient anatomy. The software will know the locations of these pins thus can output the correct configuration of the tool 3000 such that it can be modified by surgical staff and placed over the pins in a known way. The tool guidance element 3004 may now be drilled through, entering the patient anatomy in a known way according to the surgical plan.

Another embodiment of the invention is provided where a programmable tool may be registered to patient anatomy exclusively using an impression element without any sort of carrier. A digital or surgical plan is created as above based on patient imaging data. In theatre, the surgical site is exposed and the surgeon may place a guidance pin or screw at a location of their choosing such as the pin 3012 depicted in figure 20 that possesses a known orientating factor such as a flange 3014.

Alternatively, the surgeon may use a separate tool to place two parallel pins in such a configuration that the standard part of a programmable tool 3010 may be slid over the top thus ensuring a known planar orientation.

These pins must now be registered with patient anatomy so that a programmable tool may be appropriately modified and affixed to the pins such that its tool guidance feature 3004 is correctly positioned according to the surgical plan. Once the pin(s) are placed, a globular portion of sterile mouldable material may be moulded onto the surgical site ensuring that the pins pass through the globular body of material as it sets. When solidified, the globular body may be separated from the surgical site and slid off the pins retaining a surface impression of the surgical site studded with the holes left by the pins that may or may not pass all the way through the globular body.
Once remote from the surgical site, fresh sterile pins, or markers in the same shape as the pins in the surgical site, may now be placed back into the holes in the globular body such that they protrude out from the surface possessing the impression from the surgical site. This arrangement may now be held in front of, for example, a 3D optical scanner and scanned creating a 3D surface model. This 3D model will comprise the impression of the surgical site and the pins or markers extending from the impression surface. In computer software, a surgeon may now select the pin(s) or marker(s) on the computer model so that the software may differentiate between the impression surface and the markers. The software may now use the impression element surface and carry out an anatomical registration in the above way. The axis and position of the pin(s) marker(s) are inherently registered with the impression element as they are in the same 3D scan thus once the impression element is registered to patient anatomy in the normal way, the axis and position of the pin(s) marker(s) may also be expressed in the same reference frame as the patient anatomy. In this way, the physical pin(s) and marker(s) are now registered with respect to patient anatomy. As described previously, the computer software may now calculate an appropriate configuration or modification to be made to a programmable tool such that it may be slid over

the original pin(s) in situ in the surgical site and used to carry out a surgical intervention on the patient.

A surgical pin may be designed with a specifically patterned head that may leave an impression in the impression element. In this embodiment, the scanner would scan the impression element producing a model comprising the surgical site impression as well as the impression of the patterned head of the pin. This pattern may be picked up by software and used to register the location of the pin with respect to the impression element surface and subsequently to the patient anatomy. A programmable object may be attached to the head of this pin in a known way thus, after appropriate modification, it may be used to guide a tool in the above way.

Utility in surgical navigation:

The herein described guide may not solely be used for the guidance of surgical tools. Surgical navigation has utility in a number of different surgical fields and yet the majority of prior art functions with registration techniques that rely on optical registration methods or require the surgeon to touch pre-determined areas of anatomy with a digitizer arm. These methods are laborious and time consuming and often require complex and costly equipment. In many situations this approach is impractical, for example, in compact operative fields where soft tissue may obscure the view and the necessary bulky apparatus may be cumbersome and increase the operation time.

The above described elements may be used to overcome these problems. A guide may be provided with the intended function of orienting a ‘standard marker’ that will be drilled into the patient's bony anatomy. This marker can be registered with the pre-operative imaging data and patients anatomy utilising the method disclosed above. The guide may be removed from the surgical site and discarded leaving behind a ‘standard marker’ fixed to the bony anatomy. The usual

navigation techniques may now be employed such as optical tracking of the 'standard marker' thus allowing conventional navigation techniques to be used. The advantage to this approach is that the optical system may now be focused onto the fixed marker which may be away from the surgical site.

In embodiments in which an impression element is modified by a modification tool, as well as defining the orientation and axial position of a guide wire, pin or similar orthopaedic hardware, the guide may be modified such that a depth to drill may be defined. This may be explained in the following embodiment with respect to the TSA. A surgeon will not want to penetrate the anterior wall of the scapulae whilst drilling a guide wire into the glenoid cavity. Whilst the aforementioned processes are capable of guiding the axial position and orientation of the wire placement, it cannot define the depth the wire is placed into the glenoid. This problem may be overcome with the use of a stepped hole. First, a wire guidance hole will be drilled through the guide blank. A second drill bit will now be employed of a greater diameter. This will drill along the same axis and in the same position as the first hole however it will not travel the full length of the guide blank. This process will produce a stepped shoulder within the original guide hole. Once the guide is placed back into the surgical field, the surgeon may now drill through the guide with a suitable guide wire featuring a corresponding 'step' in its design to correspond with the internal 'step' within the guide hole through the guide. In planning the position of the 'step', the microprocessor of the production apparatus is pre-programmed with information regarding the location of the 'step' on the shaft of the drill bit used by the surgeon. With this information, it may calculate the depth to drill the greater diameter hole through the guide blank to thus define the depth the guide wire may be placed as the surgeon will be prevented from drilling further than the stepped shoulder allows. Alternatively, the processor may specify the position on the shaft of the guide wire to place a lockable cuff in order to specify a specific depth. This position is calculable due to the generated geometric knowledge of the impression element of the guide blank with respect to the carrier and the required depth to be drilled as defined in the surgical prescription.

In an embodiment, a guide blank may be provided possessing certain modifications to the carrier in the form of fixed members or markers, which can be considered to be fiducial markers extending out such that when the impression element surface is viewed by a 3D scanner, the fixed members of the carrier are also visible in the scan. As a result of this, the scanning process generates a digital 3D model of the impression element surface (as described above) however this model will also possess 3D geometric data of the fixed members. The members are inherently geometrically fixed with respect to the carrier thus when the impression element is scanned in the same reference frame as these members, the impression element may be spatially registered with respect to the carrier. The device processor is programmed to create a virtual model of the position of the impression element with respect to the carrier by registering the fixed members of a 'blank' model of a carrier with the 3D image of the members from the scanned guide blank.

This embodiment allows for the 3D scanning components and the, for example CNC, modification components of the aforementioned production apparatus to be split into separate assemblies. For example, an operator may now take a mould of the joint surface in the described manner with a guide blank including fiducial markers. Once hardened, the guide blank is removed from the joint surface and held, possibly simply in the surgeon's hand, with the moulded impression element facing a 3D scanner that might be held by a non-sterile assistant or positioned on a stand on a separate table. The guide blank is optically 3D scanned producing a 3D digital model comprising the moulded impression element surface and the optically visible fixed members extending from the carrier. This 3D model is sent to a processor where the surface of the impression element may be registered with patient anatomy and hence the operative prescription in the same manner as described in other embodiments. The processor also registers the moulded impression element surface with respect to the carrier due to the presence of the members in the 3D model generated by the 3D scanner. One registration is complete, the guide blank may now be clipped into the guide blank receptor

assembly of a production apparatus consisting solely of the receptor assembly and a modification tool, such as a CNC drill, cutter or marker of any configuration described above. In a similar manner to that described above, as a result of the fixed geometry of the carrier, it is only possible to affix the guide blank into the production apparatus in a known position. The contours of the impression element are spatially registered with the carrier therefore they are also inherently spatially registered with the modification tool in the production apparatus through the standardized, carrier mediated fixation method. As a result, the modification tool may drill, cut or mark the guide blank in such a way that when a tool is subsequently passed through the resulting guidance channels its path satisfies the constraints of the pre-operative prescription.

In other words, as described above, the guide blank does not necessarily have to have a carrier. The scanner, or rather the control unit, 'knows' the location of absolutely everything within the production apparatus so that if a moulded lump of impression material is solidly fixed into the production apparatus, the scanner can scan the moulded section and inherently register it to everything else within the production apparatus so that it can be appropriately modified.

In addition, by providing a fiducial marker on the carrier that is scanned along with the impression element, it is not necessary to have the scanner and modification tool in the same apparatus.

In some embodiments, instead of a modification tool, a modification guide is provided in the production apparatus. This works in substantially the same way as the modification tool, except that it is simply positioned in a desired location with respect to the guide blank to guide a separate external tool to modify the guide blank in the desired manner.

It is possible to use any surface configuration recorder to produce surface data representing a surface configuration. In the embodiments above, the surface data

is obtained using a scanner. However, in some embodiments, it is possible to use a digitiser arm which can be touched on a plurality of points on the impression element surface.

All optional and preferred features and modifications of the described embodiments and dependent claims are usable in all aspects of the invention taught herein. Furthermore, the individual features of the dependent claims, as well as all optional and preferred features and modifications of the described embodiments are combinable and interchangeable with one another.
The disclosures in United Kingdom patent application number 1320745.1, from which this application claims priority, and in the abstract accompanying this application are incorporated herein by reference.

Embodiments of the invention can be provided in accordance with the following clauses:

1. A method for the intraoperative production of a surgical guide, jig or navigation tool utilizing pre-operative imaging data.
2. An apparatus for the intraoperative modification of a jig to a planned geometry such that it may be fitted to the patient and used to guide cutting / drilling intra-operatively
3. An apparatus for the local intraoperative modification of a jig that has been fitted to a patient intra-operatively, modification to take place according to 3D digital planning data
4. An apparatus for the local intraoperative modification of a jig that has been fitted to a patient intra-operatively, modification to take place according to 3D digital planning data, said apparatus incorporating a work chamber wherein the modification of the jig takes place, said chamber may be dressed with sterile protective sheets, enclosures or bespoke lining materials such that the process of adaptation may take place in a sterile micro-environment.
5. A CNC or other variety of digital / programmable cutting or drilling apparatus for the local intraoperative modification of a jig that has been fitted to the patient intra-operatively, modification to take place according to 3D digital planning data, as described in previous clauses.
6. An apparatus for the intraoperative modification of a jig that has been fitted to the patient intra-operatively, modification to take place according to digital 3D planning data, following co registration of preoperatively acquired digital data with 3D data obtained at the time of operation.
7. A jig for use with the apparatus described in previous clauses, where the jig incorporates a prefabricated element that provides a frame of reference for digital planning and modification, and permits fixation to said apparatus.
8. A jig which is in part formed from a mouldable material, e.g. a silicone impression material or a thermoplastic material, which is used to form the

tissue fitting surface of the jig together with a rigid, standardized tray to carry said material.

9. An apparatus equipped with, or associated with a scanner capable of scanning the mouldable element of the jig to acquire 3D data to allow registration of the jig with preoperative scan data.
10. A jig for use in computer assisted orthopaedic surgery, where said jig is assembled from a mouldable material, e.g. a silicone impression material which is used to form the tissue fitting surface of the jig and a rigid tray to carry said material, wherein the tray itself provides a frame of reference for digital planning, and modification.
11. A jig which is assembled from a mouldable material, e.g. a silicone impression material which is used to form the tissue fitting surface of the jig and a rigid tray to carry said material, wherein the tray itself provides a frame of reference for digital planning and modification, also incorporating elements that facilitate connection to an apparatus capable of modifying the jig according to digital planning data
12. A device as in previous clauses where a jig is assembled from a mouldable material, e.g. a silicone impression material which is used to form the tissue fitting surface of the jig and a rigid tray to carry said material, wherein the tray itself provides a frame of reference for digital planning, and modification, and incorporates elements that facilitate connection to an apparatus capable of rapidly modifying the jig in a localised sterile enclosure, according to digital planning data
13. A method for the co-registration of patient surgical anatomy with pre-operative or intraoperative imaging data, where one dataset is acquired from that of the 3D surface of a mouldable material, intraoperatively moulded to the topography of exposed patient anatomy.
14. A jig with both a temporarily modifiable component and a standardised component, such that it may be located into position by the use of an impression material, used to take an impression of anatomy, which has been directly surgically exposed in the course of an operation.

15. A jig according to previous clauses, which once an impression has been taken of the relevant exposed anatomy, may be scanned and used to permit the co-registration of the exposed surgical anatomy to previously or intraoperatively acquired image data (e.g. CT or MRI).
16. A jig as described in the previous clause which is able to be returned into the same position from where the impression was first taken once, having been rapidly and appropriately modified by an associated apparatus to create cutting or drilling paths or channels.
17. A jig according to all previous clauses where physical fixation means may be provided at the time of moulding of the registration device, to ensure the secure placement of the tool once it is returned to the position in which the mould was taken.
18. A registration tool according to previous clauses with provision to interact with an associated apparatus and be accordingly modified to produce a surgical guide, jig or navigation aid.
19. A registration tool according to previous clauses capable of physical modification by means of a CNC process to produce a surgical drilling or cutting guide, jig, template or navigation aid.
20. An apparatus associated with the jig or registration tool described in previous clauses capable of carrying out the computer controlled modification of said customisable registration tool or jig.
21. A method and associated apparatus for the intraoperative fabrication of a surgical drilling, cutting, or positioning guide which uses a computer controlled apparatus to modify a registration tool composed of a standard component and a mouldable part, modified according to a specification generated by associated software
22. An apparatus as described in previous clauses used in combination with the jig or registration tool described in previous clauses.
23. An apparatus for the creation of surgical cutting or drilling guides, which combines a scanner and CNC mill or drill, such that an object may be modified to a surgical prescription for use as a surgical jig or cutting guide.

24. An apparatus for the creation of surgical cutting or drilling guides, which combines a scanner and CNC mill or drill, such that an object may be modified to a surgical prescription for use as a surgical jig or cutting guide within a sterile drilling chamber.
25. A method for the intra-operative production of a cutting or drilling guide or jig substantially as described within the accompanying description, figures, and clauses
26. A combination cutting or drilling guide and registration device substantially as described in the accompanying description, figures, and clauses.
27. An apparatus for the modification of a registration device/ jig substantially as described in the description, figures and clauses.

CLAIMS

1. A method of producing a modification plan for producing a surgical guide from an impression element, the method including:

obtaining surface data representing a configuration of a surface of an impression element providing an impression of a surgical site;

obtaining image data of a patient's anatomy;

obtaining surgical plan data providing a surgical plan with respect to features in the image data representing anatomical features of the patient's anatomy;

registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy;

producing a modification plan from the surgical plan data using the registration of the impression element with anatomical features of the patient's anatomy, the modification plan being a plan for modifying the impression element.

2. A method according to any preceding claim, wherein the impression element is a moulded element, preferably moulded by being placed against the surgical site.

3. A method according to any preceding claim, wherein the modification plan includes instructions for operating a production apparatus to modify or to guide modification of the impression element.

4. A method according to claim 3, including registering the impression element with the production apparatus using the surface data, the production apparatus including a modification tool for modifying the impression element or a modification guide for guiding a modification tool;

wherein producing instructions includes producing instructions based on a calibrated position of the modification tool or modification guide and the registration of the impression element with the production apparatus.

5. A method according to claim 4, including registering the impression element with a carrier carrying the impression element using the surface data.

6. A method according to any preceding claim, wherein obtaining surface data includes operating a scanner to scan the surface of the impression element.

7. A method of producing a surgical guide, including:

producing a modification plan according to any preceding claim, wherein obtaining surface data includes operating a surface configuration recorder to obtain the surface data; and

modifying the impression element in accordance with the modification plan.

8. A method according to claim 7, wherein the surface configuration recorder is a scanner.

9. A method according to claim 7 or 8, wherein modifying the impression element in accordance with the modification plan includes operating a production apparatus to modify the impression element, or to guide modification of the impression element, in accordance with the modification plan to produce the surgical guide.

10. A method of producing a surgical guide according to claim 9, wherein operating the production apparatus includes operating a modification tool of the production apparatus, operating a modification tool preferably including one or more of cutting, drilling and milling.

11. A method of producing a surgical guide according to any of claims 7 to 10, including placing a mouldable element against the surgical site to form the impression element.

12. A mouldable element for use in surgery, including:

mouldable material for being placed against a surgical site to form an impression of that site; and

a reference element coupled to the mouldable material for allowing a configuration of a surface of the mouldable material to be recorded with respect to a known point of reference.

13. A mouldable element according to claim 12, including a carrier for carrying the mouldable material, the carrier including the reference element.

14. A mouldable element according to claim 13, wherein the reference element includes a coupling element for coupling the carrier to a production apparatus in a predetermined position.

15. A mouldable element according to any of claims 12 to 14, wherein the carrier includes an identification element, the identification element optionally identifying a particular patient or a particular surgical procedure with which the mouldable element is to be used.

16. A mouldable element according to any of claims 12 to 15, wherein the carrier includes a body and at least one registration arm extending from the body, the at least one registration arm being fixed with respect to the body, the at least one registration arm being operable to register contact with bone whereby to assist registration of the mouldable element with anatomical features of a patient by providing information relating to a position of bone with respect to the body of the carrier when the carrier is in place at a surgical site.

17. A mouldable element according to any of claims 12 to 16, wherein the carrier includes a coupling element for coupling to a guiding element for guiding a surgical component to interact with a surgical site.

18. A mouldable element according to any of claims 12 to 17, wherein the carrier includes a guiding element for guiding a surgical component to interact with a surgical site.

19. A mouldable element according to claim 17 or 18, wherein the guiding element is selectively configurable.

20. A mouldable element according to any of claims 17 to 19, wherein the guiding element includes a surgical tool for being guided by the respective guiding element.

21. A mouldable element according to any of claims 17 to 20, wherein the guiding element includes a screw guide for guiding a screw to be screwed into a surgical site, the screw guide enabling registration of a screw screwed into a surgical site with anatomical features of a patient.

22. A mouldable element according to any of claims 12 to 21, wherein the mouldable material includes a first surface designed to receive an impression of a surgical site and to be scanned, and wherein the reference element includes a projection projecting laterally beyond a side of the first surface whereby to be included in a scan of the first surface.

23. A mouldable element according to any of claims 12 to 22, wherein the mouldable material includes an outer layer of thermoplastic material and an inner layer of permanently deformable material.

24. A mouldable element according to claim 23, wherein the thermoplastic material has a transition temperature below a tissue damaging threshold.

25. A surgical guide or jig including a mouldable element according to any of claims 12 to 24 having been moulded to form an impression of a surgical site to

provide a tissue fitting surface, and modified, preferably cut, drilled, or prepared, to provide a guide for a surgical tool.

26. An impression element holder, including:

a first coupling element for coupling the holder into a production apparatus in a predetermined position;

a second coupling element for coupling an impression element into the holder in a predetermined position;

a receiving zone for receiving an impression element coupled to the second coupling element without contact with a production apparatus coupled to the first coupling element.

27. An impression element holder according to claim 26, including an open side to allow an impression element held within the holder to be optically scanned.

28. A production apparatus for the production of a surgical guide, including:

a receptor assembly for receiving an impression element conforming to a shape of a surgical site;

a surface configuration recorder for recording a configuration of a surface of an impression element received by the receptor assembly to produce surface data for registering that impression element with anatomical features of a patient's anatomy and with the production apparatus; and

a modification tool for modifying an impression element received by the receptor assembly or a modification guide for guiding a modification tool; wherein the modification tool or modification guide and an impression element received by the receptor assembly are positionable in a plurality of predetermined relative positions to allow an impression element received by the receptor assembly to be modified in accordance with a modification plan, wherein a modification plan is a plan for modifying an impression element and is derived from a surgical plan and a registration of that impression element with anatomical features of a respective patient's anatomy.

29. An apparatus according to claim 28, wherein the surface configuration recorder is a scanner, preferably an optical scanner.

30. An apparatus according to claim 28 or 29, wherein the modification tool includes one or more of a cutter for cutting an impression element, a drill for drilling an impression element, a milling component for milling an impression element, a slot saw for sawing, and a marker for marking an impression element.

31. An apparatus according to any of claims 28 to 30, including:

a processor for determining, from a modification plan and a registration of the apparatus with an impression element received by the receptor assembly, a desired relative position of the modification tool or modification guide with respect to that impression element to enable that impression element to be modified in accordance with that modification plan.

32. An apparatus according to any of claims 28 to 31, wherein the processor is operable to obtain a modification plan from an external computing device.

33. An apparatus according to any of claims 28 to 32, wherein the processor is operable to obtain patient registration data providing a registration of an impression element received by the receptor assembly with anatomical features of a respective patient's anatomy, wherein the processor is operable to obtain a surgical plan, and wherein the processor is operable to calculate a modification plan from the patient registration data and the surgical plan.

34. An apparatus according to any of claims 28 to 33, wherein the processor is operable to determine how to modify an impression element in accordance with the surgical plan by using the patient registration data to determine how a respective impression element will align with a surgical site, and thereby

determining how to modify an impression element in order to provide a configuration at a surgical site that is in accordance with the surgical plan.

35. An apparatus according to any of claims 28 to 34, wherein the processor is operable to determine patient registration data from image data of a patient's anatomy and surface data from the surface configuration recorder.

36. An apparatus according to any of claims 28 to 35, wherein the processor is operable to register an impression element received in the receptor assembly with the production apparatus, preferably with the receptor assembly, using surface data from the surface configuration recorder.

37. An apparatus according to any of claims 28 to 36, wherein the processor is calibrated with a relative position of the surface configuration recorder, and the modification tool or modification guide.

38. An apparatus according to claim 37, wherein the processor is operable to adapt its calibration in response to movement of the surface configuration recorder and/or modification tool and/or modification guide.

39. An apparatus according to any of claims 28 to 38, including a control unit operable to adjust a relative position of the modification tool or modification guide with respect to an impression element received by the receptor assembly in order to place them in a desired relative position.

40. An apparatus according to claim 39, wherein the control unit is operable to adjust a position of the receptor assembly and/or the modification tool or modification guide to enable modification in accordance with a modification plan.

41. An apparatus according to claim 39 or 40, wherein the control unit is operable to control the modification tool to modify an impression element received by the receptor assembly in accordance with a respective modification plan.

42. An apparatus according to any of claims 39 to 41, wherein the control unit is calibrated with relative positions of the surface configuration recorder and of the modification tool or modification guide and optionally of the receptor assembly.

43. An apparatus according to claim 42, wherein the control unit is operable to adapt its calibration in response to movement of the surface configuration recorder and/or receptor assembly and/or modification tool and/or modification guide.

44. An apparatus according to any of claims 39 to 43, wherein the control unit is operable to obtain spatial registration data providing a registration of an impression element received by the receptor assembly with the apparatus, and wherein the control unit is operable to control the modification tool to modify a received impression element in accordance with a modification plan using the spatial registration data.

45. An apparatus according to any of claims 28 to 44, wherein the receptor assembly includes a coupling or attachment element to cooperate with a corresponding coupling or attachment element on an impression element.

46. An apparatus according to any of claims 28 to 45, wherein the receptor assembly is configured to receive an impression element holder for holding an impression element without contact with the apparatus to prevent contamination of a received impression element or the apparatus.

47. An apparatus according to any of claims 28 to 46, wherein the modification tool can releasably hold a tool element to enable a used tool element to be substituted for a new sterile tool element.

48. An apparatus according to any of claims 28 to 47, including a motor for moving the modification tool or modification guide.

49. An apparatus according to any of claims 28 to 48, including a motor for moving the receptor assembly.

50. A method including:

obtaining from a surface configuration recorder surface data representing a configuration of a surface of an impression element providing an impression of a surgical site;

obtaining data relating to a relative position of a location for the guiding element with respect to the surface;

obtaining image data of a patient's anatomy;

registering the impression element with the location for the guiding element using the surface data and the data relating to the relative position of the location for the guiding element with respect to the surface;

registering the impression element using the surface data and the image data with anatomical features of the patient's anatomy;

registering the guiding element with anatomical features of the patient's anatomy using the registration of the impression element with anatomical features of the patient's anatomy and the registration of the impression element with the location for the guiding element.

51. A method according to claim 50, wherein the data relating to a relative position of the location for the guiding element with respect to the surface includes data relating to a relative position, during the recordal of the surface data, of the surface and a carrier carrying the impression element, wherein the carrier includes or can receive the guiding element; and wherein registering the impression element with the guiding element includes registering the impression element with

the carrier using the surface data and the data relating to the relative position of the surface and the carrier.

52. A method according to claim 51, wherein obtaining data relating to a relative position of the surface and the carrier includes determining from the surface data a relative position of a reference element of the carrier with respect to the surface.

53. A method according to any of claims 50 to 52, wherein the guiding element is configurable, and the method includes:

obtaining surgical plan data providing a surgical plan with respect to features in the image data representing anatomical features of the patient's anatomy;

determining a configuration for the guiding element from the surgical plan data using the registration of the location for the guiding element with anatomical features of the patient's anatomy.

54. A method according to claim 53, including configuring the guiding element in accordance with the determined configuration.

55. A method according to any of claims 50 to 54, including guiding the surgical component using the guiding element to perform a surgical interaction with the patient.

56. A registration apparatus for use in the registration of a guiding element with a patient's anatomy, including:

a receptor assembly including a coupling element for coupling to a coupling element on a carrier for an impression element whereby to hold a carrier for an impression element in a predetermined position; and

a surface configuration recorder for recording a configuration on a surface of an impression element carried by a carrier received by the receptor assembly to

produce surface data for registering that impression element with anatomical features of a patient's anatomy and with that carrier and thereby for registering that carrier with anatomical features of a patient's anatomy.

57. A kit for producing a surgical guide, including:

an apparatus according to any of claims 28 to 49 or 56; and

at least one impression element being a mouldable element according to any of claims 12 to 24.

58. A kit for producing a surgical guide, including:

an apparatus according to any of claims 28 to 49 or 56; and

mouldable material for placing against a surgical site to form an impression element.

59. A kit according to claim 58, including at least one carrier for being attached to the or a part of the mouldable material to carry the mouldable material.

60. A computer program for performing the method of any of claims 1 to 11 or 50 to 55 when executed on a computing device.

61. A programmable guiding element for guiding a surgical intervention, including:

a coupling element for coupling the guiding element to a carrier for an impression element; and

a tool guide selectively configurable in any one of a plurality of configurations for guiding a tool to make a surgical intervention, wherein each of the plurality of configurations provides the tool guide in a different predetermined position with respect to the coupling element.

62. A guiding element according to claim 61, including a surgical tool to be guided by the tool guide.

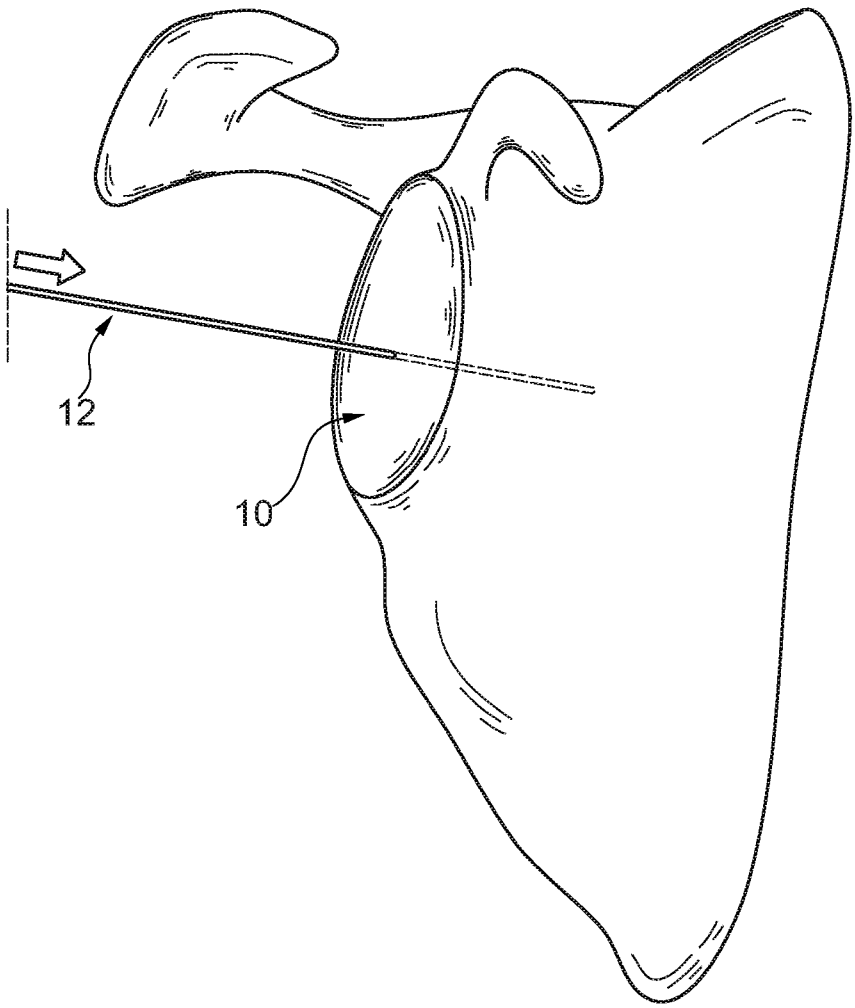
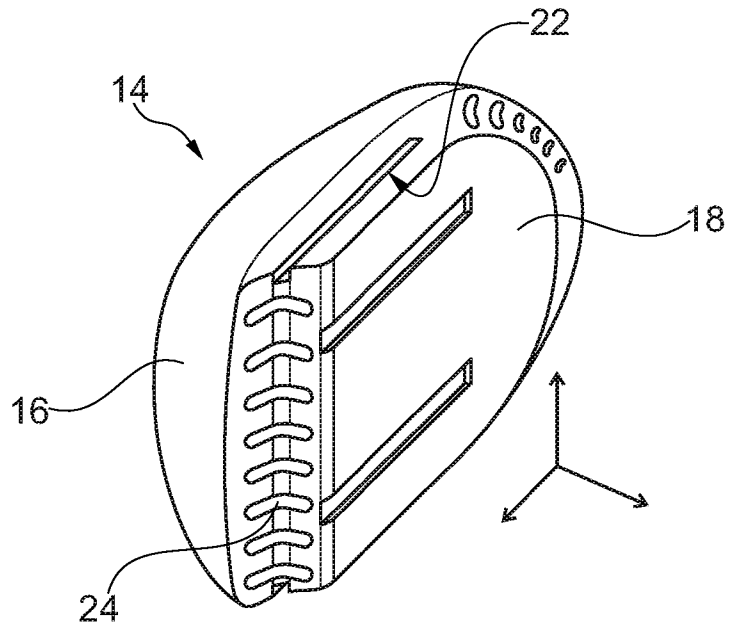
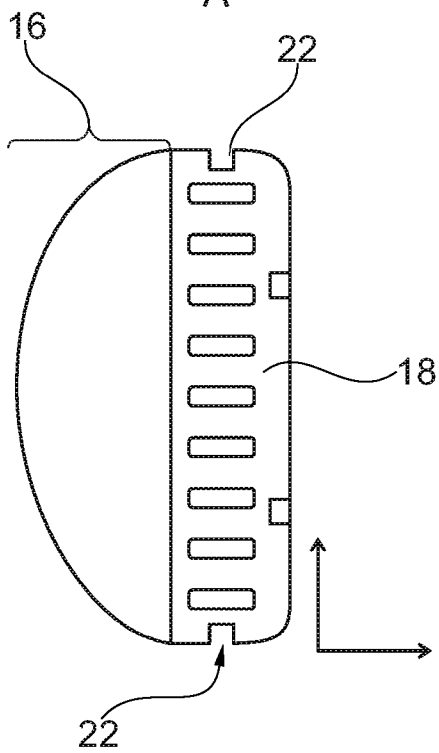


Fig. 1



A



B

Fig. 2

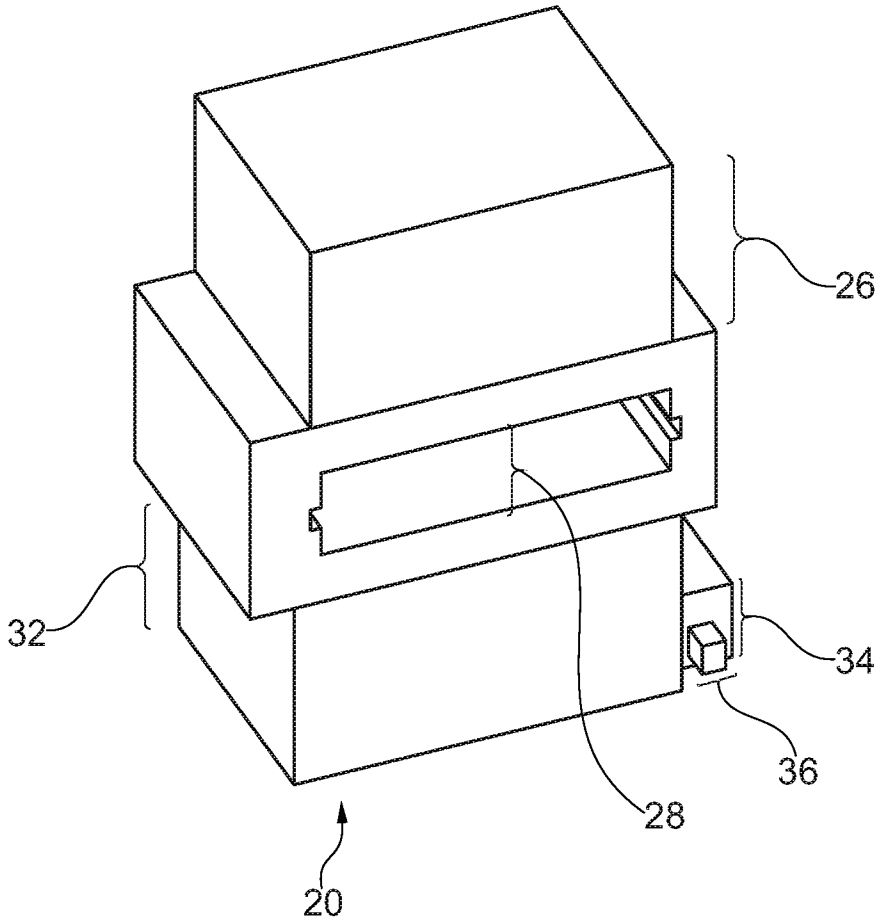


Fig. 3

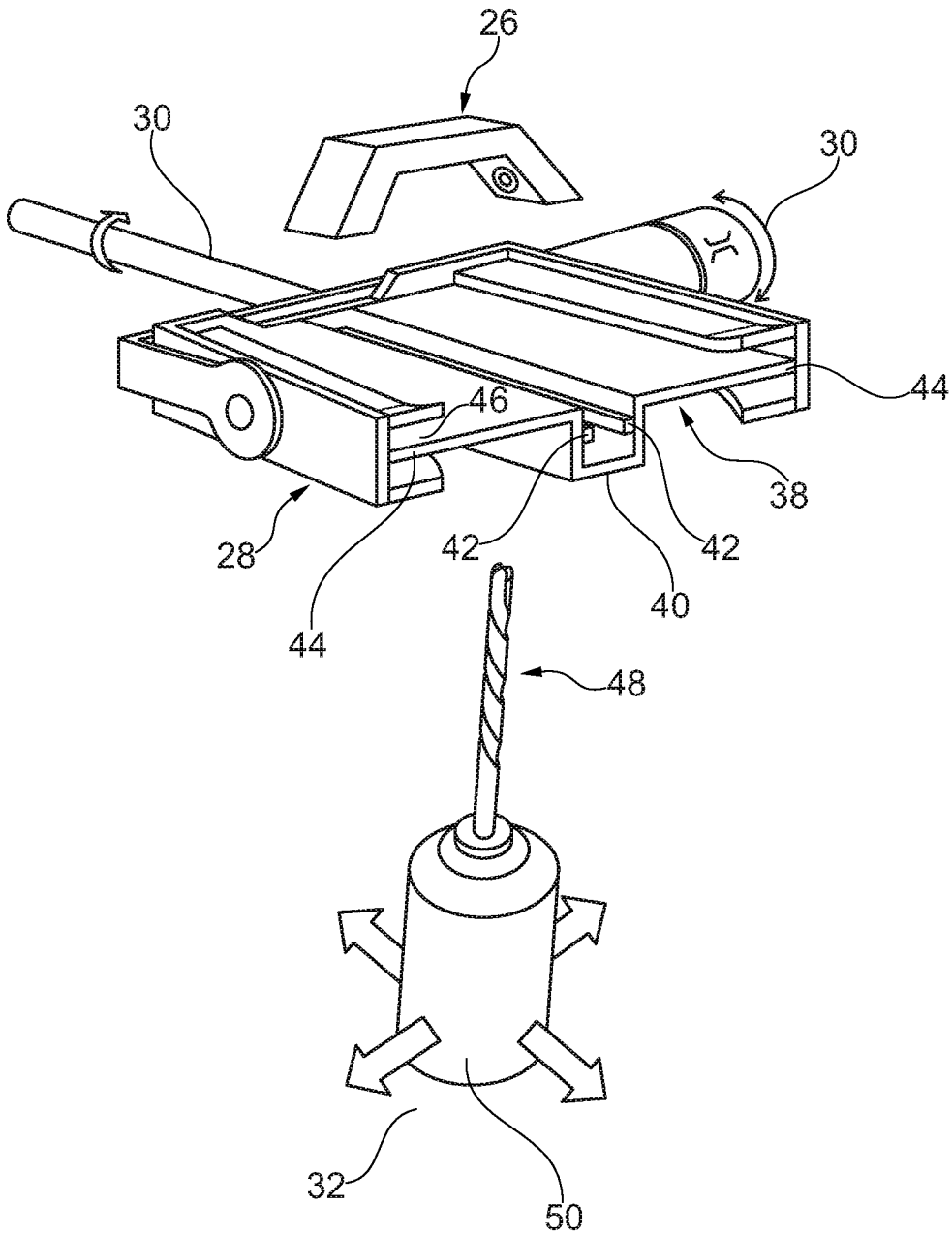


Fig. 4

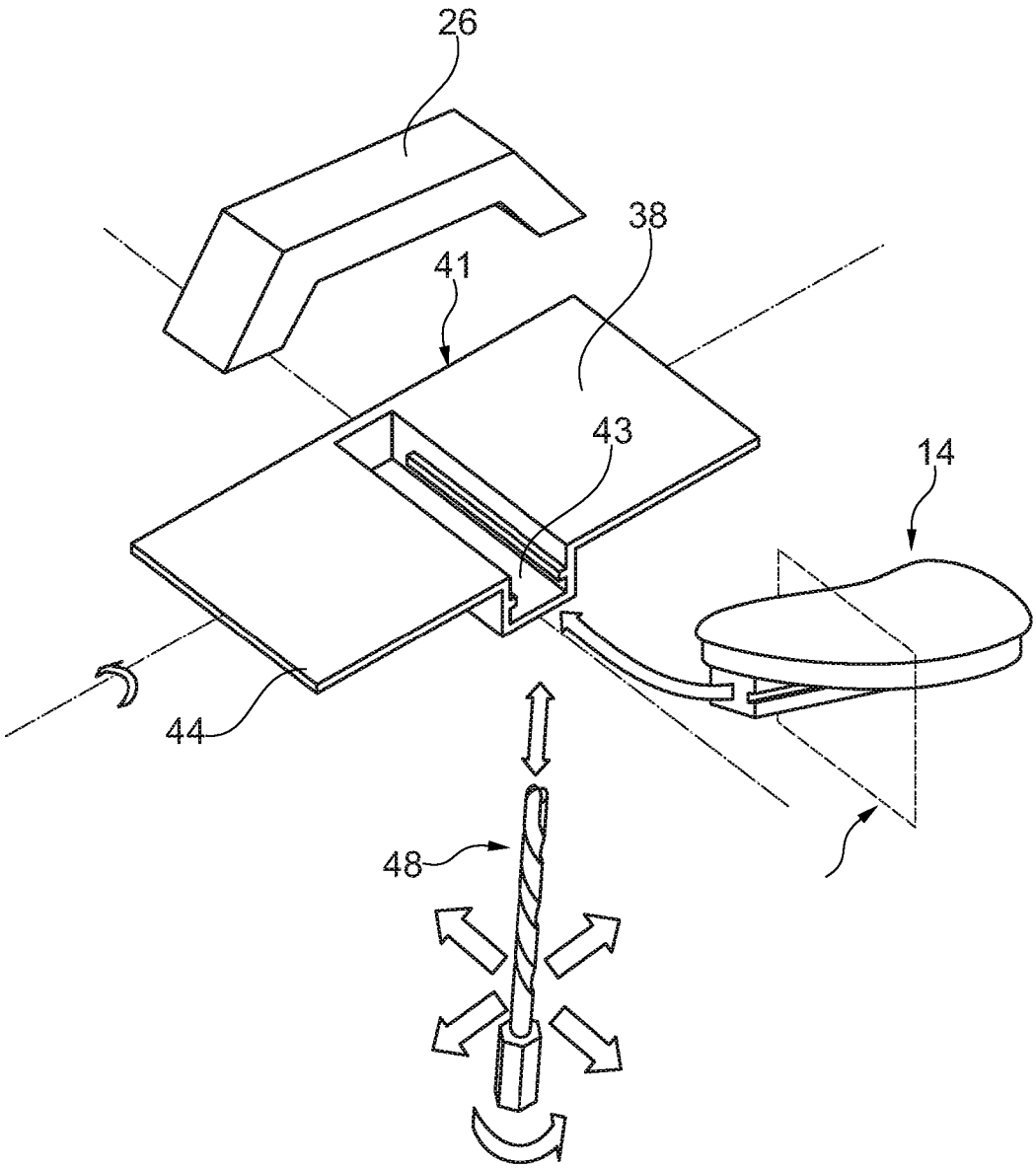


Fig. 5

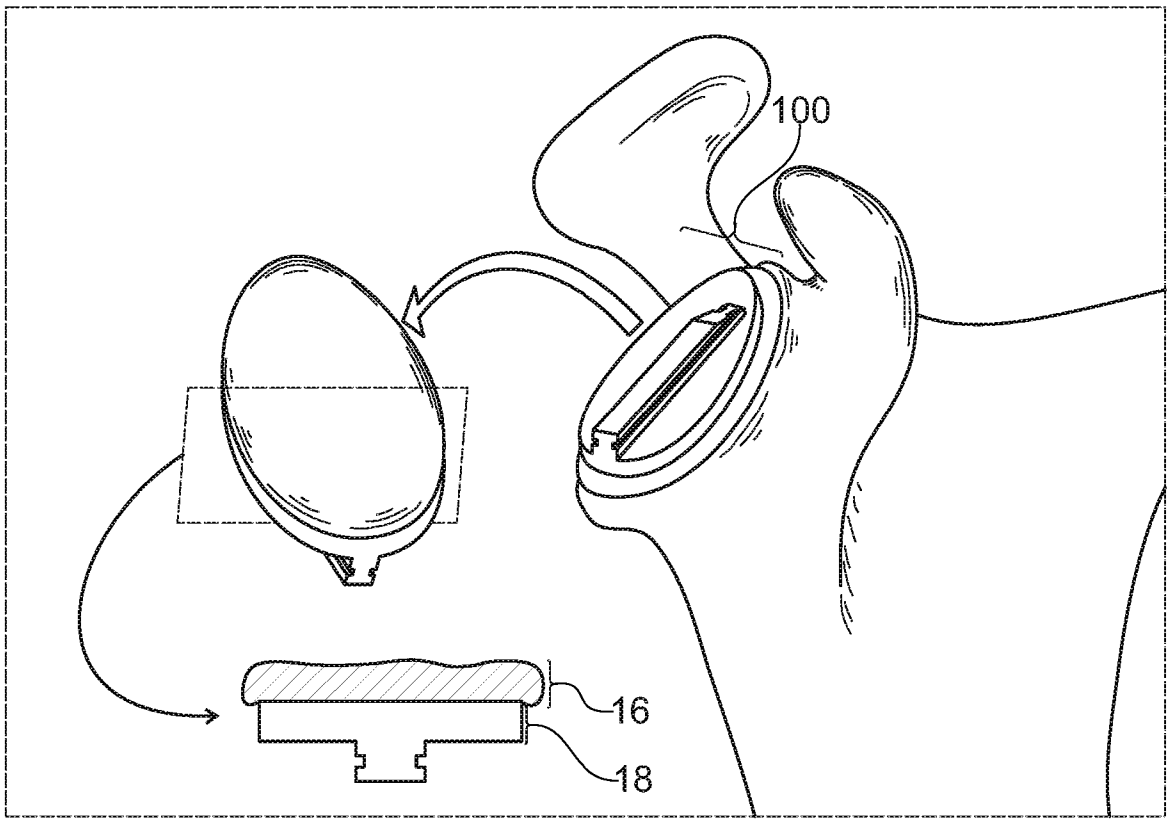


Fig. 6

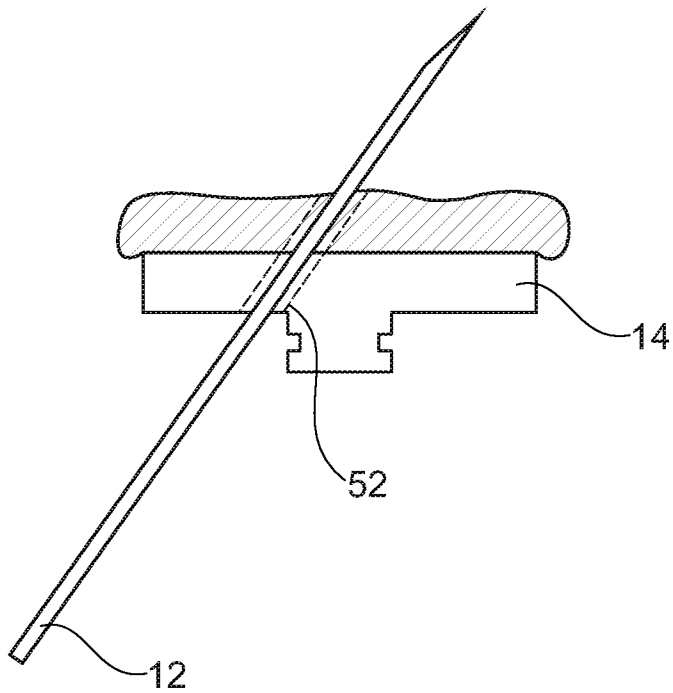


Fig. 7

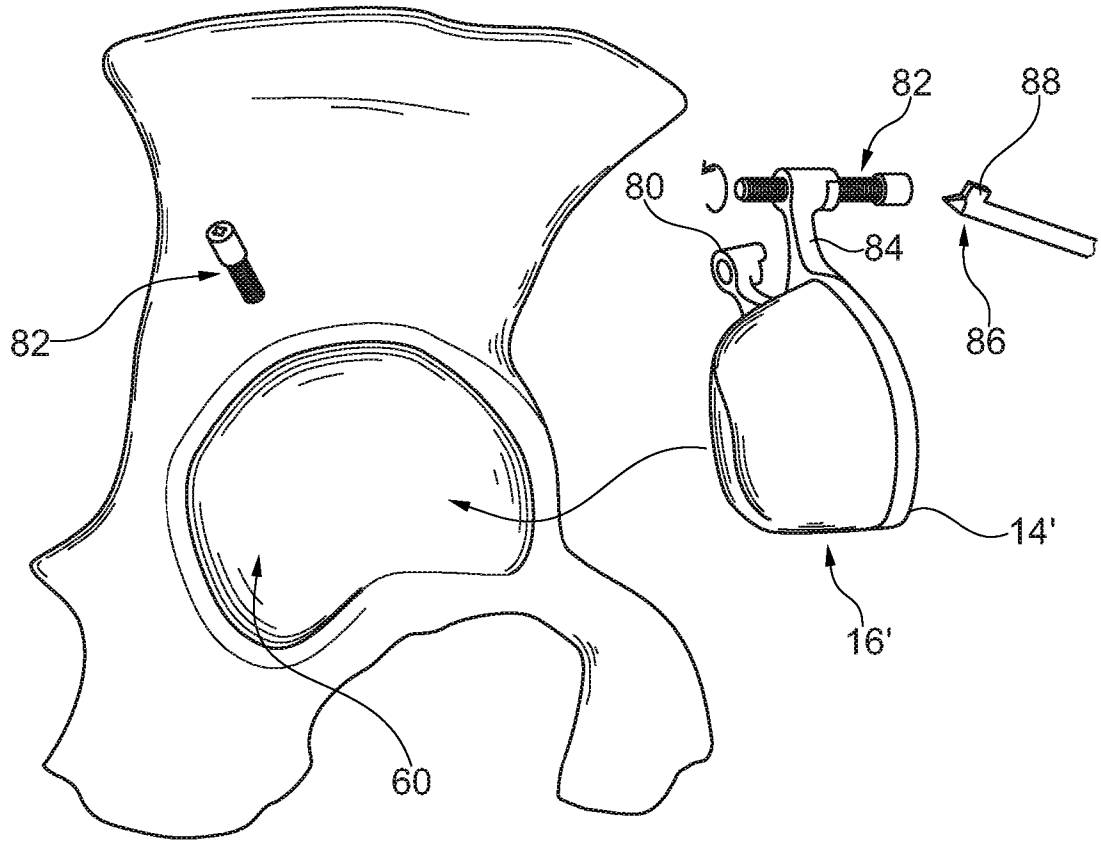


Fig. 8

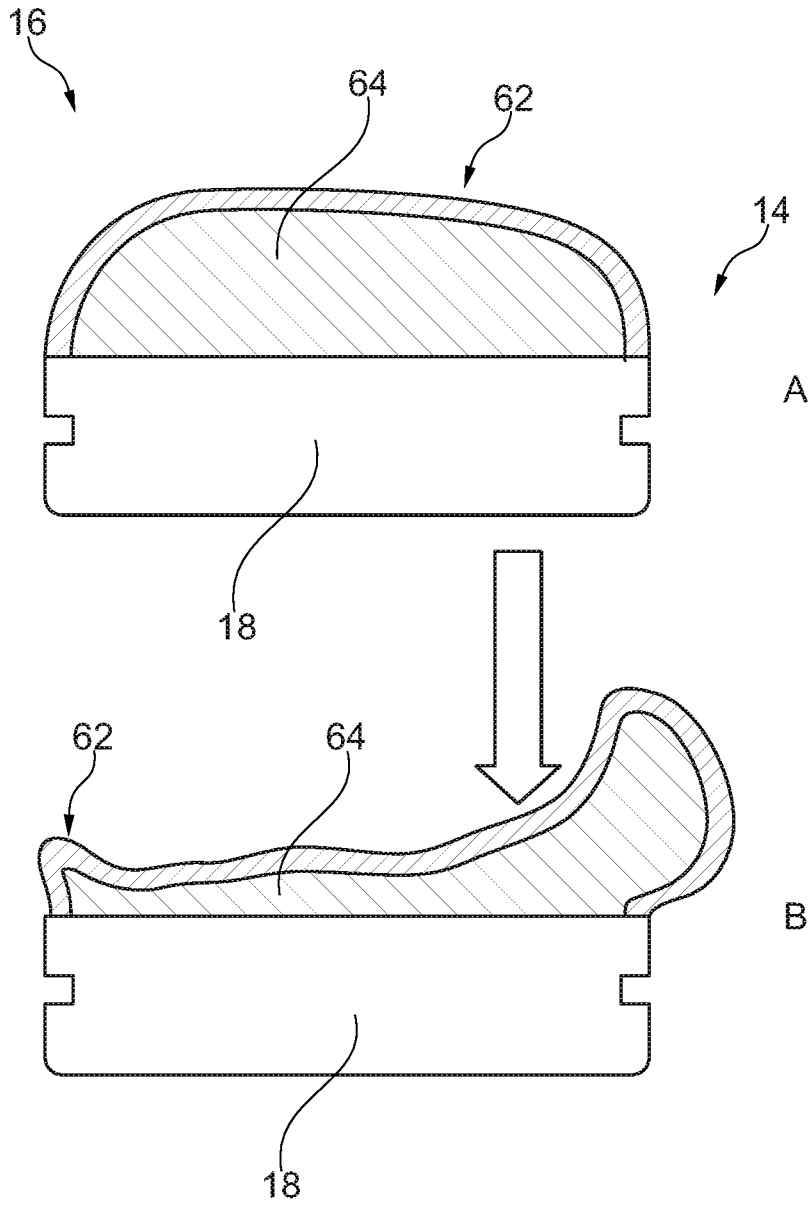


Fig. 9

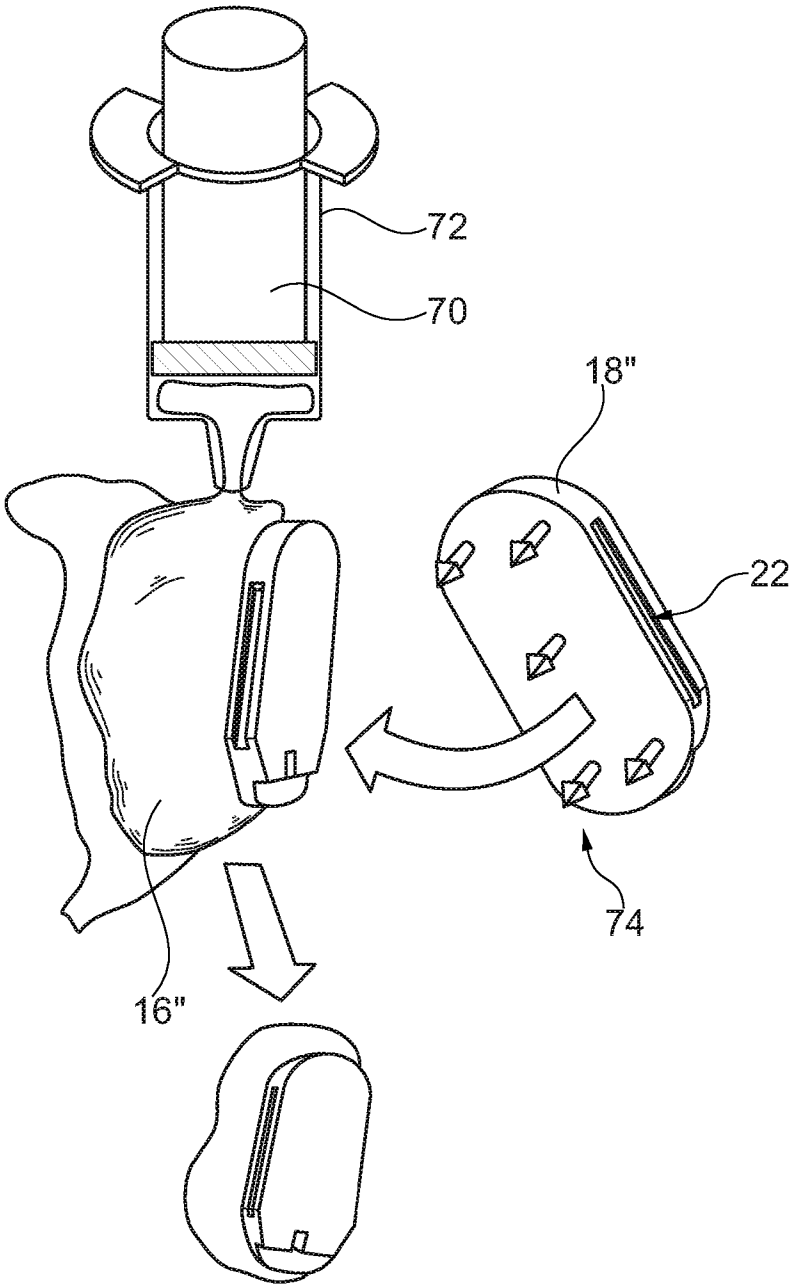


Fig. 10

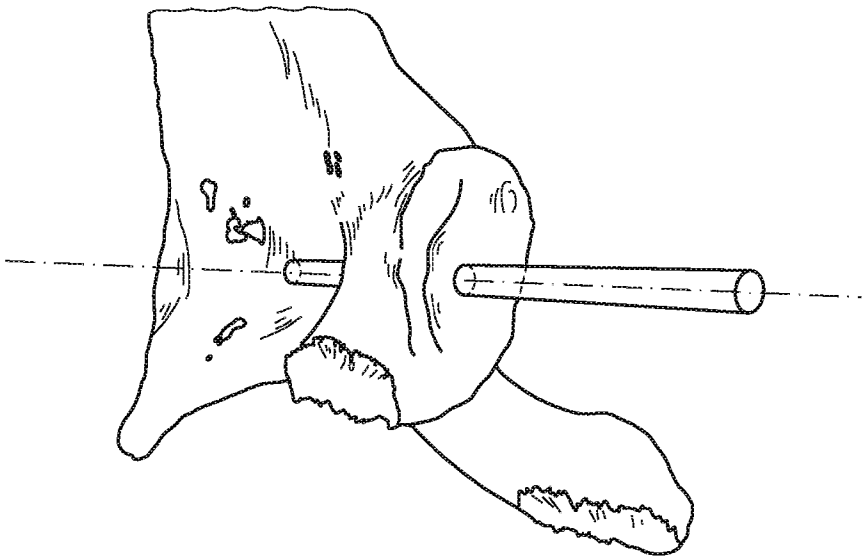


Fig. 11

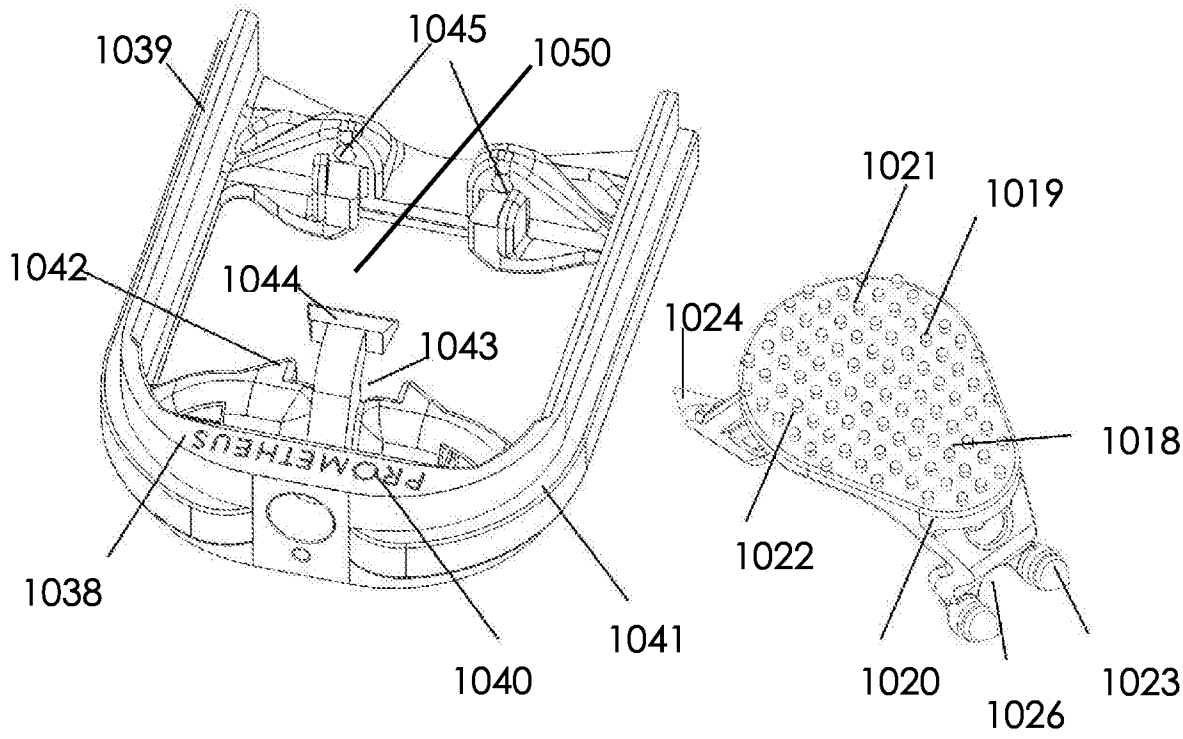


Figure 12

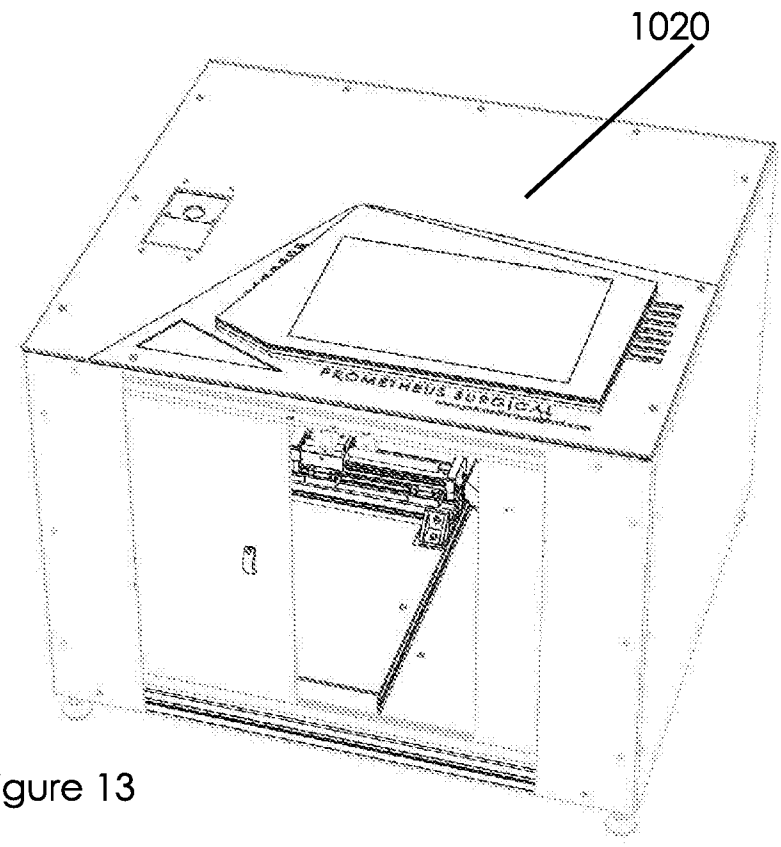


Figure 13

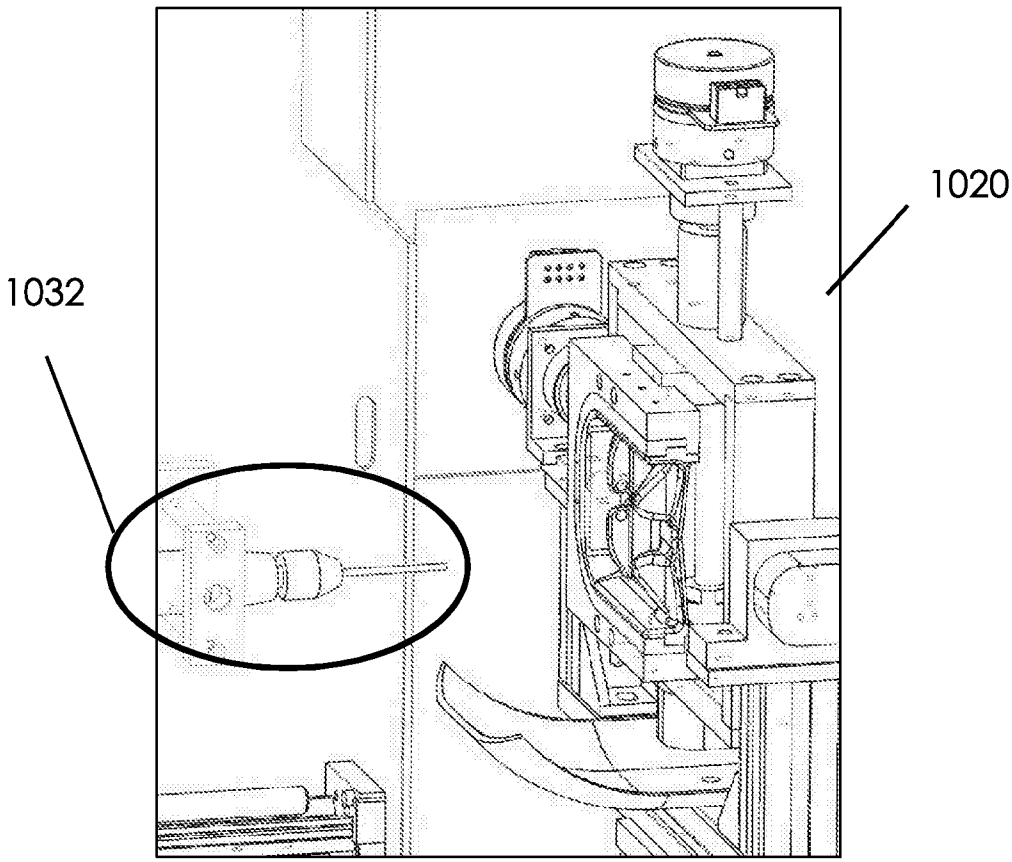


Figure 14

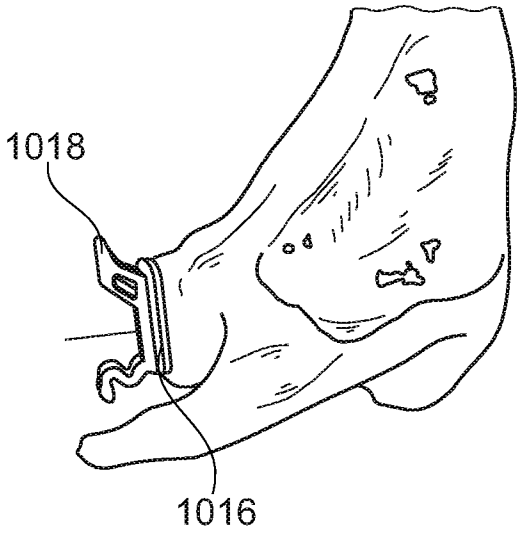


Fig. 15

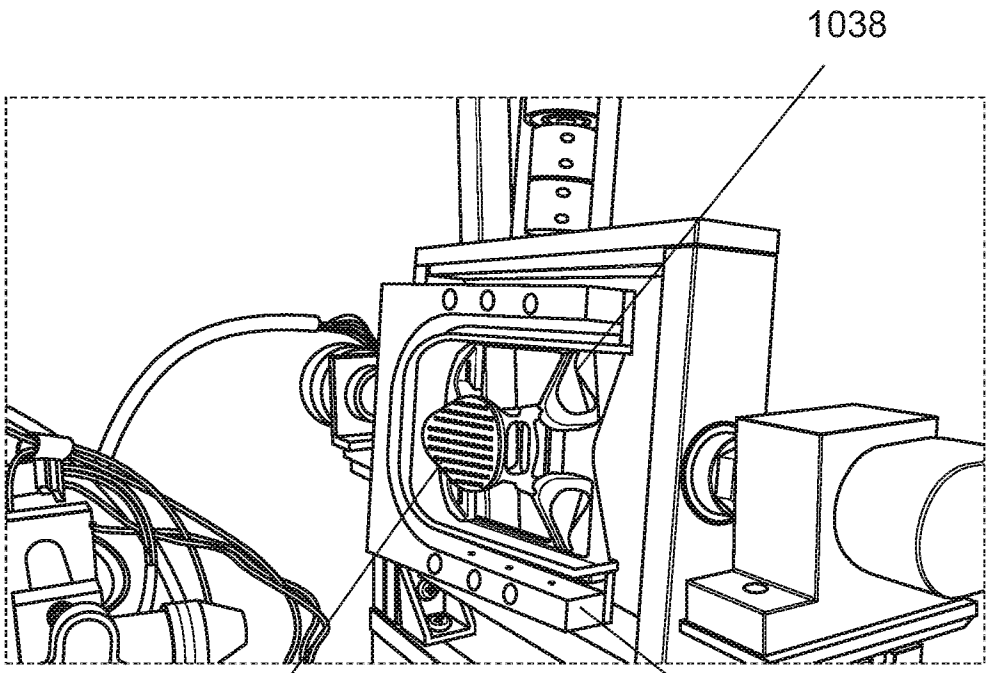


Fig. 16

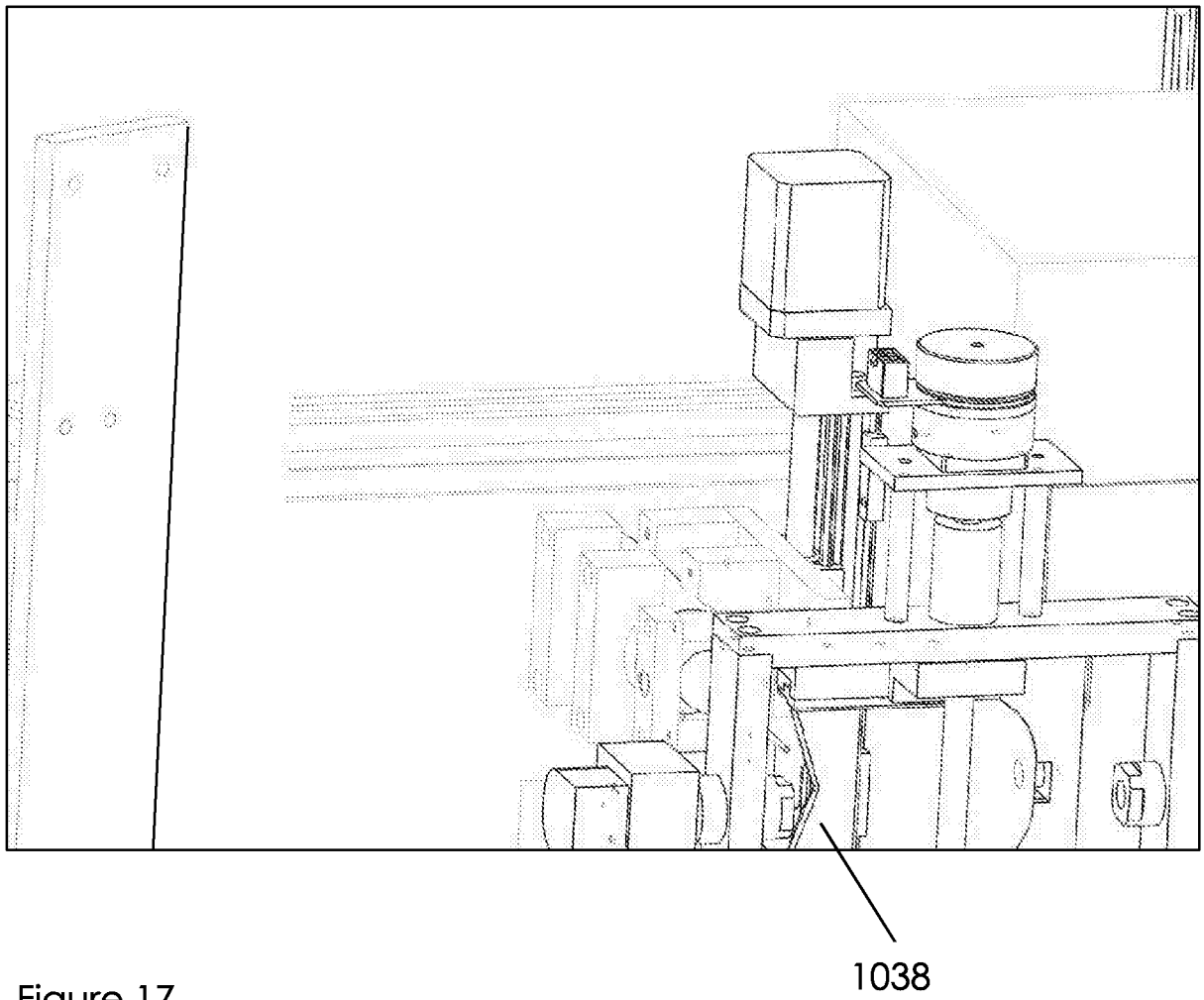


Figure 17

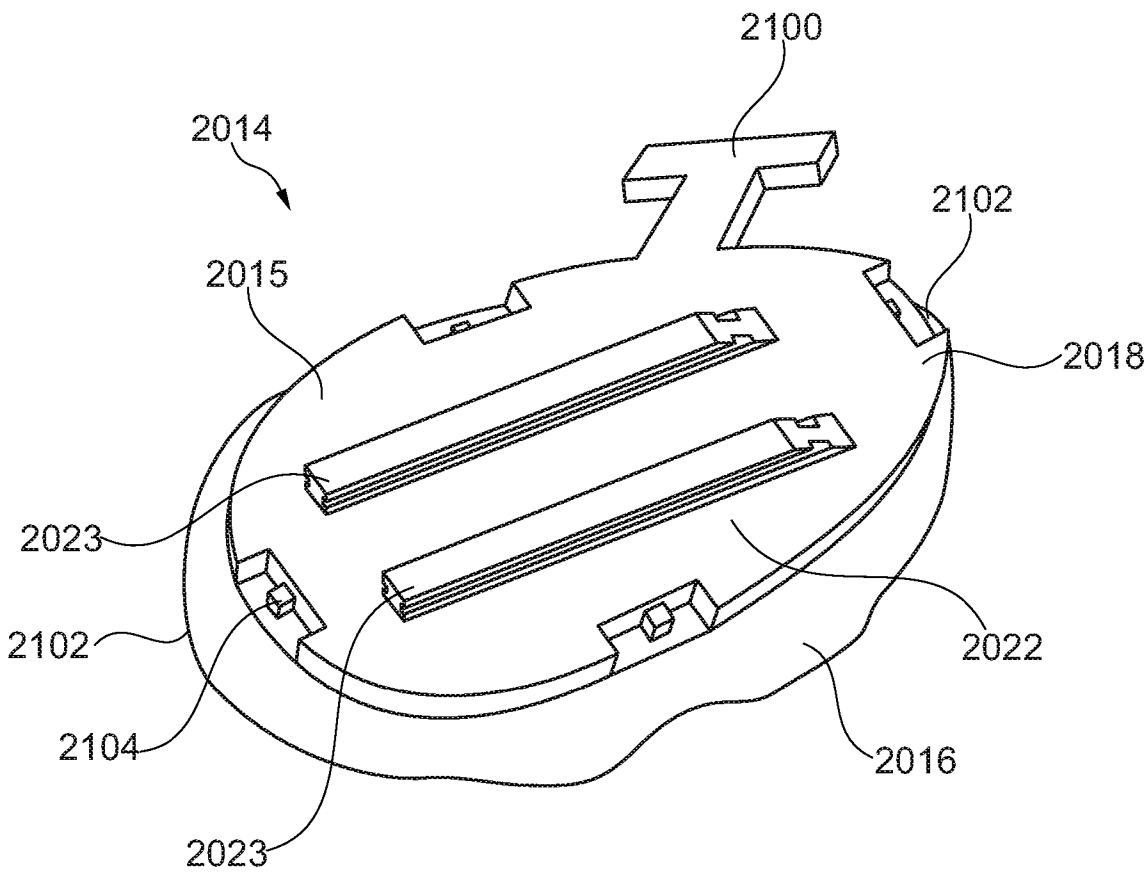


Fig. 18

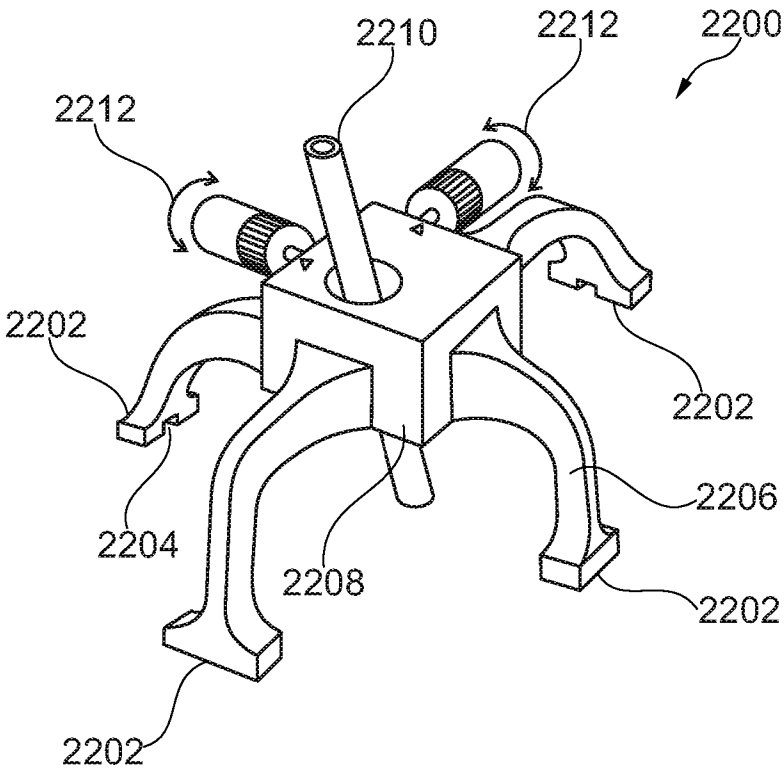


Fig. 19

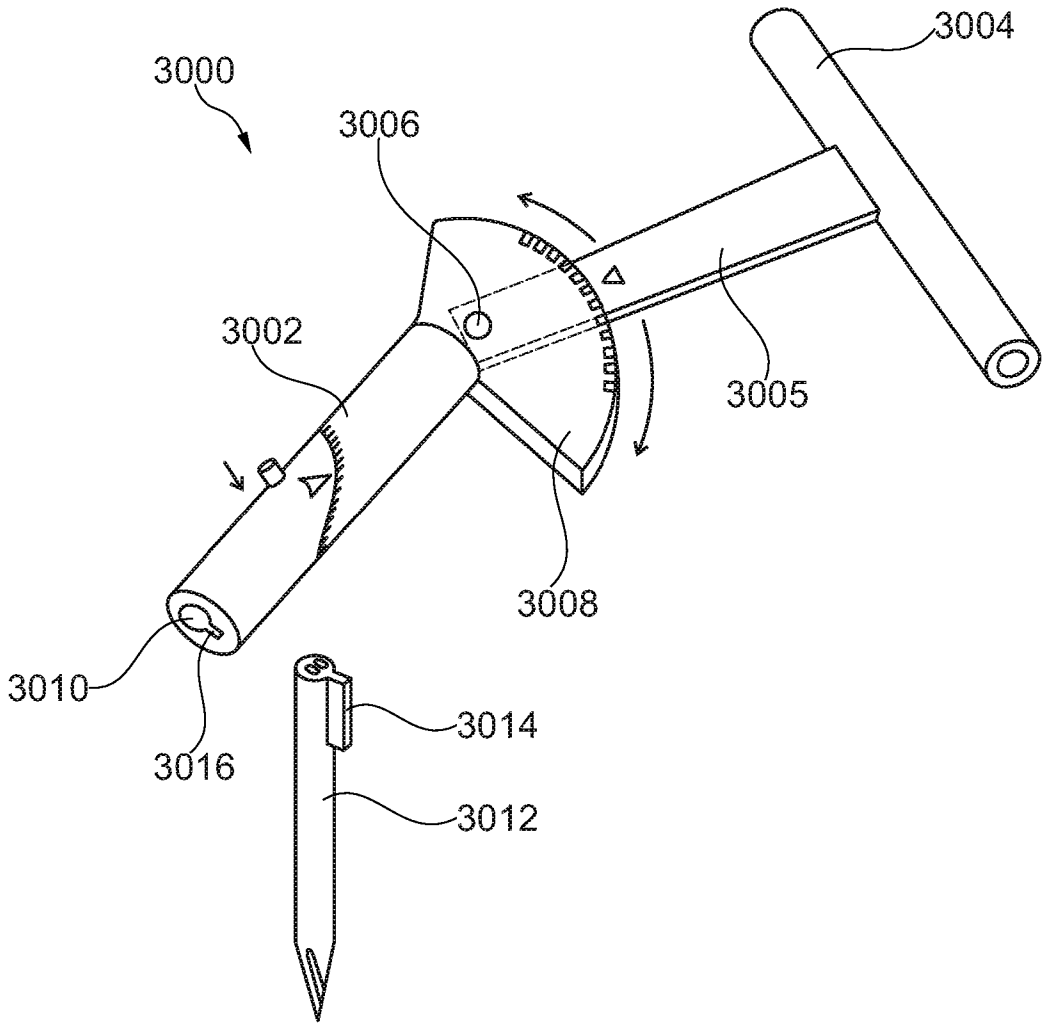


Fig. 20