US008688196B2

(12) **United States Patent**
Whitmore, III et al.

(10) **Patent No.: US 8,688,196 B2**
(45) **Date of Patent: Apr. 1, 2014**

(54) **EM TRACKING SYSTEMS FOR USE WITH ULTRASOUND AND OTHER IMAGING MODALITIES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 219 days.

(21) Appl. No.: **13/331,572**

(22) Filed: **Dec. 20, 2011**

(65) **Prior Publication Data**

US 2012/0089013 A1 Apr. 12, 2012

Related U.S. Application Data

(63) Continuation of application No. 12/335,061, filed on Dec. 15, 2008, now Pat. No. 8,086,298.

(60) Provisional application No. 61/100,870, filed on Sep. 29, 2008.

(51) **Int. Cl.**

A61B 5/055	(2006.01)
A61B 19/00	(2006.01)
A61B 5/06	(2006.01)
A61B 8/12	(2006.01)
A61B 19/08	(2006.01)
G06T 7/00	(2006.01)
A61B 17/34	(2006.01)

(52) **U.S. Cl.**

CPC . ***A61B 5/06*** (2013.01); ***A61B 5/062*** (2013.01); ***A61B 5/064*** (2013.01); ***A61B 5/065*** (2013.01); ***A61B 5/066*** (2013.01); ***A61B 8/12*** (2013.01); ***A61B 19/081*** (2013.01); ***A61B 19/201*** (2013.01); ***A61B 19/22*** (2013.01); ***A61B 19/5225*** (2013.01); ***A61B 19/5244*** (2013.01); ***G06T 7/0012*** (2013.01); ***A61B 17/3403*** (2013.01); *A61B 2017/3405* (2013.01); *A61B 2017/3413* (2013.01); *A61B 2019/5251* (2013.01)

USPC **600/424**; 128/899

(58) **Field of Classification Search**

CPC A61B 5/06; A61B 5/062; A61B 5/064; A61B 5/065; A61B 5/066; A61B 8/12; A61B 19/081; A61B 19/201; A61B 19/22; A61B 19/5225; A61B 19/5244; A61B 19/5251; A61B 17/3403; A61B 2017/3403; A61B 2017/3405; A61B 2017/3413; A61B 2019/5251; G06T 7/0012

USPC 600/114, 117, 121, 407, 424, 585; 128/899

See application file for complete search history.

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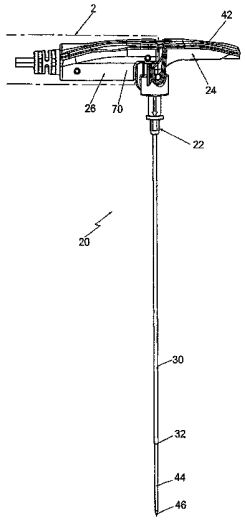
(57) **ABSTRACT**

An EMT system for use in ultrasound and other imaging modality guided medical procedures. The system includes a tool set of various components to which EM sensors can be releasably secured. Thus, the sensors can be reused, notwithstanding the disposal of other components of the tool set. Various components of the tool set include keying elements to facilitate their registration to the anatomy of the patient undergoing the procedure via the EM sensors.

7 Claims, 10 Drawing Sheets



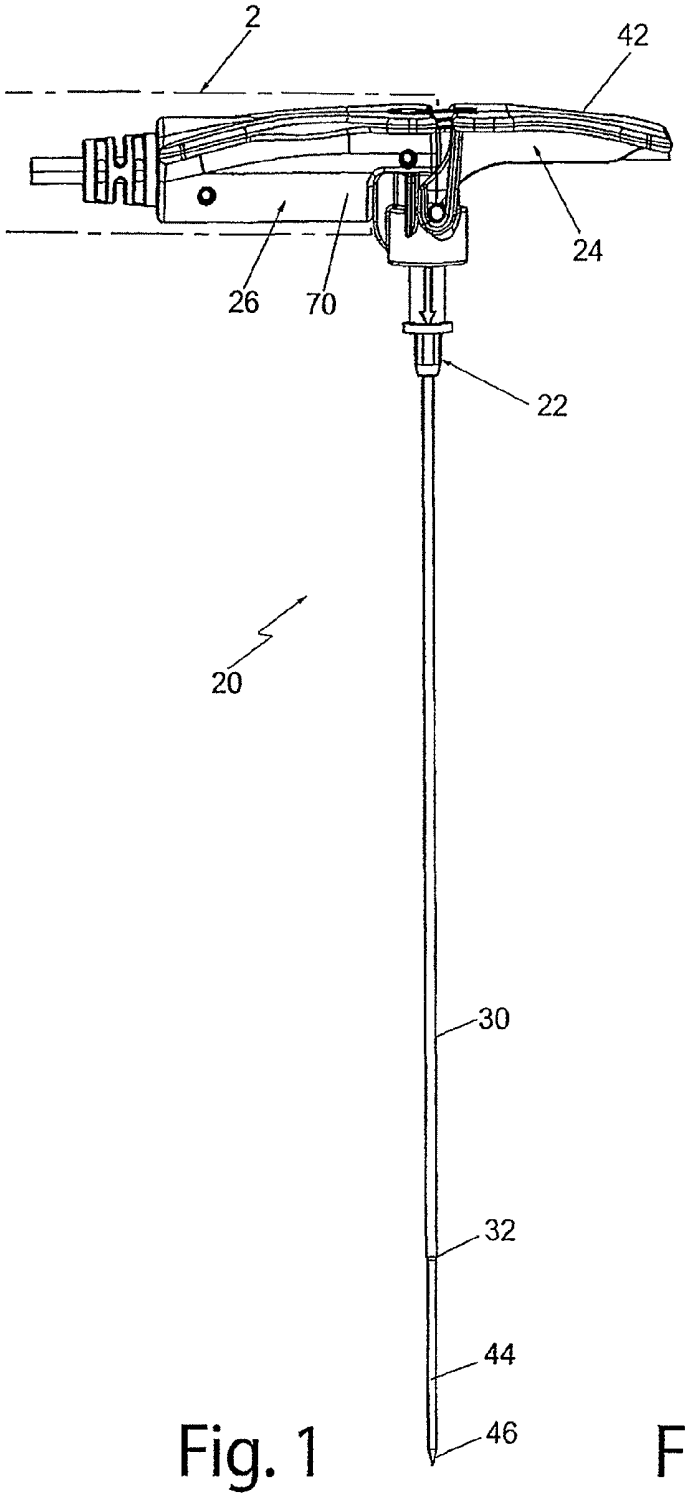


Fig. 1

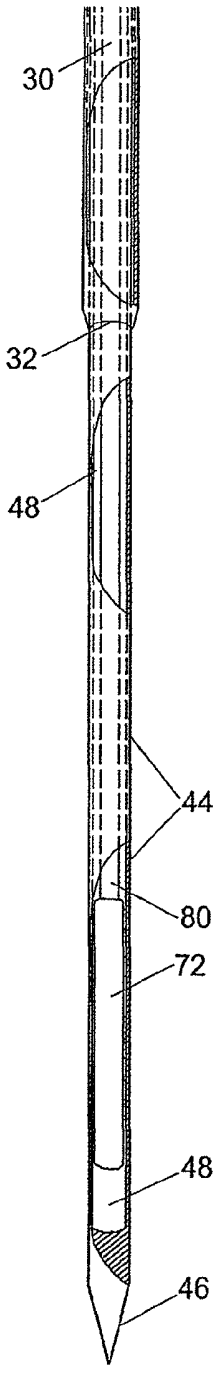


Fig. 2

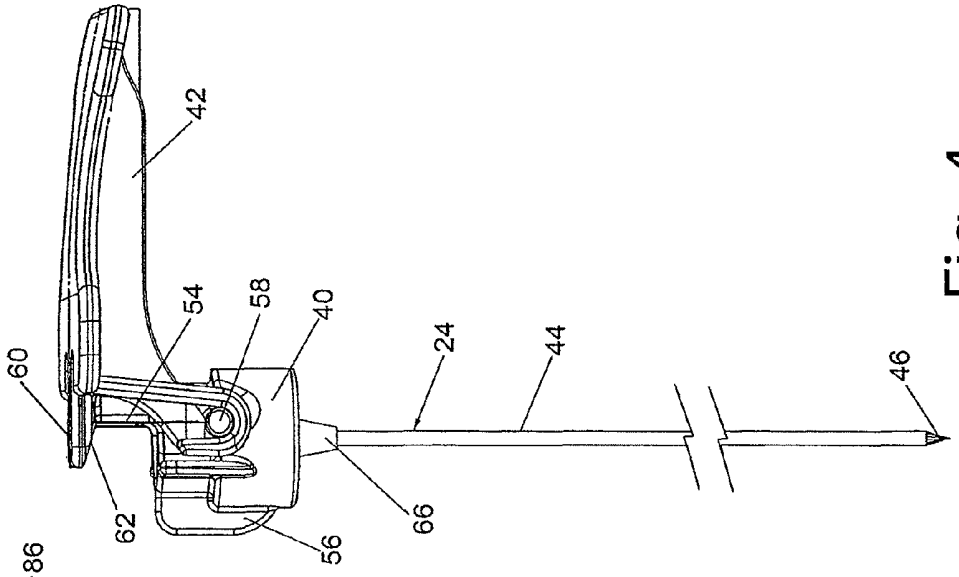


Fig. 4

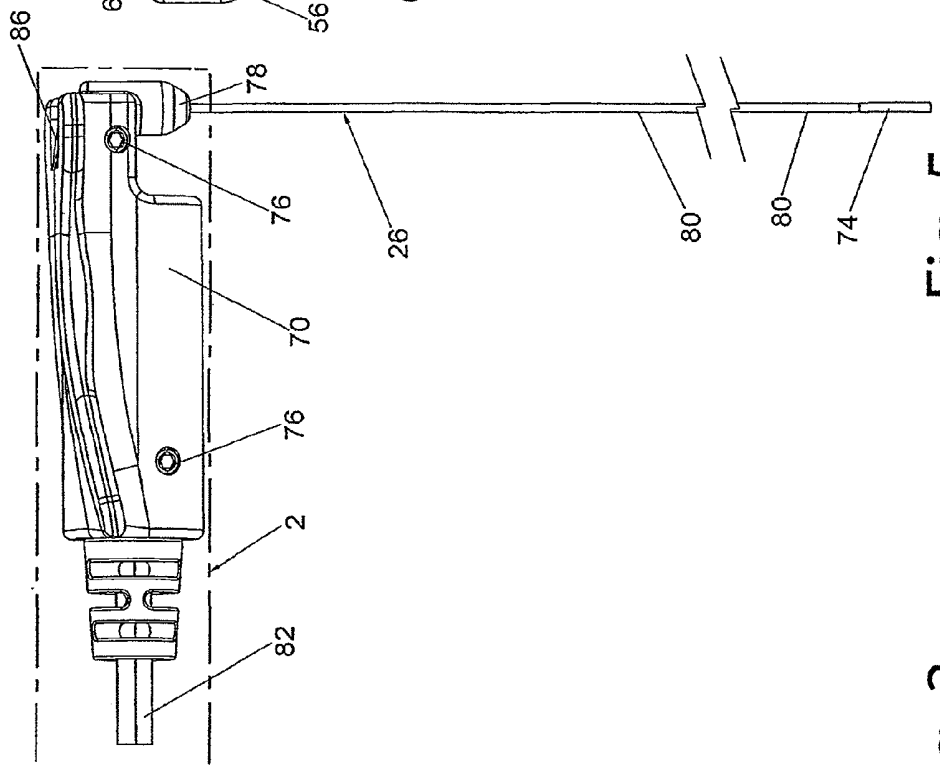


Fig. 5

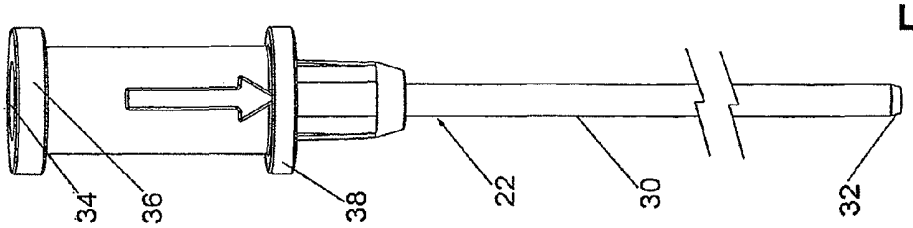


Fig. 3

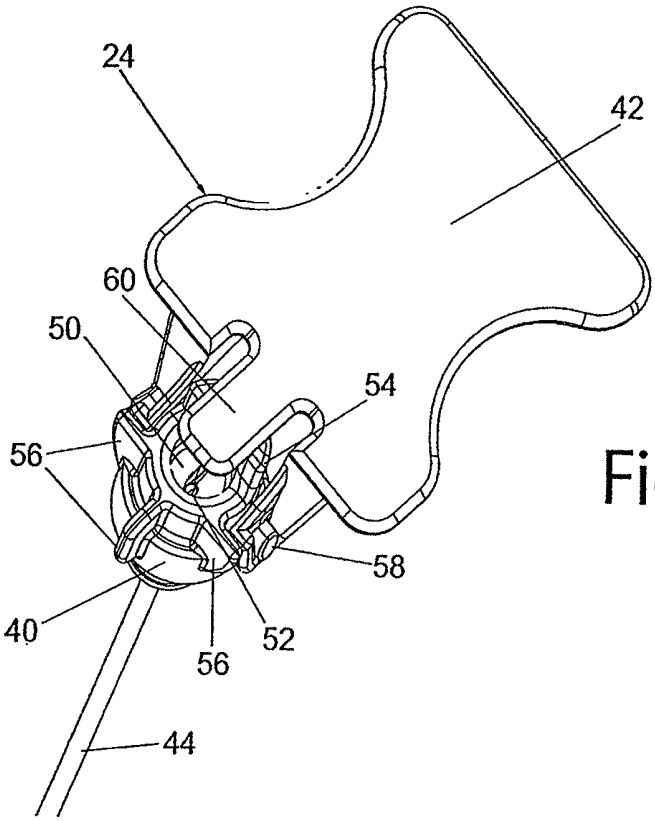


Fig. 4A

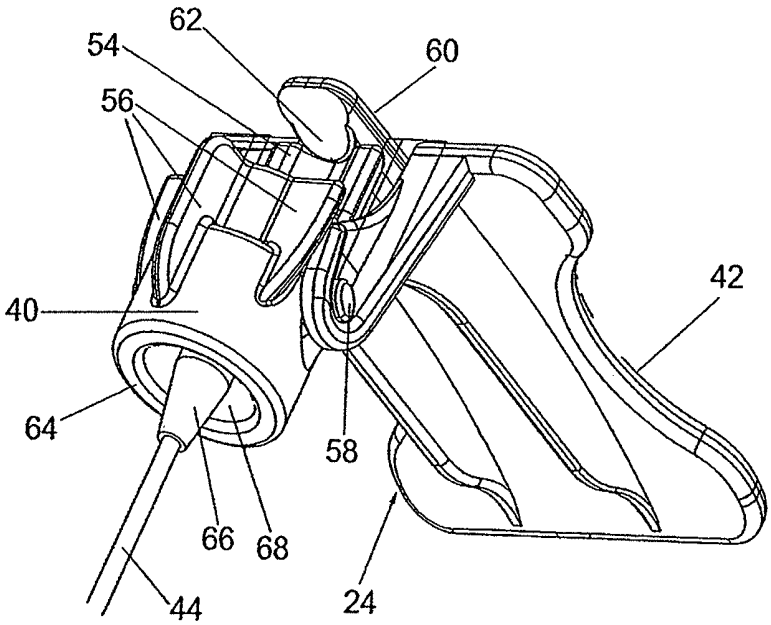


Fig. 4B

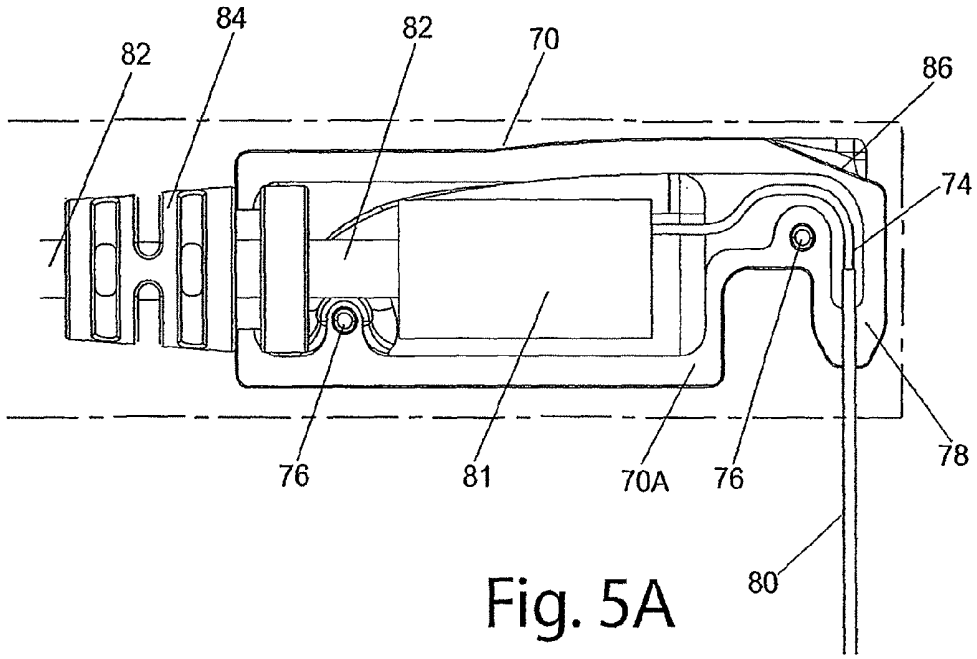


Fig. 5A

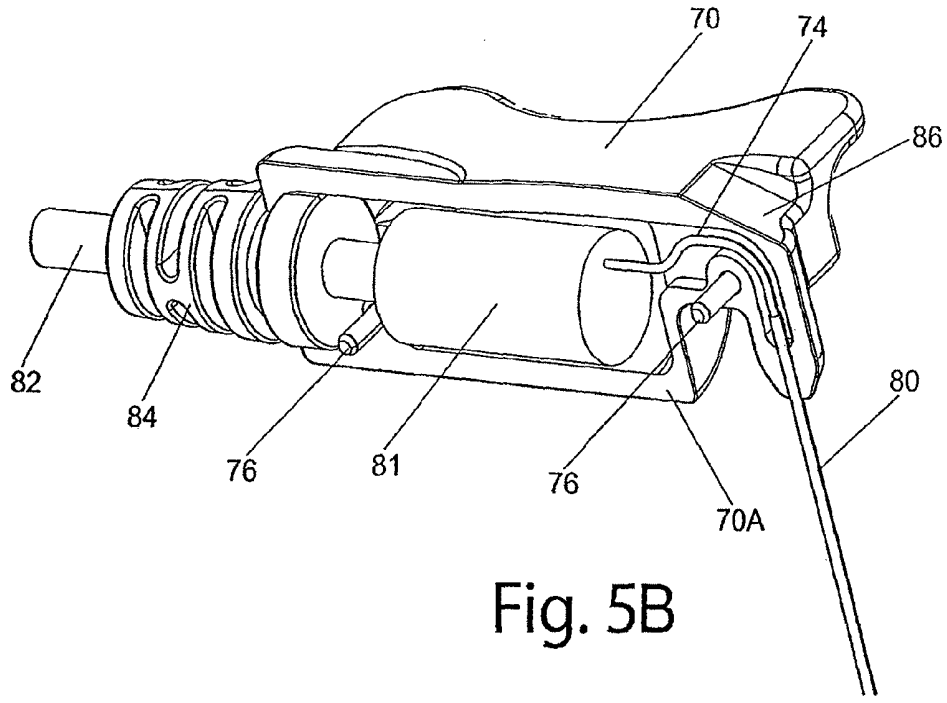


Fig. 5B

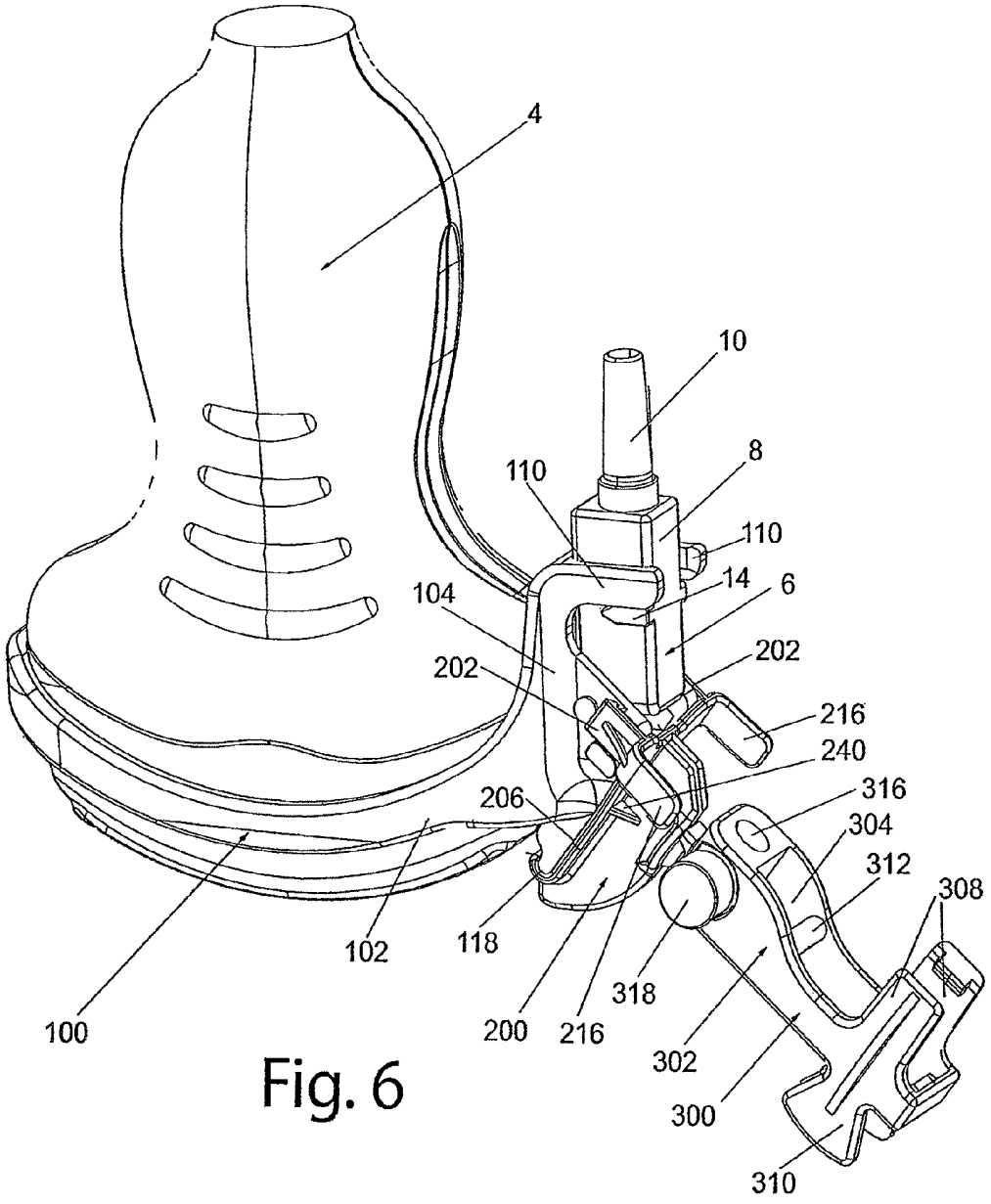

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Fig. 6

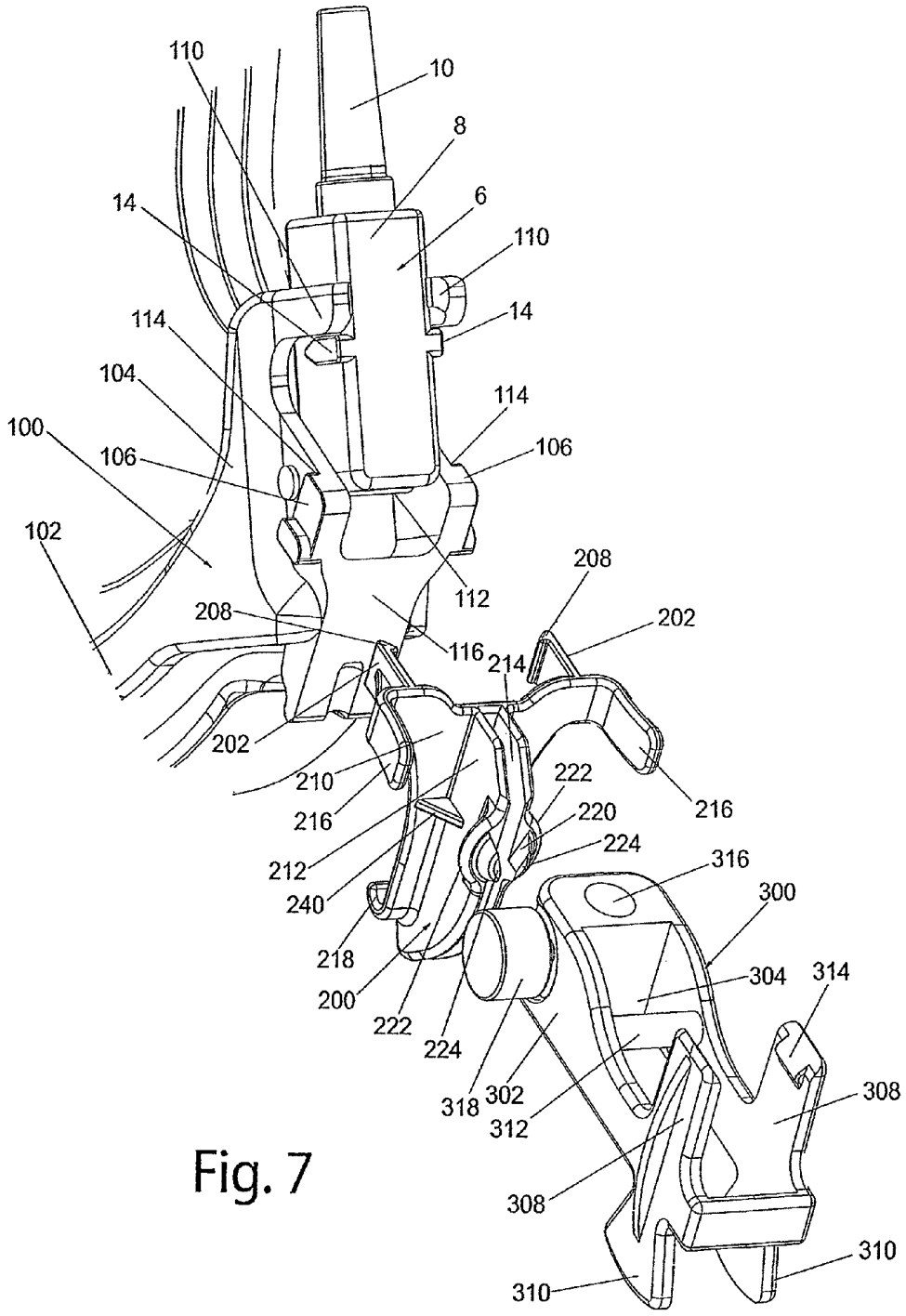
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Fig. 7

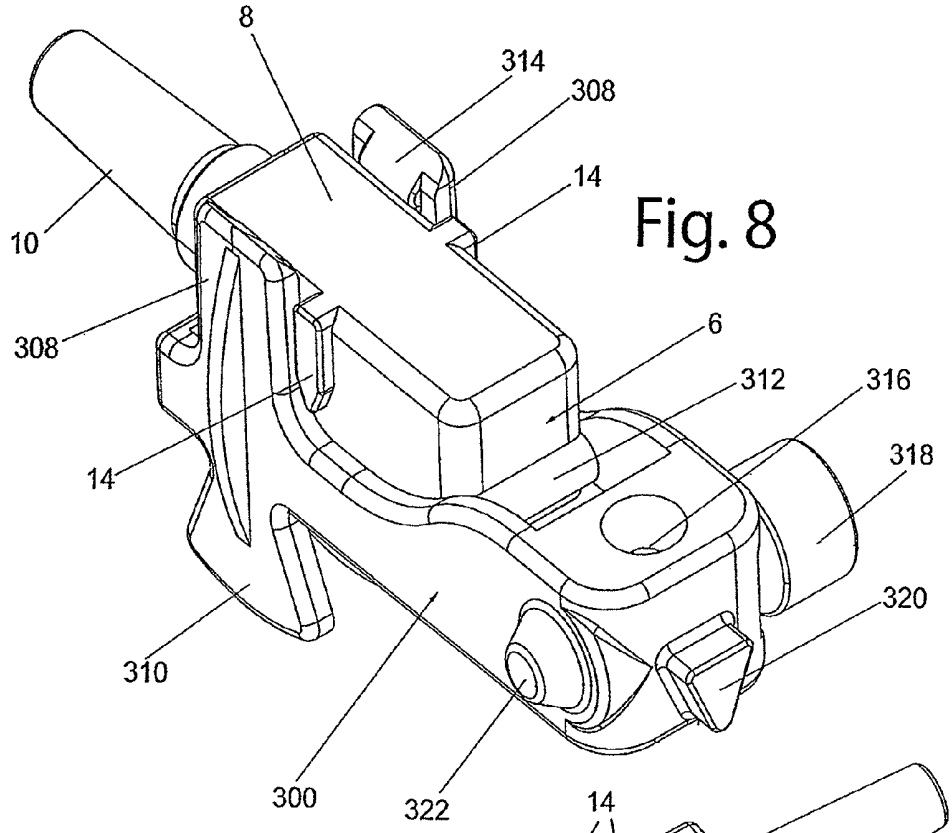
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Fig. 8

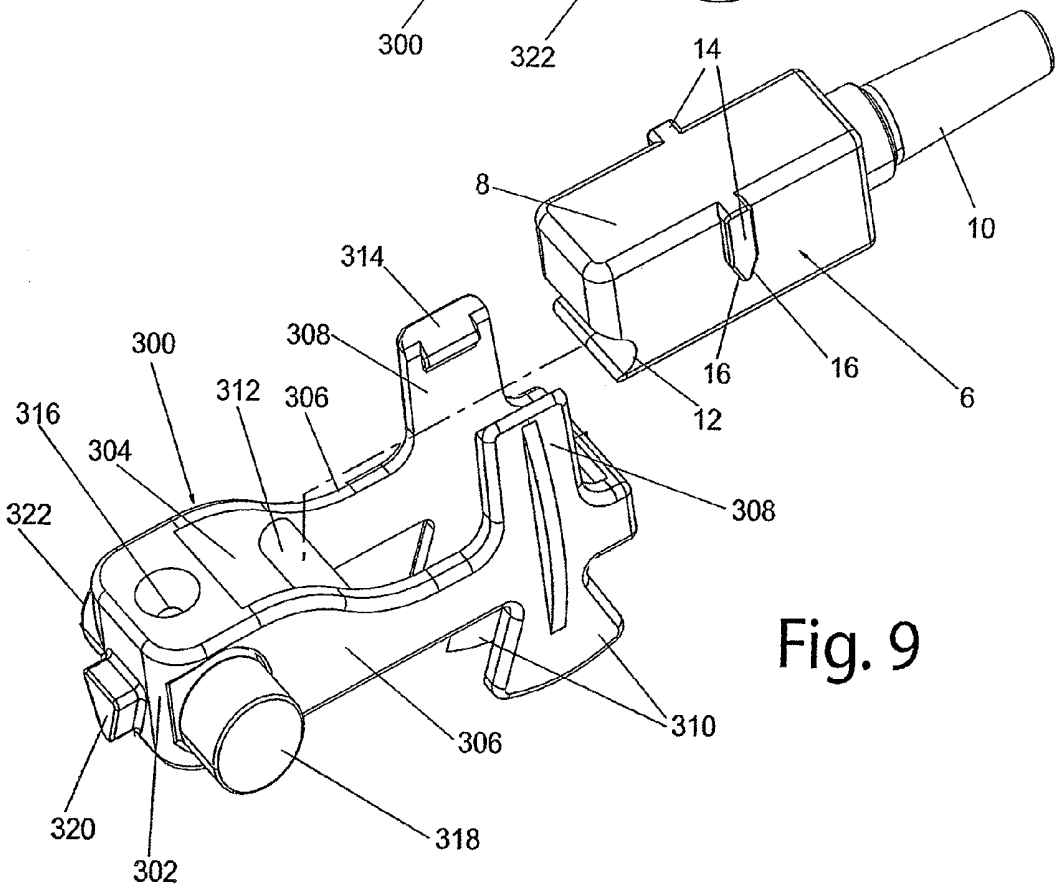
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Fig. 9

Fig. 10

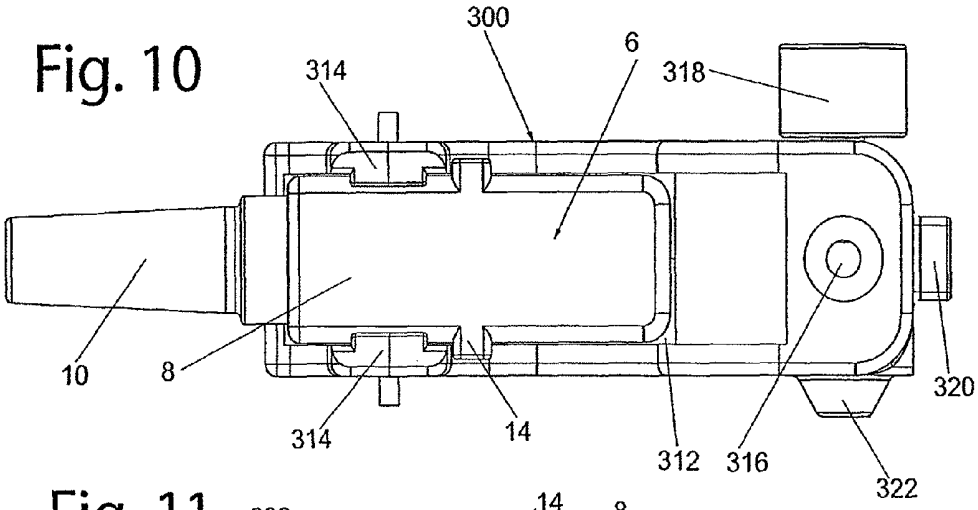
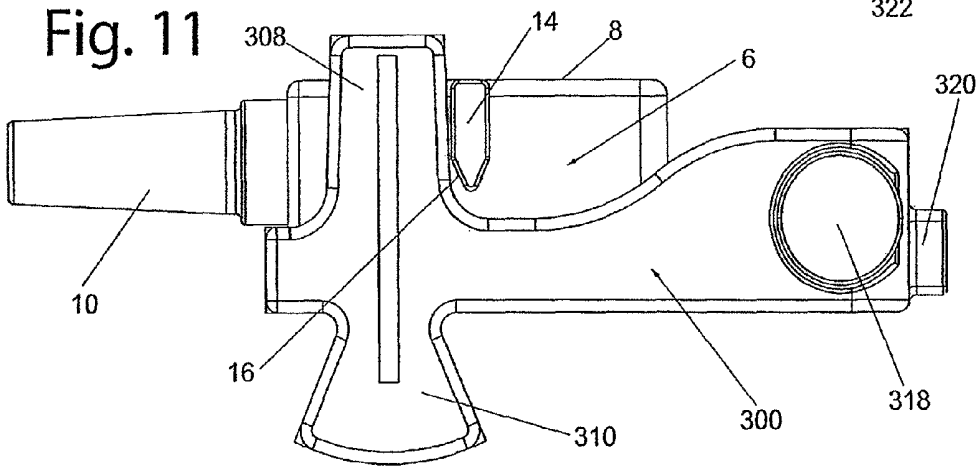


Fig. 11



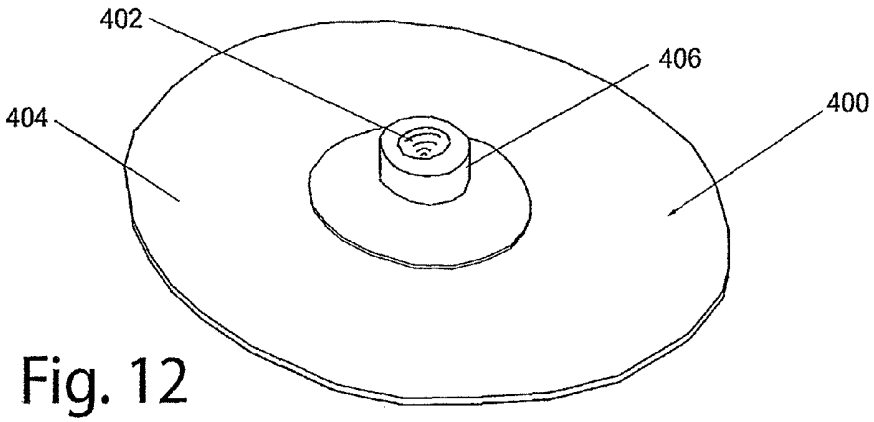


Fig. 12

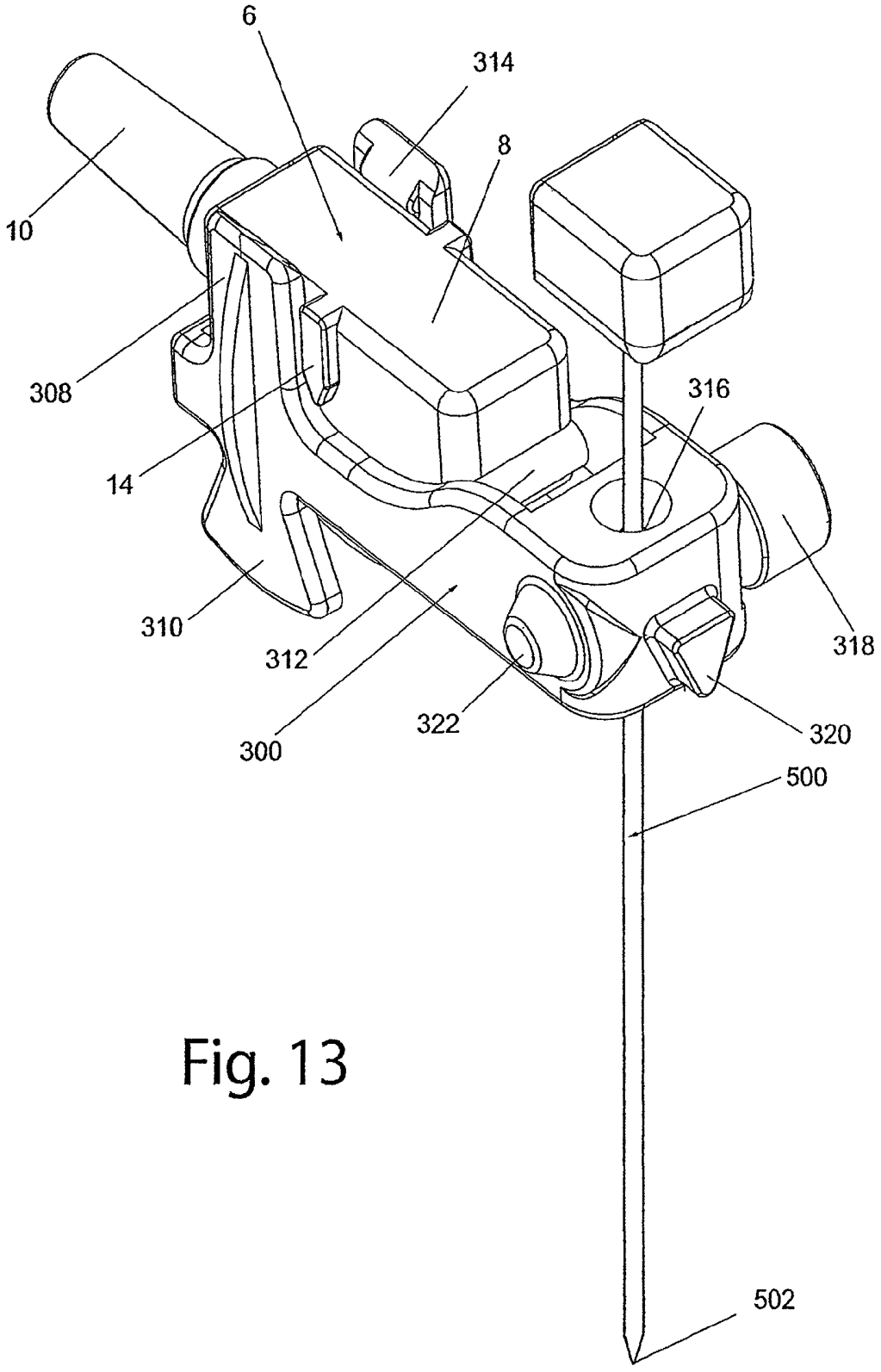
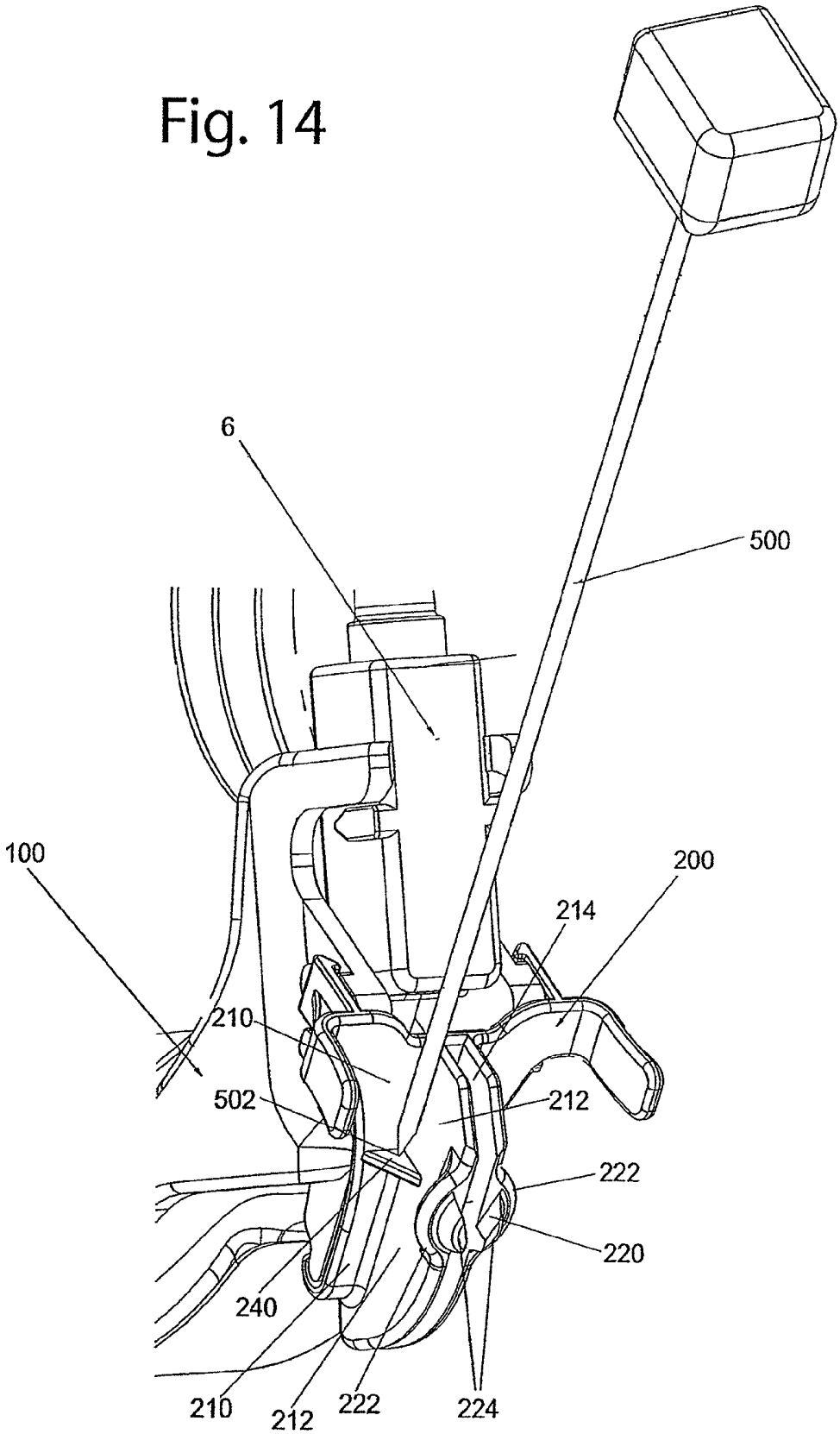


Fig. 13

Fig. 14



EM TRACKING SYSTEMS FOR USE WITH ULTRASOUND AND OTHER IMAGING MODALITIES

CROSS-REFERENCE TO RELATED APPLICATIONS

This continuation application claims the benefit under 35 U.S.C. §120 of application Ser. No. 12/335,061, filed on Dec. 15, 2008 now U.S. Pat. No. 8,086,298, and entitled "EM Tracking Systems For Use With Ultrasound Transducers", which claims the benefit of Provisional Application No. 61/100,870 filed Sep. 29, 2008 and entitled "EM Tracking Systems For Use With Ultrasound Transducers" under 35 U.S.C. §119(e), and the entire contents of each of these applications are expressly incorporated herein by reference thereto.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

"Not Applicable"

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISK

"Not Applicable"

FIELD OF THE INVENTION

This invention relates generally to medical instrument tracking system and more particularly to tools sets enabling the use of electromagnetic (EM) field multidimensional tracking technology for instrument guidance within a patient using medical images (both 2-D and 3-D data sets of real time and/or delayed and/or fused images) registered to a patient.

BACKGROUND OF THE INVENTION

Ultrasound has received widespread acceptance as a useful diagnostic tool by providing an image of the internal area of inquiry by emission of very high frequency sound waves from a transducer (commonly called a "probe") placed in contact with the patient's skin adjacent that area of inquiry. Repeated arrays of ultrasonic beams scan that area and are reflected back to the transducer, where the beams are received and the data transmitted to a processing unit. A processing unit, to which the probe is connected, analyzes the information and composes a picture for display on an associated monitor screen. For some applications the determination of the precise position or location of the probe in real time with respect to the patient's body is desirable, e.g., to correlate, register or "fuse" the ultrasonic image to other scans (digital image sets), such as CT scans, MR scans, PET scans, and the like. This real time correlation matched with targeting software can be combined with real time tracking and navigation systems and devices to navigate an instrument within a patient for minimally invasive procedures. In other settings such as CT, when ultrasound is not available or useful virtual navigation of an instrument within a patient also may be image-guided by having the images registered to the patient using fiducial markers and also registered to a navigation and tracking device or system using recently acquired volume images (data sets) that are then co-registered to both the images and the navigation system.

Optical and electromagnetic tracking (EMT) technologies are two non-mechanical, real-time, approaches for accurate instrument tracking and navigation using appropriately registered volume images (digital data sets). Both optical and electromagnetic technologies have advantages and limitations, but on balance the technological advantages of EMT for minimally invasive procedures are dominant. In particular, EMT is believed to be the preferable technology because of the ability to track objects inside the body (beyond line-of sight) and the compact size of the tracked sensors. These powered sensors typically provide position and orientation data sets of 5 or 6 degrees-of-freedom (DOF) and combined with the electronic cables required are relatively expensive.

EMT systems that support image fusion and instrument tracking are commercially available and disclosed in the patent literature. They typically enable determination of 5 or 6 DOF orientation and position of an instrument, such as a needle, by determining location, orientation, and/or positioning information relative to some coordinate system. For example, Ascension Technology Corporation makes 5 and 6 DOF position and orientation tracking devices suitable for various medical applications, e.g., to navigate, localize, and guide medical instruments for image-guided procedures. Other manufacturers/suppliers of EM tracking systems include Polhemus, Inc. Northern Digital Inc. and Medtronic, Inc. Suppliers of software, tracked needles and other instruments for clinical use that utilize these technologies in medical procedures include Traxtal Corporation and Veran Medical. Image fusion in combination with ultrasound is available from Traxtal, Inc., GE Healthcare Ultrasound and Esaote Ultrasound, among others.

Typically these tracking systems use the attenuation of oriented electromagnetic signals to determine the absolute position and orientation of a sensor, relative to a source, e.g., a magnetic field generator. The source and the sensor are connected via cables to an electronics module, which contains a microcomputer and associated electronics of the system. The source typically includes three orthogonal coils that are pulsed in rotation, one after another. Each pulse transmits a radio frequency electromagnetic signal that is detected by the sensor. The sensor also contains two or three orthogonal coils, which measure the strength of the signal from the current source coil. By using the known pulse strength at the source and the known attenuation of the strength with distance, the position and orientation of the sensor coils can be calculated by the system via triangulation techniques.

Utilizing EM sensors with ultrasonic probes can be accomplished by permanently mounting the sensor(s) on the probe or by building such sensor(s) into the probe. However, the permanent mounting approach may not be desirable if the probe is also intended to be used in applications wherein its position need not be determined. Also, the inclusion of such sensor(s) permanently on or in the probe will likely increase the cost, complexity and service requirement of the probe. Therefore external attachment, when needed, has become the commercially dominant approach. The challenge in this case is to locate and attach, when required, the removable sensor(s) to the probe in a way that that is quick, secure and ergonomic. Thus, the use of some releasable mounting system has become a required element for registration and fusion of volume image data sets from CT, MR, PET, etc. for use during real time ultrasound imaging. This has been done by several companies to date, including GE Healthcare Ultrasound, Hitachi and Esaote Ultrasound.

In U.S. patent application Ser. No. 12/111,387, filed on Apr. 29, 2008, entitled "Bracket for Mounting At Least One Position Detecting Sensor On An Ultrasonic Probe", which is assigned to the same assignee as this invention and whose disclosure is incorporated by reference herein, there is dis-

closed a bracket for use with an ultrasound transducer to releasably mount at least one sensor of a location/tracking system on the transducer and serves as one unique solution to fulfill this commercial ideal.

Other medical components or devices making use of EM sensors have been provided as part of an EMT system for use with EM tracked ultrasound transducers and also may be used in properly registered CT or CT fused with PET or MR image sets without ultrasound. These devices include needles of all types, fiducial markers with EMT sensors embedded to aid with patient and image data registration, and other tracked devices. These tracked devices, especially the needles with sensors in the tip, have been shown to have great advantages for simplifying the safe and accurate placement of these instruments during minimally invasive procedures. However, to date most devices and all existing needles using EM tip sensors have the sensor(s) permanently attached and must be discarded after a single use or require time and expense to re-process and re-sterilize. In most cases the cost of these disposable devices makes the routine use of EM tracking and navigation cost-prohibitive. Thus, until now, expense has been a serious limiting factor to general adoption of EM technology for image guidance.

The subject invention entails a complete mechanical tool set that will allow re-use of all the expensive sensor components of an EMT system to greatly reduce costs per procedure in the rapidly expanding market for image fusion and guidance. While re-using the expensive 5 and 6 DOF powered (active) EM sensors will require a more complex setup and assembly process for each use, the payoff in reduced cost per procedure is believed to be so critical that the small extra time required for such set-up will be gladly tolerated.

The complete EMT tool set for providing image guidance in ultrasound applications and for other imaging modalities includes not only the subject matter of this invention (which will be described shortly), but also dedicated system software. It is anticipated that most of such registration, navigation and image fusion software will be developed and supplied by the original equipment manufacturers of the imaging hardware.

The system of this invention is in the form of an image fusion and navigation tool set that includes a number of components. Foremost among those components is a specially designed needle (trochar) with a reusable EM sensor in the tip of the stylet. Other components include, a specially designed ultrasound bracket to accept one or more reusable EM sensor(s) and a needle guide (e.g., a slotted needle guide enabling mechanical positioning of the linear instrument within the image plane of the ultrasound transducer). In addition, the subject tool set includes a releasably securable adapter device for mounting a reusable EM sensor on any needle or elongated medical instrument (e.g., biopsy needles, syringes, ablation needles, (cryoprobes, RF probes, catheters containing a stylet, etc.)) to convert that instrument into an EM trackable instrument (which will be accurate in the absence of bending/deflection beyond the attachment point of the device), and skin surface markers for facilitating three dimensional image registration and image fusion in certain circumstances (e.g., these may not be useful in cases where ultrasound is used because more accurate registration may be achieved using internal anatomic landmarks visible on real time images). Those markers can be either the passive or active types. Passive type markers are typically sterile adhesive devices that contain only a radio-opaque marker and/or a marker visible on MR imaging. The passive markers of this invention also include a keying feature for registration using an EM sensor (contained within a housing). Active type skin surface markers are typically non-sterile adhesive devices with embedded or attached EM sensors that can with proper software support provide continuous real-time automatic registration updates for image fusion and navigation. Traxtal, Inc. and Veran Medical Technologies provide skin surface markers with embedded EM sensors, while the present invention proposes skin surface markers with attachable EM sensors. In accordance with one aspect of the present invention in order to provide active markers, passive markers are supplemented with a mounting bracket that is adapted to receive a reusable EM sensor. In addition to the foregoing, it is anticipated that the EMT tool set will also include custom sterile disposable cover/drape packages to allow sterility and re-use without reprocessing of the expensive EM sensors and connecting cables.

The EMT tool set of the subject invention is intended to support any EM technology and function with all imaging modalities alone or in combination (fusion). In particular, the components of the subject invention will enable CT, PET-CT, or MR image fusion with or without a real-time ultrasound image and 5 or 6 DOF navigation within the EM field. Properly applied, the technology of this invention will allow better visualization of target lesions in the body and highly accurate instrument navigation to reach them more quickly and safely. In particular, it is anticipated that the subject invention will be used by the full spectrum of clinicians that employ image guidance for reaching internal targets within a patient.

The subject invention's image fusion and navigation tool set is designed with a universal approach allowing components to be used across all OEM imaging platforms. It is anticipated that the subject invention will be utilized by physicians in the following specialties: interventional radiology, radiology, surgery and cardiology. Anticipated clinical applications are biopsy procedures, ablation procedures, catheter placements, intravascular procedures and endoscopic procedures.

All references cited and/or identified herein are specifically incorporated by reference herein.

SUMMARY OF THE INVENTION

In accordance with one aspect of the invention there is provided an instrument, e.g., a trochar, for insertion into the body of a patient via a sheath for use in an ultrasound-guided procedure on the patient, with the position of the instrument to be tracked with respect to the being by an EMT system. The instrument comprises an EM sensor and a first member. The first member comprises a first handle and an elongated linear stylet secured to and projecting from the first handle. The linear stylet has a distal tip portion and a hollow interior cavity terminating adjacent the distal tip portion. The EM sensor has an electrical cable connected to it. The EM sensor is disposed within the cavity located adjacent the distal tip portion of the stylet and with the electrical cable extending along the length of and out of the cavity. The sensor and the associated cable are arranged to be removed from the cavity of the stylet for reuse.

In accordance with another aspect of this invention there is provided a device for releasable mounting on an elongated, linear medical instrument used in an ultrasound-guided procedure on a patient, with the procedure being carried out by an ultrasound transducer to enable the position of the instrument to be tracked with respect to a patient by an EMT system. The instrument has a distal end portion. The device basically comprises an EM sensor and a housing for the sensor. The housing mounts the sensor and is releasably securable to the instrument at various positions along the length of the instru-

ment. The housing comprises a first keying member arranged to be releasably coupled to the ultrasound transducer, e.g., to a slotted needle guide mounted on a bracket that is mounted on the ultrasound transducer, to enable the EMT system to register the sensor with respect to the ultrasound transducer. A second keying member may be provided on the ultrasound transducer, e.g., on the needle guide, so that the distal end portion of the instrument can be releasably coupled to the second keying member to enable the EMT system to register the distal end portion of the instrument with respect to the sensor.

In accordance with another aspect of this invention there is provided an instrument guide and/or a bracket for use on an ultrasound transducer in an ultrasound-guided procedure on a patient by an elongated linear instrument. The instrument has a distal end portion. The instrument guide and/or a bracket forms a portion an EMT system and is arranged to receive the instrument. The EMT system comprises a sensor including a housing having a first keying member. The instrument guide and/or a bracket includes a first keying member adapted to be releasably coupled to the first keying member of the sensor to enable the EMT system to register the sensor with respect to the ultrasound transducer. A second keying member may be provided on the instrument guide and/or a bracket so that the distal end portion of the instrument can be releasably coupled to the second keying member to enable the EMT system to register the distal end portion of the instrument with respect to the sensor.

In accordance with another aspect of this invention there is provided an EMT system for use in an ultrasound-guided procedure on a patient by an elongated linear instrument comprising a first component adapted for mounting on an ultrasound transducer and a second component including an EM sensor. The instrument has a distal end portion. The first component is arranged to receive the instrument. The second component comprises a sensor, including a housing for the sensor. The housing comprises a first keying member. The first component comprises a first keying member adapted to cooperate with the first keying member of the housing of the second component to enable the EMT system to register the sensor with respect to the ultrasound transducer. The first component may additionally comprises a second keying member so that the distal end portion of the instrument can be releasably coupled to the second keying member to enable the EMT system to register the distal end portion of the instrument with respect to the sensor.

In accordance with another aspect of this invention there is provided an EMT system for use in an ultrasound-guided procedure on a patient comprising a first component and a second component. The first component is a marker adapted for securement to the patient. The second component comprises a sensor including a housing for the sensor. The housing comprises a first keying member. The marker comprises a first keying member adapted to cooperate with the first keying member of the housing of the second component to enable the registration of the marker with respect to the body of a patient.

DESCRIPTION OF THE DRAWING

FIG. **1** is a side elevation view of an EM trackable trochar constructed in accordance with one aspect of this invention and forming a portion of the EMT system of this invention;

FIG. **2** is an enlarged side elevational view, partially in section, showing the distal end of the trochar shown in FIG. **1**;

FIG. **3** is an enlarged isometric view of one component assembly of the trochar of FIG. **1**, namely, an assembly of a luer connector and an associated tubular sheath;

FIG. **4** is an is an enlarged isometric view of another component assembly of the trochar of FIG. **1**, namely, an assembly of a handle and stylet;

FIG. **4**A is an enlarged isometric view of the handle shown in FIG. **4**;

FIG. **4**B is another enlarged isometric view of the handle shown in FIG. **4**.

FIG. **5** is an is an enlarged isometric view of another component assembly of the trochar of FIG. **1**, namely, an assembly of another or second handle, an EM sensor and its associated cable;

FIG. **5**A is an enlarged isometric view of one of two sections of the handle shown in FIG. **5**, with the other section of that handle removed;

FIG. **5**B is another enlarged isometric view of the section of the handle shown in FIG. **5**A;

FIG. **6** is an isometric view of a conventional ultrasound transducer on which an EM sensor-mounted bracket is disposed, with a slotted needle guide mounted on the bracket and with an instrument adapter shown being registered to the needle guide, all of which form respective portions of the EMT system of this invention;

FIG. **7** is an exploded isometric view of the EMT system components shown in FIG. **6**;

FIG. **8** is an enlarged isometric view of the instrument adapter shown in FIGS. **6** and **7** having an EM sensor mounted thereon, whereupon the sensor-equipped adapter can be used with any conventional medical needle or other elongated linear medical instrument (not shown) to convert the needle/instrument into an EM trackable needle/instrument;

FIG. **9** is an exploded isometric view of the sensor-equipped adapter of FIG. **8**;

FIG. **10** is an enlarged top plan view of the sensor-equipped adapter of FIG. **8**;

FIG. **11** is an enlarged side elevation view of one side of the sensor-equipped adapter of FIG. **8**;

FIG. **12** is an isometric view of a passive EM marker constructed in accordance with this invention and having a keying feature constructed in accordance with another aspect this invention to enable a sensor-equipped adapter, like shown in FIG. **8**, or some other sensor-equipped component to be used to register the marker in the EMT system of this invention;

FIG. **13** is an enlarged isometric view showing the sensor-equipped adapter of FIG. **8** mounted on a conventional disposable needle to convert that needle into an EM trackable needle; and

FIG. **14** is an enlarged isometric view showing the needle of FIG. **13** with the sensor-equipped adapter mounted thereon in the process of being registered to the ultrasonic transducer by the EMT system of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the various figures of the drawing wherein like reference characters refer to like parts, there is shown in FIGS. **1**-**5**B an EM trackable trochar **20** forming one portion of an EMT system tool set constructed in accordance with this invention. The EM tracking tool set also includes several other components, such as an EM sensor-equipped bracket **100** (shown in FIGS. **6**-**7**), a slotted needle guide **200** (also shown in FIGS. **6**-**7**), an EM sensor-equipped adapter **300** (shown in FIGS. **8**-**10**), and an external skin marker **400** (shown in FIG. **12**).

The details of each of the components of the tool set of this invention will be described later. Suffice it for now to state that the EM trackable trochar **20** includes an EM sensor and associated components which can be reused, while the other components of that device are designed for single use and then disposal.

The bracket **100** is arranged to be mounted on a conventional ultrasonic transducer **2**, with a sterile cover (not shown) interposed therebetween and includes a mount for an EM sensor to enable the ultrasonic transducer to be registered to the anatomy of the patient undergoing the ultrasound procedure by the EMT system of which the sensor is a component.

The slotted needle guide **200** is arranged to be releasably mounted on the bracket **100** and includes a slot into which a needle, e.g., a conventional biopsy needle, can be inserted and its position detected and tracked by the ultrasonic transducer.

The EM sensor-equipped adapter **200** (shown in FIGS. **8-10**) is arranged to be mounted on any conventional needle, such as shown in FIGS. **13** and **14**, or any other elongated linear medical instrument to convert that needle/instrument into an EM trackable needle/instrument.

The external skin marker **300** is a device that is arranged to be releasably secured (e.g., by a releasable adhesive) to the skin of the patient to serve as a reference point for the EM tracking system.

Turning now to FIGS. **1-5**B the details of the trackable trochar **20** will now be described, first by describing its various components and then by describing its use and operation. The trackable trochar **20** basically comprises three component assemblies, namely, a luer lock-sheath assembly **22** best seen in FIG. **3**, a handle-stylet assembly **24** best seen in FIGS. **4**, **4**A and **4**B, and a handle-EM sensor assembly **26** best seen in FIGS. **5**, **5**A and **5**B. The handle-EM sensor assembly **26** is arranged to be reused, while the luer lock-sheath assembly **22** and the stylet-handle assembly **24** are each single-use disposable members. Since the handle-EM sensor assembly **26** is arranged for reuse, it will be provided with a sterile, single use cover **4** (shown by the phantom lines in FIGS. **1** and **5**) during use, as will be described later.

The luer lock-sheath assembly **22** is best seen in FIG. **3** and basically comprises a conventional luer lock connector **28** and a conventional sheath or cannula **30** fixedly secured together. The sheath is an elongate linear tubular member that has an open distal end **32**. The luer lock connector **28** is a hollow member whose proximal end is open at **34**, i.e., is defined by a circular side wall **36**. An annular ring **38** projects outward from the connector **28** to enable the user to readily grasp the luer lock-sheath assembly **22** during its use (to be described later). The luer lock-sheath assembly **22** is a disposable, i.e., single use, member adapted to be releasably mounted on the handle-stylet assembly **24**. To that end, the circular sidewall **36** of the luer lock-sheath assembly **22** is arranged for disposition within an annular shaped recess in the handle-stylet assembly **24** to releasably frictionally secure those components together.

The handle-stylet assembly **24** is best seen in FIG. **4** and basically comprises a hub **40**, a pivotable handle **42** and a stylet **44**. The stylet **44** is formed of any conventional material, e.g., stainless steel, and includes a sharpened or pointed distal tip **46**. The stylet is hollow along most of its length, except for its distal end portion as shown in FIG. **2**. The hollow interior of the stylet **44** forms a cavity **48** arranged for releasable receipt of an EM sensor and its associated cable forming a portion of the handle-EM sensor assembly **26**. The stylet can be of any size, e.g., 16 gauge or smaller, for co-axial technique percutaneous tracking of its tip.

The hub **40** of the handle-stylet assembly **24** is best seen in FIGS. **4**A and **4**B and basically comprises a hollow member having a central recess **50** with an opening **52** at its nadir that is in communication with the cavity **48** in the stylet **44**. An arcuate wall **54** projects upward from the hub **40**. Three reinforcing ribs **56** project outward from the hub. The hub also includes a pair of pins **58** projecting diametrically outward from it perpendicular to the longitudinal axis of the hub. The pins serve to pivotably mount the handle **42** onto the hub. The top surface of the handle **42** is flat and includes a finger **60** having a sloped, e.g., 15 degree inclined, cam surface **62** on its underside. The finger **60** is somewhat flexible for reasons to become apparent later. A circular wall **64** projects downward from the hub **40**. The point at which the stylet is connected to the hub **40** is in the form of a conically shaped projection **66**. The circular wall **64** extends about the projection **66** to form an annular recess **68** into which the circular proximal portion of the wall **36** of the luer lock connector **28** is disposed to frictionally connect the luer lock-sheath assembly **22** to the handle-stylet assembly **24**. When so connected the projection **66** of the handle-stylet assembly is located within the hollow interior of the luer lock connector **28** and the stylet **44** extends down the hollow interior of the sheath or cannula **30** and out its open end **32** (see FIG. **2**).

The handle **42** of the handle-stylet assembly **24** is arranged to be selectively moved between a locked position, such as shown in FIGS. **1** and **4**, to an unlocked position, and vice versa. When the handle **42** is in the locked position, as best seen in FIG. **4**B, the undersurface **62** of the finger **60** overhangs the top surface of the upstanding wall **54**, thereby releasably locking the handle in that position. When the handle is in the unlocked position, such as by rotating it in the clockwise direction, the finger **60** will be off of the upstanding wall **54**, thereby fully exposing the hollow interior of the recess **50** in the hub. This action readies the handle-stylet assembly **24** to be coupled to the handle-EM sensor assembly **26**, as will be described later.

The handle-EM sensor assembly **26** is best seen in FIG. **5** and basically comprises a handle **70**, an EM sensor **72** of conventional construction and an electrical cable **74** connected to the sensor **72**. The handle **70** is composed of two hollow sections which are adapted to be secured together via a pair of screws **76**. In FIGS. **5**A and **5**B only one handle section **70**A is shown. The other section of the handle **70** is of identical construction to section **70**A. As can be seen the handle **70** includes a downwardly projecting portion **78** through which a proximal portion of the sensor's cable **74** extends. The sensor cable **74** is a thin, relatively flexible member. In order to provide some rigidity or stiffness to the cable to facilitate its insertion and disposition and the sensor's insertion and disposition within the cavity **48** in the stylet a stiffening coating or tube **80** is provided along the entire length of the cable **74** from the sensor **72** up through the projection **78**. Each of the handle sections making up handle **70** is hollow immediately to the rear of the projection **78**. A cylindrical shield **81** is located within that hollow interior and serves to transition the proximal end of the small diameter sensor cable **74** into a larger and more robust cable section **82** which exits the handle **70** via a strain relief grommet **84**. The top surface of the handle **70** is generally flat (like handle **42**) and includes a downwardly canted cam surface **86** disposed immediately adjacent the projection **78**. This surface is arranged to be pressed downward by the cam surface **62** on the undersurface of the finger **60** of the handle **42** of the handle-stylet assembly **24**. This action causes the cover **2** which is disposed over the handle **70** to be tightly squeezed in the interface between the hub **40** of the handle-stylet assem-

bly **24** and the projection **78** of the handle-sensor assembly **26**, thereby isolating the sensor.

The assembly and use of the tracking trochar **20** will now be described. To that end, the handle **42** of the handle-stylet assembly **24** is pivoted in the clockwise direction to unlock it. In particular, the handle **42** is pushed downward to rotate it in the clockwise direction so that the undersurface **62** of the finger **60** flexes slightly and rides over the top surface of the upstanding wall **54** of the hub **40**, thereby freeing the handle. Continued rotation of the handle in that direction will fully expose the hollow interior of the recess **50** in the hub **40**. This enables a portion of the handle-EM sensor assembly **26** to be inserted therein so that the sensor can be disposed within the cavity in the stylet. Before doing that the cover **2** is disposed over the handle **70** of the handle-EM sensor assembly **26**. The cover **2** is a flexible somewhat resilient member, shaped like a condom, and includes a small opening at one end thereof. The cover is disposed over the handle **70** with the cable extending through the opening. The opening in the cover is sized so that it fits tightly about the stiffening coating or tube **80** on the sensor cable **74**. Once the cover **2** is in place on the handle-EM sensor assembly **26**, that assembly is moved with respect to the handle-stylet assembly **24** so that the sensor **74** enters into the recess **50**, through opening **52** and down through the central channel **48** in the stylet **44** until the sensor is located adjacent the closed distal end of the stylet, e.g., is in a position like shown in FIG. **2**. Once that has occurred the handle **42** can then be rotated back in the counterclockwise direction, whereupon the finger **60** flexes somewhat and the cam surface **62** on the underside of the finger rides over the top edge of the upstanding wall **54** of the hub until it clears the inner surface thereof, whereupon the finger snaps downward to trap the wall, thereby releasably locking the handle **42** in the closed position. In this position the cam surface **62** engages a correspondingly shaped surface **86** on the handle **70** of the handle-EM sensor assembly **26**, thereby pressing downward on that handle. This action presses the projection **78** deeper into the recess **50** of the hub of the handle-stylet assembly, thereby tightly sandwiching the cover **2** therebetween to effectively isolate the sensor from the ambient surroundings and releasably lock the two assemblies **24** and **26** together. The stylet of the connected assemblies **24** and **26** can now be inserted into the luer lock-sheath assembly **22**. To that end, the distal end of the stylet **44** is inserted into the open proximal end **34** of the luer lock connector and down through the open end **32** of the sheath until the conically shaped projection **66** of the hub of the handle-stylet assembly **24** is fully within the hollow interior of the luer lock connector, i.e., the trackable trochar is in the configuration as shown in FIG. **1**. At this point it is ready for use.

The EM sensor **72** enables the trackable trochar **20** to be tracked during its use, e.g., during any ultrasonically directed procedure, in a conventional manner by means of any suitable EM tracking system. For example, the trackable trochar **20** can be inserted percutaneously into any portion of the body of the patient while the EMT system is operated in conjunction with the ultrasound probe to monitor the trochar's position. Once in the desired position, the luer lock-sheath assembly **22** can be held in position by the user of the device while the handle-stylet assembly **24** and the handle-EM sensor assembly **26** are withdrawn as a unit, leaving the luer lock-sheath assembly **22** in place. Any elongated instrument (not shown) can then be introduced through the luer lock-sheath assembly **22** into the patient's body to accomplish the desired procedure, e.g., a biopsy procedure, an ablation procedure, a catheter placement, an intravascular procedure, and endoscopic procedure, etc.

The removed handle-stylet assembly **24** can then be disconnected from the handle-EM sensor assembly **26** and discarded. That disconnection is accomplished by pivoting the handle **42** of the handle-stylet assembly **24** in the clockwise direction to free the finger **60** from the upstanding wall **54** of the hub, as described above. The handle-EM sensor assembly **26** can then be moved with respect to the handle-stylet assembly **24** to withdraw the sensor **72** and its cable **74** from the interior of the stylet **44**. The cover **2** can then be removed from the handle-EM sensor assembly, whereupon that assembly will be ready for reuse, i.e., introduction into the hollow interior of a new handle-stylet assembly after a new cover is placed on it.

As should be appreciated from the foregoing the trackable needle trochar **20** is arranged for insertion into the body of a patient via the sheath **30** for use in an image guided procedure on the patient, with the tip position of the instrument to be tracked with respect to the patient by an EMT system. This is critical because of the high likelihood of bending of the instrument during positioning proximal to the sensor. If this weren't the case then having the sensor attached further up the shaft would be equally accurate and satisfactory in all cases. The sensor is fixed to a handle at a chosen distance away via a reinforced/stiffened section of wires. The wires are of equal or smaller diameter than the sensor in most cases. This is of considerable importance as the diameter of the sensor becomes the limiting factor in how small a needle can be used to track the tip. Cabling is provided from the handle to a receiver plug that goes to a remote power supply and signal processing box (not shown). The strain relief manner at which cable exits the handle is provided in the interest of longevity. The handle-EM sensor assembly **26** is a pre-sterilized component that is intended for single use and includes a hollow needle tipped stylet with a handle and an overlying tubular sheath. Preferably, a sterile sleeve cover including a small hole in the center of the otherwise closed end will be included with this disposable stylet and sheath in a kit for the EM sensor portion. The overlying tubular sheath has a distal end and a proximal end at which a connector (e.g., a luer lock) is located. The distal end of the tubular sheath is open. The first member comprises a first handle and an elongated linear stylet secured to and projecting from the first handle. The linear stylet has a distal tip portion that is closed/sealed and a hollow interior cavity terminating adjacent the distal tip portion. In use, the EM sensor is disposed within the stylet cavity and located adjacent the distal tip portion of the stylet with the stiffened section of electrical cable extending along the length of and out of the stylet cavity into the second handle through which the sensor wires pass. The handle of the stylet and the handle of the sensor are adapted to be releasably locked together to form a T handle when combined and to provide a lateral exit for the sensor cable from the handle of the trochar. The sterile sleeve cover is designed with a small hole in the tip that is required to let the sensor and the stiffened section of wiring leading up to the handle to pass through the sleeve yet allow the sleeve to entirely cover the remaining portion of the reusable handle and cable. The locking section of the stylet handle is designed to compress the junction of the stylet handle and the sensor handle to create a watertight seal using the sterile plastic sleeve cover as the sealing gasket at the junction. The tubular sheath **30** is of a designed length such that when locked in position over the stylet the distal tip portion of the stylet extends out of the open end of the tubular sheath. Since the sensor, the stiffened section of sensor wire, the sensor handle and the associated cable are fully covered by the combination of the sealed tip stylet and the sterile sleeve during any procedure, and are removed from the cavity

of the stylet and uncovered in a controlled manner only when the procedure is completed, it is possible to reuse the sensor repeatedly in sterile procedures without any need for cleaning or sterilization. The other components of the needle trochar assembly **20** are all single-use and disposed of at the end of a procedure.

Referring now to FIG. **6** the details of the transducer bracket **100** and its associated components will now be described. To that end, as can be seen the bracket **100** is shown releasably mounted on a conventional ultrasonic transducer or probe **4**. As is conventional a sterile cover (not shown) is interposed between the bracket and the transducer. The bracket **100** serves to releasably mount an EM sensor assembly **6** thereon. The sensor assembly **6** is a reusable component that comprises a conventional EM sensor disposed within a sealed housing **8**. With the sensor assembly **6** disposed on the transducer **4**, the transducer can be tracked with respect to some frame (not shown) or image set to fuse or register the live ultrasound image to a previously taken image, e.g., a CT scan. This enables the practitioner to navigate the patient's internal anatomy to a desired location with assurance. The sealed housing **8** is a small plastic member having an engineered shape that suits various purposes. The primary purpose is for releasably locking to various tools in the tool set. Another purpose is a keying feature (to be described later) for use in registration of the tools for checking for accuracy of position within the navigation field or for additional registration to images using the passive markers for example. The sensors placed within this housing may be larger and or less costly than the smaller sensors used for the needle trochar **20** with tip tracking described above. These are typically 6 DOF sensors and are precisely located within the housing. In addition, to assure accuracy, their position relative to the external surfaces/features of the housing is calibrated and adjusted electronically during production to a chosen, known and reproducible position. This enables the sensors to become a modular component from the standpoint of the software and other tools in the tool set so that they may be used with most of the tools in the tool set interchangeably.

The bracket **100** basically comprises a ring-like body member **102** which is arranged to snap-fit about a portion of the periphery of the probe **4**, e.g., about the lower or distal portion of the probe as shown in FIG. **6**. The bracket is preferably an integral member, e.g., a molded component formed of any suitable material, e.g., plastic. The ring-like body member **102** includes an upstanding portion **104** which forms a socket for releasably mounting the EM sensor assembly **6**. The socket **104** is defined by a pair of spaced apart walls **106** which project outward and away from the ring-like body portion to form a cavity **108** for receipt of the sensor assembly **6**. The upper end of each wall **106** is in the form of a projecting arm **110**. A cylindrical pin **112** extends through the cavity **108** between the lower end portions of the walls **106**. The pin serves as a pivot point about which the sensor assembly can rotate to releasably mount it to the bracket (as will be described shortly). Before doing that a brief discussion of the details of the construction of the EM sensor assembly **6** is in order. To that end, as best seen in FIG. **9**, the sensor assembly **6** basically comprises a generally parallelepiped shaped housing **8** in which the EM sensor itself (the electrical component, e.g., the EM coils) is mounted. The cable **10** for the sensor exits the housing **8** at the proximal end thereof at a strain relief component. The strain relief component is of significant importance to longevity of the sensor when re-used in this tool set and application(s). The corner of the housing at the distal end (i.e., the end opposite from the cable egress end) includes a semi-circular shaped recess **12** extending across the width of the housing. The radius of the recess **12** is the same or just slightly larger than the radius of the pin **112**.

The releasable mounting of the sensor assembly **6** to the bracket is accomplished by orienting it so that its body **8** is generally perpendicular to the upstanding body portion **104** of the bracket, with its semicircular recess **12** pointed towards and aligned with the pin **112** extending through the bracket's socket. The sensor assembly can then be mounted on the pin (i.e., the pin **112** received within the recess **12**) and once that has been accomplished, the sensor housing can be rotated upward about the pin, whereupon the proximal end portion of the sensor housing snap-fits between the projecting arms **110**. This action releasably locks the sensor assembly **6** in the socket of the bracket **100**. In order to guide the sensor into this releasably locked position, the sensor housing **8** includes a pair of guide members **14** on opposite sides thereof. The inner end of each guide member is in the form of a sloped cam surface **16**. As will be appreciated by those skilled in the art, when the sensor housing is rotated to lock it in place, the sloped surface of each guide will engage the undersurface of a respective one of the projecting arms **106** and ride thereover until the top (distal) surface of each guide member is in abutment with the undersurface of its respective projecting arm. When the sensor assembly is in this position it is effectively snap-fit or locked in the bracket's socket and is thus resistant from accidental disconnection. If and when it is desired to remove the sensor assembly from the bracket, all that is required is to rotate its proximal end downward, i.e., in the clockwise direction, so that it passes between the projecting arms **106**. Once the sensor housing **8** is free of those arms the sensor assembly **6** can be removed from the pin in the socket.

The bracket **100** also includes a portion for mounting the heretofore identified slotted needle guide **200** on it. In particular, the lower end portion of each wall **106** just below the pin **112** is thickened to form an undercut surface **114** (FIG. **7**). The end surfaces of the bottom portion of each wall **106** are coplanar with a sloping, guide-receiving planar surface **116**. The surface **116** is arranged to have an inner surface (to be described later) of the needle guide **200** juxtaposed to it when the needle guide is mounted on the bracket **100**. The body portion **104** of the bracket also includes a pair of axially aligned semi-circular convex surfaces **118** immediately below the lower edge of the guide receiving surface **116**. These convex surfaces serve as pivot points about which a portion of the slotted needle guide **200** can be rotated to releasably snap-fit the needle guide to the bracket. In the furtherance of the snap-fitting of the needle guide to the bracket the needle guide also includes a pair of projecting arms **202** (to be described later) that are arranged to snap-fit to respective ones of the undercut surfaces **114** of the bracket **100**.

The details of the construction of the needle guide **200** will now be described with reference to FIGS. **6** and **7**. The needle guide is preferably formed as an integral unit of any suitable material, e.g., a plastic, and basically comprises a generally T-shaped body member **204** having a generally planar front surface **206**. That surface is the surface that is arranged to be juxtaposed to the receiving surface **116** of the bracket **100** when the needle guide is mounted on the bracket. The heretofore mentioned projecting arms **202** of the needle guide project outward from the top portion of the front surface **206** of the T-shaped body member and are spaced apart by a sufficient distance to accommodate the thickened lower portion of the two walls **106** of the bracket **100** therebetween. Each of the arms **202** terminates in a flanged tip **208** having a cam or sloped outer surface and an undercut lower surface.

The body member **204** also includes a rear surface **210**, from which a pair of walls **212** extend. The walls **212** form a channel **214** between them which is adapted to receive a needle or some other elongated instrument to serve as an orientation guide to facilitate in-plane instrument manipulations within the channel. A pair of squeeze tabs **216** project backward from the upper end of the T-shaped body member adjacent respective ones of the arms **208**. The lower end the T-shaped body member at the front surface **206** is in the form of a pair of axially aligned concave recesses **218**, each of which is arranged to receive a respective one of the axially aligned semi-circular convex surfaces **118** of the bracket **100** to mount the needle guide **200** on the bracket. That action is accomplished by positioning the needle guide **200** so that it is tilted slightly downward (i.e., rotated slightly in the clockwise direction) from the orientation shown in FIGS. **6** and **7**. The needle guide is then brought into position so that its concave recesses **218** receive respective ones of the semi-circular convex surfaces **118** of the bracket. When that has been achieved, the needle guide **200** can be tilted upward, i.e., rotated in the counterclockwise direction, whereupon the cam surfaces on the tips of the arms **202** ride over the front surface of the thickened portions of the walls **106** of the bracket, until their undercut portions snap-fit into engagement with respective undercut portions **114** of those walls. This action effectively snap-fits or locks the needle guide **200** onto the transducer bracket **100** with sufficient strength to be resistant from accidental disconnection. In order to guide the needle guide **200** into this releasably locked position on the bracket **100**, the bracket **100** includes a pair of guide members **14** on opposite sides thereof. The guide members **14** are like those on the housing **8** of the EM sensor assembly **6**. To that end, the inner end of each guide member **14** on the bracket **100** is a sloped cam surface **16**. Thus, when the needle guide **200** is rotated in the counterclockwise direction to lock it in place on the bracket **100**, the sloped surface of each guide **14** member will engage the undersurface of a respective one of the projecting arms **202** and ride thereover until the top surface of each guide member is in abutment with the undersurface of its respective projecting arm. When the needle guide **200** is in this position it is effectively snap-fit or locked to the bracket and is thus resistant from accidental disconnection.

If and when it is desired to remove the needle guide **200** from the bracket **100**, all that is required is for the user to grasp the two squeeze tabs **216** between his/her fingers and squeeze them together. This action has the effect of slightly flexing the opposed arms **202** apart from each other, thereby freeing the tips of those arms from the undercut surfaces **114** of the bracket **100**. Once the tips of the arms **202** are free of the undercut surfaces **114** of the bracket, the needle guide **200** can be tilted downward (i.e., rotated in the clockwise direction) about the pivot axis formed by the engaging surfaces **118** and **218** until the arms **202** are free of the bracket.

As will be described in detail later the needle guide **200** also includes two keying components, **220** and **240**, each of which is adapted to be coupled to corresponding keying components of other portions of the EM system of this invention.

Referring to FIGS. **8-10** the details of the EM sensor-equipped adapter device **300** will now be discussed. As mentioned earlier this component is arranged to be mounted on any conventional, e.g., disposable, needle **500**, such as shown in FIGS. **13** and **14**, or any other elongated linear medical instrument (e.g., any needle, rigid catheter, needle on a syringe (i.e., forming a guided syringe, rigid scope, etc) used in an image guided procedure on a patient to convert that instrument into an EM trackable instrument. The device **300** can have different ergonomic geometries depending on the application. In general, the device **300** has a receiving feature (to be described later) for accommodating an EM sensor. The sensor is itself permanently fixed (disposed) within a special housing like that described above. The construction/shape of the device **300** allows the sensor in its housing and covered by a sterile sleeve barrier to be releasably secured to the linear instrument. Moreover, the receiving feature of the adapter device keeps the EM sensor and its housing in a fixed orientation to the linear instrument even when the sensor and its housing are covered with the sterile sleeve barrier. This allows a software calculation/determination of the location and orientation of the linear instrument in an EM field if length information is supplied once the device is fixed at a chosen point along the long axis of the instrument (as will be described later). The sleeve barrier allows re-use of the sensor without re-processing or sterilization. As will also be described later, the device **300** has a distal end portion with an adjustable cavity to accommodate and to lock to round, linear instruments of varied diameter (22 Gauge to 8 French). The adapter **300** is comprised of a frame that holds this attachment feature and a receiving feature for the EM sensor in its housing. The entire device/assembly is releasably securable to the linear instrument at various positions along the length of the instrument, but most typically will be located toward one end as far from the pointed tip as possible. In the exemplary embodiment described above it is made of injection molded plastic and is pre-sterilized for single use.

As can best be seen in FIGS. **8** and **9** the adapter **300** basically comprises a housing **302** having a cavity **304** (FIG. **9**) shaped to accommodate an EM sensor assembly **6**, like that described previously. The cavity **304** is formed between a pair of side walls **306**. A pair of fingers **308** project upward from respective ones of the side walls **306** at the proximal end of the housing **302**. A pair of squeeze tabs **310** projects downward from respective ones of the side walls **306** opposite to respective ones of the fingers **308**. A pin **312** extends between the side walls **306** within the cavity **304**. The pin **312** is constructed similarly to the pin **112** of the bracket **100** to enable the releasable pivotable mounting of the sensor assembly **6** in the cavity as will be described shortly. The free end of each of the fingers **308** includes an inwardly directed flange **314** forming a cam surface.

The distal end of the housing **302** is solid and includes a passageway or hole **316** extending fully through it. The hole is adapted to receive the elongated body of a conventional needle **500** (FIG. **13**) or any other elongated medical device, e.g., catheter, scope, etc. In order to facilitate the placement of the adapter on the needle or other elongated instrument, the entry to the hole **316** is chamfered. A thumbscrew **318** is mounted on the distal end of the housing so that its free end is in communication with the interior of the hole **316**. When a needle or other elongated instrument is extended through the adapter's hole **316**, the adapter can be positioned at any longitudinal position along the needle/instrument. Once it is in the desired position, it can be releasably locked in that position by tightening of the thumbscrew **318**, which action brings the free end of the thumbscrew into intimate engagement with the portion of the needle/instrument located within the hole.

The adapter **300** is relatively small, e.g., it takes up only approximately 1 cm of needle/instrument length, and can be mounted on or removed easily from a straight cylindrical instrument of a range of sizes (22 G to 8 French). The electrical cable of the sensor assembly **6** mounted in the housing **302** exits from the side of the housing, i.e., 90 degrees from longitudinal axis of the needle/instrument. This feature

reduces the tendency for the sensor-equipped adapter to be accidentally displaced along the needle/instrument by pulling on the sensor's cable.

The adapter **300** is preferably a disposable, single-use component, but may be constructed so that it is reusable. The sensor assembly **6**, however, being a relatively expensive component is a reusable. Thus, when used it must be isolated from the ambient surroundings. To that end a thin cover (not shown) shaped somewhat like a condom is placed over the housing **8** of the sensor assembly **6** before mounting it in the adapter **300**. The covered sensor assembly can then be releasably mounted in the house **302** of the adapter **300**. In particular, the releasable mounting of the EM sensor assembly **6** in the housing **302** of the adapter **300** is accomplished by orienting the covered body **8** of the sensor assembly until it is generally perpendicular to the longitudinal axis of the adapter's housing **302**, with the semicircular recess **12** at the distal end of the housing **8** being pointed towards and aligned with the pin **312** extending through the cavity **304**. The sensor assembly **6** can then be mounted on the pin (i.e., the pin **112** received within the recess **312** with a portion of the cover interposed therebetween) and once that has been accomplished, the covered sensor housing can be tilted downward about the pin, e.g., rotated in the clockwise direction, whereupon the proximal end portion of the sensor housing snap-fits over the cam surfaces at the tips of the projecting arms **308** and then into position between those arms. The guide members **14** operate on the distal surfaces of the arms **308** in a similar manner as described above with respect to the mounting of the sensor assembly to the bracket **100**. This action releasably locks (snap-fits) the covered sensor assembly in the adapter so that it is resistant from accidental disconnection.

If and when it is desired to remove the sensor assembly **6** from the adapter **300**, all that is required is for the user to grasp the two squeeze tabs **310** between his/her fingers and squeeze them together. This action has the effect of slightly flexing the opposed arms **308** apart from each other, thereby freeing the tips of those arms from the sensor housing **8**. Once the tips of the arms are free of the housing, the sensor assembly with its cover can be rotated about the pin **312** until it can be fully removed from the cavity of the adapter. The cover can then be disposed of and the sensor assembly readied for reuse with another adapter **300** or some other component of this system.

As should be appreciated by those skilled in the art with an EM sensor assembly mounted in the adapter **300** and the adapter mounted on a needle **500** or any other elongated instrument, the needle/instrument is effectively transformed into a device that can be readily tracked by any EM tracking system. Moreover, the adapter **300** is arranged to be registered to the transducer, which itself is registered in the EM tracking system (e.g., via the EM sensor in the bracket **100**).

The registration of the adapter **300** to the transducer is accomplished by means of a keying element. That element basically comprises a generally triangular shaped member **320** projecting outward from the distal surface of the adapter's housing **302**. The keying element **320** is adapted to cooperate with a correspondingly shaped keying element on the needle guide **200** mounted on the transducer **4** via the bracket **100**. The keying element on the needle guide for achieving that end is the heretofore identified element **220**. The details of that element will now be described with reference to FIG. **7**. In particular, as can be seen the free edge of each of the walls **212** forming the channel **214** of the needle guide includes a semi-circular flange **222** extending outward in the plane of the free edge. Each flange includes a projection **224** located thereon. Each projection **224** includes a conical surface forming a portion of its periphery and an angled side surface forming another portion of the periphery of the projection. The angled side surfaces of the two projections together define a V-shaped notch between them. The V-shaped notch forms the heretofore identified keying element **220**. In particular, the triangular projection **320** of the adapter **300** is adapted to be inserted into the V-shaped notch **220** of the needle guide **200**. With the adapter being mounted on a needle **500**, like shown in FIG. **13**, the needle can be registered to the transducer in the EM system by merely orienting the adapter so that its keying element **320** is disposed within the V-shaped notch **220** of a needle guide **200** that is itself mounted on a transducer **4** via a bracket, like bracket **100**. Thus, the EMT system can be provided with information as to the position and orientation of the needle **500**.

The conical peripheral portions of the two projections **224** that are located on the flanges **222** together form a projecting member that serves as another keying element of this invention. In particular, that other keying element can be used to register other components of the EMT system, e.g., the adhesive marker **400**, as will be described later.

As should be appreciated from the foregoing, the sensor-equipped adapter **300** is suitable to convert any conventional off-the-shelf instrument into an EM guided instrument with high accuracy as long as the instrument doesn't bend. If the needle or other instrument is bendable, so that the location of the tip may not be where expected due to the needle's bending within the body of the patient, the EMT system should be able to register or track the needle's tip. The subject invention achieves that end by providing a keying element that enables the system to register the needle's tip with respect to the sensor-equipped adapter. This is particularly important since the adapter **300** can be positioned at any longitudinal position along the needle. That keying element basically comprises a gusset **240** which is located at the interface of the wall **212** and the rear surface **210** of the needle guide. Accordingly, after the needle **500** having the sensor-equipped adapter **300** mounted thereon has been registered to the EM system by placing the adapter's keying element **320** into the corresponding keying element **220** of the needle guide **200**, as described above, the tip of the needle can be registered to the EMT system. That is accomplished by removing the needle **500**/adapter **300** combination from the needle guide **200** and orienting the needle/adapter combination like shown in FIG. **14**, so that the tip of the needle rests on the gusset **240** while the contiguous portion of the needle extends along the interface of the wall **212** and the surface **210**. The EMT system can then determine the distance between the sensor and the tip of the needle using the information as to where the sensor of the assembly **6** in the adapter **300** is now located and oriented and the information previously stored in the system when the needle/adapter was initially registered to the transducer.

It should be pointed out at this juncture that it is expected that the registering of the location and orientation of the transducer **4** with respect to the anatomy of the patient in an ultrasound procedure will be accomplished by use of the sensor assembly **6** mounted in the bracket **100**. However, it is contemplated that such registration can also be accomplished by using a sensor-equipped adapter **300** and coupling that adapter to a needle guide mounted on the transducer via a bracket **100**.

As mentioned above the EMT system of this invention also includes a skin marker **400**. That marker is a conventional device, e.g., a passive marker, which has been modified to include a keying element **402** to enable it to be registered into an EMT system using several of the components of this

invention. To that end, the skin marker **400** comprises a disk-like body **404** having an adhesive undersurface and a central hub **406** including a top surface in which a conically shaped recess is centrally located. The bottom surface of the conically shaped recess can be flat or conical. In any case, the recess forms the keying element **402**.

The sensor-equipped adapter **300** can be used to register the marker **400** into the EMT system after the marker has been positioned on the patient's body and imaged. To that end, the adapter housing **302** includes a complementary shaped and sized conical projection **322** on its side wall located generally opposite to the thumbscrew **318**. Thus, to register the passive marker **400**, all that is required is to take a sensor-equipped adapter **300** over to the passive marker so that the keying projection **322** of the marker is located within the keying recess **402**. The EMT system can then be operated to register the location of the marker. Once that has been accomplished the sensor-equipped adapter **300** can be removed.

The marker **400** can also be registered into the EMT system by means other than an EM sensor equipped adapter **300**. For example, the marker can be registered by the EM sensor mounted on the transducer bracket **100** via the use of the needle guide **200**. In particular, a transducer having a sensor-equipped bracket **100** on which a needle guide **200** is mounted, like shown in FIG. **6**, can be used to register the marker. Such action is accomplished by manipulating the transducer with the bracket/needle guide mounted thereon into an orientation such that the conical projection made up of the two flanged projections **224** of the needle guide **200** (i.e., the needle guide's "other keying element") fits within keying recess **402** of the marker. Once so positioned the EMT system can be used to record the location of the sensor mounted on the bracket to thus register the location of the marker **400**.

The marker **400** can also be registered into the EMT system by the trackable trochar **20**. For such applications it is preferable that the bottom of the keying recess **402** should have a central depression to accept the pointed tip **46** of the stylet **44**. That central depression may be formed by another conical surface. Thus, to register the marker with the tracking trochar **20**, all that is required is to insert the tip of the stylet into the recess **402** so that the tip **46** is at the nadir of that recess and then operate the EMT system to take a reading of the location of the sensor, and hence of the marker.

The EM sensor in its housing can be used interchangeably with the tool **300** and also, with the active markers, with an ultrasound transducer. To that end, a first keying member on the sensor housing is arranged so that it may (if the software is not set up to do this automatically) be releasably coupled to the ultrasound transducer for system checks. The keying member on the sensor housing may be used to calibrate or check the calibration of the system (if the software supports this), alternatively the receptacle for the key may be located elsewhere e.g., to a slotted needle guide mounted on a bracket that is mounted on the ultrasound transducer, to enable the EMT system to register the sensor with respect to the ultrasound transducer. A second keying member may be provided on the ultrasound transducer, e.g., on the needle guide, so that the distal end portion of the instrument can be releasably coupled to the second keying member to enable the EMT system to register the (length) distal end portion of the instrument with respect to the sensor when using the linear instrument device described above. Alternatively, the software may allow the user to enter this length data manually.

As should be appreciated from the foregoing the system of this invention has wide applicability in that it enables registration of the sensor-equipped adapter, definition of the virtual needle position and length for the ultrasound tracking software, and confirmation of registration of the trackable trochar.

Without further elaboration the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

We claim:

1. An instrument arranged for introduction into the body of a patient to a desired situs in the patient in an image-guided procedure on the patient, the position of the instrument to be tracked with respect to the patient by an EMT system, said instrument comprising an EM assembly, a stylet assembly, and a releasable locking assembly, said stylet assembly comprising a first elongated tubular member, a first handle and a first connector, said first tubular member having a distal tip portion and a hollow isolated interior cavity terminating adjacent said distal tip portion, said EM assembly being a replaceable unit comprising an EM sensor, a second elongated tubular member, a second handle and a second connector, said second tubular member having a distal end portion and a hollow interior cavity terminating adjacent said distal end portion at which said EM sensor is located and a proximal end portion at which said second handle and said second connector are located, said EM sensor having an electrical cable connected to said EM sensor, said releasable locking assembly comprising said first connector and said second connector, said first and second connectors being arranged to be releasably connected together whereupon when so connected they are resistant to accidental disconnection, said second tubular member of said EM assembly being arranged to be slidably releasably located within said cavity of said first tubular member of said stylet assembly, whereupon when said EM sensor is located at a predetermined position in said cavity adjacent said distal tip portion of said first tubular member of said stylet assembly said EM sensor is isolated from the interior of the body of the patient at the desired situs with said electrical cable extending along the length of and out of said cavity, said EM assembly being arranged to be locked in place thereat by said first and second connectors of said releasable locking assembly releasably engaging each other, said first and second connectors of said releasable locking assembly being arranged to be released from each other to enable said EM assembly to be slidably removed as a unit from said cavity of said first tubular member of said stylet assembly for use in another tubular member having a distal tip portion and a hollow interior cavity terminating adjacent the distal tip portion by introducing said second tubular member with said EM sensor and said electrical cable of said stylet assembly directly within the hollow interior cavity of the other tubular member, whereupon said EM sensor is located at said predetermined position adjacent the distal tip of said other tubular member.

2. The instrument of claim **1** wherein said second elongated tubular member of said EM assembly is rigid and linear.

3. The instrument of claim **2** wherein said instrument is arranged for insertion into the body of a patient via a sheath, said sheath being an elongated linear tubular member having a distal end and a proximal end, said distal end of said sheath being open, said sheath also including a connector at said proximal end of said sheath, and wherein said instrument is releasably securable to the connector of said sheath.

4. The instrument of claim **1** wherein said instrument is arranged for insertion into the body of a patient via a sheath, said sheath being an elongated tubular member having a distal end and a proximal end, said distal end of said sheath being open, said sheath also including a connector at said proximal

end of said sheath, and wherein said instrument is releasably securable to said connector of said sheath.

5. The instrument of claim **1** wherein one of said first and second handles is pivotable with respect to the other of said first and second handles to releasably secure said first and second connectors together.

6. The instrument of claim **1** additionally comprising a cover in the form of a flexible sheath.

7. The instrument of claim **6** wherein said cover has an opening therein and is arranged to be disposed over a portion of said instrument, with said cable extending through said opening in said cover.

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专利名称(译)	用于超声和其他成像模式的EM跟踪系统		
公开(公告)号	US8688196	公开(公告)日	2014-04-01
申请号	US13/331572	申请日	2011-12-20
申请(专利权)人(译)	CIVCO医疗器械CO.，INC.		
当前申请(专利权)人(译)	CIVCO医疗器械CO.，INC.		
[标]发明人	WHITMORE III WILLET F CERMAK CRAIG J		
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IPC分类号	A61B19/08 A61B5/055 A61B17/34 A61B19/00 G06T7/00 A61B5/06 A61B8/12		
CPC分类号	A61B5/065 A61B19/201 A61B2017/3405 A61B2017/3413 A61B2019/5475 A61B19/5225 A61B5/062 A61B8/0841 A61B8/12 A61B19/5244 A61B2019/5251 A61B8/0833 G06T7/0012 A61B5/066 A61B2019/5483 A61B5/064 A61B17/3403 A61B5/06 A61B2017/00725 A61B19/081 A61B19/22 A61B2017/3407 A61B8/4254 A61B34/20 A61B34/70 A61B46/10 A61B90/11 A61B90/37 A61B2034/2051 A61B2090/3975 A61B2090/3983		
优先权	61/100870 2008-09-29 US		
其他公开文献	US20120089013A1		
外部链接	Espacenet USPTO		

摘要(译)

用于超声和其他成像模态引导的医疗程序的EMT系统。该系统包括各种组件的工具组，EM传感器可以可释放地固定到该组件上。因此，尽管处理了工具组的其他部件，但是传感器可以重复使用。工具组的各种部件包括键控元件，以便于通过EM传感器将它们配准到经历过程的患者的解剖结构。