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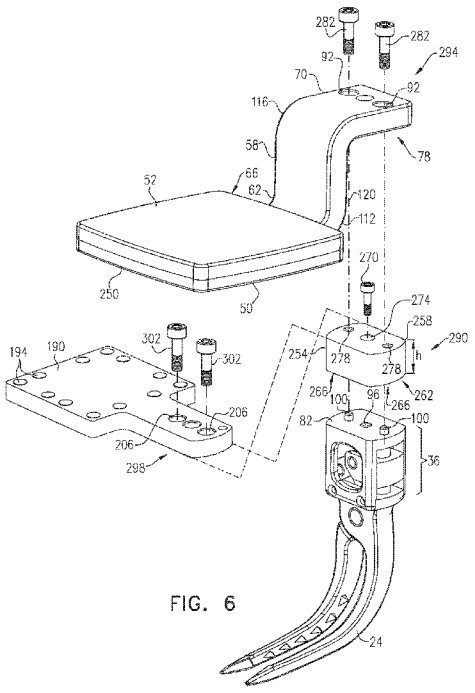


FIG. 6

(57) Abstract: A medical marking device, consisting of a radiotransparent plate having a first plurality of radiopaque elements embedded therein in a first predefined pattern and a second plurality of optical reflectors positioned on a surface in proximity to the plate in a second predefined pattern. The device also includes a sigmoid mounting arm having a first end connected to the radiotransparent plate and a second end containing one or more fastening receptacles.

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FIDUCIAL MARKER

FIELD OF THE INVENTION

The present invention relates generally to a fiducial marker, and specifically to a marker that can be used for registration of multiple frames of reference present in image guided surgery.

BACKGROUND OF THE INVENTION

In an augmented reality system that is used for image guided surgery the system should track objects used in the surgery, and/or elements of the patient undergoing the surgery. The tracking requires registration of different frames of reference operative during the surgery, including a frame of reference of the patient and a frame of reference of a fluoroscopy facility imaging the patient. The registration typically requires a fiducial marker, and a number of such markers are known. References describing examples of markers are given below.

U.S. Patent 6,314,310 to Ben-Haim et al. describes apparatus for X-ray guided surgery. The apparatus includes a reference element which is placed in contact with the body of a subject, and the element includes a plurality of fiducial marks.

U.S. Patent 7,107,091 to Jutras et al. describes a surgical device that is adapted for use with an image guided surgical system. The device facilitates monitoring inter-dependently mobile bone elements.

U.S. Patent 9,179,984 to Teichman et al. describes a navigation system that includes a multi-configuration tracking array. A plurality of tracking devices can be positioned on the multi-configuration tracking array.

U.S. Patent 9,498,231 to Haider et al. describes computer aided surgery utilizing an on tool tracking system.

U.S. Patent 9,844,413 to Doan et al. describes a monitoring system that tracks the non-visible structure of a body in three dimensions. A tracker obtains image information of an object and instruments in its vicinity, all bearing 3D tracking markers with at least one pattern segment.

U.S. Patent 9,872,733 to Shoham et al. describes a system providing a mechanical guide for drilling the holes for distal screws in intramedullary nailing surgery. The drill guide is automatically positioned by a robot relative to the distal locking nail holes, using data derived from X-ray fluoroscopic images.

U.S. Patent 10,034,713 and U.S. Patent Application 2017/0252109 to Yang et al. describe a system for tracking a position and orientation of a handheld implement. A

support member secures one or more markers relative to a longitudinal portion of the handheld implement, and a marker plane containing the markers is orientated at an angle relative to a longitudinal axis of the longitudinal portion.

U.S. Patent 10,080,616 to Wilkinson et al. describes a system that accesses image data of a bone to which a reference marker array is fixed.

U.S. Patent 10,085,709 and U.S. Patent Application 2017/0164919 to Lavallee et al. describe projecting a 3D image on at least part of 2D X-ray images and adjusting projective geometry data of the images, the adjustment comprising registration of the images with the projection of an initial 3D image using an image-to-image registration technique.

U.S. Patent 10,166,079 to McLachlin et al. describes performing intraoperative image registration during a medical procedure. A depth-encoded marker is provided to an object of interest. The marker is imageable by at least two imaging systems, and the marker has asymmetry in at least a depth dimension.

U.S. Patent 10,194,993 to Roger et al. describes a system for aiding surgery on a patient. The system includes a display device and a storage device that stores an image of at least a portion of the anatomy of the patient, including one or more surgical navigation markers positioned on the patient, for display on the display device.

U.S. Patent Application 2011/0004259 to Stallings et al. describes a device for positioning a fiducial marker on an anatomical structure. The device includes a fiducial base and a fixation member. The fiducial base comprises a turn and an extension configured to position the fiducial marker within the field of view of a tracking sensor.

U.S. Patent Application 2011/0098553 to Robbins et al. describes automatic registration of a magnetic resonance (MR) image is carried out in an image guidance system by placing MR visible markers at known positions relative to markers visible in a camera tracking system.

U.S. Patent Application 2015/0150641 to Doan et al. describes a position and orientation tracking system having one or more pattern tags, each tag comprising a plurality of contrasting portions. There is a tracker for obtaining image information about the pattern tags, and a database with geometric information describing patterns on the pattern tags.

U.S. Patent Application 2015/0366620 to Cameron et al. describes a guide for use with an access port for port-based surgery. The guide includes a body positionable over a surgical opening and a grip coupled to the body for removably receiving the access port into the surgical opening.

U.S. Patent Application 2017/0281283 to Siegler et al. describes tracking marker support structures that include one or more fiducial reference markers, where the tracking marker support structures are configured to be removably and securely attached to a skeletal region of a patient.

U.S. Patent Application 2018/0200002 to Kostrzewski describes robotic surgical systems with built-in navigation capability for patient position tracking and surgical instrument guidance during a surgical procedure, without the need for a separate navigation system.

U.S. Patent Application 2018/0318035 to McLachlin et al. describes a reference tie that is to be secured around a portion of a spine during a surgical procedure and that is to be tracked by a surgical navigation system.

U.S. Patent Application 2019/0015163 to Abhari et al. describes how navigational information relative to a site of a medical procedure is determined. The navigational information is then mapped to a common coordinate space, to determine the navigational information relative to a field of view of saved and live optical images of the surgical site.

Documents incorporated by reference in the present patent application are to be considered an integral part of the application except that, to the extent that any terms are defined in these incorporated documents in a manner that conflicts with definitions made explicitly or implicitly in the present specification, only the definitions in the present specification should be considered.

SUMMARY OF THE INVENTION

An embodiment of the present invention provides a medical marking device, including:

a radiotransparent plate having a first plurality of radiopaque elements embedded therein in a first predefined pattern and a second plurality of optical reflectors positioned on a surface in proximity to the plate in a second predefined pattern; and

a sigmoid mounting arm having a first end connected to the radiotransparent plate and a second end containing one or more fastening receptacles.

Typically, the sigmoid mounting arm is radiotransparent.

In a disclosed embodiment the sigmoid mounting arm consists of a first curved section connected to a second curved section by a straight section.

In a further disclosed embodiment the sigmoid mounting arm consists of a first curved section connected directly to a second curved section.

In a yet further disclosed embodiment the first and the second predefined patterns have no axes of symmetry and no planes of symmetry.

There is further provided, according to an embodiment of the present invention, apparatus, including:

a surgical clamp for attachment to a bone of a patient;

a spacer having a first surface and a second surface configured to connect fixedly to the surgical clamp; and

a marking device, which includes:

a radiotransparent plate having a plurality of radiopaque elements embedded therein in a predefined pattern; and

a sigmoid mounting arm having a first end fixedly connected to the radiotransparent plate and a second end, configured to mate with the first surface of the spacer, and containing one or more fastening receptacles configured for removable connection of the arm from the spacer.

In an alternative embodiment there is a fixed distance between the first and spacer surfaces.

In a further alternative embodiment the first surface includes a first plate and the second surface includes a second plate, the apparatus further having an adjustable mechanism connecting the first and the second plate configured to adjust a separation of the plates.

There is further provided, according to an embodiment of the invention, apparatus, including:

a surgical clamp for attachment to a bone of a patient;

clamp adjustment elements configured to effectuate the attachment;

a support structure enclosing the clamp adjustment elements; and

a marking device, which consists of:

a radiotransparent plate having a plurality of radiopaque elements embedded therein in a predefined pattern; and

a sigmoid mounting arm having a first end fixedly connected to the radiotransparent plate and a second end containing one or more fastening receptacles configured for removable connection of the arm from the support structure.

There is further provided, according to an embodiment of the invention, a method, including:

embedding a first plurality of radiopaque elements, arranged in a first predefined pattern, in a radiotransparent plate;

positioning a second plurality of optical reflectors on a surface in proximity to the plate in a second predefined pattern; and

connecting a first end of a sigmoid mounting arm to the radiotransparent plate, the arm having a second end containing one or more fastening receptacles.

There is further provided, according to an embodiment of the invention, a method, including:

attaching a surgical clamp to a bone of a patient;

embedding a first plurality of radiopaque elements, arranged in a first predefined pattern, in a radiotransparent plate and positioning a second plurality of optical reflectors on a surface in proximity to the plate in a second predefined pattern;

connecting a first end of a sigmoid mounting arm to the surgical clamp, the arm having a second end fixedly connected to the radiotransparent plate;

fluoroscopically scanning the radiotransparent plate, the sigmoid mounting arm, and the surgical clamp so as to form a fluoroscopic scan;

optically scanning the second plurality of optical reflectors so as to form a first optical scan;

disconnecting the first end of the sigmoid mounting arm from the surgical clamp and connecting a patient marker, having a third plurality of reflectors in a third predefined pattern, to the surgical clamp;

optically scanning the third plurality of optical reflectors so as to form a second optical scan;

deriving from the first and the second optical scans a correction vector indicative of a difference between a location and an orientation of the radiotransparent plate and a location and an orientation of the patient marker; and

in response to the correction vector and the fluoroscopic scan, determining a spatial transformation between the patient and the surgical clamp so as register a frame of reference of the patient with a frame of reference of the surgical clamp.

Typically, the method includes, in response to registration of the frames of reference, presenting to a professional performing surgery on the patient a stored image of the patient aligned with the patient.

The present disclosure will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic diagram illustrating a medical marking device as it is used during a preparatory stage of a medical procedure, according to an embodiment of the present invention;

Fig. 2 is a schematic view of the device separated from a clamp, according to an embodiment of the present invention;

Fig. 3 is a schematic exploded view of the device, according to an embodiment of the present invention;

Fig. 4 is a flowchart of steps performed in both a preparatory stage and a subsequent stage of a procedure, according to an embodiment of the present invention;

Fig. 5 is a schematic illustration of the subsequent stage of the procedure, according to an embodiment of the present invention; and

Figs. 6, 7, and 8 are schematic views of a medical marking device, according to alternative embodiments of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

OVERVIEW

An embodiment of the present invention provides a fiducial marker that is used to register different frames of reference that are present in image guided surgery on a patient. The image guided surgery may be performed by a medical professional wearing an augmented reality head-mounted display, and in order for the display to operate correctly, images of the patient presented to the professional should align with the actual patient. The registration provided by the fiducial marker ensures the necessary image alignment.

In a disclosed embodiment the marker is connected to a clamp which has been attached, in a preparatory stage of a procedure performed on a patient, to one or more spinous processes of the patient. To accommodate physical differences between patients, embodiments of the invention provide alternative systems for attaching the fiducial marker to the clamp, the alternative systems including fixed width and variable width spacers connecting the marker to the clamp.

The fiducial marker comprises radiopaque elements arranged in a predetermined pattern, so that a computerized tomography (CT) scanned image of the marker and of the patient enables frames of reference of the patient's anatomy and of the clamp to be registered in the preparatory stage.

In a subsequent stage of the procedure the fiducial marker is replaced by a patient marker. In some embodiments of the invention the fiducial marker also comprises optical reflectors and images of these may be used to accommodate different positions of the patient marker.

The registration derived in the preparatory stage is used in the subsequent stage of the procedure so that images of the patient marker are used to track the patient, and to ensure that images presented to the professional are correctly aligned.

The CT facility typically comprises an intraoperative CT scanner which has a narrow field of view, so that for the registration to be successful, the radiopaque elements of the fiducial marker and of the vertebral body should be close. Embodiments of the invention achieve this close proximity by having the fiducial marker in the form of a "step," with one part of the step comprising a plate containing the radiopaque elements, the step-like form of the fiducial marker enabling the plate to be positioned close to the vertebral body. A second part of the step attaches to the clamp, and there is a known mechanical offset between the two parts.

In embodiments of the present invention the plate is radiotransparent, and has the plurality of radiopaque elements referred to above embedded therein in the predetermined pattern. To achieve the step-like form described above, a first end of a sigmoid mounting arm is fixedly connected to the radiotransparent plate. In addition, the sigmoid mounting arm has a second end containing one or more fastening receptacles that are configured for removable connection of the arm to the clamp that is attached to the spinous processes.

In a disclosed embodiment the radiotransparent plate, the sigmoid mounting arm, and the surgical clamp are scanned fluoroscopically so as to form a fluoroscopic scan. In response to the fluoroscopic scan and the predetermined mechanical offset, a spatial transformation between the patient and the surgical clamp is determined so as to register a frame of reference of the patient with a frame of reference of the surgical clamp.

Typically, in response to registration of the frames of reference, a professional performing surgery on the patient is presented with a stored image of the patient aligned with the patient.

SYSTEM DESCRIPTION

In the following, all directional references (e.g., upper, lower, upward, downward, left, right, top, bottom, above, below, vertical, and horizontal) are only used for identification purposes to aid the reader's understanding of the present invention,

and do not create limitations, particularly as to the position, orientation, or use of embodiments of the invention.

Reference is now made to Fig. 1, which is a schematic diagram illustrating a medical marking device 10, as it is used during a preparatory stage of a medical procedure on a patient 20, according to an embodiment of the present invention. The procedure referred to herein is assumed to comprise a preparatory stage and a subsequent stage, and, as is described in more detail below, device 10 may be used during the preparatory stage. Device 10 is also herein termed a fiducial marker 10. As is also described below, a medical professional uses an augmented reality system during the subsequent stage of the procedure.

The augmented reality system projects virtual images of elements of patient 20 for viewing by the medical professional. The image projection is performed simultaneously with the professional viewing the actual patient, so that the projected images should align with the patient. In order for the projected images in the augmented reality system to align with the patient, frames of reference of the patient and of a clamp attached to a bone of the patient are registered during the preparatory stage, using marking device 10. In the subsequent stage, where the augmented reality system is used, the registration of the clamp computed in the preparatory phase is used to correctly align the images produced by the system.

In the description herein the procedure is assumed to comprise an operation on a spine of patient 20, and in order to perform the registration referred to above, prior to the operation, and in the preparatory stage of the procedure, the medical professional inserts a surgical bone clamp 24 into patient 20. A site of insertion 28 of the clamp is close to, but separate from, a site 32 of the patient's spine to be operated on during the subsequent stage of the procedure. The professional clamps clamp 24 to a section of the spine of the patient, typically to one or more spinous processes of the patient, and the clamp has a support structure 36 to which marker 10 is fastened. A clamp similar to clamp 24 is described in U.S. Patent Application 16/120,480 which is incorporated herein by reference.

Fig. 2 is a schematic view of device 10 separated from clamp 24, and Fig. 3 is a schematic exploded view of device 10, according to an embodiment of the present invention. Device 10 comprises a radiotransparent plate 50, typically formed of a biocompatible plastic such as a polyimide. A plurality of substantially similar radiopaque elements 54, herein assumed to comprise spheres, are embedded within plate 50. Elements 54 are embedded within plate 50 in a predefined pattern, which is herein

assumed to comprise points on sides of a rectangle. However, any other convenient predefined pattern may be used. In some embodiments the predefined pattern has no axis or plane of symmetry. Typically plate 50 is protected by a cover 52.

A radiotransparent sigmoid mounting arm 58, typically formed from the same biocompatible plastic as plate 50, is connected by a first end 62 of the arm to an edge 66 of the plate. A second end 70 of the arm contains one or more fastening receptacles 74 that enable the arm to be securely and fixedly fastened to support structure 36 in a predefined orientation. In embodiments of the invention, support structure 36 encloses adjustment elements 102 for clamp 24, the adjustment elements effectuating attachment of jaws of the clamp to a bone of patient 20. In an embodiment of the invention the support structure has differing depths d.

Second end 70 has a lower plane surface 78 which connects with an upper surface 82 of support structure 36. In a disclosed embodiment receptacles 74 comprise a captive screw 86 and holes 92, the screw and the holes mating respectively with a threaded hole 96 and studs 100 in upper surface 82.

As is apparent from the figures, the length of arm 58 determines the separation of plate 50 from lower surface 78 of the arm second end. Embodiments of the present invention comprise sets of devices 10, each member of the set being generally as described herein, but having a different known length of arm 58 from the other set members. Arm 58 is formed from two curved sections 112, 116, separated by a straight section 120, and the different lengths of the arm are formed by varying a length of straight section 120. In embodiments of the present invention the length of straight section 120 varies from 0 (zero) to up to approximately 7 cm, although values greater than 7 cm are possible. It will be understood that when the length of section 120 is 0 the two curved sections are connected together with no intervening straight section.

Each member of the set, comprising a respective plate 50 connected to a respective sigmoid mounting arm 58 in a step-like arrangement, may be formed as a single piece, typically by injection molding. It will be understood that each member of the set has known dimensions, so that there is a known mechanical offset between plate 50 and the second end of the arm, including the lower surface 78 of the arm second end.

Typically, for each member of a set of devices 10, the predefined pattern of radiopaque elements 54 is configured to have a one-to-one correspondence with the known mechanical offset. In this case, identification of the pattern provides a unique and unambiguous value for the mechanical offset, and providing the correspondence enables embodiments of the invention to support substantially any offset. As is described below,

the correspondence may be stored in a computer memory, and the memory may be accessed so that the unique value of the mechanical offset for a given set member may be determined from the element pattern of the member.

In addition to the sets of devices 10 described above, embodiments of the present invention also comprise sets of clamps 24 with differing depths d of support structure 36. It will be understood that for any given arm length 58, the depth d of support structure 26 determines the separation of plate 50 from a given clamp selected from the sets of clamps 24.

Returning to Fig. 1, device 10 is typically selected from the set of devices 10, and clamp 24 is typically selected from the set of clamps 24 so that when the device is attached to upper surface 82 of support structure 36, plate 50 of the device is as close as possible to site 32, i.e., to the site of the operation to be performed in the procedure subsequent stage. Once a selected device 10 has been attached to surface 82, a computerized tomography (CT) scan of the device and of the patient's spine is performed. The scan may be performed by inserting patient 20 into a CT scanning facility, typically an intra-operative CT scanner. The insertion may be implemented by bringing the CT scanning facility to patient 20, or by transporting the patient to the facility.

A processing system 104, comprising a computer processor 108 coupled to a memory 114, receives the scan of device 10 and the patient's spine, and stores the scan as an image 118 in the memory. The one-to-one correspondence referred to above may also be stored in memory 114 as a correspondence 122. The processing system is configured to analyze the stored image so as to identify the pattern formed by radiopaque elements 54, and from the identified pattern to register a frame of reference of device 10, and thus of attached clamp 24, with a frame of reference of the patient's anatomy.

Fig. 4 is a flowchart of steps performed in both the preparatory stage and the subsequent stage of the procedure, according to an embodiment of the present invention. In an initial step 150 and in an attachment step 152 of the preparatory stage, clamp 24 is inserted into patient 20 and clamped, using adjustment elements 102, to one or more spinous processes of the patient, and fiducial marker 10 is attached to support structure 36 of the clamp, as is described above with reference to Fig. 1.

In a scan step 154 a CT scan of marker 10, attached as described above, is performed, and image 118 of the scan is stored in memory 114. In an analysis step 156 the processing system analyzes the stored image, and from the analysis registers a frame

of reference of marker 10, and thus of attached clamp 24, with a frame of reference of the patient's anatomy.

It will be appreciated that the registration of step 156 uses the known mechanical offset of plate 50 with lower surface 78 to provide a location and orientation of upper surface 82 of the clamp with respect to the frame of reference of the patient's anatomy. In the cases where the one-to-one correspondence referred to above is stored as correspondence 122 in memory 114, the processing system may determine the mechanical offset, in analysis step 156, from the pattern identified by the analysis, using the stored correspondence.

Analysis step 156 also determines a spatial transformation between the patient and the surgical clamp, and this is used, together with the mechanical offset, to calculate the registration between the two frames of reference.

In a concluding step 158 of the preparatory stage, fiducial marker 10 is removed from clamp 24, leaving upper surface 82 exposed.

Fig. 5 is a schematic illustration of the subsequent stage of the procedure, according to an embodiment of the present invention. In the subsequent stage a patient marker attachment step 160 and an alignment step 162 are performed, and these steps are described further below. In the subsequent stage, a medical professional 180 operates on the patient. Professional 180 wears an augmented reality head-mounted display (HMD) 184, which is configured to present stored images that are aligned with the patient, to the professional. In order to operate, HMD 184 is coupled to processor 108 of system 104 and the stored images may be stored in memory 114. Alternatively, HMD 184 has its own dedicated processor which performs similar functions to those performed by processor 108. A head-mounted display similar to HMD 184 is described in U.S. Patent 9,928,629, which is incorporated herein by reference.

To perform the alignment for HMD 184, in attachment step 160 a patient marker 190 with known, preset, dimensions, is attached to upper surface 82 of support structure 36 of clamp 24. Marker 190 comprises fastening receptacles 198, substantially similar to receptacles 74, so that in the disclosed embodiment referred to above receptacles 198 comprise a captive screw 202 and holes 206, the screw and the holes mating respectively with threaded hole 96 and studs 100 in upper surface 82 of clamp 24. A patient marker similar to marker 190 is described in PCT Patent Application PCT/IB2019/053524, which is incorporated herein by reference.

Marker 190 comprises optical reflectors 194 incorporated into the surface of the patient marker, and the reflectors are arranged in a predetermined pattern so that an image of the reflectors can be analyzed so as to provide an unambiguous measure of the location and of the orientation of the marker.

In alignment step 162 the HMD projects visible or invisible light to patient marker 190, and acquires images of reflectors 194 of the marker. From the acquired images, the HMD processor determines the location and orientation of the patient marker. Since the patient marker has known dimensions, and is attached to upper surface 82, the processor applies the registration found in step 156 (between the frames of reference of fiducial marker 10 and the patient's anatomy) to ensure that the images projected by the HMD align with the anatomy of patient 20.

The description above provides details of how fiducial marker 10 and patient marker 190 may be attached, via clamp 24, as close as possible to site 32, i.e., to the site of the operation performed on patient 20. The following description provides further details of embodiments of the invention which may be used, alternatively or additionally, so that the patient marker and the fiducial marker are as close as possible to the site of the operation.

Fig. 6 is a schematic view of a medical marking device 250 separated from clamp 24, according to an alternative embodiment of the present invention. Apart from the differences described below, the operation of device 250 is generally similar to that of device 10 (Figs. 1 - 5), and elements indicated by the same reference numerals in both devices 250 and 10 are generally similar in construction and in operation. Device 250 is herein also termed fiducial marker 250.

In contrast to device 10, wherein second end 70 of the sigmoid arm is configured to connect directly to upper surface 82 of support structure 36, in device 250 there is an intervening spacer 254 between the sigmoid arm second end and surface 82. Spacer 254 is formed to have a pair of opposing parallel surfaces, an upper spacer surface 258 and a lower spacer surface 262, separated by a preset fixed distance h. When assembled, lower surface 262 fixedly mates with upper surface 82 of support structure 36, and lower surface 78 of the sigmoid arm removably mates with upper surface 258 of spacer 254.

So that lower spacer surface 262 can fixedly mate with support structure surface 82, the lower spacer surface has two blind holes 266 inlet into the lower spacer surface that align with and fit to studs 100. In addition, spacer 254 comprises a captive screw 270, residing in a hole 274 of the spacer. The captive screw is configured so that when it is screwed into threaded hole 96 it fastens the spacer fixedly to support structure 36,

while the head of screw 270 is within hole 274 and below upper surface 258 of the spacer. Captive screw 270 and blind holes 266 act as spacer lower surface fastening receptacles 290.

Once spacer 254 is fixed to support structure 36, sigmoid arm lower surface 78 may be removably mated with the upper surface of the spacer. The spacer upper surface comprises two threaded holes 278 which align with holes 92. To removably mate the sigmoid arm lower surface with the spacer, a pair of retaining screws 282 pass through holes 92, and are screwed into threaded holes 278. Screws 282 and threaded holes 278 act as spacer upper surface fastening receptacles 294.

Spacer 254 is typically part of a set of such spacers. In one embodiment spacers of the set have values of h in a range of 1 cm – 5 cm, but in other embodiments the set has different ranges of h. Spacer 254 is used to raise plate 50 above clamp 24 while keeping the plate as close as possible to the patient's spine, and the value of h of a selected spacer may be chosen according to patient characteristics. It will be understood that having a set of spacers 254 with different values of h replaces, or is in addition to, the requirement of different lengths of arm 58 referred to above for a set of devices 10.

During a procedure where marker 250 is used, after it has been attached, as described above, to the upper surface of spacer 254, it may be scanned fluoroscopically, and may then be removed from the spacer upper surface. After removal, as illustrated in Fig. 6, patient marker 190 may then be attached to the spacer upper surface. The patient marker attachment is implemented by screws 302, substantially similar to screws 282, penetrating holes 206 and being screwed into threaded holes 278. Screws 302 and threaded holes 278 act as fastening receptacles 298 for the patient marker, receptacles 298 being substantially similar to receptacles 294.

Referring back to the flowchart of Fig. 4, when marker 250 is used in place of marker 10, the actions described above for each of the steps of the flowchart are substantially similar, except as follows.

In step 152, spacer 254 is first fixedly attached to support structure 36, and then fiducial marker 250 is removably attached to the spacer, as described above.

In step 158 fiducial marker 250 is removed from the spacer, and in step 160 patient marker 190 is attached to the spacer, as described above.

It will be understood that because fiducial marker 250 and patient marker 190 are attached to the same location, the upper surface of the spacer, the registration found in step 156 can be used in alignment step 162.

Fig. 7 is a schematic view of a medical marking device 350 separated from clamp 24, according to an alternative embodiment of the present invention. Apart from the differences described below, the operation of device 350 is generally similar to that of device 250 (Figs. 1 - 6), and elements indicated by the same reference numerals in both devices 250 and 350 are generally similar in construction and in operation. Device 350 is herein also termed fiducial marker 350.

In contrast to device 250, which uses spacer 254 with a preset fixed distance between the upper and lower surfaces of the spacer, device 350 uses a spacer 354, herein also termed adjustable spacer 354, which has adjustable distances between an upper adjustable spacer plate 358 and a lower adjustable spacer plate 362. Elements in the two plates of adjustable spacer 354 correspond to respective elements in the two surfaces of fixed spacer 254. Thus, in upper plate 358 threaded holes 378 and a hole 374 are substantially similar to holes 278 and 274, so that hole 374 permits passage of captive screw 270. Screws 282 and threaded holes 378 act as upper adjustable spacer plate fastening receptacles 394.

In lower plate 362 holes 366 are substantially similar in diameter and position to blind holes 266, although holes 366 are not necessarily blind. Lower plate 362 also comprises a hole 374A, which aligns with hole 374 and which is sized to retain screw 270. Captive screw 270 and holes 366 act as lower adjustable spacer plate fastening receptacles 390.

Adjustable spacer 354 comprises an adjustable mechanism 400, which connects the lower and upper plates of adjustable spacer 354. Mechanism 400 maintains the upper plates substantially parallel to each other, while operation of the mechanism adjusts the separation of the plates.

In one embodiment, illustrated in Fig. 7, mechanism 400 comprises a rod 404 having clockwise and counterclockwise threads, and the threads are configured to mate with respective nuts 308, 412 slidingly attached to upper plate 358. Mechanism 400 further comprises two levers 416, 420, having their fulcra coupled to lower plate 362, and their endpoints attached to the respective nuts. Rotation of rod 404 of mechanism 400 increases or decrease the nut separation, and correspondingly decreases or increases the separation between the upper and lower plates of adjustable spacer 354.

Other mechanisms for connecting the upper and lower plates of spacer 354, that maintain the plates substantially parallel to each other while providing adjustable separation of the plates, will be apparent to those having ordinary skill in the art. All such mechanisms are assumed to be comprised within the scope of the present invention.

Referring back to the flowchart of Fig. 4, when marker 350 is used in place of marker 10, the actions described above for each of the steps of the flowchart are substantially similar, except as follows.

In step 152, lower plate 362 is first fixedly attached to support structure 36, and then fiducial marker 350 is removably attached to upper plate 358, as described above.

In step 158 fiducial marker 350 is removed from the spacer upper plate 358, and in step 160 patient marker 190 is attached to the spacer upper plate, as described above.

It will be understood that because fiducial marker 350 and patient marker 190 are attached to the same location, the upper surface of the spacer upper plate, the registration found in step 156 can be used in alignment step 162.

Fig. 8 is a schematic view of a medical marking device 450 separated from clamp 24, according to an alternative embodiment of the present invention. Apart from the differences described below, the operation of device 450 is generally similar to that of device 250 (Figs. 1 - 6), and elements indicated by the same reference numerals in both devices 250 and 450 are generally similar in construction and in operation. Device 450 is herein also termed fiducial marker 450.

In contrast to device 250, a plurality of optical reflectors 454 are positioned on a surface 458 of cover 52 of plate 50. In one embodiment reflectors 454 are arranged on the surface in a predetermined pattern, typically with no rotational axis of symmetry (other than a trivial axis of symmetry for rotating by 360°) and no mirror plane of symmetry. The predetermined pattern is configured so that an image of the reflectors can be analyzed so as to provide an unambiguous measure of the location and of the orientation of plate 50. The imaging of reflectors 454, and the analysis of the image, is substantially as described above for reflectors 194 of patient marker 190.

Device 450 is typically used with spacer 254 and/or spacer 354, described above with reference to Figs. 6 and 7. When used device 450 is used with one of these spacers, patient marker 190 may be positioned with respect to the spacer as described above. However, because of the presence of reflectors 454, patient marker 190 may instead be positioned in any other convenient location, as is explained below with reference to changes in the flowchart of Fig. 4.

For clarity, in the following description of changes to the flowchart, device 450 is assumed to be used with spacer 254. Those having ordinary skill in the art will be able to adapt the description, *mutatis mutandis*, if device 450 is used with spacer 354 or with any other spacer effectively separating plate 50 from support structure 36.

In step 152 of the flowchart, spacer 254 is first attached to support structure 36 using screw 270, and then fiducial marker 450 is attached to the spacer using screws 282, as described above.

Steps 154 and 156 are performed as described above with reference to Fig. 4, so as to register a frame of reference of marker 450, and thus of attached clamp 24, with a frame of reference of the patient's anatomy.

In step 158, prior to removal of fiducial marker 450 from the spacer, reflectors 454 of the marker are optically scanned and are imaged using HMD 184. The processor associated with HMD 184 analyzes the image to find the location and orientation of the reflectors, and thus of plate 50, in the frame of reference of the HMD. Marker 450 may then be removed from spacer 254, and the spacer may be removed from support structure 36.

Steps 160 and 162 are implemented generally as described above, so that in step 160 patient marker 190 is attached to upper surface 82 of support structure 36.

In step 162 patient marker 190 is optically scanned and is tracked, and the processor of the HMD is able to use the location and orientation of plate 50 found in step 158 to generate a correction vector, between the positions of the plate and the positions of the patient marker. The correction vector corrects for the fact that the fiducial marker and the patient marker are attached to different locations (i.e., the spacer and the support structure). In step 162 the HMD processor applies this correction vector to ensure that the images projected by the HMD align with the anatomy of patient 20.

The description above is for a particular case where patient marker 190 and fiducial marker 450 are attached to different elements related to clamp 24. Those having ordinary skill in the art will be able to adapt the description, *mutatis mutandis*, for other cases of different attachments, and all such cases are assumed to be comprised with the scope of the present invention.

It will be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

CLAIMS

We claim:

1. A medical marking device, comprising:

a radiotransparent plate comprising a first plurality of radiopaque elements embedded therein in a first predefined pattern and a second plurality of optical reflectors positioned on a surface in proximity to the plate in a second predefined pattern; and

a sigmoid mounting arm having a first end connected to the radiotransparent plate and a second end containing one or more fastening receptacles.

2. The device according to claim 1, wherein the sigmoid mounting arm is radiotransparent.

3. The device according to claim 1, wherein the sigmoid mounting arm comprises a first curved section connected to a second curved section by a straight section.

4. The device according to claim 1, wherein the sigmoid mounting arm comprises a first curved section connected directly to a second curved section.

5. The device according to claim 1, wherein the first and the second predefined patterns have no axes of symmetry and no planes of symmetry.

6. Apparatus, comprising:

a surgical clamp for attachment to a bone of a patient;

a spacer having a first surface and a second surface configured to connect fixedly to the surgical clamp; and

a marking device, which comprises:

a radiotransparent plate comprising a plurality of radiopaque elements embedded therein in a predefined pattern; and

a sigmoid mounting arm having a first end fixedly connected to the radiotransparent plate and a second end, configured to mate with the first surface of the spacer, and containing one or more fastening receptacles configured for removable connection of the arm from the spacer.

7. The apparatus according to claim 6, wherein the sigmoid mounting arm is radiotransparent.

8. The apparatus according to claim 6, wherein the sigmoid mounting arm comprises a first curved section connected to a second curved section by a straight section.

9. The apparatus according to claim 6, wherein the sigmoid mounting arm comprises a first curved section connected directly to a second curved section.

10. The apparatus according to claim 6, wherein the predefined pattern has no axis of symmetry and no plane of symmetry.

11. The apparatus according to claim 6, wherein there is a fixed distance between the first and spacer surfaces.

12. The apparatus according to claim 6, wherein the first surface comprises a first plate and the second surface comprises a second plate, the apparatus further comprising an adjustable mechanism connecting the first and the second plate configured to adjust a separation of the plates.

13. Apparatus, comprising:

a surgical clamp for attachment to a bone of a patient;

clamp adjustment elements configured to effectuate the attachment;

a support structure enclosing the clamp adjustment elements; and

a marking device, which comprises:

a radiotransparent plate comprising a plurality of radiopaque elements embedded therein in a predefined pattern; and

a sigmoid mounting arm having a first end fixedly connected to the radiotransparent plate and a second end containing one or more fastening receptacles configured for removable connection of the arm from the support structure.

14. A method, comprising:

embedding a first plurality of radiopaque elements, arranged in a first predefined pattern, in a radiotransparent plate;

positioning a second plurality of optical reflectors on a surface in proximity to the plate in a second predefined pattern; and

connecting a first end of a sigmoid mounting arm to the radiotransparent plate, the arm having a second end containing one or more fastening receptacles.

15. The method according to claim 14, wherein the sigmoid mounting arm is radiotransparent.

16. The method according to claim 14, wherein the sigmoid mounting arm comprises a first curved section connected to a second curved section by a straight section.

17. The method according to claim 11, wherein the sigmoid mounting arm comprises a first curved section connected directly to a second curved section.

18. The method according to claim 11, wherein the first and the second predefined patterns have no axes of symmetry and no planes of symmetry.

19. A method, comprising:

attaching a surgical clamp to a bone of a patient;

embedding a first plurality of radiopaque elements, arranged in a first predefined pattern, in a radiotransparent plate and positioning a second plurality of optical reflectors on a surface in proximity to the plate in a second predefined pattern;

connecting a first end of a sigmoid mounting arm to the surgical clamp, the arm having a second end fixedly connected to the radiotransparent plate;

fluoroscopically scanning the radiotransparent plate, the sigmoid mounting arm, and the surgical clamp so as to form a fluoroscopic scan;

optically scanning the second plurality of optical reflectors so as to form a first optical scan;

disconnecting the first end of the sigmoid mounting arm from the surgical clamp and connecting a patient marker, having a third plurality of reflectors in a third predefined pattern, to the surgical clamp;

optically scanning the third plurality of optical reflectors so as to form a second optical scan;

deriving from the first and the second optical scans a correction vector indicative of a difference between a location and an orientation of the radiotransparent plate and a location and an orientation of the patient marker; and

in response to the correction vector and the fluoroscopic scan, determining a spatial transformation between the patient and the surgical clamp so as register a frame of reference of the patient with a frame of reference of the surgical clamp.

20. The method according to claim 19, wherein the sigmoid mounting arm is radiotransparent.

21. The method according to claim 19, wherein the sigmoid mounting arm comprises a first curved section connected to a second curved section by a straight section.

22. The method according to claim 19, wherein the sigmoid mounting arm comprises a first curved section connected directly to a second curved section.

23. The method according to claim 19, wherein the first, second, and third predefined patterns have no axes of symmetry and no planes of symmetry.

24. The method according to claim 19, and comprising, in response to registration of the frames of reference, presenting to a professional performing surgery on the patient a stored image of the patient aligned with the patient.

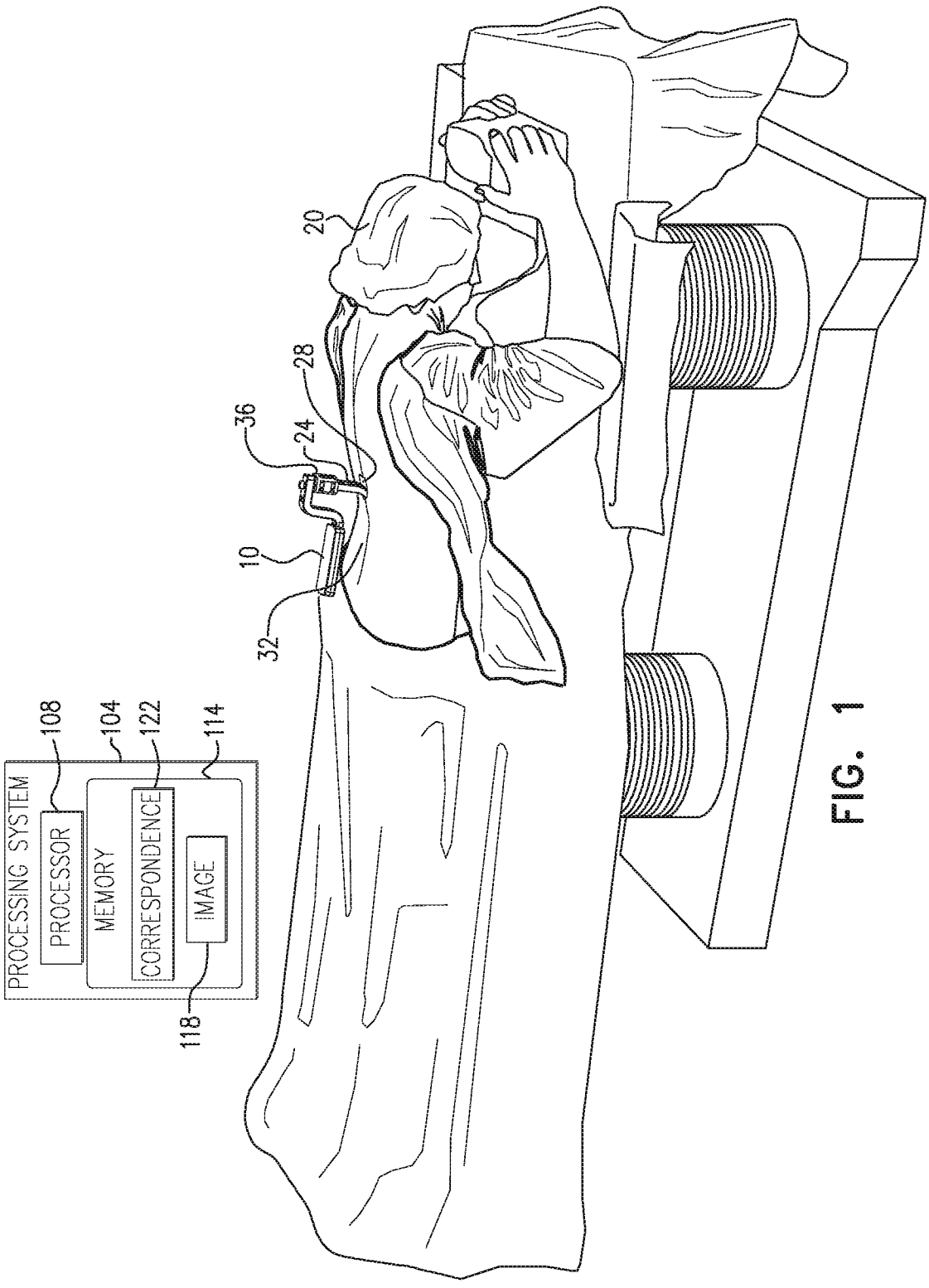

PROCESSING SYSTEM
PROCESSOR
MEMORY
CORRESPONDENCE
IMAGE
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104
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FIG. 1

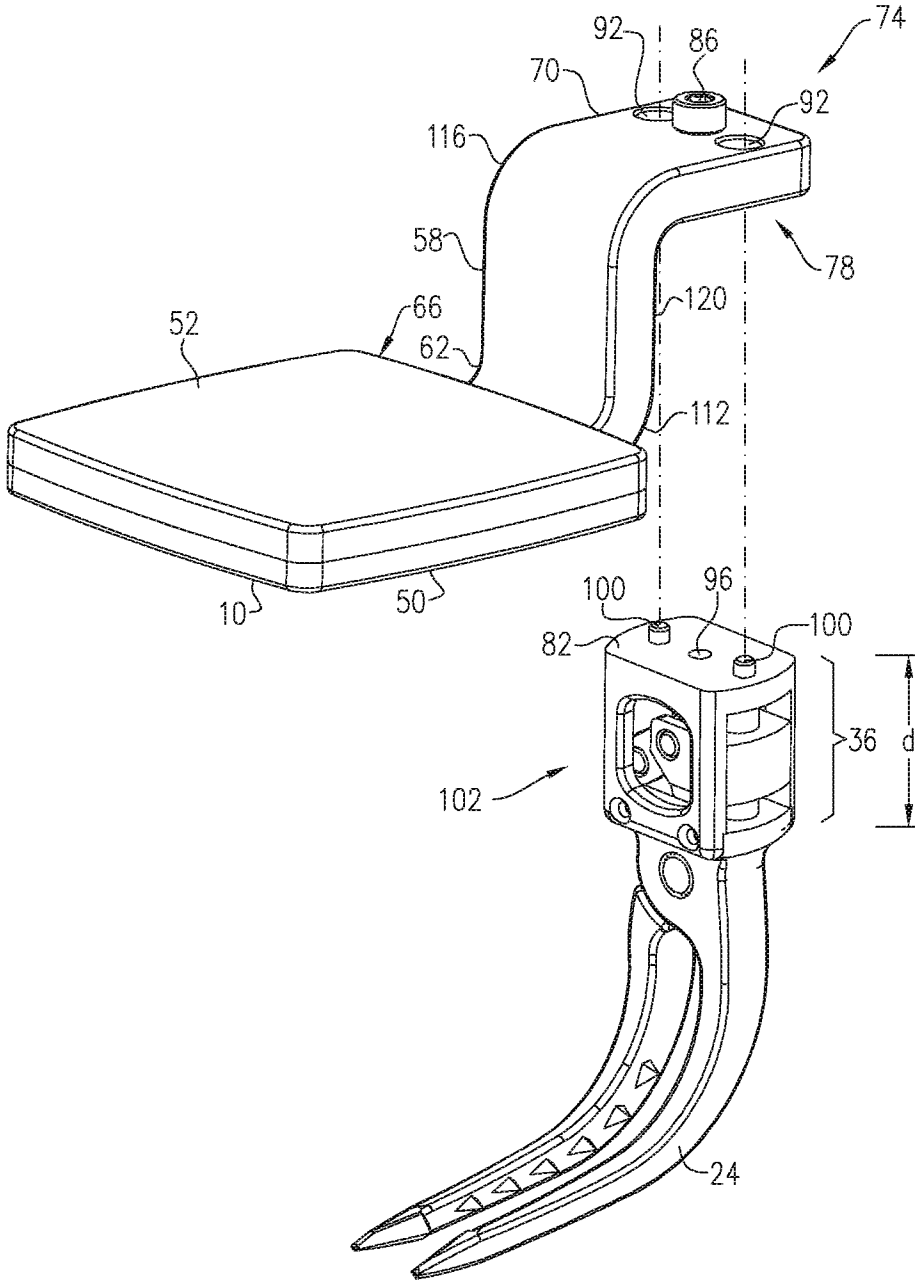

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FIG. 2

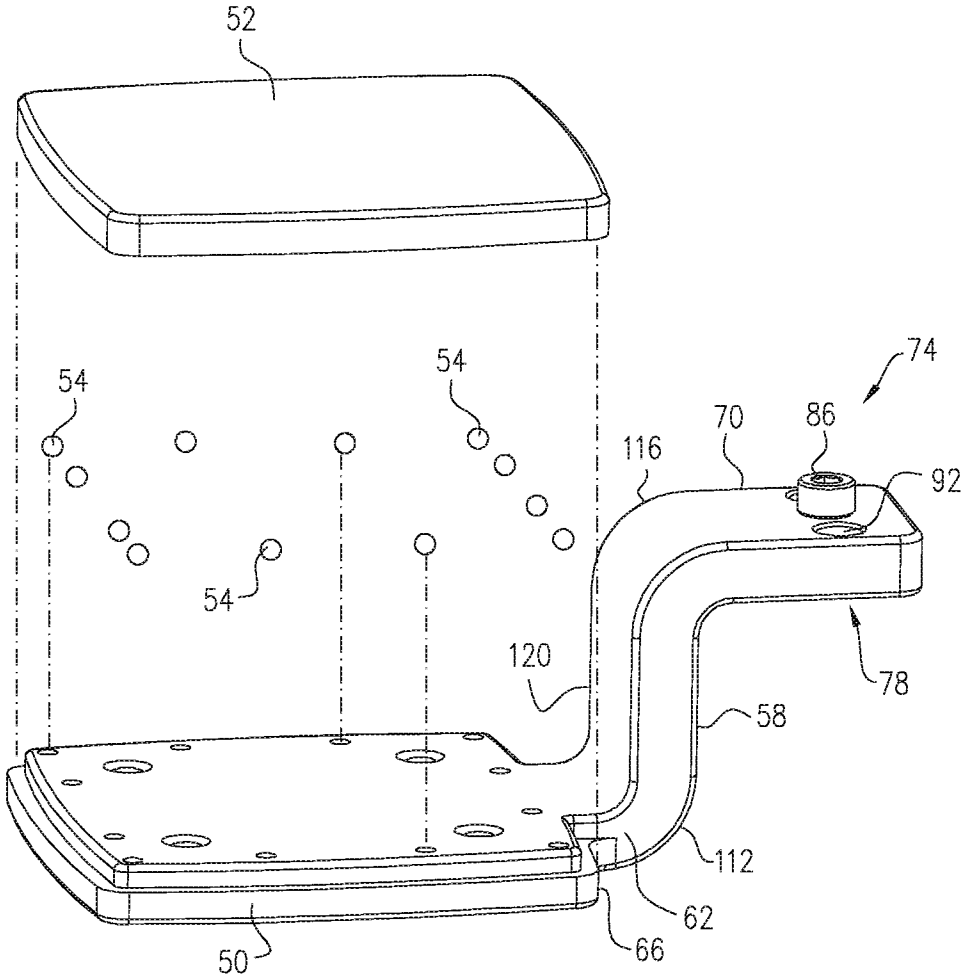


FIG. 3

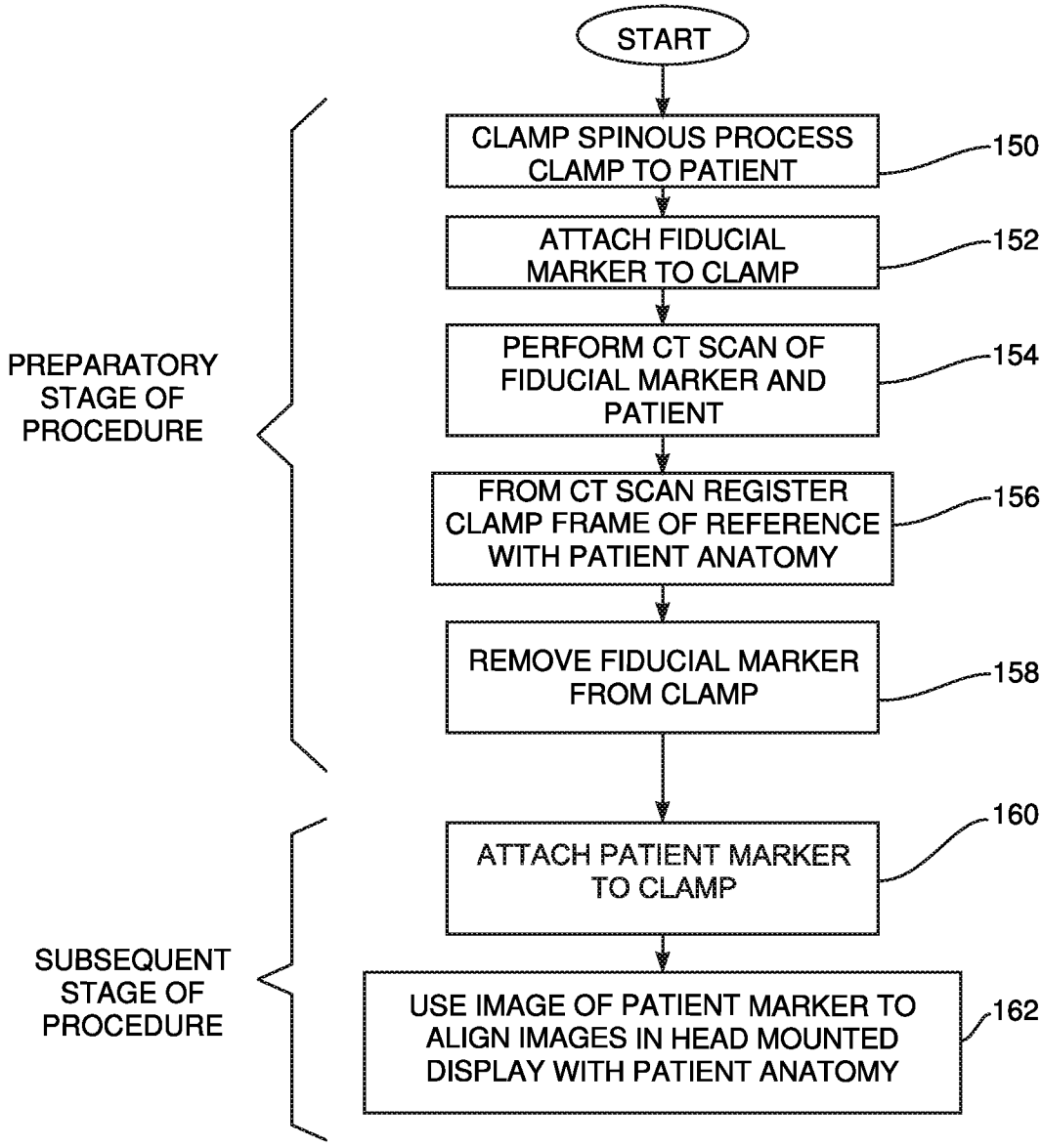

START
CLAMP SPINOUS PROCESS CLAMP TO PATIENT
150
ATTACH FIDUCIAL MARKER TO CLAMP
152
PERFORM CT SCAN OF FIDUCIAL MARKER AND PATIENT
154
FROM CT SCAN REGISTER CLAMP FRAME OF REFERENCE WITH PATIENT ANATOMY
156
REMOVE FIDUCIAL MARKER FROM CLAMP
158
PREPARATORY STAGE OF PROCEDURE
ATTACH PATIENT MARKER TO CLAMP
160
USE IMAGE OF PATIENT MARKER TO ALIGN IMAGES IN HEAD MOUNTED DISPLAY WITH PATIENT ANATOMY
162
SUBSEQUENT STAGE OF PROCEDURE

FIG. 4

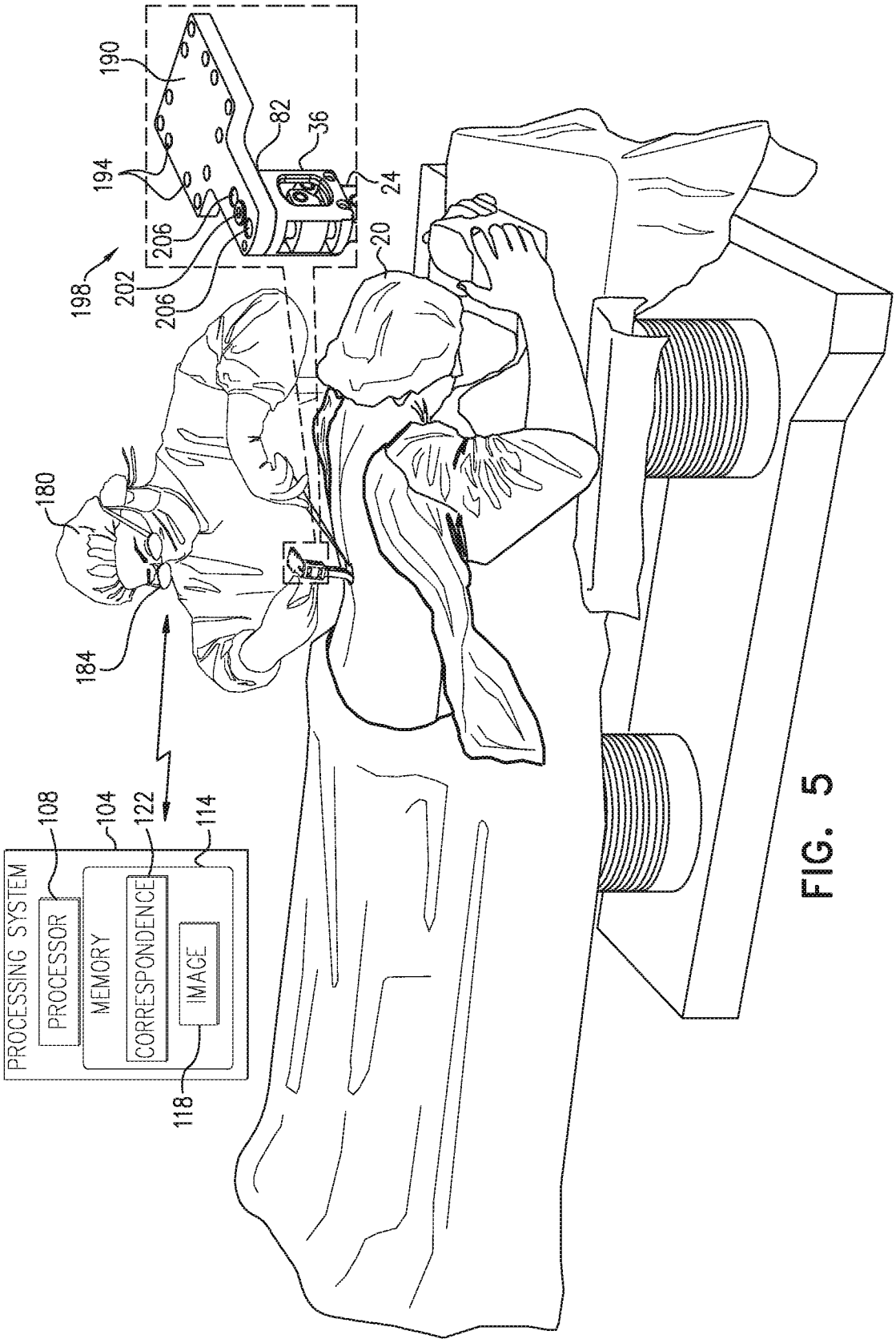

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194
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202
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206
82
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180
184
PROCESSING SYSTEM
PROCESSOR
MEMORY
CORRESPONDENCE
IMAGE
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114
118

FIG. 5

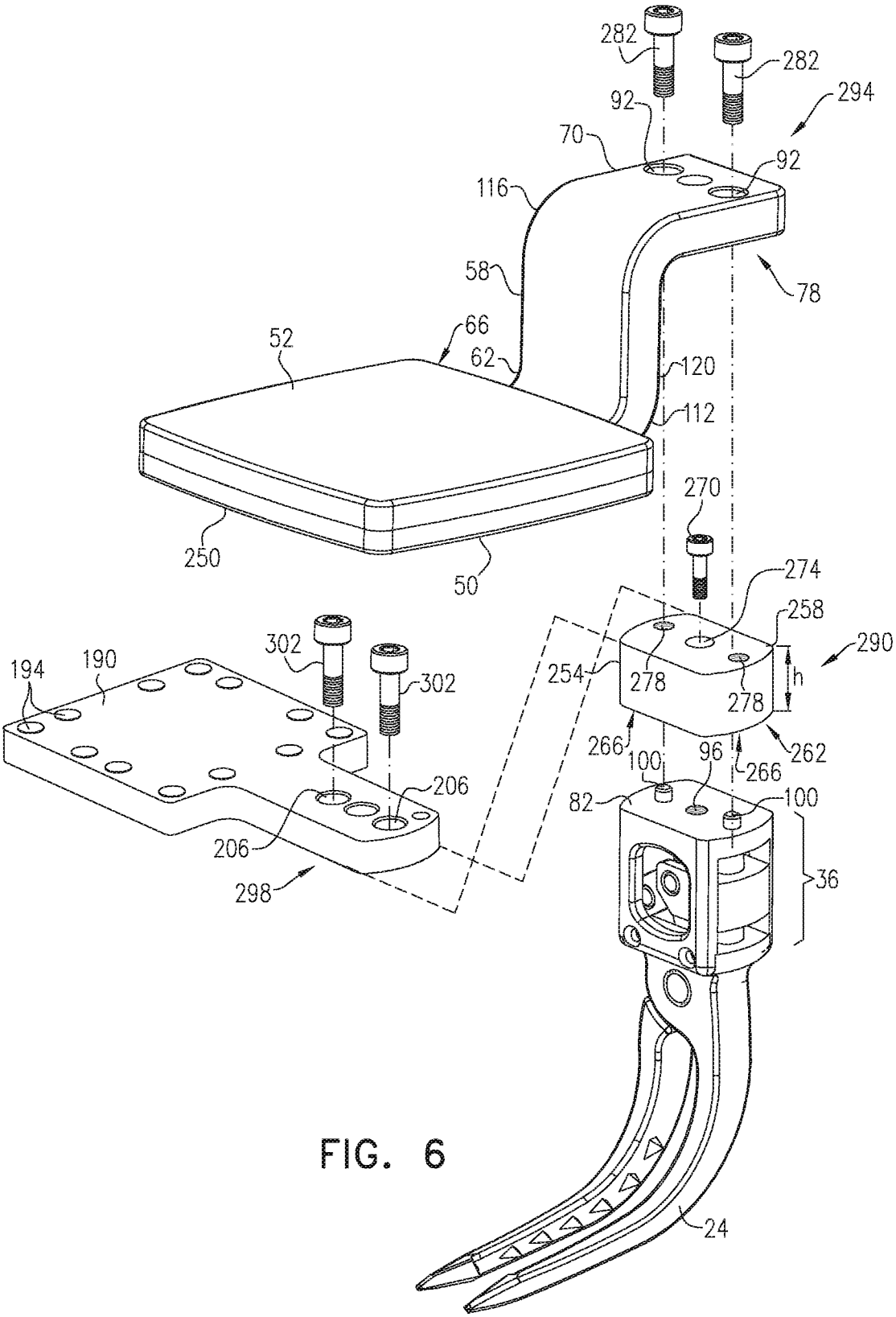

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FIG. 6

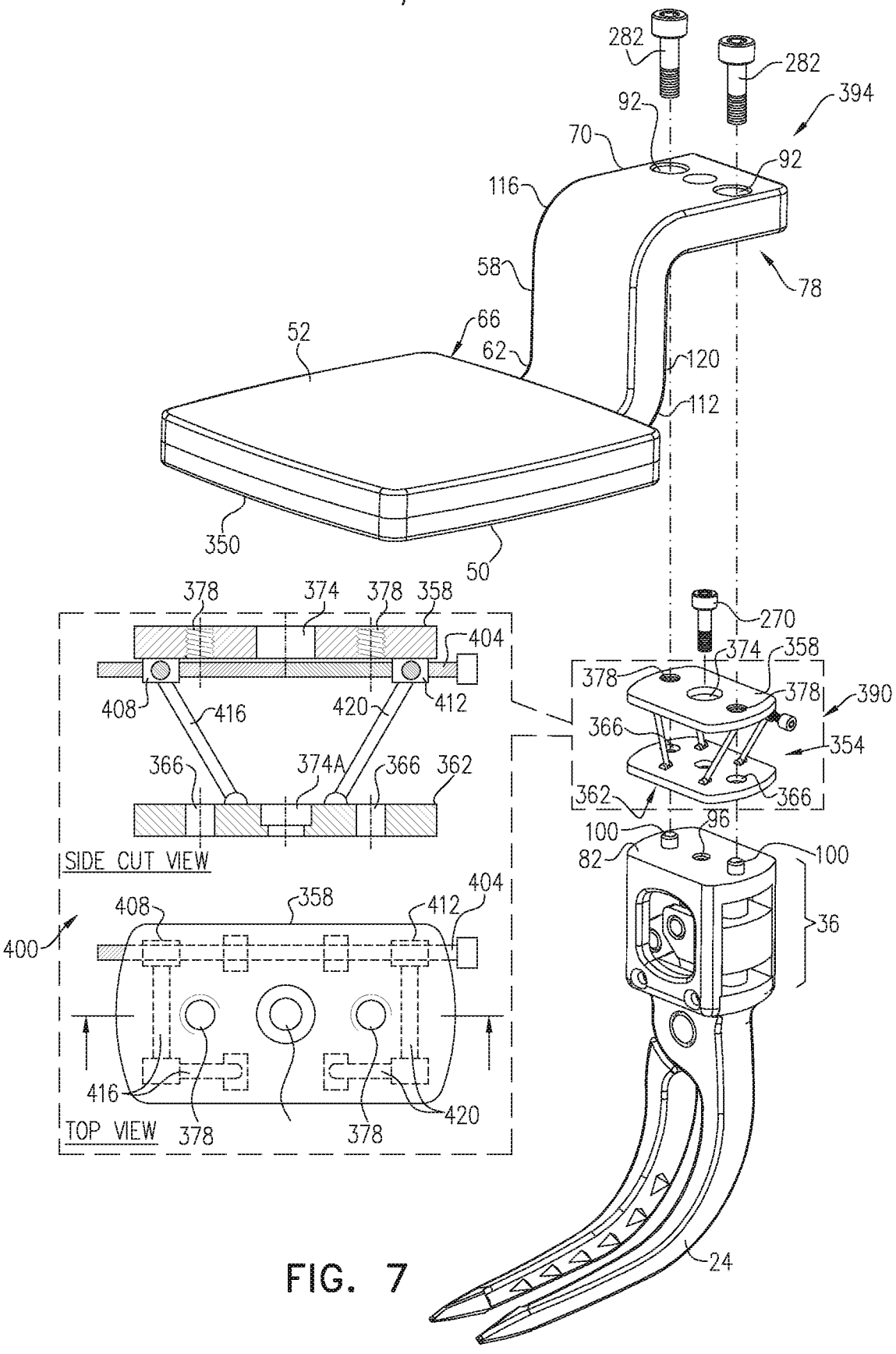

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404
408
416
420
412
366
374A
366
362
SIDE CUT VIEW
400
408
358
412
404
416
420
TOP VIEW
378
378
270
374
358
378
378
390
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354
362
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FIG. 7

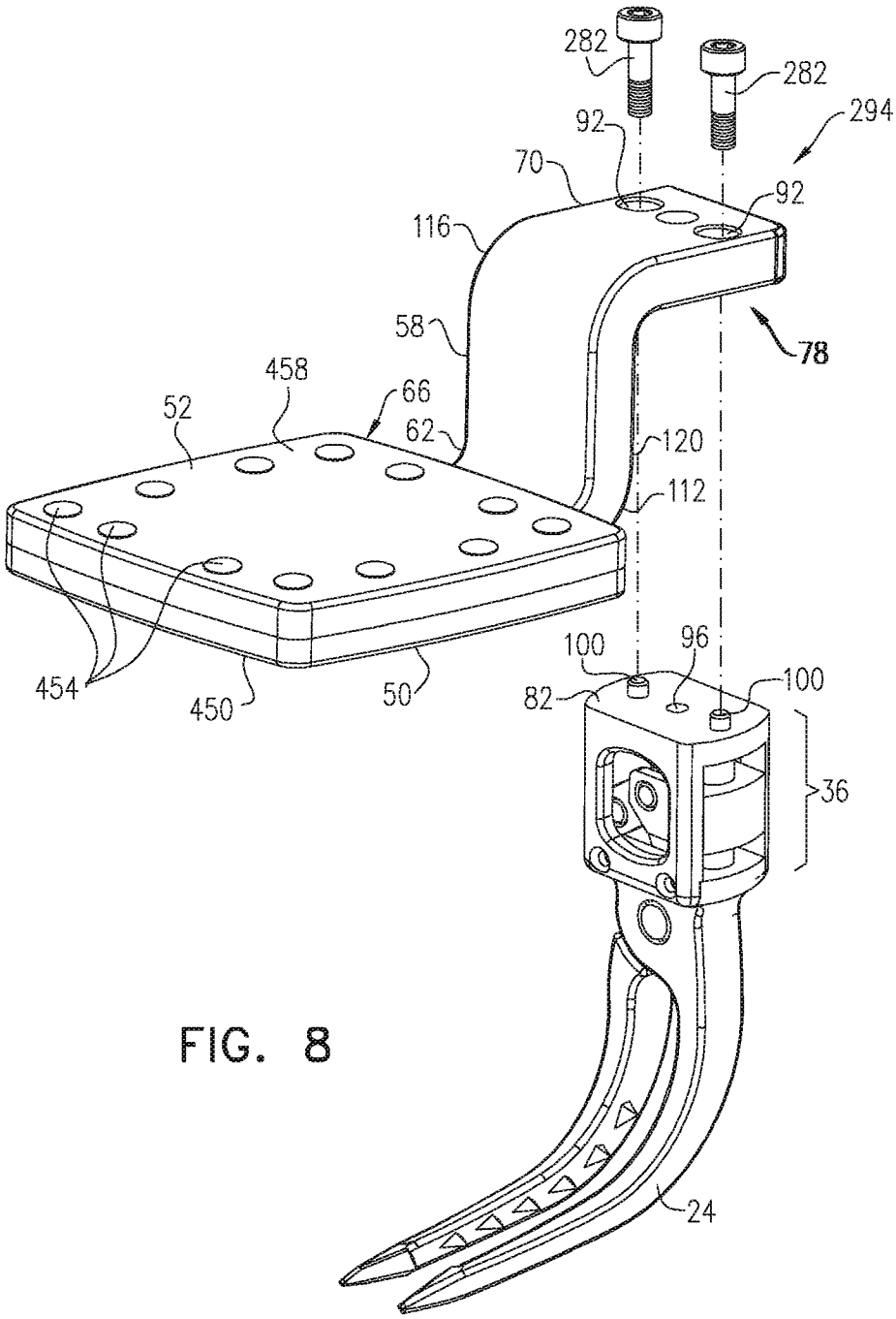

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FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2020/056893

A. CLASSIFICATION OF SUBJECT MATTER
See extra sheet.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See extra sheet.

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Databases consulted: Esp@cenet, Google Patents, Derwent Innovation, SIMILARI
Search terms used: fiducial, marker, curved, arm, clamp, proximal, adjacent, body, spinal, vertebral, tissue, patient, vector, difference.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	US 2005119639 A1 MCCOMBS et al. 02 Jun 2005 (2005/06/02) para.[0041]-[0043], [0049]; fig. 6-8, 13	1-24
A	US 2011004259 A1 SMITH & NEPHEW INC 06 Jan 2011 (2011/01/06) * the whole document *	1-24
A	EP 3216416 A1 IZI MEDICAL PRODUCTS LLC 13 Sep 2017 (2017/09/13) * the whole document *	1-24

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
04 Nov 2020	09 Nov 2020
Name and mailing address of the ISA: Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Email address: pctoffice@justice.gov.il	Authorized officer AHARONY Meytal Telephone No. 972-73-3927138

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IB2020/056893

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Information on patent family members

International application No.
PCT/IB2020/056893

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		EP 3113708 A4	01 Nov 2017
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		WO 2015150877 A1	08 Oct 2015

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2020/056893

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (20200101) A61B 90/00, A61B 17/122, A61B 34/20

CPC (20160201) A61B 90/39, A61B 17/122, A61B 90/36, A61B 2034/2046, A61B 2034/2055, A61B 2090/363, A61B 2090/365, A61B 2090/3916, A61B 2090/3937, A61B 2090/3983

B. FIELDS SEARCHED:

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

IPC (20200101) A61B 90/00, A61B 17/122, A61B 34/20

CPC (20160201) A61B 90/39, A61B 17/122, A61B 90/36, A61B 2034/2046, A61B 2034/2055, A61B 2090/363, A61B 2090/365, A61B 2090/3916, A61B 2090/3937, A61B 2090/3983