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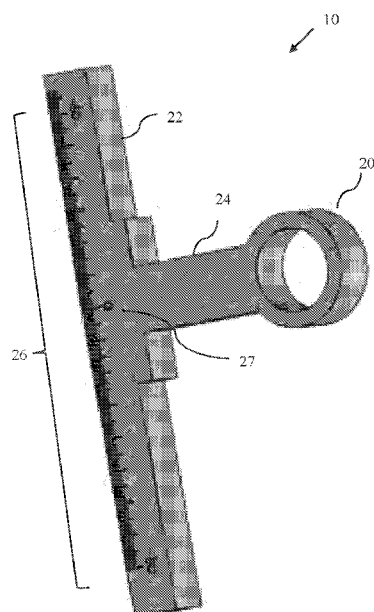


FIG. 1

(57) Abstract: An adapter to the stereotactic systems used during SEEG procedures has been developed. The adapter can significantly reduce time in the operating environment, increase the efficiency of at least one headcount and therefore decrease the overall cost of the procedure. An inexpensive adapter to the head ring of a stereotactic device should therefore expand the number of individuals treated. The device can be easily assimilated into the leading stereotactic systems.



ADAPTER FOR STEREOELECTROENCEPHALOGRAPHY SIMPLIFICATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 62/327,097, filed on April 25, 2016.

FIELD OF INVENTION

This invention relates to surgical devices. More specifically, this invention relates to an adapter to the stereotactic systems used during SEEG procedures that facilitates the precise placement of tools for the procedure.

BACKGROUND OF THE INVENTION

Epilepsy is a brain disorder which affects over 5 million adults and children in the United States and more than 150,000 people will develop epilepsy each year. According to the World Health Organization, more than 50 million individuals have epilepsy worldwide. Epilepsy is caused by stroke, brain tumors, traumatic head injuries, loss of oxygen to the brain, genetic disorders, neurological diseases, and infections of the brain. Most epileptics can control their seizures using anti-epilepsy-drugs (AEDs). However 30% to 40% of epileptics cannot control their seizures by medication alone. The non-responders to AEDs are among the primary candidates for an epileptic surgical procedure referred to as temporal resection.

Epilepsy is the fourth most common neurological disorder behind migraines, strokes and Alzheimer's disease. The most common treatments for epilepsy are medicine, surgery, implantation of electrical devices, and special dietary disciplines. Only 70% of epileptics respond to alternative treatments, leaving surgery as a potential solution for the groups that will not respond to less drastic and invasive measures.

Epileptics who cannot be treated with medication represent about 25% of the population with epilepsy, but 86% of all costs associated with the disease. Patients with uncontrolled epilepsy will generally have over \$10,000 a year in medical costs versus those with controlled epilepsy at \$2,000 per annum. The median surgical cost for procedures to address epilepsy in patients with disease that cannot be controlled with medication is in the range of about \$40,000 to \$60,000. Improvements in the equipment used to perform these procedures would significantly reduce the time required to perform these procedures, thereby lowering the cost. This would make the procedure more cost-effective and less daunting for the patient.

- 5 The present invention meets this important need of reducing time and costs of associated with the procedures by employing a device, or adapter to the head frames used in the procedures, that simplifies the adjustment and precise placement of surgical tools. The benefits of this novel adapter as will become apparent in the following disclosure.

SUMMARY OF THE INVENTION

- 10 An adapter to the stereotactic systems used during SEEG procedures has been developed. The adapter can significantly reduce time in the operating environment, increase the efficiency of at least one headcount in the surgical environment and therefore decrease the overall cost of the procedure. An inexpensive adapter to the head ring of a stereotactic device should therefore expand the number of individuals treated. The device can be easily
15 assimilated into the leading stereotactic systems.

- In a first aspect the present invention provides an adapter for a head frame base, such as those used in SEEG procedures. The head frame base to which the adapter mounts will have a vertical stabilizer and will have (0,0) origin positioning defining (x, y) positioning relative to a region in space proximate to a head frame. The adapter includes a frame attachment member
20 for attaching the adapter to the vertical stabilizer of the head frame base. A plurality of markings on the frame attachment member facilitate single-dimensional positioning of the adapter relative to a y-origin positioning of the head frame. The markings will generally operate in conjunction with marking(s) on the vertical stabilizer. The adapter also has a tool attachment member that allows a user to attach surgical tools, such as probes, to the adapter.
- 25 The tool attachment member can have a geometric center corresponding to an axis of a surgical tool. For example, the length of a probe can be viewed as an axis, which would be coextensive with, or pass through, the geometric center of the tool attachment member. This facilitates defining the location of the probe relative to a point in space. Lastly, the adapter can include an adapter arm linking the frame attachment member to the tool attachment member.
- 30 The length of the adapter arm is selected such that the geometric center of the tool attachment member aligns with the x origin of the head frame when the location of the vertical stabilizer is set at the x origin of the head frame. In an advantageous embodiment the tool attachment member is round/annular/ring-shaped. The adapter can be fabricated from a materials, such as aluminum and titanium. The choice of materials will be dependent on cost
35 and strength considerations, with a material like titanium being stronger, but costing more to fabricate.

- In a second aspect a second adapter is provided. In a similar manner to the adapter of the first aspect, the adapter for the second aspect is designed to operate in conjunction with a head frame having a vertical stabilizer and (0,0) origin positioning. The adapter for the second
40 aspect includes a tool attachment member for attaching surgical tools to the adapter. The tool

5 attachment member has a geometric center coinciding with a midline of a tool to be attached to the tool attachment member. The adapter is shaped such that the geometric center of the tool attachment member is positioned at the x-origin of the head frame when the vertical stabilizer is set at the x-origin of the frame. This facilitates positioning of a surgical tool with respect to the dimension in space defined by x. The adapter for the second aspect also
10 includes a frame attachment member for attaching the adapter to a vertical stabilizer of the head frame. The frame attachment member has a plurality of markings to facilitate single-dimensional positioning of the adapter relative to a y-axis origin positioning of the head frame. The plurality of markings includes an origin marking at the same horizontal level as the geometric center of the tool attachment member thereby allowing the adapter to be set
15 relative to the y-axis origin. An adapter body links the tool attachment member to the frame attachment member. The adapter can be fabricated from materials such as aluminum and titanium.

In a third aspect a third adapter is provided. In a similar manner to the adapter of the first aspect, the adapter for the third aspect is designed to operate in conjunction with a head
20 frame base having a vertical stabilizer and (0,0) origin positioning defining (x, y) to position tools relative to a region in space proximate to the head frame. The adapter of the third aspect includes a frame attachment member for adjustably attaching the adapter to the vertical stabilizer of the head frame base. The frame attachment member has a slot configured to receive a complementary surface on the stabilizer and coextensive with the y-
25 axis of the head frame. The attachment member has a plurality of markings to facilitate single-dimensional positioning of the adapter relative to a y origin positioning of the head frame. The adapter of the third aspect has an annular-shaped tool attachment member for attaching surgical tools to the adapter. The tool attachment member will have a geometric center corresponding to an axis of a surgical tool that will be mounted in the tool attachment member. This configuration allows the location of the mounted tool to be precisely defined
30 with respect to the (x, y) positioning. The adapter according to the third aspect will also include an adapter arm linking the frame attachment member to the tool attachment member. The length of the adapter arm is selected such that the geometric center of the tool attachment member is at the x origin of the head frame when the vertical stabilizer is set at
35 the x origin of the head frame.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the invention, reference should be made to the following detailed description, taken in connection with the accompanying drawings, in which:

FIG. 1 is a drawing showing a 3D-modeled SEEG-S adapter.

40 FIG. 2 is an image showing a 3D-printed SEEG-S adapter.

5 FIG. 3 is an image showing the 3D-printed SEEG-S adapter of FIG. 2 affixed to a base of a head frame.

FIG. 4 is a photograph of a chamfered slot being cut into a block of aluminum during the production of a SEEG-S adapter.

FIG. 5 is a photograph of the profiling and engraving of a block of aluminum during the
10 production of the SEEG-S adapter. Note the chamfered slot at the base of the adapter.

FIG. 6 is a photograph of a SEEG-S adapter affixed to the base of a head frame during accuracy testing of the adapter.

FIG. 7 is a photograph of a pair of vertical stabilizers affixed to a base of a head frame.

FIG. 8 is a photograph of a vertical stabilizer with an affixed adapter. Only the measurement
15 index grid of the adapter is shown in the photograph.

FIG. 9 is an illustration of a pair of vertical stabilizers getting affixed to a base of a head frame.

FIG. 10 is an illustration of an adapter being affixed to the vertical stabilizers of a head frame. The adapter is only partially shown in the illustration.

20 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Stereoelectroencephalography (SEEG) is surgical procedure that is used to identify areas of the brain where epileptic seizures originate. Any subsequent epilepsy surgery depends on the results of the monitoring resulting from the SEEG procedure.

During SEEG, doctors place electrodes in targeted brain areas, which are then monitored to
25 precisely locate the seizure source. Patients are observed from one to four weeks in order to capture three to five of their habitual seizures. If the implanted sensors trace problematic areas of the brain to one lobe, the patient is a candidate for temporal lobe resection. It is the identification process that is key to the surgery. However, the current approach requires a five to six hour procedure. The length of time is largely attributable to the current hardware
30 configuration being utilized, and the time necessary for technicians to adjust the hardware.

Ninety percent of epilepsy surgeries are conducted in the right temporal lobe. Enhancement to the current stereotactic system can simplify the pre-surgical evaluation of a patient with medically intractable epilepsy by reducing the overall time involved in pinpointing the origin of seizures within the brain. While it is forecast that 100,000 to 200,000 epileptics are candidates
35 for a surgical solution per year, only about 3,000 to 4,000 patients actually receive the procedure for a variety of reasons, including fear of the procedure, the need for extensive pre-operative testing and analysis, lack of insurance coverage, and the cost of the procedure. The adapter taught herein can impact the cost of the procedure by reducing the time spent in

5 the operating room. In addition, the reduced operating time may lead to improved patient outcomes and reduced hospital stays, which would further reduce costs and could help to reduce the fear of the procedure.

A major component of the cost of epilepsy surgery is the amount of time involved in placing electrodes into the brain to precisely locate the seizure focus through Magnetic Resonance
10 Imaging (MRI), Computer Tomography (CT), Positron Emission Tomography (PET), Single-Photon Emission Computed Tomography (SPECT) or electroencephalography (EEG) testing. A device, which has been designed specifically to map the brain by placing electrodes in the correct position, can reduce the time in surgery from the current average of five to six hours, down to four to five hours, and have a corresponding effect on the productivity/efficiency of
15 operating room staff.

An adapter to the stereotactic systems used during SEEG procedures has been developed. The adapter significantly reduces the time in the operating environment, increases the efficiency of at least one headcount in the surgical environment and therefore decreases the overall cost of the procedure. An inexpensive adapter to the head ring of a stereotactic device
20 should therefore expand the number of individuals treated. The device can be easily assimilated into the leading stereotactic systems.

The use of the SEEG-S adapter can dramatically reduce the cost of the procedure and make the entire process more efficient. Surgical resection of epileptogenic tissue that is based on SEEG analytics has resulted in very high success rates where success is defined as the
25 complete elimination of seizures. Unfortunately many people who cannot be treated with AEDs are unaware of a surgical alternative.

One major trend upcoming in the neurosurgery market is the increased adoption of neurostimulators to treat migraines, chronic pain, epilepsy, post-cancer therapy pain, lower back pain, and Parkinson's disease. Clinical evidence supporting the use of neuro stimulation
30 devices is increasing their adoption rate among neurosurgeons. Approximately 12% of deaths worldwide are caused by neurological disorders like epilepsy, Alzheimer's disease and Parkinson's disease. Cost-effectiveness and the cost-to-utility ratio of neurostimulation devices are slightly higher as compared to drugs, which are used as symptomatic treatment options over long durations.

35 Product Design

A stereotactic instrument is a guiding device used to intracranially implant electrodes. The implanted electrodes can provide data on the origin of the seizures and where these functional areas are located within the brain. Once this data is assembled, it is provided to the surgeon who will know what tissue can be removed and what must be preserved for a person

5 to be seizure-free without resulting in any neurological deficits as a consequence of the removal.

Generally, a stereotactic head ring is affixed to the patient's skull with pins, and then CT or MRI scanning of the head is performed. Target sites for placing the electrodes are selected using the imaging information obtained by the scan. Extremely precise mapping of the sites
10 for electrode implantation can be obtained. Stereotactic depth electrodes are fine, flexible plastic electrodes attached to wires that carry currents from deep and superficial brain structures. Currents are recorded through contact points mounted in the walls of the electrodes via fine wires, which extend through the openings of the plastic electrodes.

The mechanics behind stereotactic neurosurgery are relatively simple. Three points define a
15 volume in geometric space. If the same three points can be defined on a patient and on an image of that patient, then the three-dimensional space of that patient and image are known and can be defined relative to each other. Registration is the process whereby the location of any point on or within the patient is defined on the image, and vice versa. Stereotactic systems differ in the manner in which the spatial points are defined, the geometric coordinate
20 spaces used, and the method to register the patient and image coordinate spaces.

The present invention provides a device which has been dubbed 'SEEG-S', where the "-S" stands for "Simplification", because only two degrees of freedom are utilized to form an x and y coordinate system. Initial plans were to write a computer code that would convert the current five-degree of freedom software trajectories into a two-degree of freedom coordinate
25 system. The coordinate transform was rendered unnecessary by holding two degrees of freedom constant within the software. In addition, the device had to be precisely fabricated so both the x and y coordinates matched the CRW device. One key advantage of the device is the elimination of a step, where the doctor would need to run a separate program to translate coordinate systems.

30 Accuracy of the disclosed device is in the millimeter range, and the performance and settings of the device have been confirmed with the device attached to a head ring on a simulated skull. The range of distortions, which would be anticipated in normal use, would be included in the calibration measurement procedure unless a method is employed to eliminate the distortion effects.

35 The device was designed using Solidworks. The goal of the initial design was to create a device that maintained CRW frames (0,0) coordinates for x and y. Figure 1 shows a 3-D model of the device created in Solidworks. Once the device had been modeled, a test device was made via a polymer 3-D printer as shown in FIG. 2. The device was then field tested on an Integra head ring as shown in FIGS. 3 and 6. All measurement discrepancies were noted
40 and appropriate adjustments were made in the design.

5 Two working devices were constructed of 6061 T6 aluminum and were engraved with a measurement index grid. The adapter was made by conventional milling operations. First, a block of aluminum was end and face milled to ensure the adapter was flat and square. A chamfered slot was then cut into the block as shown in FIG. 4. After the adapter was chamfered, the adapter was placed on a CNC machine to cut the profile, the drill guide and
10 engrave the part, as shown in FIG. 5.

Validation:

The adapter was tested to ensure accuracy. In performing these tests, the fabricated adapter was compared to the original head frame. The frame was set on a dummy head and scanned with a CT scanner. Targets were set by indentations in the plastic head that can be seen with
15 the CT scan. Coordinates were obtained holding the two angular degrees of freedom constant at 90 degrees. The performance of adapter was tested against the performance of original frame to compare accuracy. Figure 6 shows the adapter during testing results with the adapter. The accuracy of the adapter was measured to be less than 1mm.

A test was also performed to time how long it took to setup the frame with the novel adapter in comparison to the original frame. A doctor selected three coordinates to use in the test. The average time found to set the frame with the adapter to a given coordinate was 30 seconds, and the adapter only required one person for the adjustment. The average time to set the original frame to a given coordinate was found to be 3 minutes 30 seconds, and the procedure required two people to set the frame.

25 It is noted that the original frame and associated attachments includes the functionality to adjust the angle in which a surgical tool enters the patient's brain. The present invention removes this functionality, which greatly simplifies the use of the device. It is found that, when performing the procedure, any detriment associated with losing this functionality is more than offset by the increase in efficiency of not having to account for these additional variables when guiding the tools. In addition, as mentioned elsewhere, a subject's seizures can often
30 be traced to the either temporal lobe. Effectively accessing this region does not require the ability of coming in at an angle.

An understanding of the design and functionality of the SEEG-S adapter is enhanced by a detailed description of the head frame to which it attaches. A CRW frame will have (0,0)
35 coordinates defined for x and y thereby defining these two-dimensional coordinates within a spatial region proximate to/defined relative to the frame. Figure 7 shows a frame 40 without any attachments. The frame 40 has a generally square shape with grooves along each side of the frame (See also FIG. 9) A vertical stabilizer 42 sliding engages the grooves on the frame 40. The frame 40 has a first head frame grid 46 having a 0 origin ("the first head frame 0
40 coordinate"; not visible in the figure) in the center of the grid that defines the location of the

5 vertical stabilizer 42 along an axis (the x-axis) of the head frame 40. The vertical stabilizer 42 will often include a marking (not shown) to define a point on the stabilizer 42 to facilitate its localization as it moves along the first head frame grid 46 of the head frame 40. Once in the desired position along the x-axis, as defined by aligning the locational mark on the vertical stabilizer 42 to the desired position along the first head frame grid 46, is achieved the vertical
10 stabilizer 42 can be locked in place on the frame 40 using a first pair of vertical stabilizer locks 44. This defines the location of the vertical stabilizer with respect to the x-axis and a first dimension of the (0,0) coordinates of the frame 40. This direction of movement along this x-axis can be referred to as "horizontal".

The vertical stabilizer 42 includes features to facilitate the attachment of accessory devices to
15 the to the vertical stabilizer 42 and the associated head frame 40 unit. In the vertical stabilizer 42 as shown in FIGS. 8 and 10 there is a vertically-oriented tongue on the vertical stabilizer 42 that is designed to engage a complimentary slot or groove on an accessory to be affixed to the vertical stabilizer 42. The relative height or location of the accessory can be adjusted by sliding the accessory into the desired position along the tongue, thereby moving the
20 accessory in the vertical direction or along the y-axis. Once the desired position is reached a second pair of vertical stabilizer locks 48 can be used to lock the accessory in that position on the vertical stabilizer. Achieving the correct vertical positioning of an accessory on the vertical stabilizer 42 is facilitated by a 0 coordinate mark 43 on the vertical stabilizer 42 ("the second head frame 0 coordinate") as shown for instance in FIG. 8.

25 Turning to the details of an embodiment of the adapter of the invention, FIG. 1 is a 3D modeled SEEG-S adapter 10 according to certain aspects of the invention. The adapter 10 is designed to replace the head ring on a commercial head frame, such as the CRW head frame from Integra. The adapter 10 has a tool attachment member or ring 20, a precision milled body 22, a horizontal arm 24, and a measurement index grid 26. The measurement index grid
30 26 and ring 20 of the adapter 10 are fabricated to achieve alignment with the (0,0) coordinates of the head frame. Laser etched y-coordinates from -60 to 80 mm are provided on the measurement index grid 26.

The x-coordinate is set by the grid on the frame of the head ring base in conjunction with the vertical stabilizer. Measurements were made to align the adapter's 0 coordinate when the
35 head ring and vertical stabilizer are lined up with 0's or at their origin. To make the adapter fit a different head frame the length of horizontal arm, such as between where the adapter attaches to the vertical stabilizer and tool holder, can be adjusted to ensure that any tools attached to the adapter line up with the x-origin on the head frame base. As for the y-coordinates, the grid may have to be adjusted up or down to accommodate another
40 manufacturer's 0 coordinate on the y-axis of the vertical stabilizer. The way this works is if the doctor gets a set of coordinates of -5,10 the device would be moved to the left on the

5 head frame to the mark of 5mm (5) and lined up with 0 on the stabilizer. Similarly the y-coordinates would be set so 0 on the vertical stabilizer lines up with 10 on the adapter.

The ring 20 is joined to the precision milled body 22 by the horizontal arm 24. The ring 20 is designed to accommodate surgical tools, such as a drill guide or a depth gauge. The ring 10 of the fabricated device had an inner diameter of one inch, but it is contemplated that the
10 shape and size of the ring can be changed to accommodate the tools that will be attached to it. More specifically, the element of the ring 20 can be more generally referred to as a tool attachment member. Tools, such as a drill guide or depth gauge, can be precisely located in a region of space, wherein the location is facilitated, in part, by the adapter 10. Regardless of the shape or nature of the ring 20, or tool attachment member, it must be capable of
15 precisely, consistently, and reproducibly affixing a tool to the adapter 10 such that the location of the tool can precisely be defined within a region of space. This can be done by defining a geometric center of the ring 20, when ring shaped.

As mentioned above, the measurement index grid 26 has markings for y-coordinates from -60 to 80 mm, with a 0 coordinate 27 in the center of the grid 26. The 0 coordinate 27 on the
20 measurement index grid 26 is designed to line up with a 0 coordinate 43 on a vertical stabilizer ("the second head frame 0 coordinate") of a head frame. In the embodiment shown the 0 coordinate also lines up with the geometric center of the ring 20. FIG. 8 shows the 0 coordinate 43, shown as an arrowhead, on the vertical stabilizer 40. By lining up with both the 0 coordinate 43 on the vertical stabilizer 40 and the geometric center of the ring 20, the
25 measurement index grid 26 is able to locate a tool affixed to the ring 20 of the adapter 10 within a single dimensional space defined by the y-axis.

The adapter 10 has a chamfered channel (not visible in FIG. 1) running the length of the body 22 on the distal-most surface from the ring 20 (see FIGS. 4-6, and 10 for the channel) and co-extensive with the measurement index grid 26. The chamfered channel on the adapter 10
30 slidingly engages a complementary surface on the vertical stabilizer, allowing the adapter 10 be moved along a single axis to achieve a desired position for a surgical tool along that y-axis axis with respect to a defined region in space. The mechanism of attachment could vary based upon the nature of the head frame and the head frame manufacturer, but a double chamfered channel with internal clamp is envisioned as an advantageous mode of
35 attachment.

FIG. 9 shows a pair of vertical stabilizers 42 slidingly engaging complementary slots on the base of a head frame 40. Turning to FIG. 10, the vertical stabilizer 42 has a pair of first knobs 46 that lock each vertical stabilizer 42 in a desired position on a head frame 40. In other words, the vertical stabilizer 42 can move linearly along an x-axis, or horizontal axis, defined

5 by slots in the head frame 40, and the position along that x-axis can be chosen by locking the pair of first knobs/locks 44 on the vertical stabilizer 42.

FIG. 10 also shows that chamfered slots 26 on the adapter 10 are matingly engaged by a horizontal tongue the vertical stabilizer 42. The vertical stabilizer 42 has a pair of second knobs 48 that lock the adapter 10 in a desired position on a head frame 40. In other words,
 10 the adapter 10 can move linearly along an y-axis, or vertical axis, defined by the tongue on the vertical stabilizer 42, and the position along that y-axis can be chosen by locking the pair of second knobs 48 on the vertical stabilizer 42.

Coextensive to the slots on the head frame 40 will be a first head frame grid 46 having a 0 origin ("the first head frame 0 coordinate") that defines the location of the vertical stabilizer 42
 15 along an axis (the x-axis) of the head frame 40. Thus, the vertical stabilizer 42 will have a marking ("the first head frame 0 coordinate") that lines up with a zero coordinate the markings of the first head frame grid 46 such that an origin for the vertical stabilizer 42 can be defined relative to the head frame 40.

Turning to FIG. 6, there is shown a head frame with an adapter (not numbered). The adapter
 20 has a surgical probe attached to the ring. A length is selected for the adapter arm such that the geometric center of the ring lines up with the 0 origin ("the first head frame 0 coordinate") of the first head frame grid 46 when the x-axis locational mark on the vertical stabilizer 42 lines up with the first head frame 0 coordinate or when the tool is otherwise precisely located at the x-axis origin.

25 The design of the SEEG-S adapter allows it to replace a head ring found in typical head frames, while allowing much greater functionality than the base head frame. By eliminating the head ring 3 degrees of freedom are eliminated with it, which reduces the adjustments that must be made. The adapter fits into the space that the head ring would attach. It is secured by pressure from clamps in the channel of a vertical stabilizer from the current head frame.

30 The user would set up the head frame as normal and affix it to the patient. The user would add the vertical stabilizer to any of the four sides for orthogonal drilling. The adapter would slide onto the vertical stabilizer and be clamped into place.

The head frames currently used allow for 5 degrees of freedom. The adapter allows for 2 degrees of freedom. While 5 degrees of freedom may be required for some coordinates, 2
 35 degrees of freedom are sufficient for a great deal of temporal lobe locations. The head frames currently in use are very difficult to setup and typically require one person on each side of the frame to adjust the coordinates. Each person would have to adjust 3 coordinates. The adapter utilizes the frames 0,0 coordinate in an x,y frame. With the adapter you would only need one person on the side of the patient you are working on. The doctor would read
 40 out the x and y coordinates and the nurse could adjust them. Timing the difference in set up

- 5 to hit the same target with either the whole head frame or head frame with adapter varied by an average of 3.5 minutes, which is significant when a procedure may require about 6-8 coordinates per side.

GLOSSARY OF CLAIM TERMS

- As used throughout the entire application, the terms "a" and "an" are used in the sense that
10 they mean "at least one", "at least a first", "one or more" or "a plurality" of the referenced components or steps, unless the context clearly dictates otherwise.

The term "and/or" wherever used herein includes the meaning of "and", "or" and "all or any other combination of the elements connected by said term".

- The term "about" or "approximately" as used herein means within 20%, preferably within 10%,
15 and more preferably within 5% of a given value or range.

- As used herein, the term "comprising" is intended to mean that the products, compositions and methods include the referenced components or steps, but not excluding others. "Consisting essentially of" when used to define products, compositions and methods, shall mean excluding other components or steps of any essential significance. Thus, a composition
20 consisting essentially of the recited components would not exclude trace contaminants and pharmaceutically acceptable carriers. "Consisting of" shall mean excluding more than trace elements of other components or steps.

- As required, detailed embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention
25 that may be embodied in various and alternative forms. The figures are not necessarily to scale, some features may be exaggerated to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention.

- 30 Certain terminology will be used in the preceding description for convenience and reference only and not for purposes of limitation. For example, the words "horizontally" and "vertically" can refer to directions in the drawings to which reference is made. The words "inwardly" and "outwardly" refer to directions toward and away from, respectively, the geometric center of the structure being referred to. This terminology includes these words, specifically mentioned
35 derivatives thereof, and words of similar import.

Furthermore, elements may be recited as being "coupled"; this terminology's use anticipates elements being connected together in such a way that there may be other components interstitially located between the specified elements, and that the elements may be connected in fixed or movable relation one to the other. Certain components may be described as being

5 adjacent to one another. In these instances, it is expected that such a relationship so described shall be interpreted to mean that the components are located proximate to one another, by not necessarily in contact with each other. Normally there will be an absence of other components positioned therebetween, but this is not a requirement. Still further, some structural relationships or orientations may be designated with the word "substantially". In
10 those cases, it is meant that the relationship or orientation is as described, with allowances for variations that do not effect the cooperation of the so described component or components.

All references cited in the present application are incorporated in their entirety herein by reference to the extent not inconsistent herewith.

15 It will be seen that the advantages set forth above, and those made apparent from the foregoing description, are efficiently attained and since certain changes may be made in the above construction without departing from the scope of the invention, it is intended that all matters contained in the foregoing description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

20 It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween. Now that the invention has been described,

5 What is claimed is:

1. An adapter for a head frame base, the head frame base having a vertical stabilizer and (0,0) origin positioning defining (x, y) positioning relative to a region in space proximate to a head frame, the adapter comprising:

a frame attachment member for attaching the adapter to the vertical
10 stabilizer of the head frame base, wherein the frame attachment member includes a plurality of markings to facilitate single-dimensional positioning of the adapter relative to a y origin positioning of the head frame;

a tool attachment member for attaching surgical tools to the adapter, wherein the tool attachment member has a geometric center corresponding
15 to an axis of a surgical tool; and

an adapter arm linking the frame attachment member to the tool attachment member, wherein the length of the adapter arm is selected such that the geometric center of the tool attachment member is at the x origin of the head frame when the vertical stabilizer is set at the x origin of the head
20 frame.
2. The adapter according to claim 1 wherein the tool attachment member is ring-shaped.
3. The adapter according to claim 1 wherein the adapter is fabricated from a material selected from the group consisting of aluminum and titanium.
- 25 4. An adapter for a head frame having a vertical stabilizer and (0,0) origin positioning comprising:

a tool attachment member for attaching surgical tools to the adapter, the tool attachment member having a geometric center coinciding with a
30 midline of a tool to be attached to the tool attachment member and wherein the geometric center is positioned at the x-origin of the head frame when the vertical stabilizer is set at the x-origin of the frame;

a frame attachment member for attaching the adapter to a vertical stabilizer of the head frame, wherein the frame attachment member includes a
35 plurality of markings to facilitate single-dimensional positioning of the adapter relative to a y-axis origin positioning of the head frame and wherein the plurality of markings includes an origin marking at the same horizontal level as the geometric center of the tool attachment member thereby allowing the adapter to be set relative to the y-axis origin;

- 5 an adapter body linking the tool attachment member to the frame attachment member.
5. The adapter according to claim 4 wherein the adapter is fabricated from a material selected from the group consisting of aluminum and titanium.
6. An adapter for the attachment and positioning of surgical tools to a head frame base, the head frame base having a vertical stabilizer and (0,0) origin positioning defining (x, y) positioning of tools relative to a region in space proximate to a head frame, the adapter comprising:
- 10 a frame attachment member for adjustably attaching the adapter to the vertical stabilizer of the head frame base, wherein the frame attachment member includes a slot configured to receive a complementary surface on the stabilizer and coextensive with the y axis of the head frame and wherein the attachment member has a plurality of markings to facilitate single-dimensional positioning of the adapter relative to a y origin positioning of the head frame;
- 15 an annular-shaped tool attachment member for attaching surgical tools to the adapter, wherein the tool attachment member has a geometric center corresponding to an axis of a surgical tool; and
- 20 an adapter arm linking the frame attachment member to the tool attachment member, wherein the length of the adapter arm is selected such that the geometric center of the tool attachment member is at the x origin of the head frame when the vertical stabilizer is set at the x origin of the head frame.
- 25 7. The adapter according to claim 6 wherein the adapter is fabricated from a material selected from the group consisting of aluminum and titanium.
- 30

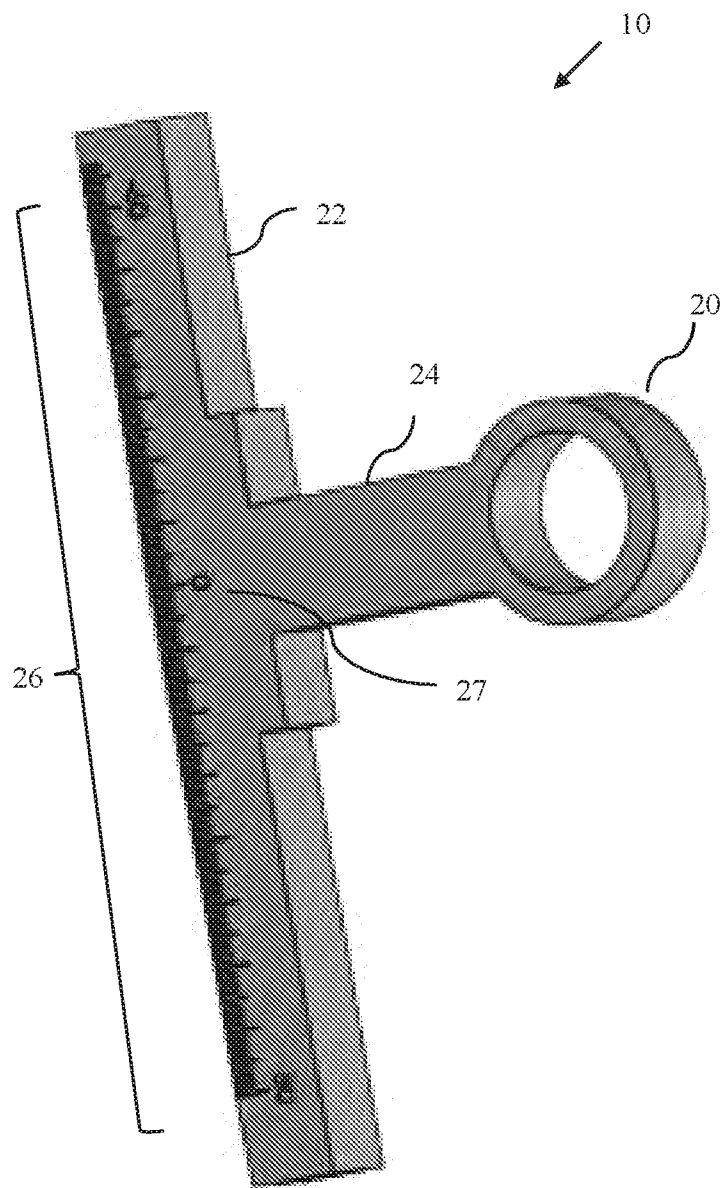


FIG. 1

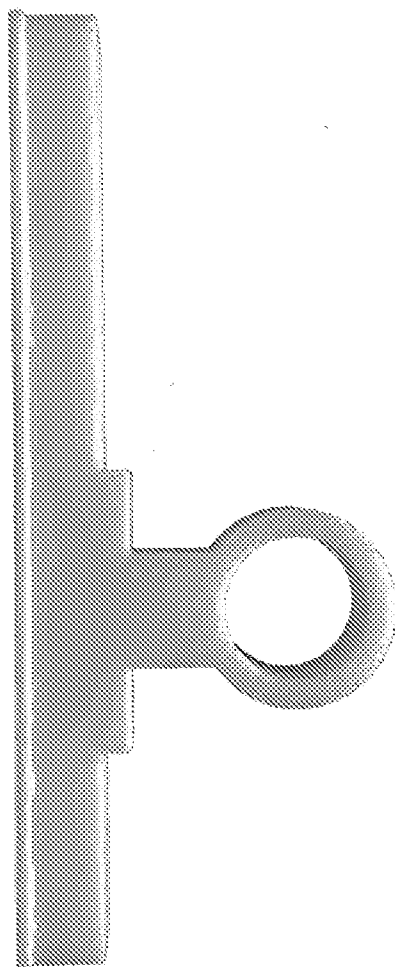


FIG. 2

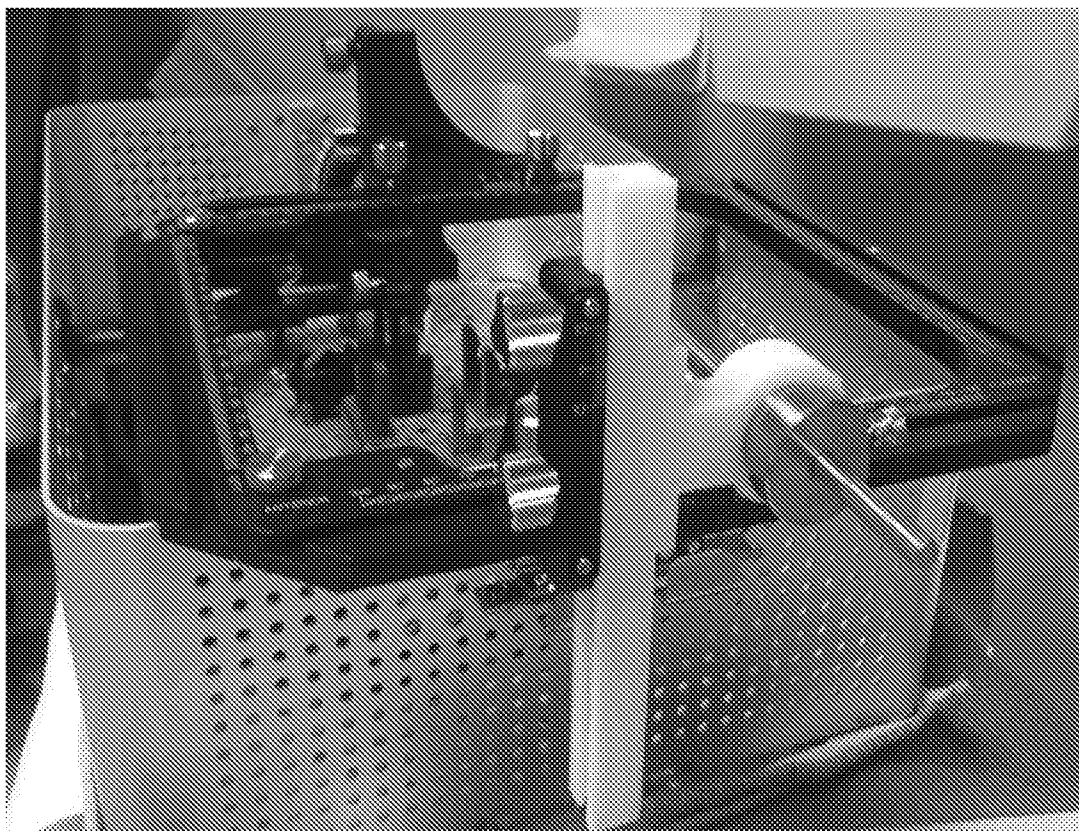


FIG. 3

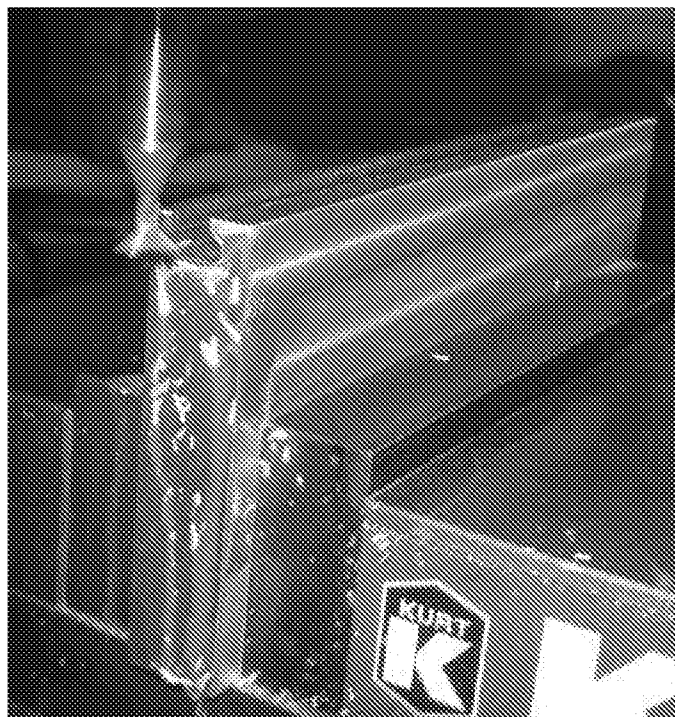


FIG. 4

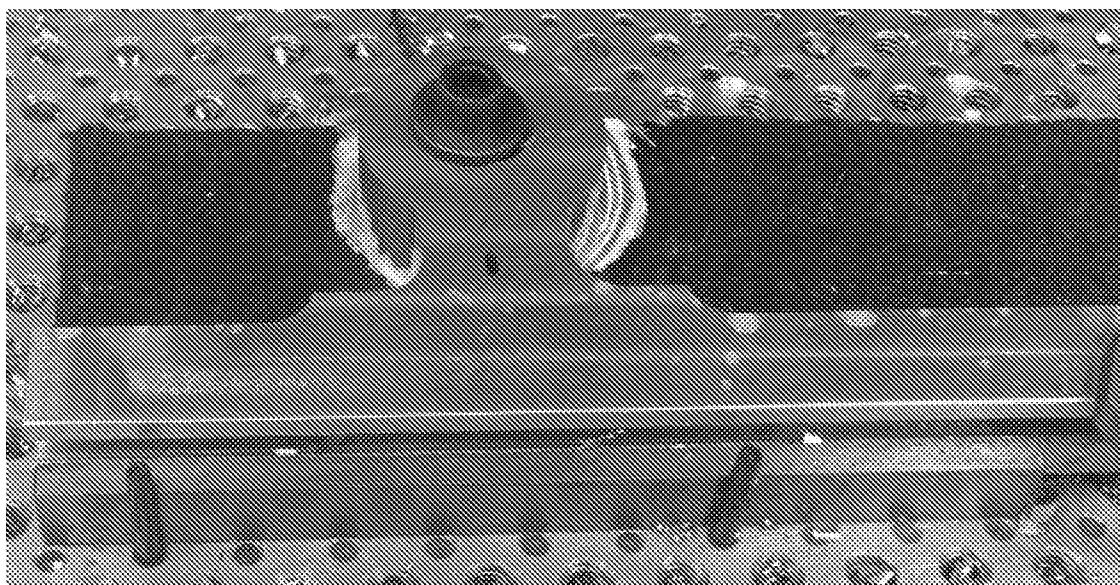


FIG. 5

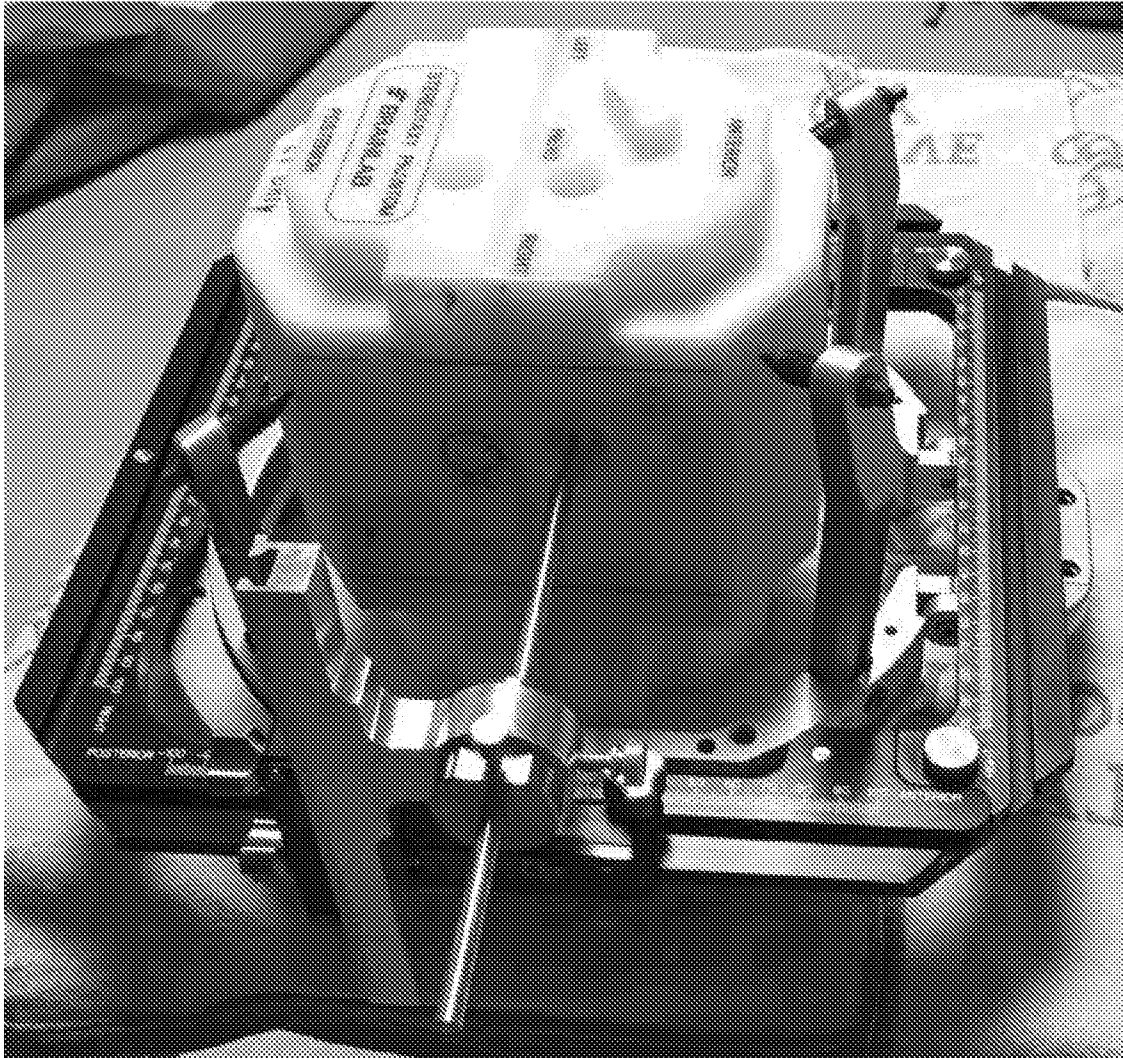


FIG. 6

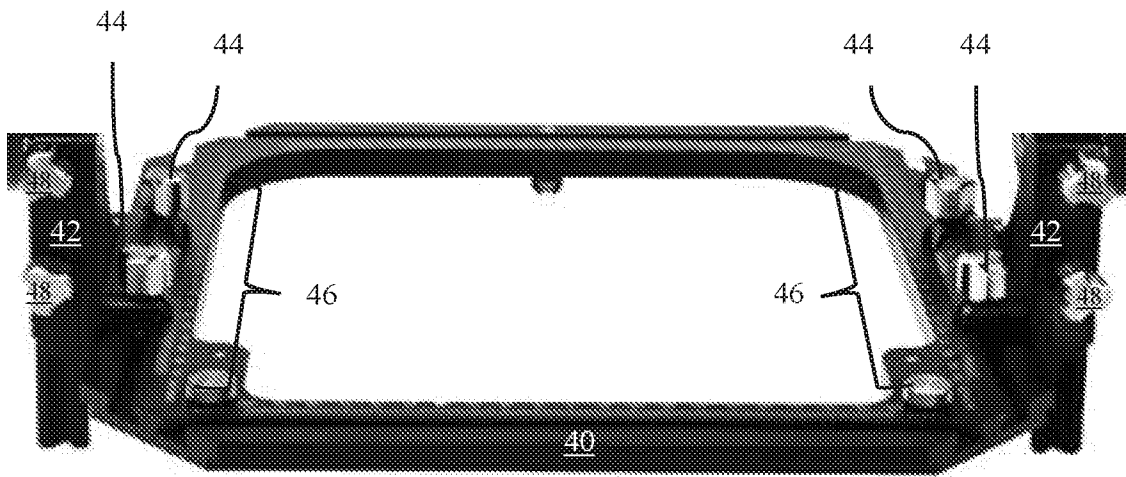


FIG. 7

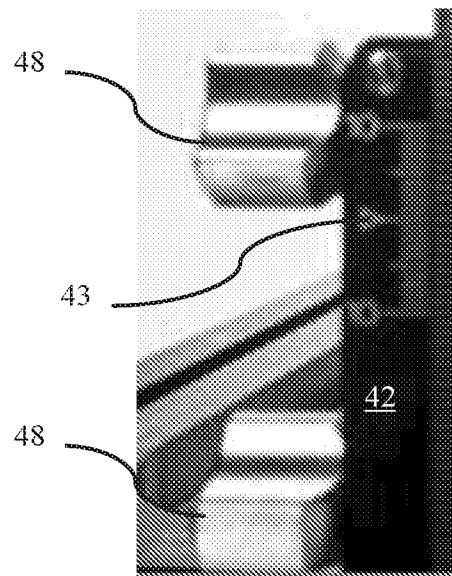


FIG. 8

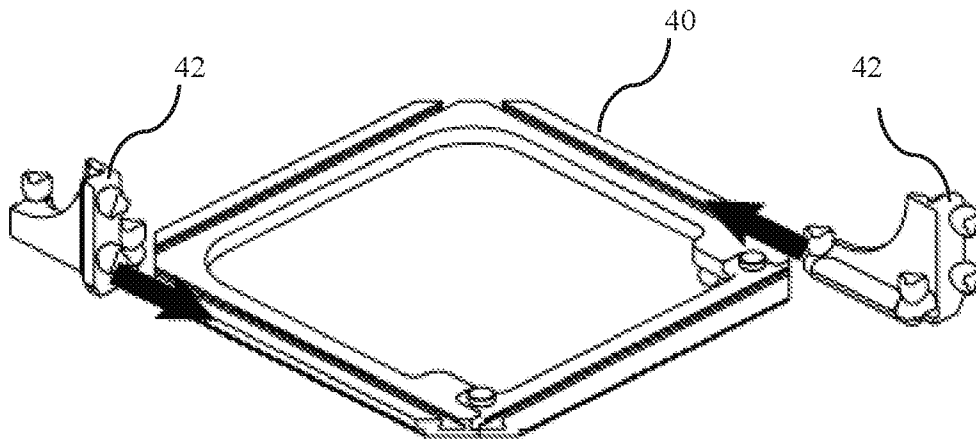


FIG. 9

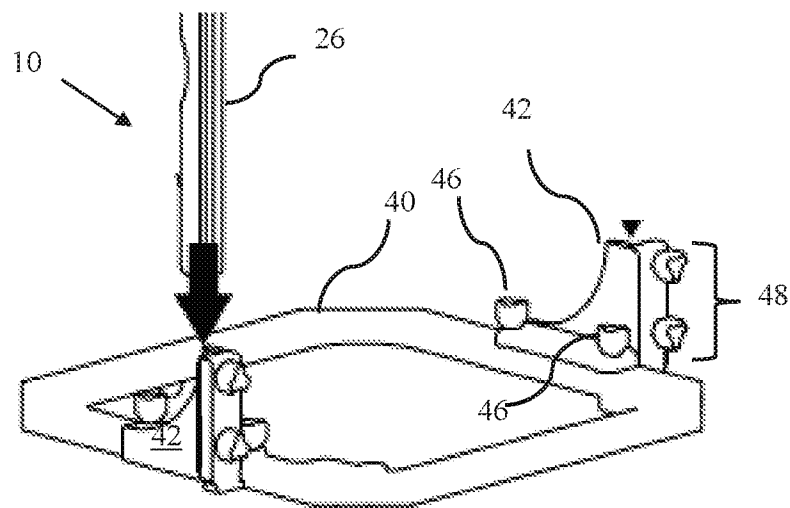


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/29408

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61B 10/00, A61B 10/02, A61B 19/00, A61B 17/00, A61B 5/0476, A61B 5/04 (2017.01) CPC - A61B10/00, A61B10/02, A61B5/055, A61B5/0555, A61B6/04, A61G13/12, A61G13/121, A61B10/0275, A61B2010/0208, A61B90/11, A61B17/00, A61B90/14, A61B90/10, A61B2090/3933, A61B2090/101, A61B5/0476, A61B5/04, A61B2090/3954, A61B5/00		
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 Search History Document		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
See Search History Document		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
See Search History Document		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,413,263 B1 (Lobdill) 02 July 2002 (02.07.2002), entire document, especially Fig. 1, 2; col 7, ln 47-50; col 7, ln 63-67; col 7, ln 31-36;	1-7
A	US 5,618,288 A (Calvo) 08 April 1997 (08.04.1997), entire document, especially Fig. 4; col 4, ln 3-6; col 3, ln 26-31;	1-7
A	US 6,283,977 B1 (Ericsson et al.) 04 September 2001 (04.09.2001), entire document, especially Fig. 1, 2; col 3, ln 46-48; col 4, ln 21-28;	1-7
A	US 2011/0040304 A1 (Li et al.) 17 February 2011 (17.02.2011), entire document	1-7
A	US 4,360,028 A (Barbier et al.) 23 November 1982 (23.11.1982), entire document	1-7
A	US 7,231,723 B1 (O'Neill et al.) 19 June 2007 (19.06.2007), entire document	1-7
A	US 7,343,205 B1 (Pianca et al.) 11 March 2008 (11.03.2008), entire document	1-7
A	US 4,805,615 A (Carol) 21 February 1989 (21.02.1989), entire document	1-7
☐ 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 "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 06 July 2017		Date of mailing of the international search report 01 AUG 2017
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300		Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774