(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 599 139 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
12.08.2009 Bulletin 2009/33

(21) Application number: **04713390.5**

(22) Date of filing: **20.02.2004**

(51) Int Cl.:
A61B 10/00 *(2006.01)* ***A61B 17/00*** *(2006.01)*
A61B 17/22 *(2006.01)* ***A61B 17/32*** *(2006.01)*

(86) International application number:
PCT/US2004/005168

(87) International publication number:
WO 2004/073524 (02.09.2004 Gazette 2004/36)

(54) **BENDABLE CUTTING DEVICE**

BIEGBARE SCHNEIDEVORRICHTUNG

DISPOSITIF D'INCISION PLIABLE

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LI LU MC NL PT RO SE SI SK TR

(30) Priority: **20.02.2003 US 449061 P**

(43) Date of publication of application:
30.11.2005 Bulletin 2005/48

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(56) References cited:
WO-A-02/100286
US-A- 6 068 603
US-A1- 2002 072 688
US-B2- 6 500 113

EP 1 599 139 B1

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates generally to devices and methods for cutting soft tissue. More specifically, devices and methods for a minimally invasive procedure for cutting or excising a volume of soft tissue such as a biopsy or a therapeutic excision of cancer are disclosed.

2. Description of Related Art

[0002] Minimally invasive procedures have instigated a need for refinement in surgical devices that can function within confined spaces, particularly in soft tissue, such as breast tissue. Devices that are typically used during open surgical procedures (i.e., scalpel, scissors, electrosurgical "pencil" electrode) are often not adaptable for use in a minimally invasive procedure. In addition, the actual procedure cannot be directly visualized as the skin incision is typically just large enough to insert the device. Minimally invasive procedures are often guided by medical imaging or by video camera as is often used in laparoscopy. In the breast, mammography, ultrasound and magnetic resonance imaging (MRI) are used to guide minimally invasive procedures. Current devices that use an oscillating sharp edge or radio frequency energy to cut the tissue retrieve a specimen of fixed volume and are not adaptable to excise lesions of different sizes or include extensions of the lesion or disease process in the excision. In particular, breast cancer often extends towards the nipple within a milk duct or towards the skin in Cooper's ligament in addition to growing outward in a radial direction. Current minimally invasive devices are designed to excise a mass and are not adaptable for excision of an associated diseased duct or Cooper's ligament. Leaving cancer behind in the duct or in Cooper's ligament increases the risk of local recurrence despite the administration of post operative radiation therapy.

[0003] Open surgical biopsy removes lesions of variable size and may include extensions of the lesion but often an excessive amount of normal breast tissue is included in the specimen leading to a poor cosmetic result. In addition, open surgical biopsy typically requires a significant skin incision resulting in a longer, permanent scar. More importantly, a diseased duct and/or disease in Cooper's ligament are not detectable either by direct vision or by palpation during an open surgical procedure. The main cancerous mass may be excised, but a diseased duct filled with cancerous cells and/or diseased Cooper's ligament is often not appreciated during the procedure and unintentionally not included in the incision.

[0004] Axial ductal ultrasound is a method of ultrasound scanning of the breast that demonstrates the internal anatomy of the breast. In particular, the ducts and lobes of the breast are identified resulting in visualization of not only a lesion, but also diseased duct(s) and extension into Cooper's ligament. Multifocal cancers or additional cancers associated with the diseased duct may also be visualized. Therefore, the entire disease process (i.e. the lesion and extensions of the lesion within the breast) is visualized and can be removed under direct, real-time-ultrasound guidance.

[0005] Accordingly, there is a need for a device and method for a minimally invasive procedure that excises lesions of variable size within a volume of tissue from a breast or other soft tissue. More specifically, there is a need for a device and method to excise a disease process within a breast that includes not only the main focus of the disease (i.e., a lesion or a mass) but also the duct or ducts that are also affected and any other anatomic extension of the disease process (e.g. growth into Cooper's ligament). Preferably, the procedure is guided using medical imaging.

[0006] U.S. 2002/0072688 A1 (SenoRx) discloses a breast biopsy system wherein pair of a longitudinal slots is disposed at the distal end of a device from which a cutting loop may be extended, the plane of said loop being variable relative to the longitudinal axis of the device. Two embodiments are described. In the first embodiment (Figures 1 to 3) a cutting element 20, retracted within a sheath 30 in a penetrating configuration, extends radially outward and generally parallel to a probe axis in a cutting configuration. In the second embodiment (Figures 17 to 19) a cutting element 20a, held close to a cannula 18a in a penetrating configuration, freely extends out of a slot 66 in the cannula 18a in a deployed cutting position.

SUMMARY OF THE INVENTION

[0007] According to the present invention, there is provided a tissue cutting device as set out in claim 1. Devices for a minimally invasive procedure for cutting or excising a volume of soft tissue such as a biopsy or a theurapeutic excision of cancer are disclosed. It should be appreciated that the present invention can be implemented in numerous ways, including an apparatus, a system, or a device. An inventive embodiment of the present invention is described below. cutting loop exit being at an exit angle relative to the probe axis, the exits being at a distal region of the probe; a cutting loop with shape memory having a preconfigured shape, the cutting loop being selectively in one of a penetrating configuration configured for the cutting device to penetrate tissue and a cutting configuration configured for the cutting loop to cut tissue, the cutting loop being generally within a profile of the probe in the penetrating configuration, and when in the cutting configuration, the cutting loop extends through the cutting loop exits and generally returns to the preconfigured shape to define a cutting configuration plane which is at a cutting angle (θ) relative to the probe axis; and, a cutting loop securing mechanism configured to selectively secure the cutting loop in the penetrating configuration and

to release the cutting loop into the cutting configuration, the cutting loop securing mechanism being either slidably disposed relative to the probe or being a groove defined in the probe proximal to the cutting loop exits. The angle (θ) of the cutting configuration plane is determined by the angle of the cutting loop exits relative to the probe axis.

[0008] These and other features and advantages of the present invention will be presented in more detail in the following detailed description and the accompanying figures which illustrate by way of example principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The present invention will be readily understood by the following detailed description in conjunction with the accompanying drawings, wherein like reference numerals designate like structural elements.

FIGS. 1A and **1B** are perspective side views of an exemplary embodiment of a cutting device with a bendable loop in a penetrating and a cutting configuration, respectively.

FIGS. 1C and **1D** are cross-sectional views of alternative embodiments of the cutting device.

FIGS. 2A and **2B** are perspective views of alternative exemplary embodiments of the cutting device with a bendable loop.

FIGS. 3A-3F are perspective views of further alternative exemplary embodiments of the cutting device with a bendable loop.

FIGS. 4A and **4B** are perspective views illustrating exemplary configurations of the loop in the cutting configuration.

FIG. 5 is a perspective view of yet another alternative exemplary embodiment of the cutting device with a bendable loop.

FIG. 6 is a perspective view illustrating an exemplary configuration of an imaging device incorporated into the probe.

FIGS. 7A and **7B** are perspective views of an alternative cutting device with a bendable loop.

FIGS. 8A-8D are schematics illustrating the cutting device used in conjunction with an imaging device to cut a volume of soft tissue.

FIG. 9 is a flowchart illustrating an imaging and cutting process employing the bendable cutting device.

DESCRIPTION OF SPECIFIC EMBODIMENTS

[0010] Devices for a minimally invasive procedure for cutting or excising a volume of soft tissue such as a biopsy or a therapeutic excision of cancer are disclosed. The following description is presented to enable any person skilled in the art to make and use the invention. Descriptions of specific embodiments and applications are provided only as examples and various modifications will be readily apparent to those skilled in the art. The general principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the invention. Thus, the present invention is to be accorded the widest scope encompassing numerous alternatives, modifications and equivalents consistent with the principles and features disclosed herein. For purpose of clarity, details relating to technical material that is known in the technical fields related to the invention have not been described in detail so as not to unnecessarily obscure the present invention.

[0011] **FIGS. 1A and 1B** are perspective views of an exemplary embodiment of a cutting device 100 with a bendable loop 34 in a retracted and an extended position, respectively. As shown in **FIG. 1A,** the cutting device 100 generally comprises a probe 20 and a handle 40. The probe 20 defines a probe axis 28 between a proximal end 24 and a distal end 22. Loop channels 26, contained within the probe 20 and generally aligned along the probe axis 28, terminate at angled exits 44 located at or near the distal end 22. Prior to terminating at the angled exits 44, the loop channels 26 change alignment from being one of generally aligned with the probe axis 28, to being one of at an angle relative to the probe axis 28. The loop channels 26 may contain an electrode 30. The electrode 30 terminates in electrode ends 32 in the proximal end 24 or the handle 40, as shown in **FIG. 1A.** The electrode 30 extends out of the cutting device 100 at the angled exits 44 such that the electrode 30 between the angled exits 44 creates the bendable loop 34.

[0012] In cross-sectional views of alternative embodiments illustrated in **FIGS.1C** and **1D,** extension of the loop 34 out of the angled exits 44 defines a loop height 46. A loop width 48 is determined by an angle β between the angled exits 44. Preferably the angle β is predetermined although the angle β may be variable. As shown in **FIG. 1C** the angle β defines a loop width 48 that is larger than the loop width 48 in the alternative embodiment illustrated in **FIG. 1D.** In yet another alternative (not shown) at least one of the loop channels 26 is a rotatable tube that terminates at the angled exit 44. Rotating one or more rotatable tubes varies the angle β which varies the loop width 48.

[0013] The probe 20 and handle 40 may be configured from any number of materials including metals, metal alloys, ceramics and/or plastics. The probe 20 and handle 40 may be configured as a single unit or as one or more separate units that are fastened together. Preferably the electrode 30 is made from a nickel titanium alloy (nitinol) with shape memory or superelastic property although any other suitable metal or metal alloy with shape memory or superelastic properties may be employed.

[0014] **FIG. 1B** illustrates the loop 34 in a cutting configuration. At least one of the angled exits 44 and/or the shape memory properties of the electrode 30 (e.g., nitinol) facilitate in configuring the loop 34 to the cutting configuration. The angled exits 44 determine a loop axis 36 defined by the loop 34 relative to the probe axis 28. A loop angle θ is defined between the probe axis 28 and

the loop axis 36. The loop 34 assumes the cutting configuration when the loop 34 is at least partially extended through the angled exits 44. Preferably, the angled exits 44 configure the loop 34 such that the loop angle θ is generally 90 degrees although the loop angle θ may be less than or greater than 90 degrees as in the embodiments illustrated in **FIGS. 4A** and **4B**, for example. In one exemplary embodiment, the angled exits 44 may be configured such that the loop angle θ is greater than 90 degrees, as illustrated in **FIG. 4A.** In an alternative embodiment, the angled exits 44 may be configured such that the loop angle θ is less than 90 degrees, as illustrated in **FIG. 4B.**

[0015] In an alternative (not shown), the loop 34 is preformed to a predetermined cutting configuration preferably before the electrode 30 is assembled into the cutting device 100. The process of preforming a loop to the predetermined configuration is well known to those skilled in the art. In particular, the electrode 30 can be positioned and maintained such that the loop 34 is in the predetermined cutting configuration and heated to a specified temperature for a predetermined length of time followed by rapid cooling. The temperature and length of time may be varied according to the type of material used for the electrode 30. Preferably the loop 34 is preformed such that the loop angle θ is approximately 90 degrees.

[0016] Referring back to **FIG. 1A,** the loop 34 is shown in a penetrating configuration where the loop 34 is positioned such that the loop angle θ is approximately 180 degrees. A groove 38 located at or near the distal end 22 of the probe 20 holds the loop 34 in the penetrating configuration. The loop 34, which is in the cutting configuration when at least partially extended (as shown in **FIG. 1B**), may be manually or mechanically positioned into the penetrating configuration. Preferably the electrode 30 is made of a material having superelastic properties (e.g., nitinol) to allow the loop 34 to be positioned into the penetrating configuration without creating a permanent kink or distortion in the electrode 30. The penetrating configuration is maintained by placement of the loop 34 into the groove 38, followed by slight retraction of the loop 34. The slight retraction keeps the loop 34 tightly held within the groove 38. In an alternative (not shown), a loop locking mechanism may be provided on the handle 40 to secure the loop 34 in the penetrating configuration. A loop controller 42 located on the handle 40 controls extension and retraction of the loop 34. Maintaining the loop 34 in the penetrating configuration enhances insertion of the probe 20 into soft tissue by creating a more linear profile to the probe 20. Keeping the partially extended loop 34 external to the probe 20 and held within the groove 38 allows for a smaller diameter probe 20. In an alternative (not shown), the loop 34 may be manually or mechanically positioned by the methods described herein such that the loop 34 is angled proximal to the angled exits 44 to assume an alternative penetrating configuration.

[0017] In an alternative embodiment illustrated in FIG. 3E, the loop 34 is further retracted into the probe 20 such that only a minimum length of the loop 34 is outside of the probe 20 as determined by the distance between the angled exits 44. Preferably the distance between the angled exits 44 is of sufficient length to prevent a kink or permanent deformity in the loop 34 when the loop 34 is retracted. In a further alternative illustrated in **FIG. 3F,** the probe 20 defines a groove 56 near the angled exits 44. The loop 34 (not shown) is positioned in the groove 56 when the loop 34 is retracted. In yet further alternatives (not shown), the retracted loop 34 may be positioned in a partial groove or in an opening in the probe.

[0018] Referring back to **FIG. 1B,** the loop 34 is further extended by the loop controller 42 and is in a cutting configuration. Further extension of the loop 34 increases the size of and releases the loop 34 from the groove 38 which allows the loop 34 to move to the cutting configuration. The change in the loop angle θ when the loop 34 moves from the penetrating configuration to the cutting configuration is preferably facilitated by the superelastic properties of the metal or metal alloy of the electrode 30. In the exemplary embodiment, the loop angle θ is approximately 90 degrees when the loop 34 is in the cutting configuration. Cutting around a volume of soft tissue is accomplished by advancing and/or retracting the probe 20 when the loop 34 is in the cutting configuration. Extension and/or retraction of the loop 34 are preferably controlled by movement of one and/or both of the electrode ends 32.

[0019] To facilitate positioning of the probe 20 in the tissue, the probe 20 and/or the loop 34 may contain a locating mechanism (not shown) to aid in determining the location of the probe 20 and/or the loop 34 within the tissue. A detecting mechanism, preferably located external to the tissue, detects the locating mechanism. The locating mechanism may include radiologic or ultrasound markers, light or other signal emitters, or such other mechanism as may be detectable by the corresponding detecting mechanism typically external to the patient.

[0020] The cross-sectional area of the electrode 30 may be round, square, triangular, rectangular, oval, diamond-shaped, polygonal or any other desired shape. One or more cutting edges on the loop 34 and/or electrode 30 may be sharpened or serrated. The electrode 30 may be in continuity with an external energy source (not shown) such as but not limited to radio frequency energy, laser and/or vibration. Other methods of cutting soft tissue may be incorporated into the loop and/or electrode including but not limited to air abrasion and/or water jet. Where the electrode 30 is energized with radio frequency, an electrical circuit may be configured as a monopolar system with the loop acting as the active electrode and a larger, dispersive grounding pad acting as the return electrode. In an alternative, the return electrode may be positioned on or near the cutting device 100 resulting in a bipolar system. Furthermore, the loop 34 and/or electrode 30 may be partially or completely insulated to expose the radio frequency energy to the

tissue at one or more predetermined locations on the loop 34. Materials that may act as insulators include but are not limited to ceramics and polymers such as polymethylsiloxane, paratetraffuoroethylene, polyimide, and/or polyetheretherketone. The loop 34 may oscillate along one or more predetermined directions to facilitate the cutting of soft tissue. The loop 34 may oscillate by movement of the electrode 30 within the loop channels 26. In an alternative, the loop 34 may oscillate by movement of the probe 20.

[0021] To facilitate tissue penetration, the loop 34 may be energized during positioning of the probe 20 when the loop 34 is in the penetrating configuration. In an alternative, as illustrated in **FIG. 2A**, the groove 38 is proximal to the distal end 22. The distal end 22 is configured as a sharpened tip that may facilitate tissue penetration but the distal end 22 may be any number of configurations that preferably aid in tissue penetration such as a sharpened edge or edges. The distal end 22 may also be energized, for example, with radio frequency energy and/or any other suitable energy. In a further alternative the distal end 22 may contain one or more penetrators 66 that protrude distally as illustrated in the embodiment in **FIG. 2B.** The penetrator 66 may be sharpened and/or may be energized with, for example, radio frequency energy to facilitate tissue penetration. Preferably energizing of the distal end 22 or the penetrator 66 is independent from and electrically isolated from energizing of the electrode 30. In an alternative (not shown), the penetrator 66 is partially or completely insulated to expose the radio frequency energy to the tissue at one or more predetermined locations on the penetrator 66. Furthermore, the penetrator 66 may oscillate in one or more predetermined directions to facilitate penetration of the soft tissue.

[0022] In the embodiment illustrated in **FIGS. 3A** and **3B,** a loop holder 60 is used to maintain the loop 34 in the penetrating configuration. In the exemplary embodiment, a holder end 62 of the loop holder 60 comprises a "Y" shaped configuration but any suitable configuration of the holder end 62 to facilitate maintaining the loop 34 in the penetrating configuration may be used. The loop holder 60 may be retracted by a loop holder controller located on the handle (not shown), for example, such that the loop 34 is released from the holder end 62 and moves to the cutting configuration.

[0023] In an alternative embodiment illustrated in **FIGS. 3C** and **3D,** a loop cover 80 is configured at least partially around the probe 20 and moves along the probe axis 28. As illustrated in **FIG. 3C**, the loop cover 80 is at or near the distal end 22 and positions the loop 34 in the penetrating configuration. When the loop cover 80 is moved along the probe axis 28 proximally toward the handle, the loop 34 is uncovered and no longer restricted by the loop cover 80 and moves to the cutting configuration as shown in **FIG. 3D.** The loop cover 80 is preferably controlled by a loop cover controller (not shown) located on the handle, for example. The cutting process is completed by retracting the loop 34 into the probe 20 and/or moving the loop cover 80 over the loop 34 to mechanically position the loop 34 into the penetrating configuration. In an alternative (not shown), the loop cover 80 is moved along the probe axis 28 distally away from the handle to uncover the loop 34.

[0024] In the embodiment illustrated in **FIG. 5,** a fixed end 50 of the electrode 30 is located at or near the distal end 22 of the probe 20 and an electrode end (not shown) of the electrode 30 is located in the proximal end 24 of the probe 20 or in the handle (not shown). The probe 20 contains a single loop channel 26 such that the probe 20 has a smaller profile (e.g., diameter) than where the probe contains multiple loop channels and/or provides more room within the probe 20 for the change in alignment of the loop channel 26 from being generally parallel to the probe axis 28 to terminating at the angled exit 44. The increased room provides for a less acute change of direction, thereby facilitating movement of the electrode 30 within the loop channel 26.

[0025] In the embodiment illustrated in **FIG. 6,** an imaging catheter 70 is positioned within the probe 20 such that the imaging catheter 70 scans an imaging area adjacent to or containing the loop 34. The exemplary embodiment shows the imaging catheter 70 in position to image an area containing the loop 34, but the imaging catheter 70 may be positioned in any suitable position along the probe 20. The imaging catheter 70 may be configured to rotate about the probe axis 28 to broaden the imaging area. The imaging catheter 70 is preferably an ultrasound transducer but may also be any other type of suitable imaging modality. The ultrasound transducer preferably has a high frequency in a range between approximately 10 MHz to 100 MHz. The proximity of the ultrasound transducer to the imaged area provides for use of a higher frequency which gives improved resolution of the imaged area. The imaging catheter 70 may acquire images that are processed to show at least a two-dimensional, a three-dimensional and/or a four-dimensional image.

[0026] The imaging catheter 70 may be employed during positioning of the probe 20 and/or during the cutting process (i.e., as the probe 20 is advanced or retracted with the loop 34 in the cutting configuration). Preferably the imaging catheter 70 images in real time the loop 34 and the volume of soft tissue being excised during the cutting process. Preferably the imaging catheter 70 and the loop 34 are moved in unison as the probe 20 is advanced or retracted during the cutting process. The imaging catheter 70 may be within the probe 20 or preferably the imaging catheter 70 is configured as separate component that slides into an imaging channel 72 contained in the probe 20. When advanced to the desired position in the imaging channel 72, the imaging catheter 70 is preferably secured in place with a lock mechanism (not shown). The position of the imaging catheter 70 relative to the loop 34 may be predetermined or varied depending on the positioning of the imaging catheter 70 within the imaging channel 72. The probe 20 and/or the

loop 34 may additionally include an enhanced visualization mechanism using medical imaging such as radiologic or ultrasound markers or may include a signaling device to provide emitted signals to be detected by an external detector.

[0027] **FIGS. 7A** and **7B** illustrate another cutting device. In **FIG. 7A,** the electrode 30 is completely contained within the probe 20 in the penetrating configuration. In **FIG. 7B,** the electrode 30 is shown extending out of the probe 20 in the cutting configuration. The electrode 30 is advanced out of the probe 20 through the exit 54, located at or near the distal end 22, by an advancement controller located on the handle (not shown), for example. When advanced through the exit 54, the shape memory properties of the electrode 30 cause the loop 34 to assume a predetermined size and shape. Configuring the loop 34 to the predetermined size and shape is performed before the electrode is assembled into the cutting device and is well know to those skilled in the art. The superelastic properties of the material allow the loop 34 to be entirely or almost entirety positioned within the probe 20 without creating a kink or permanent deformity in the loop 34. When the loop 34 is advanced out of the probe 20, the loop 34 returns to the predetermined size and shape due to the shape memory properties. The loop 34 may be energized with radio frequency energy, laser and/or vibration, for example, prior to and during advancement through the exit 54. The loop may be partially or completely insulated to facilitate the cutting process. Oscillation of the loop may additionally or alternatively be applied to facilitate the cutting process.

[0028] **FIGS. 8A-8D** are schematics illustrating a cutting process using the cutting device 100 in an area of a breast 90. In the exemplary embodiment, the area of the breast 90 contains a nipple/areolar complex 99 and a lobe 97 containing a duct 96. The duct 96 contains a lesion 94 and a disease extension 95 within the duct 96. An imaging device 110 is preferably used to locate the duct 96, the lesion 94, and disease extension 95 and guide the cutting process. In this exemplary schematic, the imaging device 110 is an ultrasound transducer although any other suitable imaging modality may be used. The imaging device 110 may acquire images that are processed to give two-dimensional, three-dimensional and/or four-dimensional images. In an alternative (not shown), the imaging catheter contained within the probe 20 as described above may be used alone or in conjunction with the imaging device 110 to guide the cutting process.

[0029] As shown in **FIG. 8A,** the probe 20 enters the breast 90 through a skin incision 98 that is preferably located at a border of the nipple/areola complex 99. In the exemplary schematic, the probe 20 is positioned under the duct 96 and the lesion 94 but in various alternatives the probe 20 may be positioned on a side of or superficial to the duct 96 and/or lesion 94. Preferably, the distal end 22 is positioned distal to the lesion 94 and any additional disease within the duct 96 (i.e., the disease extension 95) relative to the skin incision 98. The probe 20 is preferably positioned with the loop 34 in the penetrating configuration. The loop 34 may be energized using, for example, an external radio frequency energy source (not shown) to facilitate tissue penetration and positioning of the probe 20. In **FIG. 8B,** the loop 34 is energized and expanded into the cutting configuration.. Expansion releases the loop 34 from the groove 38 and energizing allows the loop 34 to cut through soft tissue as the loop 34 moves into the cutting configuration. The height and width of the loop 34 may be adjusted or varied to ensure that the entire lesion 94 and disease extension 95 is encircled by the loop 34 during the cutting process. Next, the probe 20 is retracted as illustrated in **FIG. 8C,** causing the loop 34 to cut tissue circumferentially around the lesion 94 and the disease extension 95. The imaging device 110 generally continues to keep the loop 34 and/or the area of tissue adjacent to the loop 34 within the imaging area. For example, if the imaging device 110 is an ultrasound transducer, the ultrasound transducer moves preferably in unison with the loop 34 to keep the loop 34 within the imaging area. In **FIG. 8D,** the loop 34 is proximal to the lesion 94 and the disease extension 95. The loop 34 is retracted completing the cutting process. Once retracted, energizing of the loop 34 can be terminated. In an alternative (not shown), the distal end of the probe 20 is positioned proximal to the lesion 94 and disease extension 95, the loop 34 is expanded and the probe 20 is advanced to accomplish the cutting process.

[0030] During the cutting process, the loop 34 and/or probe 20 may be configured to oscillate or move back and forth in an independent motion that is separate from the advancement or retraction of the probe 20. The independent motion enhances the cutting process. Preferably the independent motion is along a direction defined by the curvature of the loop 34. Alternatively, the independent motion is along any direction or combination of directions defined by the loop axis, the probe axis and/or a direction that is at one or more angles to the loop axis and the probe axis.

[0031] In a further alternative embodiment (not shown), a tissue collector is attached to the loop and/or the probe. The tissue collector preferably encompasses the severed tissue during the cutting process or after the cutting process is complete. The tissue collector facilitates in removal of the cut tissue from the breast. In yet a further alternative (not shown), a tissue marking mechanism may be incorporated into the cutting device to facilitate orientation of the cut tissue after removal from the breast. The tissue marking mechanism marks the specimen during the cutting process and/or after the cutting process is complete. In yet another further alternative, a soft tissue orientation and imaging guide system may be incorporated to facilitate targeting of the area of soft tissue to be excised, orient and fixate the area of soft tissue during the cutting process and facilitate movement of the imaging scanner relative to the cutting device.

[0032] **FIG. 9** is a flowchart illustrating a cutting proc-

ess 200 employing the cutting device and using an imaging device to guide the procedure. At step 202, radiological imaging, preferably axial ductal ultrasound scanning, is performed on the breast to identify a targeted volume of soft tissue that includes a lesion and the duct and/or lobe in which the lesion has developed. Preferably the targeted tissue also includes any extension of the lesion or disease process (e.g., extension of disease within the duct, growth into Cooper's ligament and multifocal lesions). The axial ductal ultrasound scanning is preferably performed prior to the cutting process 200 to delineate the lesion size, shape and position relative to the duct(s) and the lobe, and to identify disease extension within the duct(s), growth into Cooper's ligament and multifocal lesions. The axial ductal ultrasound scanning may be enhanced with the use of ultrasound contrast agents, such as described in co-pending U.S. Patent Application No. 10/167,017, entitled "Ultrasound Imaging Of Breast Tissue Using Ultrasound Contrast Agent" and filed on June 11, 2002, the entirety of which is incorporated by reference herein. The axial ductal ultrasound images may be processed to give images that are at least one of two-dimensional, three-dimensional and four-dimensional images.

[0033] At step 204, the cutting device is inserted through a skin incision on the breast. The incision is typically made in relatively close proximity to the targeted tissue being imaged. Preferably, the incision is made at the areolar border to provide for improved cosmesis. Prior to making the skin incision, the imaging and cutting process may be facilitated with the use of a soft tissue orientation and imaging guide system, such as that describe in copending U.S. Patent No. 7,149,566, entitled "Soft Tissue Orientation and Imaging Guide Systems and Methods".

[0034] At step 206, the cutting device, preferably guided using the medical imaging, is positioned adjacent to the targeted tissue in preparation for the cutting process. Preferably, the targeted tissue includes the entire lesion and the diseased duct(s) containing any extension of the lesion, multifocal lesions, growth into Cooper's ligament or the entire lobe or part of the lobe containing the lesion. During the positioning of the cutting device, the loop is held in the penetrating configuration to facilitate penetration into the soft tissue. The loop may be energized from an external energy source such as a radio frequency generator. The distal end of the probe is positioned distal to the targeted tissue relative to the skin incision.

[0035] At step 208, the loop is energized and expanded which moves the loop from the penetrating configuration to the cutting configuration. As the loop moves to the cutting configuration, tissue is cut along the path of movement.

[0036] At step 210, the loop is further expanded to increase the size of the loop such that the loop can create a circumferential cut around the targeted tissue. The height and/or width of the loop is preferably adjusted before and/or during the cutting process. Preferably the circumferential cut includes a satisfactory margin of normal tissue surrounding the lesion, the diseased ducts(s), growth into Cooper's ligament and/or multifocal lesions.

[0037] At step 212, the probe is retracted which causes the loop to create a circumferential cut around the targeted tissue. During the cutting process, the loop and/or probe may oscillate or move in a back and forth in an independent motion that is separate from the advancement or retraction of the probe to facilitate the cutting process. Preferably the imaging device images the loop and/or area of tissue adjacent to the loop during the cutting process.

[0038] At step 214, when the loop is proximal to the targeted tissue relative to the skin incision, the loop is retracted and energizing of the loop terminated, completing the cutting process 200. During the cutting process or after the cutting process is complete, a tissue collector may be employed to encompass the targeted tissue that has been cut to facilitate removal from the breast. A tissue marking system may also be employed to facilitate orientation of the targeted tissue once removed from the breast.

[0039] In an alternative, during step 206, the distal end of the probe is positioned proximal to the targeted tissue relative to the skin incision. At step 212, the probe is advanced causing the loop to create a circumferential cut around the targeted tissue. At step 214, when the loop is distal to the targeted tissue the loop is retracted.

[0040] While the exemplary embodiments of the present invention are described and illustrated herein, it will be appreciated that they are merely illustrative and that modifications can be made to these embodiments without departing from the spirit and scope of the invention. Thus, the scope of the invention is intended to be defined only in terms of the following claims as may be amended, with each claim being expressly incorporated into this Description of Specific Embodiments as an embodiment of the invention.

Claims

1. A tissue cutting device (100), comprising:

a probe (20) having a length generally defining a probe axis, the probe defining a pair of cutting loop exits (44), each cutting loop exit being at an exit angle relative to the probe axis, the exits being at a distal region (22) of the probe;

a cutting loop (34) with shape memory having a preconfigured shape, the cutting loop extending from within the probe via a first one of the pair of cutting loop exits and returning to within the probe via the other of the pair of cutting loop exits, the cutting loop being selectively in one of a penetrating configuration configured for the cutting device (100) to penetrate tissue and a cutting configuration configured for the cutting

loop to cut tissue, the cutting loop being generally within a profile of the probe in the penetrating configuration, and when in the cutting configuration, the cutting loop extends through the cutting loop exits and generally returns to the preconfigured shape to define a cutting configuration plane which is at a cutting angle (θ) relative to the probe axis
the angle (θ) of the cutting configuration plane being determined by the angle of the cutting loop exits relative to the probe axis;
a cutting loop securing mechanism (60; 80, 56) configured to selectively secure the cutting loop (34) in the penetrating configuration and to release the cutting loop into the cutting configuration, the cutting loop securing mechanism either being slidably disposed relative to the probe or being a groove defined in the probe proximal to the cutting loop exits;

2. The device of claim 1, wherein, when the cutting loop is in the cutting configuration, a cutting loop width (48) is generally determined by the angle (β) between the cutting loop exits,

3. The device of claim 1 or 2, wherein the cutting loop securing mechanism (60) extends from a distal end (22) of the probe and is at least partially slidably retractable into the probe (20).

4. The device of claim 3, wherein the cutting loop securing mechanism is a Y-shaped cutting loop holder (60).

5. The device of claim 1, wherein the cutting loop securing mechanism is a cover (80) slidably disposed over the probe (20) and configured to secure the cutting loop (34) between the loop cover (80) and the probe (20) for the penetrating configuration.

6. The device of claim 1, wherein the cutting loop securing mechanism is the groove (56) defined in the probe proximal to the cutting loop exit.

7. The device of claim 1, wherein the probe includes at least one cutting loop channel (26) terminating at the cutting loop exit (44).

8. The device of claim 1, wherein the size of the cutting loop (34) is adjustable by retracting or extending the cutting loop into and out of the probe (20) when the cutting loop is in a cutting configuration.

9. The device of claim 1, wherein the probe (20) defines two cutting loop exits (44) through which the cutting loop (34) extends.

10. The device of claim 1, wherein the cutting loop exit (44) is selectively positionable about the probe to facilitate adjusting a width of the cutting loop (34).

11. The device of claim 1, wherein the cutting loop exit (44) is selectively positionable to adjust the exit angle between the cutting loop exit (44) and the probe (20).

12. The device of claim 1, wherein at least one edge of the cutting loop is at least one of sharpened and serrated.

13. The device of claim 1, further comprising a tissue penetrator at a distal end (22) of the probe, the tissue penetrator being coupled to an energy source for supplying energy to the tissue penetrator to facilitate tissue penetration.

14. The device of claim 13, wherein the tissue penetrator is partially insulated to selectively expose the tissue to the energy.

15. The device of claim 1, wherein the probe defines an opening at a distal end (22) of the probe through which the cutting loop (34) may selectively extend for the cutting configuration and retract for the penetrating configuration.

16. The device of claim 1, further comprising a loop cover (80) disposed slidably over the probe, the loop cover being configured to secure the cutting loop between the loop cover and the probe for the penetrating configuration and to release the cutting loop into its preconfigured shape for the cutting configuration.

17. The device of claim 1, wherein the cutting loop is coupled to an energy source configured to supply energy to the cutting loop to facilitate cutting of tissue by the cutting loop.

18. The device of claim 17, wherein the energy source is selected from at least one of a radio frequency, laser, water jet, air abrasion, ultrasonic, oscillation along a predetermined distance, direction and/or frequency, oscillation along a variable distance, direction and/or frequency.

19. The device of claim 17, wherein the cutting loop (34) is partially insulated to selectively expose the tissue to the energy.

20. The device of claim 1, further comprising an imaging device generally housed in the probe.

21. The device of claim 1, further comprising a probe locating mechanism housed in the probe, the probe locating mechanism facilitates in determining the location of at least one of the probe and the cutting loop within the tissue from external to the tissue, the

probe locating mechanism being one of a light, a radiologic marker, and an ultrasound marker,

22. The device of claim 1, further comprising a tissue collector to collect tissue cut by the cutting loop.

23. The device of claim 1, further comprising a tissue marking mechanism to mark the tissue cut by the cutting loop.

Patentansprüche

1. Gewebeschneidevorrichtung (100), die aufweist:

eine Sonde (20) mit einer Länge, die im Allgemeinen eine Sondenachse definiert, wobei die Sonde ein Paar Schneideschlingenausgänge (44) definiert, wobei jeder Schneideschlingenausgang in einem Ausgangswinkel relativ zu der Sondenachse steht, wobei sich die Ausgänge in einem distalen Bereich (22) der Sonde befinden;

eine Schneideschlinge (34) mit Formgedächtnis mit einer vorkonfigurierten Form, wobei sich die Schneideschlinge von innerhalb der Sonde über einen ersten des Paars von Schneideschlingenausgängen erstreckt und nach innen in die Sonde über den anderen des Paars von Schneideschlingenausgängen zurückkehrt, wobei die Schneideschlinge sich selektiv in einer Eindringkonfiguration befindet, die so konfiguriert ist, dass die Schneidevorrichtung (100) in Gewebe eindringt, und einer Schneidekonfiguration, die so konfiguriert ist, dass die Schneideschlinge Gewebe schneidet, wobei sich die Schneideschlinge im Allgemeinen innerhalb des Profils der Sonde in der Eindringkonfiguration befindet, und wenn sie sich in der Schneidekonfiguration befindet, die Schneideschlinge sich durch die Schneideschlingenausgänge erstreckt und im Allgemeinen in die vorkonfigurierte Form zurückkehrt, um eine Schneidekonfigurationsebene zu definieren, die sich in einem Schneidewinkel (θ) relativ zu der Sondenachse befindet, wobei der Winkel (θ) der Schneidekonfigurationsebene durch den Winkel der Schneideschlingenausgänge relativ zu der Sondenachse bestimmt wird;

einen Schneideschlingen-Sicherungsmechanismus (60; 80; 56), der so konfiguriert ist, dass er selektiv die Schneideschlinge (34) in der Eindringkonfiguration sichert und die Schneideschlinge in die Schneidekonfiguration entlässt, wobei der Schneideschlingen-Sicherungsmechanismus entweder gleitend relativ zu der Sonde angebracht ist oder eine Nut ist, die in der Sonde proximal zu den Schneideschlingenausgängen definiert ist.

2. Vorrichtung nach Anspruch 1, wobei, wenn sich die Schneideschlinge in der Schneidekonfiguration befindet, die Schneideschlingenweite (48) im Allgemeinen durch den Winkel (β) zwischen den Schneideschlingenausgängen bestimmt wird.

3. Vorrichtung nach Anspruch 1 oder 2, wobei sich der Schneideschlingenmechanismus (60) von dem distalen Ende (22) der Sonde erstreckt und wenigstens teilweise gleitend in die Sonde (20) zurückgezogen werden kann.

4. Vorrichtung nach Anspruch 3, wobei der Schneideschlingen-Sicherungsmechanismus ein Y-förmiger Schneideschlingenhalter (60) ist.

5. Vorrichtung nach Anspruch 1, wobei der Schneideschlingen-Sicherungsmechanismus eine Abdekkung (80) ist, die gleitend über der Sonde (20) angebracht und so konfiguriert ist, dass sie die Schneideschlinge (34) zwischen der Schlingenabdeckung (80) und der Sonde (20) für die Eindringkonfiguration sichert.

6. Vorrichtung nach Anspruch 1, wobei der Schneideschlingen-Sicherungsmechanismus die in der Sonde proximal zu dem Schneideschlingenausgang defmierte Nut (56) ist.

7. Vorrichtung nach Anspruch 1, wobei die Sonde wenigstens einen Schneideschlingenkanal (26) aufweist, der an dem Schneideschlingenausgang (44) endet.

8. Vorrichtung nach Anspruch 1, wobei die Größe der Schneideschlinge (34) durch Zurückziehen oder Herausfahren der Schneidschlinge in und aus der Sonde (20) einstellbar ist, wenn sich die Schneideschlinge in einer Schneidekonfiguration befindet.

9. Vorrichtung nach Anspruch 1, wobei die Sonde (20) zwei Schneideschlingenausgänge (44) definiert, durch die sich die Schneideschlinge (34) erstreckt.

10. Vorrichtung nach Anspruch 1, wobei der Schneideschlingenausgang (44) selektiv um die Sonde herum positioniert werden kann, um das Einstellen der Weite der Schneideschlinge (34) zu erleichtern.

11. Vorrichtung nach Anspruch 1, wobei der Schneideschlingenausgang (44) selektiv so positioniert werden kann, dass er den Ausgangswinkel zwischen dem Schneideschlingenausgang (44) und der Sonde (20) einstellt.

12. Vorrichtung nach Anspruch 1, wobei wenigstens ein

Rand der Schneideschlinge wenigstens eines von geschärft und gezahnt ist.

13. Vorrichtung nach Anspruch 1, die des Weiteren einen Gewebe-Eindringkörper an dem distalen Ende (22) der Sonde aufweist, wobei der Gewebe-Eindringkörper an eine Energiequelle gekoppelt ist, um dem Gewebe-Eindringkörper Energie zuzuführen, um das Eindringen in das Gewebe zu erleichtern.

14. Vorrichtung nach Anspruch 13, wobei der Gewebe-Eindringkörper teilweise isoliert ist, um das Gewebe selektiv der Energie auszusetzen.

15. Vorrichtung nach Anspruch 1, wobei die Sonde eine Öffnung an dem distalen Ende (22) der Sonde definiert, durch die sich die Schneideschlinge (34) selektiv für die Schneidekonfiguration erstrecken und für die Eindringkonfiguration zurückziehen kann.

16. Vorrichtung nach Anspruch 1, die des Weiteren eine Schlingenabdeckung (80) aufweist, die gleitend über der Sonde angebracht ist, wobei die Schlingenabdeckung so konfiguriert ist, dass sie die Schneideschlinge zwischen der Schlingenabdeckung und der Sonde für die Eindringkonfiguration sichert und die Schneideschlinge für die Schneidekonfiguration in ihre vorkonfigurierte Form entlässt.

17. Vorrichtung nach Anspruch 1, wobei die Schneideschlinge an eine Energiequelle gekoppelt ist, die so konfiguriert ist, dass sie Energie an die Schneideschlinge liefert, um das Schneiden von Gewebe durch die Schneideschlinge zu erleichtern.

18. Vorrichtung nach Anspruch 17, wobei die Energiequelle ausgewählt wird aus wenigstens einem von Hochfrequenz, Laser, Wasserstrahl, Luftabrasion, Ultraschall, Oszillation entlang einer vorgegebenen Distanz, Richtung und/oder Frequenz, Oszillation entlang einer variablen Distanz, Richtung und/oder Frequenz.

19. Vorrichtung nach Anspruch 17, wobei die Schneideschlinge (34) teilweise isoliert ist, um das Gewebe selektiv der Energie auszusetzen.

20. Vorrichtung nach Anspruch 1, die des Weiteren eine Abbildevorrichtung aufweist, die im Allgemeinen in der Sonde untergebracht ist.

21. Vorrichtung nach Anspruch 1, die des Weiteren einen Sondenpositionierungs-Mechanismus aufweist, der in der Sonde untergebracht ist, wobei der Sondenpositionierungs-Mechanismus das Festlegen der Position wenigstens einer der Sonde und der Schneideschlinge innerhalb des Gewebes von außerhalb des Gewebes erleichtert, wobei der Sondenanordnungs-Mechanismus eines Lichts, eines radiologischen Markers und eines Ultraschall-Markers ist.

22. Vorrichtung nach Anspruch 1, die des Weiteren einen Gewebesammler aufweist, um Gewebe zu sammeln, das von der Schneideschlinge geschnitten wurde.

23. Vorrichtung nach Anspruch 1, die des Weiteren einen Gewebekennzeichnungs-Mechanismus aufweist, um das von der Gewebeschlinge geschnittene Gewebe zu kennzeichnen.

Revendications

1. Dispositif de découpe tissulaire (100) comprenant :

une sonde (20) d'une longueur définissant généralement un axe de la sonde, la sonde définissant une paire de sorties de boucle de coupe (44), chaque sortie de boucle de coupe se trouvant au niveau d'un angle de sortie par rapport à l'axe de la sonde, les sorties se trouvant au niveau d'une région distale (22) de la sonde ;
une boucle de coupe (34) à mémoire de forme ayant une configuration prédéfinie, la boucle de coupe s'étendant depuis l'intérieur de la sonde par une première sortie de la paire de sorties de la boucle de coupe et revenant à l'intérieur de la sonde par l'intermédiaire de l'autre sortie de la paire de sorties de la boucle de coupe, la boucle de coupe se trouvant sélectivement dans une configuration sélectionnée parmi une configuration de pénétration configurée pour le dispositif de découpe (100) afin de pénétrer dans les tissus et une configuration de découpe configurée pour que la boucle de coupe découpe les tissus, la boucle de coupe se trouvant généralement à l'intérieur d'un profilé de la sonde dans la configuration de pénétration, et lorsqu'elle se trouve dans la configuration de découpe, la boucle de coupe s'étend dans les sorties de la boucle de coupe et reprend généralement sa forme prédéfinie pour définir un plan de configuration de découpe qui se situe au niveau d'un angle de découpe (θ) par rapport à l'axe de la sonde, l'angle (θ) du plan de configuration de découpe étant déterminé par l'angle des sorties de la boucle de coupe par rapport à l'axe de la sonde ;
un mécanisme de fixation de la boucle de coupe (60 ; 80, 56) configuré pour fixer sélectivement la boucle de coupe (34) dans la configuration de pénétration et pour libérer la boucle de coupe dans la configuration de découpe, le mécanisme de fixation de la boucle de coupe étant soit dis-

posé de façon à coulisser par rapport à la sonde soit étant une rainure formée dans la sonde proximale par rapport aux sorties de la boucle de coupe.

2. Dispositif selon la revendication 1, dans lequel, lorsque la boucle de coupe se trouve dans la configuration de découpe, une largeur de boucle de coupe (48) est généralement déterminée par l'angle (β) entre les sorties de la boucle de coupe.

3. Dispositif selon la revendication 1 ou la revendication 2, dans lequel le mécanisme de fixation de la boucle de coupe (60) s'étend depuis une extrémité distale (22) de la sonde et peut au moins partiellement se rétracter en coulissant dans la sonde (20).

4. Dispositif selon la revendication 3, dans lequel le mécanisme de fixation de la boucle de coupe est un support (60) de boucle de coupe en forme de Y.

5. Dispositif selon la revendication 1, dans lequel le mécanisme de fixation de la boucle de coupe est un couvercle (80) disposé de manière à pouvoir coulisser sur la sonde (20) et configuré pour fixer la boucle de coupe (34) entre le couvercle de la boucle (80) et la sonde (20) dans la configuration de pénétration.

6. Dispositif selon la revendication 1, dans lequel le mécanisme de fixation de la boucle de coupe est la rainure (56) définie dans la sonde proximale par rapport à la sortie de la boucle de coupe.

7. Dispositif selon la revendication 1, dans lequel la sonde contient au moins un canal (26) de boucle de coupe se terminant au niveau de la sortie (44) de la boucle de coupe.

8. Dispositif selon la revendication 1, dans lequel la taille de la boucle de coupe (34) peut être ajustée par rétractation ou extension de la boucle de coupe dans et hors de la sonde (20), lorsque la boucle de coupe se trouve dans une configuration de découpe.

9. Dispositif selon la revendication 1, dans lequel la sonde (20) définit deux sorties (44) de boucle de coupe dans lesquelles la boucle de coupe (34) s'étend.

10. Dispositif selon la revendication 1, dans lequel la sortie (44) de la boucle de coupe peut être sélectivement positionnée autour de la sonde pour faciliter l'ajustement d'une largeur de la boucle de coupe (34).

11. Dispositif selon la revendication 1, dans lequel la sortie (44) de la boucle de coupe peut être sélectivement positionnée pour ajuster l'angle de sortie entre la sortie (44) de la boucle de coupe et la sonde (20).

12. Dispositif selon la revendication 1, dans lequel au moins un bord de la boucle de coupe est constitué d'au moins un bord aiguisé et denté.

13. Dispositif selon la revendication 1 comprenant en outre un dispositif de pénétration tissulaire au niveau d'une extrémité distale (22) de la sonde, le dispositif de pénétration tissulaire étant couplé à une source d'énergie destinée à alimenter en énergie le dispositif de pénétration tissulaire, afin de faciliter la pénétration tissulaire.

14. Dispositif selon la revendication 13, dans lequel le dispositif de pénétration tissulaire est partiellement isolé pour exposer sélectivement les tissus à l'énergie.

15. Dispositif selon la revendication 1, dans lequel la sonde définit une ouverture au niveau d'une extrémité distale (22) de la sonde à travers laquelle la boucle de coupe (34) peut sélectivement s'étendre dans la configuration de découpe et se rétracter dans la configuration de pénétration.

16. Dispositif selon la revendication 1 comprenant en outre un couvercle de boucle (80) disposé de manière à coulisser sur la sonde, le couvercle de la boucle étant configuré pour fixer la boucle de coupe entre le couvercle de la boucle et la sonde dans la configuration de pénétration et pour libérer la boucle de coupe dans sa configuration prédéfinie dans la configuration de découpe.

17. Dispositif selon la revendication 1, dans lequel la boucle de coupe est couplée à une source d'énergie configurée pour alimenter en énergie la boucle de coupe, afin de faciliter la découpe des tissus par la boucle de coupe.

18. Dispositif selon la revendication 17, dans lequel la source d'énergie est sélectionnée parmi au moins une source comprenant une fréquence radio, un laser, un jet d'eau, l'abrasion de l'air, des ultrasons, l'oscillation sur une distance, une direction et/ou une fréquence prédéterminée, l'oscillation sur une distance, une direction et/ou une fréquence variable.

19. Dispositif selon la revendication 17, dans lequel la boucle de coupe (34) est en partie isolée pour exposer sélectivement les tissus à l'énergie.

20. Dispositif selon la revendication 1 comprenant en outre un dispositif d'imagerie généralement logé dans la sonde.

21. Dispositif selon la revendication 1 comprenant en outre un mécanisme de positionnement de la sonde logé dans la sonde, le mécanisme de positionne-

ment de la sonde facilitant la détermination du positionnement d'au moins l'un des éléments sélectionnés parmi la sonde et la boucle de coupe à l'intérieur des tissus depuis l'extérieur des tissus, le mécanisme de positionnement de la sonde étant un dispositif sélectionné parmi une lumière, un marqueur radiologique et un marqueur aux ultrasons.

22. Dispositif selon la revendication 1 comprenant en outre un collecteur de tissus permettant de récupérer des tissus découpés par la boucle de coupe.

23. Dispositif selon la revendication 1 comprenant en outre un mécanisme de marquage tissulaire permettant de marquer les tissus découpés par la boucle de coupe.

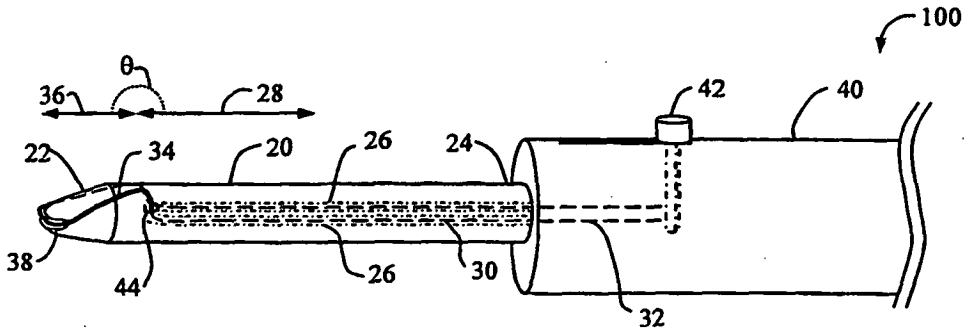


FIG. 1A

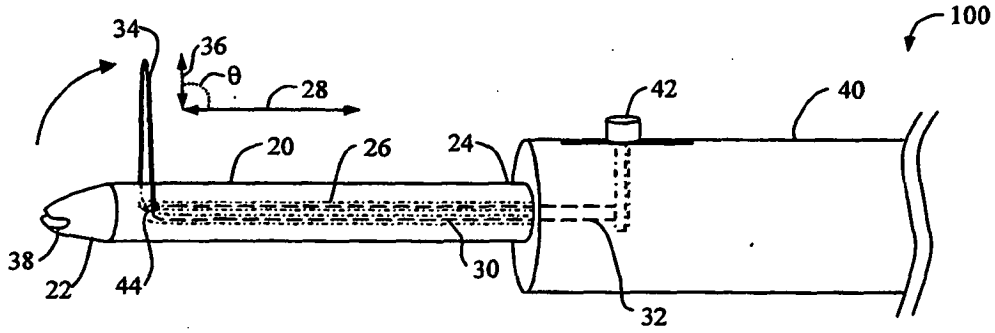


FIG. 1B

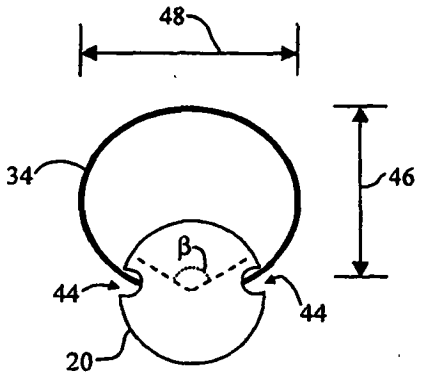


FIG. 1C

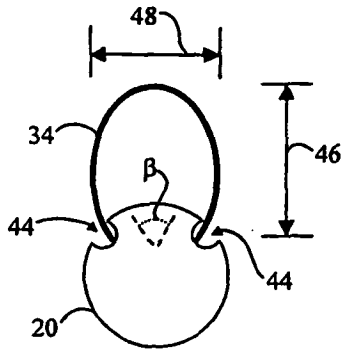


FIG. 1D

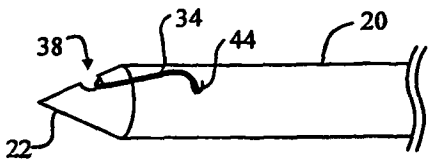


FIG. 2A

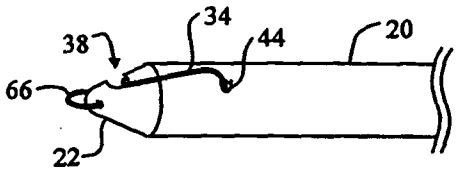


FIG. 2B

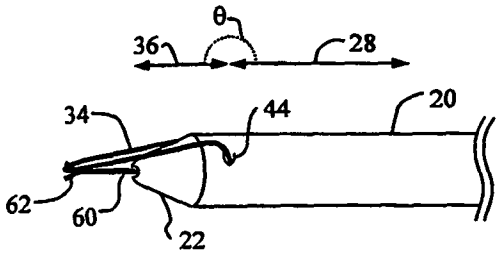


FIG. 3A

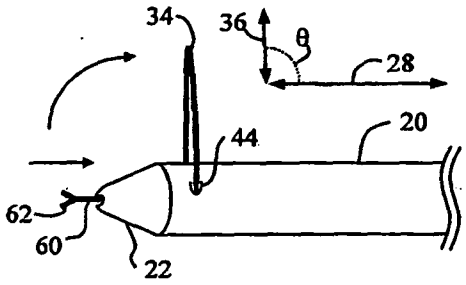


FIG. 3B

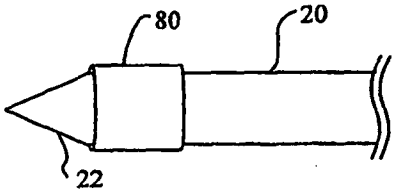


FIG. 3C

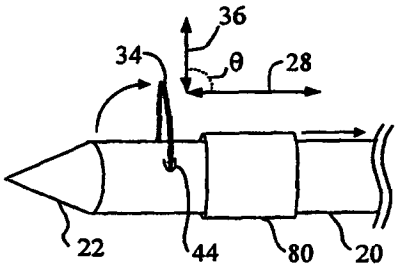


FIG. 3D

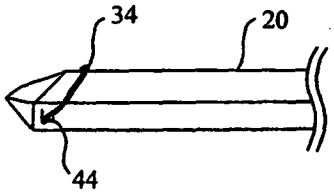


FIG. 3E

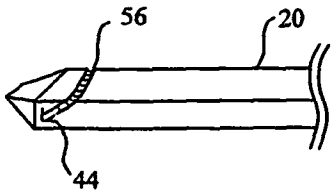


FIG. 3F

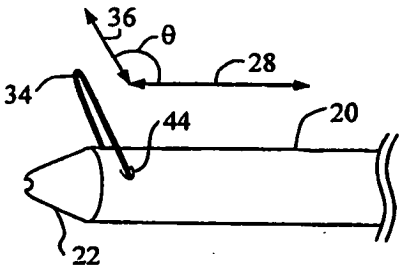


FIG. 4A

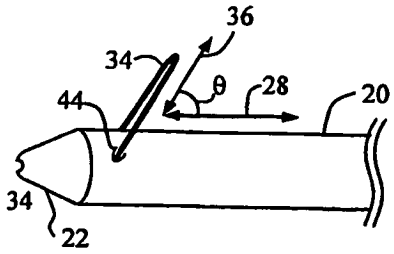


FIG. 4B

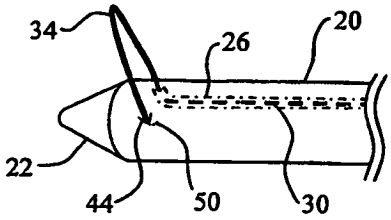


FIG. 5

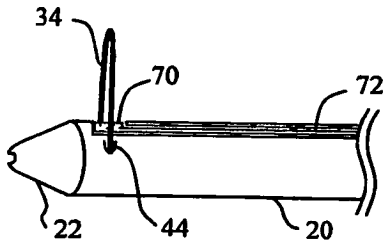


FIG. 6

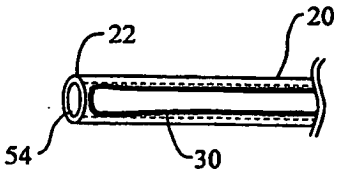


FIG. 7A

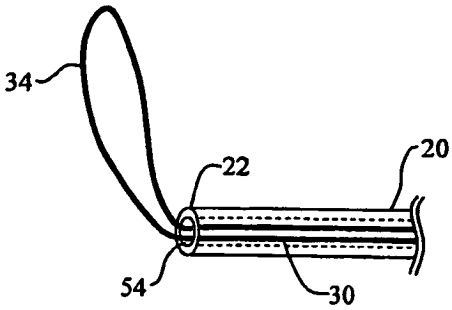
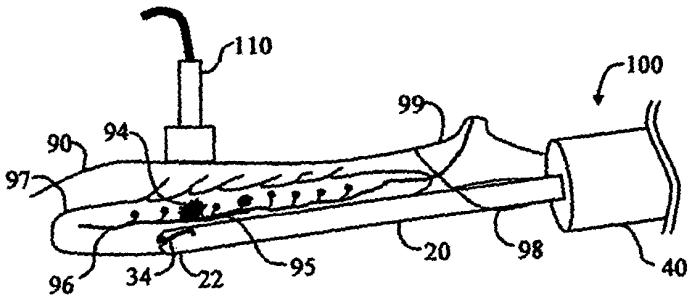


FIG. 7B

FIG. 8A



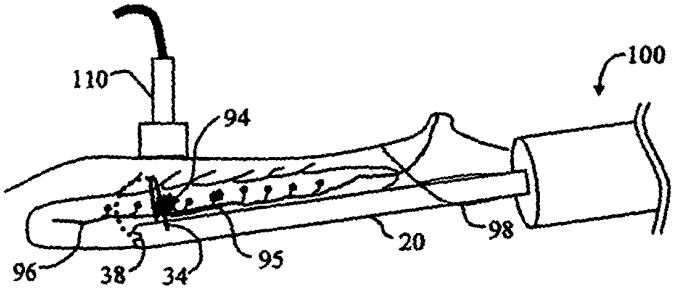
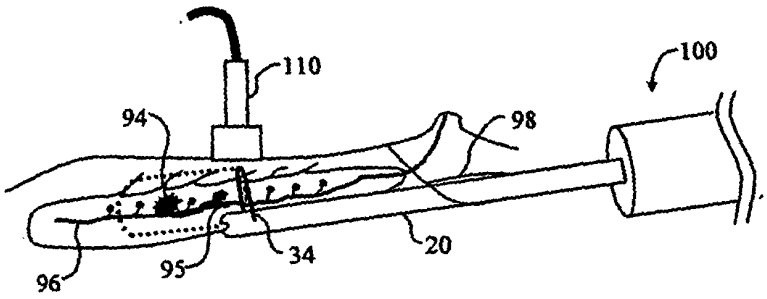


FIG. 8B

FIG. 8C



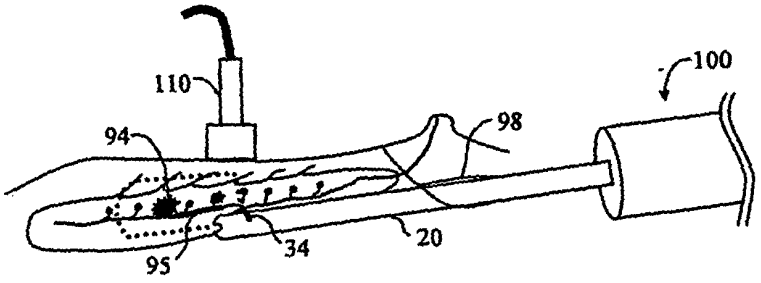


FIG. 8D

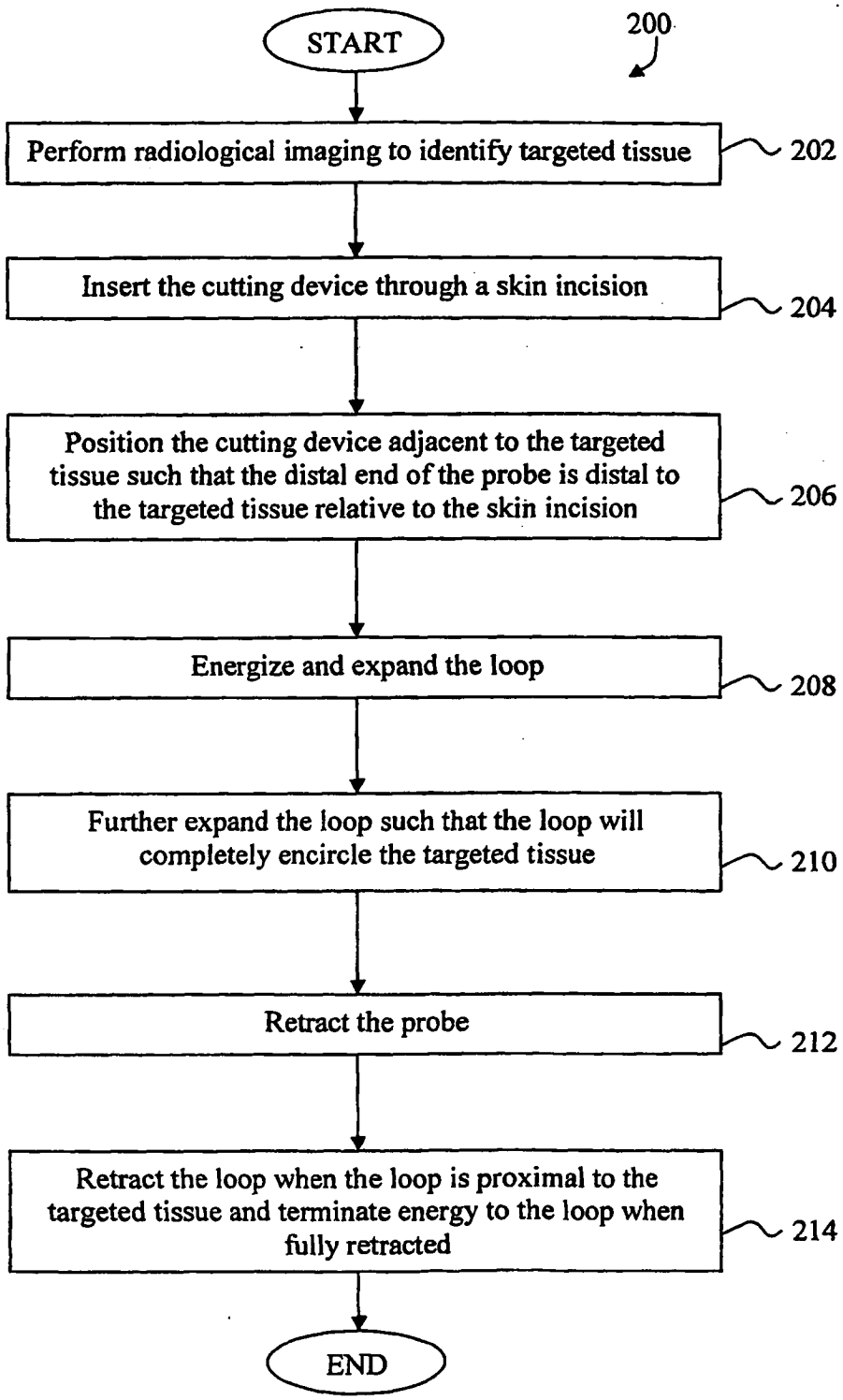

START
200
Perform radiological imaging to identify targeted tissue
202
Insert the cutting device through a skin incision
204
Position the cutting device adjacent to the targeted tissue such that the distal end of the probe is distal to the targeted tissue relative to the skin incision
206
Energize and expand the loop
208
Further expand the loop such that the loop will completely encircle the targeted tissue
210
Retract the probe
212
Retract the loop when the loop is proximal to the targeted tissue and terminate energy to the loop when fully retracted
214
END

FIG. 9

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 20020072688 A1 **[0006]**
- US 16701702 A **[0032]**
- US 7149566 B **[0033]**

专利名称(译)	可弯曲的切割装置		
公开(公告)号	EP1599139B1	公开(公告)日	2009-08-12
申请号	EP2004713390	申请日	2004-02-20
[标]申请(专利权)人(译)	医疗马诺阿		
申请(专利权)人(译)	马诺阿MEDICAL，INC.		
当前申请(专利权)人(译)	马诺阿MEDICAL，INC.		
[标]发明人	HO HUDDEE JACOB LEE ROBERTA ZUCKSWERT SAMUEL E CONSTON STAN YAMAMOTO RONALD ALLEN DON		
发明人	HO, HUDDEE, JACOB LEE, ROBERTA ZUCKSWERT, SAMUEL, E. CONSTON, STAN YAMAMOTO, RONALD ALLEN, DON		
IPC分类号	A61B10/00 A61B17/00 A61B17/22 A61B17/32 A61B8/12 A61B10/02 A61B10/04 A61B18/14		
CPC分类号	A61B10/02 A61B8/12 A61B10/0266 A61B10/04 A61B17/32 A61B17/320016 A61B17/32056 A61B2017/00867 A61B2018/00601 A61B2018/1407 A61B2018/144		
优先权	60/449061 2003-02-20 US		
其他公开文献	EP1599139A1		
外部链接	Espacenet		

摘要(译)

公开了用于切割组织的微创手术的装置和方法。该装置通常包括探针，该探针具有相对于探针的出射角的远端出口，具有形状记忆的切割环，其具有预先配置的形状，以及环形固定机构，以将切割环固定在穿透构型中并释放切割环切入配置。切割环通常在穿透构造中的探针的轮廓内。在切割配置中，切割环延伸通过切割环出口并且通常以通常由出口角度限定的切割角度返回到预先配置的形状。切割环固定机构可以是，例如，可在探针上滑动的盖子，从探针的远端尖端延伸的可滑动构件，或者在探针接近切割环出口处限定的凹槽。

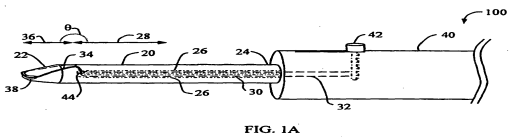

FIG. 1A

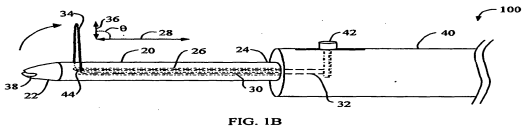

FIG. 1B

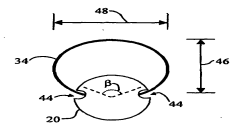

FIG. 1C

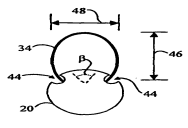

FIG. 1D