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(19) **United States**(12) **Patent Application Publication**
Vetter et al.(10) **Pub. No.: US 2007/0203428 A1**(43) **Pub. Date: Aug. 30, 2007**(54) **DEVICES AND METHODS FOR
PERFORMING PROCEDURES ON A BREAST**(75) Inventors: **James W. Vetter**, Portola Valley, CA
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(US)

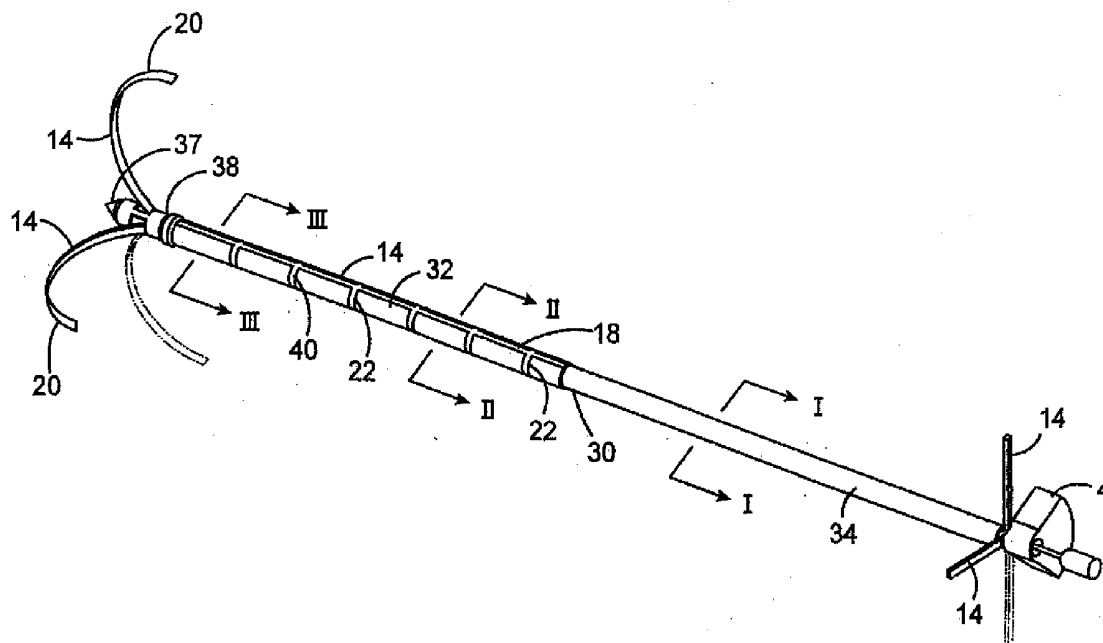
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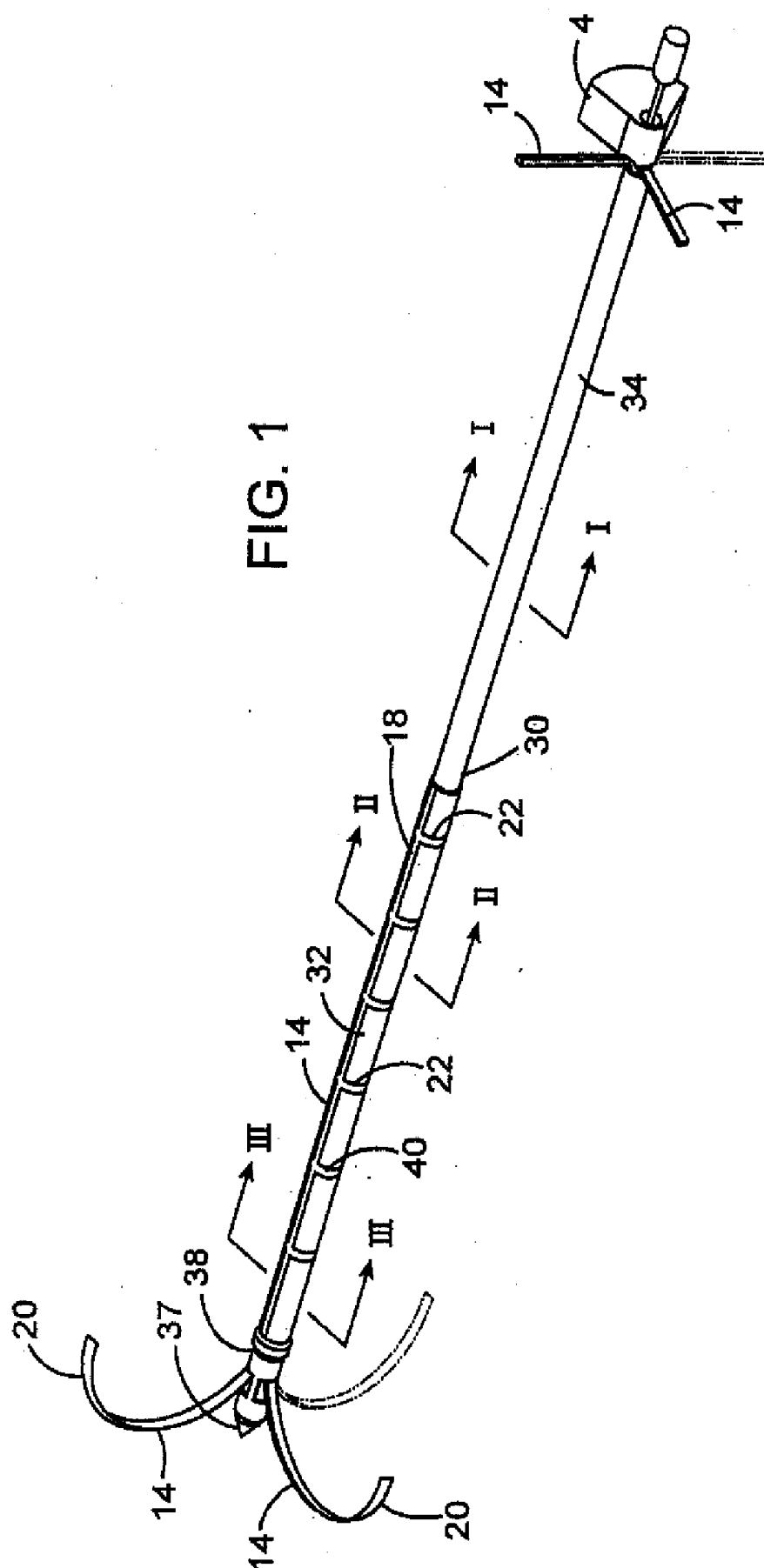
YOUNG LAW FIRM, P.C.**ALAN W. YOUNG****4370 ALPINE ROAD****SUITE 106****PORTOLA VALLEY, CA 94028 (US)**(73) Assignee: **RUBICOR MEDICAL, INC.**, Redwood
City, CA(21) Appl. No.: **11/740,858**(22) Filed: **Apr. 26, 2007****Related U.S. Application Data**(60) Division of application No. 10/923,511, filed on Aug.
20, 2004, which is a continuation-in-part of applica-
tion No. 10/732,670, filed on Dec. 9, 2003, and which
is a continuation-in-part of application No. 10/272,
448, filed on Oct. 16, 2002, now Pat. No. 6,936,014,
and which is a continuation-in-part of application No.10/796,328, filed on Mar. 8, 2004, which is a con-
tinuation-in-part of application No. 09/417,520, filed
on Oct. 13, 1999, now Pat. No. 6,423,081, which is a
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3, 1998, now Pat. No. 6,022,362.**Publication Classification**(51) **Int. Cl.****A61B 10/02** (2006.01)(52) **U.S. Cl.** **600/564; 600/565; 600/567**

(57)

ABSTRACT

A device for cutting tissue having a bowed cutting element may include a shaft having a central axis and a tissue cutting element coupled to the shaft. The tissue cutting element may be movable from a collapsed position to an expanded position and may bow outwardly when in the expanded position. The cutting element generally moves in a first plane when moving between the collapsed and expanded positions. The shaft may have a first thickness and a second thickness relative to the central axis of the shaft. The first and second thicknesses may lie in a second plane which is generally parallel to the first plane. The second thickness may be at least 1.25 times larger than the first thickness and the side of the shaft may have the second thickness leading the cutting element during rotation.





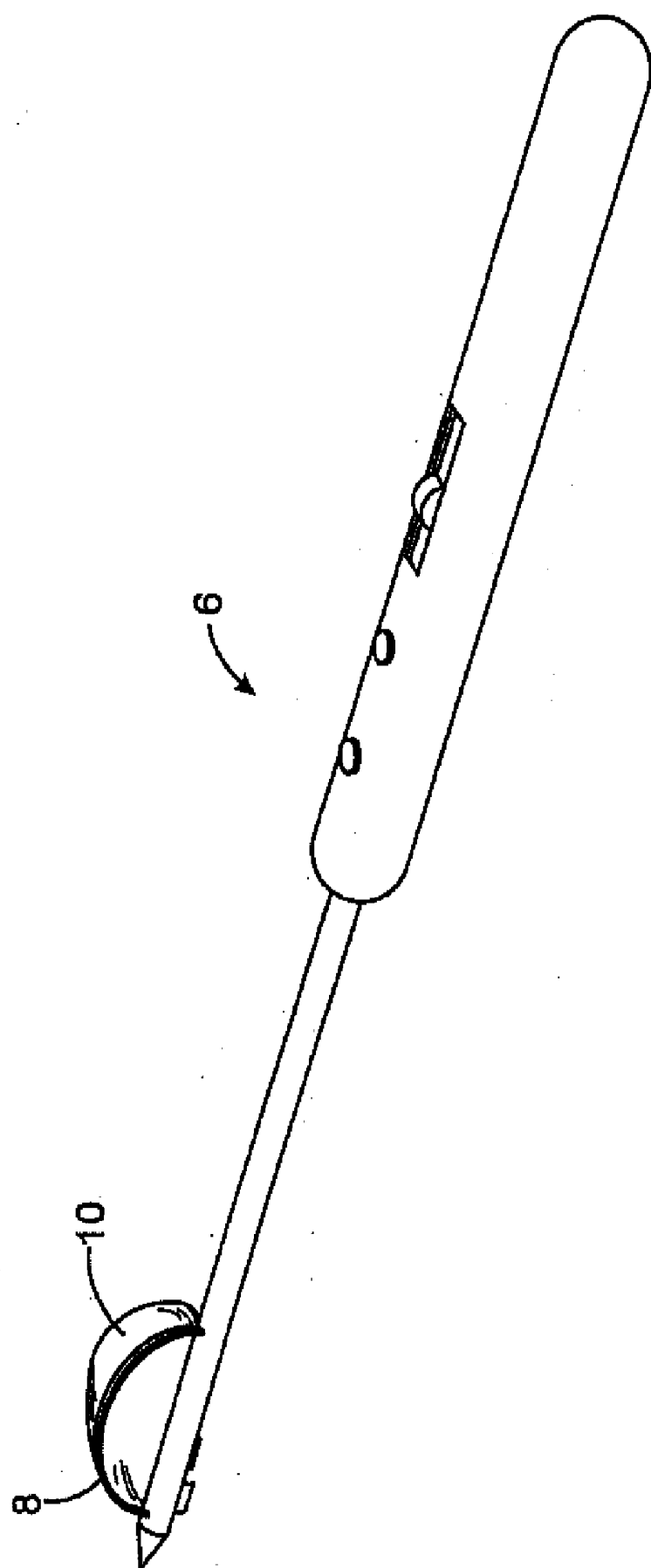


FIG. 2

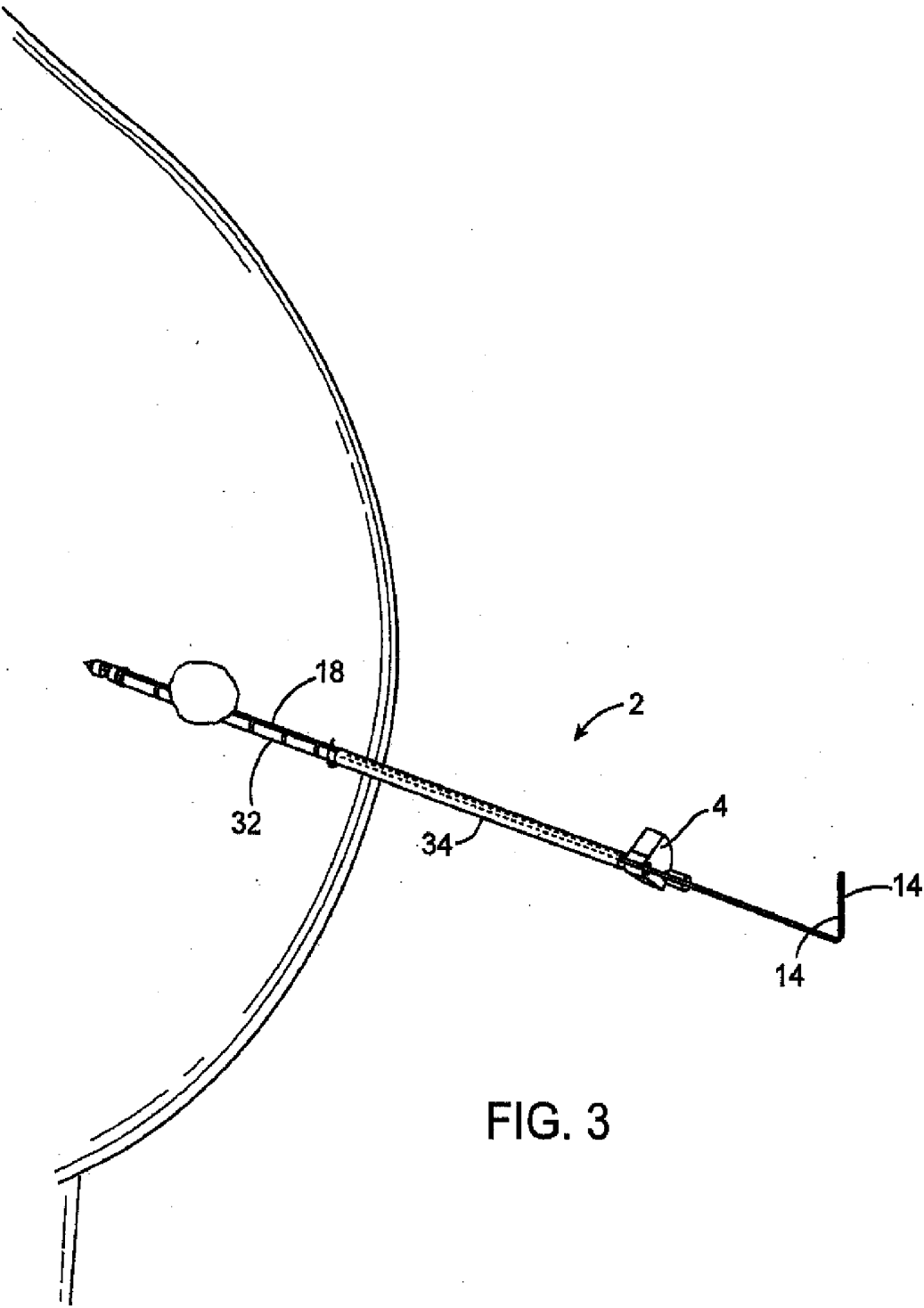


FIG. 3

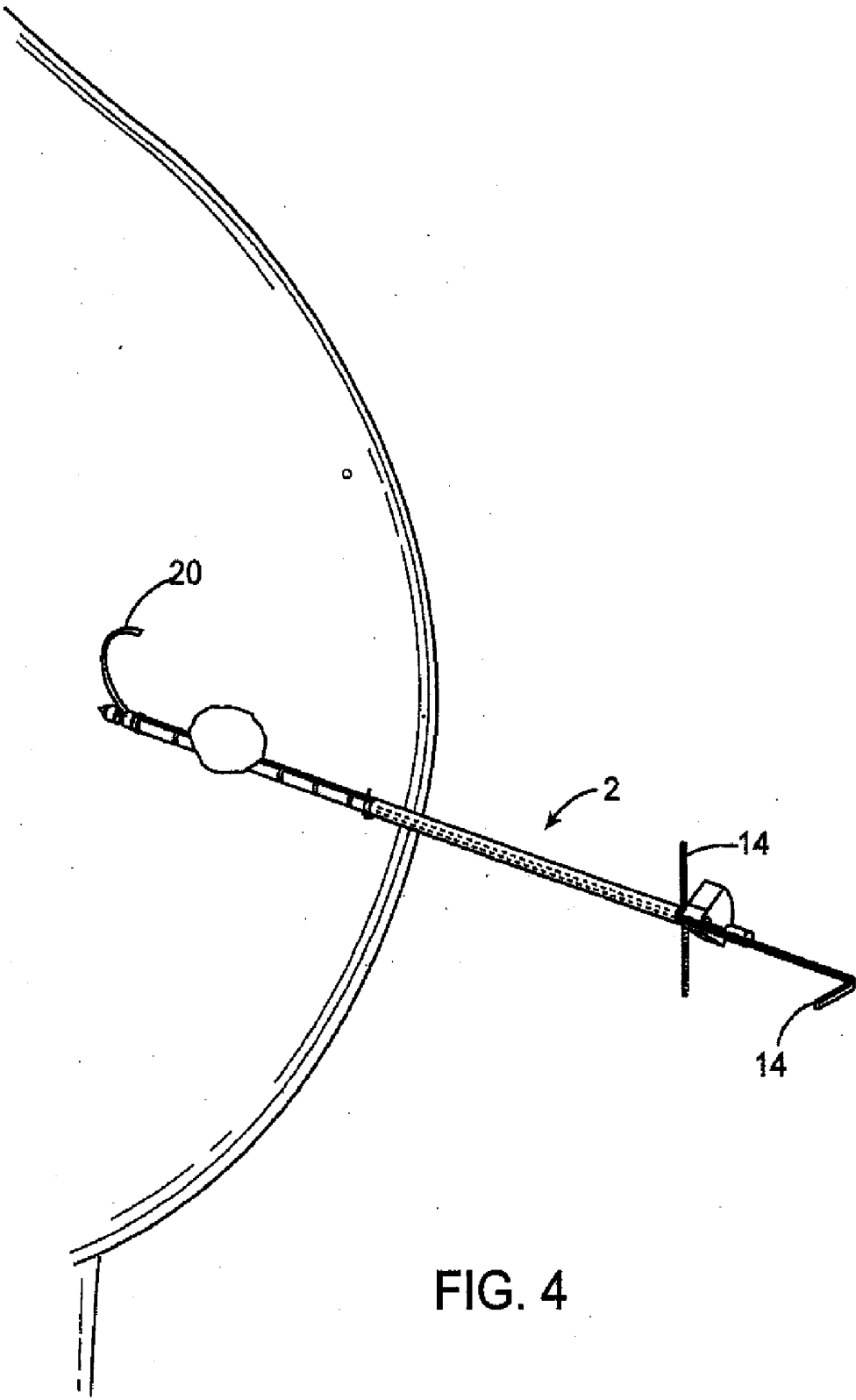
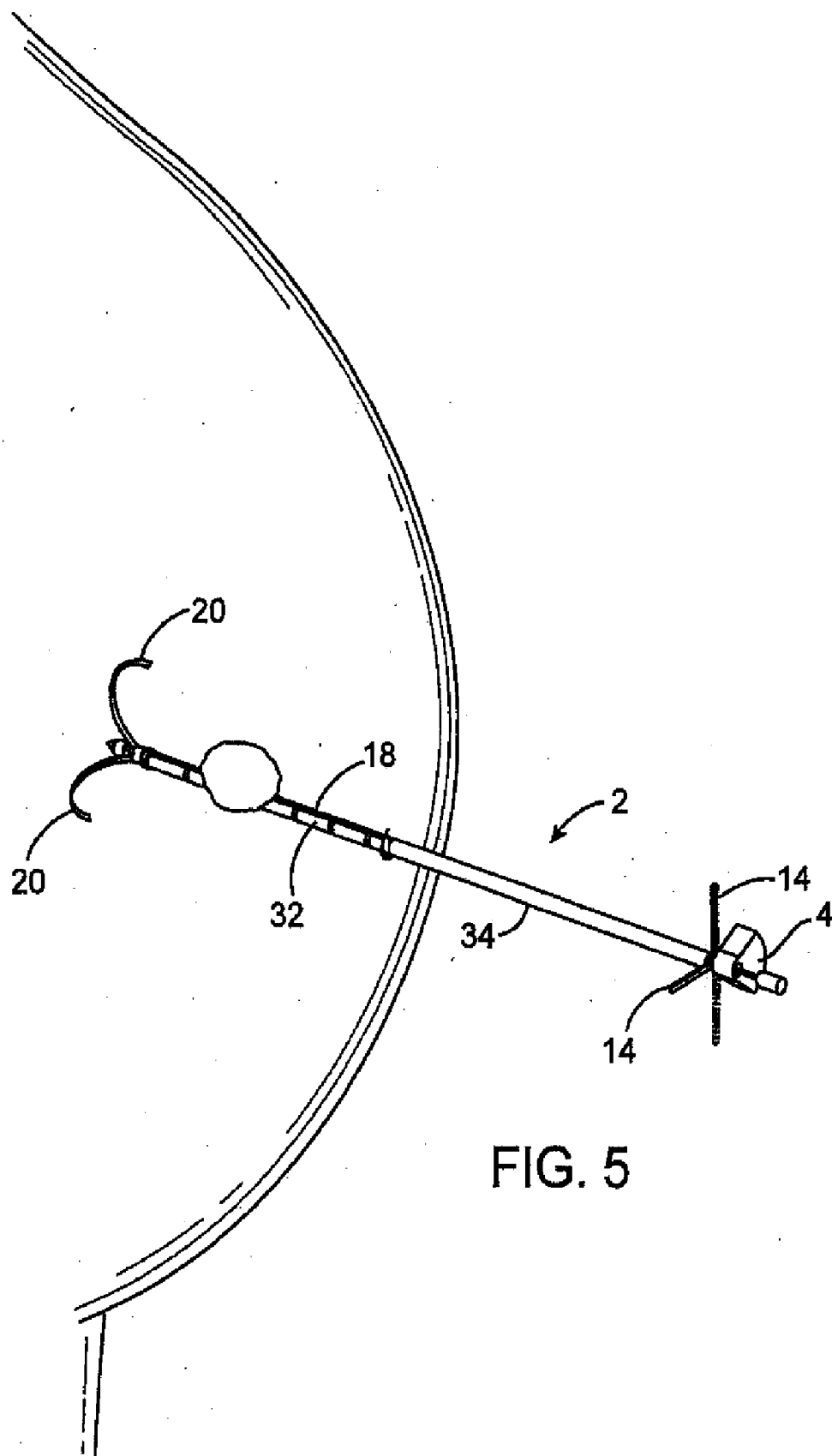
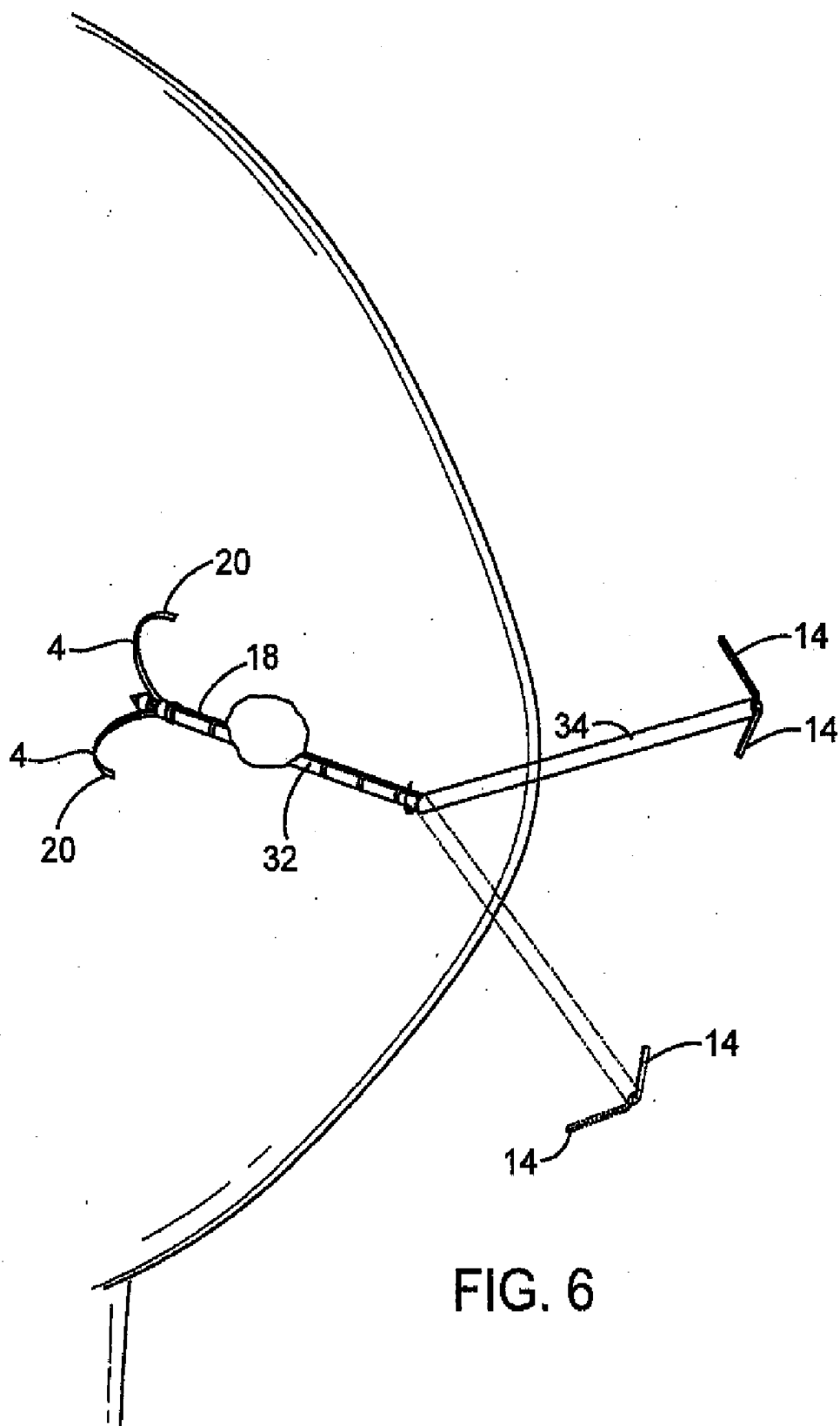
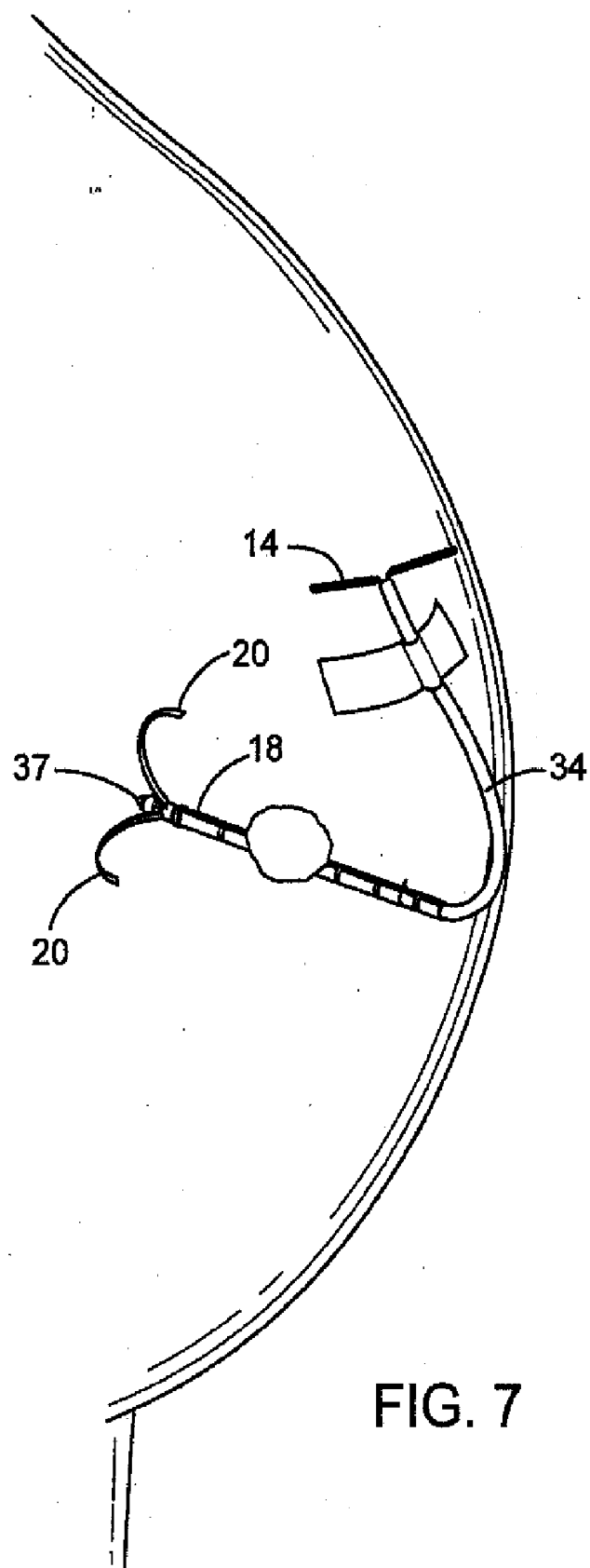
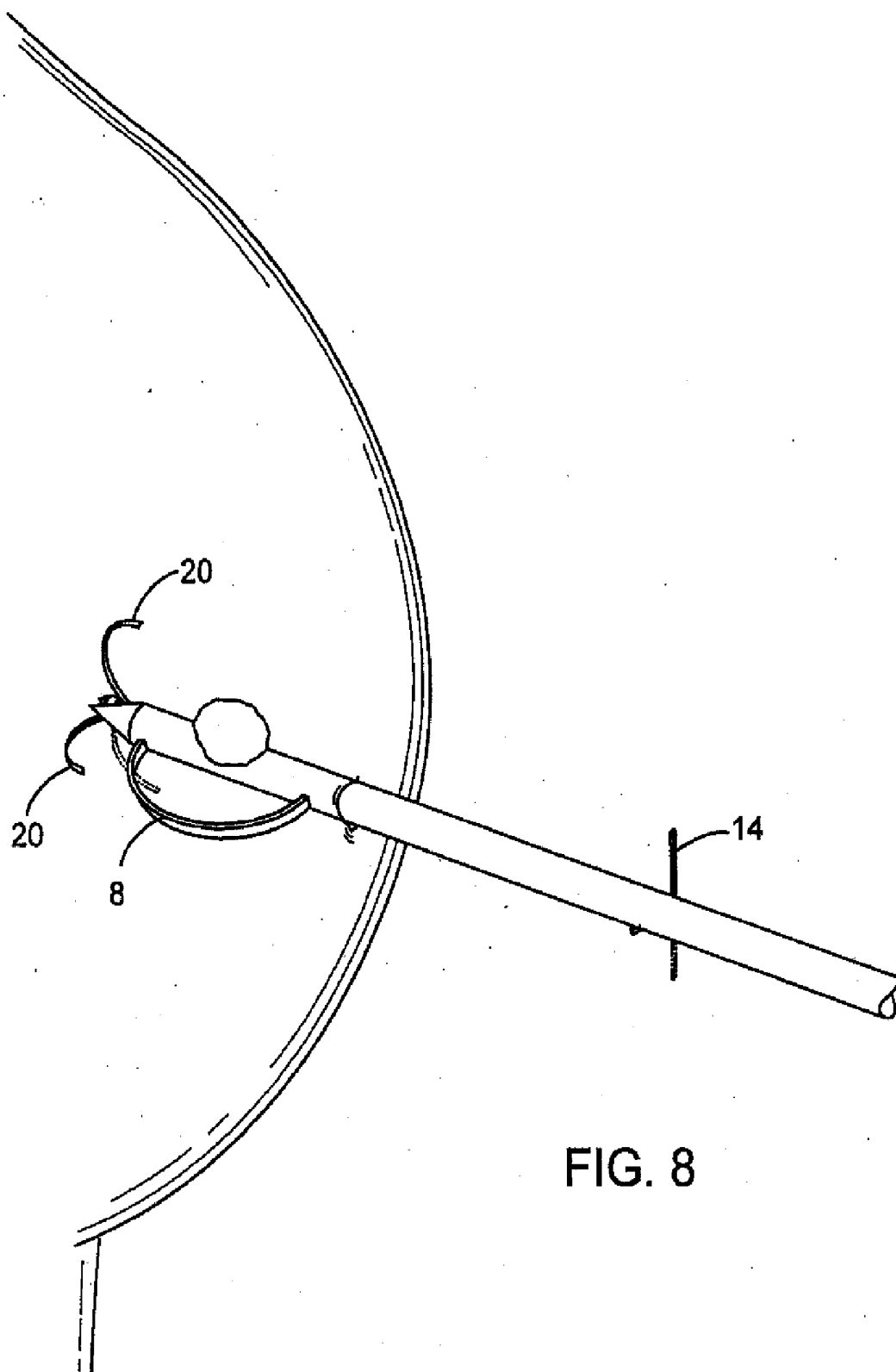


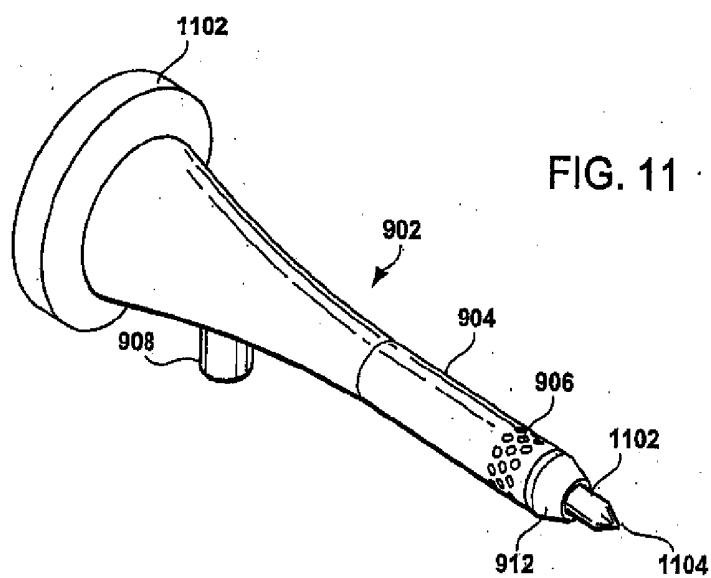
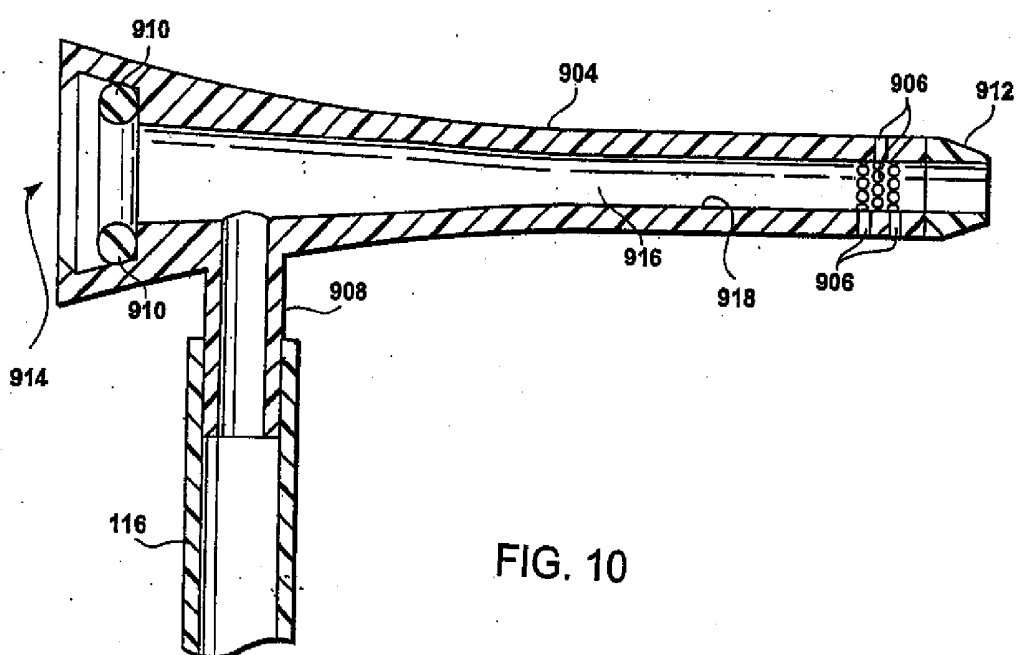
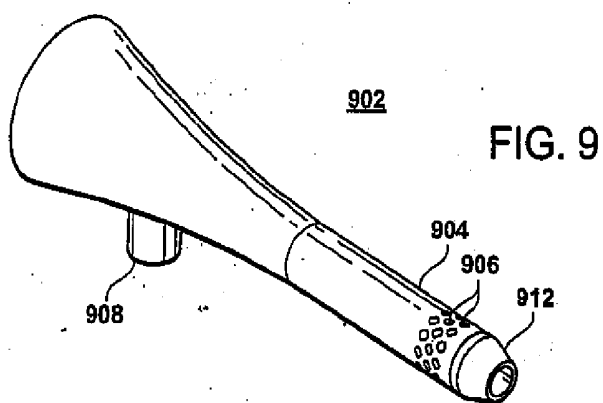
FIG. 4

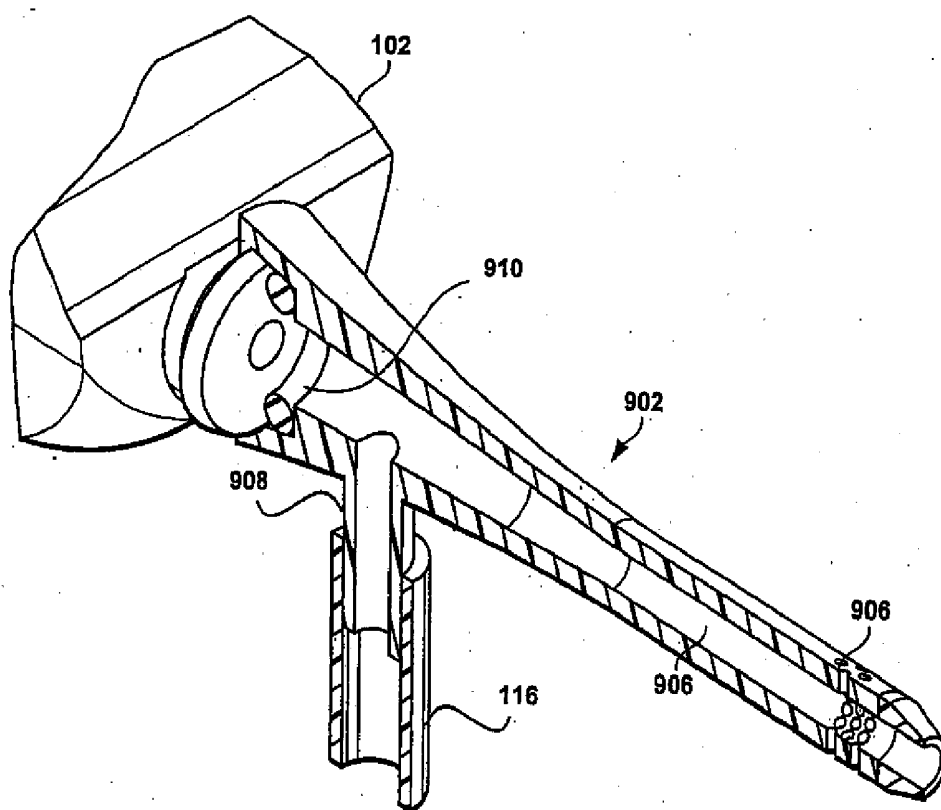
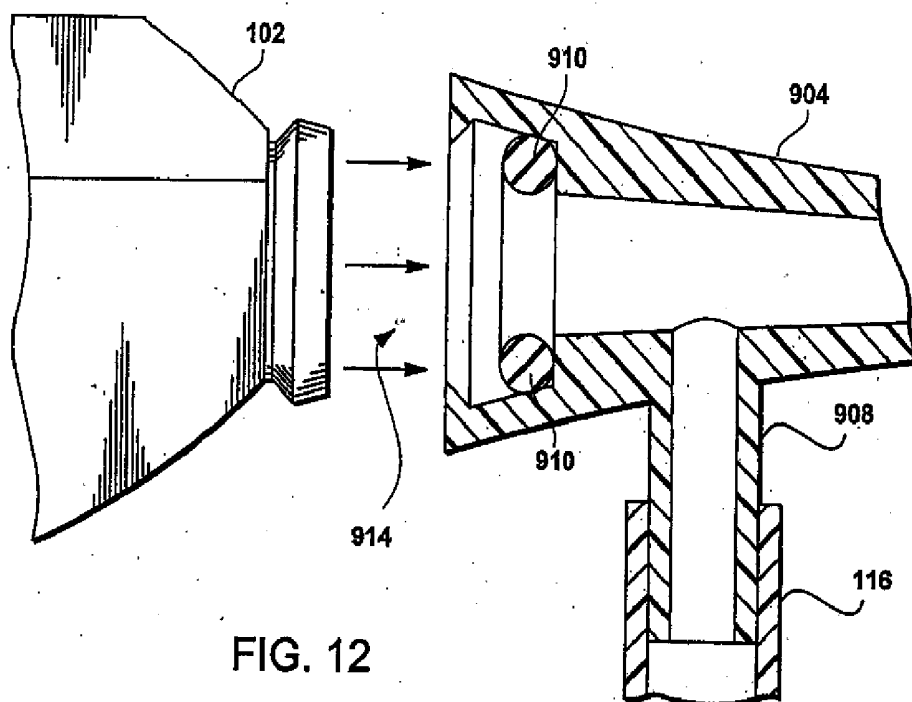


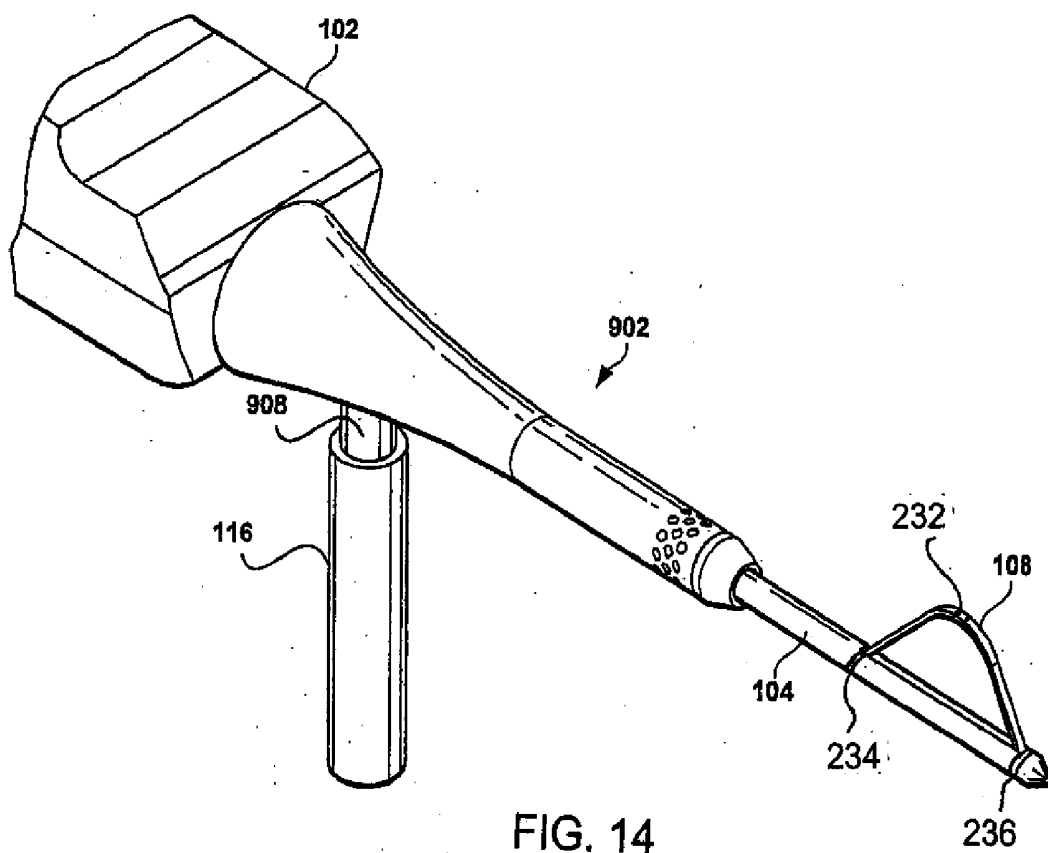












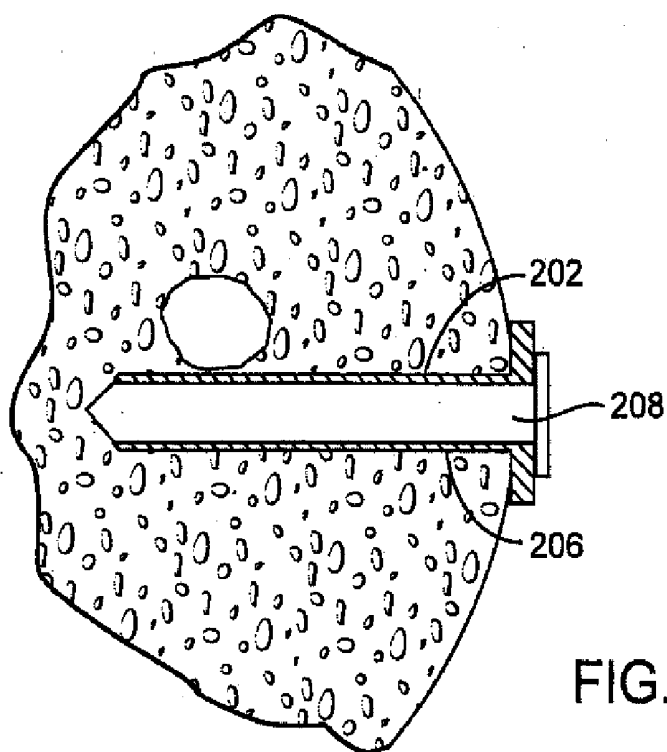


FIG. 15

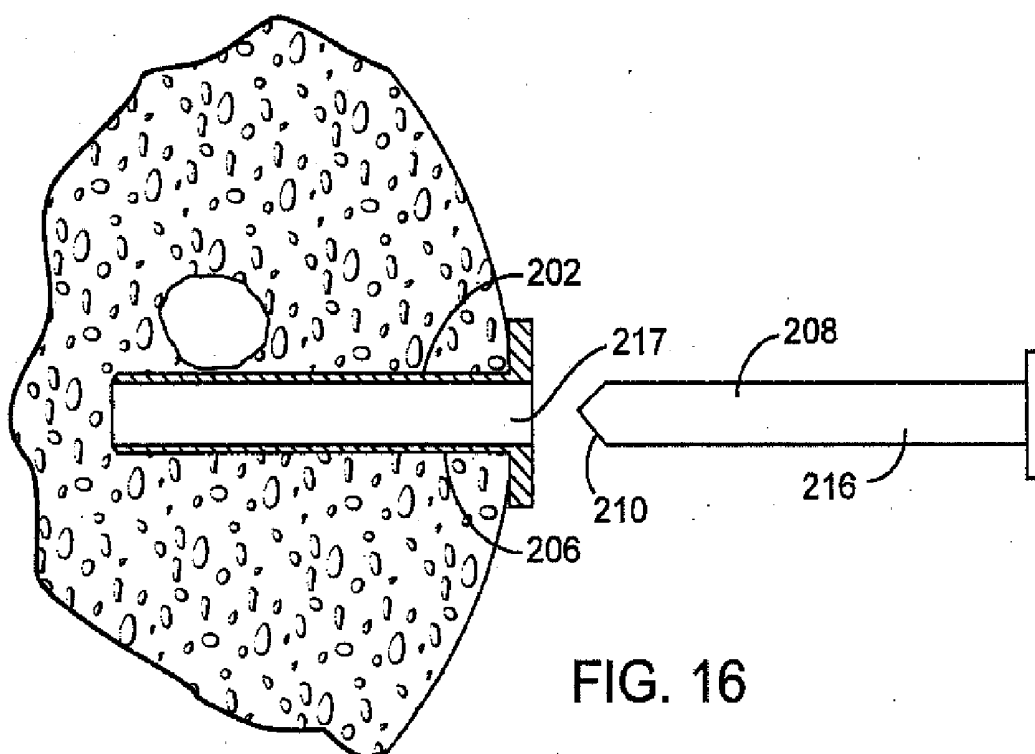
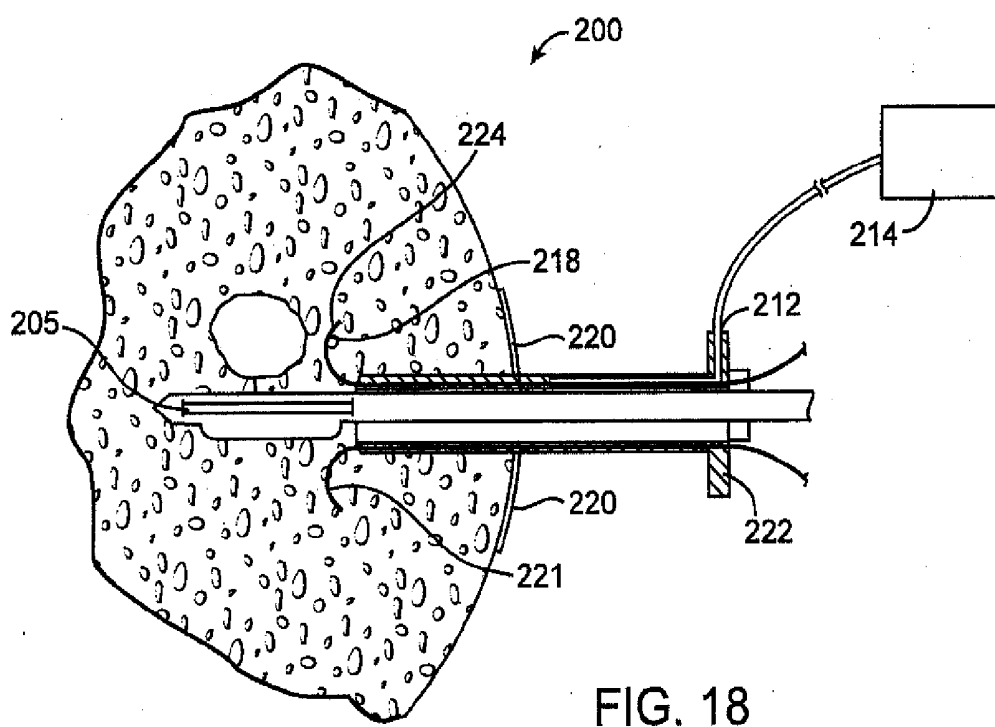
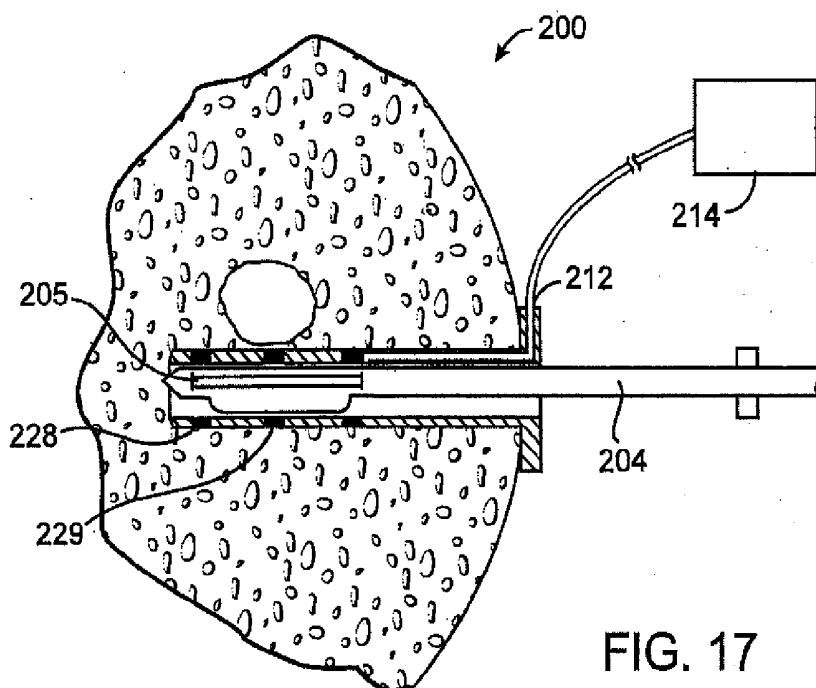
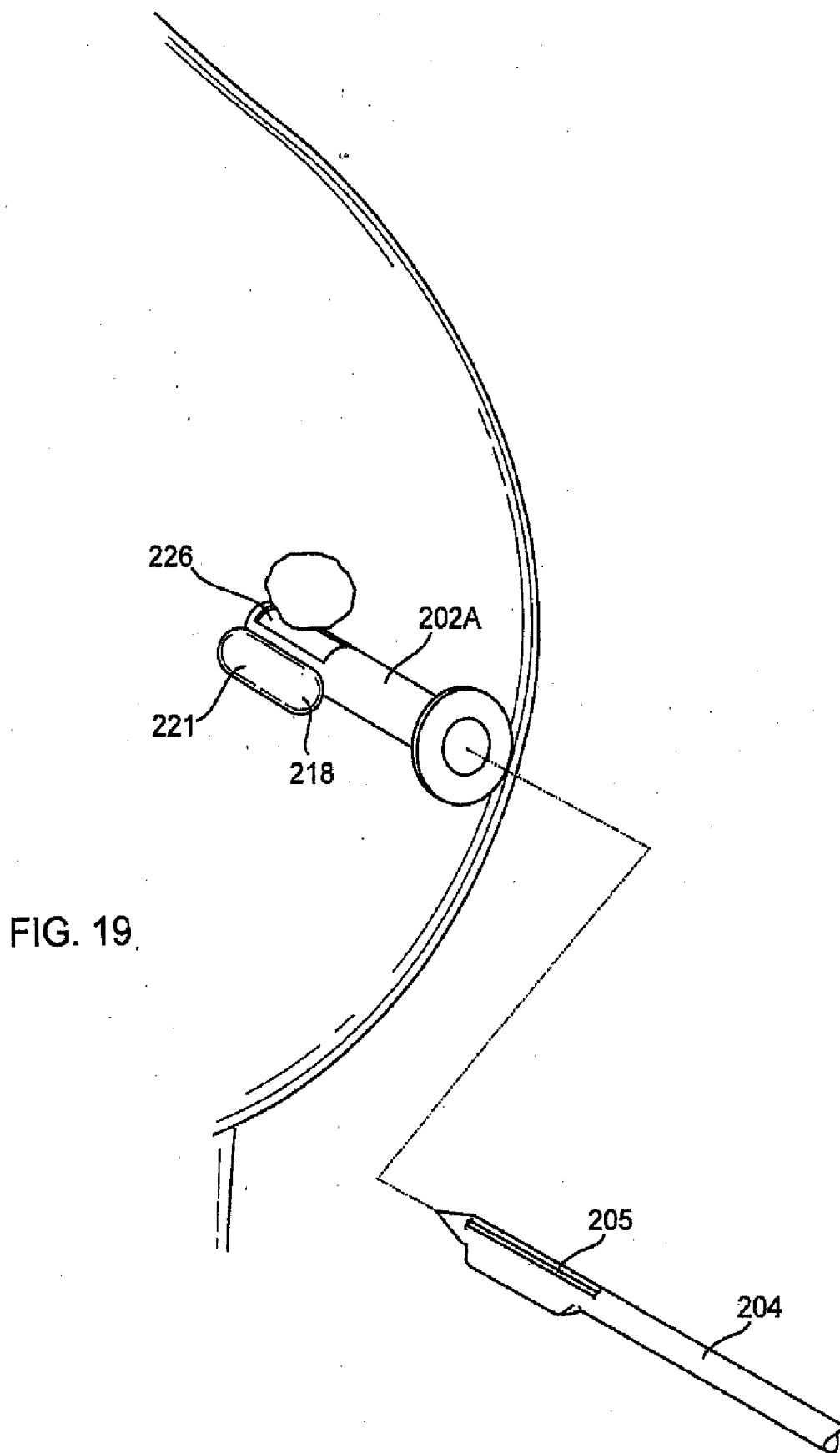
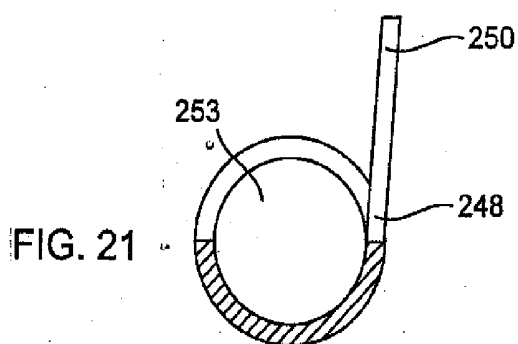


FIG. 16







I-I

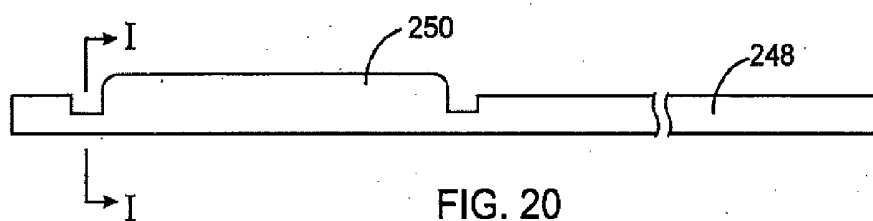


FIG. 20

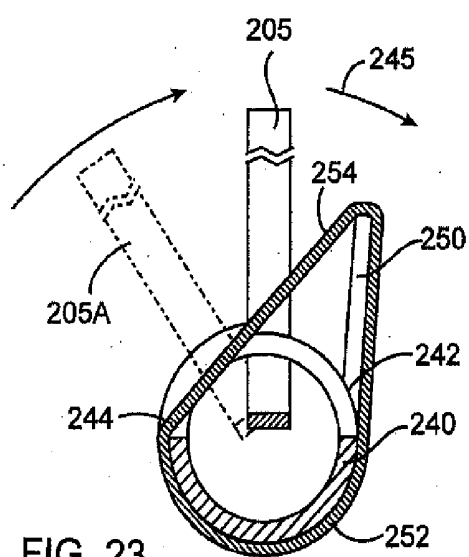


FIG. 23

II-II

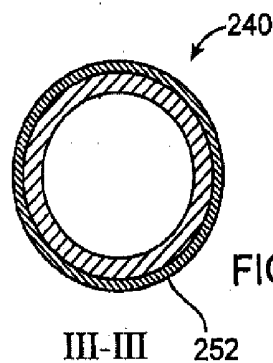


FIG. 24

III-III

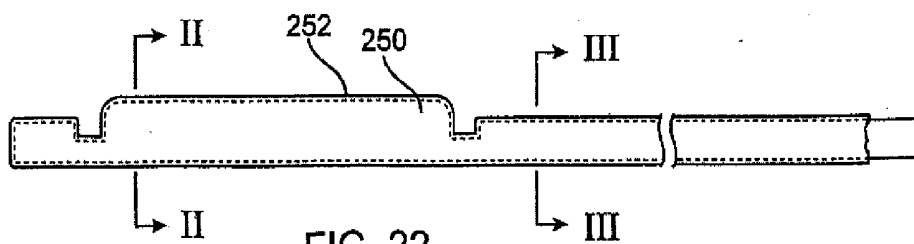


FIG. 22

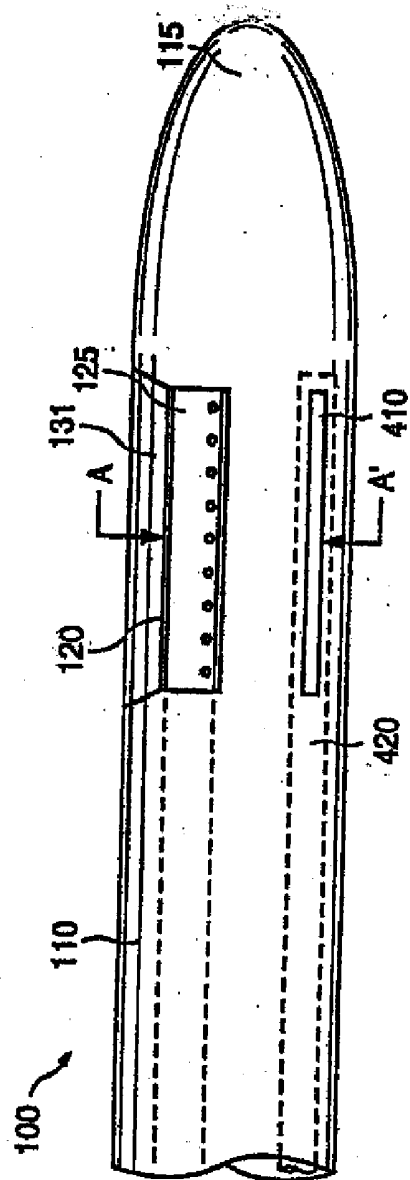


FIG. 25

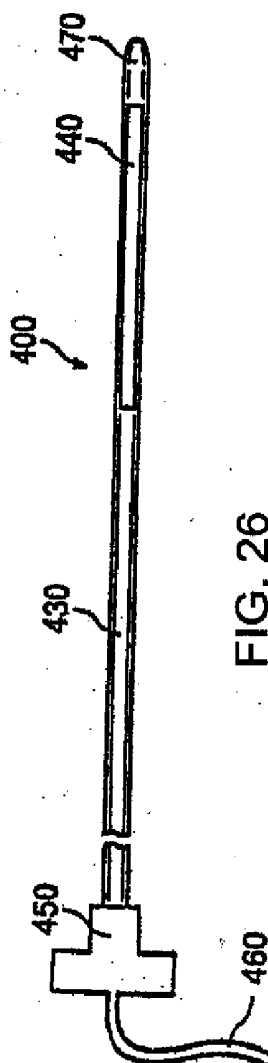


FIG. 26

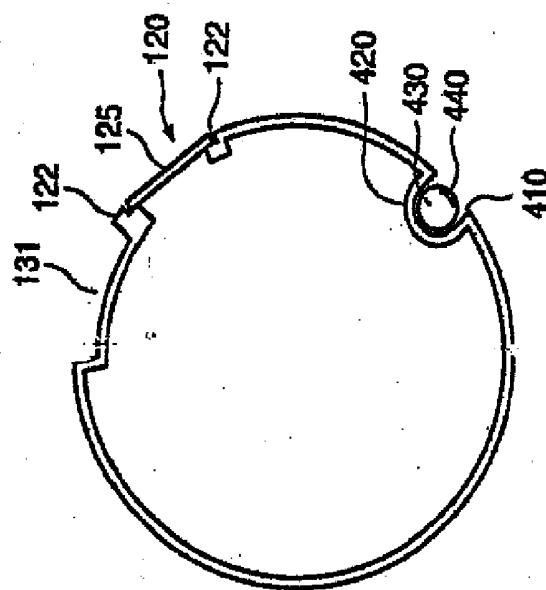


FIG. 27

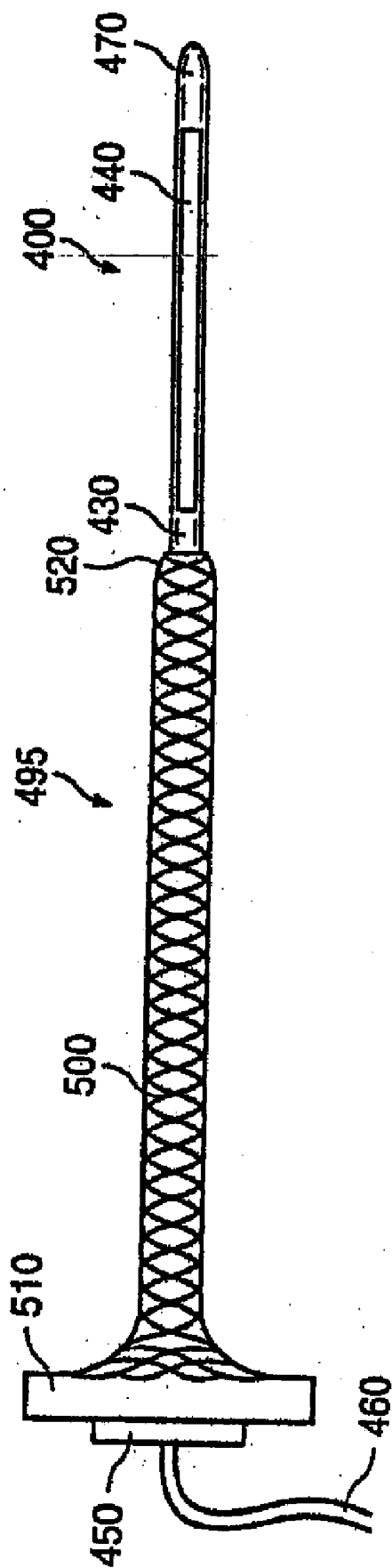


FIG. 28

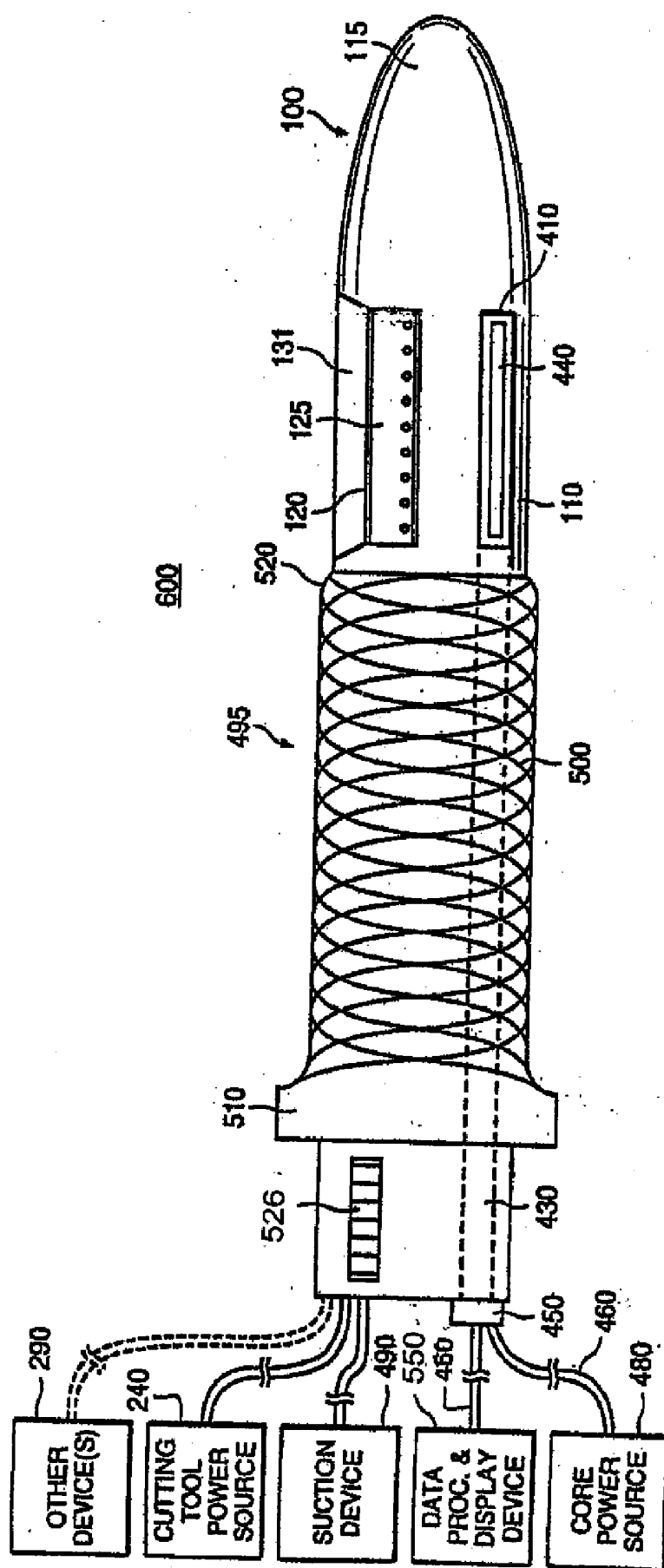


FIG. 29

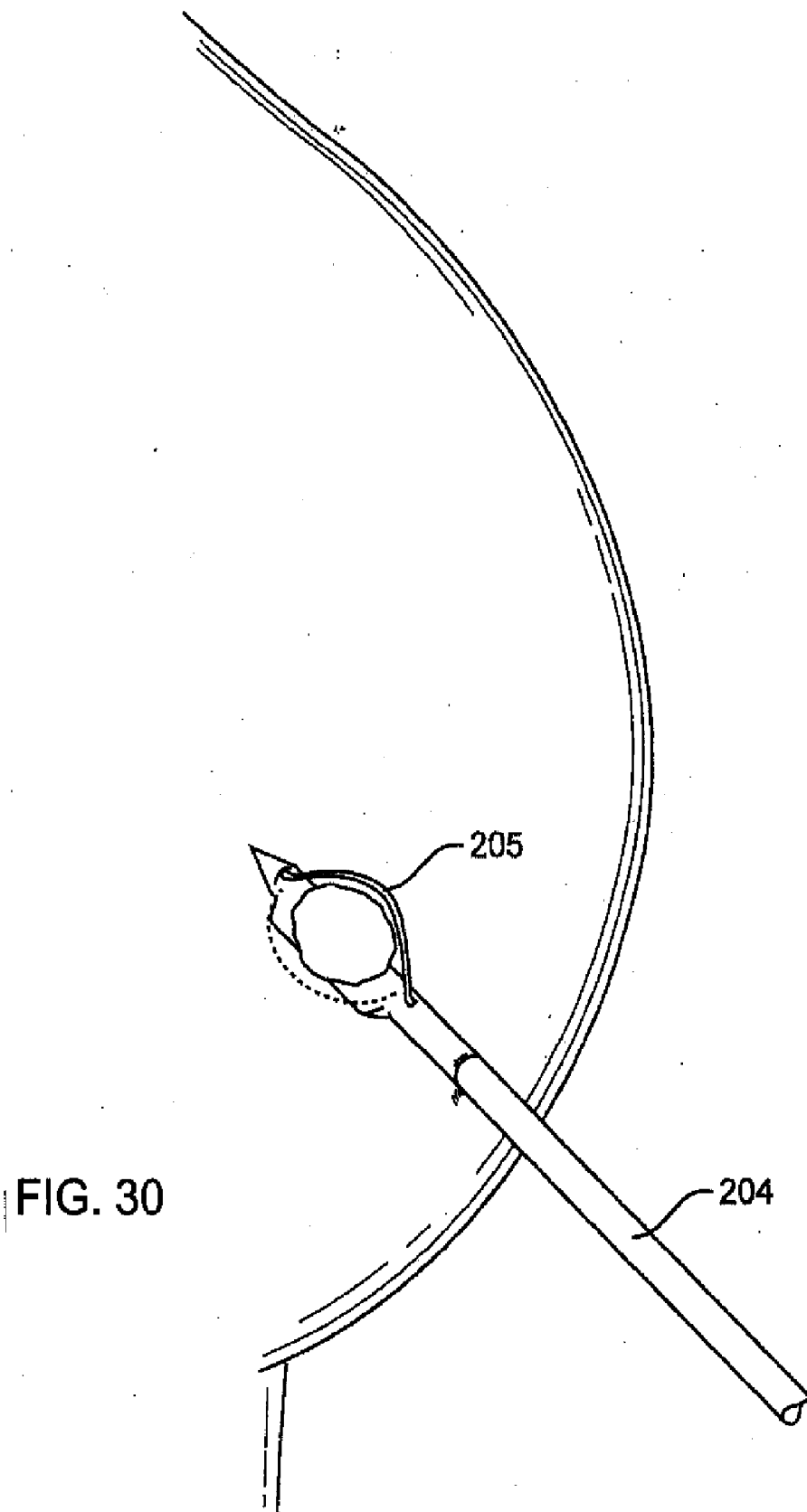


FIG. 31

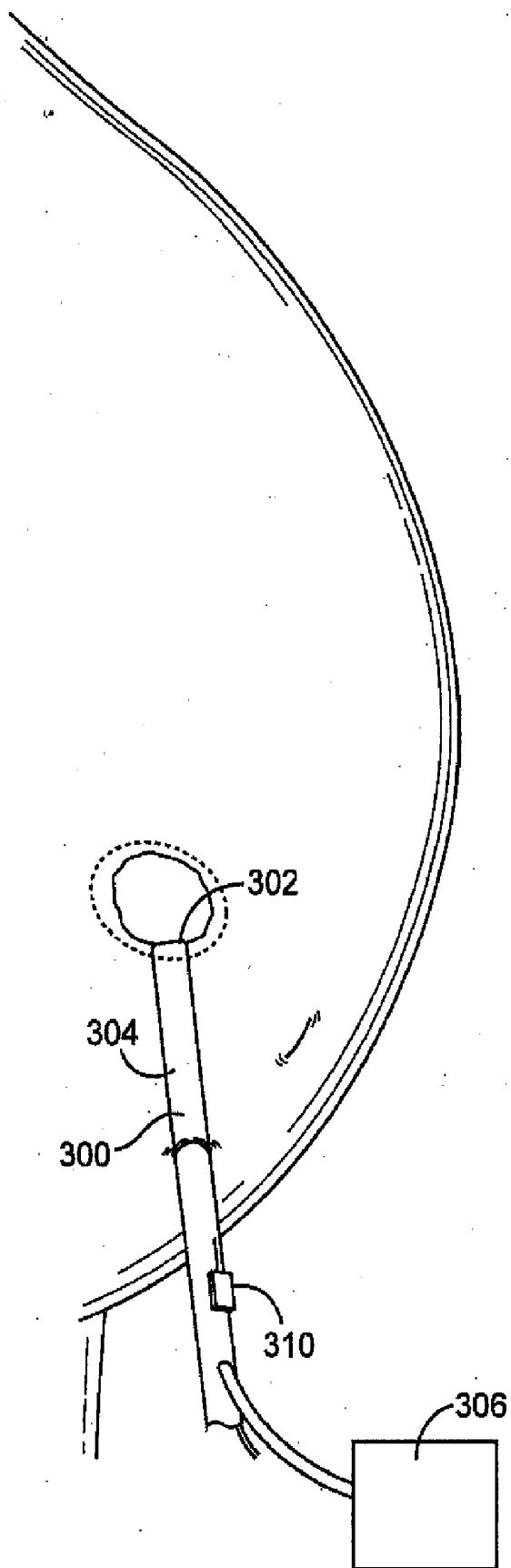
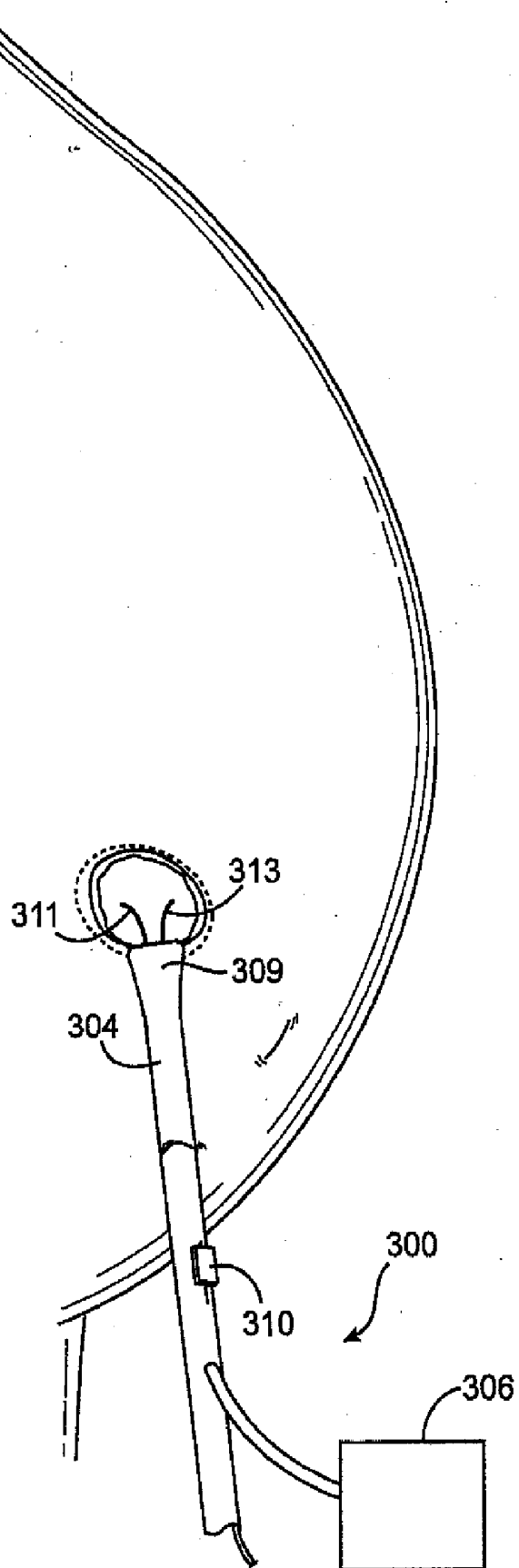
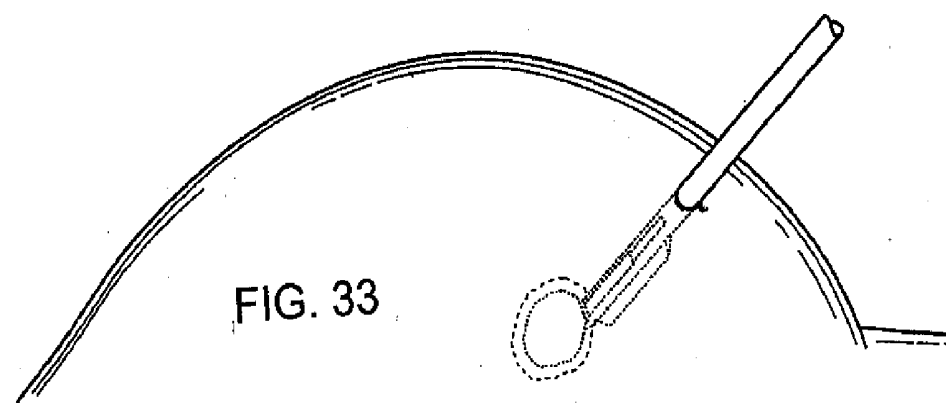
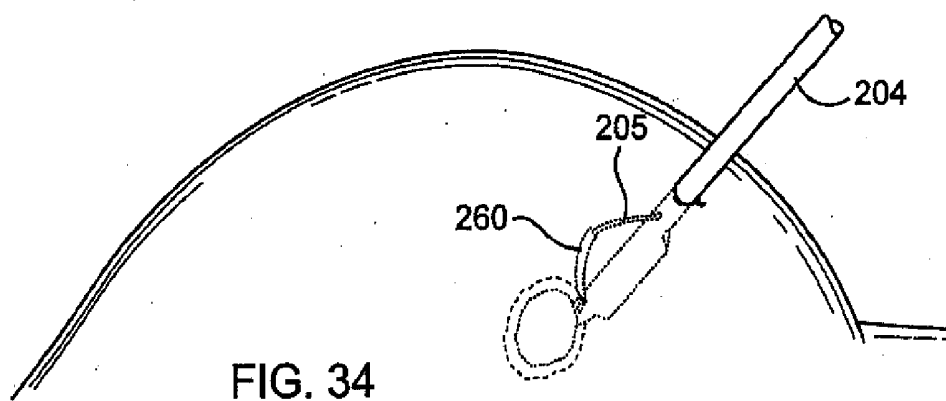
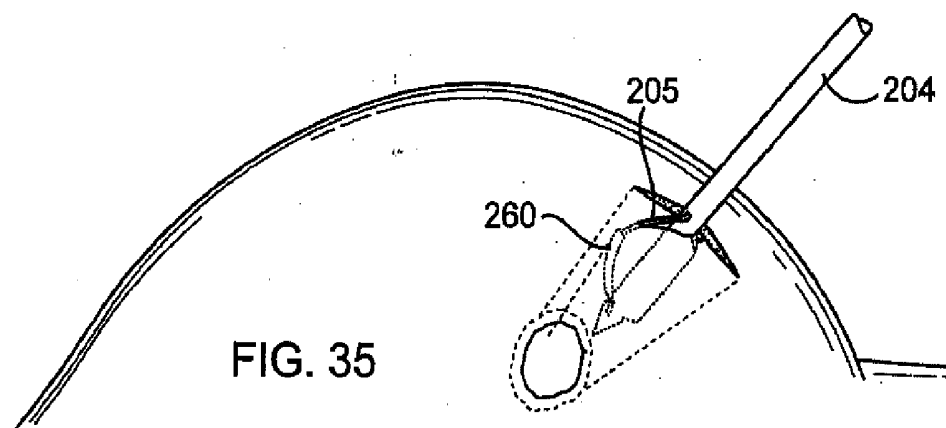


FIG. 32





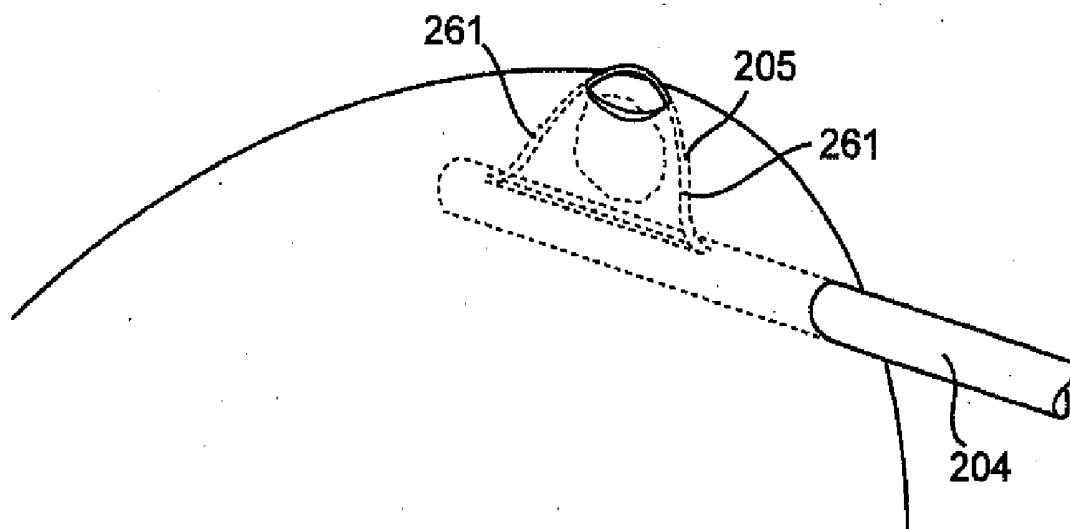


FIG. 36

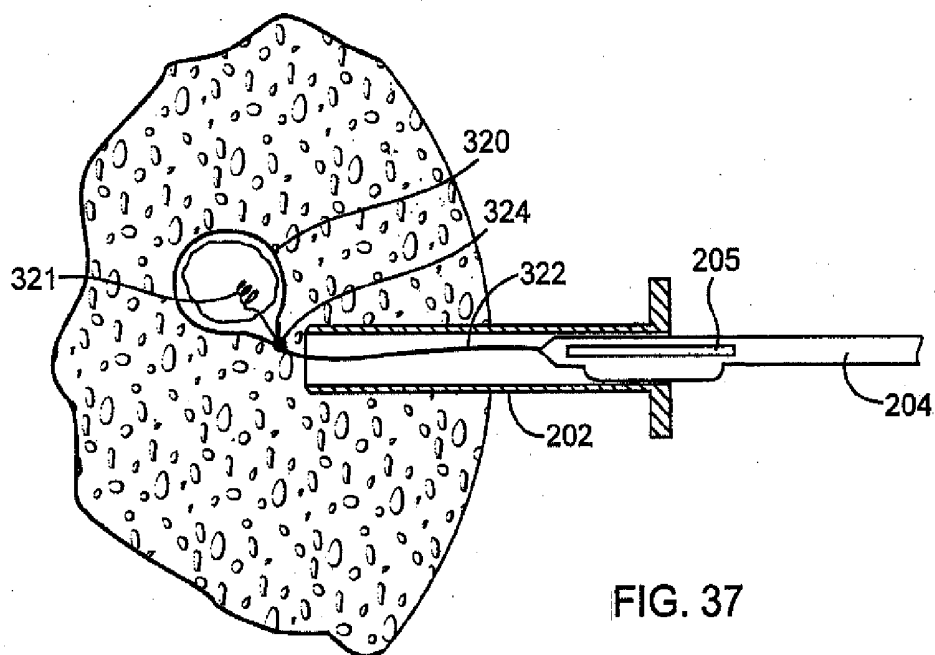


FIG. 37

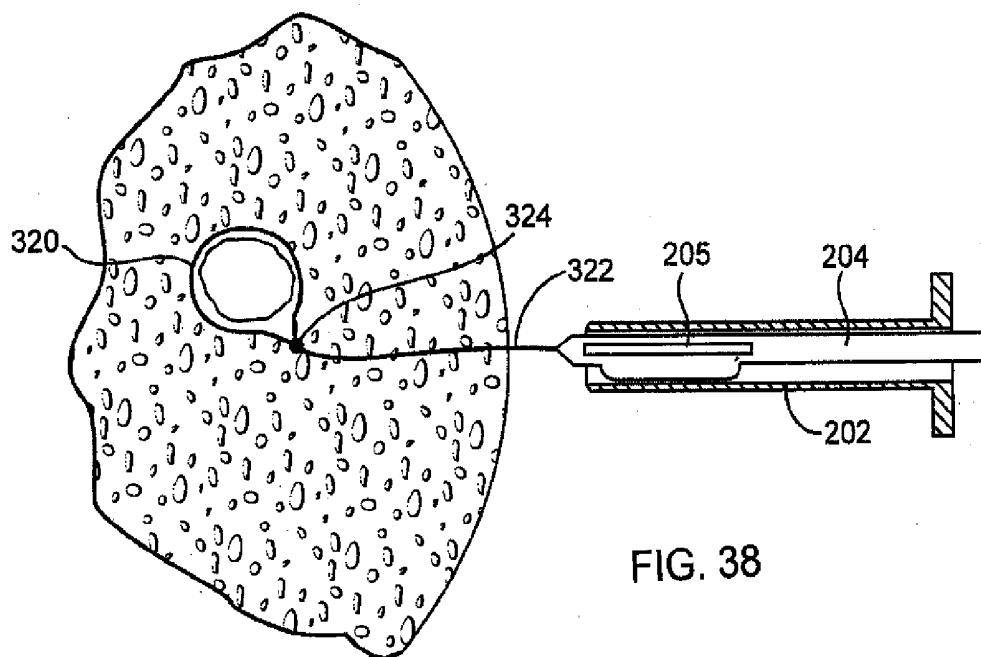


FIG. 38

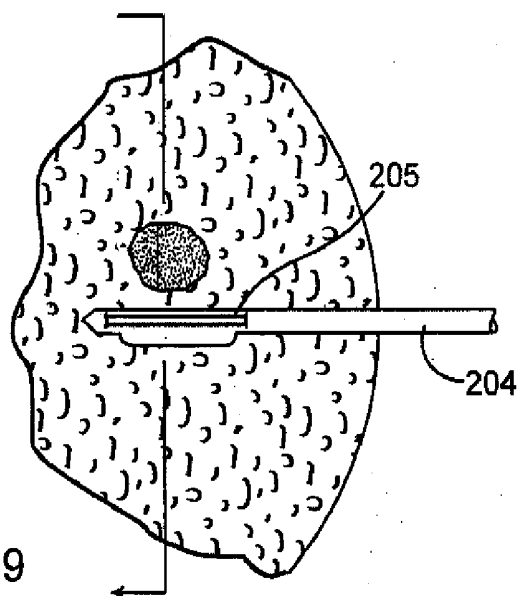


FIG. 39

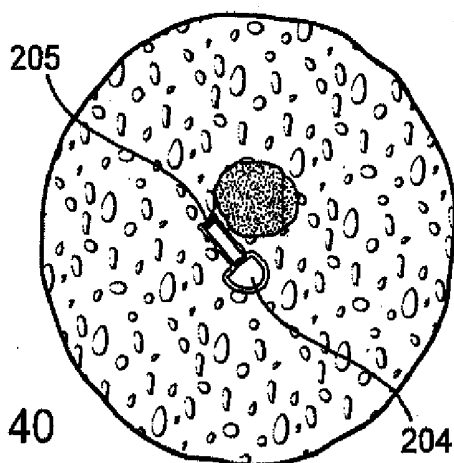


FIG. 40

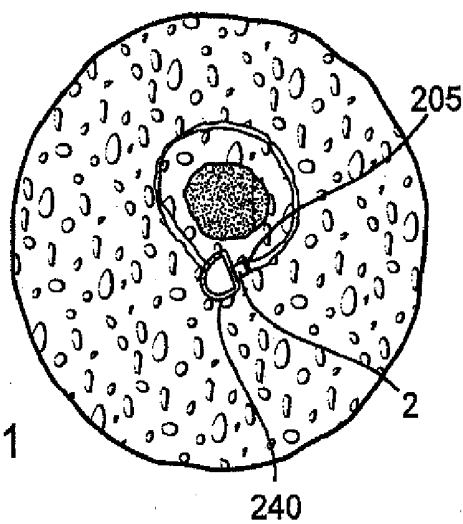


FIG. 41

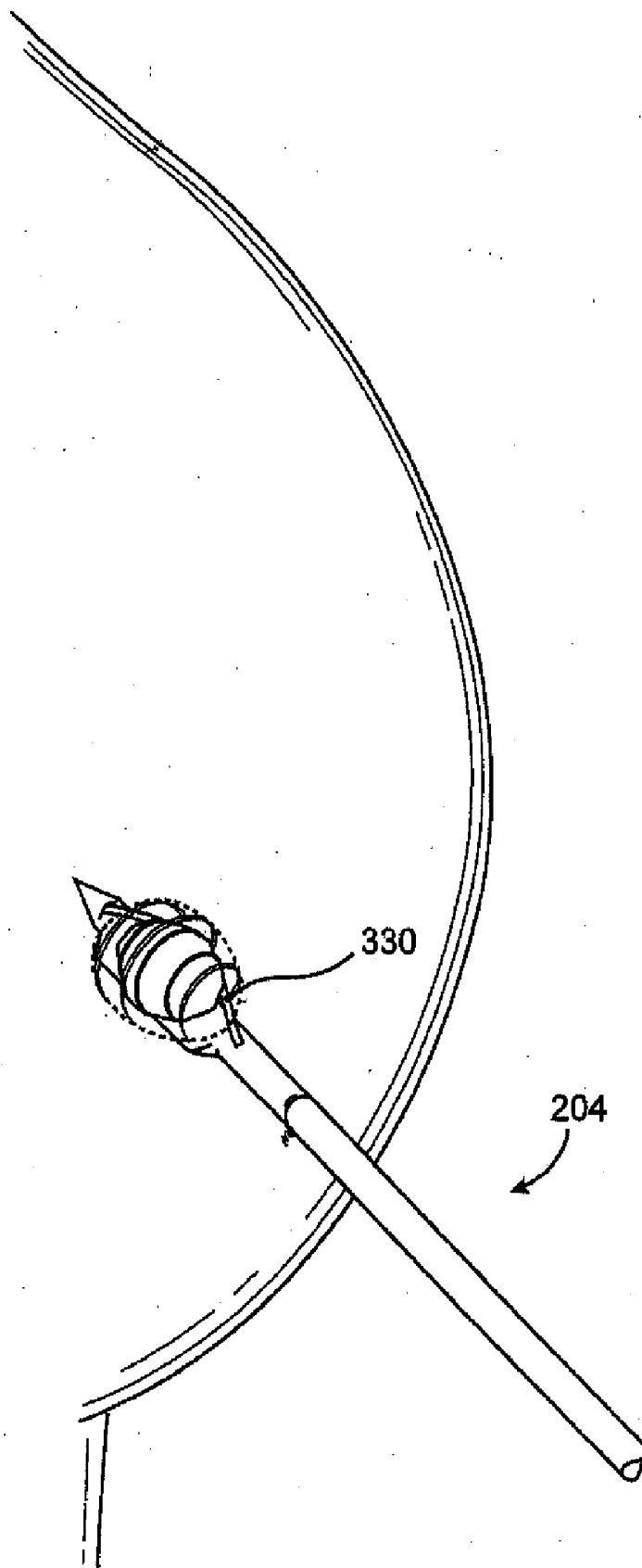


FIG. 42

DEVICES AND METHODS FOR PERFORMING PROCEDURES ON A BREAST

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a divisional of application Ser. No. 10/923,511, filed Aug. 20, 2004, which is a continuation-in-part of application Ser. No. 10/732,670, filed Dec. 9, 2003, and a continuation-in-part of application Ser. No. 10/272,448, filed Oct. 16, 2002, now U.S. Pat. No. 6,936,014, issued Aug. 30, 2005, and a continuation-in-part of application Ser. No. 10/796,328, filed Mar. 8, 2004, which is a continuation of application Ser. No. 09/417,520, filed Oct. 13, 1999, now U.S. Pat. No. 6,423,081, issued Jul. 23, 2002, which is a divisional of application Ser. No. 09/146,743, filed Sep. 3, 1998, now U.S. Pat. No. 6,022,362, issued Feb. 8, 2000, all applications and patents of which are hereby incorporated herein by reference in their entireties and from which priority is hereby claimed under 35 U.S.C. §119(e) and §120.

BACKGROUND OF THE INVENTION

[0002] 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 used to detect small, nonpalpable lesions which may appear opaque densities relative to normal breast parenchyma and fat or as clusters of microcalcifications. 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 radio-opaque 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.

[0003] Under general or local anesthesia, the surgeon may then perform a needle-localized breast biopsy. In this procedure, 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 then be excised in toto with a small margin or rim of normal breast tissue on all sides. Obtaining good margins of normal tissue using conventional techniques 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.

[0004] 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.

[0005] 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 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 using fine needle aspiration, core needle biopsy, vacuum-assisted core needle biopsy or other suitable method. 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. Core needle biopsy uses a larger size needle, usually 14 gauge to sample the lesion. Tissue architecture and histology are preserved with this method. 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. 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.

[0006] 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.

[0007] 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 to 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. 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.

SUMMARY OF THE INVENTION

[0008] According to an embodiment thereof, the present invention is a device for cutting tissue having a bowed cutting element. The device may include a shaft having a central axis; and a tissue cutting element coupled to the shaft, the tissue cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outwardly when in the expanded position, the cutting element moving generally in a first plane when moving between the collapsed and expanded positions; the shaft having a first thickness and a second thickness relative to the central axis of the shaft, the first and second thicknesses lying in a second plane which is generally parallel to the first plane, the second thickness being at least 1.25 times larger than the first thickness and the side of the shaft having the second thickness leading the cutting element during rotation.

[0009] The second thickness may be at least 1.5 times larger than the first thickness. The tissue cutting device may have a tissue collection element which holds the tissue volume cut free from the surrounding tissue.

[0010] According to another embodiment thereof, the present invention is also a device for cutting tissue using a bowed cutting element, comprising: a shaft; and a tissue cutting element coupled to the shaft, the tissue cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outwardly when in the expanded position, the tissue cutting element moving generally in a first plane when moving between the collapsed and expanded positions; the shaft may be at least 1.25 times thicker on a leading side than on a trailing side, the thickness being measured along a second plane perpendicular to the first plane, the cutting device being rotated during cutting so that the leading side leads the cutting element.

[0011] The shaft may be at least 1.5 times thicker on the leading side than on the trailing side. The shaft may be thicker on the leading side adjacent to the cutting element and may be substantially the same as the trailing side at substantially all other parts of the shaft.

[0012] According to yet another embodiment thereof, the present invention is a method of cutting tissue using a bowed cutting element, comprising the steps of: providing a tissue cutting device having a shaft and a tissue cutting element coupled to the shaft, the tissue cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outwardly when in the expanded position, the tissue cutting element moving generally in a first plane when moving between the collapsed and

expanded positions, the shaft has a first and second thicknesses lying in a second plane which may be generally parallel to the first plane, the second thickness being on a side of the shaft from which the tissue cutting element expands, the second thickness being at least 1.25 times larger than the first thickness; introducing the tissue cutting device into tissue; expanding the tissue cutting element toward the expanded position; rotating the tissue cutting device so that the cutting element moves through the tissue to cut the tissue, the cutting device being rotated in a direction in which a side having the second thickness leads the cutting element during rotation; moving the tissue cutting element back toward the collapsed position to cut a tissue volume free from the surrounding tissue.

[0013] The providing step may be carried out with the second thickness being at least 1.5 times larger than the first thickness. The providing step may be carried out with the tissue cutting device having a tissue collection element which holds the tissue volume cut free from the surrounding tissue. The providing step may be carried out with the shaft having at least the second thickness adjacent to the cutting element.

[0014] According to yet another embodiment, the present invention is a method of cutting tissue using a bowed cutting element, comprising the steps of providing a tissue cutting device having a shaft and a tissue cutting element coupled to the shaft, the tissue cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outwardly when in the expanded position, the tissue cutting element moving generally in a first plane when moving between the collapsed and expanded positions, the shaft may be at least 1.25 times thicker on a first side defined in the direction in the cutting element expands than a second side opposite the first side; introducing the tissue cutting device into tissue adjacent to a tissue volume to be removed; expanding the tissue cutting element toward the expanded position; rotating the shaft so that the cutting element moves through the tissue to cut around the tissue volume to be removed, the cutting device being rotated in a direction in which the first side of the shaft leads the cutting element during rotation; and moving the tissue cutting element back toward the collapsed position to cut a tissue volume free from the surrounding tissue.

[0015] The providing step may be carried out with the shaft being at least 1.5 times thicker on the first side than on the second side. The providing step may be carried out with the shaft being thicker on the leading side adjacent to the cutting element and being substantially the same as the trailing side at substantially all other parts of the shaft which may be introduced into the tissue.

[0016] A method of cutting a tissue mass free from surrounding breast tissue, according to still another embodiment of the present invention, may include steps of providing a tissue cutting device and a guide element, the tissue cutting device having a tissue cutting element movable from a collapsed position to an expanded position; inserting the guide element into a breast; advancing the tissue cutting device into the breast, the tissue cutting device being slidably coupled to the guide element so that the guide element guides advancement of the tissue cutting device into the breast; and cutting breast tissue with the tissue cutting device, the cutting step being carried out with the guide element indicating a cutting parameter for the cutting device.

[0017] The cutting step may be carried out with the guide element providing an indication of a depth of penetration during the advancing step. A step may be carried out of indicating a first angular position relative to a longitudinal axis of the guide element. The indicating step may be carried out by also indicating a second angular orientation, the tissue area of interest lying between the first and second angular orientations for use during the cutting step. The advancing step may be carried out with the tissue cutting device being advanced over the guide element. The advancing step may be carried out with the tissue cutting device being advanced through the guide element. The providing step may be carried out with the guide element being a tube; the inserting step may be carried out with the tube having a sharp tip which pierces the breast tissue; and the advancing step may be carried out with the tissue cutting device being introduced into the tube. A step of removing hot gasses generated during the cutting step through the tube may also be carried out. The removing step may be carried out by removing the hot gasses through a space between the tube and the tissue cutting device.

[0018] Still another embodiment of the present invention is a method of removing breast tissue, comprising the steps of providing a tissue cutting device and an insertion device having a sharp tip, the tissue cutting device having a cutting element which may be movable from a collapsed position to an expanded position, the cutting element being bowed outward when in the expanded position; inserting the insertion device into a breast with the sharp tip of the insertion device piercing the breast tissue during insertion; coupling the tissue cutting device to the insertion device so that the tissue cutting device may be slidably coupled to the insertion device; advancing the insertion device into the breast tissue while being slidably coupled to the insertion device; moving the tissue cutting element toward the expanded position after the withdrawing step; rotating the tissue cutting device to cut around the tissue to be removed; and removing the tissue which has been cut free from the surrounding tissue by the tissue cutting device.

[0019] The providing step may be carried out with the insertion device having a tubular body, the sharp tip may be removable. A step of removing the cutting element after the inserting step may also be carried out; the coupling step being carried out by introducing the cutting device into the insertion device and advancing the cutting device through the tubular body. The guide member may be secured to the tissue structure to hold the angular orientation of the guide member after completing the inserting step. The securing step may be carried out using an adhesive strip which may be adhered to a surface of the tissue through which the cutting device may be inserted. The insertion device may be withdrawn after the advancing step to expose the tissue cutting element. A step of removing gas through a space between the tubular body and the cutting device may also be carried out. The removing step may be carried out by removing the tissue through a separate incision from an incision through which the tissue cutting element extends. An angular indicator may be set on the guide member, which provides an indication of an angular extent of the tissue to be removed.

[0020] Another embodiment of the present invention is a method of forming an RF-energized bowed cutting element. The method may include steps of providing a tissue cutting

device having a cutting element coupled to a shaft, the cutting element being movable from a collapsed position to an expanded position, the cutting element being in a substantially straight configuration when collapsed and bowing outwardly from the shaft when in the expanded position; and marking a first location on the cutting element corresponding to a position on the cutting element where an apex occurs when the cutting element may be bowed outwardly, the location being marked for visualization using ultrasound.

[0021] The marking step may be carried out by also marking a second location corresponding to a proximal end and a third location corresponding to a distal end of the cutting element when the cutting element may be collapsed.

[0022] A device for cutting tissue, according to yet another embodiment of the present invention, may include a shaft; a cutting element coupled to the shaft, the cutting element being movable from a substantially straight position to an expanded position, the cutting element having an apex corresponding to a maximum radial extension of the cutting element when in the expanded position; a first ultrasound marker on the cutting element positioned on the cutting element at a position corresponding to the apex when in the collapsed position; a second ultrasound marker which marks a proximal location of the cutting element, and a third ultrasound marker which marks a distal location on the cutting element.

[0023] The first ultrasound marker may be closer to the distal location than the proximal location. The second and third ultrasound markers may be located at proximal and distal ends of the cutting element when the cutting element is in the collapsed position.

[0024] A still further embodiment is a suction sleeve for a soft tissue interventional device that may include a shaft, the suction sleeve comprising a tapered portion defining a predetermined extent, the tapered portion defining a first external surface and a first internal surface, the first internal surface defining an internal axial lumen spanning the predetermined extent, the internal axial lumen being configured to receive the shaft, the first external surface defining a suction port and a plurality of openings that open to the internal axial lumen.

[0025] According to a still further embodiment, the present invention is a method for cutting a specimen of soft tissue, comprising the steps of providing a device including a handle, a shaft coupled to the handle and defining a first end and a second end, a cutting element coupled to the second end of the shaft, and a suction sleeve disposed coaxially around the shaft between the first end of the shaft and the cutting element, the suction sleeve defining a suction port and a plurality of openings near the work element, the suction sleeve being configured to enable suction in through the plurality of openings and out through the suction port; inserting the device in the soft tissue; cutting the tissue specimen using the cutting element, and applying suction to the suction port during the cutting step.

[0026] Another embodiment is a method of excising breast tissue, comprising the steps of providing a guide element and a cutting device, the cutting device having a deployable cutting element mounted on a shaft; introducing the guide element into a patient's breast; advancing the cutting device into the patient's breast, the cutting device being slidably

coupled to the guide element so that the guide element guides the cutting device as the cutting device may be advanced into the patient's breast; deploying a cutting element on the cutting device after the advancing step; rotating the shaft so that the cutting element severs breast tissue; and removing the breast tissue which has been severed by the cutting element.

[0027] The rotating step may be carried out with the shaft rotating less than 180 degrees relative to the guide element. The providing step may be carried out with the guide element being a needle. The providing step may be carried out with the guide element having at least one indicator for indicating an angular orientation with respect to a longitudinal axis of the guide element. The rotating step may be carried out using the angular orientation indicated by the at least one indicator. The rotating step may be carried out with at least two angular orientations indicated on the guide element at least one of which being selected by the user. The removing step may be carried out with the severed breast tissue being contained in a collection element carried by the cutting device. The removing step may be carried out with the collection element surrounding and isolating the severed tissue from the surrounding tissue.

[0028] A still further embodiment of the present invention is a system for removing breast tissue, comprising: a guide element; and a cutting device, the cutting device having a deployable cutting element mounted on a shaft, the cutting device being configured to be slidably coupled to the guide element.

[0029] The guide element may be or include a needle. The guide element may have a first indicator for indicating an angular orientation. The cutting element may be deployed by bowing an elongate cutting element. The cutting element may be coupled to a source of RF energy. The system may further include a tissue collection element carried by the cutting device, the tissue collection element surrounding the severed tissue.

[0030] Another embodiment of the present invention is a method of cutting a piece of breast tissue, comprising the steps of: providing a tissue cutting device having shaft and a cutting element, the cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outward when moving from the collapsed position to the expanded position; introducing the tissue cutting device into a breast; expanding the cutting element toward the expanded position; rotating the shaft so that the cutting element cuts the breast tissue; and partially collapsing the cutting element after the expanding and rotating steps so that a portion of the tissue remains trapped between the cutting element and the shaft.

[0031] The cutting element may be locked in the partially collapsed position. The tissue with the tissue cutting device may be manipulated while the cutting element is partially collapsed. The method may include a step of manipulating the tissue with the tissue cutting device while the cutting element is partially collapsed. The tissue may be moved into a tissue collection element while the tissue is trapped by the partially collapsed cutting element. A tissue removing channel may be cut through breast tissue while the tissue is trapped between the cutting element and the shaft. The introducing step may be carried out with the tissue cutting device extending along an introduction path separate from the tissue removing channel.

[0032] These and other aspects of the present invention will become apparent from the following drawings and description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] FIG. 1 shows a needle made in accordance with the present invention.

[0034] FIG. 2 shows a tissue removing device.

[0035] FIG. 3 shows the needle introduced into a breast.

[0036] FIG. 4 shows a first anchor deployed within the breast.

[0037] FIG. 5 shows a second anchor deployed within the breast.

[0038] FIG. 6 shows a stiffener removed to provide a flexible proximal end.

[0039] FIG. 7 shows the flexible, proximal portion taped to the breast.

[0040] FIG. 8 shows a tissue removing device advanced over the needle and a cutting element deployed.

[0041] FIG. 9 is a perspective view of a combination introducer and suction sleeve, according to another embodiment of the present invention.

[0042] FIG. 10 is a side cross-sectional view of the combination introducer and suction sleeve of FIG. 9.

[0043] FIG. 11 is a perspective view of the combination introducer and suction sleeve of FIG. 9, with a trocar inserted therein.

[0044] FIG. 12 is a side cross-sectional view of the combination introducer and suction sleeve of FIG. 9, illustrating exemplary structure with which the suction sleeve may attach to the interventional device.

[0045] FIG. 13 is a perspective cross-sectional view of the combination introducer and suction sleeve, attached to an exemplary interventional device.

[0046] FIG. 14 is a perspective view of another embodiment of a suction sleeve according to the present invention, coupled to an exemplary interventional device.

[0047] FIG. 15 shows another guide element used to introduce a cutting device into the tissue.

[0048] FIG. 16 shows a piercing element removed from a lumen in the guide member.

[0049] FIG. 17 shows a cutting device introduced into the guide element.

[0050] FIG. 18 shows guide member retracted and anchored to the tissue with needles and an adhesive tape.

[0051] FIG. 19 shows a perspective view of another guide member having a window through which the cutting element extends when cutting the tissue.

[0052] FIG. 20 shows a tube which is cut to form a lip.

[0053] FIG. 21 is a cross-sectional view of FIG. 21 along line I-I.

[0054] FIG. 22 shows the tube of FIG. 21 covered with a shrink tube.

[0055] FIG. 23 is a cross-sectional view of FIG. 23 along line II-II with the addition of a cutting element shown in an expanded or bowed configuration.

[0056] FIG. 24 is a cross-sectional view of FIG. 23 along line III-III.

[0057] FIG. 25 shows another device for cutting or incising tissue.

[0058] FIG. 26 shows a removable core.

[0059] FIG. 27 is a cross-sectional view of the device of FIG. 26 along line A-A.

[0060] FIG. 28 shows the removable core positioned within a sheath.

[0061] FIG. 29 shows the cutting or incising device positioned within the sheath.

[0062] FIG. 30 shows the cutting device positioned so that the cutting element will sweep around the tissue area being removed.

[0063] FIG. 31 shows a tissue removal device introduced through another incision.

[0064] FIG. 32 shows the tissue removal device attached to the tissue.

[0065] FIG. 33-35 show use of the tissue cutting device to create a path for removing the tissue.

[0066] FIG. 36 shows the cutting device used to penetrate the tissue to create a tissue removal incision.

[0067] FIG. 37 shows the tissue contained within a tissue collection element having a tether which is coupled to the tissue cutter.

[0068] FIG. 38 shows the tissue cutter removed with the tether extending from the excised tissue.

[0069] FIG. 39 shows a side view of a tissue cutting device adjacent a tissue area to be removed.

[0070] FIG. 40 shows the cutting element beginning to sweep around the tissue area.

[0071] FIG. 41 shows the cutting element partially retracted to trap tissue between the cutting element and the shaft of the device.

[0072] FIG. 42 shows the tissue cutting device marking the tissue.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0073] Referring to FIGS. 1-8, a needle 2 may be used to guide another medical device, such as a tissue cutting device 6, when performing a procedure on the breast. Any suitable tissue cutting device may be used such as the devices disclosed in U.S. Pat. Nos. 6,440,147 and 6,022,362 which are also hereby incorporated by reference. The tissue cutting device 6 has a cutting element 8 capable of assuming positions between collapsed and bowed positions. The tissue cutting device 6 is pivoted or rotated so that the cutting element 8 sweeps through and cuts the tissue along an arc. A tissue collection element 10 may also be provided which collects the tissue being cut. The needle 2 may also include

a stiffener 4 which is used in the manner described in application Ser. No. 10/272,448, filed Oct. 16, 2002.

[0074] The needle 2 may also have one or more indicators 14 to mark an angular position relative to the longitudinal axis 16 of the needle 2. The indicator 14 extends radially outward from the needle at a angle selected by the user. The indicator 14 may also simply be a longitudinal stripe 18 or other marking on the shaft which indicates a particular angular orientation on the needle 2. The indicator 14 may provide information to the user regarding various parameters depending upon the procedure being performed. For example, when using the device 6 described above, the angular position, or positions, provides the user with the angular extent of the tissue to be removed.

[0075] The indicators 14 may be coupled to one more anchors 20 which are deployed to anchor the needle 2. The anchor 20 is preferably curved, such as J- or C-shaped, and extends radially to lie within the same angular orientation as the indicator 14. An advantage of coupling the indicator 14 to the anchor 20 is that anchor 20 itself provides information regarding the relative orientation of the needle 2, anchor 20 and tissue area of interest. Thus, the anchor 20 itself may be one of the indicators 14. Although the anchor 20 and indicator 14 are preferably aligned at the same angular orientation, they may also be offset to account for the geometry of other devices used with the needle 2. As can be appreciated, of course, the indicators 14 may also be independent of any anchoring elements. For example, the needle 2 may be placed in the breast and the indicators 14 could then be moved to selected angular position(s). The needle 2 may also have depth markers 22 along the body. The anchor 20 is preferably a stainless steel wire having a sharpened tip to pierce through the tissue. The orientation of the anchor 20 is partially guided by the geometry of the arc-shaped lumens (not shown) receiving the anchors 20.

[0076] Use of the device is now described in connection with a tissue removal procedure with reference to FIGS. 1-8. Of course, other procedures may be performed without departing from the scope of the invention. The needle 2 is introduced into the area of interest under suitable guidance such as ultrasound visualization. Once the needle 2 has been introduced in a desired or known orientation relative to the tissue area of interest, the entire needle 2 is rotated so that the first indicator 14 and marker 18 are aligned with a first angular position relative to the tissue area of interest. The first anchor 20 is then deployed into the tissue with the anchor 20 deployed at the selected angular orientation. The second indicator 14 is then rotated to a second selected angular orientation with respect to the area of interest. The second orientation is determined by visualizing the area of interest relative to the needle 2 and/or first anchor 20 to determine the appropriate location for the second anchor 20. The second anchor 20 is then deployed by advancing the anchor into the tissue. As can be appreciated, the needle 2 and anchors 20 themselves provide visual landmarks for locating the area of interest. The markings on the needle 2 and the indicators 14 also help to guide use of the tissue cutting device 6 as described herein.

[0077] The stiffener 4 is then removed to provide the flexible proximal portion. The flexible proximal portion may be taped to the patient to prevent inadvertent contact as shown in FIG. 7. When performing the procedure, the

flexible condition may be maintained to provide the benefit described above such as the ability to pull from varying angles as compared to a conventional rigid needle. The tissue removal device 6 may then be coupled to the needle 2 as shown in FIG. 8 and then advanced while being guided by the needle 2. The needle 2 may be introduced to a predetermined depth where the longitudinal stop 38 guides the depth of introduction of the tissue removal device. Of course, the needle 2 may be introduced deeper into the tissue with the user using the depth markings 40 on the needle 2 and/or tissue removal device 6 to determine the appropriate introduction depth for the tissue removal device 6. The cutting element 8 is then deployed to the bowed position and the cutting element 8 is swept through tissue to cut around the tissue area of interest. The tissue is then collected by the collection element 10 for removal. The device 6 is then withdrawn and anchors 30, which are described in more detail in application Ser. No. 10/272,448, filed Oct. 16, 2002, are retracted to permit withdrawal of the needle 2 as well.

[0078] FIG. 9 is a perspective view of a combination introducer and suction sleeve 902. The sleeve 92 may be used in the same manner as the guide members described herein and such uses is expressly incorporated here. FIG. 10 is a side cross-sectional view thereof. Considering now FIGS. 9 and 10 collectively, the first external surface 904 of the combination introducer and suction sleeve 902 may have a generally tapered or funnel shape, in that it defines a relatively narrow diameter distal end and a relatively wider proximal end. Such a generally funnel or tapered shape eases the introduction of the device 802 within tissue. The combination introducer and suction sleeve 902 has a suction port 908 that opens to an internal lumen 916 defined by the internal surface 918. The combination introducer and suction sleeve 902 also includes a second external surface 912 that defines a tapered appearance. Defined within the first and/or second external surfaces 904, 912 are a plurality of openings 906 that open to the internal lumen 916. In FIGS. 9-11, only the first external surface 904 defines such openings 906, although the openings are not limited to this surface. The suction port 908 is configured to couple with a vacuum line, as shown at 116. The combination introducer and suction sleeve 902 may further include structures to couple to one or more devices. Such coupling structure(s) may include, for example, a snap or interference fitting 914 and/or one or more O-rings, such as shown at 910.

[0079] FIG. 11 is a perspective view of the combination introducer and suction sleeve of FIG. 9, with a trocar 1102 inserted therein. According to an embodiment of the present invention, the trocar 1102 may be inserted into the combination introducer and suction sleeve 902 and the assembly may be packaged as a (preferably single use) unit. According to another embodiment of the present invention, a physician may utilize the assembly as follows:

[0080] An incision into tissue is made with a blade;

[0081] The physician then inserts the assembly including the trocar 1102 into the tissue and pushes the combination introducer and suction sleeve 902 into the tissue through the incision into position under or near the lesion or targeted site within the tissue. The pointed and/or sharp distal tip 1104 of the trocar 1102 and the tapered profile of the combination introducer and suction sleeve 902 aid the assembly's advancement within the tissue;

[0082] The trocar 1102 may then be removed from the combination introducer and suction sleeve 902 and a desired (excisional RF, for example) device may then be inserted therethrough, with the shaft thereof disposed within and protruding from the internal lumen 916;

[0083] The combination introducer and suction sleeve 902 may then be pulled back until it contacts, snaps and/or otherwise locks onto the device, as shown at FIGS. 12 and 13. In FIGS. 12 and 13, only the handle 102 of the device is shown, and the shaft 104 thereof is omitted for clarity of illustration. Examples of a tissue cutting device coupled to the combination introducer and suction sleeve 902 coupled thereto is shown in FIG. 14;

[0084] A vacuum line, such as shown at 116, may then be attached to the suction port 908;

[0085] If needed, the device with the combination introducer and suction sleeve 902 attached thereto may then be repositioned at, near, under or within the target lesion, as desired. This repositioning may be carried out under ultrasound guidance, for example. The openings 906 may aid with the ultrasound visualization. The combination may include other features and/or markings to increase the visibility thereof under various imaging modalities, and

[0086] The physician may then continue with the intended procedure as per the instructions for use of the device utilized.

[0087] Alternatively, the trocar 1102 may be removed from the combination introducer and suction sleeve 902 and the desired RF device introduced and locked therein. The distal tip of the desired RF device protruding from the distal end of the combination introducer and suction sleeve 902 may then be used to reach the intended biopsy site.

[0088] Alternately still, a stopcock may be attached to the suction port 908 instead of the suction line 116 and one or more beneficial agents (e.g., antibiotics, fibrin, lidocaine) may be delivered to a target site through the openings 906.

[0089] The present combination vacuum sleeve and suction sleeve 902 may aid in positioning a biopsy or other interventional device where it is needed. For example, interventional devices that include a rather bulky or high-drag distal end may be readily positioned at the intended site by means of the introducer functionality of the combination 902. While the combination 902 is advantageous before the biopsy or other interventional procedure is started by easing the positioning of the biopsy instrument at or near the target site, it is also useful during the procedure itself, as it is effective in evacuating hot gasses and fluids from the biopsy cavity, thereby decreasing collateral tissue thermal damage. The same combination may then also be used to treat the cavity post-procedure by, for example, providing a ready-made pathway for the introduction of beneficial agents, compositions and/or cavity treatment devices to the cavity or lesion site.

[0090] Referring now to FIGS. 15-18, another system 200 and method are shown wherein the same or similar reference numbers refer to the same or similar structure. As mentioned above, a guide member 202 may be used to guide a cutting device 204. The guide member 202 may be any of the suitable guide members described herein including the needle 2 of FIGS. 1-8 or the introducer 902 of FIGS. 9-14.

The cutting device **204** may be any of the cutting devices described herein or another suitable device such as those described in U.S. Pat. No. 7,044,956, issued May 16, 2006, which is hereby incorporated herein by reference in its entirety. The cutting device **204** has a cutting element **205** which bows outwardly when expanded.

[0091] The guide member **202** has a tubular body **206** and a removable penetrating element **208** having a sharp tip **210** for piercing tissue during introduction. The guide member **202** also has a port **212** coupled to a vacuum source **214** for removing hot gasses generated during cutting. The penetrating element **208** has a shaft **216** extending through a lumen **217** in the guide member **202**. The guide member **202** may include one or more anchors **218** which holds the guide member **202** at the desired position. The anchor **218** may simply be an adhesive strip **220** which the user peels away from the body and adheres to the skin. The anchor **218** may also be another suitable anchor such as one or more needles **221** which are advanced into the tissue. The anchors **218** help to resist movement of the guide member **202** so that the guide member **220** may be used to guide longitudinal and even rotational positioning of the cutting device **204** as explained herein. Referring to FIG. 19, the anchor **218** may also be a balloon **221** which is inflated to anchor the guide member.

[0092] After the guide member **202** has been introduced to the desired depth, the penetrating element **208** is then removed and the tissue cutting device **204** is introduced and advanced into the guide member **220** (FIG. 17). The guide member **202** may include a stop **222** which prevents further advancement of the tissue cutting device **202** so that the device **204** remains in the same longitudinal position. The guide member **202** may also include one or more angular indicators **224** which may be the anchors **218**. Referring to FIG. 19, another guide member **202A** is shown which has a window **226** oriented in the desired direction of cutting. The window **226** guides the user by limiting and/or defining the cutting motion to help guide the cutting procedure. The use and structural features of the guide member **220**, indicators **224**, anchors **218** and stop **222** may be the same or similar to those described in connection with FIGS. 1-8.

[0093] Referring again to FIG. 14, the cutting element **108** preferably has an ultrasound marker **232** at an anticipated apex of the cutting element **108** when the cutting element **108** is expanded to help position the device. The apex **232** does not necessarily correspond with the geometric middle of the cutting element **108** when the cutting element **108** is collapsed since only one end of the cutting element **108** may be moved to bow the cutting element **108** outward. For example, the proximal end of the cutting element **108** may be advanced distally to bow the cutting element **108** outward in which case the first marker **232** would appear to be closer to the proximal end when the cutting element **108** is collapsed. The cutting device **204** may also include a second marker **234** and a third marker **236** which correspond to the ends of the cutting element **108** when the cutting element **108** is collapsed. Referring again to FIG. 17, the guide member **20** may have a first marker **229**, corresponding to an anticipated apex **229** of the cutting element **108**, and a second marker **228** and a third marker **230** corresponding to the ends **228**, **230** of the cutting element **108** when collapsed. In this manner, the guide member **202** may help properly position the cutting device. Of course, any of the guide

members or tissue cutting devices described herein, such as the needle **2**, may also have the ultrasound markers positioned in this manner. The cutting element and the guide may be marked in any suitable manner. For example, the cutting element or guide may include a hollow area which would enhance the ultrasound signature. When placing a marker on the cutting element, the marker may be designed to be easily visible when the cutting element **205** is powered at a level lower than the power level used during cutting. For example, the cutting element **205** may be designed to become more visible when an RF generator is switched to coagulation mode which has lower power than the cutting mode used when cutting tissue.

[0094] Referring now to FIGS. 20-24, the tissue cutting device **204** may have a shaft **240** with an asymmetrical cross-sectional shape adjacent to the cutting element **205** to aid parting off the tissue when completing the cutting operation. The shaft **240** is thicker in the direction in which the cutting element **205** expands as compared to the direction opposite cutter expansion. Stated another way, the shaft **240** may be thicker on a leading side **242**, which leads the cutting element when rotated in the direction of arrow **245**, than on an opposing or trailing side **244**. The shaft **240** may also be thicker on the leading side in a direction substantially perpendicular to expansion of the cutting element **205A** (shown mounted to shaft **240** in the dotted-line position). Cutting element **205A** is mounted to the shaft **240** in an orientation about 90 degrees from the orientation of the cutting element **205**. Of course, the cutting element **205A** may be mounted to the shaft **240** in other orientations relative to the thicker part of the shaft such as any position between element **205** and element **205A**. Stated still another way, the cutting element **205** may be oriented and mounted on the shaft **240** in any manner which provides a thicker side within the first 90 degrees of the leading side compared to the shaft thickness in the 90 degrees trailing the cutting element **205**. In the various suggested configurations described, the thicker part of the shaft **240** is preferably at least 1.25 times, 1.50 times, or even 1.75 times thicker than the thinner part of the shaft **240**.

[0095] The shaft **240** may be formed in any suitable manner. Referring to FIGS. 20-24, for example, a metallic tube **248** is cut to form a lip **250** which is bent outwardly to provide the thicker shaft section. The tube **248** is then covered with a shrink tube **252** and heated to bond the shrink tube **252** to the tube **248**. The shrink tube **252** covers the opening in the tube created by formation of the lip **252**. The shrink tube **252** also forms a beveled surface **254** which covers an opening **253** in the tube **248** created by the lip **250**.

[0096] Use of the system **200** is now described with reference again to FIGS. 15-19. The guide member **202** is introduced into the tissue to an appropriate depth relative to the tissue to be removed. As explained above, the guide member **202** may be used to help define and/or guide aspects of the cutting motion such as the depth of insertion and/or one or more angular positions indicating the angular extent of the targeted tissue. For example, the ultrasound marker **229** may be used to position the guide member **202** so that the anticipated apex of the cutting element **205** is positioned appropriately. When the guide member **202A** of FIG. 19 is used, the cutting window **226** is positioned in the desired angular orientation which positions the tissue to be removed within the window **226**. The window **226** may have an

opening a bit larger than the anticipated requirement so that the window 226 guides, but not necessarily overly limits, the angular and longitudinal position of the cutting device 204.

[0097] Once the guide member 202, 202A has been positioned properly relative to the desired cutting operation the tissue penetrating element 208 may be removed and the cutting device 204 is introduced into the guide member 202. The guide member 202 is then retracted a predetermined amount so that the guide member 202 is properly positioned to remove hot gases generated during RF cutting as described above. When using the guide member 202A having the cutting window 226, the guide member does not, of course, need to be retracted.

[0098] The cutting device 204 is then used to cut around the tissue to be removed. The tissue may be removed in a tissue collection element 10 (see FIG. 2). Alternatively, vacuum means may also be used to remove the tissue as now described and further described in application Ser. No. 10/796,328, filed Mar. 8, 2004. The cutting device 204 may be any suitable cutting device such as those described in Pat. No. 7,044,956, issued May 16, 2006.

[0099] Referring now to FIGS. 25-29, another system is shown which uses a sheath 495 to receive one or more devices such as a core 400, which may be used for imaging, and an excisional device 100 which is used to cut the tissue. The core 400 has an active element 440 configured to perform intra-tissue imaging and of relaying information back to a display device (shown in FIG. 30) 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.

[0100] To accommodate the removable transducer core 400, the excisional device 100 of FIG. 25 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, a 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.

[0101] FIG. 26 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 and may be used alone or in addition to surface ultrasound to localize the lesion with a great degree of precision.

[0102] FIG. 27 shows a cross section of the embodiment of the excisional device 100 of FIG. 25, taken along line AA'. As shown in FIG. 27, the cutting tool 125 is exposed through the transducer window 120. The window 120 may, as shown in FIG. 27, 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 FIGS. 25 or 27. 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.

[0103] FIG. 28 shows the removable core 400 inserted within the expandable sheath 495. The expandable sheath 495 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. 28, 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.

[0104] FIG. 29 shows another embodiment of a soft tissue excisional device assembly 600 according to the present invention. In the configuration shown in FIG. 29, 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. 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. The tissue collection device **260** is not shown, for clarity but may be used in any manner described herein or in the applications or patents incorporated herein without departing from the scope of the invention.

[0105] In FIG. 29, the excisional device **100** is shown inserted within the expandable sheath **495**. Indeed, the excisional device **100**, in FIG. 29, 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 element or tool **125** and the transducer window **410** extends therethrough. The meshwork **500**, in FIG. 30, 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 **526** (a turn knob **526** shown in FIG. 29) to be manually accessible to the surgeon.

[0106] 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 **550** 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 or any suitable RF power source found in most operating rooms), 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**. Any other suitable cutting or excisional device may be used in connection with the present invention such as those described in U.S. Pat. No. 7,044,956, issued May 16, 2006.

[0107] The vacuum means may be associated with the cutting tool **125** (FIG. 25) or the cutting device **204** (FIG. 17) or may be a separate removal device **300** as shown in FIG. 30. As will be further described, the tissue may also be removed through the same incision or a separate incision from the incision through which the cutting device **204** extends. Referring still to FIG. 31, the tissue removal device **300** may have one or more suction ports **302** at a distal end **308**. The suction port **302** is coupled to a lumen **304** which in turn is coupled to a vacuum source **306**. The suction port **302** can be flared outwardly to enhance suction adherence and to help retract tissue away from the tissue being removed as shown in FIG. 32. The end **308** may have longitudinal slots (not shown) covered by an elastic cover **309** which permits the end **308** to flare outwardly in a manner similar to expandable trocars and cannulae as is known in the art. The end **308** may be actuated with a thumb switch **310** or other suitable actuator. Of course, the tissue removal device **300** may also directly grasp or pierce the tissue with piercing elements **311**, such as needles **313**, rather than relying on suction adherence. For example, the tissue removal device **300** may advance needles **312** into the tissue to anchor and grasp the tissue.

[0108] The tissue removal device **300** may be introduced through the same incision as the tissue cutting device **204** or

may be introduced through a different incision. For example, the user may choose to introduce the cutting device **204** based primarily on the desired orientation of the cutting device **200** relative to the tissue area being removed. The user may then choose the removal incision based on other factors such as proximity to the skin or for cosmetic considerations. Referring to FIGS. 33-35, the removal incision may be partially or completely created with the tissue cutting device **204**. For example, the cutting element **205** may be expanded and energized when the shaft is being withdrawn and/or advanced so that the cutting element **205** creates a tissue channel. This procedure may be repeated to create the desired channel such as an X- or Y-shaped channel. The cutting element **205** may have a movable insulating sheath **260** which covers a portion of the cutting element **205**, such as the distal portion of the element **205**, to prevent inadvertent cutting of the tissue being removed when creating the tissue channel. Use of a movable insulating sleeve **260** is described in Pat. No. 7,198,626, issued Apr. 3, 2007, which is hereby incorporated herein by reference in its entirety.

[0109] Referring to FIG. 36, the cutting element **205** may also be used to create a separate incision for removal of the tissue by cutting a channel directly from the area in which the tissue has been cut and extending outwardly from the severed portion. The cutting element **205** is positioned so that further extension and bowing of the cutting element **205** will essentially create a path outwardly from the severed portion of the tissue. This procedure may be performed after severing the tissue in this area so that the cutting element **205** can be initially positioned without RF power. The ultrasound markers described herein, and in particular the marker near the apex of the cutting element **205** when expanded and bowed, are particularly useful in properly positioning the cutting element **205** at this time. The cutting element **205** may then be powered with RF to partially or completely create the tissue channel. This procedure may be desirable when the cutting procedure causes the cutting element **205** to pass near the skin. The cutting device **204** may also include a movable insulating sleeve **261** which covers part of the cutting element **205**, such as portions on the ends of the cutting element **205**, during this part of the procedure to reduce the excess lateral cutting during creation of the tissue channel.

[0110] When removing the tissue, the tissue may be contained within a tissue collection element **320** released by the cutting device **204** when the tissue is severed or which is deployed by itself after excision of the tissue. The tissue collection element **320** may simply trail the cutting element **205** similar to the patents and applications incorporated by reference herein in which the tissue collection element remains coupled to the device.

[0111] FIG. 37 shows the collection element **320** containing the tissue with a tether **322** extending from the tissue collection element **320** and being withdrawn as the cutting device **204** is removed. The tether **322** may be used to guide advancement and engagement of the tissue removal device **300**. For example, the tissue collection element **320** may have a connector **324** which engages the removal device **300** with a suitable mechanical, magnetic or suction connection. The connector **324** may be positioned at the end of the tether **322** so that engagement with the connector **324** is easily guided by the tether **322**.

[0112] Referring still to FIG. 37, the tether 322 may be particularly useful when removing the tissue through a separate incision since the tether 322 can be easily retrieved using a conventional suture snare or the like. The tether 322 may also be used without the tissue collection element 320 by simply attaching the tether 320 to the tissue with a needle, screw 321 (see FIG. 37) or other suitable attachment feature. The tether 320 may be delivered by the cutting device 204 or may be part of another device such as the tissue removal devices described herein.

[0113] Referring to FIGS. 39-41, still another aspect of the present invention is shown. The tissue cutting device 204 is shown and all features and aspects of the tissue cutting devices described herein are incorporated here. The tissue cutting device 204 is shown sweeping around the tissue to be removed. The cutting element 205 is then partially retracted so that only a small piece of tissue connects the tissue to be removed from the surrounding tissue as shown in FIG. 41. The tissue cutting device 205 may then be used to manipulate the tissue to assist or prepare the tissue for removal. The tissue cutting device 204 may be designed to lock the cutting element 205 in the partially opened position of FIG. 41 to trap the tissue between the cutting element 205 and the shaft 240 so that the cutting device 204 may be used to manipulate the tissue. For example, the tissue may be manipulated while the tissue is being encapsulated in a tissue collection element or when the tissue is being engaged by any of the tissue removal devices described herein such as the device 300. When it is desired to remove the tissue, the cutting element 205 is collapsed further to complete the cut.

[0114] The tissue cutting device 204 may also mark the tissue sample and/or the tissue surrounding the tissue sample as shown in FIG. 42. Marking the tissue may assist in identifying the tissue for removal or to mark the tissue remaining in the body for subsequent therapy or treatment. The tissue may be marked in any suitable manner such as those described in application Ser. No. 10/871,790, filed Jun. 17, 2004, which is hereby incorporated herein by reference in its entirety. For example, the tissue cutting device 204 may have one or more dye injection ports 330 to mark the tissue. Of course, the cutting device may also leave behind a marker, such as a spiral spring or coil as described above, to mark the tissue rather than marking the tissue with a dye or the like. It is understood that marking the tissue being removed and/or marking the tissue remaining in the body may be used in connection with any of the other features and aspects of the present invention including use with any of the tissue cutting or removal devices described herein.

[0115] The present invention has been described in connection with the preferred embodiments, however, it is understood that many alternatives are possible without departing from the scope of the invention.

What is claimed is:

1. A device for cutting tissue having a bowed cutting element, comprising:

a shaft having a central axis; and

a tissue cutting element coupled to the shaft, the tissue cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outwardly when in the expanded position, the

cutting element moving generally in a first plane when moving between the collapsed and expanded positions;

the shaft having a first thickness and a second thickness relative to the central axis of the shaft, the first and second thicknesses lying in a second plane which is generally parallel to the first plane, the second thickness being at least 1.25 times larger than the first thickness and the side of the shaft having the second thickness leading the cutting element during rotation.

2. The device of claim 1, wherein:

the second thickness is at least 1.5 times larger than the first thickness.

3. The device of claim 1, wherein:

the tissue cutting device has a tissue collection element which holds the tissue volume cut free from the surrounding tissue.

4. A device for cutting tissue using a bowed cutting element, comprising:

a shaft; and

a tissue cutting element coupled to the shaft, the tissue cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outwardly when in the expanded position, the tissue cutting element moving generally in a first plane when moving between the collapsed and expanded positions;

wherein the shaft is at least 1.25 times thicker on a leading side than on a trailing side, the thickness being measured along a second plane perpendicular to the first plane, the cutting device being rotated during cutting so that the leading side leads the cutting element.

5. The device of claim 4, wherein:

the shaft is at least 1.5 times thicker on the leading side than on the trailing side.

6. The device of claim 4, wherein:

the shaft is thicker on the leading side adjacent to the cutting element and is substantially the same as the trailing side at substantially all other parts of the shaft.

7. A method of cutting tissue using a bowed cutting element, comprising the steps of:

providing a tissue cutting device having a shaft and a tissue cutting element coupled to the shaft, the tissue cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outwardly when in the expanded position, the tissue cutting element moving generally in a first plane when moving between the collapsed and expanded positions, wherein the shaft has a first and second thicknesses lying in a second plane which is generally parallel to the first plane, the second thickness being on a side of the shaft from which the tissue cutting element expands, the second thickness being at least 1.25 times larger than the first thickness;

introducing the tissue cutting device into tissue;

expanding the tissue cutting element toward the expanded position;

rotating the tissue cutting device so that the cutting element moves through the tissue to cut the tissue, the

cutting device being rotated in a direction in which a side having the second thickness leads the cutting element during rotation;

moving the tissue cutting element back toward the collapsed position to cut a tissue volume free from the surrounding tissue.

8. The method of claim 7, wherein:

the providing step is carried out with the second thickness being at least 1.5 times larger than the first thickness.

9. The method of claim 7, wherein:

the providing step is carried out with the tissue cutting device having a tissue collection element which holds the tissue volume cut free from the surrounding tissue.

10. The method of claim 7, wherein:

the providing step is carried out with the shaft having at least the second thickness adjacent to the cutting element.

11. A method of cutting tissue using a bowed cutting element, comprising the steps of:

providing a tissue cutting device having a shaft and a tissue cutting element coupled to the shaft, the tissue cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outwardly when in the expanded position, the tissue cutting element moving generally in a first plane when moving between the collapsed and expanded positions, wherein the shaft is at least 1.25 times thicker on a first side defined in the direction in the cutting element expands than a second side opposite the first side;

introducing the tissue cutting device into tissue adjacent to a tissue volume to be removed;

expanding the tissue cutting element toward the expanded position;

rotating the shaft so that the cutting element moves through the tissue to cut around the tissue volume to be removed, the cutting device being rotated in a direction in which the first side of the shaft leads the cutting element during rotation; and

moving the tissue cutting element back toward the collapsed position to cut a tissue volume free from the surrounding tissue.

12. The method of claim 11, wherein:

the providing step is carried out with the shaft being at least 1.5 times thicker on the first side than on the second side.

13. The method of claim 11, wherein:

the providing step is carried out with the shaft being thicker on the leading side adjacent to the cutting element and being substantially the same as the trailing side at substantially all other parts of the shaft which is introduced into the tissue.

14. A method of cutting a tissue mass free from surrounding breast tissue, comprising the steps of:

providing a tissue cutting device and a guide element, the tissue cutting device having a tissue cutting element movable from a collapsed position to an expanded position;

inserting the guide element into a breast;

advancing the tissue cutting device into the breast, the tissue cutting device being slidably coupled to the guide element so that the guide element guides advancement of the tissue cutting device into the breast; and

cutting breast tissue with the tissue cutting device, the cutting step being carried out with the guide element indicating a cutting parameter for the cutting device.

15. The method of claim 14, wherein:

the cutting step is carried out with the guide element providing an indication of a depth of penetration during the advancing step.

16. The method of claim 14, further comprising the step of:

indicating a first angular position relative to a longitudinal axis of the guide element.

17. The method of claim 16, wherein:

the indicating step is carried out by also indicating a second angular orientation, wherein the tissue area of interest lies between the first and second angular orientations for use during the cutting step.

18. The method of claim 14, wherein:

the advancing step being carried out with the tissue cutting device being advanced over the guide element.

19. The method of claim 14, wherein:

the advancing step is carried out with the tissue cutting device being advanced through the guide element.

20. The method of claim 14, wherein:

the providing step is carried out with the guide element being a tube;

the inserting step being carried out with the tube having a sharp tip which pierces the breast tissue; and

the advancing step is carried out with the tissue cutting device being introduced into the tube.

21. The method of claim 20, further comprising the step of:

removing hot gasses generated during the cutting step through the tube.

22. The method of claim 21, wherein:

the removing step is carried out by removing the hot gasses through a space between the tube and the tissue cutting device.

23. A method of removing breast tissue, comprising the steps of:

providing a tissue cutting device and an insertion device having a sharp tip, the tissue cutting device having a cutting element which is movable from a collapsed position to an expanded position, the cutting element being bowed outward when in the expanded position;

inserting the insertion device into a breast with the sharp tip of the insertion device piercing the breast tissue during insertion;

coupling the tissue cutting device to the insertion device so that the tissue cutting device is slidably coupled to the insertion device;

advancing the insertion device into the breast tissue while being slidably coupled to the insertion device;

- moving the tissue cutting element toward the expanded position after the withdrawing step;
- rotating the tissue cutting device to cut around the tissue to be removed; and
- removing the tissue which has been cut free from the surrounding tissue by the tissue cutting device.
- 24.** The method of claim 23, wherein:
- the providing step is carried out with the insertion device having a tubular body, wherein the sharp tip is removable.
- 25.** The method of claim 24, further comprising the step of:
- removing the cutting element after the inserting step;
- the coupling step being carried out by introducing the cutting device into the insertion device and advancing the cutting device through the tubular body.
- 26.** The method of claim 24, further comprising the step of:
- securing the guide member to the tissue structure to hold the angular orientation of the guide member after completing the inserting step.
- 27.** The method of claim 26, wherein:
- the securing step is carried out using an adhesive strip which is adhered to a surface of the tissue through which the cutting device is inserted.
- 28.** The method of claim 23, further comprising the step of:
- withdrawing the insertion device after the advancing step to expose the tissue cutting element.
- 29.** The method of claim 28, further comprising the step of:
- removing gas through a space between the tubular body and the cutting device.
- 30.** The method of claim 23, wherein:
- the removing step is carried out by removing the tissue through a separate incision from an incision through which the tissue cutting element extends.
- 31.** The method of claim 23, further comprising:
- setting an angular indicator on the guide member which provides an indication of an angular extent of the tissue to be removed.
- 32.** A method of forming an RF-energized bowed cutting element, comprising the steps of:
- providing a tissue cutting device having a cutting element coupled to a shaft, the cutting element being movable from a collapsed position to an expanded position, the cutting element being in a substantially straight configuration when collapsed and bowing outwardly from the shaft when in the expanded position; and
- marking a first location on the cutting element corresponding to a position on the cutting element where an apex occurs when the cutting element is bowed outwardly, the location being marked for visualization using ultrasound.
- 33.** The method of claim 32, wherein:
- the marking step is carried out by also marking a second location corresponding to a proximal end and a third location corresponding to a distal end of the cutting element when the cutting element is collapsed.
- 34.** A device for cutting tissue, comprising:
- a shaft;
- a cutting element coupled to the shaft, the cutting element being movable from a substantially straight position to an expanded position, the cutting element having an apex corresponding to a maximum radial extension of the cutting element when in the expanded position;
- a first ultrasound marker on the cutting element positioned on the cutting element at a position corresponding to the apex when in the collapsed position;
- a second ultrasound marker which marks a proximal location of the cutting element, and
- a third ultrasound marker which marks a distal location on the cutting element.
- 35.** The device of claim 34, wherein:
- the first ultrasound marker is closer to the distal location than the proximal location.
- 36.** The device of claim 35, wherein:
- the second and third ultrasound markers are located at proximal and distal ends of the cutting element when the cutting element is in the collapsed position.
- 37.** A suction sleeve for a soft tissue interventional device that includes a shaft, the suction sleeve comprising a tapered portion defining a predetermined extent, the tapered portion defining a first external surface and a first internal surface, the first internal surface defining an internal axial lumen spanning the predetermined extent, the internal axial lumen being configured to receive the shaft, the first external surface defining a suction port and a plurality of openings that open to the internal axial lumen.
- 38.** A method for cutting a specimen of soft tissue, comprising the steps of:
- providing a device including a handle, a shaft coupled to the handle and defining a first end and a second end, a cutting element coupled to the second end of the shaft, and a suction sleeve disposed coaxially around the shaft between the first end of the shaft and the cutting element, the suction sleeve defining a suction port and a plurality of openings near the work element, the suction sleeve being configured to enable suction in through the plurality of openings and out through the suction port;
- inserting the device in the soft tissue;
- cutting the tissue specimen using the cutting element, and
- applying suction to the suction port during the cutting step.
- 39.** A method of excising breast tissue, comprising the steps of:
- providing a guide element and a cutting device, the cutting device having a deployable cutting element mounted on a shaft;
- introducing the guide element into a patient's breast;
- advancing the cutting device into the patient's breast, the cutting device being slidably coupled to the guide

element so that the guide element guides the cutting device as the cutting device is advanced into the patient's breast;

deploying a cutting element on the cutting device after the advancing step;

rotating the shaft so that the cutting element severs breast tissue; and

removing the breast tissue which has been severed by the cutting element.

40. The method of claim 39, wherein:

the rotating step is carried out with the shaft rotating less than 180 degrees relative to the guide element.

41. The method of claim 39, wherein:

the providing step is carried out with the guide element being a needle.

42. The method of claim 39, wherein:

the providing step is carried out with the guide element having at least one indicator for indicating an angular orientation with respect to a longitudinal axis of the guide element.

43. The method of claim 42, wherein:

the rotating step is carried out using the angular orientation indicated by the at least one indicator.

44. The method of claim 42, wherein:

the rotating step is carried out with at least two angular orientations indicated on the guide element at least one of which being selected by the user.

45. The method of claim 39, wherein:

the removing step is carried out with the severed breast tissue being contained in a collection element carried by the cutting device.

46. The method of claim 45, wherein:

the removing step is carried out with the collection element surrounding and isolating the severed tissue from the surrounding tissue.

47. A system for removing breast tissue, comprising:

a guide element; and

a cutting device, the cutting device having a deployable cutting element mounted on a shaft, the cutting device being configured to be slidably coupled to the guide element.

48. The system of claim 47, wherein:

the guide element is a needle.

49. The system of claim 47, wherein:

the guide element has a first indicator for indicating an angular orientation.

50. The system of claim 47, wherein:

the cutting element being deployed by bowing an elongate cutting element, the cutting element being coupled to a source of RF energy.

51. The system of claim 47, further comprising:

a tissue collection element carried by the cutting device, the tissue collection element surrounding the severed tissue.

52. A method of cutting a piece of breast tissue, comprising the steps of:

providing a tissue cutting device having shaft and a cutting element, the cutting element being movable from a collapsed position to an expanded position, the cutting element bowing outward when moving from the collapsed position to the expanded position;

introducing the tissue cutting device into a breast;

expanding the cutting element toward the expanded position;

rotating the shaft so that the cutting element cuts the breast tissue; and

partially collapsing the cutting element after the expanding and rotating steps so that a portion of the tissue remains trapped between the cutting element and the shaft.

53. The method of claim 52, further comprising the steps of:

locking the cutting element in the partially collapsed position,

manipulating the tissue with the tissue cutting device while the cutting element is partially collapsed.

54. The method of claim 52, further comprising the steps of:

manipulating the tissue with the tissue cutting device while the cutting element is partially collapsed.

55. The method of claim 52, further comprising the steps of:

moving the tissue into a tissue collection element while the tissue is trapped by the partially collapsed cutting element.

56. The method of claim 52, further comprising the step of:

cutting a tissue removing channel through breast tissue while the tissue is trapped between the cutting element and the shaft;

the introducing step being carried out with the tissue cutting device extending along an introduction path separate from the tissue removing channel.

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摘要(译)

用于切割具有弓形切割元件的组织的装置可包括具有中心轴的轴和连接到轴的组织切割元件。组织切割元件可以从收缩位置移动到扩展位置，并且当处于扩展位置时可以向外弯曲。当在折叠和展开位置之间移动时，切割元件通常在第一平面中移动。轴可以具有相对于轴的中心轴线的第二厚度和第一厚度。第一和第二厚度可以位于第二平面中，该第二平面通常平行于第一平面。第二厚度可以是第一厚度的至少1.25倍，并且轴的侧面可以具有在旋转期间引导切割元件的第二厚度。

