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(54) **SYSTEM AND METHOD FOR PLACEMENT
OF NEUROSTIMULATION LEADS**

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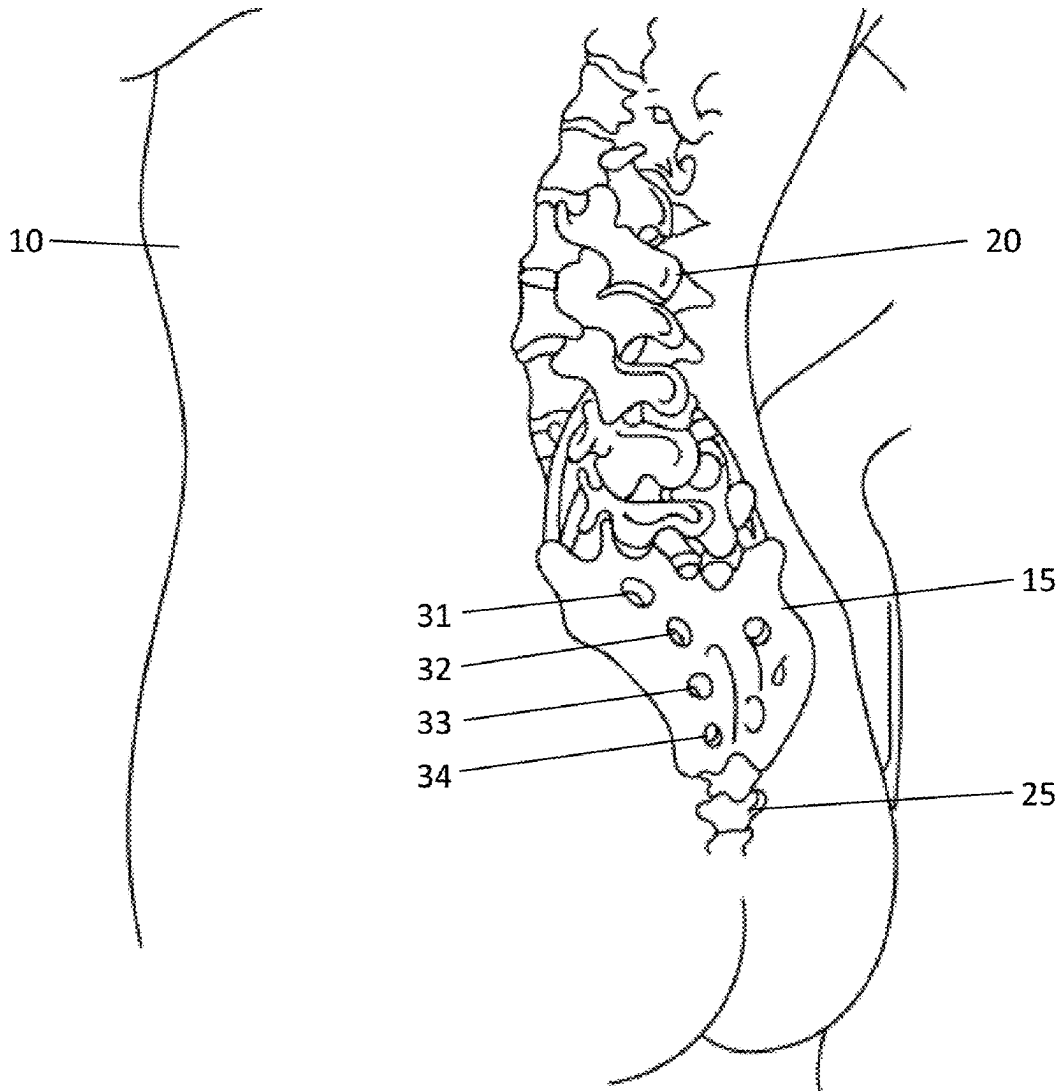
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(2) Date: **Oct. 14, 2024**

(57)

ABSTRACT

A system and method for locating and guiding a peripheral nerve evaluation (PNE) lead. The system comprising an X-ray system to capture images of the patient. The images are processed by the system and are provided to a user to utilize a measurement device for inserting a needle for placing leads for the PNE procedure.



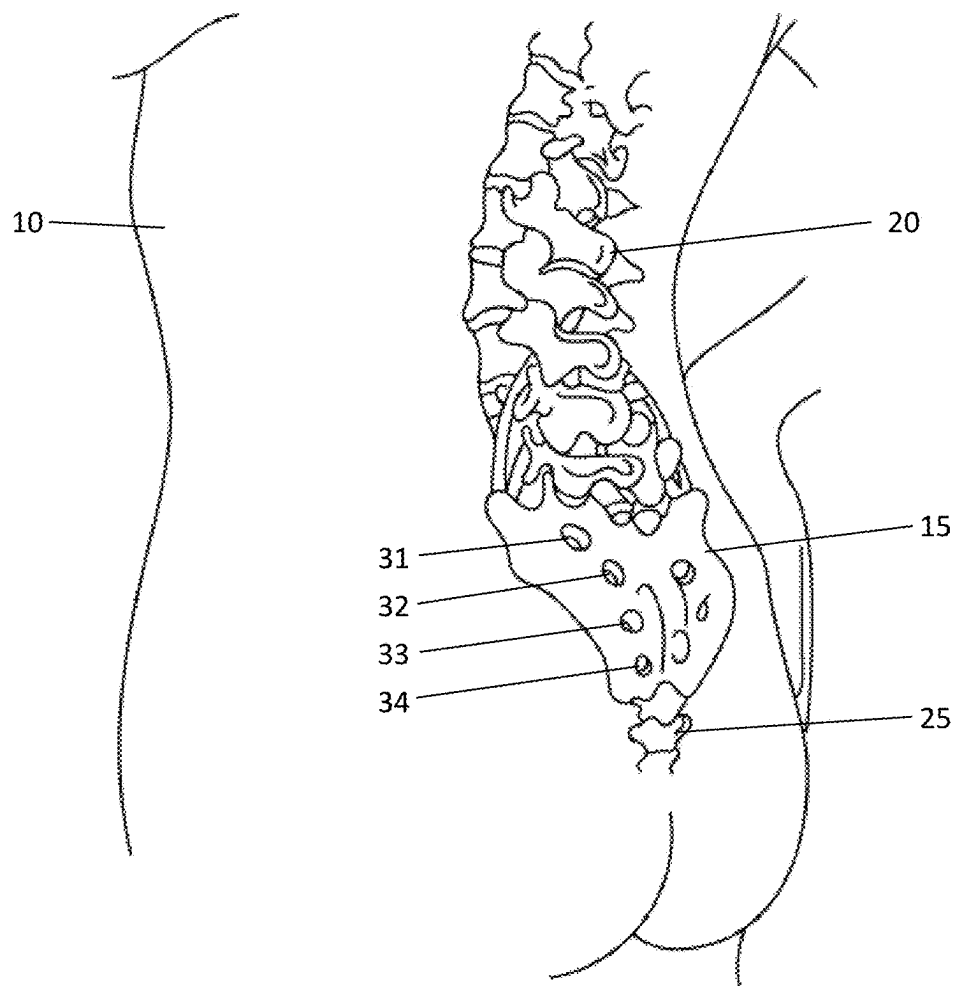


FIG. 1

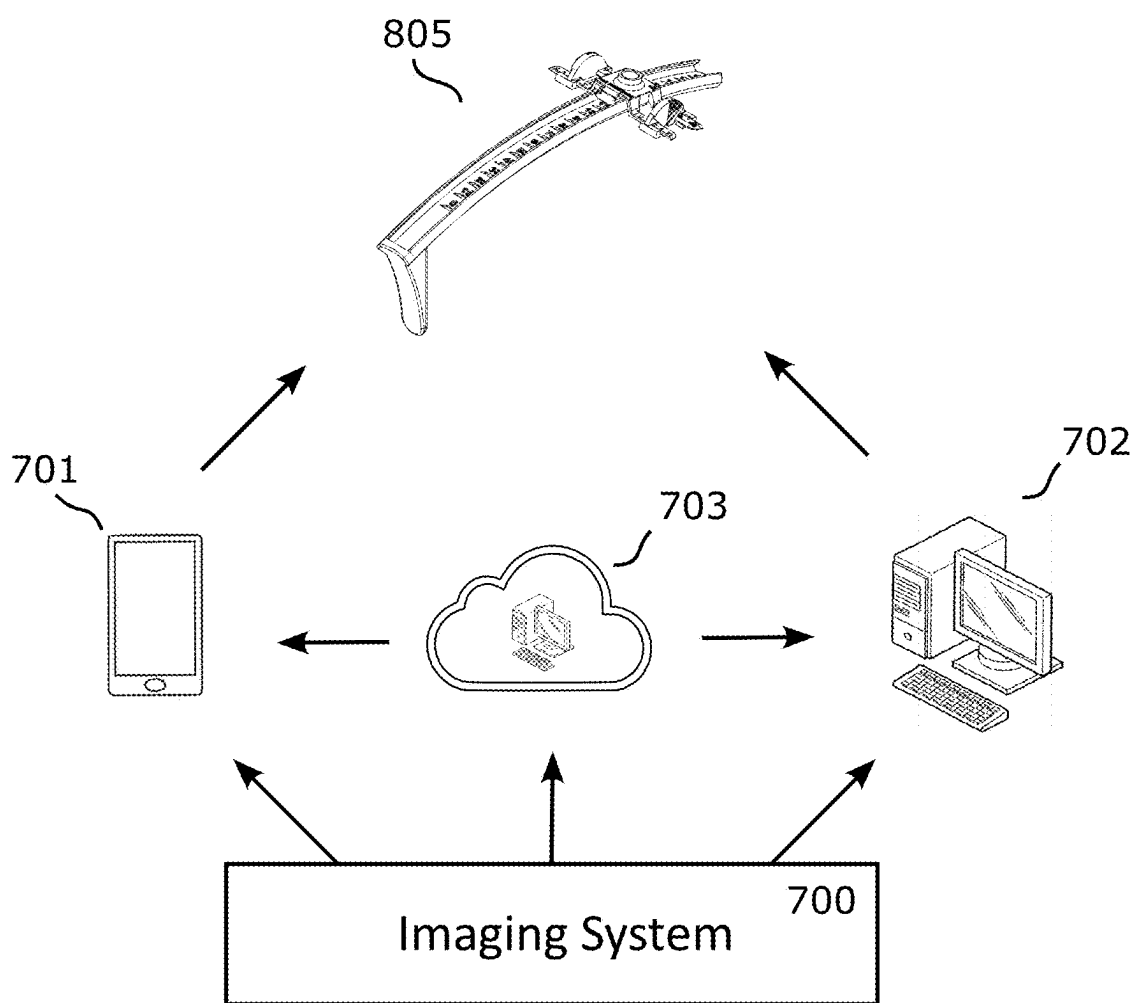


FIG. 2

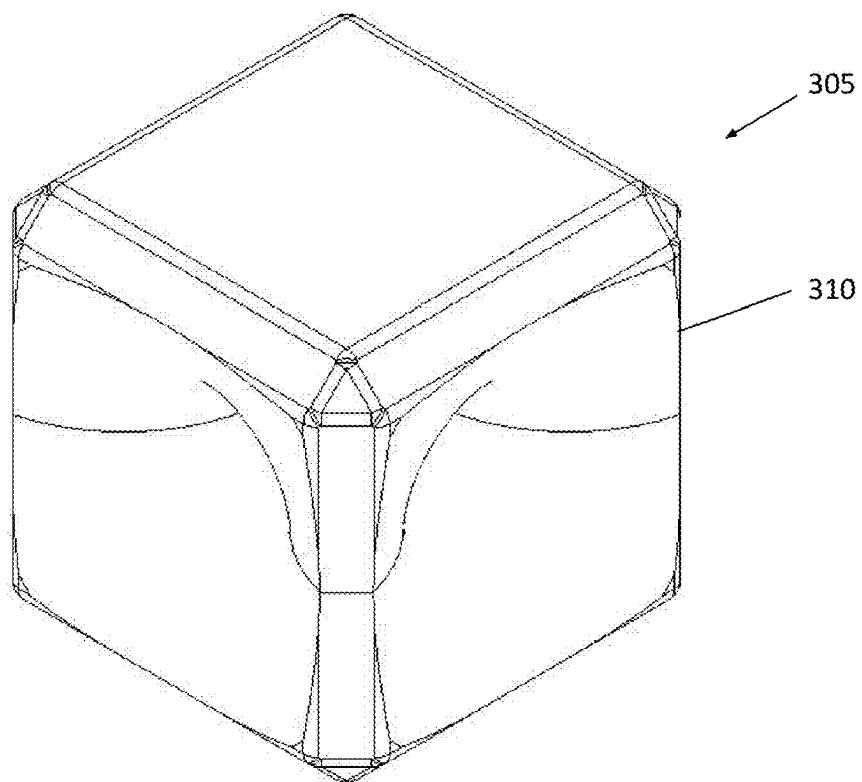


FIG. 3

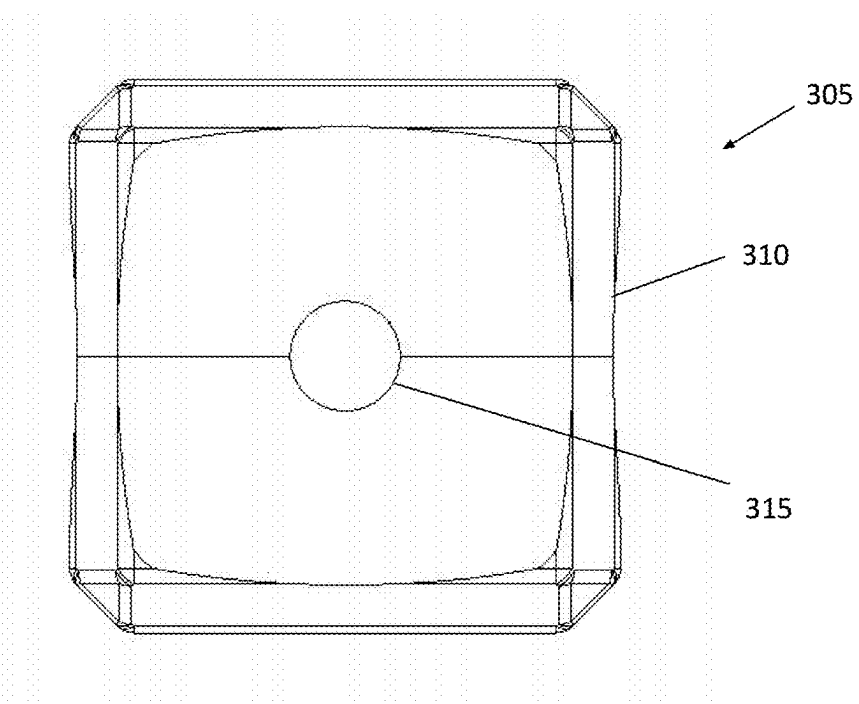


FIG. 4

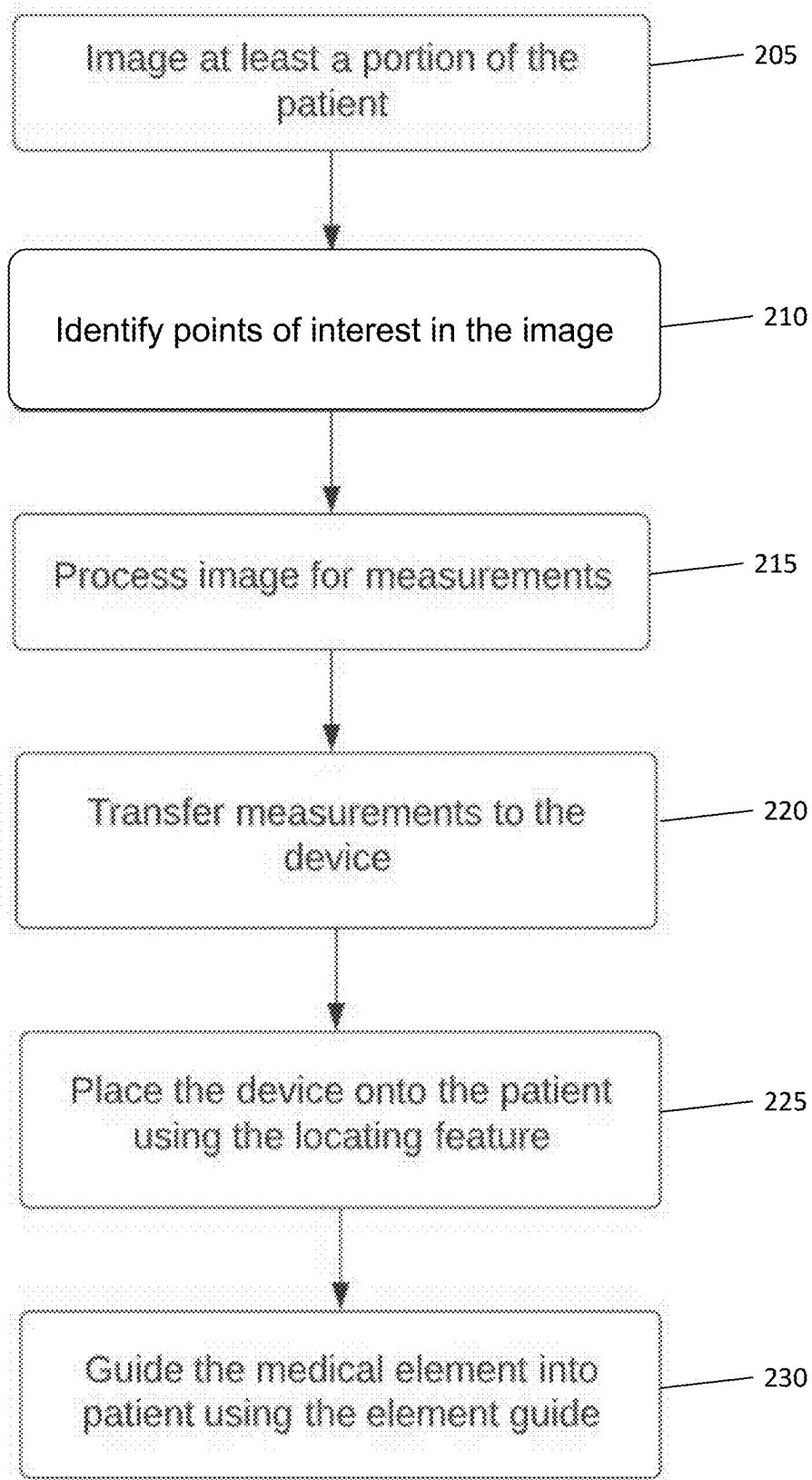


FIG. 5

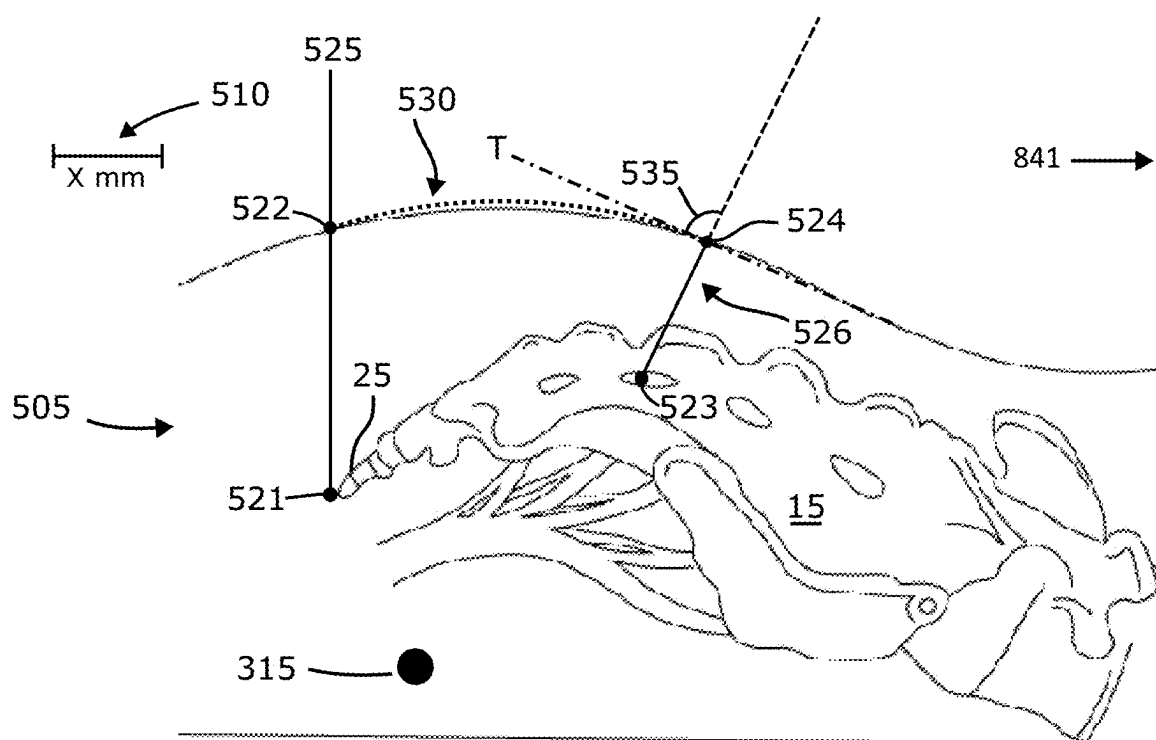


FIG. 6

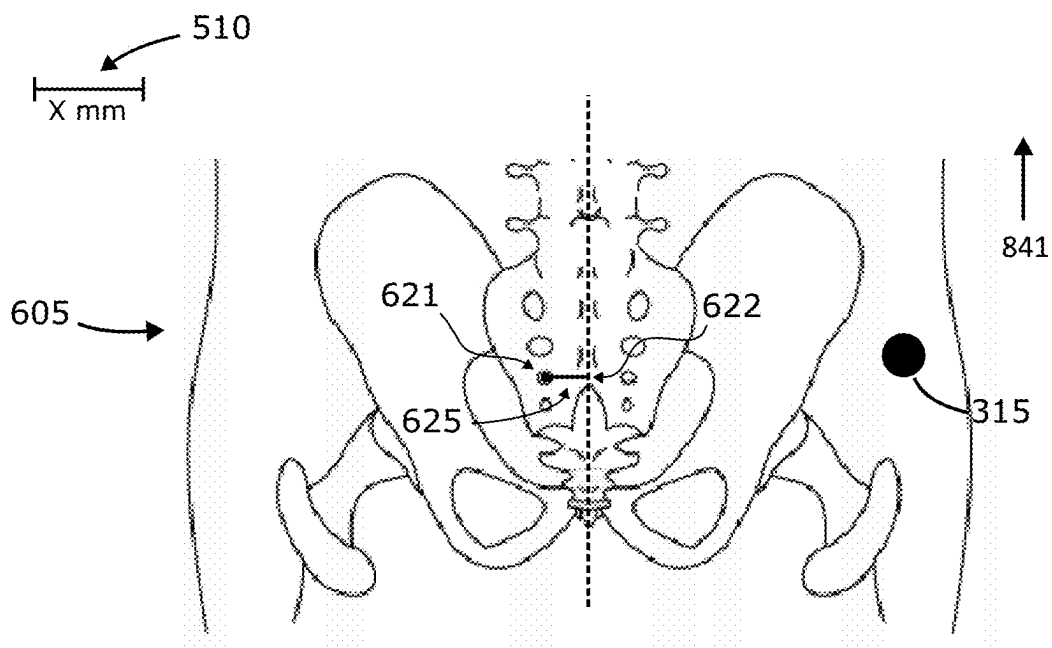


FIG. 7

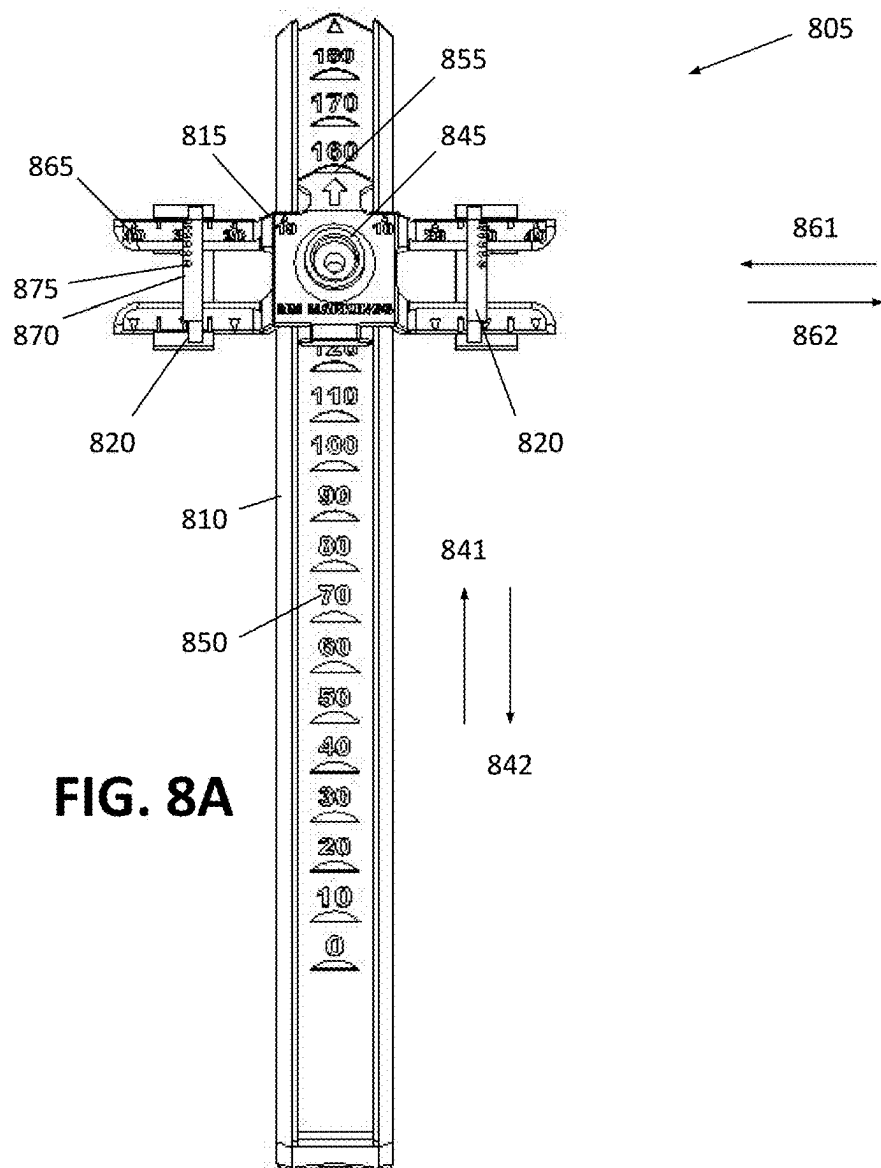


FIG. 8A

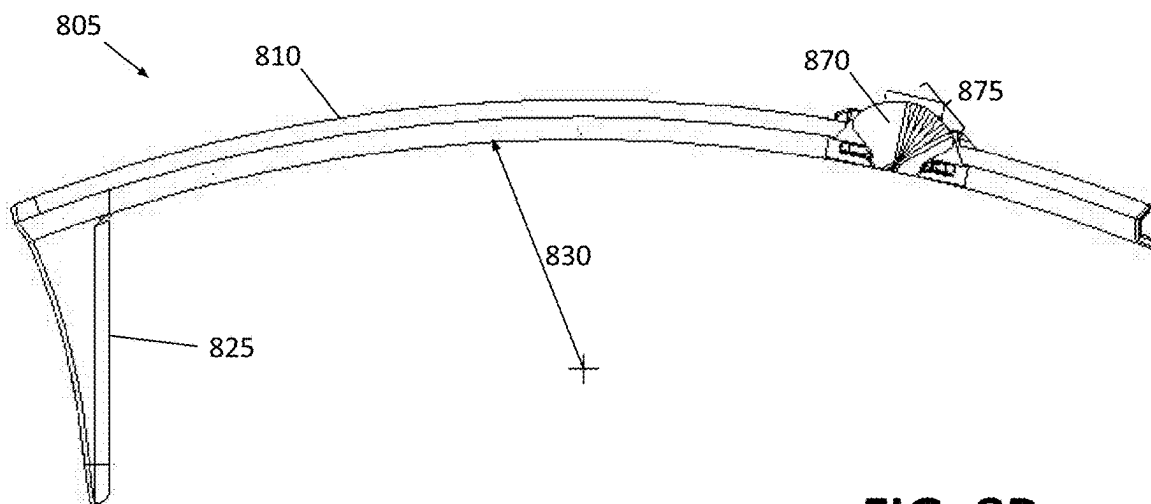


FIG. 8B

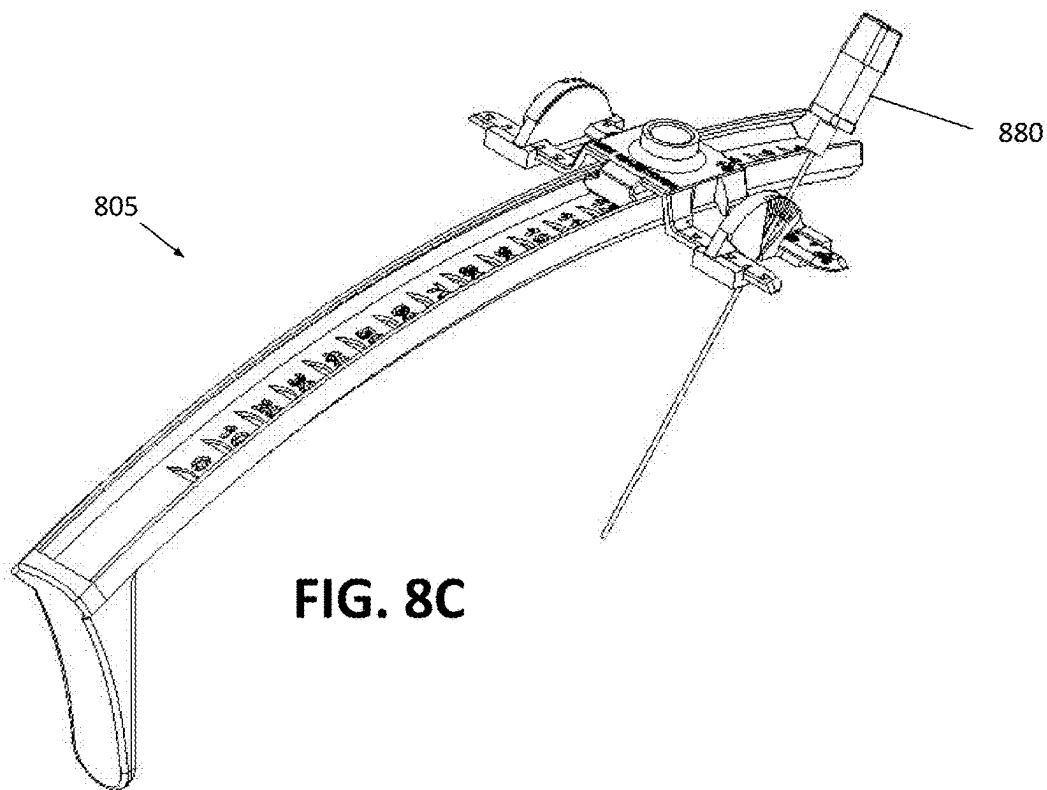


FIG. 8C

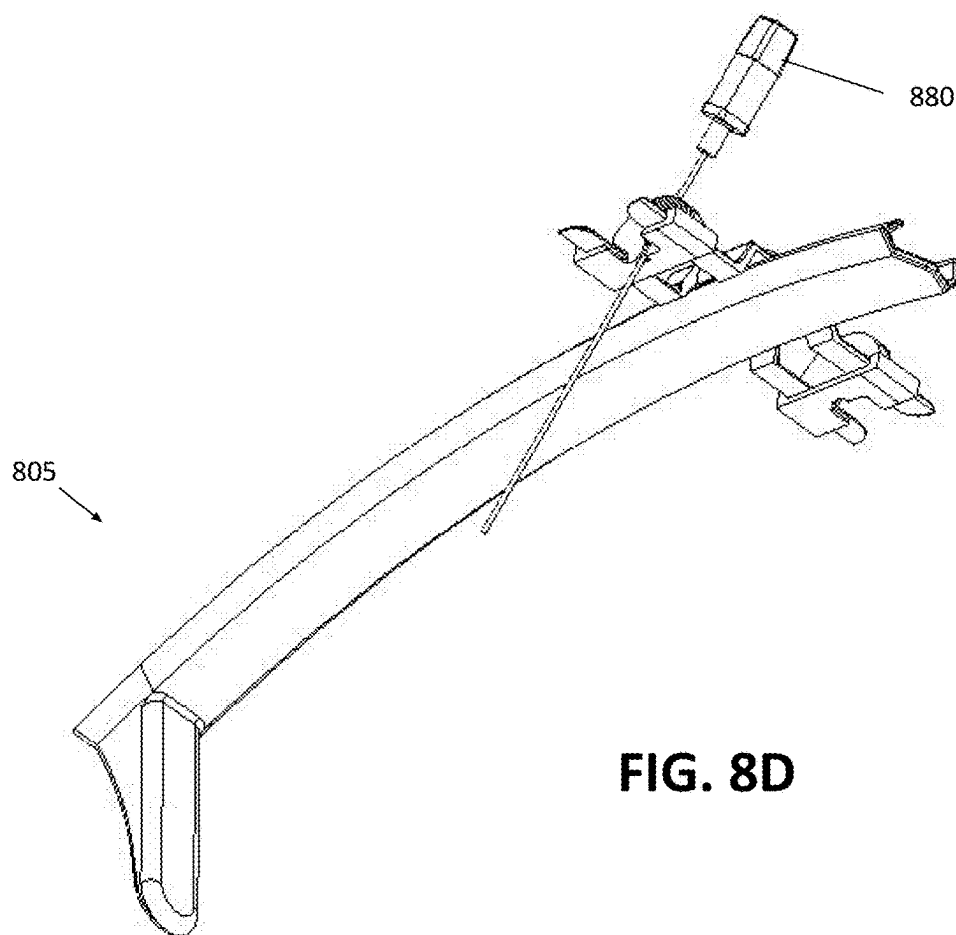
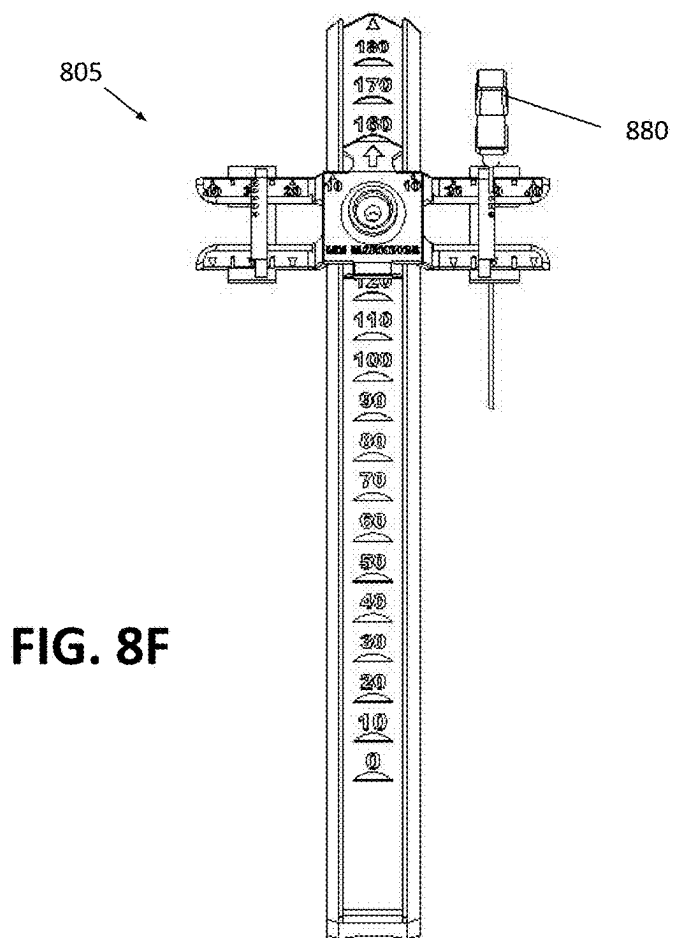
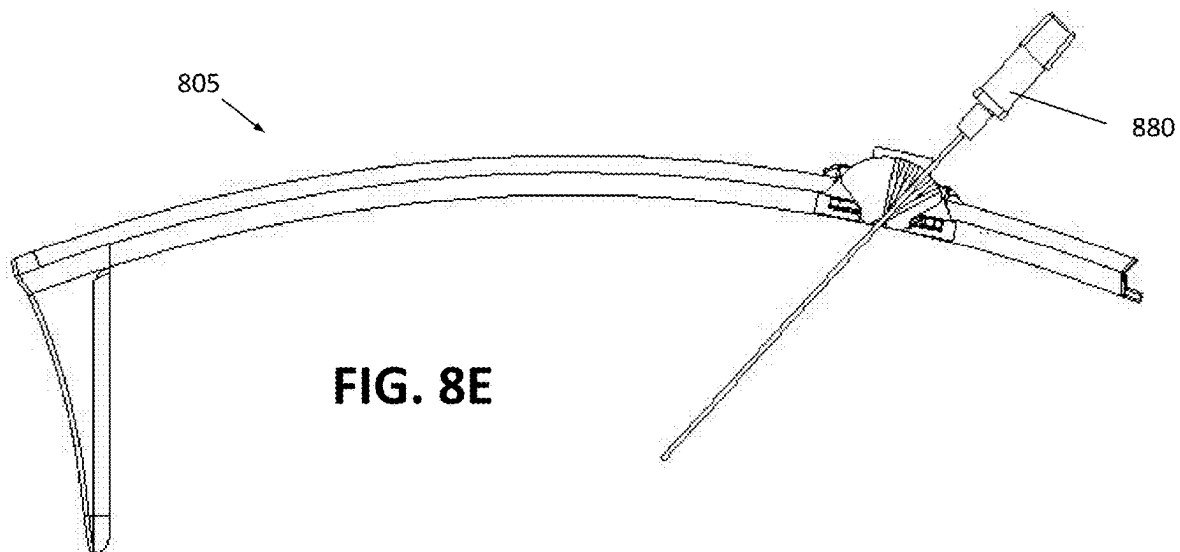


FIG. 8D



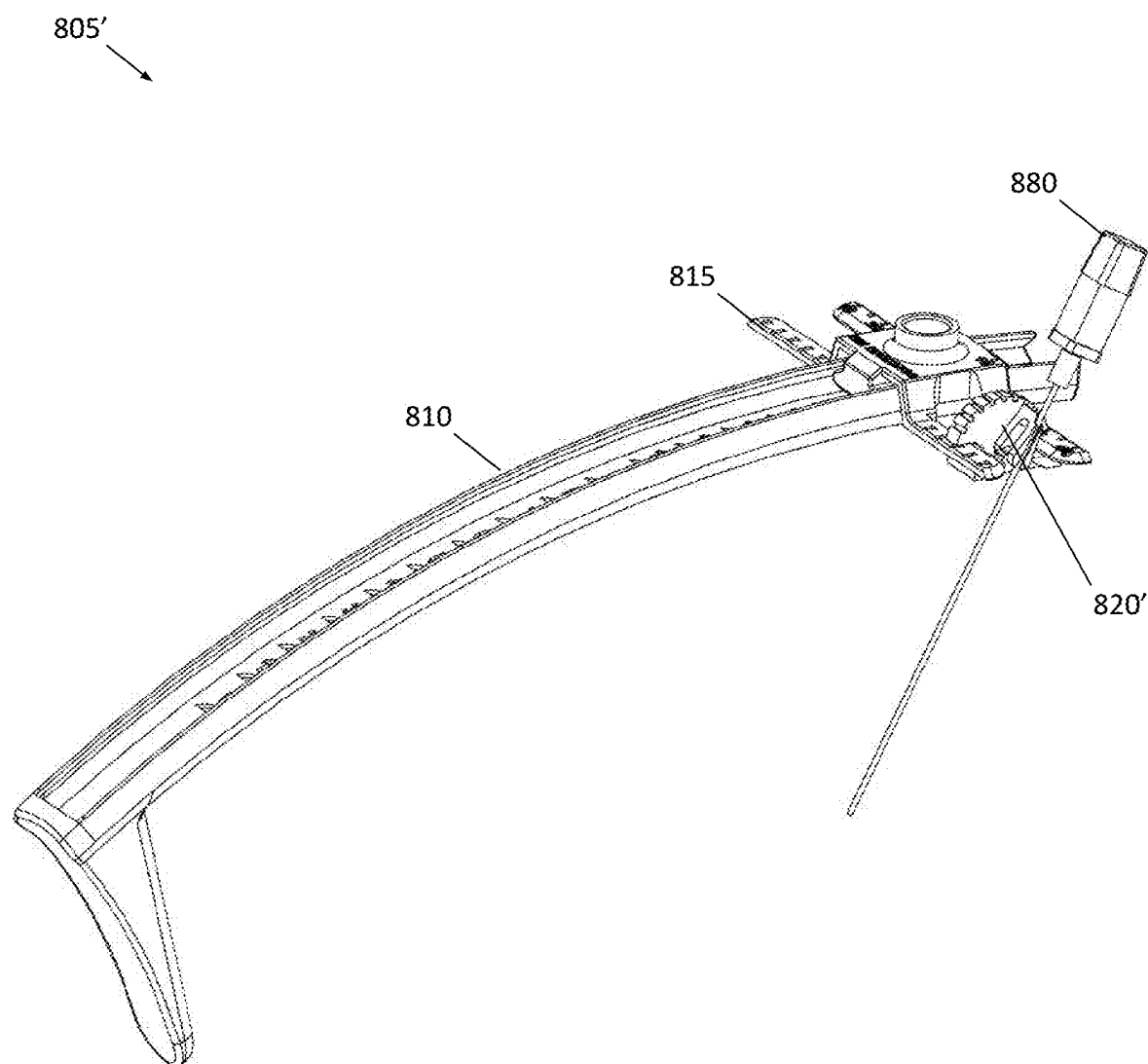


FIG. 8G

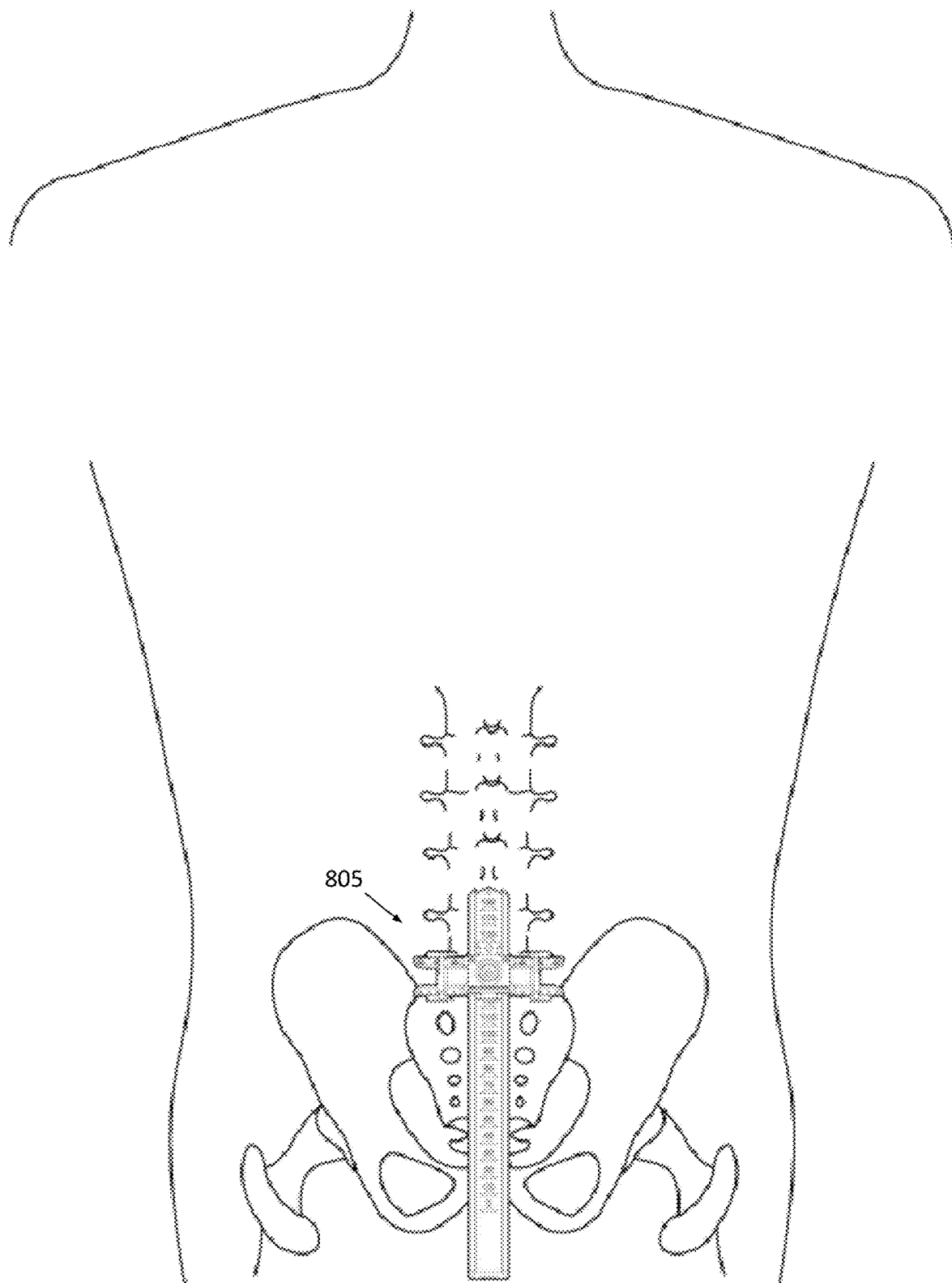


FIG. 9

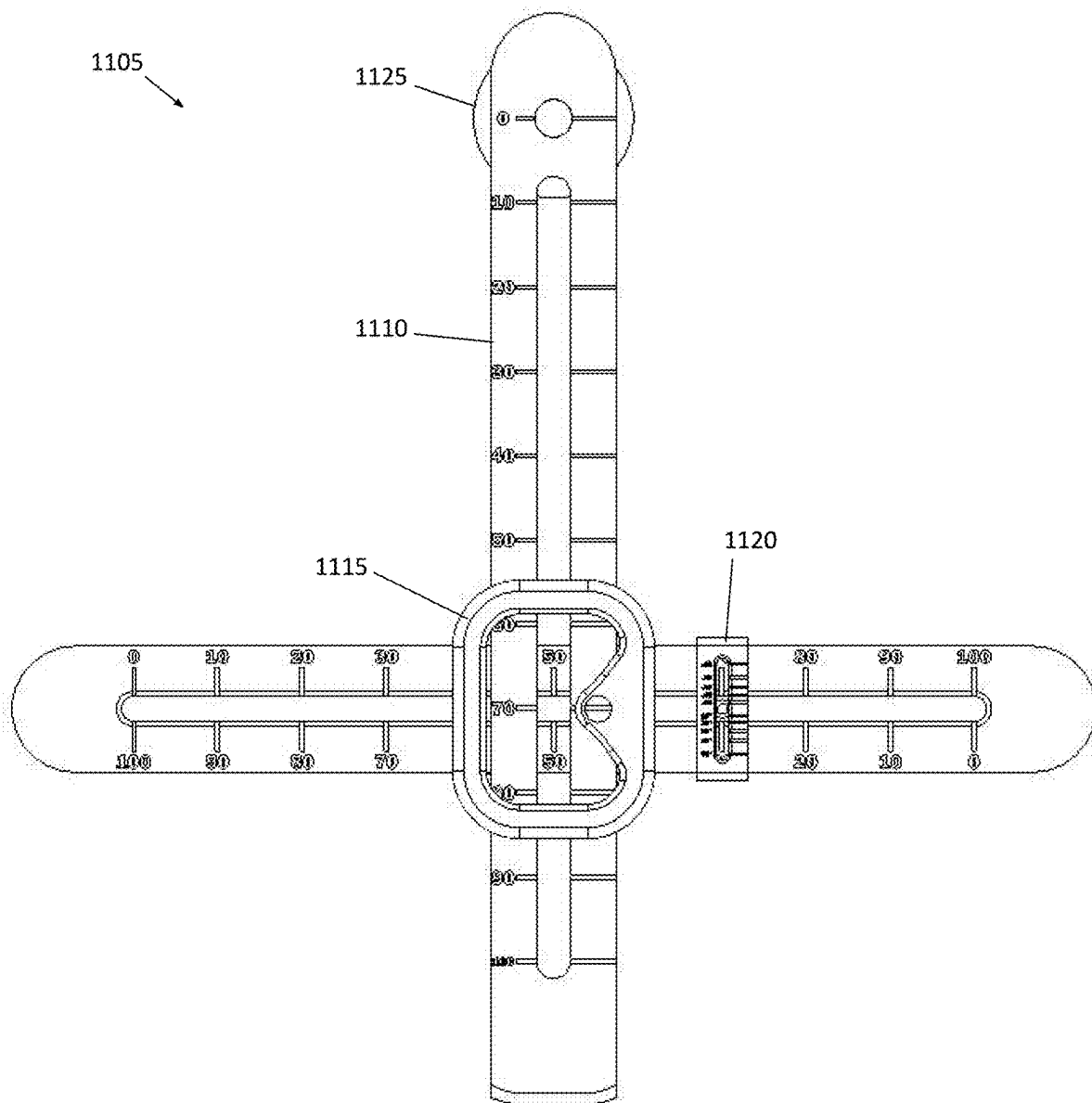


FIG. 11A

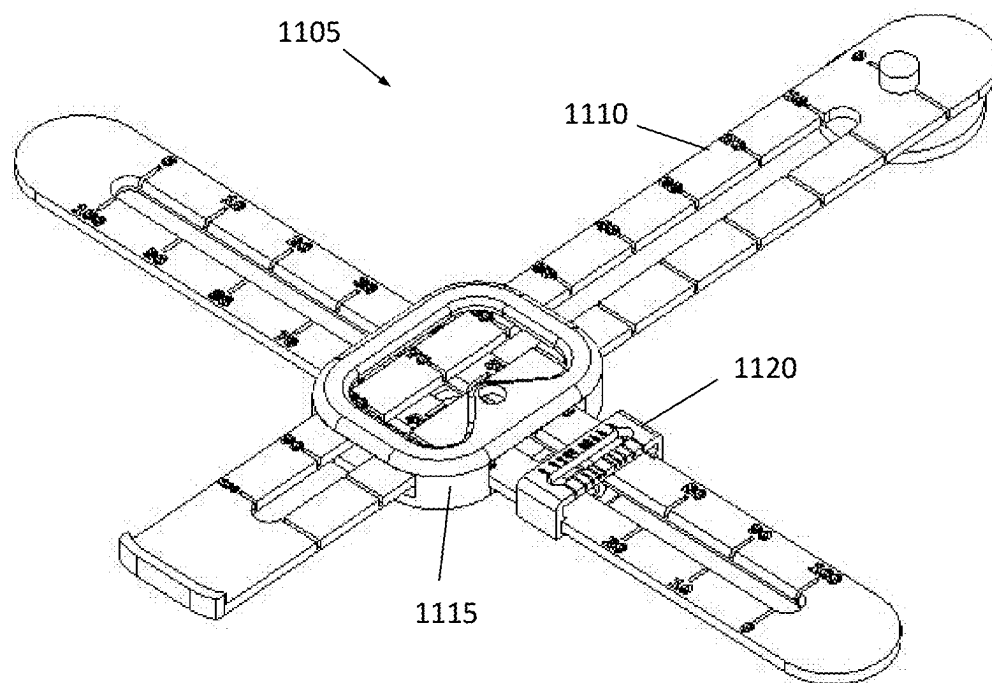


FIG. 11B

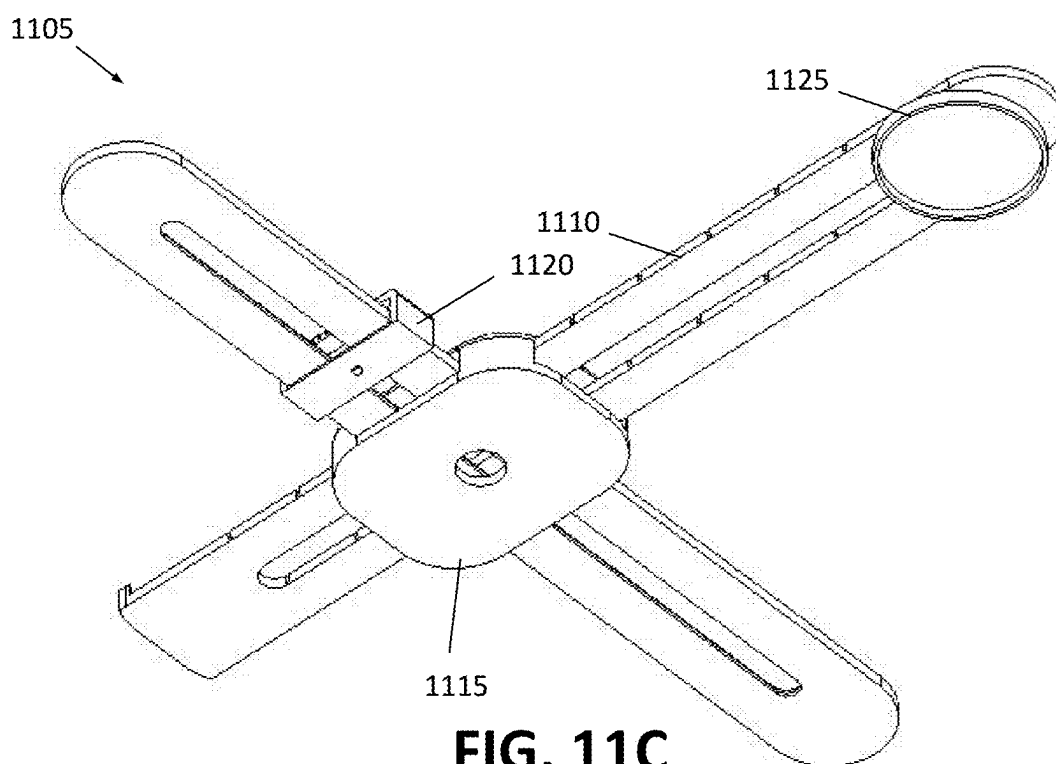
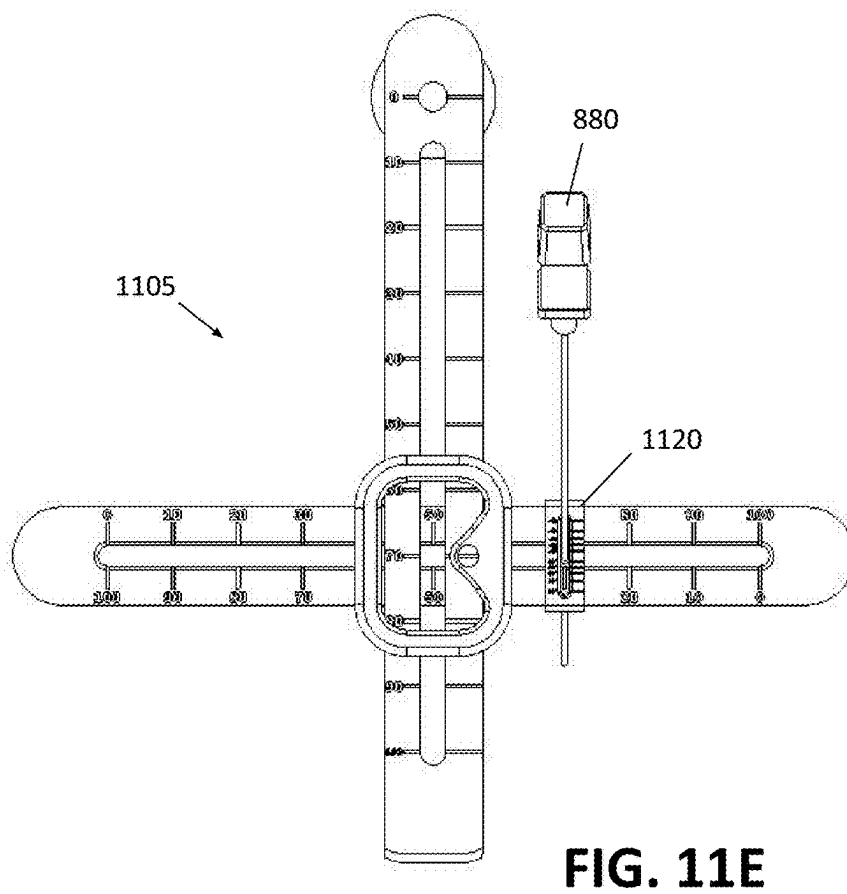
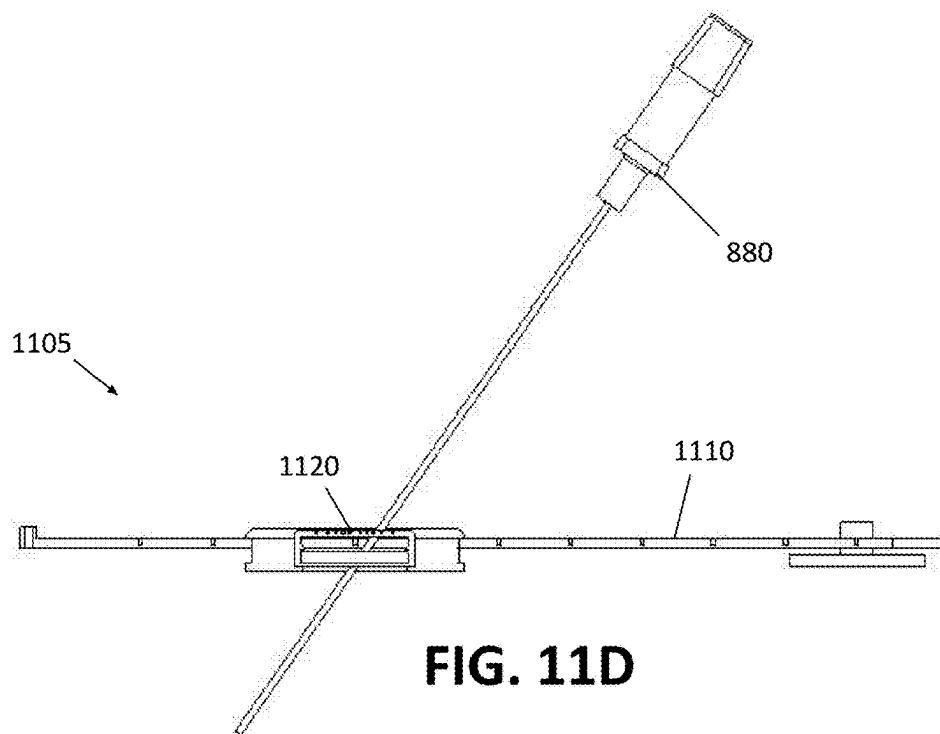


FIG. 11C



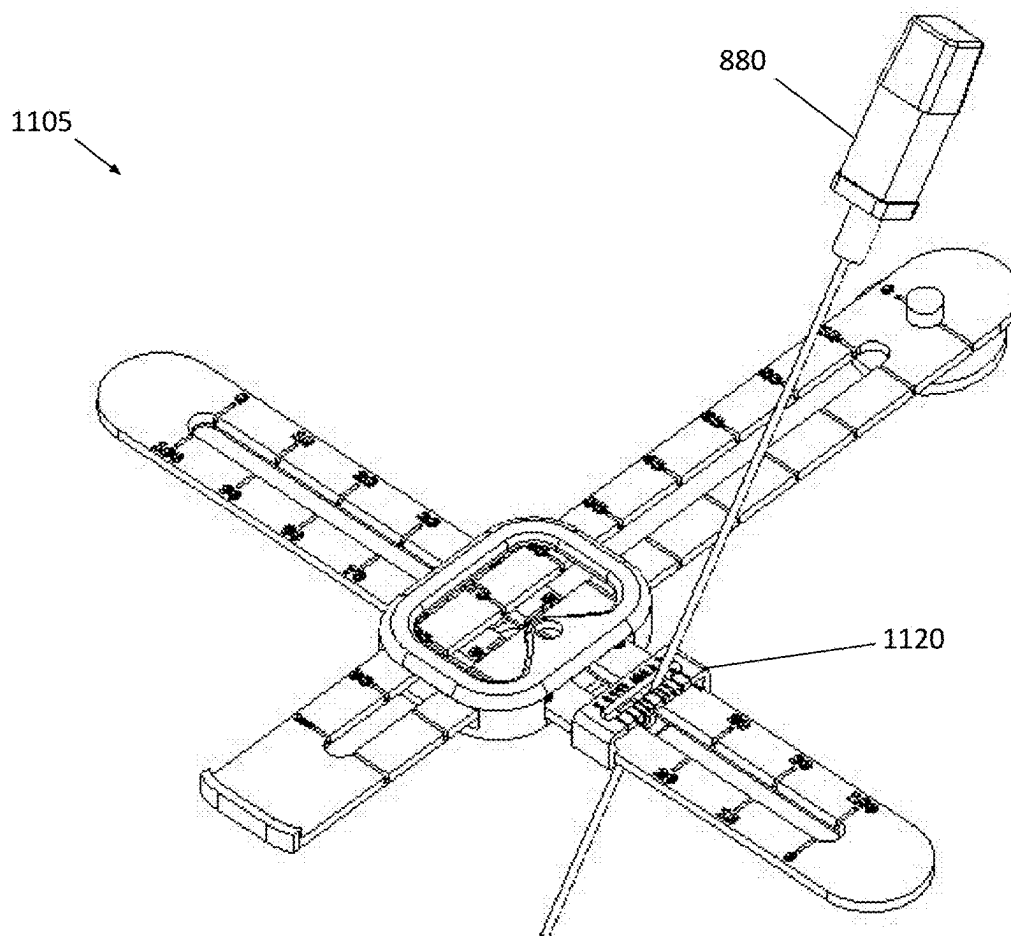


FIG. 11F

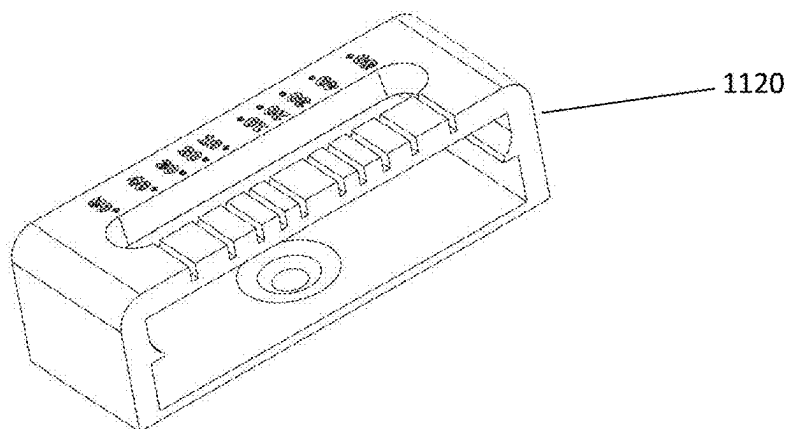


FIG. 11G

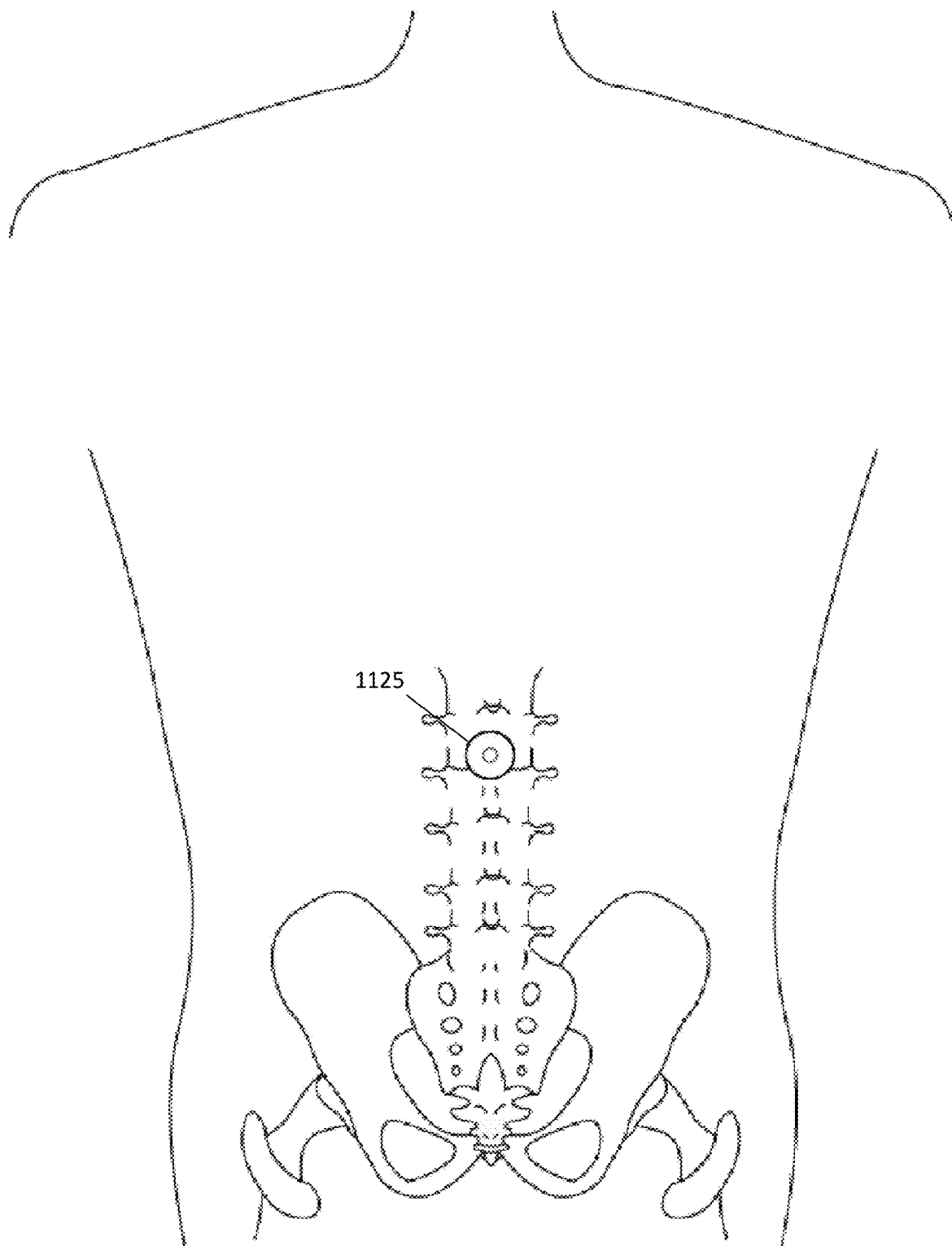


FIG. 12

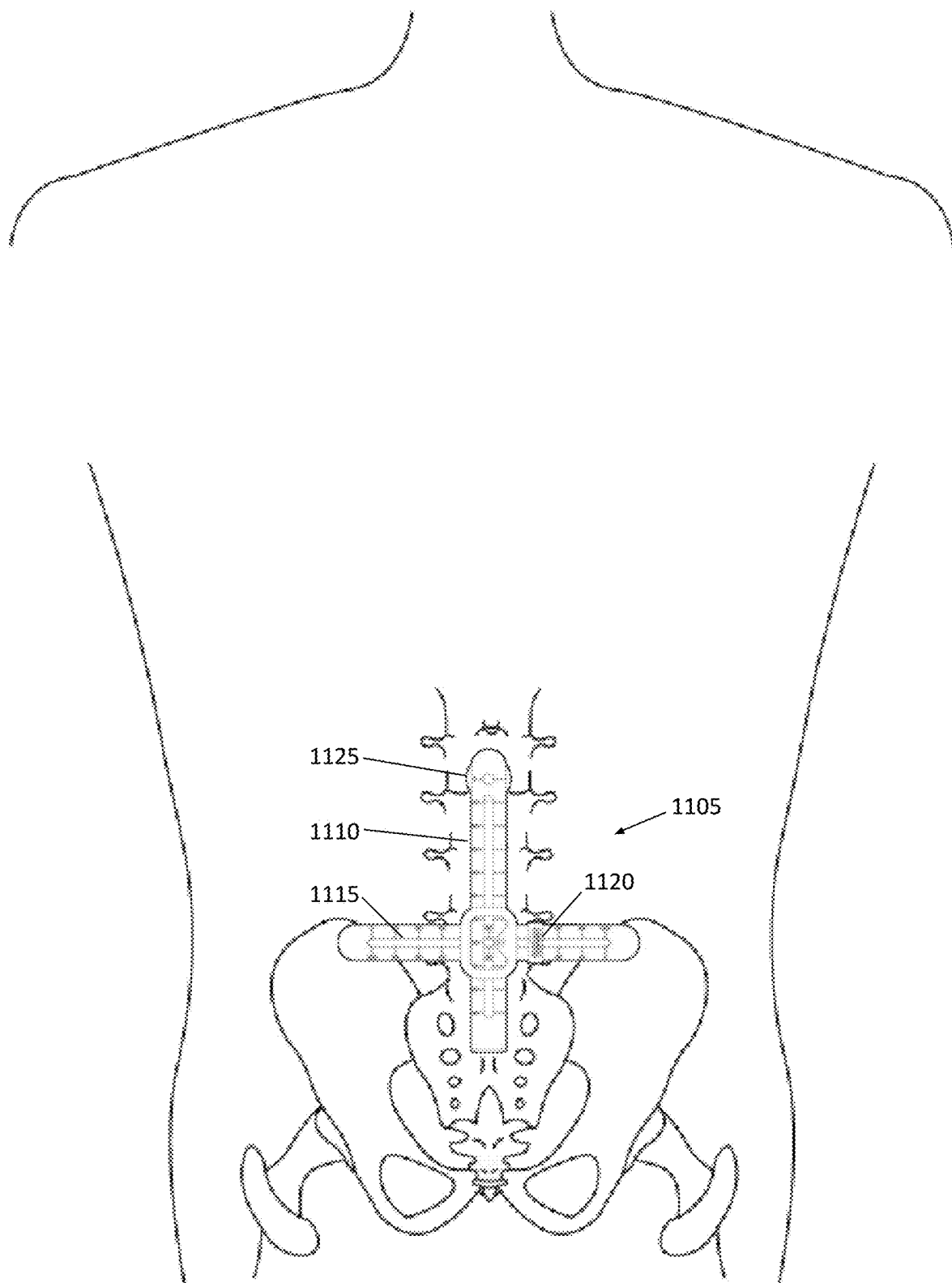


FIG. 13

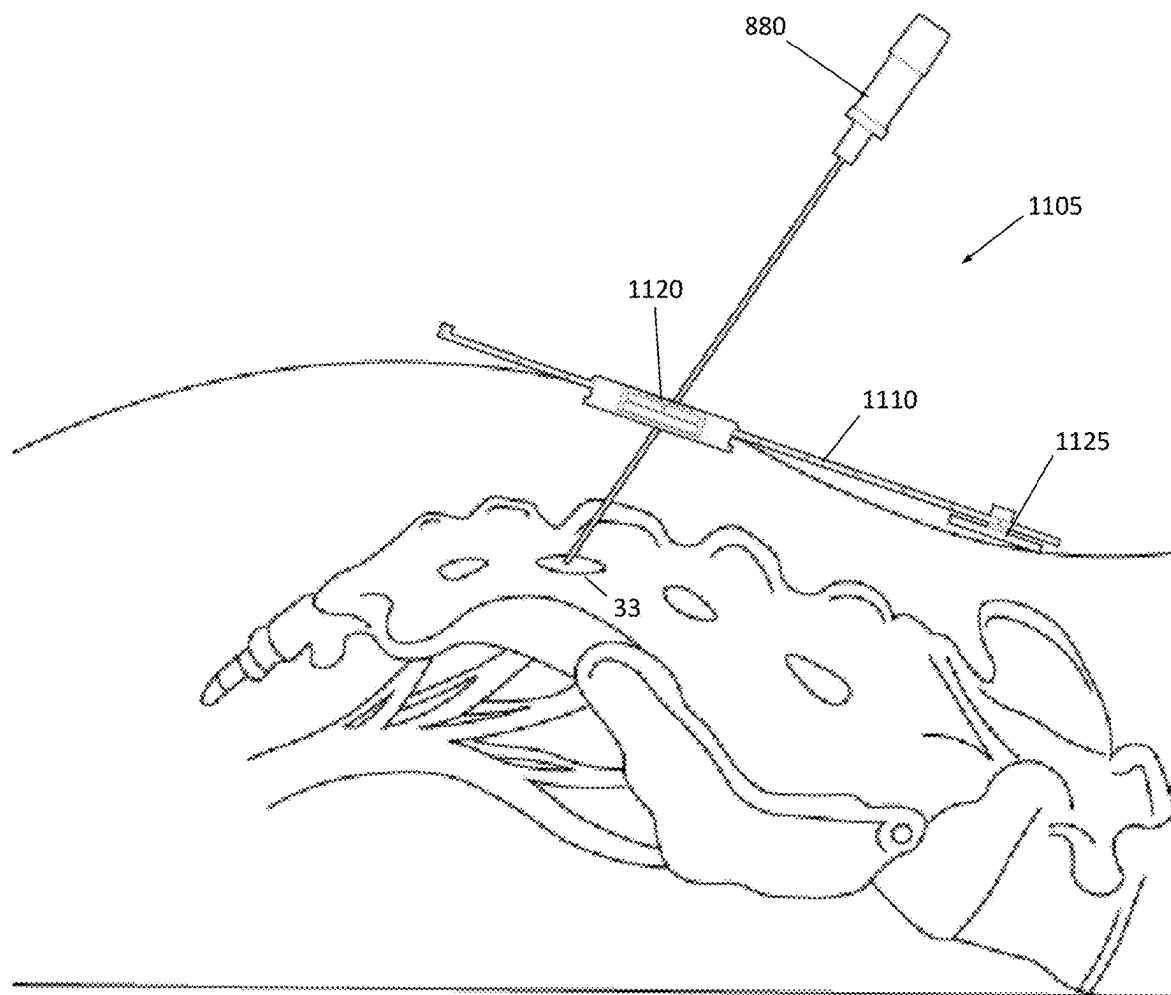


FIG. 14

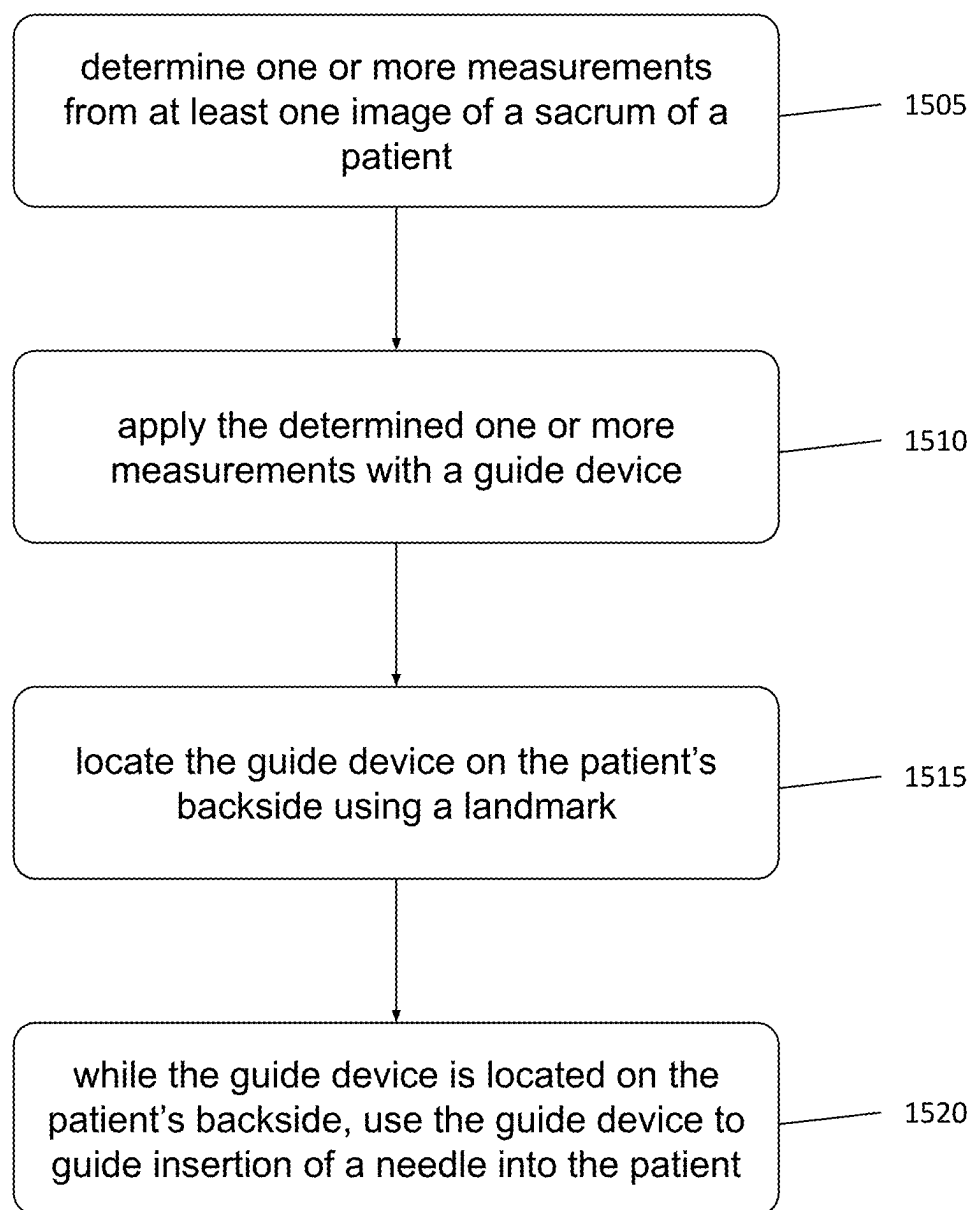


FIG. 15

SYSTEM AND METHOD FOR PLACEMENT OF NEUROSTIMULATION LEADS

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application No. 63/411,904 filed Sep. 30, 2022, and U.S. Provisional Patent Application No. 63/331,474 filed Apr. 15, 2022, both of which are incorporated by reference herein in their entireties.

GENERAL DESCRIPTION

[0002] This application relates to devices and methods to assist with the placement of leads used in neurostimulation. In the exemplary embodiment, the device and method relate to the placement of an electrical lead used in sacral neuromodulation, and more particularly, to a device and method for locating the sacral foramina during a peripheral nerve evaluation (PNE) procedure in order to place the electrical leads of a PNE system in the appropriate position.

[0003] Sacral neuromodulation is a treatment for bladder and bowel dysfunction, which involves implanting a device that provides controlled electrical stimulation to the sacral S3 spinal nerve in the patient. Prior to receiving a permanent implant, the patient undergoes a procedure called a peripheral nerve evaluation (PNE). The procedure involves implanting temporary leads into the patient with the leads connected to an external pulse generator, and then observing results for a period of time, usually anywhere between 3 to 14 days. If the results meet certain clinical standards, then the patient may be a candidate for receiving an implantable pulse generator for sacral neuromodulation.

[0004] Current techniques for lead placement during the evaluation procedure involve identifying palpable skeletal or bony landmarks on the patient and inserting a foramen needle into the patient based on the location of these landmarks. The objective during this procedure is to insert the foramen needle through the skin and into the S3 foramen such that an electrical stimulation lead may be provided along the sacral S3 spinal nerve. The procedure may be performed in an operating room setting with fluoroscopic or other image guidance to provide for more accurate placement of the leads. However, this procedure is most often performed in an office setting under local anesthesia and without imaging. In an office setting, the placement method is essentially a “blind” insertion method because it does not rely on a picture or fluoroscopy of the patient’s anatomy.

[0005] When fluoroscopy or other imaging is not used, such as in the office setting, the physician inserts the foramen needle from outside the patient’s body and into the S3 foramen based on experience and by referencing the palpable landmarks. The physician cannot see the S3 foramen when they are attempting to place the foramen needle through the S3 foramen. The use of palpable skeletal or bony landmarks is based on normal anatomy without consideration for anatomic or pathologic variations. This may lead to improper placement of leads in an office setting and eventual failure of the PNE. For example, it is often the case that plural attempts are required to locate the S3 foramen and successfully insert the foramen needle through it. In some instances, due to multiple failed attempts at proper needle placement, a patient may even abandon the PNE (and thus sacral neuromodulation altogether) without ever having the

leads properly placed. Misplaced leads may also lead to a less than ideal clinical outcome and a premature abandonment of an otherwise efficacious treatment. Thus, there remains a demand and need to provide an improved system and method for PNE lead placement

SUMMARY

[0006] The embodiments disclosed herein relate to devices and methods that improve efficacy and efficiency of locating the sacral foramina during a sacral neuromodulation procedure. Embodiments include imaging a portion of the patient, identifying internal points of the patient in the imaging, calculating measurements based on the imaging and the identified points, transferring the measurements to a device, placing the device on and exterior to the patient using a locating feature, and guiding a medical element (e.g., a foramen needle) into the patient using an element guide of the device. The disclosed embodiments help the physician more accurately locate the S3 foramen and provide an improvement over conventional techniques that are less accurate at locating the S3 foramen during a blind insertion.

[0007] According to one embodiment disclosed herein a method includes the steps of: determining one or more measurements from at least one image of a sacrum of a patient; applying the determined one or more measurements with a guide device; locating the guide device on the patient’s backside using a landmark; and while the guide device is located on the patient’s backside, using the guide device to guide insertion of a medical element into the patient.

[0008] According to another disclosed embodiment a device for guiding medical element insertion includes: an elongated base with a locating feature that references a landmark on a patient; a head that is translatable along the elongated base in a first direction; a medical element guide that is translatable along the head in a second direction perpendicular to the first direction, wherein the medical element guide is configured to identify the entry location and angle of insertion of a medical element into the patient.

[0009] In yet another disclosed embodiment, a system and method is disclosed that includes one or more computer readable storage media having program instructions collectively stored on the one or more computer readable storage media or remote cloud based services. The program instructions are executable to: receive at least one image of a sacrum of a patient; display image; receive user input defining points of interest in the displayed image; determine one or more measurements for a medical element guide based on the points of interest and a predefined dimension of the medical element guide; and output the determined one or more measurements to a user.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 shows an exemplary partial view of the human anatomy.

[0011] FIG. 2 shows the elements of an exemplary medical element locating and placement system.

[0012] FIG. 3 shows an example of a radiopaque landmark device.

[0013] FIG. 4 shows an example of a radiopaque landmark device.

[0014] FIG. 5 shows a flowchart of an exemplary method of locating an insertion point and placement of a medical element.

[0015] FIGS. 6 and 7 show exemplary implementations of identifying points in a fluoroscopic image and processing the image for measurements.

[0016] FIGS. 8A-G show an exemplary needle guide device.

[0017] FIG. 9 shows an example of placing a needle guide device on a patient using a locating feature.

[0018] FIG. 10 shows an example of guiding a medical element into the patient using a needle guide device.

[0019] FIGS. 11A-G show an exemplary needle guide device.

[0020] FIG. 12 shows an example of a locating element affixed to a patient.

[0021] FIG. 13 shows an example of a locating element affixed to a patient and a needle guide device placed on the patient's back and connected to the locating element.

[0022] FIG. 14 shows an example of needle insertion using the needle guide device of FIGS. 11A-F.

[0023] FIG. 15 shows a flowchart of an exemplary method for locating and placing a needle into a patient for the purpose of placing a PNE lead.

DETAILED DESCRIPTION

[0024] The particulars shown herein are by way of example and for purposes of illustrative discussion of the disclosed embodiments and are presented to provide a readily understood description of the principles and conceptual aspects. In this regard, no attempt is made to show structural details in more detail than is necessary for a fundamental understanding, and the description taken together with the drawings make apparent to those skilled in the art how the disclosed devices and methods may be embodied in practice.

[0025] FIG. 1 shows an exemplary partial view of certain skeletal components of a human torso 10 including the sacrum 15 at the base of the spine 20, and the coccyx 25 at the base of the sacrum 15. As shown in FIG. 1, the sacrum 15 includes two groups of sacral foramina, or openings through which the sacral nerves pass, arranged in two vertical rows, each respectively located on either side of the medial sacral crest. In FIG. 1, foramen 31 corresponds to the S1 foramen, foramen 32 corresponds to the S2 foramen, foramen 33 corresponds to the S3 foramen, and foramen 34 corresponds to the S4 foramen. Only one group of sacral foramina is shown and numbered in FIG. 1. A system and method for accurately locating a selected one of the foramina 31-34 and inserting a needle through the selected one of the foramina to access a nerve for implanting a component of a sacral neuromodulation system is disclosed herein. Embodiments are described herein with respect to locating and inserting a foramen needle through the S3 foramen; however, the described system and method is not limited to use with the S3 foramen.

[0026] FIG. 2 shows the components of medical element placement system 100 which includes an imaging system 700 that may communicate with one or more electronic devices. Although X-ray or fluoroscopic imaging is preferred, other imaging technologies that show and distinguish internal bone structure of the patient may be used. The electronic device may include a smartphone or other mobile device 701, a computer 702, or any other known electronic

device that is capable of receiving inputs from the imaging system 700 and displaying outputs on the display of the electronic device. In addition to (or as an alternative to) the display, the electronic device may provide various indications to the user through audible or visual alerts or messaging. The imaging system 700 is configured to capture images of a patient requiring a PNE procedure. The medical element placement system 100 requires images to be taken in both the anterior-posterior (or posterior-anterior) and lateral planes in order to provide the measurements required to place the PNE lead in the correct location. Once the images have been captured, images from the imaging system 700 may be sent to the electronic device(s) which is configured to run or function with an application (e.g., software) that is configured to process the images and provide information that may be used to properly position a needle guide device 805 on the patient and mark the patient as necessary to identify the insertion point for a foramen needle used for placement of the PNE lead.

[0027] In one embodiment, the application may run using a cloud-based computing service 703 that communicates with the electronic device. The cloud-based computing service may perform the calculations required to identify a preferred point of needle entry (and angle) and provide the resulting location and angle to the electronic device. The electronic device may run the application (or a web client that accesses a cloud-run version of the application) described below with respect to FIGS. 6 and 7, and the application may provide various information on the display (e.g., screen) on the screen of the electronic device. For example, the electronic device may display the coordinates (e.g., markings on the needle guide device 805) and angle to be used for needle insertion on the patient. The information provided by the application can then be applied to the needle guide device 805 to aid in the placement and insertion of a needle onto the patient.

[0028] The program may also incorporate the use of machine learning or artificial intelligence (AI) in order to provide enhanced image recognition capabilities. The image recognition capability or feature may allow the program or application to automatically provide the points of interest, draw or impose the required lines on the image, and calculate measurements based on the images provided to the program. The image recognition feature may also provide the points of interest regardless of the orientation of the patient during the imaging. Thus, if the patient appears in an inconsistent position with regard to the axis of the image, the measurements may still be obtained due to the ability of the employed AI to recognize the anatomical points of interest. As mentioned above, the “drawing” of lines may be visible to the user of the program or merely performed inherently as part of the operation of the program or application that determines or calculates the required measurements and the preferred location for needle insertion.

[0029] FIGS. 3 and 4 show an example of a radiopaque landmark device 305 that may be used with the imaging of the patient. The imaging includes an X-ray of the lateral plane of the patient showing both the sacrum 15 and coccyx 25 of the patient. The imaging may also include one or both of the anterior-posterior (AP) or posterior-anterior (PA) planes of the same area (i.e., showing the sacrum and coccyx of the patient). The radiopaque landmark device 305 may be placed on the patient during the X-ray imaging in the field of view of the imaging device 700. The radiopaque land-

mark device **305** includes a radio-transparent housing **310** and a radiopaque element **315**. The radio-transparent housing **310** is composed of a material that is relatively transparent to an X-ray device (or whatever imaging technology is used). Plastic may be used for the radio-transparent housing **310**, for example. The radio-transparent housing **310** provides for easy placement handling of the radiopaque landmark device **305** onto the patient when images are being taken. The radiopaque element **315** is composed of a material that is relatively opaque to an X-ray (or whatever imaging technology is used). Stainless steel may be used for the radiopaque element **315**, for example. The radiopaque element **315** has a predefined dimension that is used with the X-ray image(s) to define a scale of the image(s) of the patient and provide a reference to properly determine the measurements required to locate the insertion point for a needle on a patient. In a particular embodiment, the radiopaque element **315** includes a sphere of a predefined diameter so that the radiopaque landmark device **305** may be placed in any orientation on the patient during the imaging. Many other known landmark devices may be utilized, such as radiopaque devices with different predetermined shapes and dimensions. Landmark devices may be fixed onto the patient or the radiographic table where X-ray image is taken.

[0030] FIG. 5 shows a flowchart of an exemplary method. Step **205** includes imaging a portion of the patient. The images of the patient may be obtained with the patient in various positions. The imaging system **700** may capture images of the patient's sacrum **15** and coccyx **25** in both the anterior-posterior (or posterior anterior) and the lateral planes. The processing software of the imaging system **700** may set the appropriate dimensions using a scale provided by a radiopaque landmark device or by the imaging system **700**. The processing software of the imaging system **700** may automatically manipulate the image further in order to clarify the image (e.g. modifying contrast or brightness of the image). The image may also be further clarified once transferred to the electronic device.

[0031] Step **210** includes identifying internal points of interest related to the patient in the imaging to determine key measurements used in the calculation. Step **215** includes calculating measurements that identify the recommended insertion location of the needle based on the imaging and the identified points. These measurements may be used to position elements of the needle guide device **805**. The software may also calculate the needle entry angle α and the minimum needle length. The minimum needle length is defined as the minimum needle length that is required to reach the target location (e.g., the S3 sacral foramen).

[0032] Step **220** includes transferring the measurements calculated in Step **215** to the needle guide device **805**. Step **225** includes placing the needle guide device **805** on and exterior to the patient using a locating feature. Step **230** includes guiding a medical element (e.g., a foramen needle) into the patient using an element guide of the device **805**. Embodiments implementing these steps will become apparent from the following figures and associated descriptions.

[0033] FIGS. 6 and 7 show shows an exemplary X-ray image **505** in which the radiopaque element **315** of the radiopaque landmark device **305** is visible. Because the radiopaque element **315** has a predefined diameter, this known measurement of the radiopaque element **315** may be used to define a scale for the X-ray image **505**. This scale may be used by the application when calculating measure-

ments as described herein. A scale indicator **510** (e.g., a scale line embedded and depicted on an x-ray image) may also be provided as an alternative to the landmark device **305**, when the imaging system **700** is capable of including an automatic scaling function that provides a scale of the image. The scale indicator **510** may adjust to correspond to the selected image magnification by a user. In both alternatives (e.g., using the radiopaque landmark device **305** or the automatic scaling function), the image is provided with a scale of the image that may be used when calculating the measurements necessary to identify the location for needle insertion required for proper lead placement. When an image scale **510** cannot be provided by the imaging system **700**, it is essential that the radiopaque landmark is used so that the image can still be properly measured.

[0034] FIGS. 6 and 7 also show exemplary implementations of identifying points in the image(s) and processing the image(s) for measurements that may be used at steps **210** and **215**, respectively. The measurements refer to the coordinates or location of the needle insertion point on the patient. As mentioned above, these measurements can be transferred to the needle guide device **805**. The image(s) from step **205** are uploaded to an electronic device (not shown) for processing. The electronic device may be, for example, a desktop computer, laptop computer, tablet computer, or a smartphone that runs a specialized software (e.g., a proprietary application). The application may be part of a software program product as described herein. Alternatively, all or part of the processing may be conducted in a cloud-based application.

[0035] The electronic device may include a display for displaying images (e.g., X-rays taken at step **205**) and a user input mechanism that permits the user to identify points in a displayed image. The display and user input mechanism may be combined in a touchscreen display, for example, that can display an image and receive user touch input defining points of interest in the image. The display and user input mechanism may be separate, for example, such as a display screen that displays an image and a mouse or trackball that controls a pointer (e.g., cursor, arrow, etc.) superimposed on the displayed image, and a button the user may depress to provide define a current location of the pointer on the image as a point of interest in the image.

[0036] The step of identifying points in the image in step **210** includes importing the one or more images from step **205** into the application running on the electronic device. The application establishes a scale of the image(s) using either the predefined dimension of the radiopaque element **315** in the image(s) or a scale indicator (e.g., such as scale indicator **510**) provided with the image(s). Step **210** may optionally include the application adjusting visual aspects of the image(s), such as contrast, etc. FIG. 6 shows an example of a simplified lateral X-ray image **505** that includes a scale indicator **510** that defines a scale of the image **505**.

[0037] With continued reference to FIG. 6, the application receives user input via the electronic device. The user uses the image to identify the points of interest in the image **505**. The user may interact with the image (e.g., via a touch screen, keyboard, stencil, etc.) to identify the points of interest. There are four points of interest **521**, **522**, **523**, and **524** that are defined by user input. The application may provide one or more messages to the user that prompt the user to provide their input for one or more of the points of interest. The user provides input to define the first point of

interest **521** at the tip (e.g., distal end) of the coccyx in the image **505**. In response to receiving this input, the application draws a vertical line **525** upward from the first point of interest **521**. While the line **525** is displayed, the user provides input to define the second point of interest **522** at the intersection of the line **525** and the outer surface of the skin of the patient. The user provides input to define the third point of interest **523** at the center of the targeted foramen, in this case the S3 sacral foramen, in the image **505**. In response to receiving this input, the application draws a line **526** perpendicular to the sacrum at third point of interest **523** and upward toward the outer surface of the skin of the patient. While the line **526** is displayed, the user provides input to adjust or confirm that the line **526** is perpendicular to the sacrum and provides input to define the fourth point of interest **524** at the intersection of the line **526** and the outer surface of the skin of the patient.

[0038] In the event that the images are not fully legible (i.e., S3 not fully visible) the application may suggest where to target the S3 foramen based on other points of interest. For example, as an alternative to asking for point of interest **523**, the program may ask locations of the lumbosacral joint (the junction of L5 vertebrae and S1) and the caudal tip of the coccyx **521**. The program may then estimate the location of **523** by calculating a point halfway between the lumbosacral joint and the caudal tip of the coccyx **521**. Other alternatives may include providing estimations of where the S3 foramen is located by providing known measurements of the average location of the S3 foramen of the human anatomy (e.g., S3 is approximately 11 cm from the tip of the coccyx).

[0039] The method described herein may include utilizing image processing software. For example, the application interacting with the electronic device may include image processing software to facilitate processing the image. The image processing software may provide the user with the ability to utilize the following functions with regard to the image: pan, zoom, windowing, scroll, crosshair, filtering (brightness and contrast adjustment), measurement of distance, angles and areas, image rotation/flip, etc. The aforementioned image processing capabilities may run in the background of the application and software without user input, or may be provided as options for the user to manipulate the image in order to assist with the identification of points of interest.

[0040] The image processing software may be specialized for handling the image files typically associated with fluoroscopy images (e.g., DICOM files). Digital Imaging and Communications in Medicine (DICOM) is the international standard for medical images and related information. DICOM defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use. The processing software may provide the ability to create a 3D reconstruction model of the patient and the patient's skeletal structure in order to assist in the location of the sacral foramen and preferred needle entry point. In addition, the image processing software may be configured to anonymize and de-identify any patient details retained in the image so that the image can be employed in machine learning and AI applications.

[0041] Processing the image for measurements at step **215** includes determining a length measurement, an angle measurement, and a depth measurement based on the points of interest defined by the user at step **210**. The application

determines the length measurement, the angle measurement, and the depth measurement based on: the coordinates (e.g., X-Y cartesian coordinates) of each of the points of interest in a coordinate system defined for the image; the scale of the image relative to the same coordinate system; and one or more predefined dimensions of a device that will be utilized as a needle guide using the determined length measurement and angle measurement. The one or more predefined dimensions of the device include a predefined radius of curvature of an elongated base of the device. The application uses this information (e.g., the coordinates, the scale, and the predefined dimensions of the device) as inputs to an algorithm or program that employs established geometric and trigonometric formulas and calculations to determine: (i) a length of an arc **530** that extends between the second point **522** and the fourth point **524** where the arc has the predefined radius of curvature; (ii) an angle **535** between the line **526** and a tangent of the arc **530** at the fourth point **524**; and (iii) a length of the line **526** between the third point **523** and the fourth point **524**. The determined length of the arc **530** between the second point **522** and the fourth point **524** includes the length measurement, the determined angle **535** includes the angle measurement, and the determined length of the line **526** between the third point **523** and the fourth point **524** includes the depth measurement. The application outputs the determined measurements to the user, e.g., via display. The angle **535** may be calculated as the angle between an extension of the line **526** and a tangent line "T" that is tangent to the arc **530** at point **524**.

[0042] FIG. 7 shows an example of a posterior-anterior (PA) X-ray image **605**. The application receives user input via the computing device when the user identifies points of interest in the image **605**. The user may interact with the image (e.g., via a touch screen, keyboard, stencil, etc.) to identify the supplemental points of interest **621**, **622** on the image. The first supplemental point of interest **621** is located at the center of the S3 foramen in the image **505**. In response to receiving this input from the user, the application draws a line **625** that intersects the point **621** and is perpendicular to the centerline of the sacrum. While the line **625** is displayed, the user identifies the second supplementary point of interest **622** at the intersection of the line **625** and the centerline of the sacrum. In this example, the application uses the coordinates of the points **621** and **622** to determine a lateral distance between the points **621** and **622**. The application outputs the determined measurement to the user, e.g., via a display. The user may edit any one or more of the points of interest (i.e., **521**, **522**, **523**, **524**, **621**, **622**) and the program may automatically recalculate the measurements outputted based on the updated point(s) automatically. The step of identifying the supplementary points of interest may be omitted, and the application can assume a standard distance in the range of about 20 to 25 mm, based on published research or studies.

[0043] FIGS. 8A and 8B show an exemplary needle guide device **805**. The device **805** includes an elongated base **810**, a sliding lateral member **815**, and medical element guides **820**. The device **805** includes a depending portion **825** that extends downward from a bottom surface of the elongated base **810**. The bottom surface of the elongated base **810** has a radius of curvature **830** that is one of the one or more predefined dimension of the device described with respect to FIG. 6 and used in the application to determine measurements. In another embodiment, the elongated base **810** may

not be entirely curved or arc shaped. Instead, the elongated base **810** may include a flat portion which better conforms to the topographical shape of the patient. In one embodiment, the optional flat portion is located at the end of the elongated base **810** positioned closer to the head of the patient. The sliding lateral member **815** may also slide along this flat portion.

[0044] The elongated base **810** may include a coccyx locating feature (e.g., the depending portion **825**) that is used to locate the device **805** on to the patient. The coccyx locating feature is pressed against the coccyx while the arced feature is located along the midline defined by the sagittal plane of the patient. The arced feature of the elongated base **810** is a predefined arc geometry that is used by the application for determining measurements at step **215**. The sliding lateral member **815** slides along the elongated base **810** and remains square to the elongated base **810**. The sliding lateral member **815** may be locked at a specific location along the elongated base **810**. The elongated base **810** has measurements included to set the sliding lateral member **815** at the location determined by the calculations and measurements from patient imaging. The sliding lateral member **815** includes lateral rails that allow for the use of the medical element guide **820**. The medical element guide **820** slides laterally along the sliding lateral member **815** and remains square to the sliding lateral member **815**. The lateral placement may be set based on imaging measurements or standard practices. The medical element guide **820** allows for needle placement at various degrees. The medical element guide **820** allows the user to fix the needle at a defined angle in use. The medical element guide **820** and the sliding lateral member **815** are also designed to allow removal of the device **805** while a needle remains with the patient. The marks on the needle are also used to measure the depth of the needle placement. This measurement is generated during image measurements and may be used to located depth of the foramen needle in the patient.

[0045] The sliding lateral member **815** may be moved translationally relative to the elongated base **810** in a first direction **841** (i.e., cephalad direction) and a second direction **842** (i.e., caudad direction) opposite the first direction along a length of the elongated base **810**. The sliding lateral member **815** includes a locking mechanism **845** that permits a user to selectively lock (e.g., prevent) and unlock (e.g., permit) the translational movement of the sliding lateral member **815** relative to the elongated base **810**. The locking mechanism may include a thumb screw or other conventional or later developed locking mechanism that may be used to selectively lock (e.g., prevent) and unlock (e.g., permit) the translational movement of one device sliding along another device. The elongated base **810** may include indicia **850** that correspond to units of the length measurement determined at step **215**. In the example shown in FIG. **8A**, the indicia **850** include a scale of millimeters from 0 to 180 along the length of the elongated base **810**.

[0046] With continued reference to FIG. **8A**, the step of transferring the measurements to the device **220** includes moving the sliding lateral member **815** to a position on the elongated base **810** such that an indicator **855** of the sliding lateral member coincides with a location in the scale of the indicia **850** that matches the length measurement determined at step **215**. In the example of FIG. **6**, the length measurement is determined to be 136.8 mm. Using this exemplary length measurement, at step **220** the user would move the

sliding lateral member **815** along the elongated base **810** until the indicator **855** coincides with a location corresponding to the number 136.8 on the scale of the indicia **850**. In situations where the number of the length measurement does not align exactly with one of the numbers of the indicia **850**, the user may interpolate a position for the indicator **855** between two numbers of the indicia **850** that best matches the length measurement. After positioning the sliding lateral member **815** on the elongated base **810** according to the length measurement, the user locks the sliding lateral member **815** relative to the elongated base **810** using the locking mechanism **845**.

[0047] In the example shown in FIG. **8A**, the device **805** includes medical element guides **820** that may be moved translationally relative to the sliding lateral member **815** in a first direction **861** and a second direction **862** opposite the first direction, where the direction of translation of the medical element guides **820** relative to the sliding lateral member **815** is perpendicular to the direction of translation of the sliding lateral member **815** relative to the elongated base **810**. The device **805** includes respective locking mechanisms that permit a user to selectively lock (e.g., prevent) and unlock (e.g., permit) the translational movement of each medical element guide **820** relative to the sliding lateral member **815**. The locking mechanism may include a thumb screw or other conventional or later developed locking mechanism that may be used to selectively lock (e.g., prevent) and unlock (e.g., permit) the translational movement of one device sliding along another device. Alternative to locking mechanisms, the sliding lateral member **815** and/or the medical element guides **820** may include detents that define predefined locations of the medical element guides **820** on the sliding lateral member **815**.

[0048] Each wing of the sliding lateral member **815** may include indicia **865** that correspond to units of the lateral distance determined at step **215** (e.g., as described at FIG. **7**). In the example shown in FIG. **8A**, the indicia **865** include a scale of millimeters from 10 to 40 along the transverse dimension of the sliding lateral member **815**.

[0049] With continued reference to FIG. **8A**, transferring the measurements to the device at step **220** may include moving the medical element guides **820** to positions on the wings of the sliding lateral member **815** such that a position indicator of each medical element guide **820** head coincides with a location in the scale of the indicia **865** that matches the lateral distance determined at step **215**. In the example of FIG. **6**, the lateral distance is determined to be 20 mm. Using this exemplary length measurement, at step **220** the user would move each medical element guide **820** along its wings of the sliding lateral member **815** until a position indicator on the medical element guide **820** coincides with a location corresponding to the number 20 in the scale of the indicia **865**. In situations where the number of the lateral distance does not align exactly with one of the numbers of the indicia **865**, the user may interpolate a position for the indicator between two numbers of the indicia **850** that best matches the lateral distance. After positioning the medical element guides **820** on the wings of the sliding lateral member **815** according to the lateral distance, the user may lock the medical element guides **820** relative to the sliding lateral member **815**.

[0050] With continued reference to FIGS. **8A** and **8B**, in embodiments each of the medical element guides **820** includes a graduated needle guide **870** including plural

needle guide slots **875** arranged at different predefined angles. The different predefined angles are within a range that is most likely to include the determined angle measurement of most patients. For example, the different predefined angles are within a range of 90 degrees to 140 degrees with a discrete one of the plural needle guide slots **875** arranged at increments of 10 degrees within this range. Each respective one of the plural needle guide slots **875** may be provided with indicia that indicates the angle of the respective one of the plural needle guide slots **875**. Step **220** may include selecting one of the plural needle guide slots **875** based on the angle measurement determined at step **215**. For example, for an angle measurement of 106.5 degrees, the user would select the one of the plural needle guide slots **875** that has an angle closest to 106.5 degrees. In an example in which the needle guide slots are arranged at a 10-degree increment between 90 degrees and 140 degrees, the user would select the 110 degrees angle guide slot for an angle measurement of 106.5 degrees.

[0051] Other mechanisms for guiding the needle at selected angles may be utilized as an alternative to the guide slots **875**. For example, FIG. **8G** shows an exemplary embodiment of the device **805'** in which each of the medical element guides **820'** includes a single needle slot and the medical element guide **820'** is rotatable around an axis that is parallel to the directions defined by **861** and **862** and perpendicular to the directions defined by **841** and **842** relative to the sliding lateral member **815** to plural different positions that correspond to different insertion angles of a needle into the patient. The plural different positions may correspond to different insertion angles in predefined increments of 10 degrees, for example. In this manner, the angle adjustment of the medical element guide **820'** may function in the manner of an adjustable protractor that is affixed to the sliding lateral member **815**. The rotation of the medical element guides **820'** relative to the sliding lateral member **815** may be selectively locked and unlocked using a locking mechanism. The elements of the device **805'** function in the same manner as those elements of the device **805** with the exception that the medical element guide **820'** having a single needle guide that is rotatable to different angles and the medical element guide **820** having plural needle guides at different angles. The angle of the needle may also be guided by alternative mechanisms such as element **1120** shown in FIG. **11A**. The increments of the needle guides described herein could be varied as suitable for the procedure being performed. For example, the guide angles could be positioned at angle increments ranging 5 to 20 degrees. In addition, the various guides disclosed herein may be sized to accommodate various size such as, for example, Gauge 20 and Gauge 19 needles.

[0052] In the manner described above, measurements determined at step **215** are transferred (e.g., by the user) to the device **805**. In one example, the scales of the different indicia on the device **805** correspond to the scales of the different measurements determined at step **215**. In another example, the measurements determined at step **215** are converted to values within the range of scales of the different indicia on the device **805** using predefined conversion formulas. In this manner, the application may output a set of numbers (e.g., the exact measurements or the converted values), and the user may adjust the device based on the numbers provided in this output.

[0053] FIGS. **8C**, **8D**, **8E**, and **8F** show views of the device **805** with a foramen needle **880** in one of the guide slots **875** of one of the medical element guides **820**. As shown in FIGS. **8C-F**, the guide slots are open on an outer end so that the medical element guide **820** may be moved away from the foramen needle **880** when the foramen needle **880** is inserted into the patient body. This permits adjusting the placement of the medical element (needle) angle or removal of the device **805** from the patient after a foramen needle **880** have been inserted using each of the medical element guides **820**.

[0054] FIG. **9** shows an example of placing the device **805** on the patient using a locating feature. Step **225**, described above, may include locating the device of the patient using a location feature. After transferring the measurements to the device **805** at step **220** (e.g., as described with respect to FIGS. **8A** and **8B**), the user places the device **805** on the patient, i.e., the same patient that was imaged at step **205**. Placing the device **805** at step **220** includes positioning the device **805** on the outer surface of the skin of the patient who is in a prone position with the depending portion **825** of the device positioned adjacent to the coccyx of the patient and the elongated base **810** of the device **805** aligned with the spine of the patient.

[0055] FIG. **10** shows an example of guiding a medical element into the patient using the device **805**. FIG. **10** shows the device **805** placed on the patient as described with respect to step **225** and FIG. **9**, e.g., with the device **805** on the outer surface of the skin of the patient who is in a prone position, with the depending portion **825** of the device positioned adjacent to the coccyx **25** of the patient, and the elongated base **810** of the device **805** aligned with the spine of the patient. After transferring the measurements to the device **805** at step **220** and then placing the device **805** on the patient at step **825**, step **230** includes using the device **805** placed on the patient as a guide for inserting a needle (e.g., a foramen needle **880**) into the patient. The user starts the foramen needle **880** in the selected one of the needle guide slots **875** (e.g., selected based on the angle measurement) and inserts the foramen needle **880** through this selected guide slot and into the patient. The location and angle of the needle insertion into the patient are defined by the device **805**, which has been adjusted based on measurements determined from the location of the S3 foramen and other landmarks in this patient's imaging. Due to this, the location and angle of the needle insertion using the inventive method and device has a much higher rate of success of accurately locating the S3 foramen **33** in the patient compared to conventional blind techniques.

[0056] The foramen needle **880** may be provided with indicia that indicate a depth of insertion of the needle into the patient. The user may insert the foramen needle into the patient using the depth of insertion indicia to determine when the tip of the foramen needle **880** is close to the nerve in the S3 foramen.

[0057] After inserting a respective foramen needle on either side of the patient in the manner described, the medical element guides **820** may be moved inward along the sliding lateral member **815** away from the respective foramen needle, such that the device **805** may be removed from the patient. After inserting the foramen needle in the patient in this manner, the PNE procedure may proceed in a conventional fashion. For example, portions of the foramen needle may be removed and remaining portions of the

foramen needle still in the patient may be used to insert implantable device leads into the patient.

[0058] FIGS. 11A-F show aspects of another example of a needle guide device **1105**. The device **1105** includes an elongated base **1110**, sliding lateral member **1115**, and one or two medical element guides **1120**, all of which operate in a similar manner as those similarly named elements described with respect to FIGS. 8A-F. The device **1105** includes a locating element **1125** that is connectable to the elongated base **1110**. The locating element **1125** includes a disc or other shaped structure that is affixed to the patient during the imaging (e.g., step **205**). The locating element **1125** may be affixed to the patient using adhesive or other methods. The locating element is affixed to the patient prior to imaging (e.g., at step **205**) and remains fixed to the patient throughout needle insertion (e.g., at step **230**). FIG. **12** shows an example of the locating element **1125** affixed to the patient. FIG. **11G** shows an example of the medical element guide **1120**.

[0059] The locating element **1125** includes a radiopaque portion that is visible in the imaging. The identifying points of interest (e.g., step **210**) and processing the image for measurements (e.g., step **215**) are performed based on the radiopaque portion of the locating element **1125** for the first point of interest and landmark rather than the tip of the coccyx as described at FIG. **6**. In embodiments that utilize the device **1105**, the application is programmed with geometric relationships that are based on the landmark coordinates of the locating element **1125** on the patient in the image, the coordinates of the S3 foramen in the image, and the predefined dimensions of the elongated base **1110**. Using this information, the application uses the geometric relationships to determine a length measurement, an angle measurement, and a depth measurement, e.g., in a manner similar to that described above but with different use defined points of interest and with different geometric relationships.

[0060] After determining the length measurement, an angle measurement, and a depth measurement for the device **1105**, the user transfers these measurements to the device **1105** (e.g., at step **220**). This may be performed in a manner similar to the description of step **220** with device **805**. For example, the application may output numbers that corresponds to measurements along the degrees of freedom of the device **1105**, and the user may adjust the positions of the elements of the device **1105** based on these numbers. For example, the application may output a first number that is based on the determined length measurement, and the user may adjust the position of the sliding lateral member **1115** along the elongated base **1110** based on this number and based on indicia on the elongated base **1110**.

[0061] After adjusting the device **1105** based on the determined measurements, the user places the device on the patient using the locating feature. In this embodiment, the locating feature includes the locating element **1125**. The elongated base **1110** is configured to connect to the locating element **1125**, e.g., via snap fit or other connection mechanism. A portion of the elongated base **1110** that connects to the locating element **1125** may include a locating feature of the device and the locating element **1125** includes a landmark on the patient. Step **225** may include placing the device **1105** on the patient's back while the patient is in a prone position, connecting the elongated base **1110** to the locating element **1125** that is already affixed to the patient's back, and aligning the elongated base with the spine of the patient.

FIG. **13** shows an example of the locating element **1125** affixed to the patient and the device **1105** placed on the patient's back and connected to the locating element **1125**.

[0062] After placing the device **1105** on the patient, the user utilizes the device **1105** as a guide for inserting a needle into the patient. Step **230** includes the user using the device **1105** as a guide for inserting a foramen needle **880** into the patient. As shown in FIG. **11G**, the medical element guide **1120** may include an element that defines an aperture and plural angles that the user can select based on the determined angle measurement. The user puts the tip of the needle at the aperture at a base of the medical element guide **1120** and aligns the foramen needle **880** with a selected one of plural angles on the medical element guide **1120** based on the determined angle measurement. The needle arranged in this manner is then inserted into the patient. FIG. **14** shows an example of needle insertion using the device **1105** as a guide. The location and angle of the needle insertion into the patient are defined by the device **1105**, which has been adjusted based on measurements determined from the location of the S3 foramen and other landmarks in this patient's imaging. Due to this, the location and angle of the needle insertion using the inventive method and device has a much higher rate of success of accurately locating the S3 foramen in the patient compared to conventional blind techniques.

[0063] The devices described herein (e.g., devices **805/805'/1105**) are not limited to use with a foramen needle (such as foramen needle **880**) and may be used to guide the insertion of other types of medical elements into the patient. For example, the devices may be used to guide insertion of medical elements including but not limited to foramen needles, other types of needles, leads, instruments, scopes, etc.

[0064] FIG. **15** shows a flowchart of an exemplary method for locating and placement of a medical element. Step **1505** includes determining one or more measurements from at least one image of a sacrum of a patient. In a non-limiting example, the measurements are determined in the manner described at FIGS. **6** and/or **7**. Step **1510** includes applying the determined one or more measurements with a guide device. In a non-limiting example, the applying step includes making one or more adjustments to the device **805/805'/1105** based on the determined one or more measurements in the manner described herein. Step **1515** includes locating the guide device on the patient's backside using a landmark. In non-limiting examples, the locating may be performed in the manner described at FIGS. **9-10** or FIGS. **12-14**. In a non-limiting example, the landmark includes the patient's coccyx. In a non-limiting example, the landmark includes a locating element affixed to the patient. Step **1520** includes, while the guide device is located on the patient's backside, using the guide device to guide insertion of a needle into the patient. In non-limiting examples, the guiding insertion may be performed in the manner described at FIG. **10** or FIG. **14**.

[0065] As will be understood from the present disclosure an exemplary method is disclosed that includes the steps of: determining one or more measurements from at least one image of a sacrum of a patient; applying the determined one or more measurements with a guide device; locating the guide device on the patient's backside using a landmark; and while the guide device is located on the patient's backside, using the guide device to guide insertion of a medical element into the patient.

[0066] In embodiments of the method, the guide device may be adjustable and applying the determined one or more measurements with the guide device may include adjusting the guide device based on the one or more measurements.

[0067] In embodiments of the method, the landmark includes the patient's coccyx.

[0068] In embodiments of the method, the landmark includes a locating element affixed to the patient.

[0069] In embodiments of the method, the at least one image includes an image of a pelvis of the patient in a lateral plane. In embodiments of the method, the at least one image includes an image of the pelvis of the patient in a posterior-anterior plane or an anterior posterior plane. In embodiments of the method, the at least one image includes an X-ray or a CT scan.

[0070] In embodiments of the method, the one or more measurements are determined based on user input defining points of interest in the at least one image. In embodiments of the method, the points of interest in the image include a location of a foramen in the sacrum. In embodiments of the method, the one or more measurements are determined based on a predefined dimension of the guide device.

[0071] In embodiments of the method, the guide device on the patient's backside defines a location and an angle of entry of the medical element into the patient's body.

[0072] In embodiments of the method, the medical element includes a needle.

[0073] In another disclosed embodiment, a device for guiding medical element insertion may include: an elongated base with a locating feature that references a landmark on a patient; a head that is translatable along the elongated base in a first direction; and a medical element guide that is translatable along the head in a second direction perpendicular to the first direction, wherein the medical element guide is configured to identify the entry location and angle of insertion of a medical element into the patient.

[0074] In embodiments of the device, the elongated base is arced with a radius of curvature.

[0075] In embodiments of the device, the locating feature depends downward from the elongated base; the landmark includes the patient's coccyx; and the locating feature is configured to be located against the patient's coccyx when the device is placed on the patient's backside.

[0076] In embodiments of the device, the landmark includes a locating element affixed to the patient; and the locating feature includes a portion of the device that connects to the locating element. In embodiments of the device, the locating element includes a radiopaque marker.

[0077] In embodiments of the device, the medical element includes a needle.

[0078] In embodiments of the device, the entry location and angle of the medical element into the patient are configured to cause the medical element to pass through a selected foramen in the patient's sacrum.

[0079] In embodiments of the device, the medical element guide defines plural different angles for the angle of insertion of the medical element into the patient. In embodiments of the device, the plural different angles include plural different predefined angles that are defined by plural grooves in the medical element guide. In embodiments of the device, the plural different angles are defined by plural rotational locations of the medical element guide relative to the head.

[0080] As will be understood from the present disclosure a computer program product may be provided that includes

one or more computer readable storage media having program instructions collectively stored on the one or more computer readable storage media, where the program instructions are executable to: receive at least one image of a sacrum of a patient; display the image; receive user input defining points of interest in the displayed image; determine one or more measurements for a medical element guide based on the points of interest and a predefined dimension of the medical element guide; and output the determined one or more measurements to a user.

[0081] In embodiments of the computer program product the points of interest include: a first point at a tip of the patient's coccyx or other landmark; and a second point at a foramen in the patient's sacrum. In embodiments of the computer program product the points of interest further include: a third point at an intersection of a surface of the patient's skin and a first line extending from the first point; and a fourth point at an intersection of the surface of the patient's skin and a second line extending from the second point.

[0082] In embodiments of the computer program product the medical guide element is configured to define a location and angle of insertion of a medical element into the patient while the medical guide element is located on the patient's backside.

[0083] Additional embodiments may include manufacturing and/or using the device **805** or **1105** as described herein. Also, instructions for using the device **805** or **1105** as described herein may be provided. The instructions may be provided in print and/or in video.

[0084] A training platform may be provided for the disclosed method and device. The training platform is a software platform for doctors, sales reps, or any other person that needs to learn or practice the invented technique/method. The software platform allows users to upload mock patients and go through the measurement process, e.g., at steps **210** and **215**. The software may be configured to grade the user on the accuracy of their user inputs and offer suggestions and tip on how to improve user input. The platform may be used to train and certify users virtually. The platform administrator can deploy training modules and updates to train and update users on the best practices. The platform administrator can also collect data on user experience and interaction. The platform can provide educational animations for various processes and procedures. Future data collection may be employed in this platform of later processing and optimization.

[0085] A training model may also be provided. The training model is a physical model used to train doctors, sales reps, physician assistances, nurses, etc., using the methods and devices **805** and/or **1105**. The training model allows users to practice placement of the sacral lead alone or in use with the virtual training platform. The training model includes the sacral bone structure as well as surrounding bone and tissue structure important to this procedure. The training model includes a soft tissue simulating structure where the opacity may be adjusted to control internal visualization allowing users to block or see within the model. The training model includes targets that may be contacted or "hit" to confirm proper placement of the leads. When a target is hit a signal may be produced to confirm the proper placement. Additionally, the model anatomy may be adjusted to different levels to practice on different anatomies. This may be achieved by changing bone placement to

change the dimensions needed to place the stimulator. This may also be achieved with different physical models altogether to represent different case complexities and scenarios.

[0086] Additionally, an AI platform may be provided. The AI platform may be configured to collect X-ray, measurement, and lead placement data that is obtained from monitoring the software platform, the success rate of patients, etc., and to use this data to optimize the lead/needle placements. The data may be used to facilitate machine learning to automatically identify points of interest for needle placement and the resulting measurements used for employing a guide tool on a patient. This data may be used to predict and optimize placement of leads resulting in more efficient conversions from an external pulse generator (EPG) to an implantable pulse generator (IPG).

[0087] An application (e.g., software) as described herein may include computing code stored on a computer readable storage medium and executed by processing circuitry of a computing device (e.g., computing device **700**) to perform the functions described herein. The computing code may include routines, programs, objects, components, logic, data structures, and so on that perform particular tasks or implement particular data types that the code uses to carry out the functions of embodiments described herein. The application may be stored on a portable device (e.g., a USB drive). In addition, the application may include processing capability for handling the image files (e.g., DICOM files). Alternatively, the application may be configured to operate cooperatively from image processing software.

[0088] It is noted that the foregoing examples have been provided merely for the purpose of explanation and are in no way to be construed as limiting of implementations of the present invention. While aspects of the present invention have been described with reference to an exemplary embodiment, it is understood that the words which have been used herein are words of description and illustration, rather than words of limitation. Changes may be made, within the purview of the appended claims, as presently stated and as amended, without departing from the scope and spirit of the present disclosure in its aspects. Although implementations of the present invention have been described herein with reference to particular means, materials and embodiments, implementations disclosed herein are not intended to be limited to the particulars disclosed herein; rather, implementations of the present invention extend to all functionally equivalent structures, methods and uses, such as are within the scope of the appended claims.

What is claimed is:

1. An apparatus for guiding insertion of a needle into a patient receiving sacral nerve stimulation therapy, the apparatus comprising:

- an elongated base having a first set of indicia, configured to extend longitudinally along the back of the patient and, wherein the base is configured to lay adjacent to and be pressed against the coccyx of the patient;
- a lateral member slidably attached to the elongate base, wherein the lateral member includes a second set of indicia; and
- an element guide mounted to the lateral member configured to aid the insertion of the needle into the patient at a predetermined angle at the target location.

2. The apparatus of claim **1**, further including an adjustable needle guide attached to the element guide.

3. The apparatus of claim **1**, wherein the first set of indicia corresponds to a distance cephalad along the elongate base from an end of the coccyx.

4. The apparatus of claim **3**, wherein the second set of indicia corresponds to a distance laterally away from the patient's spine.

5. The apparatus of claim **1**, further comprising a radiopaque locating element configured to be selectively attached to the elongated base.

6. The apparatus of claim **5**, wherein the first set of indicia corresponds to a distance relative to the locating element.

7. An apparatus for guiding insertion of a needle for sacral nerve stimulation therapy into a patient, the apparatus comprising:

- an elongate base, having a first set of indicia configured to extend longitudinally along the back of the patient and, wherein the base is configured to lay adjacent to and be pressed against the coccyx of the patient;

- a lateral member, having a second set of indicia; wherein the lateral member is slidably attached to the elongate base;

- a guide body slidably attached to the lateral member, wherein the guide body is configured to move in a direction perpendicular to the elongate base; and

- wherein the guide body includes an angled guide configured to guide the needle to a target location on the patient at a predetermined angle.

8. The apparatus of claim **7**, the guide body includes a plurality of grooves configured to guide the needle.

9. The apparatus of claim **8**, wherein the plurality of grooves is disposed in a fanned pattern.

10. The apparatus of claim **7**, wherein the guide body further includes an aperture located on the base of the guide body and a third set of indicia disposed along a length of a slot on a top surface of the guide body.

11. The apparatus of claim **7**, further comprising a radiopaque locating element configured to be selectively attached to the elongated base.

12. The apparatus of claim **11**, wherein the first set of measurement markings corresponds to a distance relative to the locating element.

13. The apparatus of claim **7**, wherein the first set of indicia correspond to a distance cephalad along the elongate base relative to a vertical reference line extending from an end of the coccyx to the elongate base.

14. The apparatus of claim **13**, wherein the predetermined angle is measured relative to a line tangent to an arc length of the apparatus.

15. A method for marking a location on a patient for inserting a needle for placement of a lead for nerve stimulation therapy, the method includes the steps of:

- obtaining a scaled image of a patient;
- selecting the tip of a patient's coccyx shown in the image;
- imposing a first line on the image, wherein the first line extends from the tip of the coccyx to a surface of the patient's skin;
- imposing a second line on the image, wherein the second line extends from the target location perpendicular of the patient's sacrum to the surface of the patient's skin;
- calculating measurements corresponding to the location on the patient;
- retrieving the measurements; and
- marking the patient based on the measurements using a measuring device.

16. The method of claim **15**, wherein the method is employed to identify the insertion location for a needle used for lead placement adjacent the S3 foramen of the patient.

17. The method of claim **15**, wherein measurements include a calculated distance on the measuring device cephalad from the first line.

18. The method of claim **17**, further comprising inserting the needle into the patient at the location to a patient's foramen.

19. The method of claim **15**, wherein measurements include a needle entry angle, wherein the calculation of the needle entry angle is derived from the second line and a line tangent to the arc length of the apparatus.

20. The method of claim **15**, wherein the measuring device includes an elongate base, having a first set of indicia, configured to extend longitudinally across the patient's back and lay adjacent to the patient's coccyx and a lateral member, having a second set of indicia, slidably attached to the elongate base.

21. The method of claim **15**, wherein at least one of the steps of imposing the first line and imposing the second line is accomplished using AI based on image recognition.

22. The method of claim **21**, wherein the imposing steps are accomplished without regard to the orientation of the patient on the image.

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