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(54) GUIDANCE AND INSERTION SYSTEM

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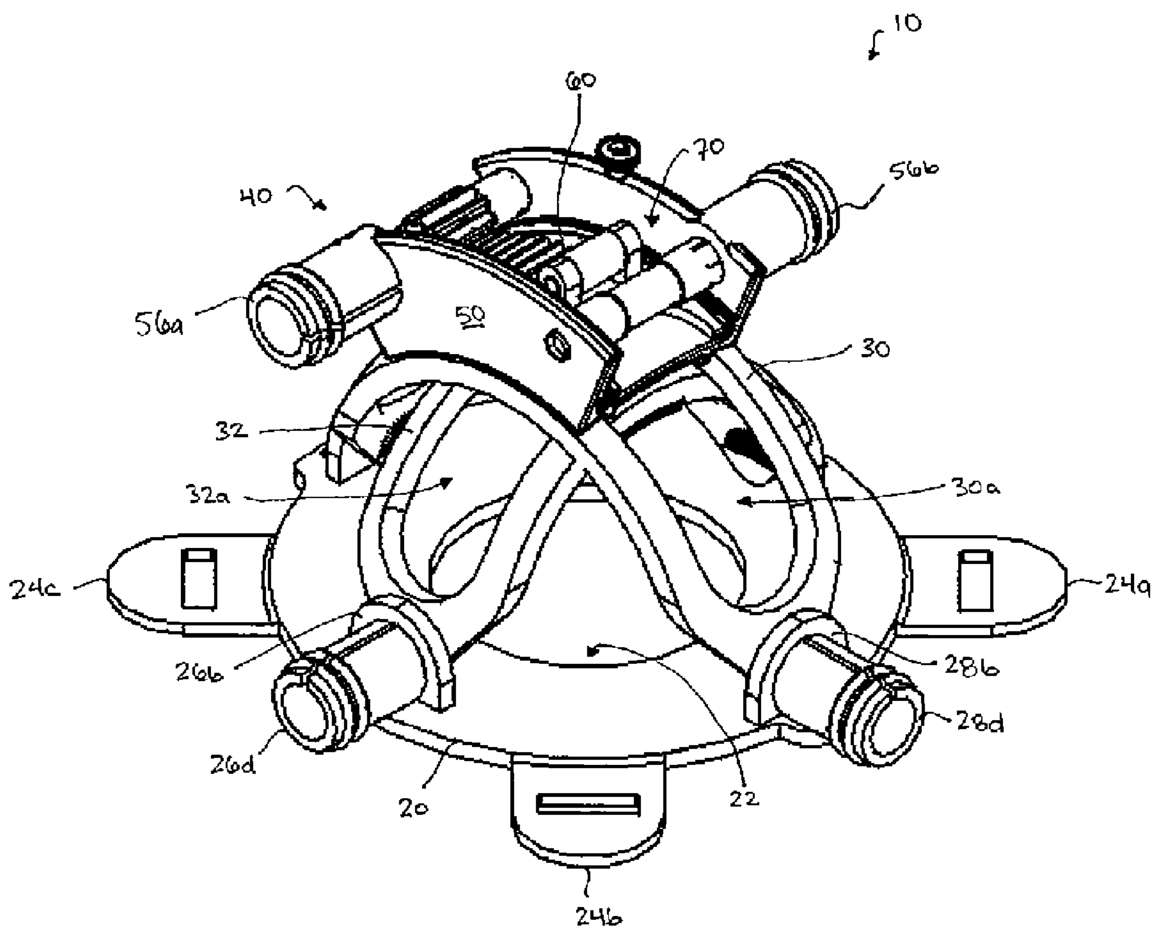
(57) **ABSTRACT**

Methods and devices are provided for guiding and inserting a tool into an object, such as tissue. In an exemplary embodiment, a guidance and insertion device is provided that can be remotely controlled to adjust an insertion trajectory of a tool, and to advance the tool into tissue to a desired penetration depth. The tool can be, for example, a biopsy device, a brachytherapy device, or a lumpectomy device. The device can be configured for use with an imaging apparatus, such as computed tomography (CT) images, to allow the device and tool to be operated while viewing the device positioned in relation to a target surgical site. The device can also be configured to be positioned directly on a patient, so as to passively compensate for respiratory chest motion, and it can include features to passively compensate for needle oscillation. In other exemplary embodiments, the device can be entirely disposable.



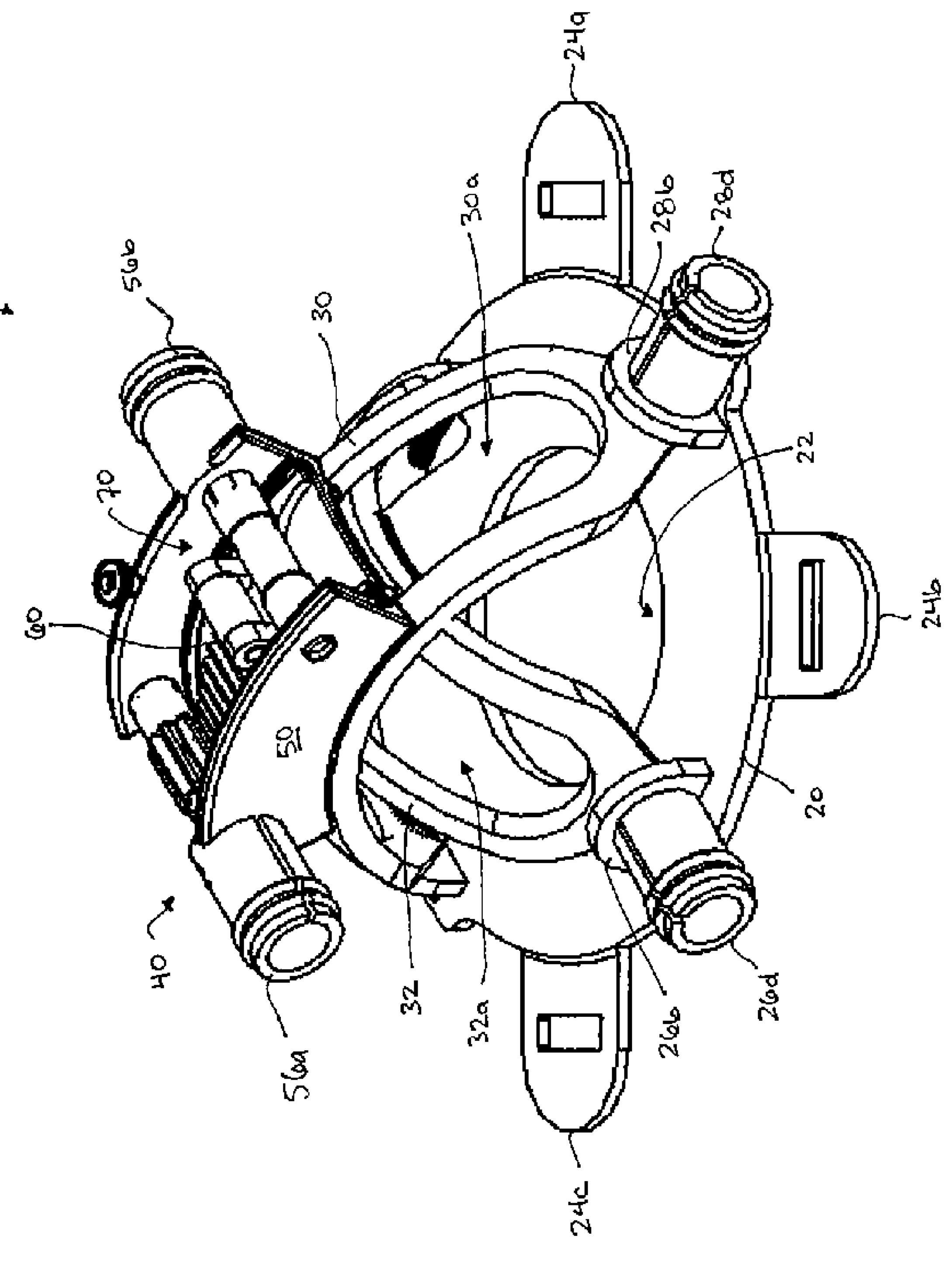

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FIG. 1A

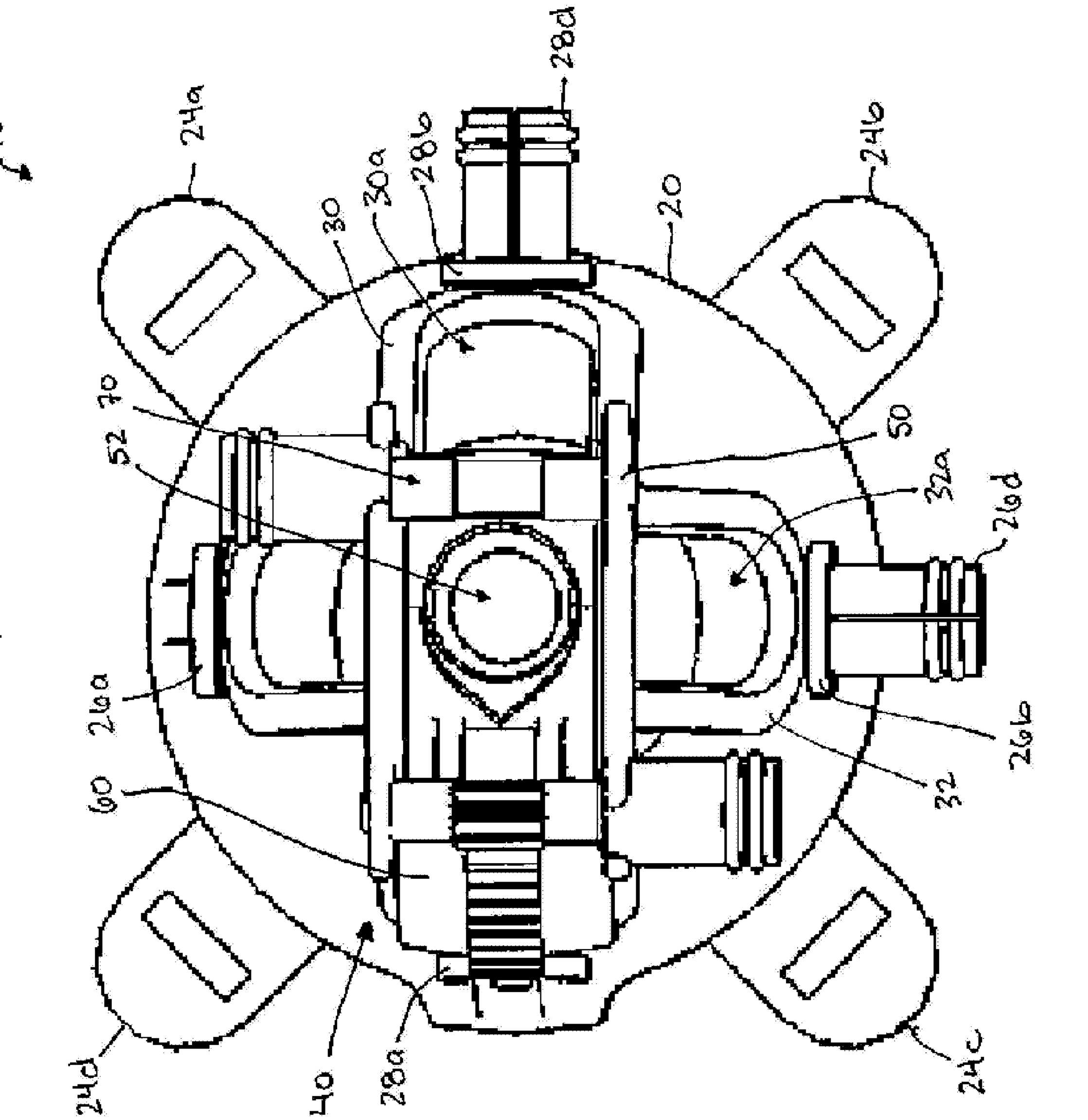
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FIG. 1B

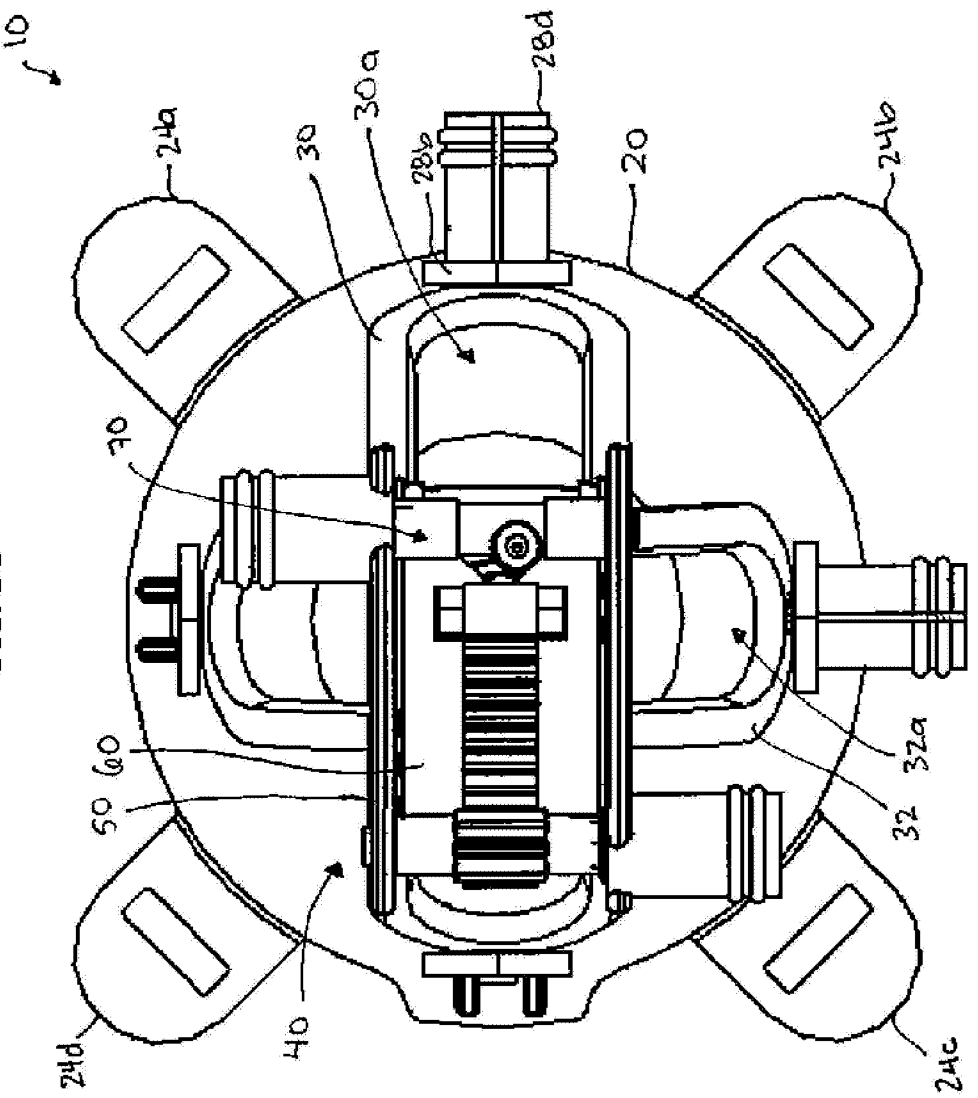

FIG. 1C

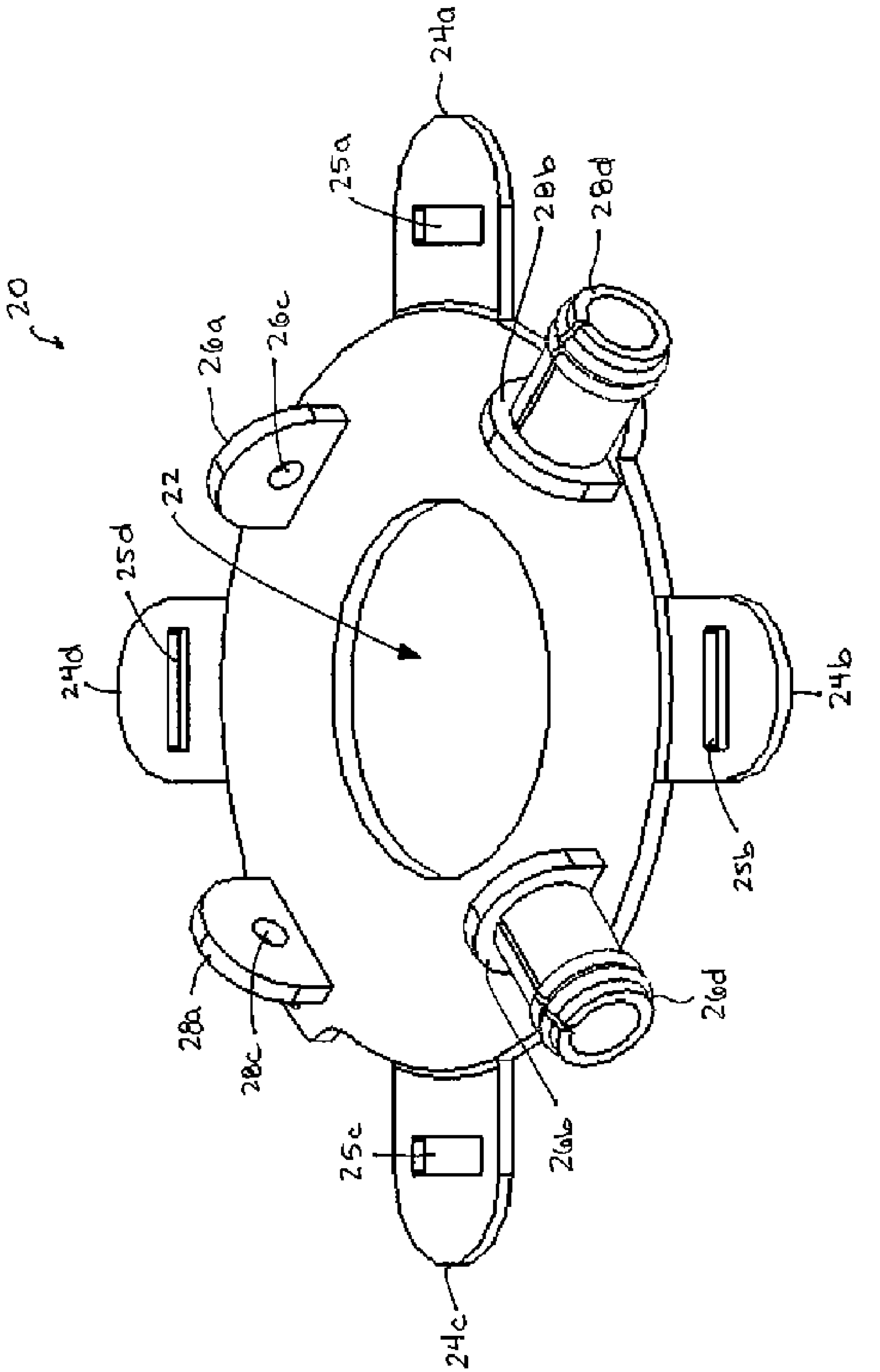
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FIG. 2

FIG. 3

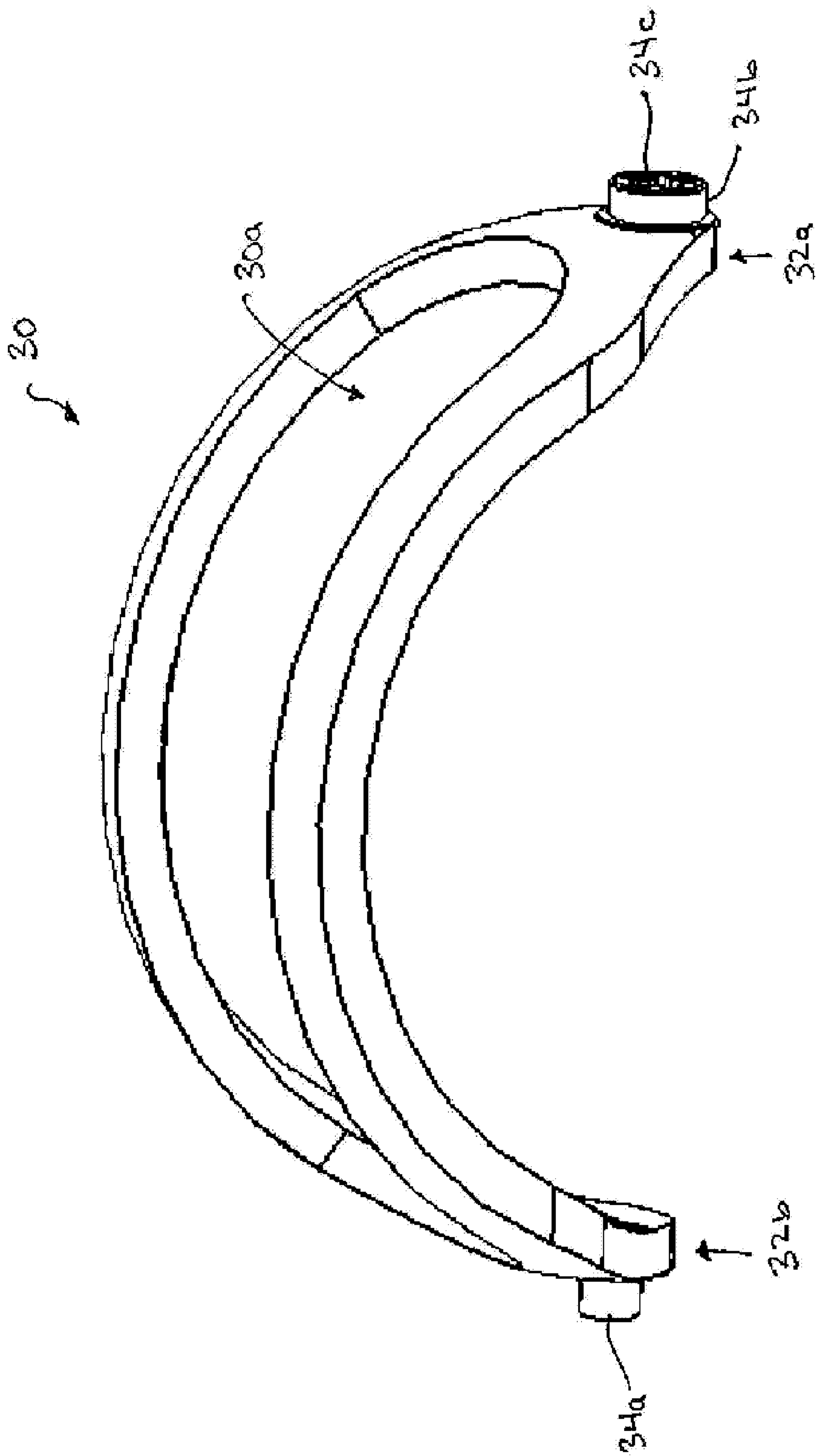


FIG. 4A

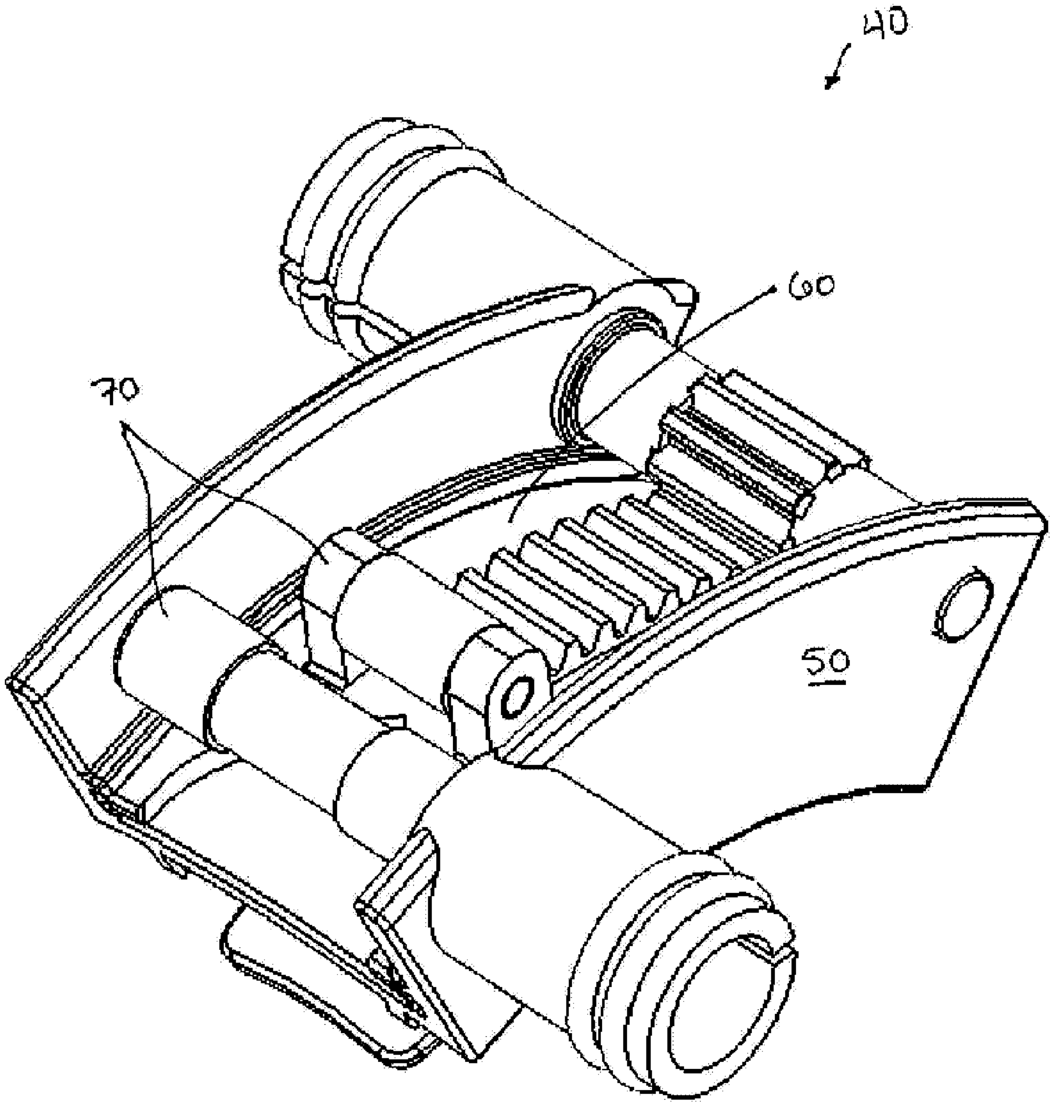
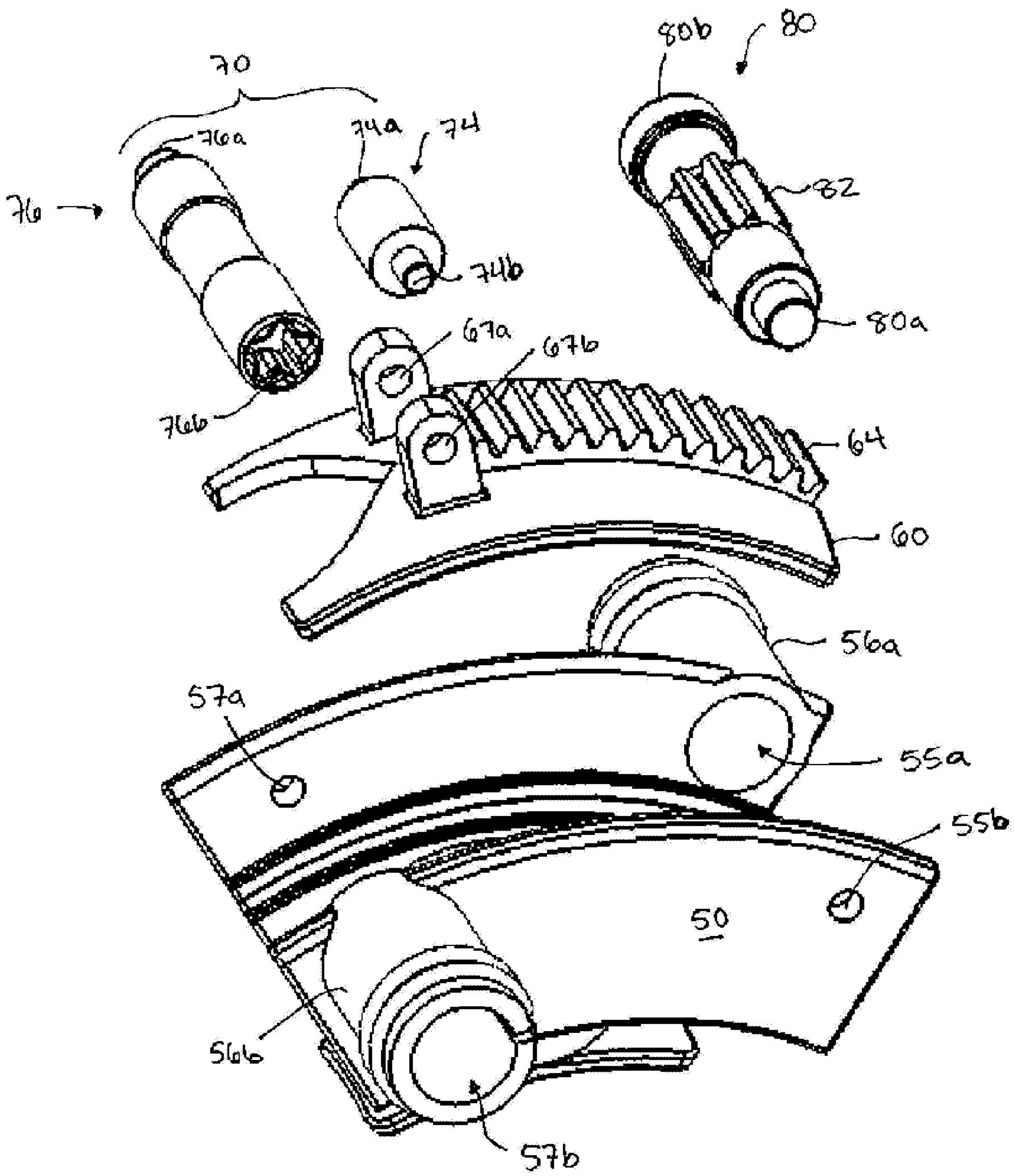


FIG. 4B



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74b
80b
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56b
57b

FIG. 5A

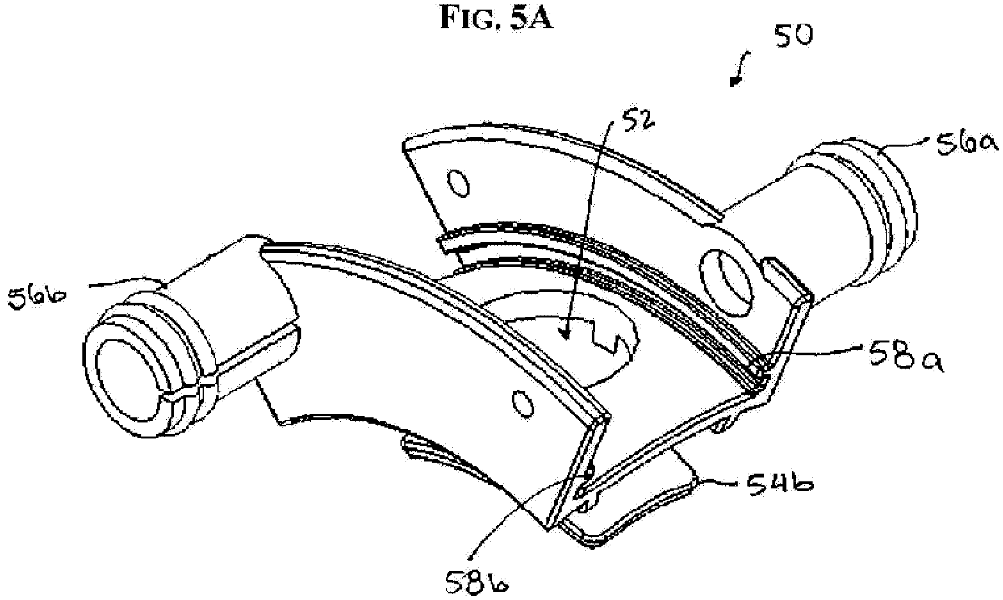
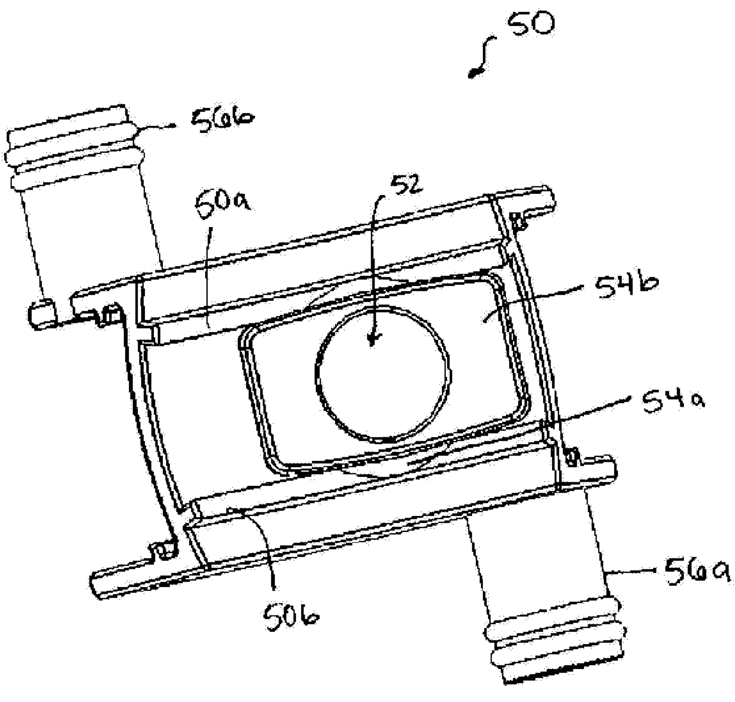


FIG. 5B



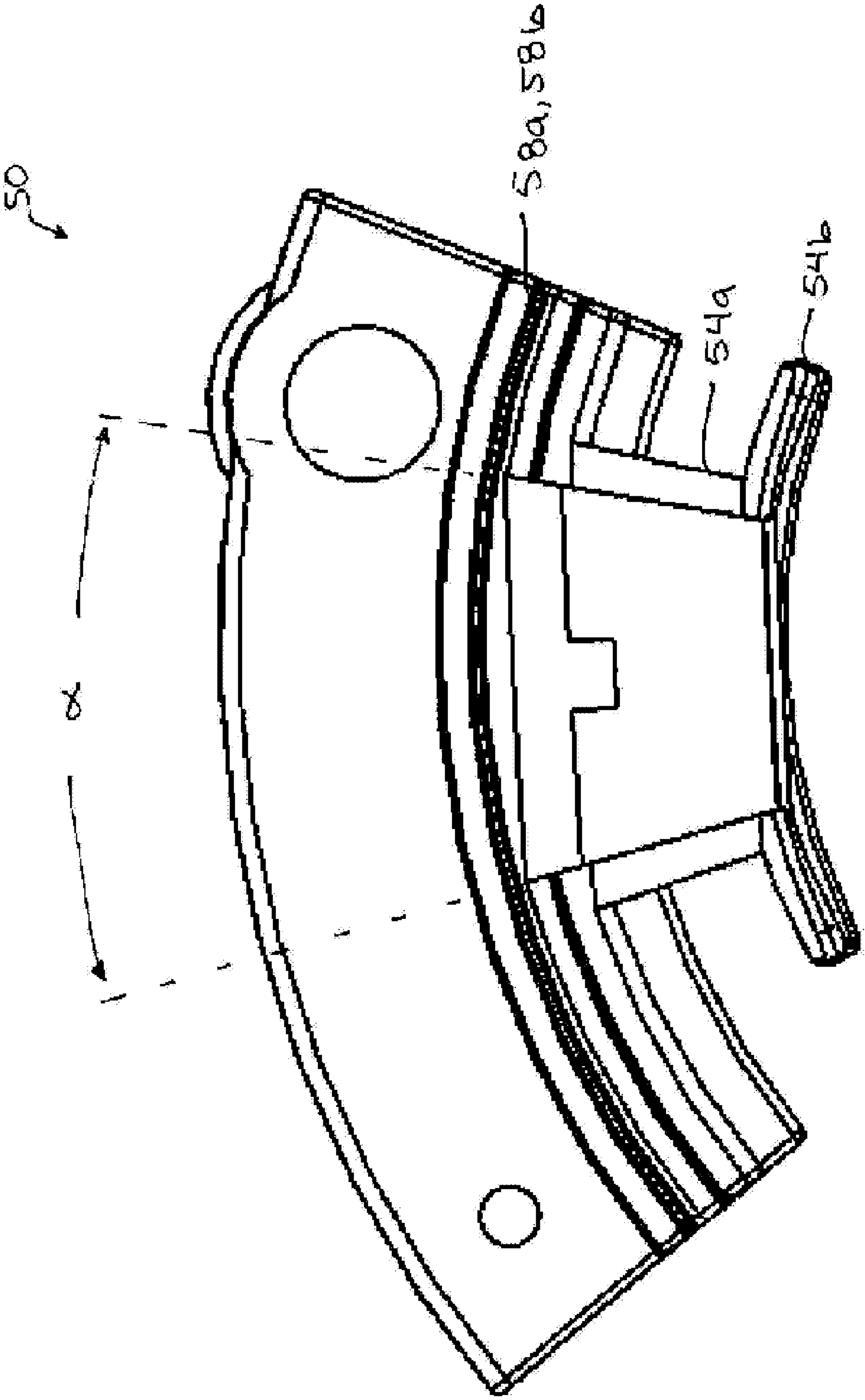


FIG. 5C

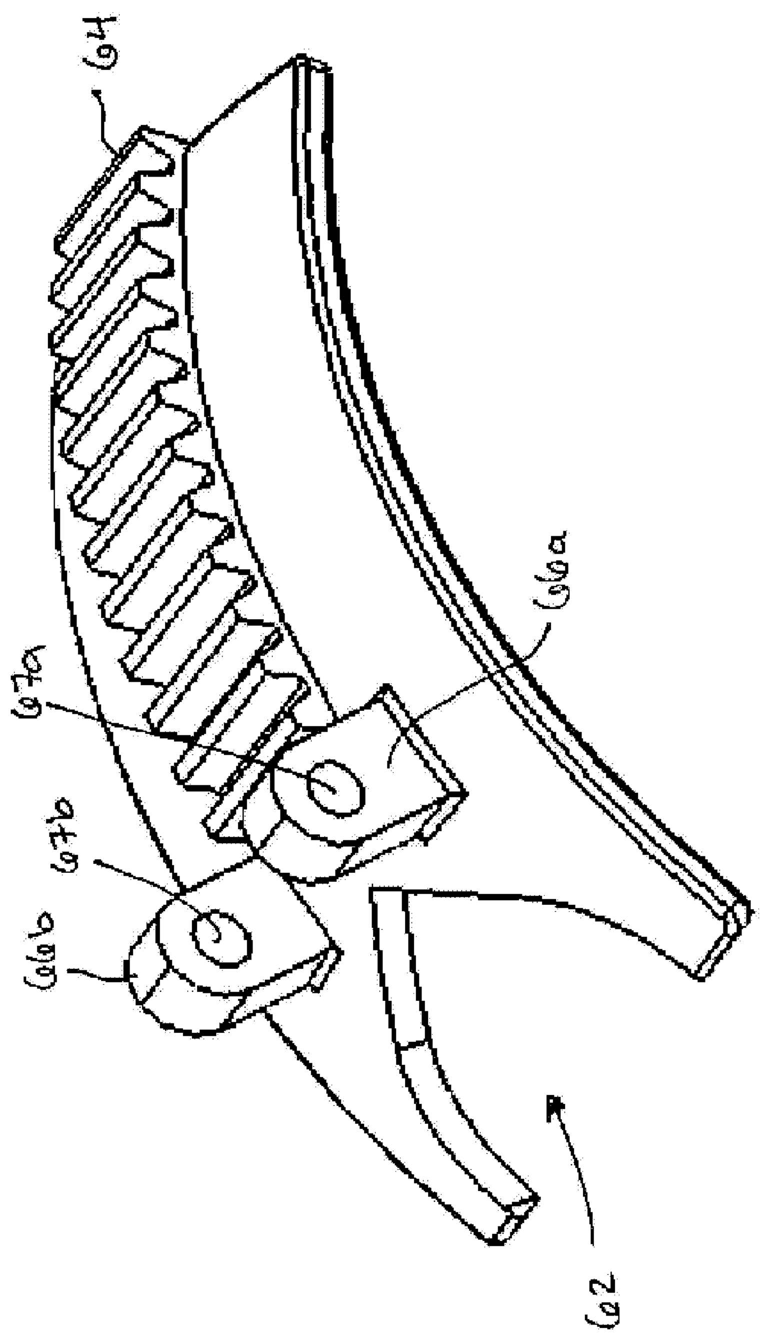


FIG. 6

FIG. 7

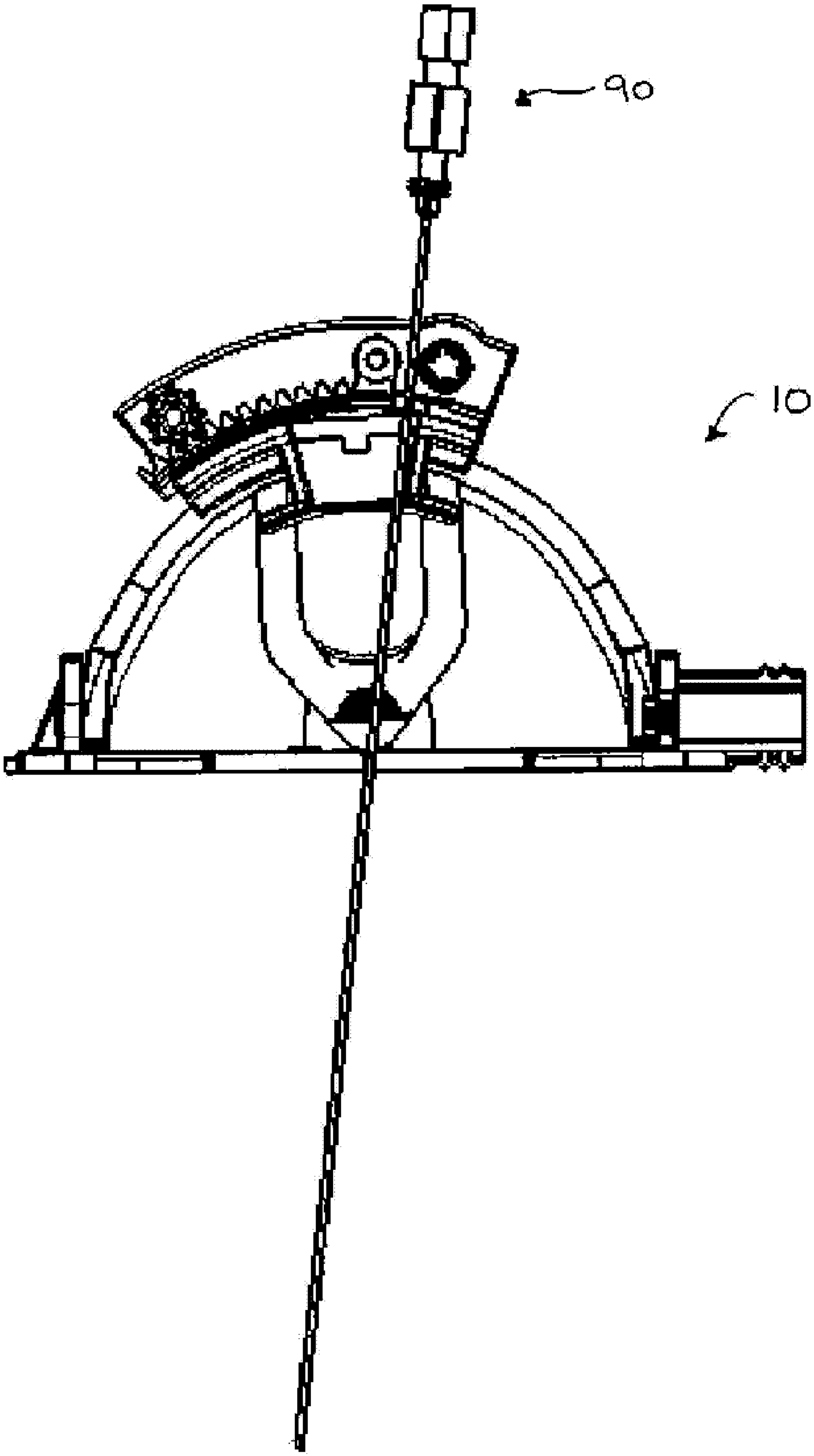


FIG. 8A

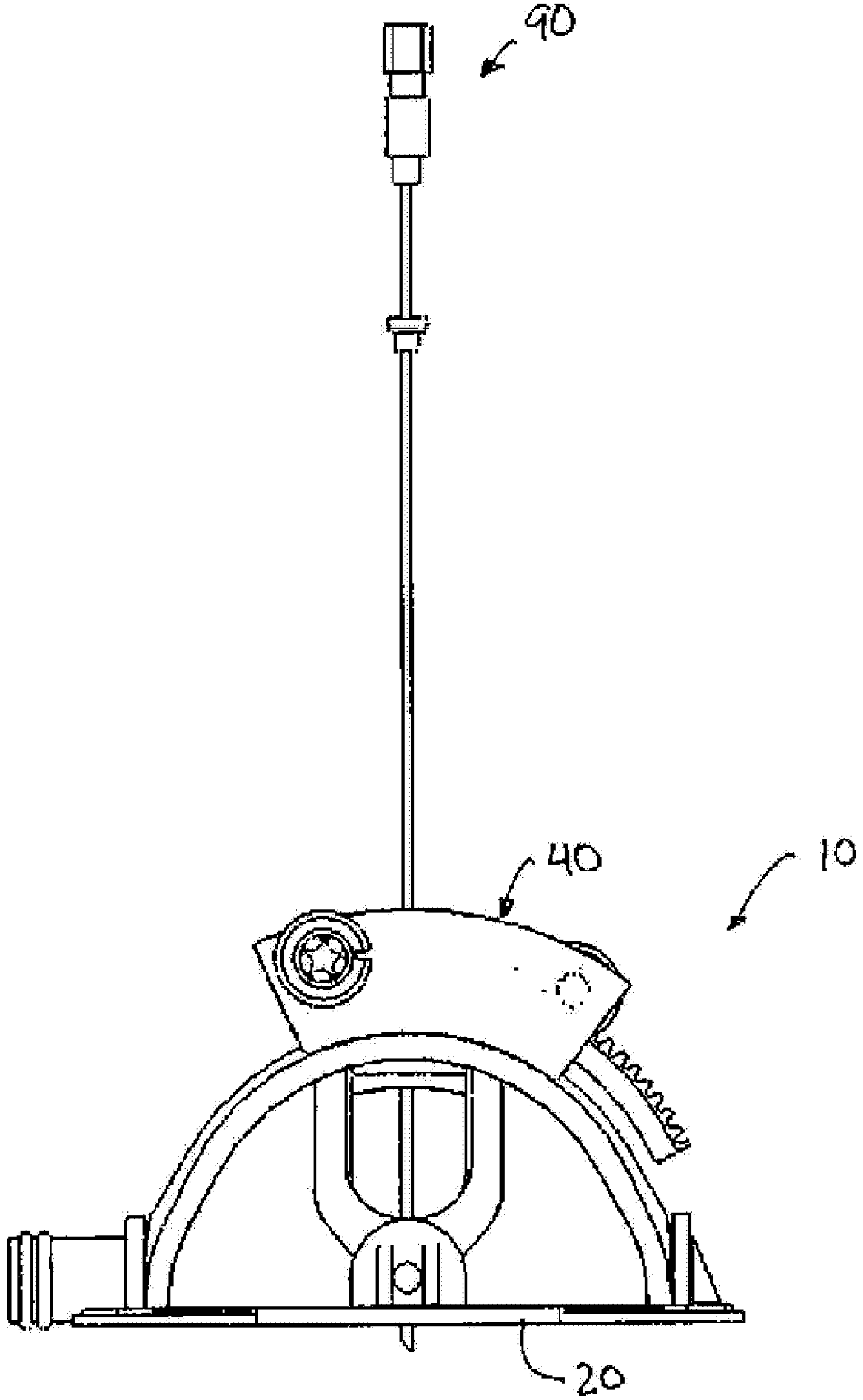


FIG. 8B

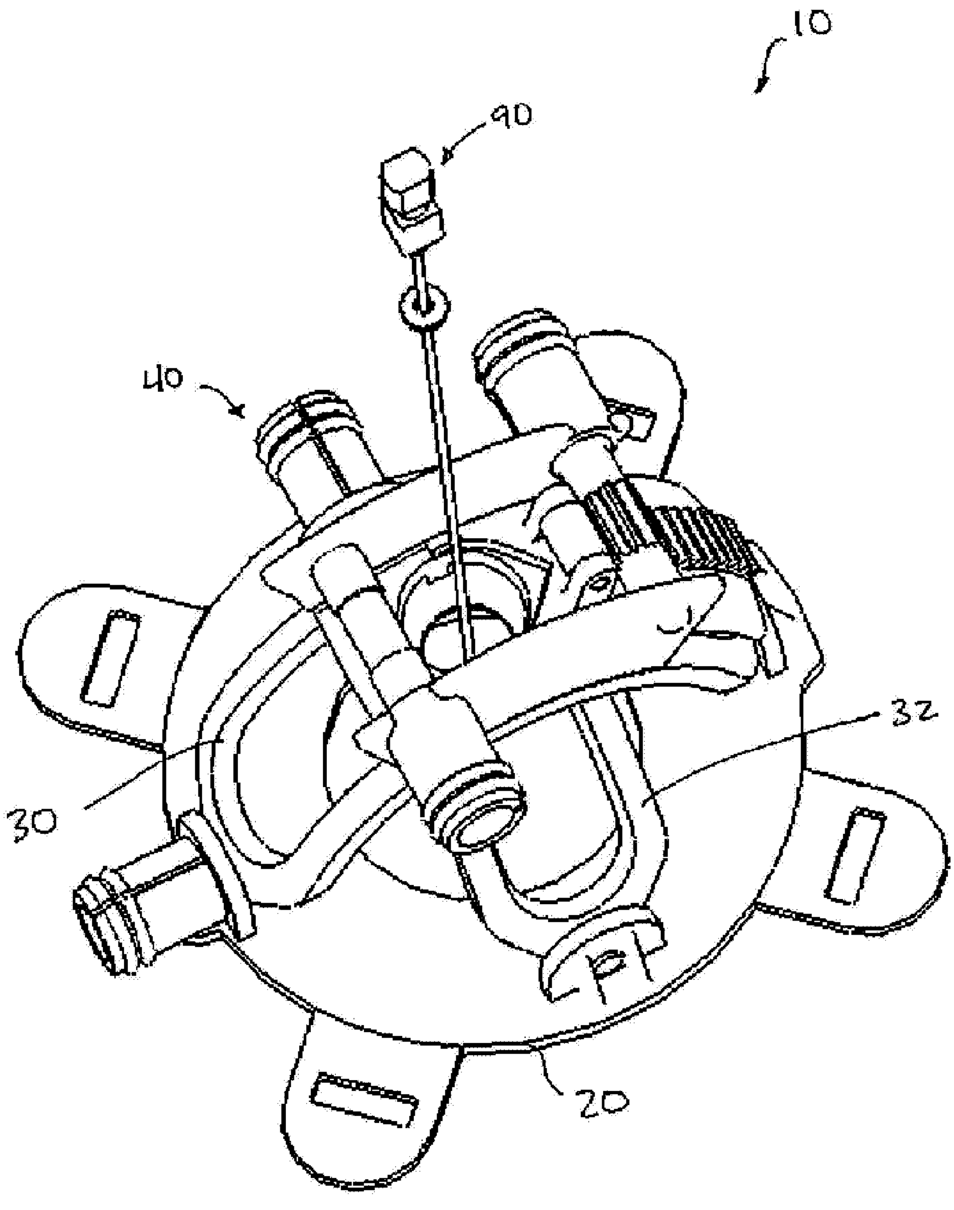


FIG. 8C

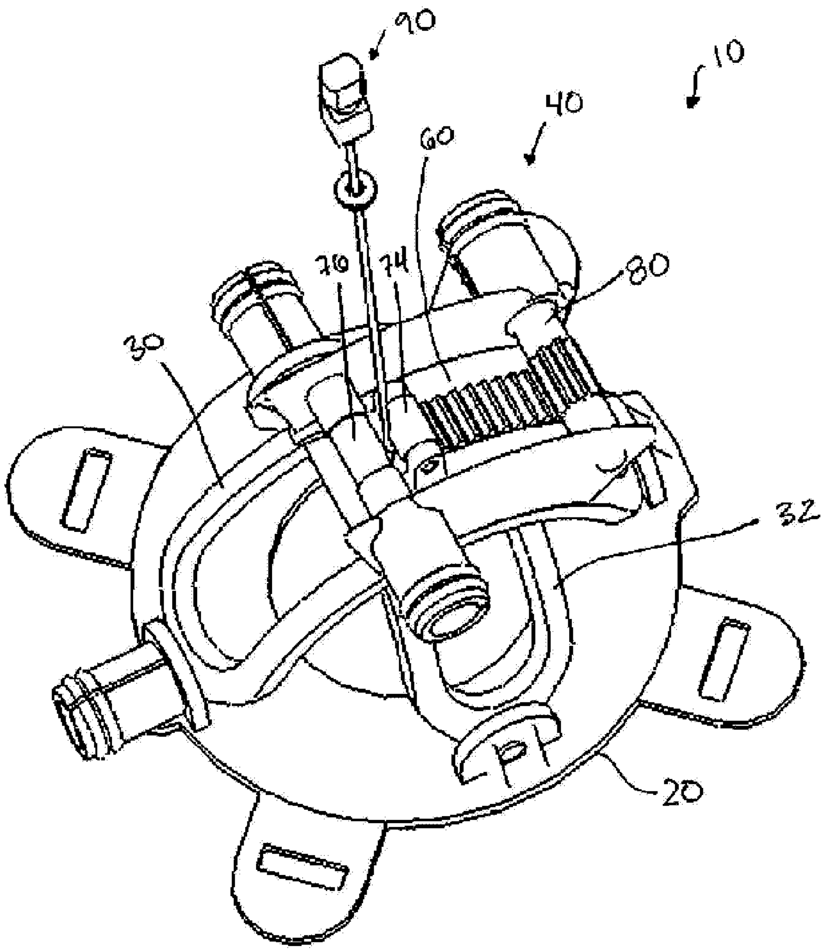


FIG. 8D

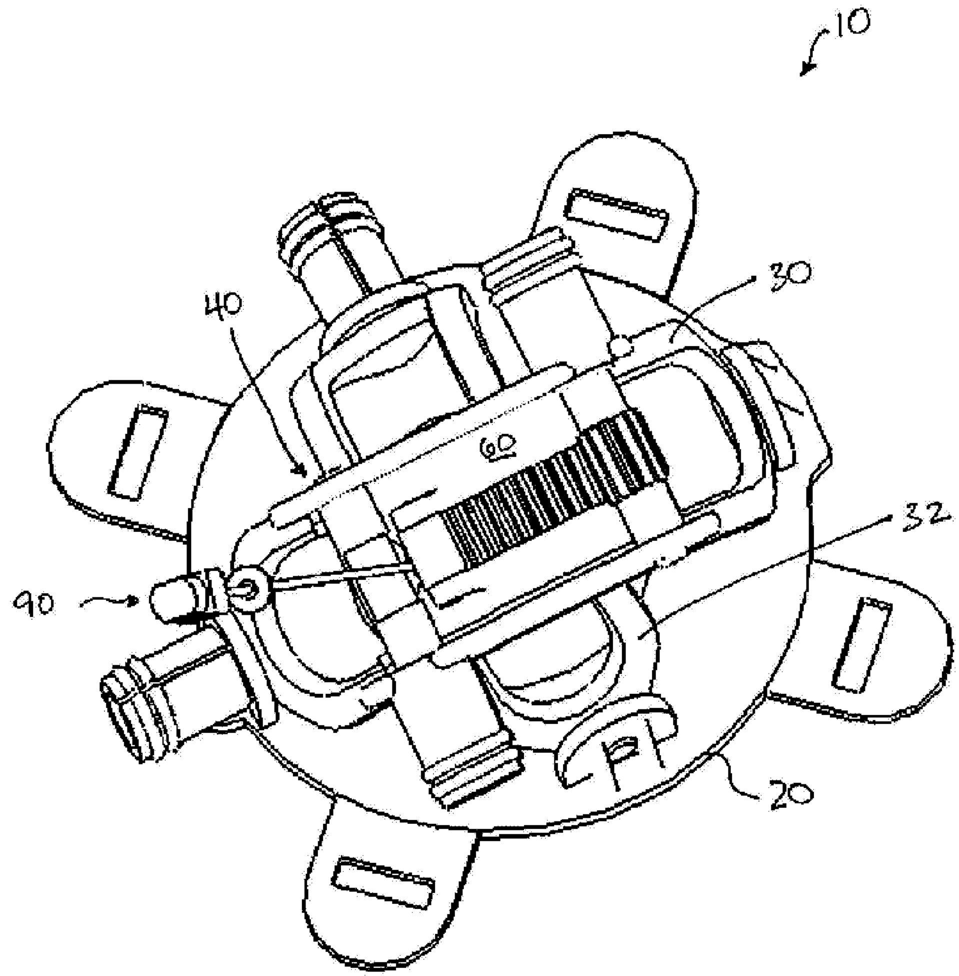


FIG. 8E

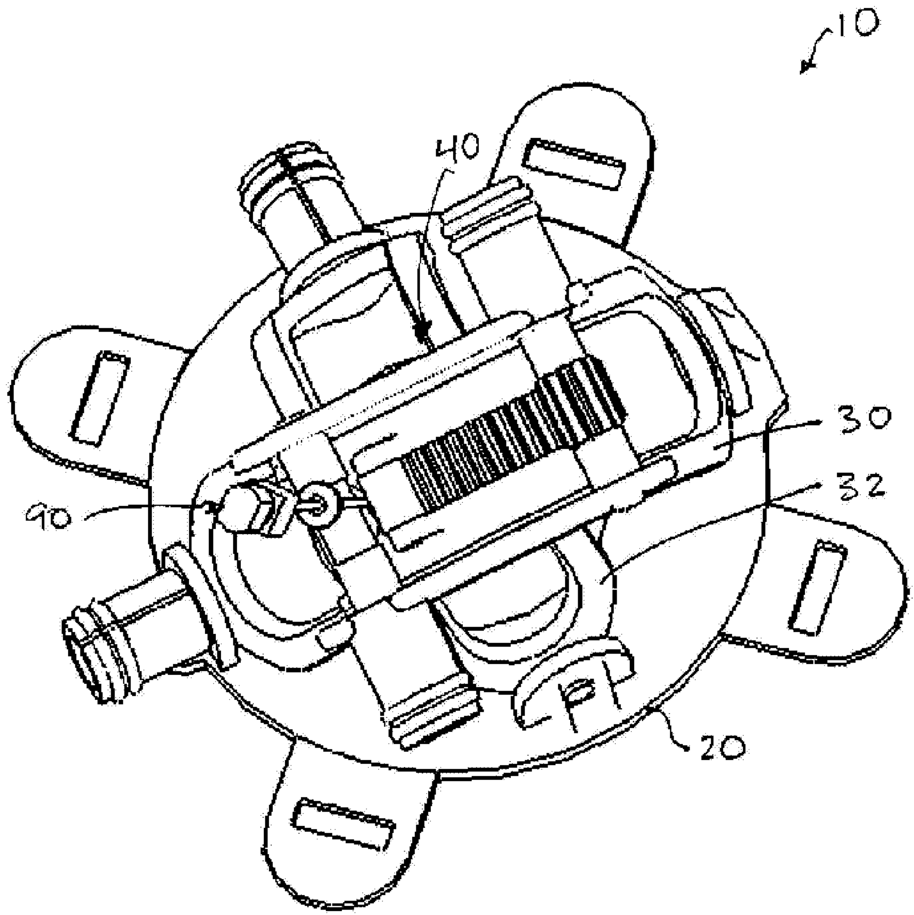


FIG. 8F

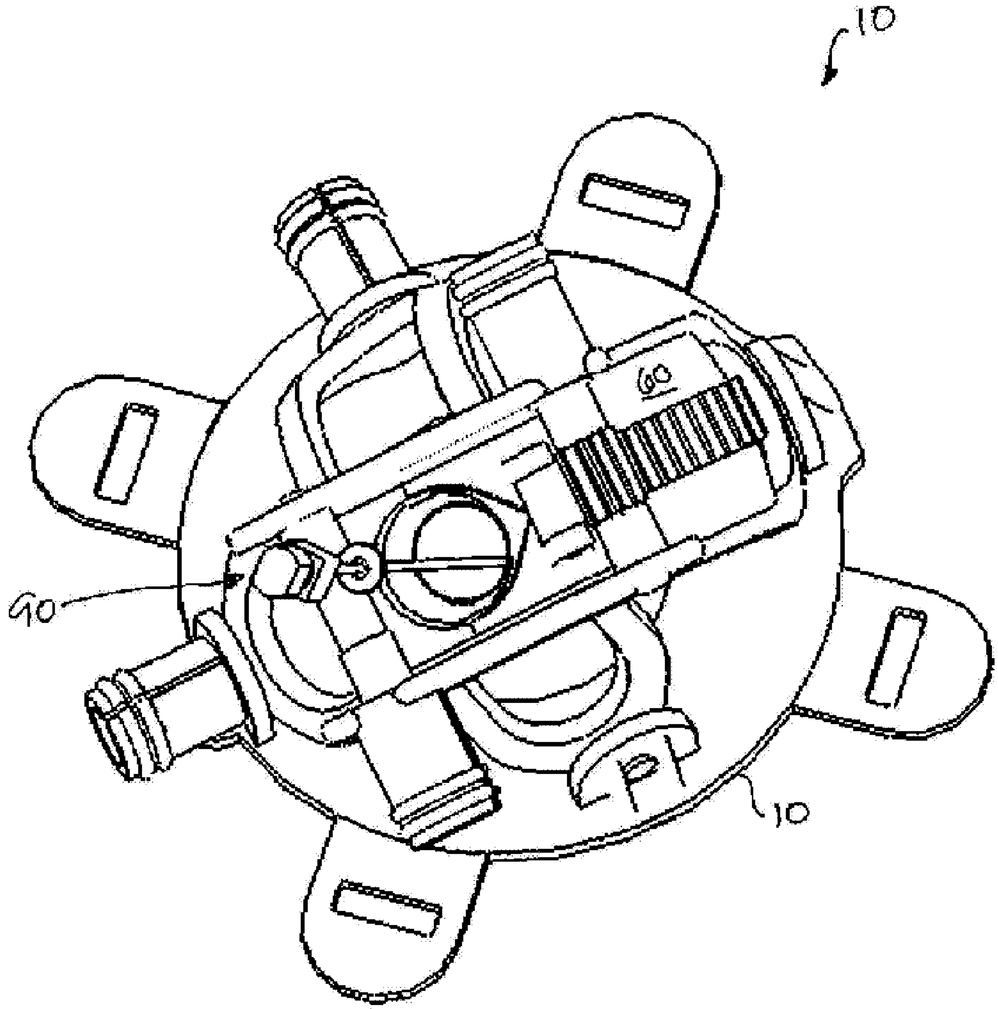
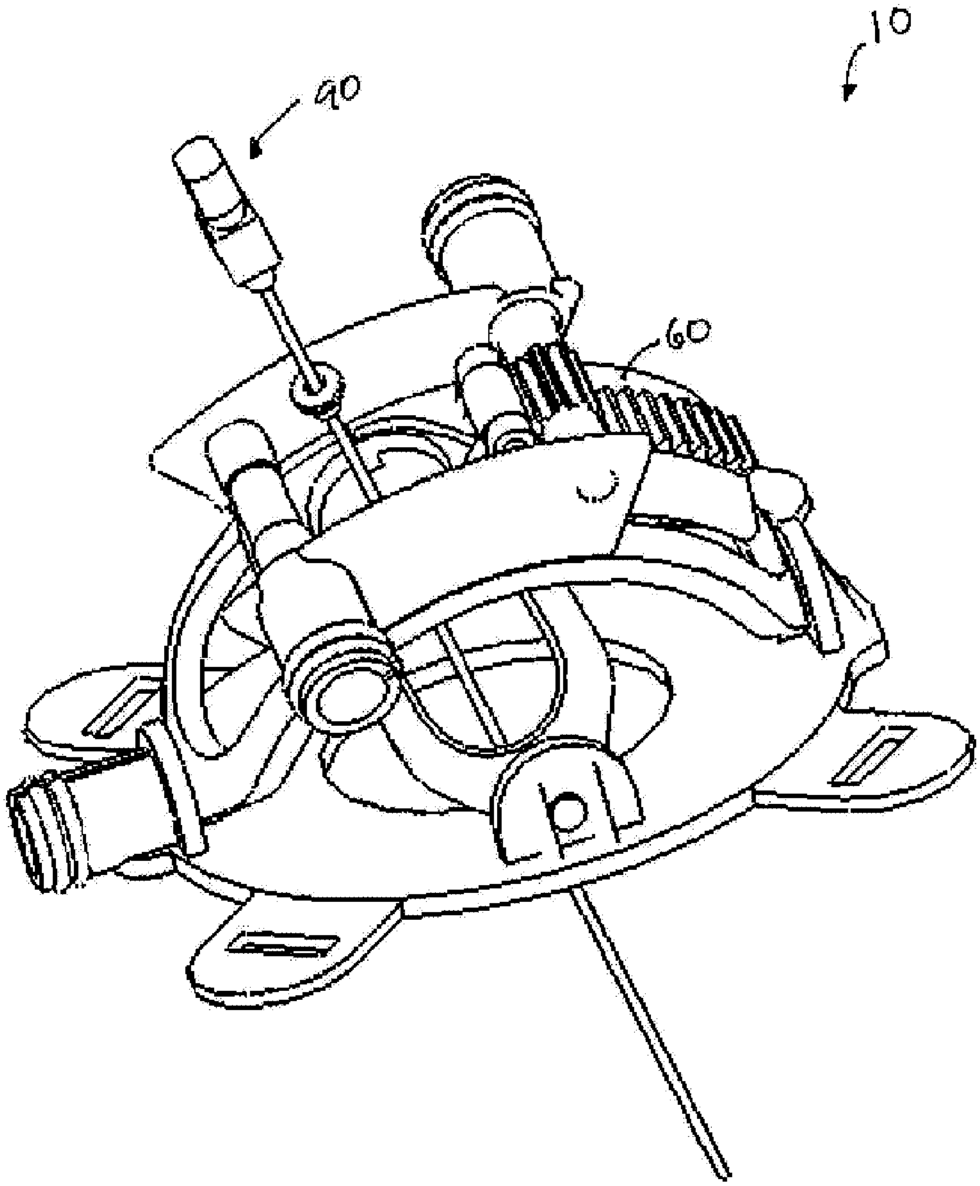


FIG. 8G



GUIDANCE AND INSERTION SYSTEM

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present invention claims priority to U.S. Provisional Application No. 60/647,867, which was filed on Jan. 28, 2005 and entitled "Needle Guidance System for Percutaneous Lung Biopsy," which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to methods and devices for guiding and inserting a tool into a target surgical site.

BACKGROUND OF THE INVENTION

[0003] Needle biopsies are performed to retrieve a sample of human tissue or fluid for histological and chemical analysis. A 14 to 20 gauge needle is inserted through a patient's skin until it reaches the target surgical site from where the sample is extracted. When it is desirable to target a particular region, such as a lesion caused by lung cancer, the procedure is often carried out under the guidance of computed tomography (CT). This results in an iterative procedure whereby, following an initial scan to target the biopsy site and planning the insertion trajectory, in terms of angle and depth, the needle is incrementally inserted and the patient is repeatedly scanned to verify and adjust the needle position. Often the CT gantry is tilted to coincide with the needle's plane of insertion so that the metallic needle is clearly visible in a single CT scan slice. This interactive procedure necessitates that a doctor and support staff repeatedly shuttle between the radiation-shielded control room (during scanning) and the CT room (when manipulating the needle) and that the patient be moved in and out of the CT scanner's ring to allow access to the insertion site.

[0004] Accordingly, there remains a need for improved methods and devices for guiding and inserting a needle or other tools into a patient.

BRIEF SUMMARY OF THE INVENTION

[0005] The present invention provides methods and devices for guiding and inserting a tool into an object, such as a body or tissue. In one exemplary embodiment, a guidance and insertion system is provided having a support base that is adapted to be located with respect to a tissue surface, a carriage that is movably mounted on the support base and that defines a passage, such as an aperture or viewing window, therethrough for receiving a tool, and a driver coupled to the carriage and adapted to drive a tool through the passage and into the object positioned beneath the support base.

[0006] While the carriage can be movably coupled to the support base using a variety of techniques, in one exemplary embodiment the carriage is movably mounted to the support base by first and second support arms that are movably coupled to the support base. The first and second arms can have a variety of shapes and sizes, but in one embodiment each support arm can have a substantially arcuate shape, and they can extend substantially transverse to one another. Each arm can also include an opening formed therein. The openings can overlap one another such that a portion of the carriage can extend through the openings in the first and second support arms. In use, the arms can be rotatably coupled to the support base and movement of the first and second support arms relative to one another can move the carriage relative to the support base. Each of the first and second arms can also include a drive socket formed thereon and adapted to couple to a motor for individually moving the first and second support arms relative to the support base. The motor can optionally be configured to be remotely actuated to allow the device to be used simultaneously with an imagining apparatus.

[0007] The carriage can have a variety of configurations, but in one embodiment it can include an engagement mechanism slidably disposed thereon and adapted to slidably move to engage a tool extending through the passage. The engagement mechanism can include an opening, such as a cut-out, formed therein and adapted to seat a tool extending through the passage. The cut-out is preferably configured to urge the tool into a predetermined position. The carriage can also include a driver rotatably coupled thereto and adapted to rotate to slide the engagement mechanism within a track formed in the carriage. In one embodiment, the driver can include at least one roller that is adapted to rotate to drive a tool through the passage. In certain exemplary embodiments, the driver includes an active roller that is adapted to couple to a motor for rotating the roller, and a passive roller. The active roller can be coupled to the carriage, and the passive roller can be coupled to an engagement mechanism that is slidably disposed on the carriage and that is adapted to slidably move to engage a tool extending through the passage.

[0008] A method for guiding and inserting a tool into an object, such as a patient, is also provided, and in one exemplary embodiment includes positioning a guide system on a tissue surface of a patient such that the guide system is positioned over a target surgical site, and positioning a tool through a viewing window of the guide system. In an exemplary embodiment, the tool can be positioned by penetrating a distal portion of the tool into tissue. The method can also include actuating the guide system to engage the tool positioned within the viewing window, actuating the guide system to adjust a trajectory of the tool while viewing an image of the guide system and the target surgical site, and actuating a driver mechanism on the guide system to advance the tool into tissue and toward the target surgical site. In an exemplary embodiment, the guide system can be actuated to adjust a trajectory of the tool by pivoting at least one arm pivotally coupled to a support base of the guide system. The arm(s) can have a carriage mounted thereon and defining the viewing window extending therethrough. In another exemplary embodiment, the tool can be engaged by slidably moving an engagement mechanism disposed on the carriage to a closed position. The tool can be positioned between an active roller and a passive roller in the engaged position, and the active roller can be actuated to advance the tool. In another exemplary embodiment, an image of the guide system and the target surgical site can be viewed using computer tomography, and the guide system and driver mechanism can be simultaneously actuated remotely, i.e., a distance away from the device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

[0010] **FIG. 1A** is a perspective view of one exemplary embodiment of a guidance and insertion device;

[0011] **FIG. 1B** is a top view of the guidance and insertion device of **FIG. 1A**, showing an engagement mechanism in an open position;

[0012] **FIG. 1C** is a top view of the guidance and insertion device of **FIG. 1A**, showing an engagement mechanism in a closed position;

[0013] **FIG. 2** is a perspective view of a support base of the guidance and insertion device of **FIGS. 1A-1C**;

[0014] **FIG. 3** is a perspective view of a support arm of the guidance and insertion device of **FIGS. 1A-1C**;

[0015] **FIG. 4A** is a perspective view of a carriage assembly of the guidance and insertion device of **FIGS. 1A-1C**, showing a carriage, an engagement mechanism, and a driver;

[0016] **FIG. 4B** is an exploded view of the carriage assembly shown in **FIG. 4A**;

[0017] **FIG. 5A** is a perspective view of the carriage shown in **FIGS. 4A and 4B**;

[0018] **FIG. 5B** is a bottom view of the carriage shown in **FIG. 5A**;

[0019] **FIG. 5C** is a cross-sectional view of the carriage shown in **FIGS. 5A and 5B**;

[0020] **FIG. 6** is a perspective view of the engagement mechanism shown in **FIGS. 4A and 4B**;

[0021] **FIG. 7** is a cross-sectional view of the guidance and insertion device of **FIGS. 1A-1C**;

[0022] **FIG. 8A** is a side view of a guidance and insertion system, showing the guidance and insertion device of **FIGS. 1A-1C** and a needle positioned through a viewing window formed in the device;

[0023] **FIG. 8B** is a perspective view of the guidance and insertion system shown in **FIG. 8A**, showing a viewing window for allowing movement of the needle;

[0024] **FIG. 8C** is a perspective view showing the guidance and insertion system of **FIG. 8B** with a sliding engagement mechanism moved to a closed position to engage the needle;

[0025] **FIG. 8D** is a top view showing the guidance and insertion system of **FIG. 8C** with first and second arms of the device pivoted to move a carriage of the device, thereby adjusting an insertion trajectory of the needle;

[0026] **FIG. 8E** is a top view showing the guidance and insertion system of **FIG. 8D** with the needle advanced by a driver mechanism on the guidance and insertion device;

[0027] **FIG. 8F** is a top view showing the guidance and insertion system of **FIG. 8E** with the engagement mechanism moved to an open position to release the needle; and

[0028] **FIG. 8G** is a perspective viewing of the guidance and insertion system shown in **FIG. 8F**.

DETAILED DESCRIPTION OF THE INVENTION

[0029] Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

[0030] The present invention provides methods and devices for guiding and inserting a tool, such as a biopsy device, a brachytherapy device, computer chip, wires, or a lumpectomy device, into tissue. In an exemplary embodiment, a guidance and insertion device is provided that can be remotely controlled to adjust an insertion trajectory of a tool, and to advance the tool into tissue to a desired penetration depth. The device can be configured for use with an imaging method, such as computed tomography (CT), magnetic resonance imaging (MRI), X-ray fluoroscopy, or ultrasound, to allow the device and tool to be operated while simultaneously viewing the device positioned in relation to a target surgical site. The device can also be configured to be positioned directly on a patient, so as to passively compensate for respiratory chest motion, and it can include features to passively compensate for oscillation of the needle or any other tool. In other exemplary embodiments, the device can be entirely disposable.

[0031] **FIGS. 1A-1C** illustrate one exemplary embodiment of a guidance and insertion device **10** for guiding and inserting a tool into tissue. In general, the device **10** includes a support base **20** that is adapted to be positioned on a tissue surface. First and second support arms **30**, **32** are movably coupled to the support base **20**, and each arm **30**, **32** includes an opening **32*a***, **32*b*** formed therethrough. The device **10** can also include a carriage assembly **40** that is movably coupled to the first and second support arms **30**, **32**. The carriage assembly **40** can include a carriage **50** defining a passage, referred to herein as a viewing window **52** (**FIG. 1B**), for receiving a tool, an engagement mechanism **60** that is configured to engage a tool extending through the viewing window **52**, and a driver mechanism **70** for driving the tool through the viewing window **52**. In use, the guidance and insertion device **10** can be positioned on a tissue surface of a patient, and a tool (not shown) can be positioned through the viewing window **52** in the carriage **50**. The engagement mechanism **60** can be moved from an open position (**FIG. 1B**) to a closed position (**FIG. 1C**) to engage the tool, and the first and second arms **30**, **32** can be moved relative to the support base **20**, thereby adjusting a position of the carriage **50** and the tool extending therethrough. An image of the device, tool, and target tissue site can be simultaneously used to facilitate positioning of the carriage **50** and thus the tool insertion trajectory. Once the tool is properly positioned, the driver mechanism **70** can be actuated to drive the tool into tissue to a desired penetration depth. Imaging can likewise be used to simultaneously view and facilitate insertion of the tool to a proper depth. In an exemplary embodiment, the device **10** is used to guide and insert a biopsy probe or needle to a target surgical site, such as a tumor. A person skilled in the art will appreciate, however, that the device can be used to guide and insert a variety of tools.

[**0032**] The support base **20** of the device can have a variety of configurations, shapes, and sizes, but it is preferably adapted to be positioned on a tissue surface of a patient, and to provide a stable footing for supporting the carriage assembly **40**. In the illustrated embodiment, as shown in more detail in **FIG. 2**, the support base **20** has a generally planar, circular configuration with an opening **22** formed therethrough. The opening **22** is configured to provide access to a target tissue site, and thus it preferably has a size and shape that is sufficient to receive a tool therethrough. A person skilled in the art will appreciate that the support base **20** and the opening **22** formed therethrough can have a variety of other shapes and sizes. For example, the support base **20** and/or opening can be square, oval, rectangular, triangular, etc. The support base **20** can also be shaped to match the contour of a patient's body, or various organs. For example, the support base **20** can be substantially concave or convex to facilitate positioning at a particular location on a patient's body. The support base can, on other embodiments, be comprised of two components, a lower and standardized upper portion, wherein the lower portion comprises a range of parts, each part being shaped to match the contour of a specific part of a patient's body, and the standardized upper portion being adapted to mate to any of the various lower portion parts.

[**0033**] The support base **20** can also include one or more securing mechanisms or features, such as holes, slots, tabs, or adhesive stickers, etc., to secure the support base **20** to a tissue surface. As shown in **FIG. 2**, the support base **20** includes four tabs **24***a*, **24***b*, **24***c*, **24***d* disposed therearound. The tabs **24***a-d* can be used to tape the support base **20** to a tissue surface. Alternatively, or in addition, the tabs **24***a-d* can include slots **25***a*, **25***b*, **25***c*, **25***d* formed therein for receiving a strap or other element to secure the support base **20** onto a patient. While four tabs are shown, the support base **20** can include any number of tabs, and/or it can include a variety of other features to temporarily secure the support base **20** to a tissue surface.

[**0034**] As indicated above, the support base **20** is preferably configured to support the carriage assembly **40**. In an exemplary embodiment, the carriage assembly **40** is movably coupled to the support base **20** by the first and second arms **30**, **32**. Accordingly, the support base **20** can include features for mating the first and second arms **30**, **32** to the support base **20**. As shown in **FIG. 2**, the support base **20** includes a first pair of mating elements **26***a*, **26***b* extending from and positioned on opposed sides of the support base **20** for receiving the first support arm **30**, and a second pair of mating elements **28***a*, **28***b* extending from and positioned on opposed sides of the support base **20** for receiving the second support arm **32**. The configuration of each mating element **26***a*, **26***b*, **28***a*, **28***b* can vary depending on the configuration of the first and second arms **30**, **32**, which will be discussed in more detail below, but in an exemplary embodiment the first and second pair of mating elements **26***a*, **26***b*, **28***a*, **28***b* are configured to pivotally mate the support arms **30**, **32** to the support base **20**. This can be achieved using, for example, a pin and bore connection. As shown in **FIG. 2**, each mating element **26***a*, **26***b*, **28***a*, **28***b* is in the form of an upstanding tab having a bore (only two bores **26***c*, **28***c* are shown) formed therein for receiving a corresponding pin formed on the first and second arms **30**, **32**. The position of each mating element **26***a*, **26***b*, **28***a*, **28***b* can also vary depending on the desired position of the first and second arms **30**, **32** relative to one another. In an exemplary embodiment, as shown, the first pair of mating elements **26***a*, **26***b* are positioned 90° offset from the second pair of mating elements **28***a*, **28***b* and thus the mating elements **26***a*, **26***b*, **28***a*, **28***b* are spaced equidistantly around the perimeter of the support base **20**. As a result, when the first and second arms **30**, **32** are mated to the mating elements **26***a*, **26***b*, **28***a*, **28***b*, the arms **30**, **32** will extend substantially transverse to one another such that they intersect one another.

[**0035**] As further shown in **FIG. 2**, two of the mating elements, e.g., mating elements **26***b* and **28***b*, can optionally include a connecting element **26***d*, **28***d* formed thereon for connecting a motor to the first and second arms **30**, **32**, as will be discussed in more detail below. Each connecting element **26***d*, **28***d* can have a variety of configurations, and the particular configuration can vary depending on the configurations of the motors that are used to rotate the first and second arms **30**, **32** relative to the support base **20**. In the illustrated embodiment, each connecting element **26***d*, **28***d* is merely a cylindrical housing or socket having an opening extending therethrough for receiving a driver on a motor, and a band formed on an external surface thereof and configured to engage and prevent rotation of the motor. The opening in each connecting element **26***d*, **28***d* is preferably aligned with the opening formed in the mating elements **26***b*, **28***b* to allow the driver on the motor to extend through the connecting elements **26***d*, **28***d* and to mate to a drive socket formed on the first and second arms **30**, **32**, as will be discussed in more detail below. A person skilled in the art will appreciate that various techniques can be used to connect one or more motors to the device **10**, or alternatively the motor(s) can be integrally formed on or built into the device thus eliminating the need for any connecting elements. The use of external motors, however, allows the motor, which never contacts the patient, to be unclipped from the device. The device can then be discarded.

[**0036**] The first and second arms **30**, **32** can also have a variety of configurations, but in an exemplary embodiment the arms **30**, **32** are configured to pivotally couple to the support base **20**, and they are adapted to hold and position the carriage assembly **40** a distance above the support base **20**. **FIG. 3** illustrates one of the arms **30** in more detail. As shown, the arm **30** has a generally elongate, arcuate shape with opposed ends **32***a*, **32***b* that are adapted to mate to the mating elements, e.g., elements **28***a*, **28***b*, on the support base **20**. As previously discussed, in an exemplary embodiment a pin and bore connection is used to mate the arms to the connecting elements **26***a*, **26***b*, **28***a*, **28***b* on the support base **20**. As shown in **FIG. 3**, the first and second ends **32***a*, **32***b* of the arm **30** each include a pin **34***a*, **34***b* formed thereon and adapted to extend into the bore (only one bore **28***c* is shown in **FIG. 2**) formed in the mating elements **28***a*,

28*b* on the support base **20**. The second arm **32** can have a configuration that is similar to the first arm **30**.

[0037] As indicated above, two of the mating elements, e.g., mating elements **26***b*, **28***b*, can include connecting elements **26***d*, **28***d* for mating to a motor. Accordingly, one of the pins on each arm **30**, **32** can include a drive socket formed therein for receiving the driver on the motor connected to the connecting element. As shown in **FIG. 3**, pin **34***b* includes a drive socket **34***c* formed therein for receiving a driver on a motor. The drive socket **34***c* can have a shape, such as a hexagonal or square shape, for receiving a driver having a complementary shape. As a result, when the driver is positioned within the socket **34***c*, rotation of the driver will be effective to apply a rotational force to the socket **34***c*, thereby rotating the arm **30**. Exemplary motors for rotating the arms **30**, **32** will be discussed in more detail below.

[0038] Each arm **30**, **32** can also include a slit or opening formed therein. The shape and size of the opening in each arm **30**, **32** can vary, but in an exemplary embodiment the openings in the arms **30**, **32** are configured to overlap to receive a portion of the carriage assembly **40** therethrough. Such a configuration will allow the arms **30**, **32** to form a double-track for moving the carriage assembly **40** relative to the support base **20**, as will be discussed in more detail below. **FIG. 3** illustrates arm **30** having an elongate opening **30***a* extending therethrough between the first and second ends **32***a*, **32***b* thereof. When the arms **30**, **32** are mated to the support **20**, as shown in **FIGS. 1A-1C**, the openings **30***a*, **32***a* overlap and a portion of the carriage assembly **40** extends therethrough.

[0039] The carriage assembly **40** is shown in more detail in **FIGS. 4A and 4B**, and as shown the carriage assembly **40** generally includes a carriage **50** defining an opening for receiving a tool, an engagement mechanism **60** for engaging a tool extending through the opening in the carriage **50**, and a driver mechanism **70** for driving a tool through the opening in the carriage **50**. A person skilled in the art will appreciate that the carriage assembly **40** can have a variety of other configurations, and that various other techniques can be used to engage, position, and drive a tool into tissue.

[0040] The carriage **50** is shown in more detail in **FIGS. 5A-5C**, and as shown the carriage **50** is in the form of a housing having a generally arcuate bottom surface with opposed sidewalls extending therefrom. The arcuate bottom surface of the carriage **50** allows the carriage **50** to slide along one of the support arms, e.g., the first support arm **30** as shown in **FIGS. 1A-1C**, and the sidewalls allow the carriage **50** to slidably receive the engagement mechanism **60** for engaging a tool extending through the carriage **50**. As further shown in **FIGS. 5A and 5B**, the carriage **50** includes an opening or viewing window **52** extending through the bottom surface thereof for receiving a tool. The viewing window **52** can extend through a hollow housing **54***a* that is coupled to the bottom surface of the carriage **50**, and that forms an extension on the carriage **50**. The hollow housing **54***a* allows the carriage **50** to be coupled to the first and second support arms **30**, **32**. In particular, the housing **54***a* can extend through the openings **30***a*, **32***a* in the first and second support arms **30**, **32** to allow the carriage **50** to be engaged and moved in response to movement of the support arms **30**, **32**. The particular shape of the hollow housing **54***a* can vary depending on the shape of the openings **30***a*, **32***a* in the arms **30**, **32**, as well as the size and shape of a tool to be inserted therethrough. In an exemplary embodiment, the housing **54***a* has a shape and a size that is sufficient to allow a variety of tools of various sizes to be inserted therethrough. The shape and size of the housing **54***a* is also preferably configured to allow a tool to pivot within the viewing window **52**, thus loosely retaining a tool in a generally upright position while allowing the tool to be moved and manipulated. The viewing window **52** can also have a size that allows the device **10** to be removed over a tool implanted within a patient. In the embodiment shown in **FIG. 5C**, the housing **54***a* is generally cone-shaped and defines a conical range of motion within which a tool can pivotally move. The angle α of the cone can vary depending on the desired range of motion and the particular tool being used, but in one exemplary embodiment the cone angle α is in the range of 10 to 15°.

[0041] As further shown in **FIGS. 5A-5C**, the carriage **50** can also include a flange **54***b* formed around a terminal end of the housing **54***a*. The flange **54***b* can be configured to retain or lock the carriage **50** on the support arms **30**, **32**, preventing accidental disengagement during use of the device. The flange **54***b* can also have a shape that allows the carriage **50** to be easily disassembled and removed from the supports arms **30**, **32**, if desired. As shown in **FIGS. 5A and 5C**, the flange **54***b* is substantially rectangular. Such a configuration allows the flange **54***b* to be inserted at an angle through the openings **30***a*, **32***a* in the supports arms **30**, **32** when the openings **30***a*, **32***a* are aligned with one another, and then one of the arms, e.g., the second arm **32**, can be rotated 90° to lock the carriage **50** onto the arms **30**, **32**. The arms **30**, **32** can then be slightly compressed and snapped between the first and second pair of mating elements **26***a*, **26***b*, **28***a*, **28***b* on the support base **20**.

[0042] The carriage **50** can also include rails **50***a*, **50***b* formed on an inferior or bottom surface thereof for facilitating positioning of the carriage **50** relative to the support arms **30**, **32**. In particular, the carriage **50** is preferably configured to rest on one of the arms, e.g. the first arm **30**. The rails **50***a*, **50***b* can extend along the bottom surface of the carriage **50**, and they can be configured to be positioned within the opening **30***a* in the first arm **30**, or around the first arm **30**. The rails **50***a*, **50***b* can prevent rotation of the carriage **50** relative to the first arm **30**, thereby preventing the carriage **50** from being removed. The rails **50***a*, **50***b* can also facilitate sliding movement of the carriage **50** along the first arm **30**.

[0043] As further shown in **FIGS. 5A and 5C**, the carriage **50** can further include tracks **58***a*, **58***b* formed therein for slidably receiving the engagement mechanism **60**, which is adapted to engage a tool extending through the viewing window **52** in the carriage **50**. The illustrated tracks **58***a*, **58***b* are in the form of opposed rails that extend along internal sidewalls of the carriage **50**, and that define a groove for slidably seating the engagement mechanism **60**.

[0044] The carriage **50** can also include other features, such as first and second connecting elements **56***a*, **56***b* for mating a motor to a driver **80** for moving the engagement mechanism **60** and a driver **70** for advancing a tool, as will be discussed below. The first and second connecting elements **56***a*, **56***b* can be similar to the connecting elements **26***d*, **28***d* on the support base **20**, and in particular they can be in the form of substantially cylindrical housings having a bore extending therethrough for receiving a driver on a motor.

[0045] An exemplary engagement mechanism **60** is shown in more detail in **FIG. 6**, and as shown it has a generally elongate shape with an arcuate profile. The arcuate shape allows the engagement mechanism **60** to slidably seat within the tracks **58***a*, **58***b* formed in the carriage **50**, and to move between an open position (shown in **FIG. 1B**), in which the engagement mechanism **60** is spaced a distance apart from the viewing window **52** to provide access to the viewing window **52**, and a closed position (shown in **FIG. 1C**), in which the engagement mechanism **60** extends over the viewing window **52** to engage a tool extending through the viewing window. To facilitate engagement of a tool extending through the viewing window **52**, the engagement mechanism **60** can include a cut-out **62** formed therein and adapted to receive a tool. While the cut-out **62** can have a variety of shapes of sizes, in one exemplary embodiment, as shown in **FIG. 6**, the cut-out is substantially triangular. Such a shape will allow the cut-out **62** to urge a tool, such as a needle, into horizontal alignment with the cut-out **62**.

[0046] As explained above, the engagement mechanism **60** is preferably movable between an open and closed position. Slidable movement of the engagement mechanism **60** can be achieved using a variety of techniques, but in one exemplary embodiment the carriage **50** includes a driver **80** formed thereon and adapted to slide the engagement mechanism **60** within the tracks **58***a*, **58***b* formed in the carriage **50**. One exemplary driver **80** is shown in **FIGS. 4A and 4B**, and as shown the driver **80** is in the form of a shaft having teeth or gears **82** formed thereon. The gears **82** are configured to mate to corresponding teeth or gear, i.e., a rack **64**, formed on a surface of the engagement mechanism **60**. As a result, rotation of the driver **80** in a first direction is effective to slide the engagement mechanism **60** in a first direction within the carriage **50**, and rotation of the driver **80** in an opposite direction is effective to slide the engagement mechanism **60** in a second, opposite direction within the carriage **50**, thereby moving the engagement mechanism **60** between the open and closed positions. The driver **80** can be rotated using a motor, as will be described in more detail below. Preferably, opposed ends **80***a*, **80***b* of the driver **80** are configured to be rotatably positioned within opposed openings **55***a*, **55***b* formed in the carriage **50**. One of the ends, e.g., end **80***b*, can include a drive socket formed therein for receiving a driver on a motor. The drive socket can be similar to drive socket **34***c* previously described with respect to **FIG. 3**. In use, when the driver **80** is coupled to the carriage **50**, a motor can be coupled to the connecting element **56***a* to allow a driver on a motor to be positioned through the connecting element **56***a* and to be coupled to the drive socket on the driver **80**. Actuation of the motor will rotate the driver, thereby rotating the drive socket and thus the driver **80** to move the engagement mechanism **60**.

[0047] As previously explained, the carriage assembly **40** can also include a driver **70** for driving a tool through the viewing window **52** and into tissue. **FIGS. 4A and 4B** illustrate one exemplary embodiment of a driver **70** that includes a passive roller **74** mated to the engagement mechanism **60**, and an active roller **76** mated to the carriage **50**. The active roller **76** is configured to be rotated by a driver to drive a tool through the viewing window **52**, and the passive roller **74** is configured to rotate as a result of movement of the tool relative thereto, as will be discussed below. The rollers **74**, **76** can be mounted on the engagement mechanism **60** and carriage **50** using a variety of techniques, but in an exemplary embodiment each roller **74**, **76** includes opposed ends that are configured to be received within corresponding openings or bores. In particular, the active roller **76** can include opposed ends **76***a*, **76***b* that extend into corresponding bores **57***a*, **57***b* which are formed in opposed sidewalls of the carriage **50**. The passive roller **74** can include opposed ends **74***a*, **74***b* that extend into corresponding bores **67***a*, **67***b* formed in the engagement mechanism **60**. The bores **67***a*, **67***b*, which are shown in **FIGS. 4B and 6**, are formed in opposed arms **66***a*, **66***b* formed on and extending from a surface of the engagement mechanism **60**. The opposed arms **66***a*, **66***b* are positioned adjacent to the cut-out **62** to allow the passive roller **74** to be positioned adjacent to the drive roller **76** when the engagement mechanism **60** is in the closed position. As a result, a tool extending through the viewing window **52** will be engaged between the passive and active rollers **74**, **76**.

[0048] In order to actuate the driver **70**, one end of the active roller **76**, e.g., end **76***b*, can include a socket formed therein and configured to receive a driver on a motor. The socket can be similar to socket **34***c* previously described with respect to **FIG. 3**. In use, when the active roller **76** is coupled to the carriage **50**, a motor can be mated to the connecting element **56***b* such that the driver on the motor extends through the connecting element and into the socket formed in the drive roller **76**. As a result, when the motor is actuated the driver will rotate to rotate the socket, thereby rotating the drive roller **76**. The drive roller **76** will thus cause a tool positioned between the drive roller **76** and the passive roller **74** to advance into tissue. The drive roller **76** can also be driven in a reverse direction to retract the tool from tissue. **FIG. 7** illustrates the device **10** having a tool, in the form of a biopsy needle **90**, extending therethrough. As shown, the engagement mechanism **60** is in the closed position such that the tool **90** is positioned within the cut-out portion in the engagement mechanism **60**, and is engaged between the passive and active rollers **74**, **76**.

[0049] In order to facilitate movement of a tool, the drive roller and/or the passive roller **74**, **76** can optionally include a protective member, such as rubber, disposed around at least a portion thereof. The protective member can be effective to decrease the contact stresses between the roller(s) **74**, **76** and the tool, and it can improve traction between the roller(s) **74**, **76** and the tool as the tool is driven into or out of tissue.

[0050] As indicated above, a motor can be used to rotate the arms **30**, **32** relative to the support base **20** and thereby position the viewing window **52** in the carriage assembly **40** at a desired orientation. A motor can also be used to slide the engagement mechanism **60** within the carriage **50**, thereby engaging and disengaging a tool extending through the viewing window **52**. A motor can further be used to rotate the active roller **76** to advance and retract a tool extending through the viewing window and engaged between the active roller **76** and the passive roller **74** in the engagement mechanism **60**. In an exemplary embodiment a separate motor is configured to removably mate to each connecting element **26***d*, **28***d*, **56***a*, **56***b* to allow each motor to be individually actuated to control movement of the arms **30**,

32, movement of the engagement mechanism **60**, and actuation of the driver **70** for advancing and retracting a tool. Such a removable connection is particularly advantageous as it allows the entire device **10** to be formed from a disposable material, such as a polymer. The motors, which do not contact the patient's skin, can simply be detached from the device **10** after use and the device **10** can be discarded.

[**0051**] While various types of motors can be used to perform each of task, one exemplary type of motor that can be used is a step motor, which is an electromagnetic, rotary actuator that mechanically converts digital pulse inputs to incremental shaft rotation. With the appropriate logic, step motors can be bidirectional, synchronous, provide rapid acceleration, stopping, and reversal, and will interface easily with other digital mechanisms. As a result, the motors can allow for accurate and precise control of each movement. One exemplary step motor is a series AM 1020 Motor with a planetary gear head and a 256:1 reduction. The step angle of the motor is 18° thus allowing an angular position resolution of 0.07° to be obtained. The motor also has the ability to orientate a tool positioned within the viewing window **52** by moving the arms **30**, **32** at a speed of about 360°/s, and to drive a tool into tissue at a rate of about 20 mm/s. In other embodiments, a DC motor, hydraulics, battery power, or other techniques can be used to actuate the drivers and rotate the arms.

[**0052**] In another embodiment, the device **10** can include markers in the support base **20**, support arms **30**, **32**, and/or carriage assembly **40**. The markers can be formed from a radiopaque material to allow the markers to be viewed in an image of the patient to create reference points in a coordinate system, that, for example, may include the patient, target surgical site, device, and/or imaging apparatus. The reference points can be used to facilitate automatic targeting of the tool to the target surgical site. For example, the device **10** may contain metallic parts in the support base **20** that would appear in a CT image, allowing one skilled in the art to calculate the correct input parameters for the device **10** to insert the tool to the target surgical site.

[**0053**] **FIGS. 8A-8G** illustrate an exemplary method for using the device **10**. While the device **10** can be used to guide and insert a variety of tools into tissue, in one exemplary embodiment the device **10** is used to guide and insert a biopsy needle into tissue to remove a sample for analysis. The device **10** can be positioned directly on a tissue surface (not shown) of a patient at a location above a target surgical site, such as a tumor. Since the device **10** is positioned on the patient, the device will move with the patient, for example with the rise and fall of the patient's chest during breathing. A motor can be connected to each connecting element **26***d*, **28***d*, **56***a*, **56***b* on the device **10**, as previously discussed. The motors can be coupled to a control box, which in turn can be connected to a computer to allow the motors to be remotely actuated. The device **10** can be secured to the patient using the tabs **24***a*, **24***b*, **24***c*, **24***d* on the support base **20** and straps, adhesives, etc. Once the device **10** is secured, a biopsy needle **90** can be positioned through the viewing window **52** in the carriage assembly **40**, as shown in **FIG. 8A**. The engagement mechanism **60** will be in the open position to provide access to the viewing window **52**. A distal tip of the needle **90** is then positioned at the insertion point, and it can be at least partially penetrated into the tissue. In this position, the needle **90** is free to pivot within the viewing window **52**, as shown in **FIG. 8B**.

[**0054**] In an exemplary embodiment, the device **10** can be used with an imaging method and system, such as computed tomography (CT), magnetic resonance imaging (MRI), ultrasound, X-ray, X-ray fluoroscopy, etc. The device **10** can be formed from a non-metallic material, such as plastic, so that the device **10** does not interfere with the image, and it can be sized to fit within the confines of, for example, a CT or MRI machine. A plastic device with MRI-compatible motors, such as a piezoelectric motor, can be used safely in an MRI machine's strongly magnetic environment. Once positioned on the patient, the operator can exit the room and operate the device remotely from a control room containing the computer for controlling the motors. The patient can be scanned with the device **10** and needle **90** positioned on the patient, and an image can be viewed. While simultaneously viewing the image, the user can control the needle's insertion angle and depth remotely through an intuitive interface. As shown in **FIG. 8C**, the motor coupled to the engagement mechanism **60** can be actuated to rotate the driver **80** and thereby slide the engagement mechanism **60** to the closed position. This will cause the cut-out portion on the engagement mechanism **60** to engage and orient the needle **90** with the cut-out portion, and to position the needle **90** between the passive and active rollers **74**, **76**. Either prior to or after closing the engagement mechanism **60**, the motor attached to each of the first and second arms **30**, **32** can be individually actuated to rotate the first and second arms **30**, **32** to a desired angular orientation relative to the support base **20**. As the first and second arms **30**, **32** pivot relative to the support base **20**, the carriage assembly **40** will move, as shown in **FIG. 8D**, thereby positioning the needle **90** at a desired angular orientation. The particular angular orientation of the needle **90** can be confirmed using the imaging apparatus, and if necessary, the arms **30**, **32** can be further moved to reposition the carriage assembly **40** and thus the needle **90** until a desired angular orientation is achieved.

[**0055**] Once the needle **90** is properly oriented at a desired insertion angle, the motor coupled to the active roller **76** can be actuated to rotate the active roller **76**, thereby driving the needle **90** into the tissue, as shown in **FIG. 8E**. The motor can be used to control the insertion speed and/or depth, which can be viewed using the imaging apparatus. The device can optionally include feedback for assessing unusual torque loads on the motor and to stop needle insertion when the torque load exceeds a predetermined load. The insertion depth can also be controlled using a stop formed on the needle **90** to limit the insertion depth of the needle. For example, a proximal portion of the needle **90** can include a flange disposed therearound and configured to abut against the passive and active rollers **74**, **76**. A clamp could also be used to function as a depth stop. In other embodiments, a camera or other imaging mechanism can be mounted directly on the device or needle to facilitate viewing of the needle relative to the target surgical site. The needle **90** could also optionally include depth markings formed thereon to indicate the insertion depth.

[**0056**] After the needle **90** is fully inserted to obtain a tissue sample from a target surgical site, the driver can optionally be actuated to rotate the active roller **76** in an opposite direction, thereby removing the needle **90** from the tissue. Alternatively, the needle **90** can remain deployed and the engagement mechanism **60** can be moved to the open position to allow a surgeon to remove the needle **90**, as shown in **FIGS. 8F and 8G**. This is particularly advantageous as the needle **90** can be loosely retained by the device **10**, and still remain penetrated within the patient. The needle **90** can thus move with the patient or any internal organs, thus reducing the risk of damaging internal tissues or organs. The device **10** can also optionally be removed before the needle **90** is removed from the patient by sliding the device **10** over the needle **90**. A person skilled in the art will appreciate that the steps can be performed in virtually any order and may vary depending on the procedure being performed.

[**0057**] As previously indicated, a software interface can optionally be used in conjunction with the imaging apparatus and the device **10** to control positioning of the needle **90**. For example, the software can be configured to receive the insertion angle and to command the device to attain that position. Alternatively, the software can be configured to determine the insertion angle and to command the device to attain that angle. Small "jogs" are also possible, allowing the tool to be moved in increments, such as 5°. The user inputs are converted into desired rotations and speed and sent to the controller which in turn sends step commands to the individual motor drivers. The needle insertion depth can similarly be controlled. In other embodiments, the device **10** can include a joystick or wand for actuating the device.

[**0058**] One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. A guidance and insertion system, comprising:

a support base adapted to be placed on a tissue surface;

a carriage movably mounted on the support base and defining a viewing window therethrough for receiving a tool; and

a driver coupled to the carriage and adapted to drive a tool through the viewing window and into tissue positioned beneath the support base.

2. The system of claim 1, wherein the carriage is movably mounted to the support base by first and second support arms that are movably coupled to the support base.

3. The system of claim 2, further comprising a first drive socket formed on the first support arm and adapted to couple to a motor for moving the first support arm relative to the support base, and a second drive socket formed on the second support arm and adapted to couple to a motor for moving the second support arm relative to the support base.

4. The system of claim 2, wherein the first and second support arms are rotatably coupled to the support base.

5. The system of claim 2, wherein the first support arm extends substantially transverse to the second support arm.

6. The system of claim 2, wherein the first and second support arms each include an opening formed therein, and wherein a portion of the carriage extends through the openings in the first and second support arms such that movement of the first and second support arms relative to one another is effective to move the carriage relative to the support base.

7. The system of claim 6, wherein each support arm has a substantially arcuate shape, and wherein the first and second support arms extend substantially transverse to one another such that the openings overlap to receive a portion of the carriage.

8. The system of claim 1, wherein the carriage includes an engagement mechanism slidably disposed thereon and adapted to slidably move to engage a tool extending through the viewing window.

9. The system of claim 8, wherein the engagement mechanism includes a cut-out formed therein and adapted to seat a tool extending through the viewing window, the cut-out being configured to urge the tool into a predetermined position.

10. The system of claim 8, further comprising a driver rotatably coupled to the carriage and adapted to rotate to slide the engagement mechanism within a track formed in the carriage.

11. The system of claim 1, wherein the driver comprises at least one roller adapted to rotate to drive a tool through the viewing window.

12. The system of claim 11, wherein the at least one roller comprises an active roller adapted to couple to a motor for rotating the roller, and a passive roller, the active and passive rollers being configured to engage a tool positioned therebetween and extending through the viewing window.

13. The system of claim 12, wherein the active roller is coupled to the carriage, and the passive roller is coupled to an engagement mechanism that is slidably disposed on the carriage and that is adapted slidably move to engage a tool extending through the viewing window.

14. The system of claim 1, wherein the support base includes a plurality of securing mechanisms formed thereon and adapted to facilitate securing of the support base to a patient.

15. The system of claim 1, wherein the system is at least partially formed from a polymeric material.

16. A method for guiding and inserting a tool into tissue, comprising:

positioning a guide system on a tissue surface of a patient such that the guide system is positioned over a target surgical site;

positioning a tool through a viewing window of the guide system;

actuating the guide system to engage the tool positioned within the viewing window;

actuating the guide system to adjust a trajectory of the tool based on an image of the guide system and the target surgical site; and

actuating a driver mechanism on the guide system to advance the tool into tissue.

17. The method of claim 16, wherein positioning the tool further comprises penetrating a distal portion of the tool into tissue.

18. The method of claim 16, wherein actuating the guide system to adjust a trajectory of the tool comprises pivoting at least one arm pivotally coupled to a support base of the guide system, the at least one arm having a carriage mounted thereon and defining the viewing window extending therethrough.

19. The method of claim 18, wherein engaging the tool comprises slidably moving an engagement mechanism disposed on the carriage to a closed position.

20. The method of claim 19, wherein the tool is positioned between an active roller and a passive roller in the engaged position, and wherein actuating a driver mechanism to advance the tool comprises rotating the active roller.

21. The method of claim 16, wherein an image of the guide system and the target surgical site is viewed using computer tomography.

22. The method of claim 16, wherein the guide system and driver mechanism are actuated remotely.

23. The method of claim 16, wherein the guide system is secured to the tissue surface using a mating element.

24. The method of claim 16, wherein the tissue is a target surgical site.

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