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(54) **EXCISIONAL BIOPSY DEVICES AND METHODS**

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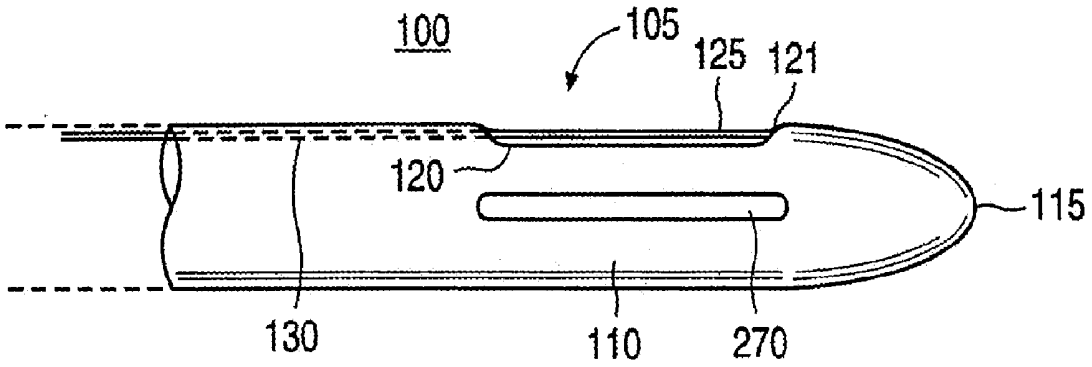
(57) **ABSTRACT**

An excisional biopsy device includes a tubular member having a window near a distal tip thereof; a cutting tool, a distal end of the cutting tool being attached near the distal tip of the tubular member, at least a distal portion of the cutting tool being configured to selectively bow out of the window and to retract within the window; and a tissue collection device externally attached at least to the tubular member, the tissue collection device collecting tissue excised by the cutting tool as the biopsy device is rotated and the cutting tool is bowed. An excisional biopsy method for soft tissue includes the steps of inserting a generally tubular member into the tissue, the tubular member including a cutting tool adapted to selectively bow away from the tubular member and an external tissue collection device near a distal tip of the tubular member; rotating the tubular member; selectively varying a degree of bowing of the cutting tool; collecting tissue severed by the cutting tool in the tissue collection device; and retracting the tubular member from the soft tissue. The tubular member may include an imaging transducer and the method may include the step of displaying information received from the transducer on a display device and the step of varying the degree of bowing of the cutting tool based upon the displayed information from the imaging transducer. Alternatively, the imaging transducer may be disposed within a removable transducer core adapted to fit within the tubular member.



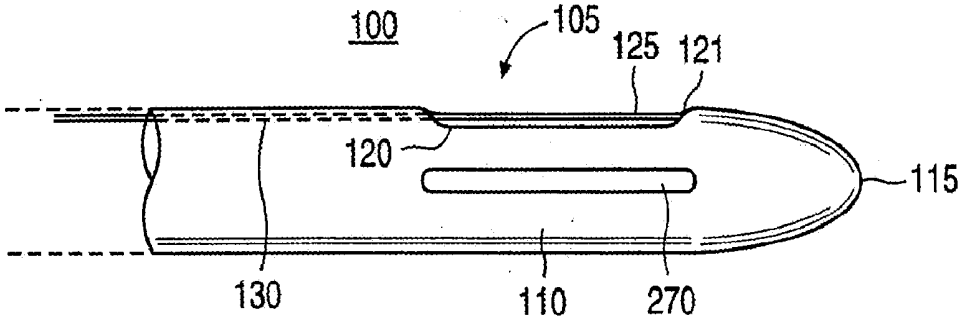


FIG. 1A

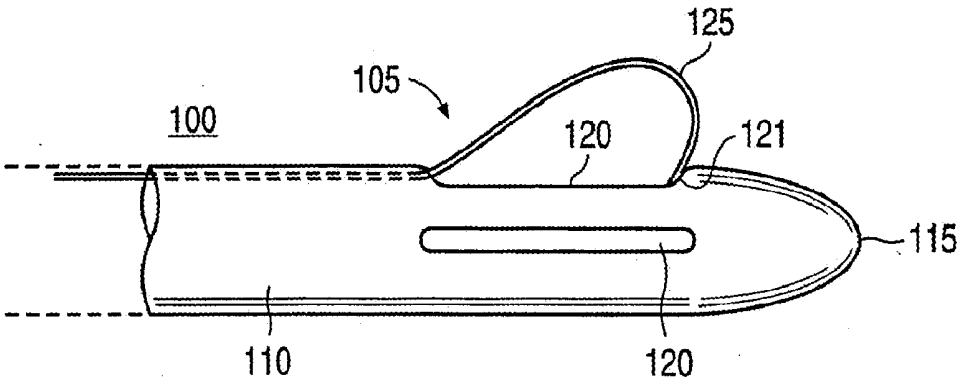


FIG. 1B

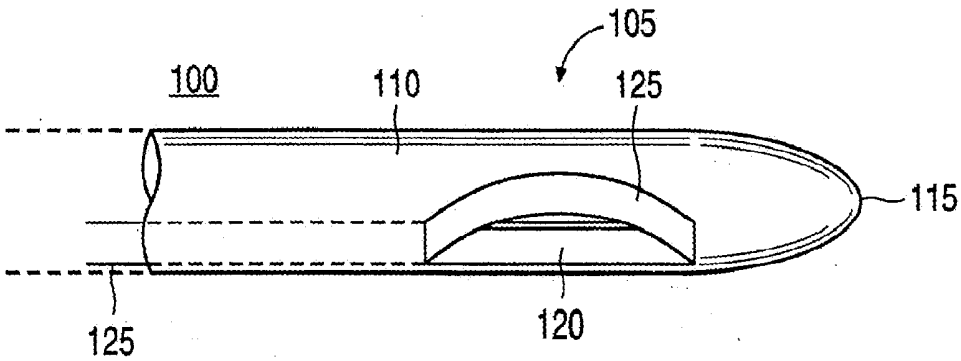


FIG. 1C

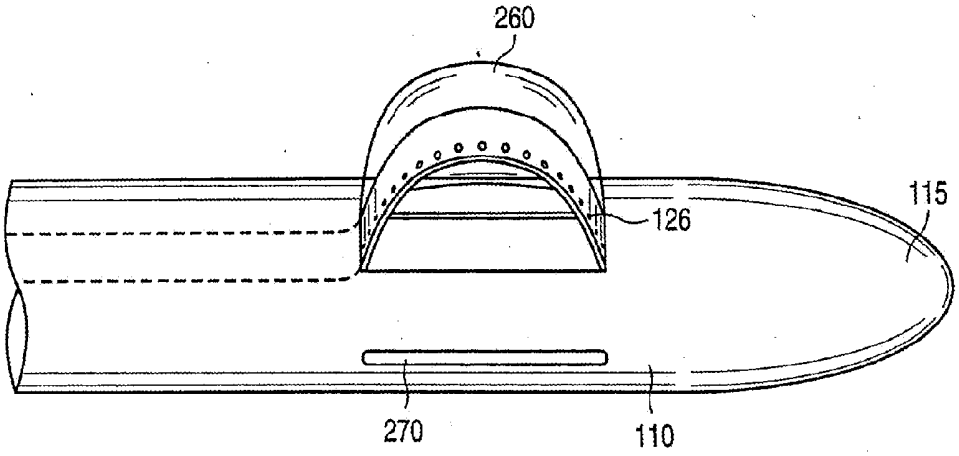


FIG. 2A

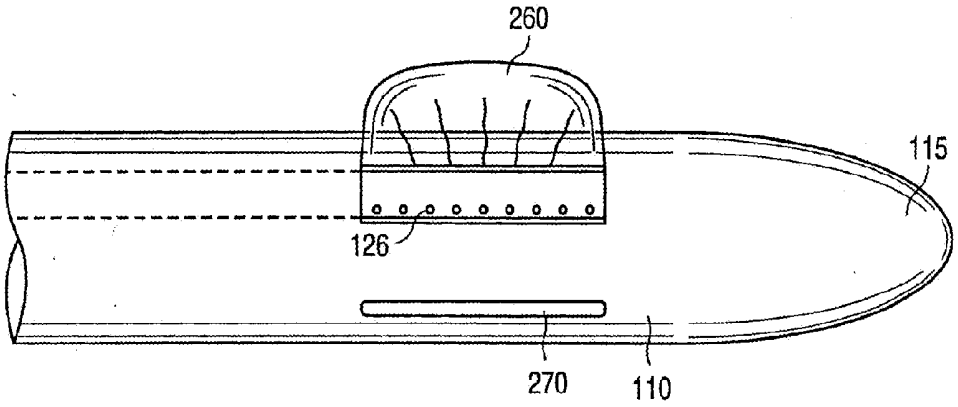


FIG. 2B

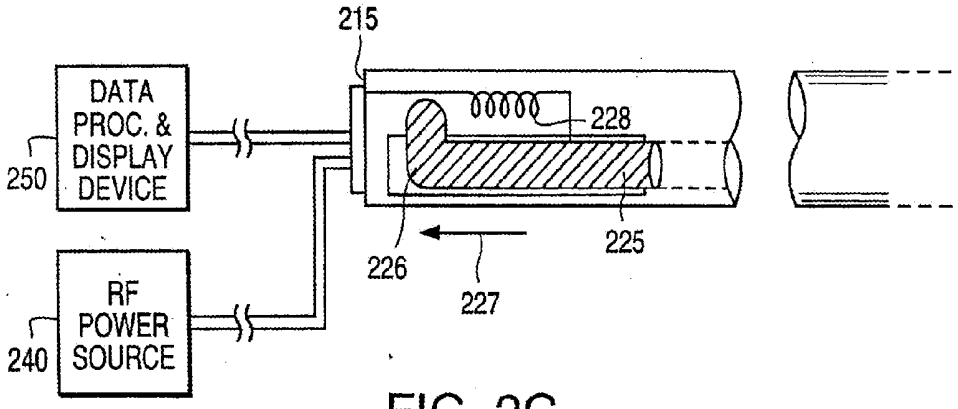


FIG. 2C

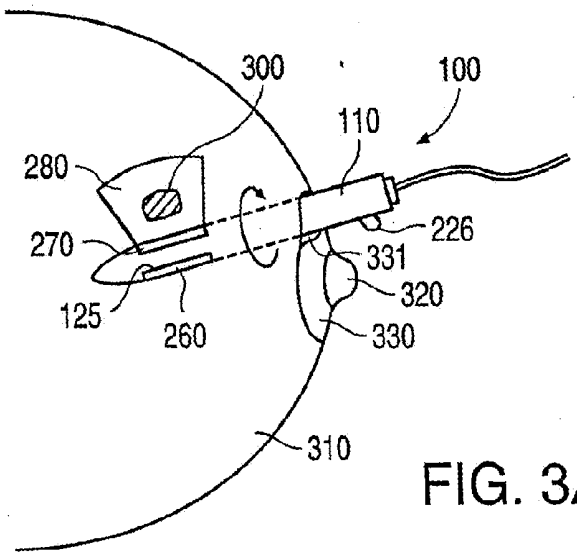


FIG. 3A

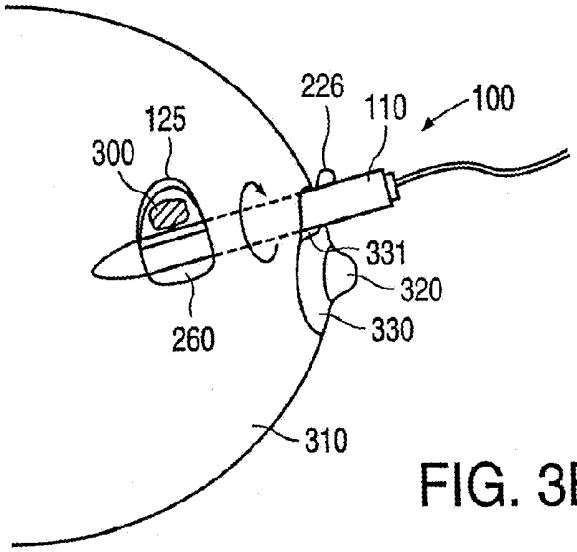


FIG. 3B

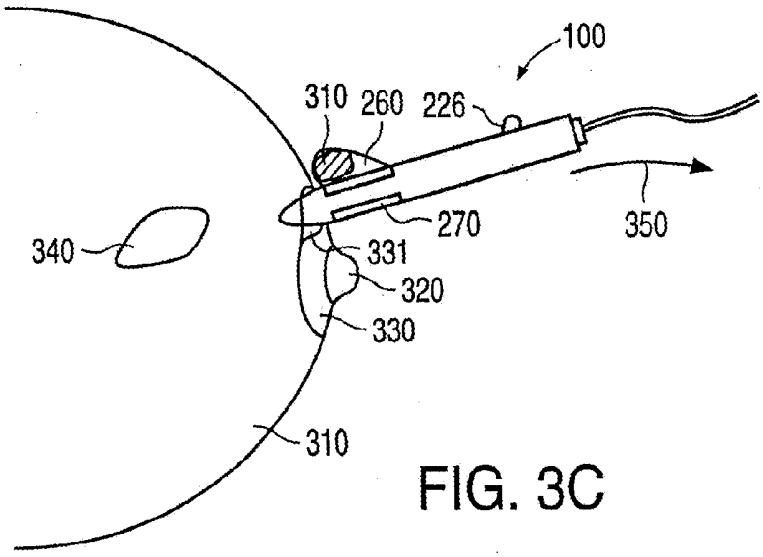


FIG. 3C

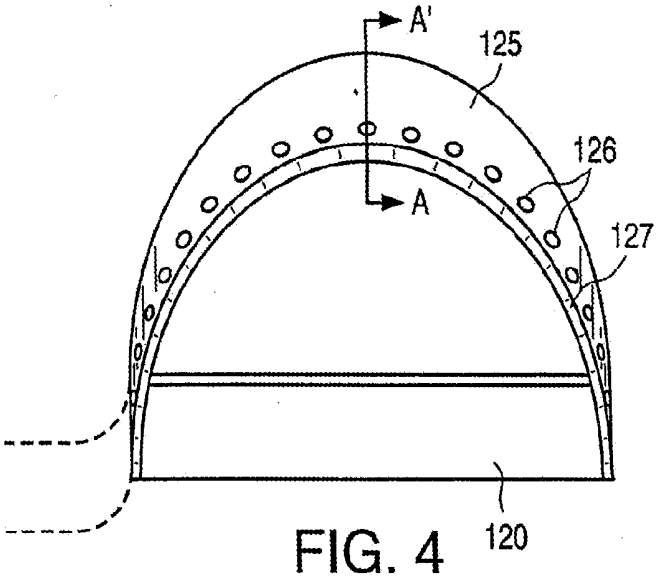


FIG. 4

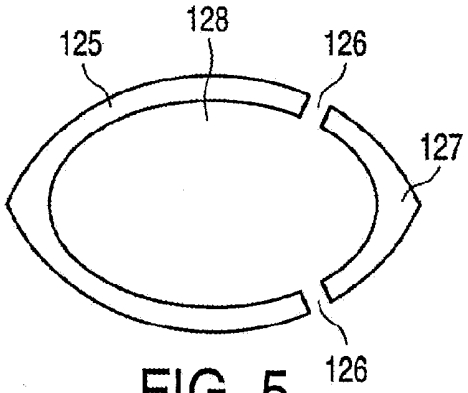


FIG. 5

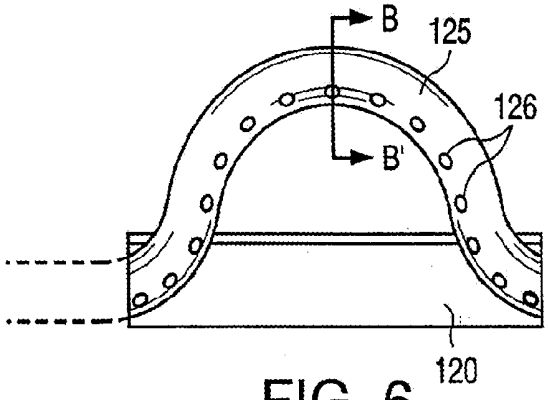


FIG. 6

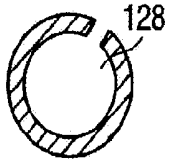


FIG. 7

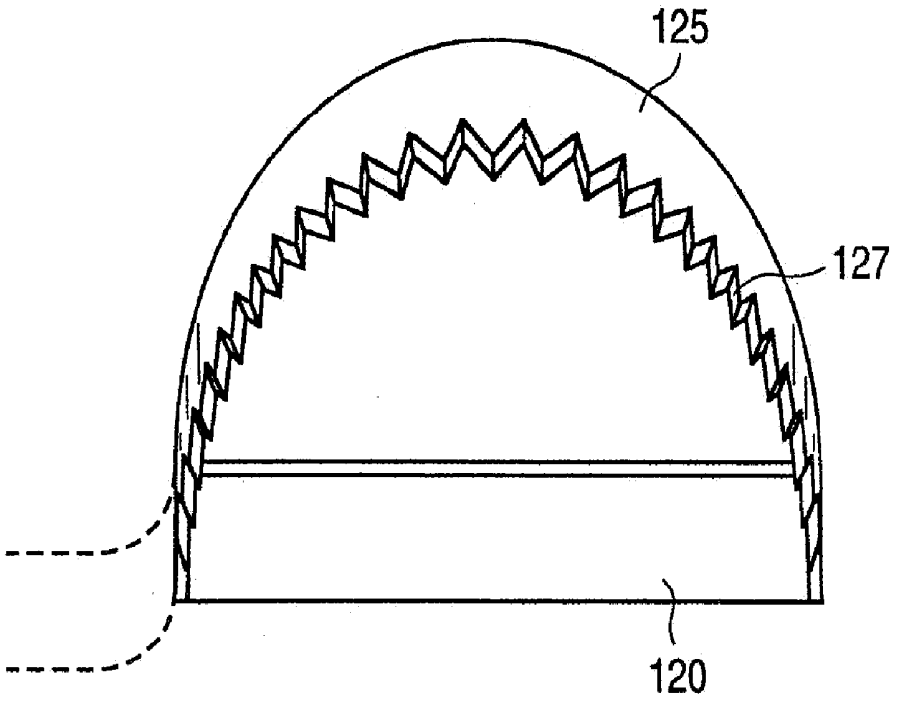


FIG. 8

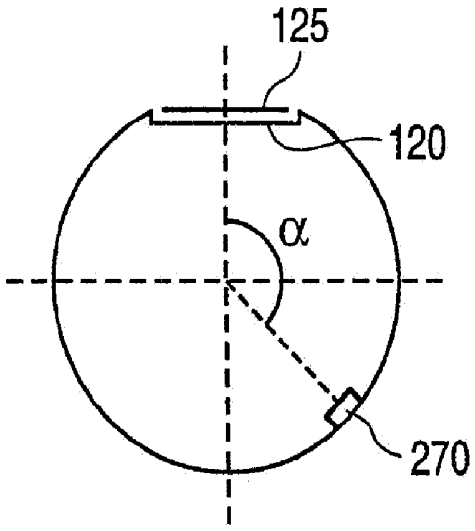


FIG. 9

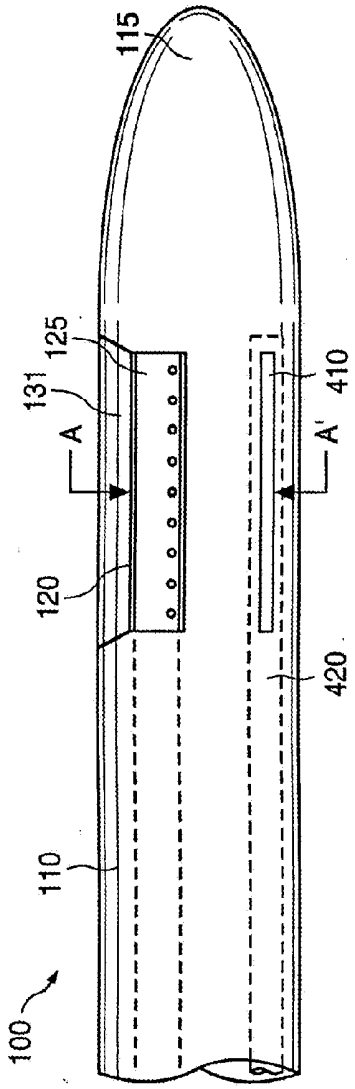


FIG. 10

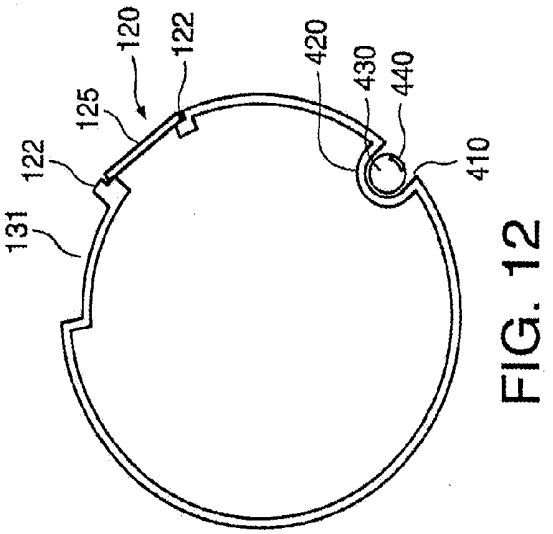


FIG. 12

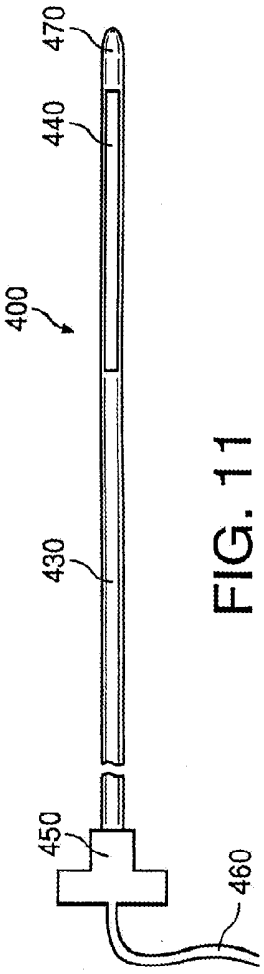


FIG. 11

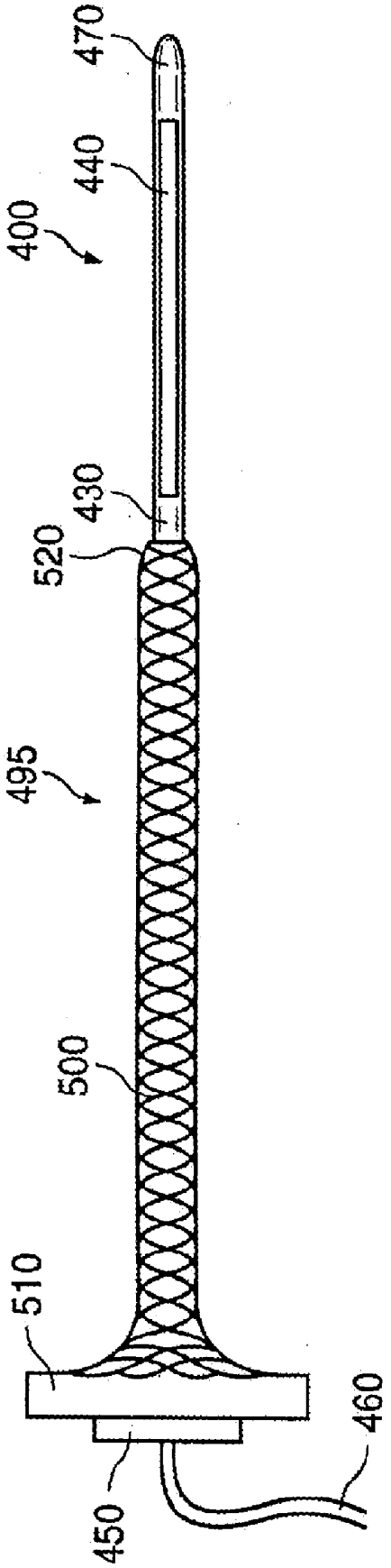


FIG. 13

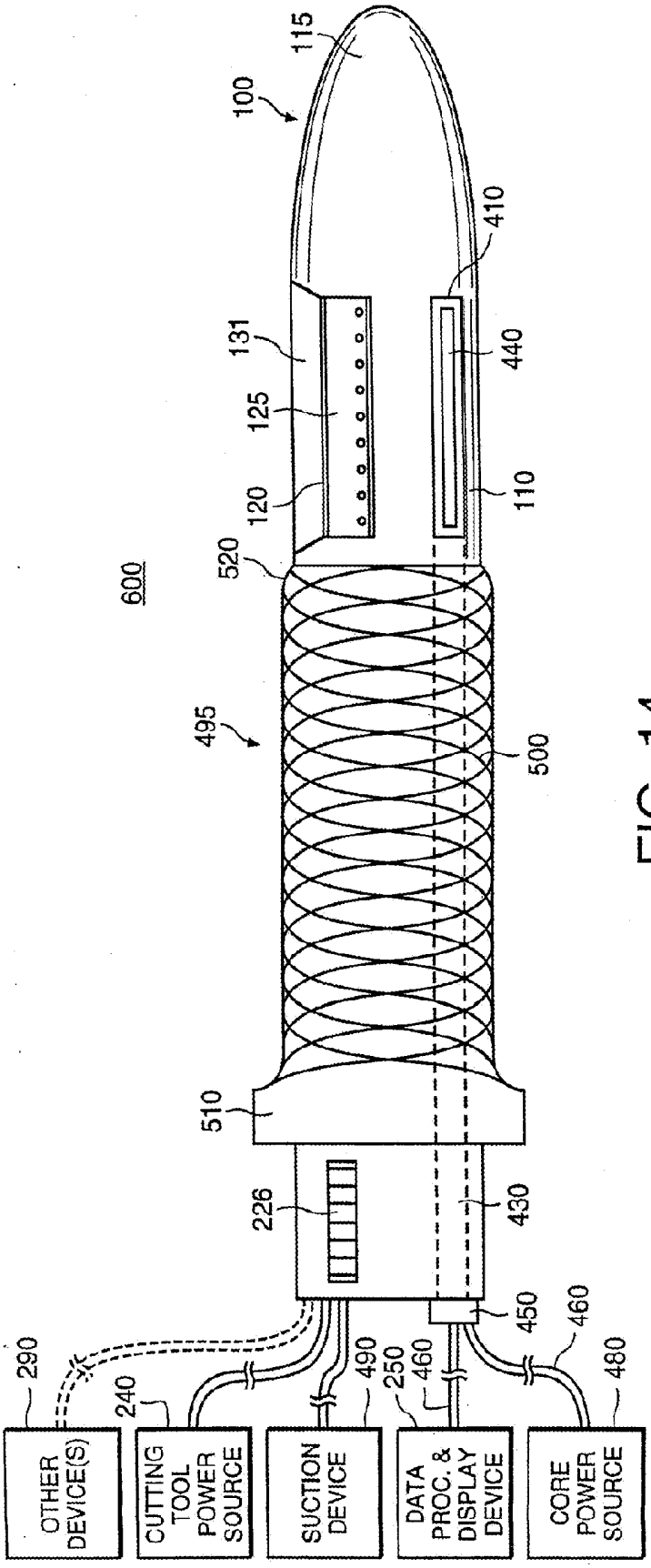

600
100
115
410
440
131
125
120
110
520
495
500
510
226
430
450
460
290
240
490
250
460
480
OTHER DEVICE(S)
CUTTING TOOL POWER SOURCE
SUCTION DEVICE
DATA PROC. & DISPLAY DEVICE
CORE POWER SOURCE

FIG. 14

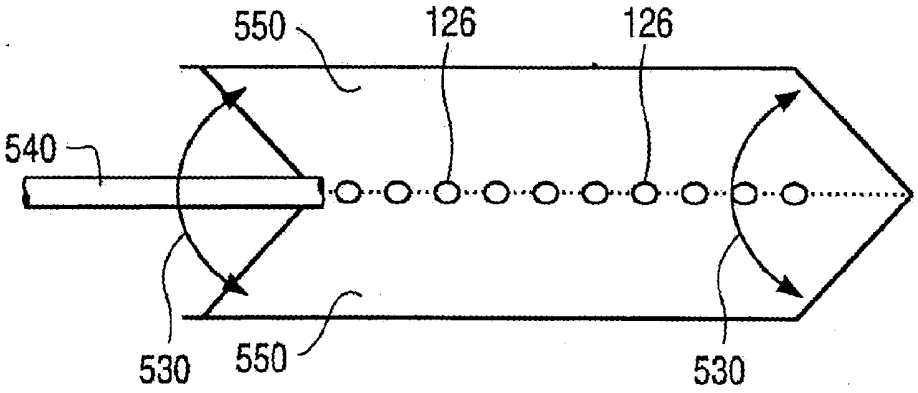


FIG. 15

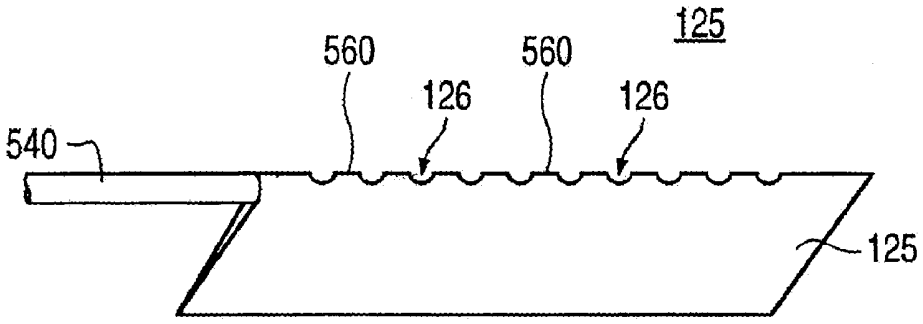


FIG. 16

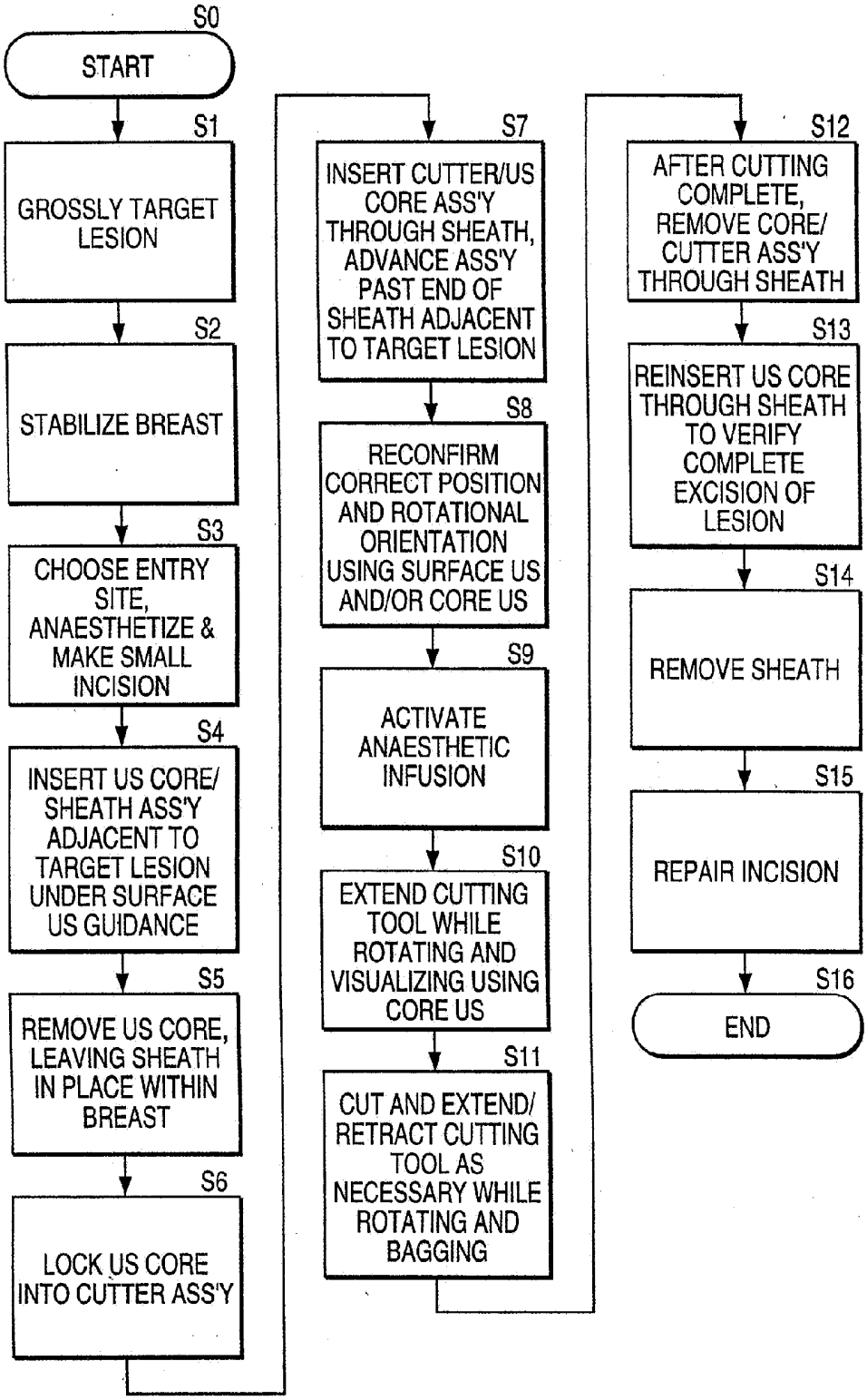

S0
START
S1
GROSSLY TARGET LESION
S2
STABILIZE BREAST
S3
CHOOSE ENTRY SITE, ANAESTHETIZE & MAKE SMALL INCISION
S4
INSERT US CORE/ SHEATH ASS'Y ADJACENT TO TARGET LESION UNDER SURFACE US GUIDANCE
S5
REMOVE US CORE, LEAVING SHEATH IN PLACE WITHIN BREAST
S6
LOCK US CORE INTO CUTTER ASS'Y
S7
INSERT CUTTER/US CORE ASS'Y THROUGH SHEATH, ADVANCE ASS'Y PAST END OF SHEATH ADJACENT TO TARGET LESION
S8
RECONFIRM CORRECT POSITION AND ROTATIONAL ORIENTATION USING SURFACE US AND/OR CORE US
S9
ACTIVATE ANAESTHETIC INFUSION
S10
EXTEND CUTTING TOOL WHILE ROTATING AND VISUALIZING USING CORE US
S11
CUT AND EXTEND/ RETRACT CUTTING TOOL AS NECESSARY WHILE ROTATING AND BAGGING
S12
AFTER CUTTING COMPLETE, REMOVE CORE/ CUTTER ASS'Y THROUGH SHEATH
S13
REINSERT US CORE THROUGH SHEATH TO VERIFY COMPLETE EXCISION OF LESION
S14
REMOVE SHEATH
S15
REPAIR INCISION
S16
END

FIG. 17

EXCISIONAL BIOPSY DEVICES AND METHODS

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention pertains to the field of soft tissue excisional biopsy devices and methods. In particular, the present invention relates to the field of devices and methods for excising suspicious lesions from soft tissue, such as breast tissue.

[0003] 2. Description of the Related Art

[0004] Breast cancer is a major threat and concern to women. Early detection and treatment of suspicious or cancerous lesions in the breast has been shown to improve long term survival of the patient. The trend is, therefore, to encourage women not only to perform monthly self-breast examination and obtain a yearly breast examination by a qualified physician, but also to undergo annual screening mammography commencing at age 40. Mammography is the only screening modality available today that can detect small, nonpalpable lesions. These nonpalpable lesions may appear as opaque densities relative to normal breast parenchyma and fat or as clusters of microcalcifications.

[0005] The conventional method for diagnosing, localizing and excising nonpalpable lesions detected by mammography generally involves a time-consuming, multi-step process. First, the patient goes to the radiology department where the radiologist finds and localizes the lesion either using mammography or ultrasound guidance. Once localized, a radiopaque wire is inserted into the breast. The distal end of the wire may include a small hook or loop. Ideally, this is placed adjacent to the suspicious area to be biopsied. The patient is then transported to the operating room. Under general or local anesthesia, the surgeon performs a procedure called a needle-localized breast biopsy. In the needle-localized breast biopsy, the surgeon, guided by the wire previously placed in the patient's breast, excises a mass of tissue around the distal end of the wire. The specimen is sent to the radiology department where a specimen radiograph is taken to confirm that the suspicious lesion is contained within the excised specimen. Meanwhile, the surgeon, patient, anesthesiologist and operating room staff, wait in the operating room for confirmation of that fact from the radiologist before the operation is completed. The suspicious lesion should ideally be excised in toto with a small margin or rim of normal breast tissue on all sides. Obtaining good margins of normal tissue is extremely dependent upon the skill and experience of the surgeon, and often an excessively large amount of normal breast tissue is removed to ensure that the lesion is located within the specimen. This increases the risk of post-operative complications, including bleeding and permanent breast deformity. As 80% of breast biopsies today are benign, many women unnecessarily suffer from permanent scarring and deformity from such benign breast biopsies.

[0006] More recently, less invasive techniques have been developed to sample or biopsy the suspicious lesions to obtain a histological diagnosis. The simplest of the newer techniques is to attempt visualization of the lesion by external ultrasound. If seen by external ultrasound, the lesion can be biopsied while being continuously visualized. This technique allows the physician to see the biopsy needle as it actually enters the lesion, thus ensuring that the correct area is sampled. Current sampling systems for use with external ultrasound guidance include a fine needle aspirate, core needle biopsy or vacuum-assisted biopsy devices.

[0007] Another conventional technique localizes the suspicious lesion using stereotactic digital mammography. The patient is placed prone on a special table that includes a hole to allow the designated breast to dangle therethrough. The breast is compressed between two mammography plates, which stabilizes the breast to be biopsied and allows the digital mammograms to be taken. At least two images are taken 30 degrees apart to obtain stereotactic views. The x, y and z coordinates targeting the lesion are calculated by a computer. The physician then aligns a special mechanical stage mounted under the table that places the biopsy device into the breast to obtain the sample or samples. There are believed to be three methods available to biopsy lesions using a stereotactic table: (1) fine needle aspiration, (2) core needle biopsy and (3) vacuum-assisted core needle biopsy.

[0008] Fine needle aspiration uses a small gauge needle, usually 20 to 25 gauge, to aspirate a small sample of cells from the lesion or suspicious area. The sample is smeared onto slides that are stained and examined by a cytopathologist. In this technique, individual cells in the smears are examined, and tissue architecture or histology is generally not preserved. Fine needle aspiration is also very dependent upon the skill and experience of the operator and can result in a high non-diagnostic rate (up to about 83%), due to inadequate sample collection or preparation.

[0009] Core needle biopsy uses a larger size needle, usually 14 gauge to sample the lesion. Tissue architecture and histology are preserved with this method. A side-cutting device, consisting of an inner trough with an outer cutting cannula is attached to a spring-loaded device for a rapid semi-automated firing action. After the lesion is localized, local anaesthetic is instilled and a small incision is made in the skin with a scalpel. The device enters the breast and the needle tip is guided into the breast up to the targeted lesion. The device is fired. First, the inner cannula containing the trough rapidly penetrates the lesion. Immediately following this, the outer cutting cannula rapidly advances over the inner cannula cutting a sample of tissue off in the trough. The whole device is then removed and the sample retrieved. Multiple penetrations of the core needle through the breast and into the lesion are required to obtain an adequate sampling of the lesion. Over 10 samples have been recommended by some.

[0010] The vacuum-assisted breast biopsy system is a larger semi-automated side-cutting device. It is usually 11 gauge in diameter and is more sophisticated than the core needle biopsy device. Multiple large samples can be obtained from the lesion without having to reinsert the needle each time. A vacuum is added to suck the tissue into the trough. The rapid firing action of the spring-loaded core needle device is replaced with an oscillating outer cannula that cuts the breast tissue off in the trough. The physician controls the speed at which the outer cannula advances over the trough and can rotate the alignment of the trough in a clockwise fashion to obtain multiple samples.

[0011] If a fine needle aspirate, needle core biopsy or vacuum-assisted biopsy shows malignancy or a specific benign diagnosis of atypical hyperplasia, then the patient needs to undergo another procedure, the traditional needle-localized breast biopsy, to fully excise the area with an adequate margin of normal breast tissue. Sometimes the vacuum-assisted device removes the whole targeted lesion. If this occurs, a small titanium clip should be placed in the

biopsy field. This clip marks the area if a needle-localized breast biopsy is subsequently required for the previously mentioned reasons.

[0012] Another method of biopsying the suspicious lesion utilizes a large end-cutting core device measuring 0.5 cm to 2.0 cm in diameter. This also uses the stereotactic table for stabilization and localization. After the lesion coordinates are calculated and local anesthesia instilled, an incision large enough is permit entry of the bore is made at the entry site with a scalpel. The breast tissue is cored down to and past the lesion. Once the specimen is retrieved, the patient is turned onto her back and the surgeon cauterizes bleeding vessels under direct vision. The incision, measuring 0.5 to larger than 2.0 cm is sutured closed.

[0013] The stereotactic table requires awkward positioning of the patient and may be extremely uncomfortable. The woman must lie prone during the entire procedure, which may be impossible for some patients. In addition, the lesion to be biopsied must be in the center working area of the mammography plates. This may be extremely difficult and uncomfortable for the patient if the lesion is very posterior near the chest wall or high towards the axilla.

[0014] The woman is subjected to increased radiation exposure as multiple radiographs are required throughout the course of the procedure to: (1) confirm that the lesion is within the working area of the mammography plates, (2) obtain the stereotactic coordinates (at least two views), (3) verify the positioning of the biopsy needle prior to obtaining tissue, and (4) verify that the lesion was indeed sampled. If any difficulty is encountered during the procedure, additional radiographic exposures are required to verify correction of the problem.

[0015] Using the core needle biopsy or vacuum-assisted device, bleeding is controlled only by manual pressure. Bleeding is generally not an issue with fine needle aspiration, but is a legitimate complication of the former two methods. Ecchymoses, breast edema and hematomas can occur. This causes increased post-procedural pain and delays healing. Rarely, the patient may require an emergency operation to control and evacuate a tense hematoma.

[0016] Another major concern is the possibility of tumor dissemination. The core needle biopsy and vacuum-assisted devices both cut into the tumor and carve out multiple samples for examination. While cutting into the tumor, cancerous cells may be dislodged. Cutting across blood vessels at the same time may allow the freed cancerous cells access to the blood stream, thus possibly seeding the tumor beyond its original locus. The long-term consequences of tumor seeding with the risk of bloodborne metastases are unknown at this time, as the techniques are relatively new. However, documented instances of cancerous cells seeding locally into needle tracks exist. There are numerous reports of metastases growing in needle tracks from previous biopsies of a cancerous mass. Most of these are from lung or liver cancers. However, at least one case of mucinous carcinoma of the breast growing in a needle track has been reported. The long-term consequences of neoplasm seeding into needle tracks are currently unknown, again because the techniques are relatively new. Some recommend excision of the entire needle track, including the skin entry site, during the definitive surgical procedure for a diagnosed cancer, whether it be a lumpectomy or a mastectomy. Others assume that with a lumpectomy, the post-operative radiation therapy will destroy any displaced cancer cells in the needle track. With the trend towards treating very small cancers only by excision and without a post-excision course of radiation therapy, the risk of cancer cells metastasizing and growing in needle tracks is very real.

[0017] The large core cutting device (0.5 cm to 2.0 cm) generally eliminates the risk of needle track seeding as it is designed to excise the lesion intact. A stereotactic table is required with the same inherent awkwardness for the patient, as discussed above. Bleeding is controlled, albeit manually, requiring that the patient wait until the end of the procedure to be turned over. Compression is used to stabilize the breast and localize the lesions. The breast, however, may be torqued and distorted between the compression plates such that when the plates are removed after the biopsy, the large core track left behind may not be straight, but actually tortuous. This can result in permanent breast deformity.

[0018] The location of the insertion site into the breast is dictated by the positioning of the breast in the machine and not by the physician. The entry site is usually away from the nipple-areolar complex and is usually located on the more exposed areas of the breast. For the fine needle aspirate, core biopsy and vacuum-assisted devices, the incision is usually very small and the scar almost unappreciable. However, in the case of the large core biopsy device (0.5 to 2.0 cm), a large incision is needed. Such a large incision often results in a non-aesthetically placed scar.

[0019] The newer conventional minimally invasive breast biopsy devices have improved in some ways the ability to diagnose mammographically detected nonpalpable lesions. These devices give the patient a choice as to how she wants the diagnosis to be made. Moreover, these devices are substantially less expensive than the older traditional needle-localized breast biopsy. They are not, however, the final solution. Due to the above-discussed problems and risks associated with compression, needle-track seeding, blood borne metastases, bleeding, radiation exposure and awkwardness of the stereotactic table, more refined devices and methods are needed to resolve these issues. Also, the conventional biopsy devices do not consider margins in their excisions and if cancer is diagnosed, the patient must undergo a needle-localized breast lumpectomy to ensure that adequate margins are removed around the cancer. Devices and methods, therefore, must address the problem of obtaining adequate margins so that a second procedure is not required. Margins, moreover, cannot be assessed while the breast is being compressed.

SUMMARY OF THE INVENTION

[0020] It is, therefore, an object of the present invention to provide devices and methods to efficiently and safely excise suspicious lesions from the breast. It is also an object of the present invention to provide devices and methods that remove the entire lesion intact with the minimum amount of normal tissue surrounding the lesion needed to provide adequate margins. It is a further object of the present invention to provide devices and methods that provide hemostasis in the breast to minimize complications of ecchymosis, hematoma formation, and breast edema. It is another object of the present invention to provide methods and devices to provide intra-tissue ultrasonic guidance to provide real time, in situ monitoring of the procedure. A still further object is to provide devices and methods that allow the physician to minimize the size of the incision though which the procedure is performed and to leave an aesthetically acceptable scar on the breast.

[0021] In accordance with the above-described objects and those that will be mentioned and will become apparent below, an embodiment of an excisional biopsy device according to the present invention comprises:

[0022] a tubular member having a window near a distal tip thereof;

[0023] a cutting tool, a distal end of the cutting tool being attached near the distal tip of the tubular member, at least a distal portion of the cutting tool being configured to selectively bow out of the window and to retract within the window; and

[0024] a tissue collection device externally attached at least to the tubular member, the tissue collection device being adapted to collect a tissue sample severed by the cutting tool as the biopsy device is rotated and the cutting tool is bowed.

[0025] According to further embodiments, the distal portion of the cutting tool may comprise a thin ribbon sharpened on a leading edge thereof. The leading edge of the thin ribbon may be serrated. The tubular member may comprise an internal guide allowing a proximal portion of the cutting tool to slide therein when a proximal end of the cutting tool is pushed in a distal direction or pulled in a proximal direction. The cutting tool may further comprise an interior lumen; and a plurality of through holes in the distal portion thereof, the through holes being in fluid communication with the interior lumen. The tissue collection device may comprise a bag within which the excised sample of tissue is collected. An opening of the bag may be at least co-extensive with the window in the tubular member. The tissue collection device may be configured to open and to close as the cutting tool is selectively bowed and retracted, respectively. The tissue collection device may comprise a bag attached to the tubular member and to a trailing edge of the distal portion of the cutting tool, the bag opening and closing as the cutting tool is bowed and retracted, respectively. An ultrasound sensor may be mounted within the distal portion of the tubular member, the ultrasound sensor being disposed within the tubular member so as to image tissue about to be cut by the cutting tool as the biopsy device is rotated. The ultrasound sensor may be electrically connected to at one or more data processing and display devices to allow either a real time or a near real time graphical representation of the tissue to be cut. The distal portion of the cutting tool may be electrically connected to an RF or other power source. The distal portion of the cutting tool may comprise a thin wire.

[0026] An invasive interventional device for soft biological tissue, according to a further embodiment of the present invention, comprises

[0027] a rotatable tubular member having a distal tip adapted to penetrate the tissue;

[0028] a work element disposed near the distal tip of the tubular member, the work element acting upon the tissue coming into contact therewith as the tubular member rotates;

[0029] an ultrasound transducer disposed near the distal tip of the tubular member and away from the work element, so that the transducer sweeps a plane within the tissue ahead of the work element as the tubular member rotates; and

[0030] means for controlling an operation of the work element based upon information gathered from the ultrasound transducer.

[0031] According to still further embodiments, the ultrasound transducer may be tuned within a range from about 7.5 MHz to about 20 MHz. The ultrasound transducer may be disposed within the tubular member at an angle α relative to the work element, the angle α being no smaller than that necessary to effectively control the operation of the work element in response to the information gathered from the transducer as the tubular member rotates. The angle α is preferably less than about 180 degrees. The work element may comprise at least one device selected from the group consisting of: an abrasive device, a reciprocating cutting device, a bowing cutting device, an electro surgical device, a laser device and a vibrating device. The ultrasonic transducer may be connected to at least one data processing and display device to allow an operator of the device to ascertain a structure of the tissue and to control the operation of the work element before the tissue comes into contact with the work element as the device rotates. The work element may comprise a cutting tool, a distal end of the cutting tool being attached near the distal tip of the tubular member, at least a distal portion of the cutting tool being configured to selectively bow out of a window in the tubular member and to retract within the window. The controlling means may include means for selectively bowing and retracting the cutting tool.

[0032] According to yet another embodiment, an excisional biopsy method for soft tissue, according to the present invention, comprises the steps of:

[0033] inserting a generally tubular member into the tissue, the tubular member including a cutting tool adapted to selectively bow away from the tubular member and an external tissue collection device near a distal tip of the tubular member;

[0034] rotating the tubular member;

[0035] selectively varying a degree of bowing of the cutting tool;

[0036] collecting tissue severed by the cutting tool in the tissue collection device; and

[0037] retracting the tubular member from the soft tissue.

[0038] The rotating step may be carried out by manually rotating the tubular member. The tubular member may further include an imaging transducer and the method may further include the steps of displaying information received from the transducer on a display device; and varying the degree of bowing of the cutting tool based upon the displayed information from the imaging transducer. The cutting tool may comprise an electrosurgical blade and the method may further comprise the step of varying the power (for example, RF power) applied to the electro surgical blade based upon information received from the transducer. A step of stabilising the soft tissue in an uncompressed state prior to the inserting step may also be carried out. A step of controlling the cutting tool to assume a non-extended state may be carried out prior to the inserting step and before the retraction step. The tissue collection device assumes a closed configuration when the cutting tool assumes the non-extended state. The extension of the cutting tool may be controlled by selectively and manually pushing and retracting a proximal end of the cutting tool in the distal and proximal directions, respectively. The cutting tool may comprise an interior lumen and a plurality of through holes in fluid communication therewith, and the method may further comprise the step of delivering at least one fluid to the tissue via the plurality of through holes.

[0039] The present invention may also be viewed as an imaging and treatment method for soft tissue, comprising the steps of:

[0040] inserting a tubular member into the soft tissue, the tubular member including an ultrasonic transducer mounted near a distal end of the tubular member;

[0041] rotating the tubular member within the soft tissue;

[0042] displaying an output of the ultrasonic transducer on a display device; and

[0043] acting upon the soft tissue based upon the displayed output.

[0044] According to further preferred embodiments, the ultrasonic transducer may be tuned to within a frequency range of between about 7.5 MHz to about 20 MHz. The acting step may include a step of severing a selectively variable volume of soft tissue from a main tissue mass. A step of collecting the severed volume of tissue in a tissue collection device mounted externally to the tubular member may also be carried out.

[0045] According to a further embodiment, an excisional biopsy device, according to the present invention, comprises:

[0046] a tubular member having a first and a second window near a distal tip thereof;

[0047] a cutting tool configured to selectively bow out of the first window and to retract within the first window; and

[0048] a removable transducer core, the transducer core including an active transducer element configured to face out of the second window when the removable transducer core is fitted within the tubular member.

[0049] The removable core may be adapted to snap fit within the tubular member. The active transducer element may, for example, include an ultrasound transducer. The removable transducer core may include a tapered distal tip configured to readily penetrate soft tissue. An external tissue collection device may be attached to the cutting tool and/or to the tubular member. The tubular member may further comprise a recessed section adjacent a trailing edge of the cutting tool, the recessed section being adapted to receive the external tissue collection device. An expandable sheath may also be included, the expandable sheath being adapted to receive the removable transducer core and the tubular member.

[0050] The present invention may also be viewed as a method of excising a lesion from soft biological tissue using an excisional biopsy system including a generally tubular member having a cutting tool, a removable transducer core adapted to fit within the tubular member and an expandable sheath, comprising the steps of:

[0051] fitting the transducer core through the expandable sheath,

[0052] inserting the transducer and sheath though an incision in the tissue;

[0053] imaging a target site within the tissue by energizing the transducer core,

[0054] removing the transducer core from sheath while leaving the sheath in place within the tissue;

[0055] securing the core within the generally tubular member so the core faces outwardly from the tubular member;

[0056] sliding the tubular member through the expandable sheath until the cutting tool is positioned adjacent the lesion;

[0057] cutting the lesion with the cutting tool; and

[0058] retracting at least the tubular member from the incision.

[0059] A step of stabilizing the breast in one of an uncompressed and a slightly expanded state prior to the inserting step may also be carried out. The sheath may remain within the tissue after the retracting step and the method may further comprise the step of re-inserting the transducer core within the sheath and imaging the target site to insure that the lesion has been excised. A step of collecting the cut lesion within an external tissue collection device secured to the tubular member may also be carried out. Both the tubular member and the sheath may be retracted from the incision.

[0060] The present invention may also be viewed as an excisional biopsy device, comprising:

[0061] a single use disposable tubular member having a window near a distal tip thereof, the tubular member including a cutting tool, a distal end of the cutting tool being attached near the distal tip of the tubular member, at least a distal portion of the cutting tool being configured to selectively bow out of the window and to retract within the window; and

[0062] a single use disposable tissue collection device externally attached at least to the tubular member, the tissue collection device collecting tissue severed by the cutting tool as the biopsy device is rotated and the cutting tool is bowed.

[0063] In yet another embodiment, the present invention is an excisional biopsy device, comprising:

[0064] a single use disposable tubular member having a first and a second window near a distal tip thereof, the tubular member including a cutting tool configured to selectively bow out of the first window and to retract within the first window; and

[0065] a removable transducer core, the transducer core including an active transducer element configured to face out of the second window when the removable transducer core is fitted within the tubular member.

BRIEF DESCRIPTION OF THE DRAWINGS

[0066] For a further understanding of the objects and advantages of the present invention, reference should be made to the following detailed description, taken in conjunction with the accompanying figures, in which:

[0067] FIG. **1**A shows an embodiment of the excisional device according to the present invention with the cutting tool in its flat, retracted configuration.

[0068] FIG. **1**B shows the excisional device of FIG. **1**A with its cutting tool in an extended, bowed configuration.

[0069] FIG. **1**C shows another view of the excisional device of FIG. **1**A.

[0070] FIG. **2**A depicts the distal region of another embodiment of the excisional device according to the present invention, showing the excisional device together with the external tissue collection attached thereto in the open configuration.

[0071] FIG. **2**B shows the excisional device of FIG. **2**A together with the external tissue collection attached thereto in the closed configuration.

[0072] FIG. **2**C shows an embodiment of the proximal region of the excisional device according to the present invention.

[0073] FIG. **3**A depicts the operation of an embodiment of the excisional device and method according to the present invention.

[0074] FIG. **3**B further shows the operation of an embodiment of the excisional device and method according to the present invention.

[0075] FIG. **3**C further depicts the operation of an embodiment of the excisional device and method according to the present invention.

[0076] FIG. **4** shows a detailed view of a cutting tool suitable for use with the excisional device according to the present invention.

[0077] FIG. **5** shows a cross section of the cutting tool, taken along line AA' in FIG. **4**.

[0078] FIG. **6** shows a detailed view of another cutting tool suitable for use with the excisional device according to the present invention.

[0079] FIG. **7** shows a cross section of the cutting tool, taken along line BB' in FIG. **6**.

[0080] FIG. **8** shows another embodiment of a cutting tool suitable for use with the excisional biopsy device according to the present invention.

[0081] FIG. **9** is a cross-sectional schematic of the tubular member **110**, to illustrate the relative placements of the cutter window **120** and of the transducer **270** about the circumference of the tubular member **110**. Unnecessary details have been omitted for clarity.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0082] FIGS. **1**A, **1**B and **1**C show an embodiment of the distal region **105** of the excisional biopsy device **100** according to the present invention. Considering FIGS. **1**A, **1**B and **1**C collectively, the distal region **105** of the excisional biopsy device **100** includes a generally tubular member **110** having a generally tapered distal tip **115**. The distal tip **115** is configured to penetrate soft tissue, such as breast tissue, lung tissue, liver tissue and the like. Preferably, therefore, the distal tip **115** and the distal region **105** of the excisional biopsy device **100** present a smooth, and relatively atraumatic profile to the soft tissue in which it is designed to penetrate. Alternatively, the tip **115** may be sharply pointed and/or may include an energy source (not shown) to facilitate cutting through the tissue. The tubular member **110** may be formed of rigid and hard plastic, or may be made of stainless steel, for example. Preferably, the tubular member **100** is used once and disposed of, for both safety and functional reasons.

[0083] A cutter window **120** is disposed within the tubular member **110**. The cutter window **120** may be, for example, a shallow trench formed in the tubular member **110**. As best seen in FIG. **1**C, the cutter window **120** may be a shallow and substantially rectangular trench in the tubular member **110**, or may be, for example, a thin, shallow I-shaped trench. The excisional biopsy device **125** includes a work element, such as a cutting tool **125**. The distal end of the cutting tool **125** is attached to the tubular member **110** near its distal tip **115**. For example, the distal end of the cutting tool **125** may be attached to the distal-most point **121** of the cutter window **120**. The cutting tool **125**, however, may alternatively be attached to other points within the distal region **105**. The distal portion of the cutting tool **125** is exposed through the cutter window **120**. The remaining portion of the cutting tool **125** is disposed within an internal guide or lumen **130** of the generally tubular member **110**. The internal guide **130** constrains the movement of the cutting tool **125** and allows the cutting tool **125** to freely slide therein, parallel to the longitudinal axis of the tubular member **110**. With particular reference now to FIG. **2**C, the proximal portion **225** of the cutting tool **125** emerges from the internal lumen **130** near the proximal end **215** of the tubular member **110**. The proximal end of the cutting tool **125** may, for example, include a push or turn knob **226**. The push or turn knob **226** allows the operator of the excisional biopsy device **100** to selectively push the cutting tool **125** in the distal direction (away from the physician and toward the distal tip **115**) or retract the cutting tool **125** in the proximal direction (toward the physician and away from the distal tip **115**). To assist in controlling the movement of the cutting tool **125**, the cutting tool is preferably biased in the proximal direction, as symbolized by the arrow **227** in FIG. **2**C. This biasing may be effectuated by means of a spring **228** attached at or near the proximal end **215** of the tubular member **110** and to the proximal portion **225** of the cutting tool **125**. In this manner, the default configuration of the cutting tool **125** is the retracted position, wherein the cutting tool **125** lies substantially flat within the cutter window **120** of the tubular member **110**.

[0084] The cutting tool **125**, when pushed in the distal direction by the physician applying pressure in the distal direction on the push or turn knob **226** or equivalent structure, slides within the internal guide **130** of the tubular member **110**. As the distal end of the cutting tool **125** is attached near the distal end of the tubular member **110** or to the distal-most point **121** of the cutter window **120**, the portion thereof exposed through the cutter window **120** tends to bow outwardly, extending out of the cutter window **120**, as shown in FIG. **1**B. The extension out of the cutter window **120** and the degree of bowing may be controlled by the physician, by appropriate action on the push or turn knob **226**. Thus, the possible range of extension and bowing is potentially infinite, being limited only by the physician's ability to control the cutting tool **125** by finely pushing and retracting the push or turn knob **226**. The degree of extension, as well as the shape of the bowed portion of the cutting tool, therefore, may be controlled by selectively sliding the cutting tool within the internal guide **130** of the tubular member **110**.

[0085] The shape of the bowed portion and the ease with which the distal portion of the cutting tool **125** bows outwardly may be varied by varying the physical characteristics of the cutting tool **125**. Preferably, the cutting tool is formed of a resilient, readily deformable material that, when unstressed, returns to its original unbiased configuration. For example, a nickel titanium alloy may be used for the cutting tool **125**, to allow the cutting tool **125** to exhibit shape-memory characteristics. The shape of the cutting tool **125** in its bowed and extended configuration (FIG. **2**) may be further controlled by varying, for example, the thickness of the cutting tool over the portion thereof exposed through the cutter window **120**. A locally thicker portion of the cutting tool **125** will not bend as readily as a locally relatively thinner portion thereof. Judiciously varying the thickness, for example, of the cutting tool **125**, therefore, allows the curvature of the bowed portion thereof to be controlled.

[0086] As shown in FIGS. **1**A, **1**B, and with reference to FIG. **1**C, pushing on the push or turn knob **226** (or any such functionally equivalent structure) causes the cutting tool **125** to bow outwardly and extend out from the cutter window **120** of the tubular member **110**, as shown in FIG. **1**B. Similarly, retracting the push or turn knob **226** (or any such functionally equivalent structure) causes the cutting tool **125** to flatten out within the cutter window **120** and to assume a configuration (shown in FIG. **1**A) that may be substantially flush with the outer surface of the tubular member **110**. In this configuration, the tubular member **110** may easily penetrate soft tissue, such as breast, lung, liver or other soft body tissue.

[0087] In operation, the surgeon makes an incision into the patient's skin, such as the surface of the breast. The excisional biopsy device **100** then may be directly introduced into the

breast tissue, or an expandable sheath (shown at reference numeral **495** in FIG. **13**) may be introduced into the incision and thereafter expanded as the excisional biopsy device **100** is introduced therein. In any event, the excisional biopsy device is introduced into the breast tissue itself and positioned, for example, adjacent to the lesion in the breast or adjacent the target site from which the excision is to take place. During the introduction of the excisional biopsy device **100** into the soft tissue, the cutting tool **125** is in its retracted configuration wherein the portion thereof exposed through the cutter window **120** is substantially flat. The excisional device **100**, in this configuration, therefore, exhibits a smooth and tapered profile to the surrounding tissue. Once the device **100** has been determined to have been properly positioned within the soft tissue, the device is rotated about its longitudinal axis. The rotation may be carried out manually, or the rotation of the device may be carried out by a motorized unit disposed within the proximal region of the device **100**. As the device **100** rotates, the surgeon causes the cutting tool **125** to bow outwardly and to extend from the cutter window **120**. Preferably, the degree of bowing and outward extension is at least sufficient to include the lesion (such as the targeted microcalcification within the breast) within the space between the cutter window **120** and the cutting tool **125**. The cutting tool **125** cuts the tissue as the device **100** is rotated, thereby severing the lesion from its surrounding breast tissue mass. By completing at least one revolution within the breast tissue, the cutting tool **125** sweeps a volume of revolution of breast tissue and severs that volume from the main tissue mass. Such volume of revolution includes at least the targeted lesion. Preferably, the volume of revolution severed from the main tissue mass not only includes the targeted lesion, but also includes a margin of healthy tissue surrounding the lesion. The degree of extension and bowing of the cutting tool **125** may be varied within a given revolution of the excisional biopsy device **100**. In this manner, it is possible to exert fine control over the amount of tissue cut away from the main tissue mass, as well as fine control over the shape of the severed mass.

[0088] After the lesion and preferably a margin of healthy tissue around the lesion have been severed, the severed tissue may be removed from the main tissue mass. This removal of the severed tissue may be effectuated by any number of means, including the retraction of the excisional biopsy device **100** from the main tissue mass. Alternately, severed tissue extraction may be carried out by means of the structure and method to be described below.

[0089] The cutting tool **125** may, as shown in FIG. **1**C, be configured as a thin ribbon. The thin ribbon **125** shown in FIG. **1**C is preferably sharpened on its leading edge to facilitate cutting through tissue and sometimes fibrous and calcified masses. The leading edge of the cutting tool **125** is that edge thereof that first comes into contact with the tissue to be severed as the device **100** is rotated. Such a sharpened leading edge is shown in FIG. **4** at reference numeral **127**. The width of such a ribbon cutting tool **125** is preferably smaller than the width of the cutter window **120** into which it recedes when the cutting tool **125** is retracted in the proximal direction.

[0090] Another embodiment of the cutting tool **125** is shown in FIG. **8**. To decrease the forward resistance of the cutting tool **125** as it slowly cuts through tissue, the leading edge of the portion thereof exposed through the cutter window **120** may be serrated, including a plurality of teeth **127**. In turn, the leading edge of the plurality of teeth **127** may include a sharpened edge. In this manner, as the excisional device **100** rotates, only the forward-most tips of the teeth **127** will initially come into contact with the tissue to be cut, thus reducing the tissue surface upon which the force of the rotating cutting blade **125** is applied. Thus, the cutting blade **125** of FIG. **8** is believed to be highly effective in cutting through even relatively dense or fibrous tissue while minimizing the torque to be applied to the excisional biopsy device **100** as it is caused to rotate within the main soft tissue mass.

[0091] Referring to FIG. **4** and also to FIG. **5**, the cutting tool **125** may further comprise an interior lumen **128** running an entire length or a portion of the length of the cutting tool **125**. The cutting tool **125** may further include a plurality of through holes **126** in the distal portion of the cutting tool **125** exposed through the cutter window **120**. The plurality of through holes **126** are in fluid communication with the internal lumen **128**. In use, the internal lumen **128** may be connected, in the proximal portion of the excisional biopsy device **100**, to a fluid reservoir. The fluid reservoir, which may be internal or external to the proximal section of the device **100**, supplies the distal portion of the cutting tool **125** with, for example, anaesthetic (such as, for example, lidocaine) and/or antibiotic fluid. In this manner, such anaesthetic and/or antibiotic fluid (or other fluid) may be delivered precisely to the tissue surrounding the cutting tool **125** as it rotates. A precisely dosed anaesthetic, for example, may be delivered to the very site where it is most needed. As such anaesthetic is delivered only where it is needed, the effect thereof is near instantaneous, and the patient feels little or no pain as the excisional biopsy device **100** according to the present invention is rotated within her breast, or other soft tissue. FIG. **5** shows a cross-section of the cutting tool **125** of FIG. **4**, taken along line AA' in FIG. **4**.

[0092] Care should be exercised in selecting the configuration and materials for the cutting tool **125** shown in FIGS. **4** and **5**. Indeed, the configuration and materials selected should allow the cutting tool **125** to bow and extend out of the cutter window **120** of the device **100** without, however, pinching or substantially disrupting the flow of fluid delivered via the internal lumen **128** of the cutting tool **125**, if the cutting tool **125** is provided with such. For example, the cutting tool **125** may be made of a shape-memory metal, such as nickel-titanium and/or the proximal portion of the cutting tool **125** may be formed relatively thicker than other portions thereof.

[0093] Another embodiment of the cutting tool **125** is shown in FIGS. **15** and **16**. As shown therein, the cutting tool **125** may be formed by a thin sheet of steel or shape memory alloy. The sheet may include a plurality of through holes **126** to allow the anaesthetic or other fluid to be instilled therethrough. A small tube **540** may be disposed on the sheet, aligned with the through holes **126**. The sheet may be folded in the direction indicated by the arrows **530**, thus securing the tube **540** between the two folded sides of the sheet. The edges **550** of the sheet may be sealed together to render them fluid tight. For example, the sides **550** of the sheet may be welded together or secured by other means known to those of skill in the metal working arts. The edges **560** between the through holes **126** may be sharpened, to allow the cutting tool **125** to efficiently cut through soft tissue. As shown in FIG. **16**, the tube **540** may deliver anaesthetic or other fluid to the cutting tool **125**, which delivers minute amounts thereof precisely where it is needed: where the cutting edges **560** of the cutting tool **125**, thereby affording the patient immediate relief and minimizing the amount of anaesthetic that need be delivered.

The proximal end of the tube **540** may be in fluid communication with an anaesthetic reservoir (not shown) and/or an anaesthetic pump (also not shown).

[0094] Alternatively, the cutting tool **125** may include a thin wire, such as shown at **125** in FIGS. **6** and **7**. In this case, an external radio frequency (hereafter, RF) power source **240** (shown at **240** in FIG. **2**C) supplies the cutting tool **125** with RF energy via two bipolar electrodes (not shown) attached to the cutting tool **125** of FIG. **6**. Other energy sources may also be used within the context of the present invention, RF power being discussed herein for illustrative purposes only. The RF power delivered by the RF power source **240** allows the cutting tool **125** of FIG. **6** to become an electrosurgical cutting and/or an electrocoagulating tool by selectively varying the power applied to the cutting tool **125**. Suitable generators for such an electrosurgical cutting device **125** are known to those of skill in this art. An example of such a suitable generator is described in U.S. Pat. No. 4,903,696 issued Feb. 27, 1990 and assigned to Everest Medical Corporation, Brooklyn Center, Minn., the disclosure of which is incorporated herewith in its entirety. As with the cutting tool **125** shown in FIGS. **4** and **5**, the cutting tool **125** of FIGS. **6** and **7** includes an internal lumen **128** and a plurality of through holes **126** to allow anaesthetic or other fluid to be delivered to the surrounding tissue as the cutting tool **125** cuts through the soft tissue as the device **100** is rotated.

[0095] As alluded to above, the excisional biopsy device **100** according to the present invention cuts out a (not necessarily symmetrical) volume of revolution as it cuts through the soft tissue upon rotation of the generally tubular member **110**. This severed mass of tissue may be stabilised using an extendable tissue anchoring device, which anchoring device also assists in the retrieval of the severed tissue sample from the breast. The anchoring device may, for example, include a suction device or other substantially rigid anchor member to anchor the tissue sample. Alternatively, the severed tissue sample may be collected in a tissue collection device, as shown at reference numeral **260** in FIGS. **2**A and **2**B. The tissue collection device **260** is attached externally to the tubular member **110**, and preferably also to the trailing edge of the cutting tool **125**. The tissue collection device **260** is preferably formed of a thin and flexible plastic membrane shaped like a bag. The opening of the bag-shaped collection device **260** is preferably co-extensive with the opening **120** and is preferably attached to the tubular member **110** and to the trailing edge of the cutting tool **125**. In this manner, the opening or "mouth" of the bag-shaped collection device **260** opens and closes along with the bowing and retraction, respectively, of the cutting tool **125**. Indeed, the "mouth" of the bag-shaped collection device **260** is opened when the cutting tool **125** is bowed and extended out of the cutter window **120** and substantially closed when the same is retracted within the cutter window **120**, as the two edges (one attached to the tubular member **110** just adjacent to the edge of the cutter window **120** and the other attached to the trailing edge of the cutting tool **125**) of the collection device are then pressed together.

[0096] Therefore, when the excisional device **100** is inserted into soft tissue and rotated, the cutting tool **125** may be caused to bow and to extend outwardly from the cutter window **120** and caused to cut tissue coming into contact therewith. As the device **100** rotates and cuts, the tissue between the cutting tool **125** and the tubular member **110** tends to advance toward and into the collection device. As the cutting tool **125** is in its bowed and extended state, the "mouth" or opening of the bag-shaped collection device **260** is also correspondingly open, allowing the severed tissue to collect therein. As the revolution of the tubular member **100** is completed, the cutting tool **125** may be retracted and caused to assume a configuration wherein it is disposed within the recessed cutter window **120**, substantially flush with the outer surface of the tubular member **110**, as shown in FIG. **2**B. In this configuration, the collection device **260** is closed, thereby securing the excised tissue sample therein. The device **100** may then be safely retracted from the main tissue mass, such as the breast. As the excised sample is physically isolated from the remaining tissue mass, the probability of seeding the surrounding tissue with potentially abnormal cells is markedly decreased. This probability is also further decreased, as the excisional device **100** according to the present invention allows the surgeon to obtain adequate margins of healthy tissue surrounding the target lesion by choosing the degree of bowing and extension of the cutting tool **125**. In this manner, the integrity of the lesion itself is not violated, thereby maintaining tissue architecture intact.

[0097] As the collection device **260** is preferably formed of a thin and flexible membrane, it is able to lay substantially flat against the outer surface of the tubular member **110** or slightly recessed within the cutter window **120** during insertion thereof into the soft tissue. The collection device **260**, therefore, offers little additional drag and resistance to the device **100** as it is inserted into the incision made in the patient's skin during or prior to the procedure. Suitable materials for the tissue collection device **260** include plastics and nylon, for example. Any strong adhesive may be utilized to secure the tissue collection device **260** to the tubular member **110** and to the cutting tool **125**. Other means of securing the collection device **260** may also be employed without, however, departing from the scope of the present invention. Likewise, the tissue collection device **260** may be formed of a material other than specifically enumerated herein while remaining within the spirit of the present invention. Preferably, the shape and size of the tissue collection device **260** are such as to minimize drag on the excisional biopsy device **100** as it is inserted and rotated into the tissue. For example, the tissue collection device **260** preferably should be only as large as necessary to contain the excised tissue sample.

[0098] The excisional biopsy device **100** according to the present invention is preferably accurately positioned adjacent to the lesion within the breast or other organ. Toward that end, the present invention allows the surgeon to gain near real time or real time information as to the internal structure of the soft tissue during the procedure itself. Referring now back to FIGS. **1** and **2**C, the present invention may include a transducer **270** mounted within the distal portion of the tubular member **110**. This transducer **270** is preferably adapted to image tissue about to be cut by the cutting tool **125** as the excisional biopsy device **100** is rotated within the soft tissue. Indeed, the transducer **270** preferably generates information relative to the tissue about to be cut—that is, tissue that that has not yet been brought into contact with the cutting tool **125** as the tubular member **110** rotates about its longitudinal axis. In this manner, as the rotational speed of the excisional biopsy device **100** is preferably quite slow (the rotation may be manually carried out or may be caused by a slow moving motorized unit attached to the tubular member **110**), the surgeon may evaluate the information generated by the transducer **270** and may, based upon this information, vary the

degree of bowing and extension of the cutting tool **125**. For example, when the device **100** is positioned adjacent to the lesion of interest and rotated, the transducer **270** will detect the presence and location of the lesion before the lesion comes into contact with the cutting tool **125**. After the lesion has been detected by the transducer **270**, the surgeon may push on the push or turn knob **226** or other structure that causes the cutting tool to bow and extend from the cutter window **120**. The lesion (and preferably an adequate margin of healthy tissue) will then be severed from the main mass, and optionally collected, for example, in the tissue collection device **260**. When the transducer **270** indicates that the rotation of the tubular member has brought the cutting tool **125** past the lesion, the cutting tool **125** may be retracted within the cutter window **120**. The cutting, it can be seen, may be specifically tailored to the size and shape of the lesion within the main tissue mass in near real time or in real time, thereby allowing the surgeon to excise all of the tissue required and only the tissue that is necessary to achieve the intended results.

[0099] Preferably, the transducer **270** is an ultrasound sensor mounted substantially flush with the external surface of the tubular member **110**. The ultrasound sensor **270** is preferably electrically connected, via a communication channel such as electrical conductors, to at least one data processing and display device, shown at reference **250** in FIG. **2**C. The data processing and display device(s) **250** allows the surgeon to see, in near real time or in real time, the internal structure of the tissue about to be cut by the cutting tool **125**. This allows the surgeon not only to see a graphical representation of the internal structure of the tissue during the procedure itself, but also allows the surgeon to assure himself or herself that the entire lesion or group of lesions has been properly excised by, for example, rotating the tubular device within the tissue while the cutting tool is retracted within the cutter window **120** while the transducer **270** is energized. Viewed from another aspect, therefore, the present invention is an intra-tissue ultrasound imaging device that may, but need not include a cutting tool, such as referenced by numeral **125** in the figures.

[0100] In operation, the (e.g., ultrasound) transducer sweeps a plane (graphically shown at **280** in FIG. **3**A) within the tissue ahead of the work element, such as cutting tool **125**. In selecting the operational characteristics of the ultrasound transducer **270**, the surgeon must balance the required resolution (i.e., the smallest feature that must be discernable) with the degree of penetration of the ultrasound waves within the tissue and the intensity of the ultrasonic waves generated. In general, higher frequencies allow better resolution. However, high frequencies do not penetrate the tissue as far as do lower frequency ultrasound waves. Preferably, the ultrasound transducer **270** is tuned within the range from about 5 MHz to about 20 MHz. More preferably, the ultrasound transducer **270** is tuned within the range of about 7.5 MHz to about 20 MHz. For example, in the case wherein the excisional biopsy device **100** according to the present invention is used within the female breast, the ultrasound transducer may be tuned within the range of about 10 MHz to about 13 MHz.

[0101] To effectively image the internal tissue structure prior to cutting it with, for example, the cutting tool **125**, the transducer **270** must be positioned within the tubular member **110** away from the cutting tool **125**. With reference to FIG. **9**, the transducer **270** may be disposed within the tubular member at an angle α relative to the cutting tool **125**. The angle α is preferably no smaller than that necessary to effectively control the operation of the work element (such as cutting element **125**) in response to information gathered from the transducer **125** as the tubular member **110** rotates. This angle α, therefore, is dependent at least upon the rotational speed imposed upon the tubular member **110** and upon the time necessary for the surgeon to assimilate the information generated by the transducer and to effectively control the cutting tool **125** in response to such information. Preferably, the angle α is less than about 180 degrees.

[0102] When used in conjunction with an intra-tissue ultrasound transducer, such as shown at **270**, the excisional biopsy device **100** according to the present invention may include a variety of work elements in place of or in addition to the cutting tool **125**. Such work elements include, for example, an abrasive device, a reciprocating cutting device, an electro surgical device or a vibrating device.

[0103] In the case of lesions within the breast, it is useful to stabilize the breast prior to imaging and performing invasive procedures. Such stabilization is conventionally performed by compression plates that squeeze the breast and compress the tissue therein. Such compression is necessary to allow x-ray radiation, as used in mammography, to produce a useful image. Although such compression is not needed or believed to be desirable according to the present invention, stabilization of the breast remains necessary. For this purpose, the breast stabilization device described in commonly assigned U.S. patent application Ser. No. 09/_____, filed 1998, the disclosure of which is incorporated herein in its entirety, may be useful.

[0104] Reference is now made to FIGS. **3**A, **3**B and **3**C, which illustrate an embodiment of the excisional biopsy method according to the present invention. Although FIGS. **3**A-**3**C illustrate an embodiment of the present invention within the context of breast surgery, it is to be understood that the present inventive method is equally applicable to other soft tissue masses, such as, for example, lung, thyroid or liver tissue, with only minor modifications which will become apparent to skilled practitioners in this art.

[0105] Turning first to FIG. **3**A, a small incision **331** is made in the breast **310**, preferably in the peri-areolar region. Preferably, the breast is stabilised, using, for example, the breast stabilising device disclosed in U.S. patent application Ser. No. 09/_____ referred to above. The portion of the device **100** that remains outside of the soft tissue may include attachment means (not shown) for clamping the device to a rim structure, for example, to allow stable operation and precise guidance thereof. The small incision is preferably made on the border of the areola **330** surrounding the nipple **320**, as this provides a better cosmetic scar than on the skin on the side of the breast **310**. Depending on the size of the lesion and the size of the excisional biopsy device **100** to be inserted therein, an expandable sheath (an example of which is shown at reference numeral **495** in FIG. **13**) may be inserted into the breast tissue. In any event, the excisional biopsy device **100** is inserted into the breast tissue and positioned adjacent the lesion **300**, which may be, for example, a microcalcification or other abnormal lesion. Once in position, the device **100** is rotated, for example, in the direction indicated in FIG. **3**A. The portion of the excisional biopsy device **100** that remains outside the soft tissue may have a greater diameter than the portion thereof that is designed to penetrate the soft tissue. This aids in manual rotation of the device **100**. In the configuration depicted in FIG. **3**A, the cutting tool **125** is retracted

within the cutter window **120** and the tissue collection device **260**, if present, is substantially flat against the external surface of the tubular member **110**. The device **110** is rotated about its longitudinal axis and the transducer **270** is energized, the information therefrom being transmitted to, for example, the display device **250** shown in FIG. **2**C. When the lesion **300** comes into view, the surgeon then gauges the size, shape and location thereof and controls the bowing and extension of the work element, such as cutting tool **125** based on the information received from the transducer **270** and displayed upon the display **250**. FIG. **3**B depicts the situation wherein the lesion **300** has been imaged and the surgeon has extended the cutting tool **125** to sever the lesion **300** from the surrounding breast tissue. The severed tissue may be received and collected in a tissue collection device **260**, as the device **100** rotates. Anaesthetic and/or antibiotic (or other) fluids may be delivered directly to the affected tissue by through holes **126** (best seen in FIGS. **2**A, **2**B and FIGS. **4**-**7**), greatly decreasing pain during the procedure

[0106] After the lesion and any desired margin of healthy tissue is severed from the main breast tissue mass, the cutting tool **125** is retracted within the cutter window **120**. This closes the tissue collection device **260**, if present, and allows the entire device **100** to be retracted from the breast in the direction of arrow **350**, as shown in FIG. **3**C. If the tissue collection device **260** is present, the lesion **300** will be isolated from surrounding tissue by the membrane of the tissue collection device **260**, thus minimizing any possibility of seeding potentially abnormal cells to surrounding breast tissue. Moreover, the tissue architecture of the retrieved lesion **300** is substantially preserved, thereby allowing accurate histopathology to be performed upon the entire mass excised from the breast. Indeed, any compression such tissue may undergo is believed to be solely due to the retraction of the device back through the entrance track of the device **100** in the uncompressed breast tissue. Thereafter, when the excisional device **100** is removed from the breast **310**, the push or turn knob **226** may be acted upon to extend and bow the cutting tool **125**, thereby allowing the excised lesion to be retrieved from the tissue collection device **260** for examination. If the tissue collection device is not present, conventional suction means may be employed to extract the severed lesion from the surrounding breast tissue. Bleeding is controlled by suitably varying the RF or other power source applied to the electrosurgical cutting tool **125**, if present, to stem the bleeding by cauterizing the tissue coagulating the blood.

[0107] After the procedure, a small cavity remains in the breast where the lesion had previously been. However, since no compression of the breast was carried out, no expansion of the tissue occurs after the procedure, unlike conventional techniques. Therefore, the cavity and the entrance and exit path of the device remain as small as possible, leading to fewer complications, less tissue trauma and improved aesthetics.

[0108] According to another embodiment of the present invention, shown in FIGS. **10**, **11** and **12**, the transducer **270** is replaced by a removable transducer core **400**. The removable transducer core **400** includes an active element **440** configured to perform intra-tissue imaging and of relaying information back to a display device (shown in FIG. **14**) via a communication channel, such as shown at reference numeral **460**. The communication channel **460** may be wireless or may include, for example, optical fibers and/or electrical conductors. The active element **440** may draw power from an internal battery (not shown) or from a power source, such as shown at reference numeral **480**. The active element **440** may include an ultrasound transducer. Other types of transducers may be used instead of or in addition to an ultrasound transducer. The removable transducer core **400** preferably includes a generally tubular shaft **430**. A proximal section **450** is included near the proximal portion of the transducer core **400**.

[0109] To accommodate the removable transducer core **400**, the excisional device **100** of FIG. **10** includes an internal lumen **420** through which the removable transducer core **400** may be inserted. Preferably, the excisional device **100** is used once and disposed of, for safety and functional reasons. The removable transducer core **400**, however, may either be disposable or re-usable for a limited number of uses. To allow the active element **440** of the transducer core **400** to image the lesion to be excised and the surrounding tissue, the generally tubular member **110** of the excisional device **100** includes a transducer window **410**. When the removable transducer core **400** is inserted within the internal lumen **420**, the proximal section **450** of the core **400** preferably snaps into a locked configuration with the proximal end of the excisional device **100**. When in its locked configuration, the active element **440** of the transducer core **400** is aligned with and faces the transducer window **410**, to allow the active element **440** to image the lesion and the surrounding tissue therethrough.

[0110] FIG. **11** shows an embodiment of the removable core **400** according to the present invention. As the removable core **400** may advantageously be used independently of the excisional device **100**, the removable core **400** includes a distal tapered tip **470**, to allow it to easily penetrate soft tissue. Moreover, its thin profile allows the surgeon to insert the removable core **400** within soft tissue without, however, unduly damaging the tissue or making a large incision. The removable core **400** allows the surgeon to precisely localize the lesion to be excised from within the tissue itself. For example, the active element **440** of the removable core **400** may include an ultrasound transducer having similar characteristics as the sensor **270**, and may be used alone or in addition to surface ultrasound to localize the lesion with a great degree of precision.

[0111] FIG. **12** shows a cross section of the embodiment of the excisional device **100** of FIG. **10**, taken along line AA'. As shown in FIG. **12**, the cutting tool **125** is exposed through the transducer window **120**. The window **120** may, as shown in FIG. **12**, include support guides **122** to support and guide the cutting tool **125** as it is outwardly extended and bowed. The tissue collection device **260**, for clarity, is not shown in either FIG. **10** or **12**. However, to accommodate the bulk of the excised tissue sample collected in the tissue collection device **260** after the cutting and collecting operation described herein, the tubular member **110** may include a recessed section **131**. The recessed section provides space for the collected (e.g., bagged) tissue sample in the tissue collection device **260** when the excisional device is removed from the soft tissue mass. In this manner, the collected tissue sample within the tissue collection device **260** does not protrude from the generally smooth outer surface of the excisional device **100** upon retraction of the latter from the soft tissue mass from which the tissue sample is excised. The internal lumen **420** allows the removable core **400** to slide therein and to properly position the active element **440** facing the transducer window **410**.

[0112] FIG. **13** shows the removable core **400** inserted within an expandable sheath **495**. The expandable sheath

includes a proximal base section **510**. Attached to the proximal base section **510** is a generally cylindrical expandable meshwork **500** of, for example, plastic or nylon fibers. The meshwork **500** may be somewhat tapered at its distal end **520**, to provide a smooth transition between the expandable meshwork **500** and the removable core device **400**. The proximal section **450** of the core **400** may snap-fit to the proximal base section **510** of the expandable sheath **495**, so as to be securely and removably attached thereto. As shown in FIG. **13**, the expandable meshwork **500** expands just enough to accommodate the removable core **400** inserted therein. In practice, the expandable sheath **495** and removable core **400** assembly may be inserted within the soft tissue together, to allow the surgeon to image the lesion prior to inserting the somewhat greater diameter excisional device **100** therein. Thereafter, the surgeon may retract the removable core **400** from the expandable sheath **495**, leaving the expandable sheath **495** in place within the soft tissue, such as the breast.

[0113] FIG. **14** shows another embodiment of a soft tissue excisional device assembly **600** according to the present invention. In the configuration shown in FIG. **14**, the removable core **400** is inserted and secured within the excisional device **100** so that the active element **440** faces out of the transducer window **410**. As in FIG. **10**, the tissue collection device **260** is not shown, for clarity. In FIG. **14**, the excisional device **100** is shown inserted within the expandable sheath **495**. Indeed, the excisional device **100**, in FIG. **14**, is shown inserted within and past the distal end **520** of the meshwork **500**, so the distal portion of the excisional device **100** including the cutting tool **125** and the transducer window **410** extends therethrough. The meshwork **500**, in FIG. **14**, has expanded to accommodate the diameter of the excisional device **100**. The proximal portion of the excisional device **100** may extend from the proximal base section of the expandable sheath **495**. This allows the push or turn knob **226** (a turn knob **226** shown in FIG. **14**) to be manually accessible to the surgeon. A number of peripheral devices may be connected to the assembly **600**. Examples of such include a core power source **480**, which may be, for example, an electrical source for an ultrasound transducer, one or more data processing and display devices **250** on which the internal structure of the tissue imaged by the active element **440** of the core **400** may be displayed, suction means **490**, a cutting tool power source (a variable RF energy source, for example), and/or other devices **590**. The suction device **490** may provide a suction force to the window **120** through an internal lumen to facilitate cutting of the tissue by the cutting tool **125**.

[0114] The excisional device assembly **600** may be rotated in toto, or the excisional device **100** may be rotated independently of the expandable sheath **495**, depending upon the degree of friction between the two. Preferably, the excisional device **100** is removable from the expanded sheath **495** shown in FIG. **14**, while leaving the expanded sheath **495** in place within the soft tissue. In this manner, after retraction of the excisional device **100** from the sheath **495**, the sheath **495** remains in place within the soft tissue to allow other instruments to be inserted therethrough. For example, the removable core **400** may, after the excisional procedure proper, be re-inserted through the expanded sheath **495** to the excision site. Thereafter, the surgeon may cause the active element **440** of the removable core **400** to become energized, to image the excision site to insure that the complete lesion has been removed from the soft tissue mass. To do this, the surgeon may rotate the removable core **400** within the expanded sheath **495** while observing the display or displays for signs of the lesion. If none is found, it is probable that the entire lesion has been successfully removed and the surgeon may then retract the core **400** from the sheath **495** and the sheath from the tissue mass and repair the incision made prior to inserting the assembly therein. Alternatively, the surgeon may choose to remove both the expanded sheath **495** and the core **400** simultaneously.

[0115] FIG. **17** shows an embodiment of the method of excisional biopsy method according to the present invention. In FIG. **17**, it is assumed that the soft tissue from which the lesion is to be excised is breast tissue and that the active element **440** of the removable core **400** is an ultrasound transducer. Other combinations are possible, and the present invention should not be limited to applications related to breast tissue and ultrasound. The removable core **400** and the active element **440**, in FIG. **17**, are together abbreviated as "US CORE", a shorthand expression for the phrase "ultrasound core" and the word "assembly" is abbreviated to "Ass'y". Moreover, it is to be understood that the steps shown in FIG. **17** constitute but a broad outline of one possible embodiment of the present inventive method. Therefore, other additional steps may be inserted between the steps shown in FIG. **17**, or other steps may be substituted for some of the displayed steps without, however, departing from the scope of the present invention.

[0116] The method starts at step S**0**. In step S**1**, the lesion within the breast is grossly targeted, using, for example, standard or stereotactic surface ultrasound. In step S**1**, a rough estimate of the location of the lesion within the breast is obtained. The surgeon, after having located the general location of the lesion, may mark the location thereof on the ultrasound display or displays and/or on the corresponding surface of the breast, with an "X", for example. The breast is stabilized in step S**2**. Preferably, the breast is stabilized in an uncompressed or slightly expanded state, in the manner disclosed in the commonly assigned and co-pending U.S. patent application Ser. No. 09/_____ previously discussed and incorporated by reference herein. The woman's other breast is preferably placed within a counterpart breast stabilizing device, which helps to immobilize the woman during the procedure. One of the ultrasound ports of the breast stabilizing device is aligned with the lesion, for example, by aligning one of its ultrasound ports with the marked location on the breast. Suction is then applied to the breast stabilizing device, in the manner described in the above-referenced application and a correctly oriented surface ultrasound device is secured to the ultrasound port of the stabilizing device. Other means of stabilizing the breast may also be used without, however, departing form the present invention.

[0117] In step S**3**, an entry site on the breast is chosen. Preferably, the peri-areolar region is chosen as the incision site, as scars within the peri-areolar region are less visible than scars in more exposed regions of the breast and for other anatomical reasons. The incision site is then anaesthetized, both on the skin surface and subcutaneously. Also in step S**3**, a small incision is made at the chosen incision site. Preferably, the incision is large enough to accommodate the expandable sheath **495** with the removable core **400** inserted therein. In step S**4**, the expandable sheath **495**, together with the removable core inserted therethrough, is inserted into the incision made in step S**3**. Under surface ultrasound guidance, for example, the sheath **495**/core **400** assembly is navigated adjacent to the lesion. If the sheath **495**/core **400** assembly can be

properly positioned adjacent to the target lesion, the method according to the present invention proceeds to step S5. If the sheath 495/core 400 assembly cannot be properly positioned adjacent to the target lesion, all or a portion of the above-detailed steps are repeated until proper positioning of the sheath 495/core 400 assembly is achieved, adjacent to the target lesion.

[0118] Assuming now that step S4 has been completed to the surgeon's satisfaction, the core 400 is removed from the expandable sheath 495 and the expandable sheath 495 is left in place within the breast, as shown in step S5. In step S6, the removable core 400 is inserted within the internal lumen 420 of the tubular member of the excisional device 100 and locked securely in place, so that the active element 440 (in this case, an ultrasound transducer) is aligned with and faces out of the transducer window 410 of the device 100. Again leaving the expandable sheath 495 in place within the breast, the excisional device 100 (with the core 400 secured therein) is advanced through the expandable sheath 495. The sheath 495 then expands within the breast tissue to accommodate the somewhat larger diameter of the excisional device 100. The excisional device 100 is advanced past the tapered distal end 520 of the sheath 495, so the assembly including the sheath 495, the excisional device 100 and the removable core 400 is positioned adjacent to the target lesion within the breast tissue, as shown in step S7.

[0119] In step S8, the correct position adjacent the target lesion and the correct rotational orientation of the aforementioned assembly (FIG. 14) is confirmed, using surface ultrasound and/or the core ultrasound 400. The active element 440 of the core 400 is particularly well suited for this task, as the excisional device 100 may be rotated within the tissue, and positioned so the cutting tool 125 is properly positioned to allow it to rotate, extend and bow outwardly in such a manner as to precisely sever the lesion from the surrounding tissue with an adequate margin of healthy tissue. Indeed, the ultrasound transducer 440, as it rotates along with the excisional device 100, images the lesion before the cutting tool 125 cuts it, thereby allowing the surgeon to optimally deploy the cutting tool based upon his or her observation of the imaged tissue on a display or displays. In step 9, the surgeon may activate an anaesthetic infusion, the anaesthetic being delivered by the cutting tool 125 via the plurality of through holes 126, best seen in FIGS. 4 and 6. Step S9 may be skipped if the cutting tool 125 does not provide for through holes 126 or if the surgeon does not deem it necessary to anaesthetize the tissue during the rotation of the cutting tool 125. For example, the tissue may have been previously anaesthetized. While rotating at least the excisional device 100 (with the removable core 400 secured therein), the cutting tool 125 is extended using, for example the push or turn knob 226 shown in FIGS. 2C and 14, thereby causing the cutting tool 125 to extend from the window 410 and to bow outwardly, as shown in step S10. Depending on the amount of friction between the excisional device 100 and the expandable sheath 495 (which may be freely chosen depending upon the choice of material for the meshwork 500 and the configuration of the mesh), the sheath 495 may rotated along with the excisional device 100. The degree of extension and bowing may be finely controlled by the surgeon as the excisional device 100 is rotated, either manually or by a motorized unit (not shown) coupled thereto. As the cutting tool is rotated, the severed tissue sample is preferably collected (e.g., bagged) in a tissue collection device 260 (FIGS. 2A and 2B), as shown at step S11. The blood vessels may be coagulated as the cutting tools rotates and cuts the tissue, or afterwards. In step S12, after the excisional device 100 has completed at least one revolution within the breast and has cut a volume of revolution therein, including at least the target lesion and preferably a margin of healthy tissue surrounding the lesion, the excisional biopsy device 100 and removable core 400 assembly are retracted through the sheath 495, leaving the sheath 495 once again in place within the breast. Preferably, the tissue collection device 260 and the tissue sample it encloses lie within the recessed section 131 of the generally tubular member 110. In this manner, the filled collection device 260 does not protrude or protrude too much from the surface of the tubular member 110, thereby allowing the retrieved tissue sample to be readily retracted with the excisional device 100 through the sheath 495.

[0120] After retraction of the excisional device 100, the core 400 may be retracted from the device 100 and re-inserted through the sheath 495 left in place within the breast. The core 400 is then advanced adjacent to the excision site, and rotated to allow the surgeon to image the excision site to insure that the entire lesion has indeed been removed, as shown in step S13. Some or all of the above steps may be repeated should the imaging of the excision site by the core 400 within the sheath 495 reveal that a portion of the target lesion was not excised. Assuming that all of the target lesion has been removed, the incision is repaired by, for example, suturing the peri-areolar incision site. The method ends at step S16.

[0121] While the foregoing detailed description has described several embodiments of this invention, it is to be understood that the above description is illustrative only and not limiting of the disclosed invention. For example, the shape of the cutting tool 125 may differ from that shown in the Figures. Other transducers and/or work elements may be added or substituted for those shown and described herein. For example, a piezoelectric transducer may be advantageously utilized to vibrate the cutting tool 125 at high frequencies. A number of other modifications will no doubt occur to persons of skill in this art. All such modifications, however, should be deemed to fall within the scope of the present invention. Thus, the invention is to be limited only by the claims as set forth below.

1-35. (canceled)

36. An excisional biopsy device, comprising:

a tubular member having a first and a second window near a distal tip thereof;

a cutting tool configured to selectively bow out of the first window and to retract within the first window; and

a removable transducer core, the transducer core including an active transducer element configured to face out of the second window when the removable transducer core is fitted within the tubular member.

37. The device of claim 36, wherein the removable core is adapted to snap fit within the tubular member.

38. The device of claim 36, wherein the active transducer element includes an ultrasound transducer.

39. The device of claim 36, wherein the removable transducer core comprises a tapered distal tip configured to readily penetrate soft tissue.

40. The device of claim 36, further comprising an external tissue collection device attached at least to the cutting tool.

41. The device of claim 40, wherein the tubular member further comprises a recessed section adjacent a trailing edge of the cutting tool, the recessed section being adapted to receive the external tissue collection device.

42. The device of claim **36**, further comprising an expandable sheath, the expandable sheath being adapted to receive the removable transducer core and the tubular member.

43. Method of excising a lesion from soft biological tissue using an excisional biopsy system including a generally tubular member having a cutting tool, a removable transducer core adapted to fit within the tubular member and an expandable sheath, comprising the steps of:

fitting the transducer core through the expandable sheath,

inserting the transducer and sheath though an incision in the tissue;

imaging a target site within the tissue by energizing the transducer core,

removing the transducer core from sheath while leaving the sheath in place within the tissue;

securing the core within the generally tubular member so the core faces outwardly from the tubular member;

sliding the tubular member through the expandable sheath until the cutting tool is positioned adjacent the lesion;

cutting the lesion with the cutting tool; and

retracting at least the tubular member from the incision.

44. The method of claim **43**, further comprising the step of stabilizing the breast in one of an uncompressed and a slightly expanded state prior to the inserting step.

45. The method of claim **43**, wherein the sheath remains within the tissue after the retracting step and wherein the method further comprises the step of:

re-inserting the transducer core within the sheath and imaging the target site to insure that the lesion has been excised.

46. The method of claim **43**, further comprising the step of collecting the cut lesion within an external tissue collection device secured to the tubular member.

47. The method of claim **43**, wherein both the tubular member and the sheath are retracted from the incision.

48. An excisional biopsy device, comprising:

a single use disposable tubular member having a window near a distal tip thereof, the tubular member including a cutting tool, a distal end of the cutting tool being attached near the distal tip of the tubular member, at least a distal portion of the cutting tool being configured to selectively bow out of the window and to retract within the window; and

a single use disposable tissue collection device externally attached at least to the tubular member, the tissue collection device collecting tissue severed by the cutting tool as the biopsy device is rotated and the cutting tool is bowed.

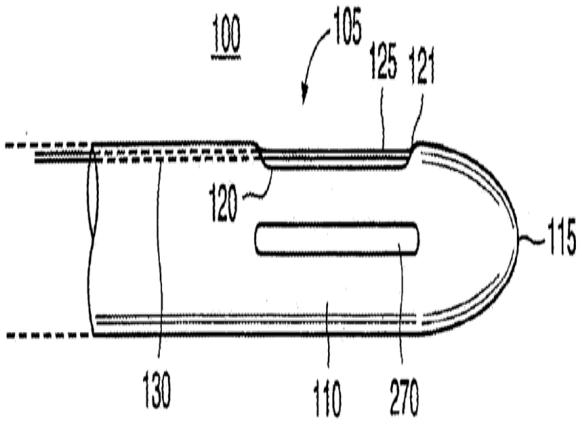
49. An excisional biopsy device, comprising:

a single use disposable tubular member having a first and a second window near a distal tip thereof, the tubular member including a cutting tool configured to selectively bow out of the first window and to retract within the first window; and

a removable transducer core, the transducer core including an active transducer element configured to face out of the second window when the removable transducer core is fitted within the tubular member.

* * * * *

专利名称(译)	切除活组织检查装置和方法		
公开(公告)号	US20110021948A1	公开(公告)日	2011-01-27
申请号	US12/895698	申请日	2010-09-30
[标]申请(专利权)人(译)	RUBICOR医疗		
申请(专利权)人(译)	RUBICOR医药有限责任公司		
当前申请(专利权)人(译)	ENCAPSULE医药有限责任公司		
[标]发明人	LEE ROBERTA VETTER JAMES W		
发明人	LEE, ROBERTA VETTER, JAMES W.		
IPC分类号	A61B10/02 A61B1/00 A61B8/12 A61B10/00 A61B10/04 A61B10/06 A61B17/22 A61B17/28 A61B17/32 A61B17/3211 A61B18/14 G01B17/00 G01B17/06		
CPC分类号	A61B10/02 A61B8/461 A61B10/0275 A61B10/04 A61B17/320725 A61B18/1482 A61B2017/00287 A61B2018/00011 A61B2018/1407 A61B2018/1475 A61B2019/5278 A61B2019/528 A61B2218/002 A61B8/085 A61B10/0266 A61B2090/3782 A61B2090/3784		
外部链接	Espacenet USPTO		

摘要(译)

切除活组织检查装置包括管状构件，该管状构件在其远端尖端附近具有窗口;切割工具，切割工具的远端附接在管状构件的远侧末端附近，切割工具的至少远侧部分构造成选择性地从窗口弯出并在窗口内缩回;组织收集装置至少外部连接到管状构件上，当活检装置旋转并且切割工具弯曲时，组织收集装置收集由切割工具切除的组织。用于软组织的切除活组织检查方法包括将大致管状构件插入组织中的步骤，管状构件包括适于选择性地远离管状构件弯曲的切割工具和靠近管状构件的远端尖端的外部组织收集装置;旋转管状构件;选择性地改变切削工具的弯曲程度;收集由组织收集装置中的切割工具切断的组织;并使管状构件从软组织缩回。管状构件可包括成像换能器，并且该方法可包括在显示装置上显示从换能器接收的信息的步骤，以及基于来自成像换能器的显示信息改变切割工具的弯曲程度的步骤。或者，成像换能器可以设置在可拆卸的换能器芯内，该换能器芯适于装配在管状构件内。