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(54) **ULTRASOUND DEVICE FOR NEEDLE PROCEDURES**

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(51) **Int. Cl.**

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A61B 10/02	(2006.01)
A61B 8/13	(2006.01)
A61B 8/08	(2006.01)
A61B 17/00	(2006.01)

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

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(58) **Field of Classification Search**

None

See application file for complete search history.

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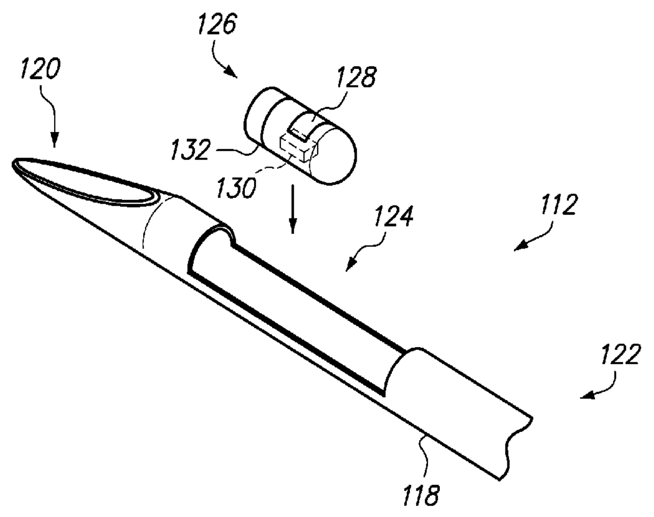
(57) **ABSTRACT**

A novel ultrasound device for needle procedures is disclosed that comprises a needle with an integrated ultrasound transducer. The transducer may be part of a drop-in, self contained beacon unit that fits within the needle shaft. The transducer may alternatively include electrical leads connectable to an electrical subsystem housed within an adapter that is connectable to a handle. Alternatively, the electrical subsystem may be housed within a handle connectable to the needle by a bayonet-mount configuration, a slide-and-click configuration, or a cartridge configuration. The electrical subsystem is preferably configured to control when the transducer emits an ultrasound pulse. The handle may include all or part of a vacuum means for applying negative pressure to tissue disposed near a tissue sample aperture.

11 Claims, 7 Drawing Sheets



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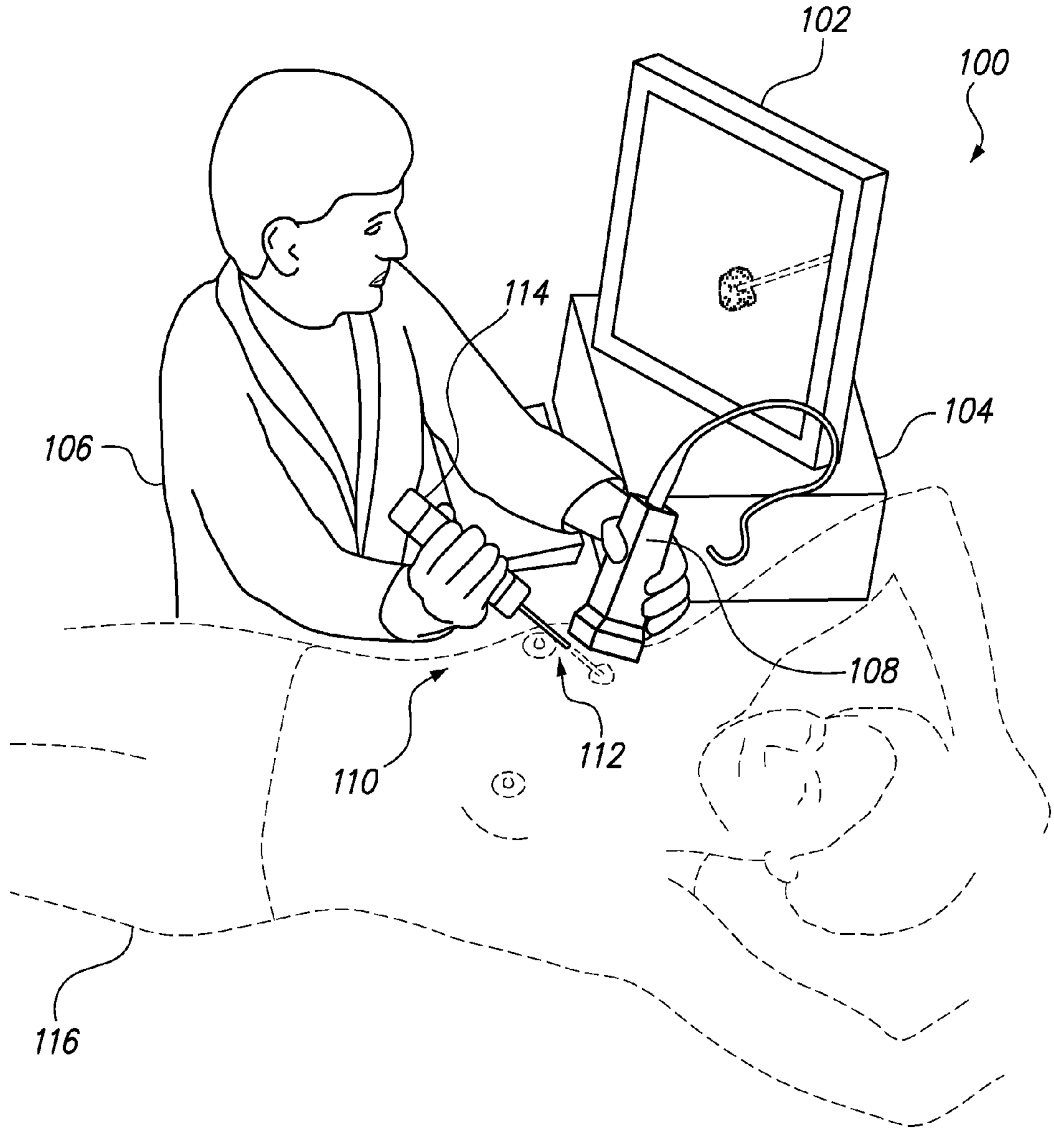


FIG. 1

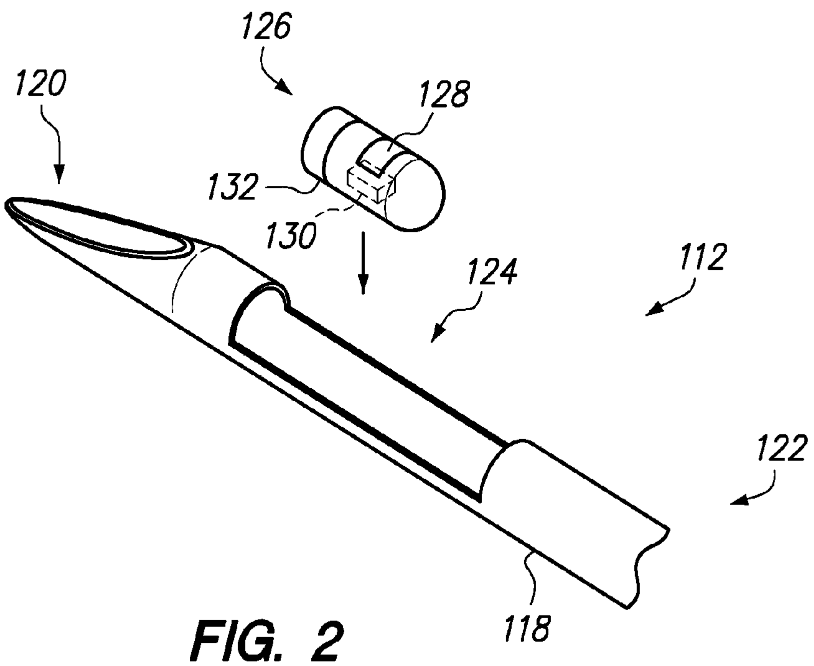


FIG. 2

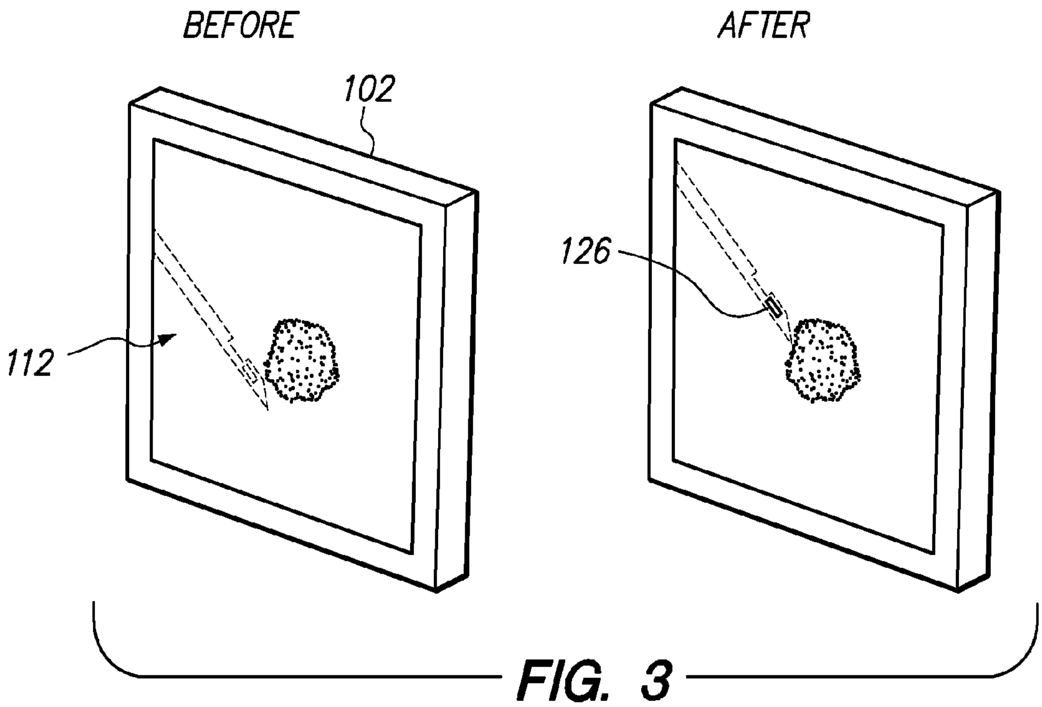


FIG. 3

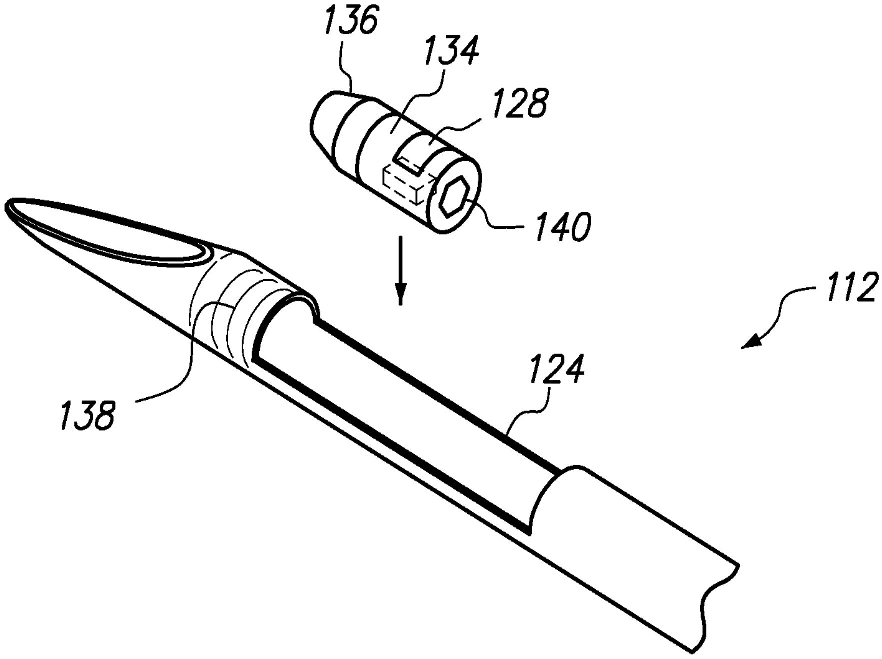


FIG. 4

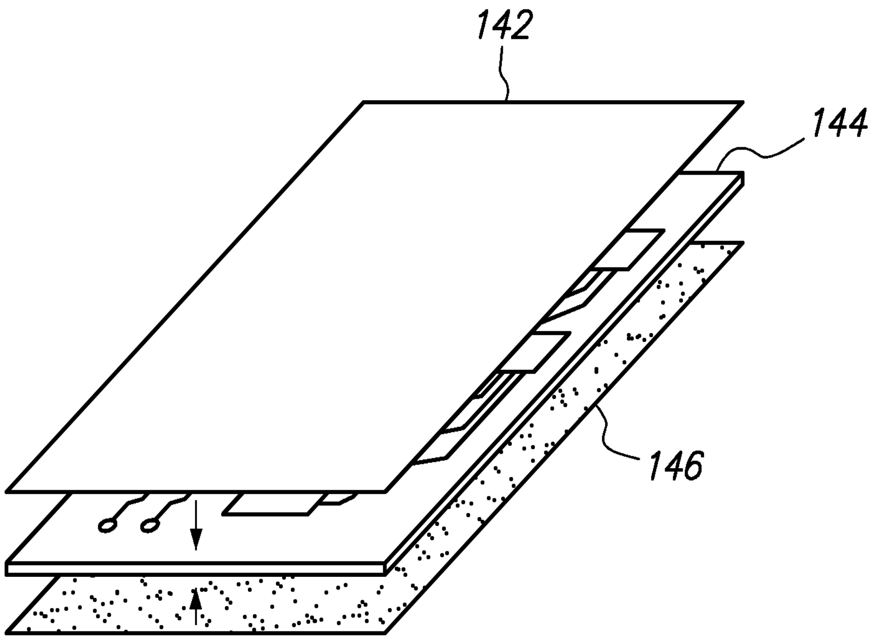
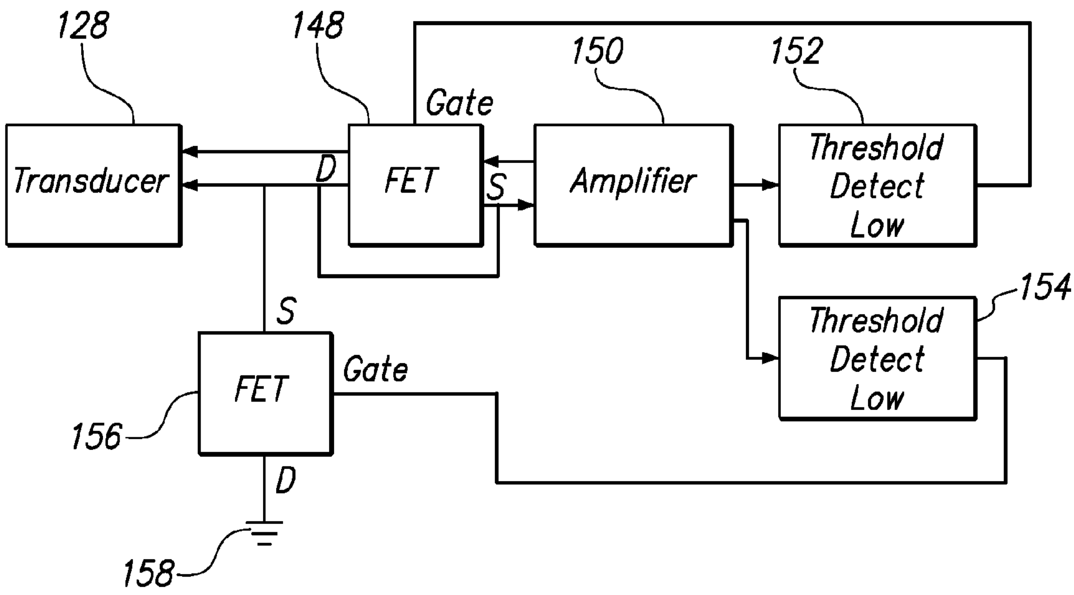


FIG. 5



128
148
150
152
Gate
Transducer
D
FET
S
Amplifier
Threshold Detect Low
154
Threshold Detect Low
S
FET
Gate
156
D
158

FIG. 6

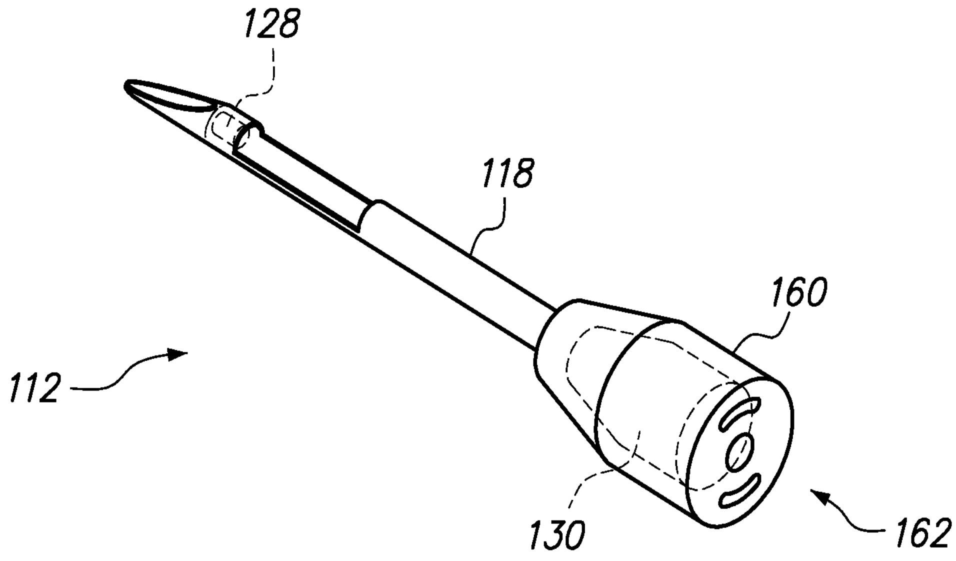


FIG. 7

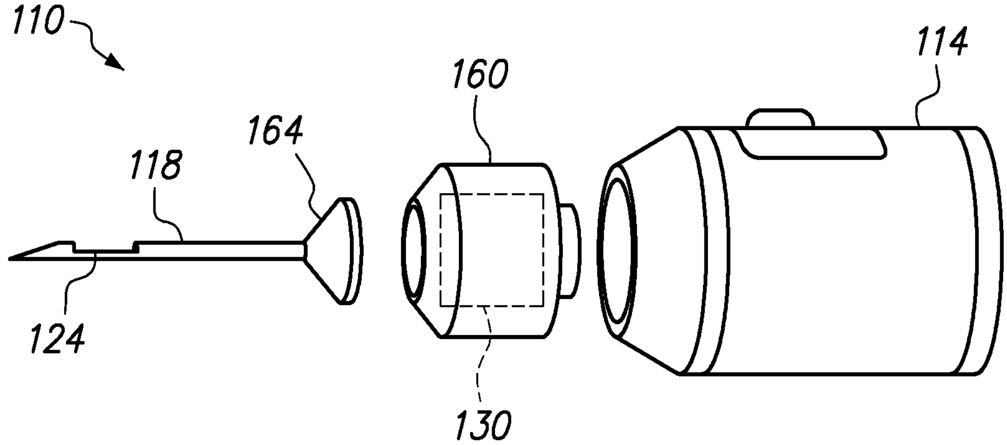


FIG. 8

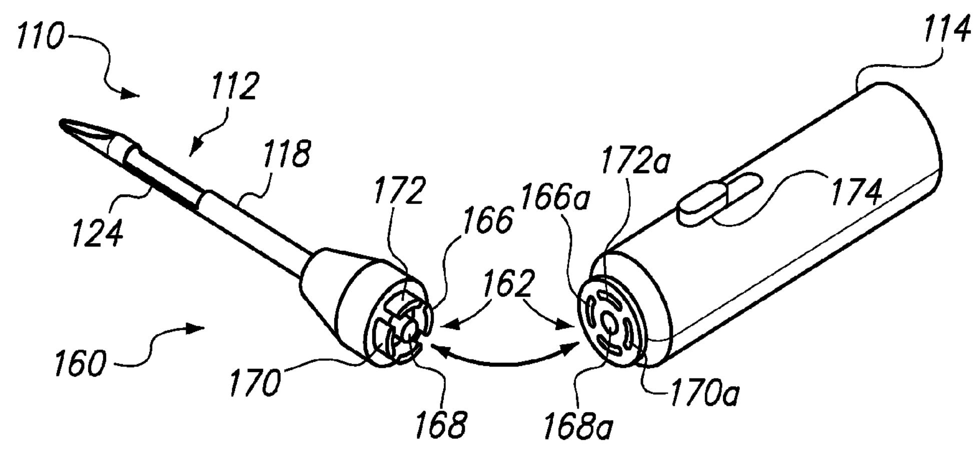


FIG. 9

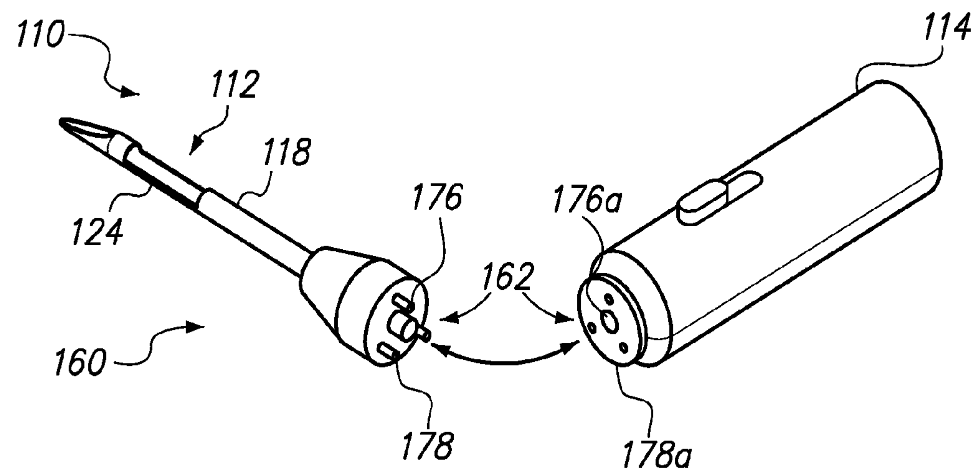


FIG. 10

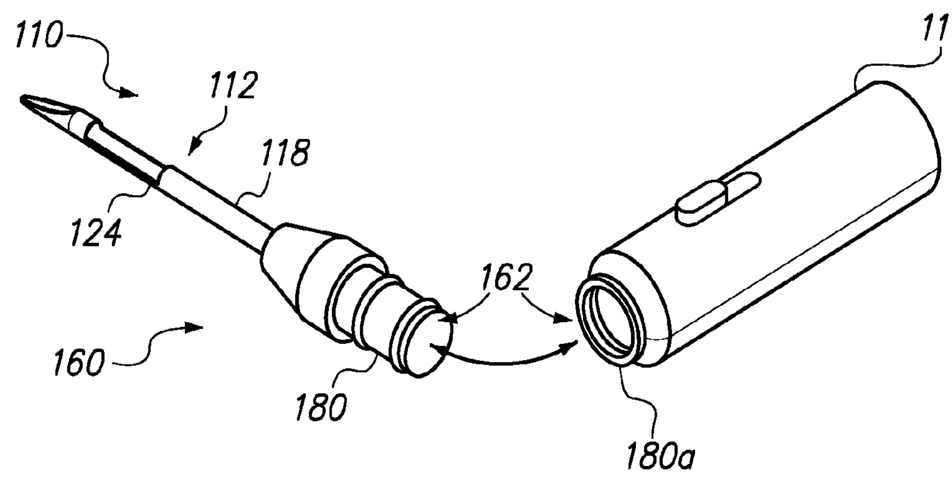


FIG. 11

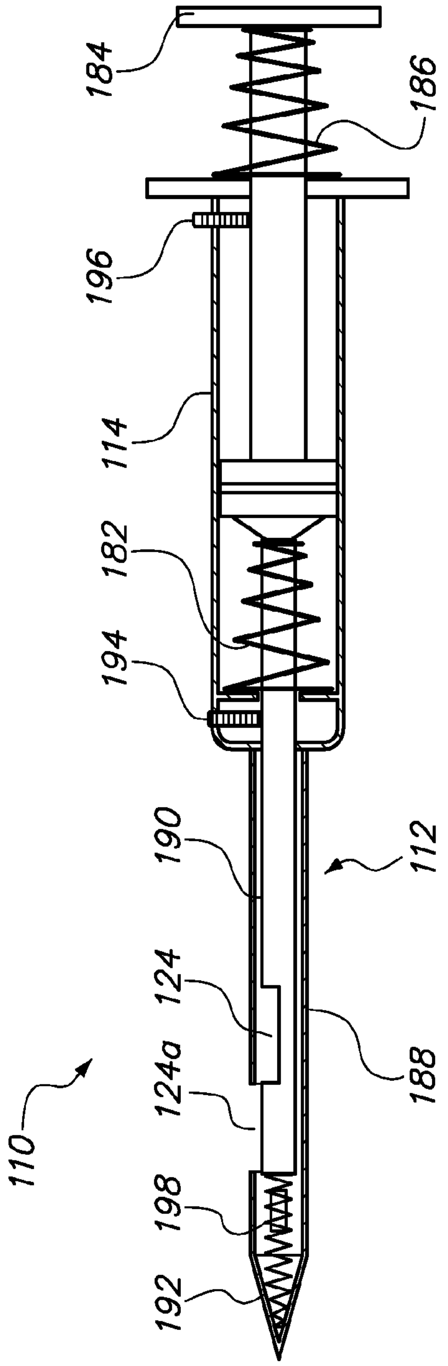

184
186
196
114
182
194
190
112
124
124a
188
110
198
192

FIG. 12

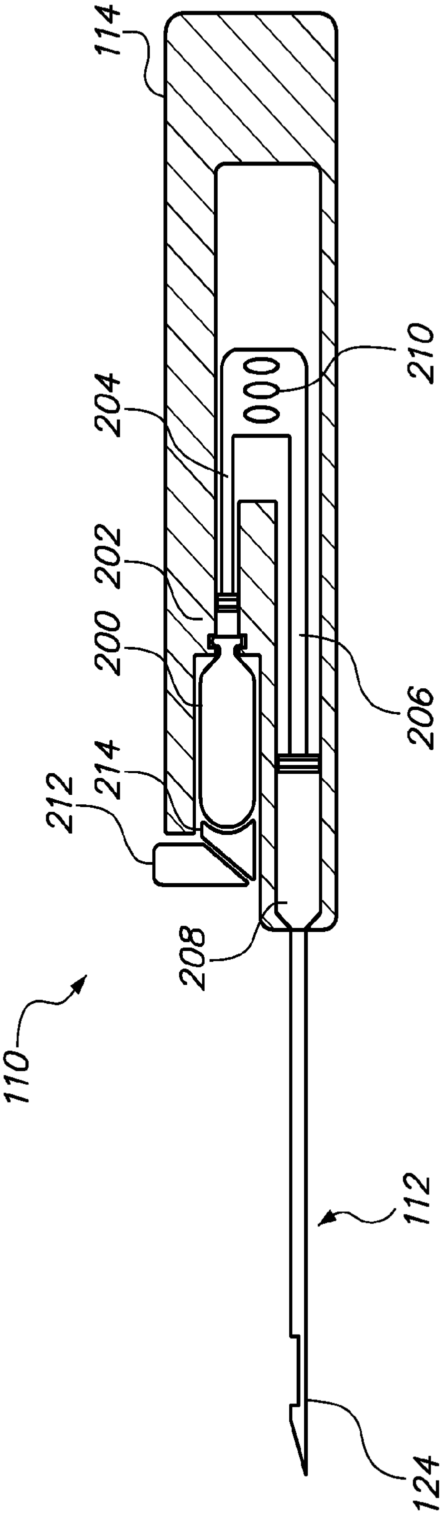

114
210
204
202
200
214
212
206
208
110
112
124

FIG. 13

ULTRASOUND DEVICE FOR NEEDLE PROCEDURES

CROSS-REFERENCE TO RELATED APPLICATION

The present application claims benefit of and priority to U.S. Provisional Patent Application Ser. No. 61/674,818 filed on Jul. 23, 2012 entitled "Ultrasound Device for Needle Procedures," the entire contents of which are hereby incorporated by reference herein.

BACKGROUND

The present disclosure generally relates to ultrasound imaging systems and medical devices and more particularly to the use of such systems and devices for needle procedures such as biopsies, nerve blocks, and vascular access.

Ultrasound is the most common medical imaging modality after X-ray imaging. The benefits of ultrasound are clear: it is safe, relatively affordable, and fast. Given these benefits, it is no surprise that ultrasound usage is increasing.

Doctors commonly use ultrasound to guide needle placement in patients. For example, where there is a suspicion of breast cancer, a practitioner will use ultrasound on a patient to visualize a suspicious lesion and subsequently guide a needle to acquire a tissue sample from that lesion for testing. Such needle procedures are typically difficult for a number of reasons. First, ultrasound image-guided procedures require expert hand-eye coordination. Second, even under optimal imaging conditions, ultrasound can be difficult for a number of reasons. The resulting ultrasound image does not accurately depict the exact location of tools, such as needles or catheters, due to the specular reflector nature of the materials of the tools. Furthermore, ultrasound images can be colorless, speckled, and difficult to interpret. These factors add to time and complexity of ultrasound-guided procedures while decreasing precision and confidence.

Myriad approaches try to address these and other issues. For example, U.S. Pat. No. 5,329,927 describes a vibrating mechanism coupled to a cannula or needle for Doppler enhanced visualization. Such an arrangement unfortunately requires additional workflow steps including having to sterilize and then attach the vibrating mechanism. Furthermore, smaller ultrasound units may not have Doppler capability required for functionality.

Several needle manufacturers have used echogenic or texturing methods to enhance needle visibility such as that described in U.S. Patent Application Publication 2012/0059247. The texture is generally a dimpling or scoring of a typically smooth surface to reduce the specular reflector properties. Results show that these textured needles only provide slight benefit in ideal conditions.

Another approach to try to effect accurate needle guidance is to restrict the motion of the needle within the ultrasound imaging plane. For example, U.S. Pat. No. 6,485,426 describes a frame that clips onto the ultrasound imaging probe and biopsy needle to direct the needle. Such an arrangement unfortunately also adds steps to workflow and sterilization. Furthermore, the arrangement severely limits the important aspect of range of motion for needle manipulation.

Yet another attempt to improve ultrasound guidance is by way of an electromagnetic ("EM") position sensing system to detect the needle tip in relation to the ultrasound imaging probe and then annotate the ultrasound image accordingly. Such a system is made by Ultrasonix. However, this system is a proprietary one that requires specific compatibility between

the needles and the imaging system and therefore limits the range of procedures. Furthermore EM sensing is costly, requires a calibration step, and is prone to registration error with the ultrasound image.

Ultrasonix also released a spatial compounding feature for enhanced needle visualization. This feature relies on enhancing straight line features in the image, and therefore requires the needle to be in the imaging plane to be useful.

A further attempt to improve ultrasound guidance involves a stylet having an ultrasound transducer associated therewith, wherein the stylet is carried within a hollow biopsy needle. Such an arrangement is described in U.S. Pat. Nos. 5,158,088; 4,407,294; and 4,249,539. In particular, the stylet is a wired, non-disposable device that signals acoustically and/or electronically between the tool in question and the ultrasound imaging device for ultrasound image enhancement. Unfortunately, this attempt also introduces a number of additional steps into the clinical workflow. For example, using the stylet requires an additional step of placing the stylet into the hollow needle. Moreover, as the stylet is non-disposable, it must be sterilized before each use. In addition, because the stylet must be used along with other tools, only certain types of tools are compatible with the system.

Accordingly, an ultrasound device for needle procedures that is simple to use, wireless, disposable, accurate, and compatible with pre-existing ultrasonic diagnostic imaging systems and devices is therefore desired.

SUMMARY

One exemplary embodiment of the disclosed subject matter is a needle device having a needle adapted to cut tissue and an ultrasound transducer integrated with the needle. The needle may be a hollow shaft having a tissue sampling aperture with one or more sharp surfaces for cutting tissue. The transducer is preferably integrated near or about one end of the needle shaft.

In one aspect of the disclosed embodiments, the transducer is part of a drop-in, self contained beacon unit that fits within the needle shaft. The beacon unit is preferably self-powered and self-controlled. The beacon unit may include an integrated circuit in communication with the transducer, which may be a piezoelectric film. The integrated circuit or the like is configured to control when the transducer emits an ultrasound pulse. The drop-in beacon unit may be attachable to the needle shaft by an adhesive layer associated with the beacon unit itself. Alternatively, the beacon unit may have external threading and the needle shaft may have internal threading wherein the beacon unit may be screw-fit within the needle shaft or similar arrangement such as a friction-fit configuration.

In another aspect of the disclosed embodiments, the transducer may be integrated at a distal end of a needle shaft, wherein the transducer includes electrical leads for connecting to an electrical subsystem housed in an adapter or a handle. If an adapter is used, it is configured to attach to the end of the needle shaft opposite the transducer. The adapter is also configured to attach to the handle.

In another aspect of the disclosed embodiments, a needle shaft having a transducer at a distal end and a tissue sampling aperture proximate the transducer is coupled to a handle by an attachment means. The attachment means may include a bayonet mount configuration, a slide-and-click configuration, or a cartridge configuration. The handle may include all or part of a vacuum means for suctioning in tissue disposed at or near the tissue sample aperture. In one embodiment, the vacuum means is mechanically driven by way of springs and

a plunger slidably disposed within the handle. In another embodiment, the vacuum means is gas-powered by way of a high-pressure canister disposed within the handle.

BRIEF DESCRIPTION OF THE DRAWINGS

Some non-limiting exemplary embodiments of the disclosed subject matter are illustrated in the following drawings. Identical or duplicate or equivalent or similar structures, elements, or parts that appear in one or more drawings are generally labeled with the same reference numeral, optionally with an additional letter or letters to distinguish between similar objects or variants of objects, and may not be repeatedly labeled and/or described. Dimensions of components and features shown in the figures are chosen for convenience or clarity of presentation. For convenience or clarity, some elements or structures are not shown or shown only partially and/or with different perspective or from different point of views.

FIG. **1** is a perspective view of an embodiment of the inventions disclosed herein being used by a medical practitioner to help perform a biopsy;

FIG. **2** illustrates an aspect of an embodiment of the inventions disclosed herein and particularly the aspect of a drop-in beacon transducer unit;

FIG. **3** illustrates "before and after" ultrasound images wherein the exact location of the needle tip of an embodiment of the inventions disclosed herein may be seen on the "after" ultrasound image once a drop-in beacon transducer unit is activated;

FIG. **4** illustrates a threaded housing aspect of a drop-in beacon transducer unit;

FIG. **5** illustrates another aspect and particularly an integrated circuit disposed between a transducer film and an adhesive layer;

FIG. **6** illustrates a schematic of an exemplary electrical subsystem;

FIG. **7** illustrates another aspect and particularly a needle device with a transducer and an adapter with electrical subsystem;

FIG. **8** illustrates another aspect of the inventions disclosed herein and particularly a needle device with a transducer and a removable adapter with electrical subsystem, wherein the adapter is in turn coupled to a handle;

FIG. **9** illustrates a bayonet-mount aspect of the disclosed inventions;

FIG. **10** illustrates a slide-and-click aspect of the disclosed inventions;

FIG. **11** illustrates a cartridge-mount aspect of the inventions disclosed herein;

FIG. **12** illustrates a mechanically powered vacuum aspect; and

FIG. **13** illustrates a gas-powered vacuum aspect of the disclosed inventions.

DETAILED DESCRIPTION

A general problem in the field of needle devices using ultrasound to guide the needle during a needle procedure is an inaccurate representation on an ultrasound imaging display of the actual locale of the needle tip within a patient's body. A general solution is an ultrasound needle device comprising a needle shaft and a transducer integrated within a distal end of the needle shaft.

A technical problem in the field of biopsy devices is accurate tissue sampling. A technical solution implementing the spirit of the disclosed inventions is a needle shaft adapted to cut tissue and a transducer disposed about the distal end of the needle shaft. The transducer may be part of a drop-in, self contained beacon unit that fits within the needle shaft. The transducer may alternatively include electrical leads connectable to an electrical subsystem housed within an adapter that is connectable to a handle. Alternatively, the electrical subsystem may be housed within a handle connectable to the needle shaft by a bayonet mount configuration, a slide-and-click configuration, or a cartridge configuration. The electrical subsystem is preferably configured to control when the transducer emits an ultrasound pulse. The handle may include all or part of a vacuum means for suctioning in tissue disposed at or near a tissue sampling aperture of the needle shaft.

Potential benefits of the general and technical solutions provided by the disclosed subject matter include a "plug and play" disposable transducer beacon unit designed for use with a needle shaft. Other potential benefits include a disposable needle and transducer unit easily mountable to an adapter that is in turn easily attachable to a handle. Further potential benefits include a biopsy device quickly attachable to a handle that may include efficient mechanical or pneumatic structures for pulling tissue into the device.

A general nonlimiting overview of practicing the present disclosure is presented below. The overview outlines exemplary practice of embodiments of the present disclosure, providing a constructive basis for variant and/or alternative and/or divergent embodiments, some of which are subsequently described.

FIG. **1** is a perspective view of an embodiment of the inventions disclosed herein being used by a medical practitioner to help perform a biopsy. The disclosed inventions need not be limited to use for a biopsy but may instead be used in a variety of needle procedures, including but not limited to nerve blocks and vascular access. As seen in FIG. **1**, a practitioner **106** is using an ultrasound imaging system **100** to extract a tissue sample from a patient **116**. The system **100** may include a display **102**, computer **104**, ultrasound imaging probe **108**, and novel needle device **110** according to one or more aspects of the inventions disclosed herein.

The display **102** of the ultrasound imaging system **100** displays the real-time sonogram of the tissue. The practitioner uses this display **102** to visualize, for example, a suspected lesion and needle for guidance. It is here where the needle shaft of the needle device **110** is supposed to be visualized going into the suspected lesion. The probe **108** is used to image the suspected lesion located inside the body of the patient **116**.

The needle device **110** includes a handle **114** attachable to a needle **112** that is adapted to cut tissue and an ultrasound transducer integrated with the needle **112**. The needle **112** is preferably a hollow shaft having a tissue sampling aperture with one or more sharp surfaces for cutting tissue. The transducer is preferably integrated near or about one end of the needle shaft. "Integrated" means affixed permanently or temporarily inside or outside the needle shaft, or alternatively a part of the needle shaft **118**.

In use, the practitioner uses the imaging probe **108** (in one hand) to guide the needle device **110** (in the other hand) by viewing the ultrasound display **102**. The needle device **110** may be vacuum assisted to draw tissue into the tissue sampling aperture. Exemplary vacuum assist mechanisms are illustrated in FIGS. **12** and **13**. The needle device **110** may be a completely disposable or modular device with disposable needle and transducer.

FIG. **2** illustrates an aspect of an embodiment of needle device **110** and particularly a needle **112** having a needle shaft **118** with a distal end **120** and a proximate end **122**. The shaft

118 is preferably a hollow cylinder formed by walls having a cut-out to create a tissue sampling aperture 124 disposed between the distal and proximate ends 120, 122. The walls of the tissue sampling aperture 124 are preferably sharp for cutting tissue during a biopsy procedure. A drop-in beacon transducer unit 126 is integrated with the needle shaft 118 at or about the distal end 120 near the tip of the shaft 118. The beacon unit 126 contains an ultrasound transducer 128 and optionally the supporting electronic subsystem 130 and/or power supply 132. In this manner, the beacon unit 126 may advantageously be a "plug and play" disposable component meant for integration with existing needle devices.

FIG. 3 illustrates "before and after" ultrasound images wherein the exact location of the tip of a needle of an embodiment of the inventions disclosed herein may be seen on the "after" ultrasound image once a drop-in beacon transducer unit 126 is activated. Such an invention is clearly highly valuable to those skilled in the art.

The beacon unit 126 may be bonded, threaded, or otherwise attached or fitted to or within some component of the needle shaft 118 being used during the needle procedure. FIG. 4 illustrates a threaded housing aspect of a drop-in unit 126. In particular, FIG. 4 shows that the beacon unit 126 may comprise a housing 134 with external threading 136 and the needle shaft 118 may have internal threading 138 wherein the beacon unit may be screw-fit within the needle shaft 118 or similar arrangement. The housing 134 of the beacon unit 126 may have a hex slot 140 or the like for screwing the unit 126 into the walls of the shaft 118. Alternatively, the housing 134 may also be the needle shaft 118 itself or a sub-component of the needle assembly, as in the case of biopsy needles that have multiple components.

A drop-in beacon unit such as that illustrated in FIGS. 2 through 4 may be fabricated by way of one or more of the following steps. Start with a hollow tube with outer diameter of approximately 3 millimeters and length of approximately 5 to 10 millimeters. Add an integrated circuit for the electrical subsystem, such as system 130 illustrated in FIG. 2. Drill a hole in the side of the tube to accommodate wiring (not shown) and transducer (such as that shown in FIG. 2). Run a wire from the integrated circuit to an electrical interconnect and to the hole and also to an optional power supply. The power supply may be a small, high voltage battery 132 that may fit within the self-contained beacon unit 126 or in the handle 114. Alternatively, the beacon unit 126 may be wirelessly powered by the use of wireless power technology disclosed by one or more of the following United States patents, each of which is incorporated by reference as if fully disclosed herein: U.S. Pat. Nos. 6,289,237; 6,615,074; 6,856,291; 7,027,311; 7,057,514; 7,084,605; 7,373,133; 7,383,064; 7,403,803; 7,440,780; 7,567,824; 7,639,994; and 7,643,312. Next, fill the hollow tube with non-conductive acoustic backing material (not shown) and cure. If a battery is to be used, add the battery 132. Then place piezoelectric material in the hole, completing electrical connection with wiring. Finally, create the acoustic bond and coat the unit 126 with paralyne.

Instead of a drop-in beacon unit arrangement such as that illustrated in FIGS. 2 through 4, the beacon transponder unit 126 may comprise a film or flex circuit that is wrapped or bonded onto the needle shaft 118 or needle sub-component. FIG. 5 depicts an integrated film embodiment of a self-contained beacon unit 126. Turning in detail to FIG. 5, transducer 128 may comprise a piezoelectric ultrasound transducer film or material. This film material 142 may either be rigid or flexible with electrodes (not shown) on both the top and bottom surfaces to receive and apply a voltage potential across the transducer 128. An integrated circuit 144 may be fabricated on either a substrate such as a silicon wafer or printed circuit board and be connected to both electrodes of the piezoelectric transducer film 142. The integrated circuit 144 may be coupled with a logic and/or power source to comprise in whole or in part the electrical subsystem 130 for the beacon unit 126. An adhesive layer or patch 146 may serve as a coupling interface between the needle shaft 118 and beacon unit 126. If the beacon unit 126 is not a self-contained or self-powered unit, electrical leads (not shown) may be in communication with the film 142. In such case, when the transducer 128 receives and sends acoustic pulses from and to the imaging probe 108, the leads will be used to conduct the electrical signals to and from the transducer 128 to the electrical subsystem 130.

FIG. 6 illustrates a schematic of an exemplary electrical subsystem of the disclosed inventions, such as electrical subsystem 130 depicted in FIG. 2. The electrical subsystem 130 may particularly be designed such that it is built to receive and send ultrasound pulses automatically through the transducer 128. The electrical subsystem 130 preferably and advantageously is configured to control when an ultrasound pulse from the transducer 128 is to be emitted.

Turning in detail to FIG. 6, a signal from transducer 128 is amplified by amplifier 150 and then sent to a high threshold detector 154 and a low threshold detector 152. If the signal is above the low threshold, the field effect transistor 148 is closed and the amplified signal is sent back to the transducer 128. However, once the amplified signal reaches above the high threshold, the field effect transistor 156 closes and connects the transmitting line to ground 158 to stop the transmission of the signal. In this manner, the system 100 sends back ultrasound pulses to achieve the desired end result, such as the bright beacon-like image on the ultrasound imaging monitor depicted in the "after" version of FIG. 3.

FIG. 7 illustrates another aspect of an embodiment of the inventions disclosed herein and particularly a needle 112 with a transducer 128 integrated at a distal end of a needle shaft 118. At the opposite end thereof is an adapter 160 with electrical subsystem 130. The adapter 160 has electrical/mechanical connection means 162 for connection to a handle such as that shown in FIG. 1. The integrated unit illustrated in FIG. 7 is advantageously disposable.

FIG. 8 illustrates another aspect of an embodiment of the inventions disclosed herein and particularly a needle device 110 with a transducer 128 integrated at a distal end of a needle shaft 118. At the opposite end thereof is a connector 164 that is attachable to a removable adapter 160 with electrical subsystem 130. The adapter 160 is attachable to a handle 114.

FIG. 9 illustrates a bayonet-mount aspect of the disclosed inventions. As shown in FIG. 9, needle device 110 comprises a needle 112 with needle shaft 118 including a tissue sampling aperture 124, transducer (not shown) disposed at or about aperture 124, adapter 160 with electrical/mechanical connection means 162 and particularly a bayonet configuration thereof, and handle 114 with button 174 for actuating the device 110. In association with adapter 160, the connection means 162 may comprise one or more of the following: a male mechanical interconnect locking mechanism 166, a vacuum channel 168, an electrical (+) lead connect 170, and an electrical (−) lead connect 172. In association with handle 114, the connection means 162 may comprise one or more of the following: a female mechanical interconnect locking mechanism 166*a*, a vacuum channel 168*a*, an electrical (+) lead connect 170*a*, and an electrical (−) lead connect 172*a*.

FIG. 10 illustrates a slide-and-click aspect of the disclosed inventions. As shown in FIG. 10, needle device 110 comprises a needle 112, adapter 160 with electrical/mechanical connection means **162**, and handle **114**. Connection means **162** may comprise complementary mechanical and electrical interconnects **178**, **178***a* that slide and click into one another. A vacuum port **176**, **176***a* enables negative pressure to be applied to tissue at or about the distal end of needle **112**.

FIG. **11** illustrates a cartridge-mount aspect of the inventions disclosed herein. As shown in FIG. **11**, needle device **110** comprises a needle **112**, adapter **160** with electrical/mechanical connection means **162**, and handle **114**. Connection means **162** may comprise a male cartridge insert **180** at the end of needle **112** opposite tissue sampling aperture **124** and a female component **180***a* in handle **114**. The cartridge insert **180** may contain the electrical contacts so the electrical subsystem **130** (not shown) in the handle **114** may be connected to the transducer **128** (not shown) at the distal tip of the needle shaft **118**.

FIG. **12** illustrates a cross-sectional view of another aspect of an embodiment of the inventions disclosed herein and particularly a mechanically powered vacuum aspect. The integrated tissue-cutting needle device **110** includes a vacuum means in the form of a needle-syringe arrangement. In particular, as seen in FIG. **12**, a plunger barrel or handle **114** contains a spring **182** so when plunger **184** is depressed (barrel is in "empty" position), the spring **182** resists and applies force to push the plunger **184** back into the "full" position. The tendency of the plunger **184** to return to the "full" position creates negative air pressure in the barrel chamber. The spring **182** need not be within the barrel chamber, as the same force may be achieved from a spring **186** between the plunger shaft and the outside of the chamber.

The needle device **110** illustrated in FIG. **12** may comprise a cutting mechanism that may include two nested, concentric thin-walled tubes **188**, **190**. The outer tube **188** ends in a sharp cone-tip **192**. A spring **198** inside the tip of the outer tube **188** pushes against the inner tube **190**. Both tubes **188**, **190** may include sampling notches **124**, **124***a* in the tube walls **188**, **190**, positioned so when the inner tube **190** fully compresses the tip-spring **198**, both sampling notches **124**, **124***a* line up and the cutter is considered in the "open" position. The edges of the sampling notches **124**, **124***a* are sharp so when the inner tube **190** slides and the sampling notches **124**, **124***a* becomes "shut," the action is like a guillotine, cutting whatever tissue is within the notches **124**, **124***a*.

To initiate the vacuum and cutting mechanisms, the user must first depress the plunger **184** to the "empty position." The air-tight plunger **184**, in addition to displacing air from the barrel and compressing the plunger spring **182** or **186**, also pushes against the inner needle tube **190**, which compresses the needle spring **192**. With the plunger **184** in the fully depressed position, cams **194**, **196** activate to cock each spring **182**, **186** in their compressed position. One cam **196** engages the plunger shaft to hold the plunger **184** in the "empty" position. The other cam **194** engages the inner needle tube **190** to hold the cutter window **124** in the "open" position.

With the needle vacuum and cutter cocked, the user then inserts and guides the needle **112** to the appropriate location within the body of the patient **116**. Upon identifying the suspicious lesion, the user engages the vacuum by disrupting the plunger-cam **196**. This disruption allows the spring **182** to decompress until the next cam-engagement point on the plunger shaft to create negative pressure in the barrel chamber. This negative pressure is continuous to the sampling notch **124** in the needle **112**, which pulls tissue into the notch **124**. If the vacuum pressure is not sufficient, the user can disrupt the plunger-cam several more times until the spring is fully decompressed.

Once sufficient tissue is pulled into the sampling notch **124**, the user then disrupts the cutter-cam **194**. This releases the spring action on the inner cutting tube **190**, closing the "guillotine." With the tissue sample cut, the user removes the needle **112** from the patient **116** and then removes the sample from the needle **112**.

FIG. **13** illustrates a cross-sectional view of a gas-powered vacuum aspect of an embodiment of the disclosed inventions. In particular, FIG. **13** depicts a gas-powered vacuum assisted device sub-component of ultrasound device **110** that may be integrated within the handle **114**. As seen in FIG. **13**, handle **114** may contain a high-pressure gas canister **200** that may contain liquid carbon dioxide, compressed air, or the like. The pressure from the gas in this canister **200** is released when a sharp pin **202** pierces the canister **202**, releasing the gas to press up against the positive pressure piston **204** coupled to the negative pressure piston **206** via the physical connection **210**. When the negative pressure piston **206** is forced to the right side of FIG. **13**, a vacuum is created in the vacuum cylinder **208**. This vacuum cylinder **208** extends into the needle **112** via a needle vacuum cylinder attachment on the needle **112** where it terminates at the sampling aperture **124**. Thus, when the gas canister **200** is forced into the pin **202** via the canister button cam **214** upon actuation of button **212**, a vacuum is applied to the vacuum cylinder **208** in the needle **112**. Tissue is then pulled into the sampling aperture **124** where a cutting mechanism, such as sharp walls forming the sample aperture **124**, may excise the tissue.

While certain embodiments have been described, the embodiments have been presented by way of example only and are not intended to limit the scope of the inventions. Indeed, the novel devices and methods described herein may be embodied in a variety of other forms; furthermore, various omissions, substitutions, and changes in the form of the devices and methods described herein may be made without departing from the spirit of the inventions. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of the inventions.

The invention claimed is:

1. An ultrasound device for needle procedures comprising:
- a core biopsy needle comprising a shaft with a distal end and a proximate end, wherein the shaft includes a tissue sampling aperture within the shaft between the distal end and the proximal end;
- a cutting mechanism disposed to cut tissue into the tissue sampling aperture; and
- a drop-in transducer within the tissue sampling aperture;

wherein the transducer comprises:
- a piezoelectric film;
- an integrated circuit in communication with the piezoelectric film; and
- an adhesive that attaches the transducer in the tissue sampling aperture.

2. The device according to claim **1**, wherein the transducer is disposed about one end of the needle.

3. The device according to claim **1** further comprising an adapter attachable to the needle at the proximate end of the shaft and a handle attachable to the adapter.

4. The device according to claim **3** further comprising an electrical subsystem in communication with the transducer, wherein the electrical subsystem is disposed within the adapter.

5. The device according to claim **1** further comprising a handle attached to the needle.

6. The device according to claim **1** further comprising a handle attached to the needle and a vacuum mechanism that pulls tissue into the tissue sampling aperture.

7. The device according to claim **1** further comprising an electrical subsystem in communication with the transducer, wherein the electrical subsystem is configured to control when an ultrasound pulse from the transducer is to be emitted.

8. The device according to claim **1** wherein the transducer and needle shaft are adapted to screw-fit together.

9. The device according to claim **1** further comprising a vacuum mechanism that pulls tissue into the tissue sampling aperture.

10. The device according to claim **1** wherein the integrated circuit is configured to control when the transducer emits an ultrasound pulse.

11. The device according to claim **1** further comprising a handle and a connection mechanism adapted to connect the handle to the needle shaft.

* * * * *

专利名称(译)	用于针程序的超声装置		
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[标]申请(专利权)人(译)	MUNG JAY C 康明斯THOMAS		
申请(专利权)人(译)	绿豆，JAYÇ CUMMINS，THOMAS		
当前申请(专利权)人(译)	CLARITRAC INC.		
[标]发明人	MUNG JAY C CUMMINS THOMAS		
发明人	MUNG, JAY C CUMMINS, THOMAS		
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CPC分类号	A61B8/4254 A61B8/0841 A61B8/13 A61B8/4263 A61B8/4472 A61B8/4483 A61B8/4494 A61B8/461 A61B10/0275 A61B10/0283 A61B2017/00106 A61B8/54 A61B90/39 A61B2090/3929		
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外部链接	Espacenet USPTO		

摘要(译)

公开了一种用于针程序的新型超声装置，其包括具有集成超声换能器的针。换能器可以是安装在针杆内的插入式自包含信标单元的一部分。换能器可替代地包括可连接到电子子系统的电引线，该电子子系统容纳在可连接到手柄的适配器内。或者，电子子系统可以通过卡口安装配置，滑动和点击配置或盒配置容纳在可连接到针的手柄内。电子子系统优选地配置成控制换能器何时发射超声脉冲。手柄可包括全部或部分真空装置，用于向设置在组织样本孔附近的组织施加负压。