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Burbank et al.

(10) **Patent No.: US 6,638,234 B2**
(45) **Date of Patent: Oct. 28, 2003**

(54) **SENTINEL NODE LOCATION AND BIOPSY**

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(73) Assignee: **SenoRx, Inc.**, Aliso Viejo, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/727,112**

(22) Filed: **Nov. 29, 2000**

(65) **Prior Publication Data**

US 2001/0002250 A1 May 31, 2001

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/159,467, filed on Sep. 23, 1998, now Pat. No. 6,261,241, and a continuation-in-part of application No. 09/477,255, filed on Jan. 4, 2000, now Pat. No. 6,471,700, and a continuation-in-part of application No. 09/356,187, filed on Jul. 16, 1999, now Pat. No. 6,312,429, which is a continuation-in-part of application No. 09/146,185, filed on Sep. 1, 1998, now Pat. No. 6,540,693, which is a continuation-in-part of application No. 09/057, 303, filed on Apr. 8, 1998, now Pat. No. 6,331,166

(60) Provisional application No. 60/076,973, filed on Mar. 3, 1998.

(51) **Int. Cl.**[7] **A61B 10/00**; A61B 6/00; A61B 18/18

(52) **U.S. Cl.** **600/564**; 600/562; 600/431; 606/41; 606/45

(58) **Field of Search** 600/436, 562, 600/564–567, 420, 424, 431; 606/32, 39, 40, 41, 45–48, 167; 607/101, 113; 424/9.1; 128/898

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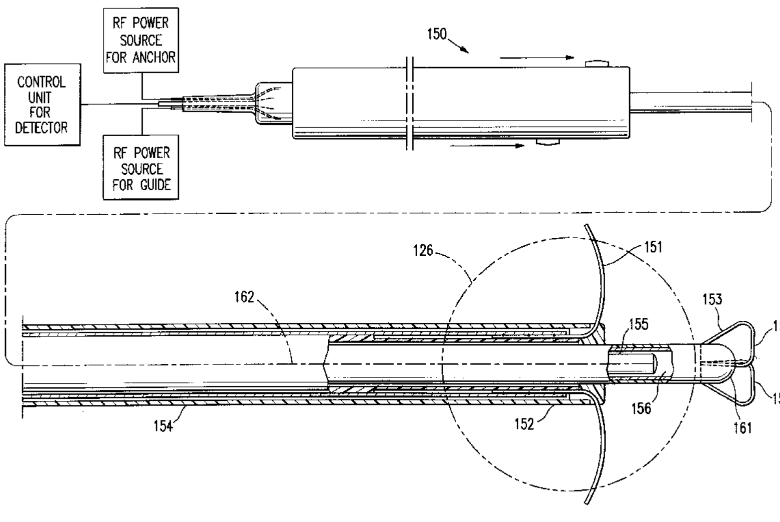
(74) *Attorney, Agent, or Firm*—Duane Morris LLP

(57) **ABSTRACT**

A method and apparatus for locating and accessing a patient's sentinel lymph nodes which are associated with a lesion site of the patient. A radiopharmaceutical is injected at or near a lesion site within a patient's body. The migration of the radiopharmaceutical and accumulation of the radiopharmaceutical in a sentinel node of the patient is monitored with a gamma camera or radiation energy detector from outside the patient's body. The sentinel node can then be accessed with a cannula having an RF energy electrode on the distal end of the cannula which is activated during insertion of the cannula. Once the distal end of the cannula is positioned adjacent the sentinel node, an anchor device is inserted through the cannula. The distal end of the anchor device is then positioned in the sentinel node and secured to the sentinel node to be used as a locator for subsequent procedures.

14 Claims, 14 Drawing Sheets



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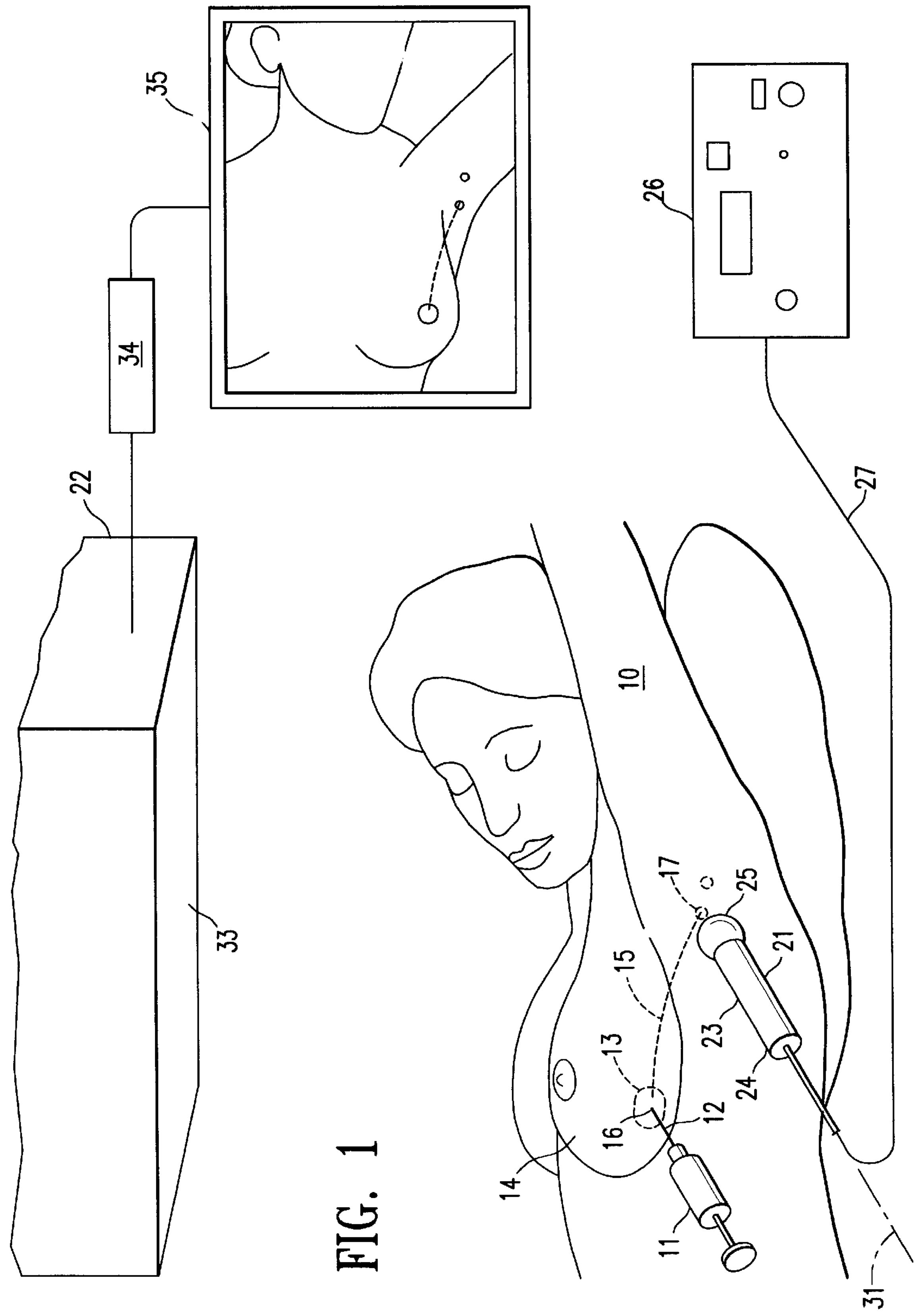

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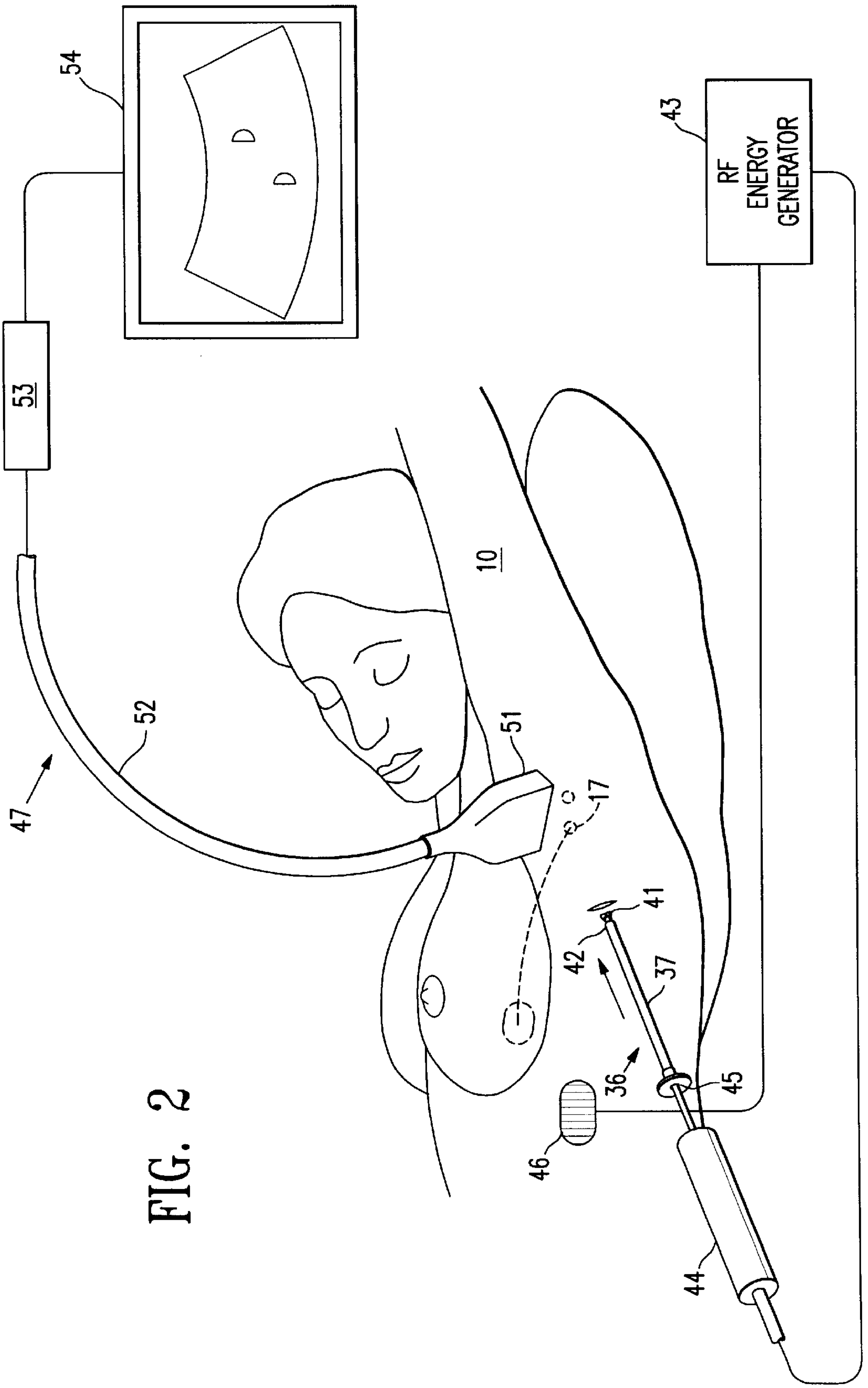

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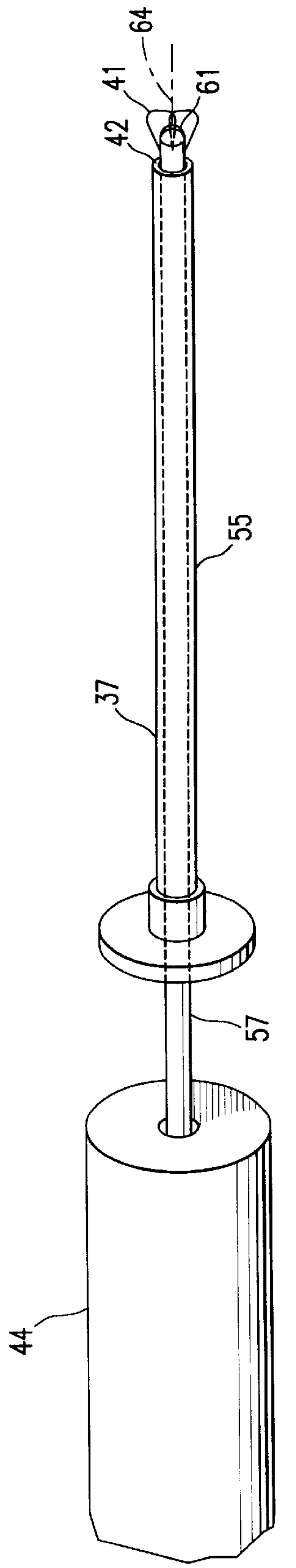

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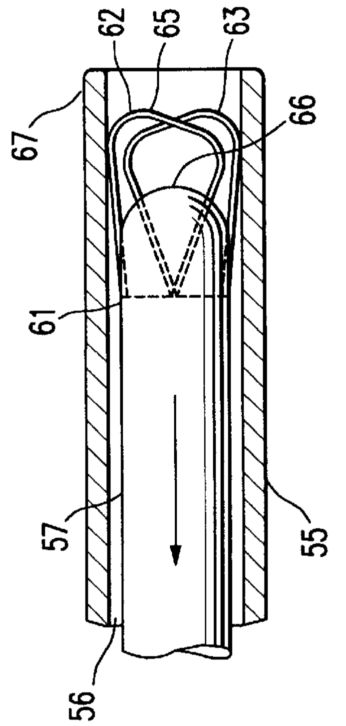

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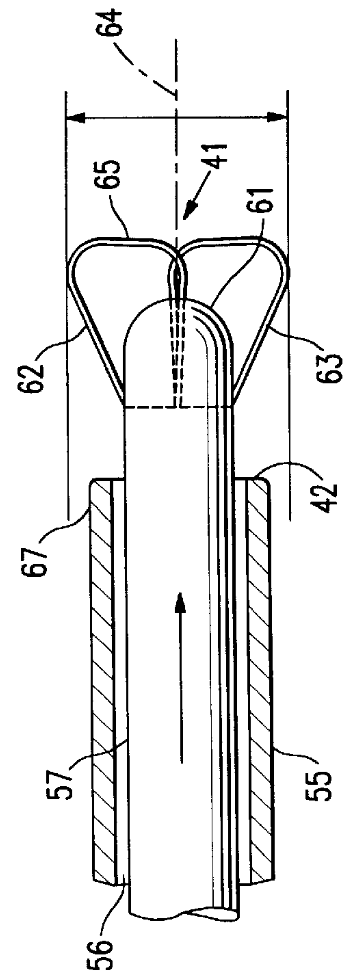

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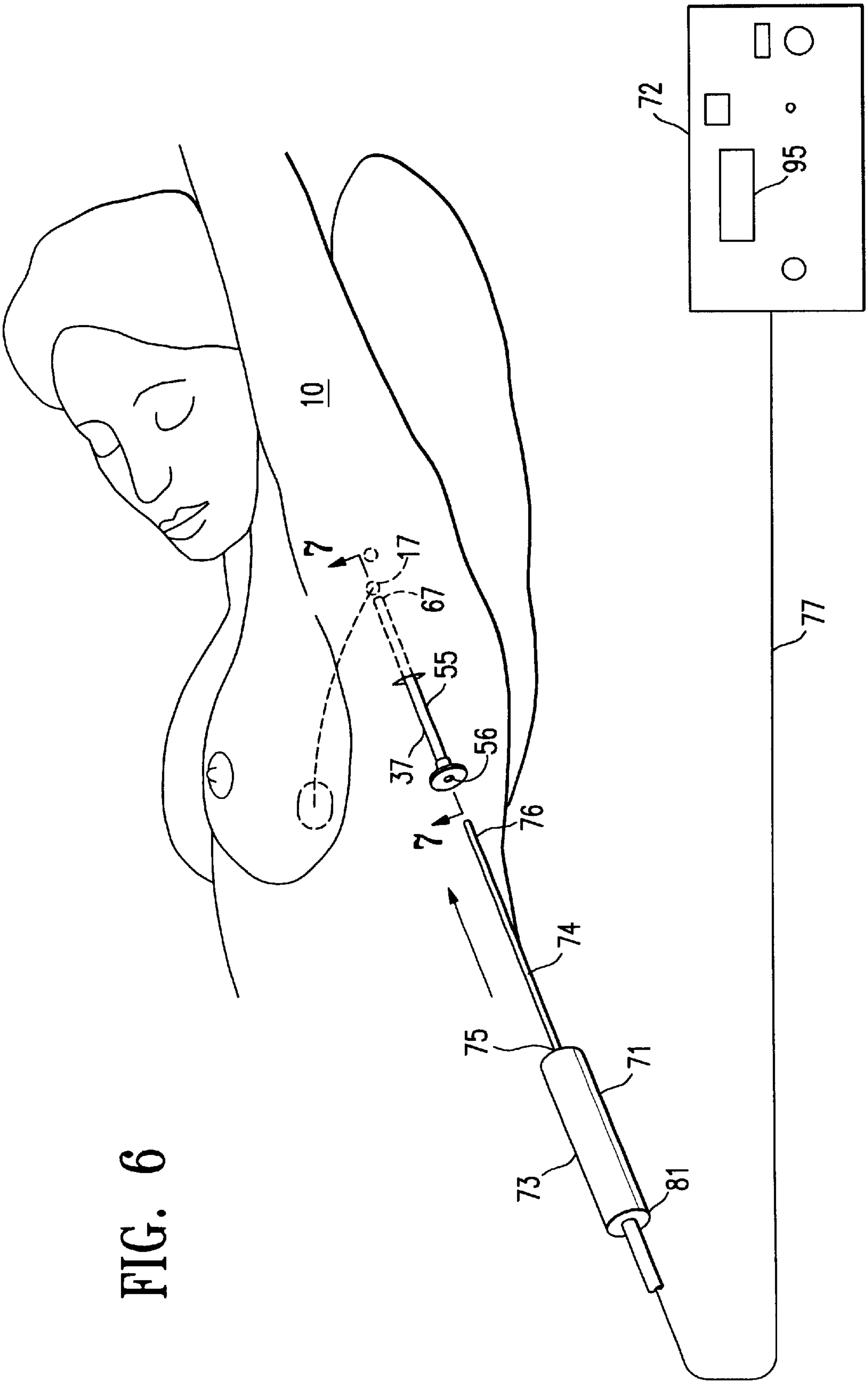

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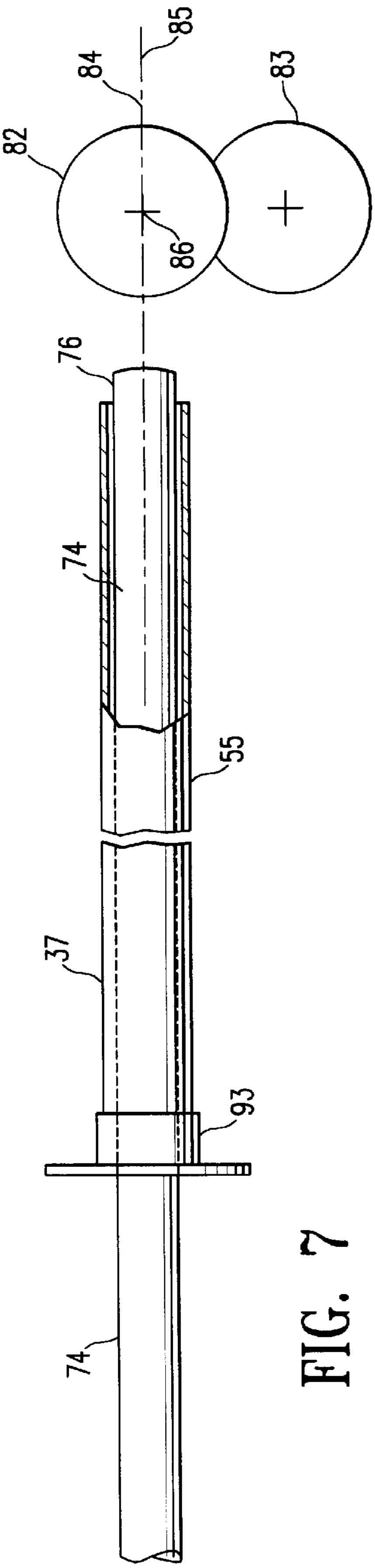
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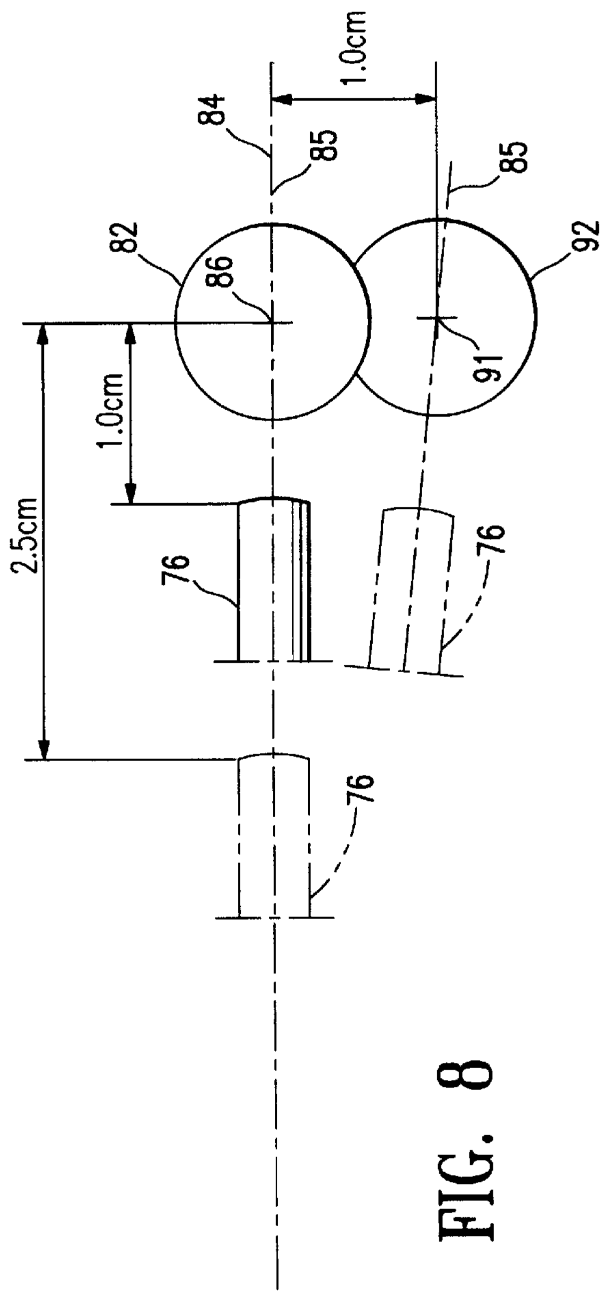
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1.0cm
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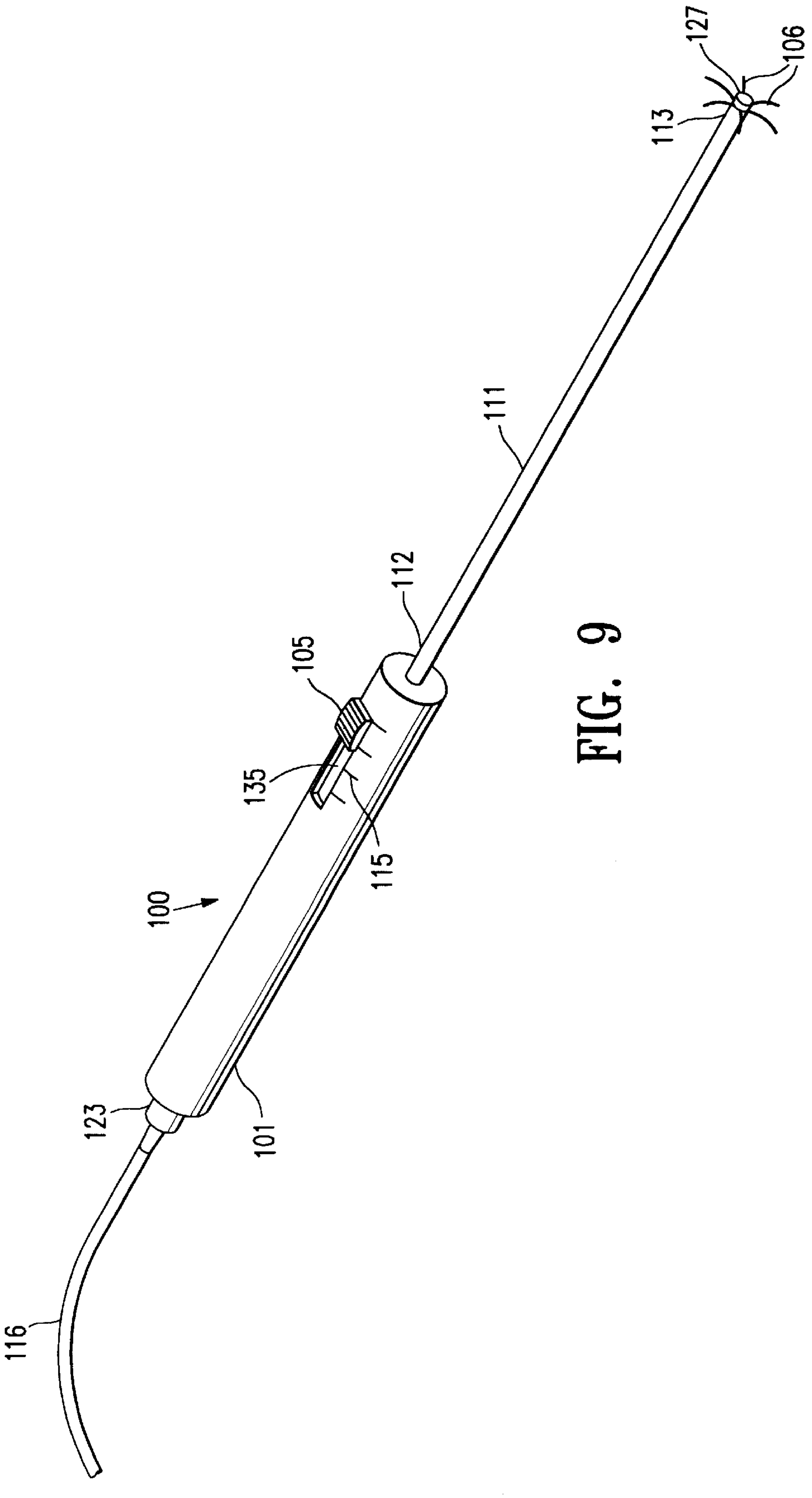

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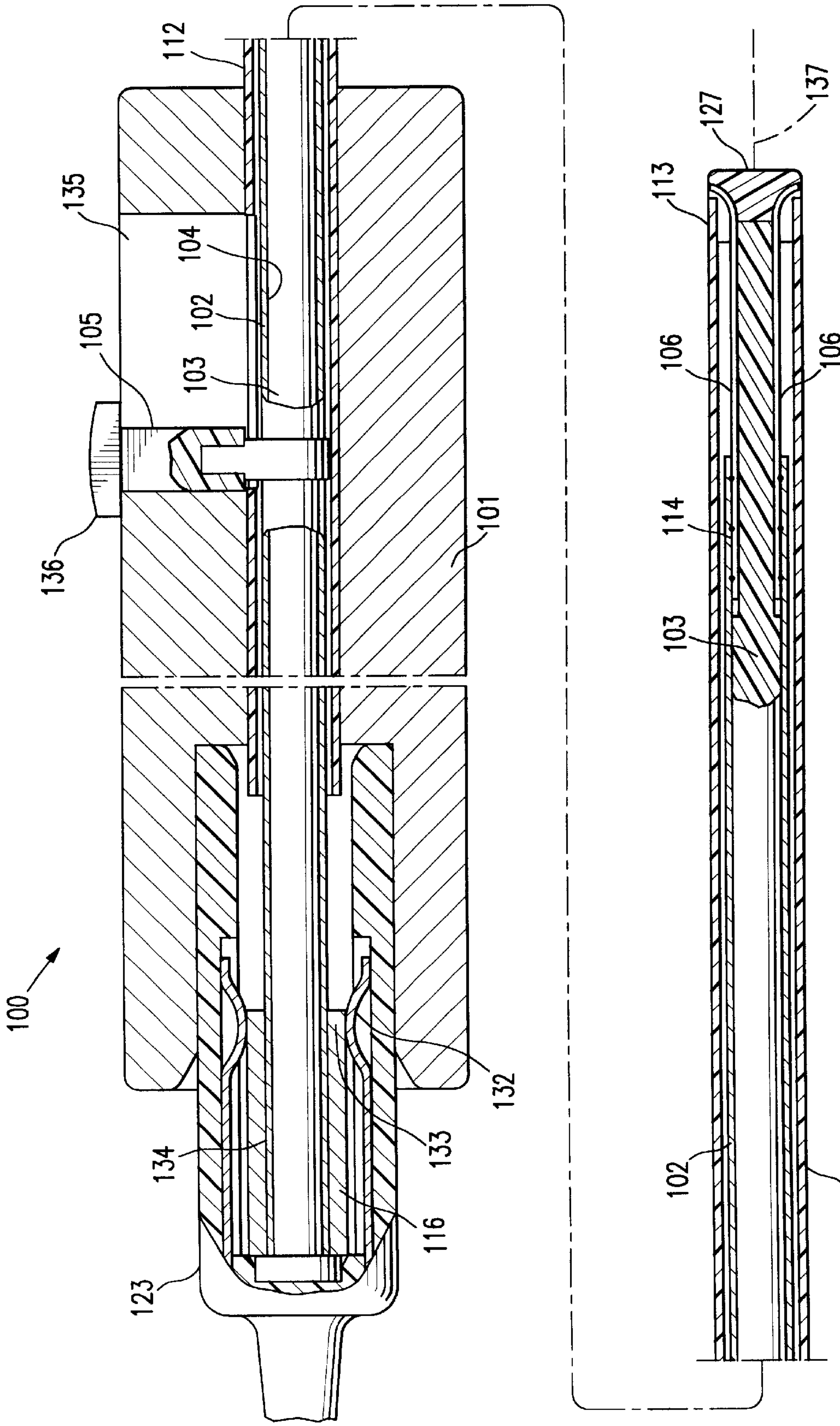
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FIG. 10

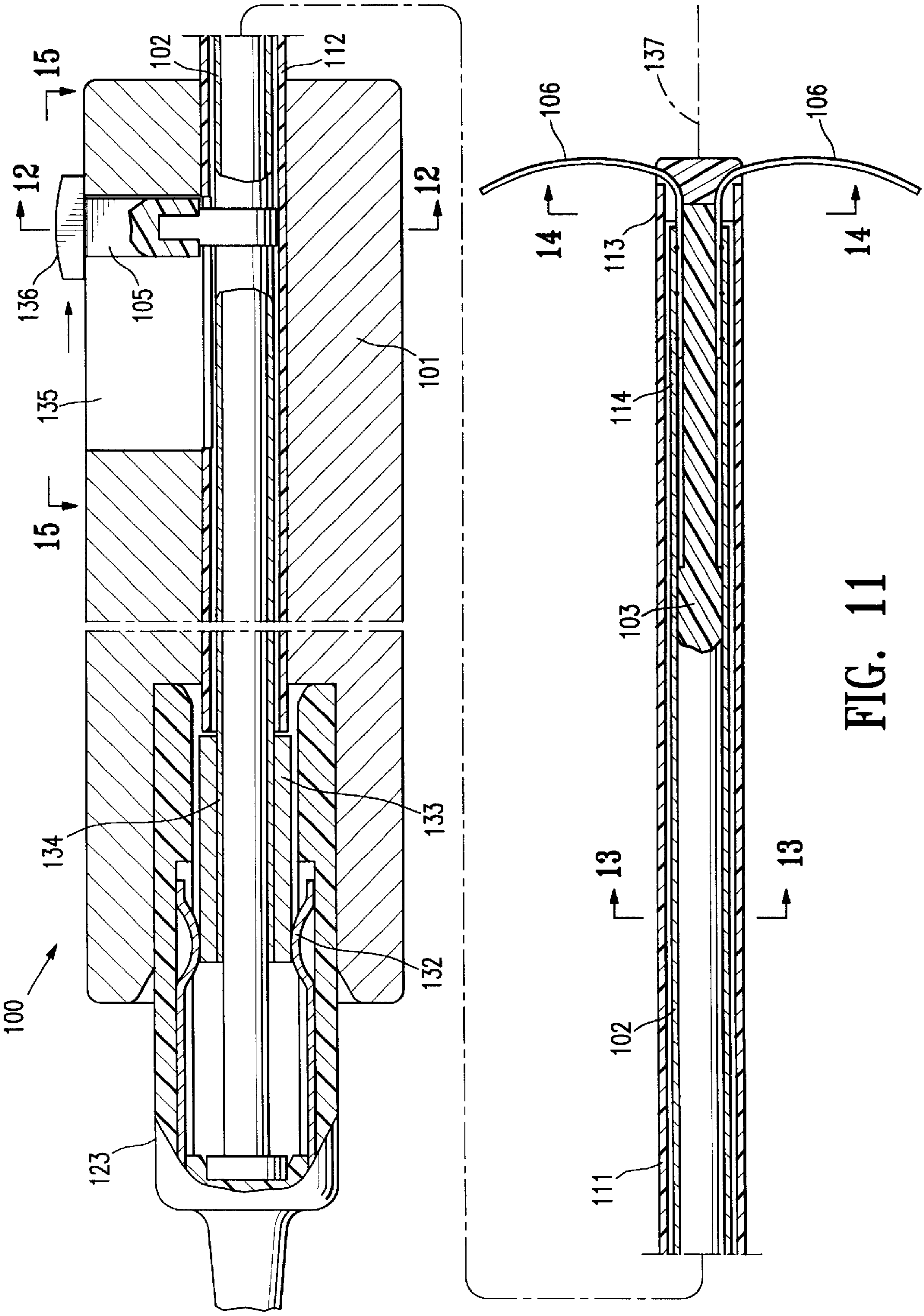
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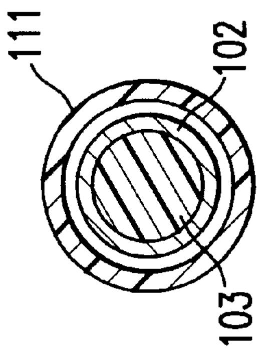
FIG. 11



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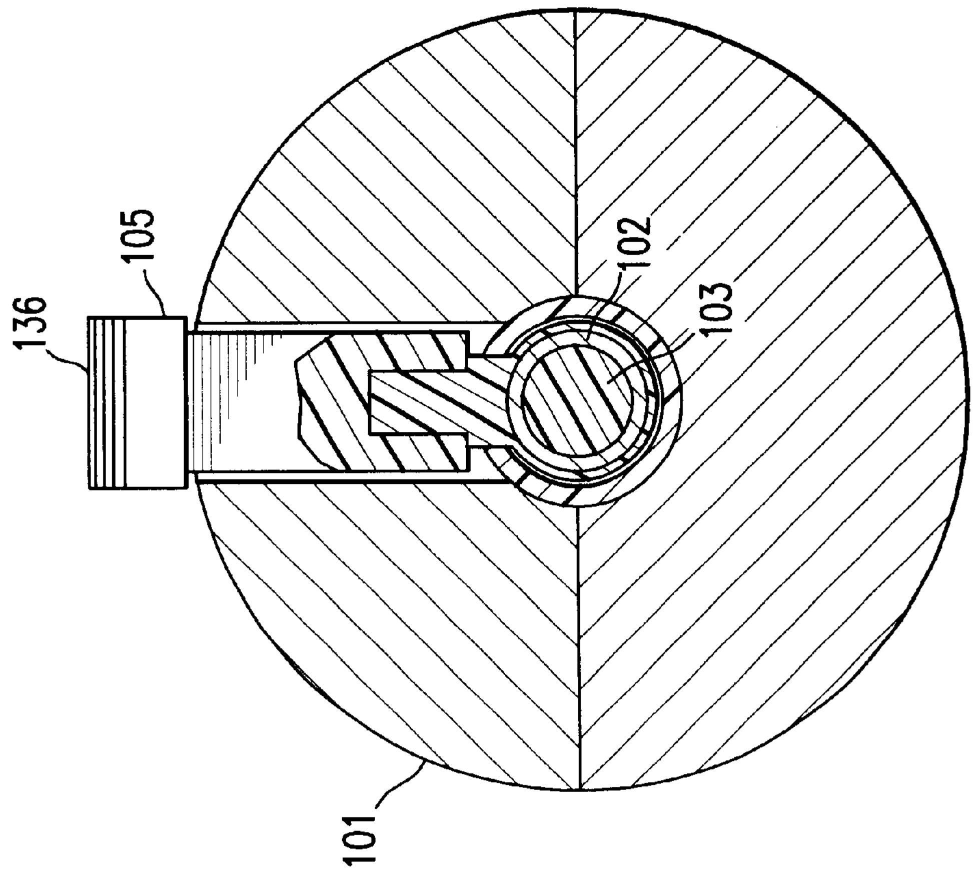

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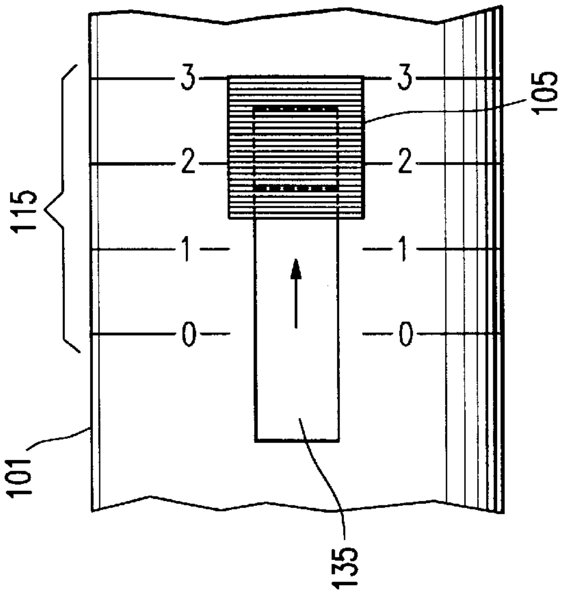

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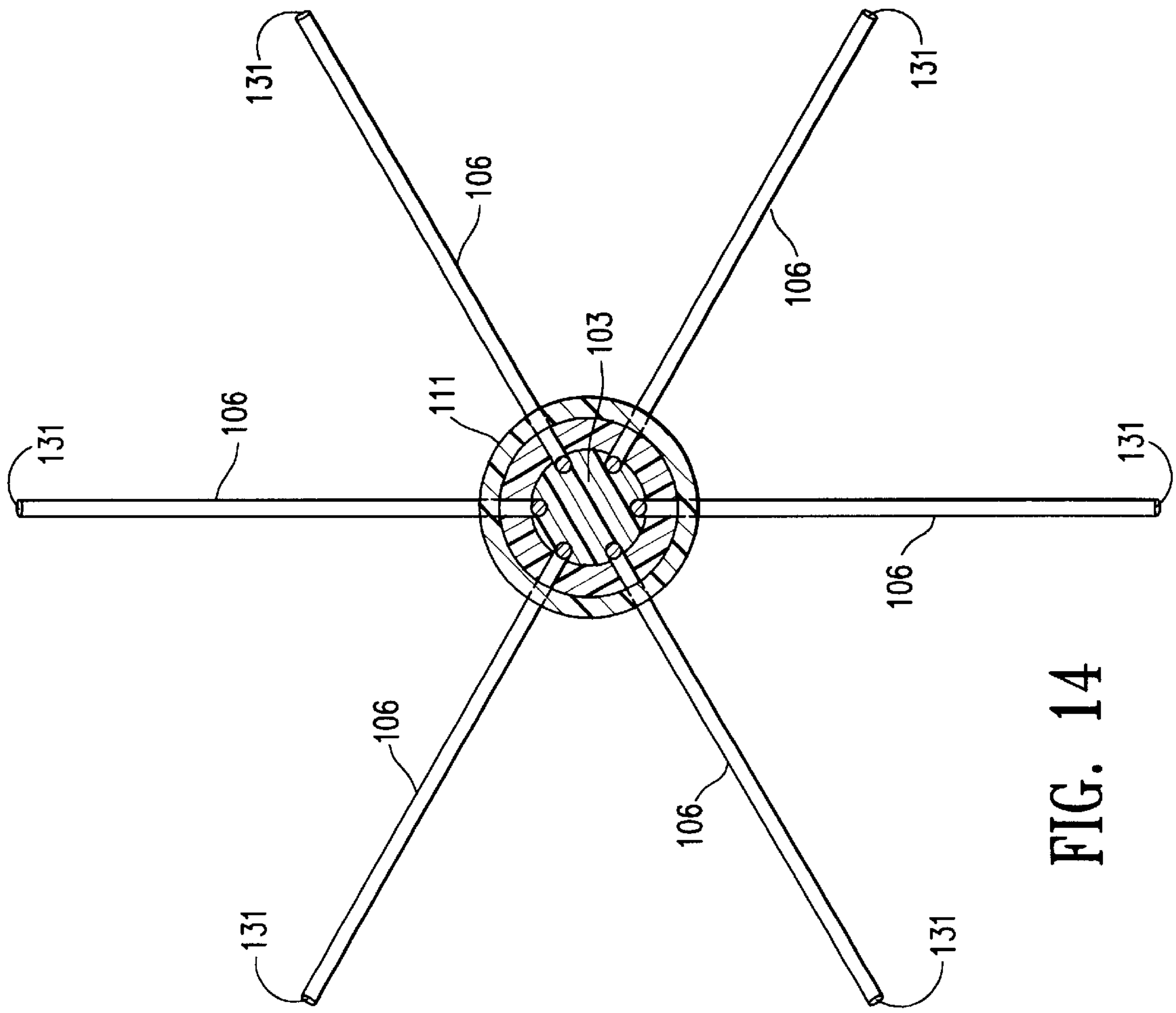

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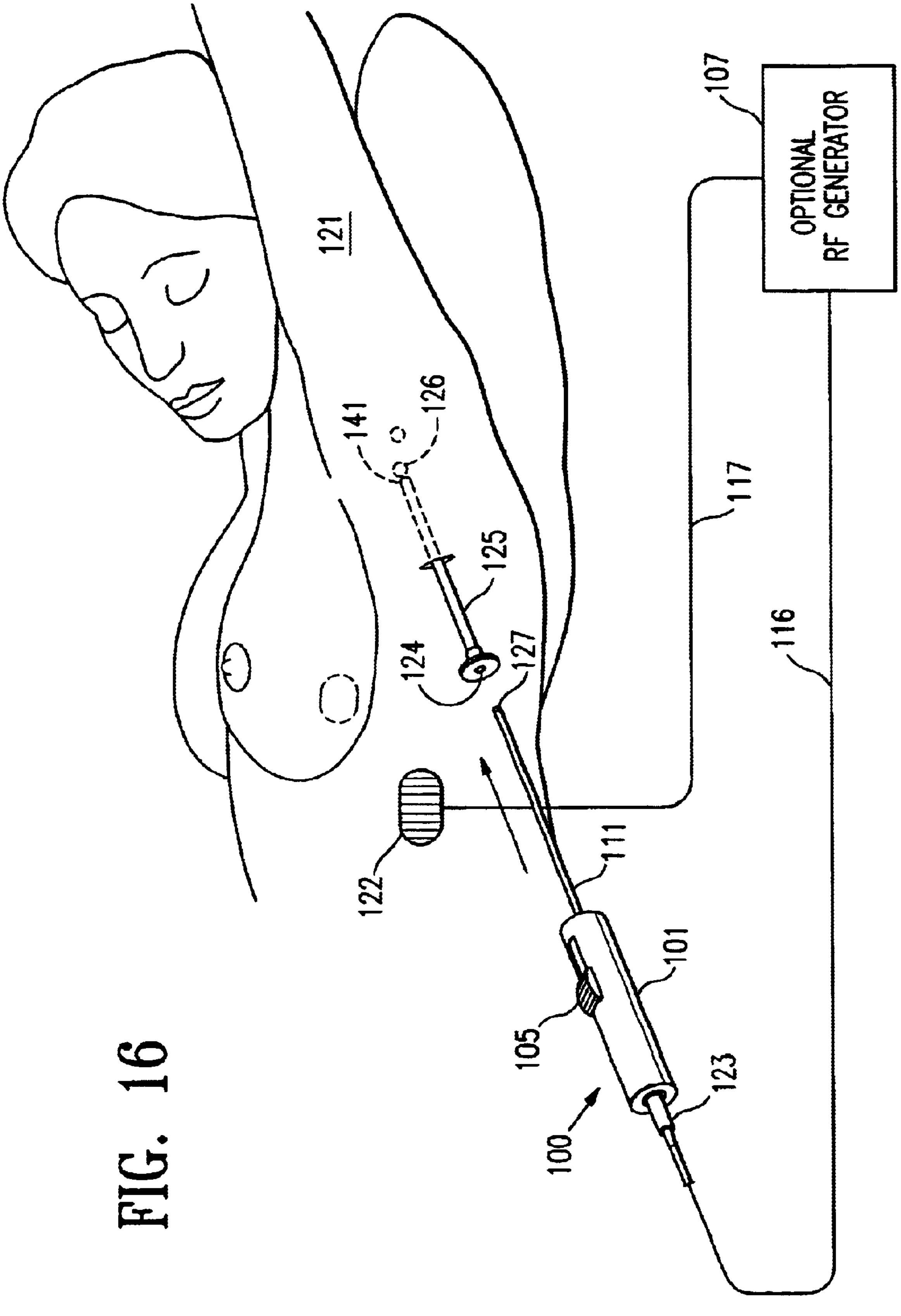

107
OPTIONAL
RF GENERATOR
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FIG. 16

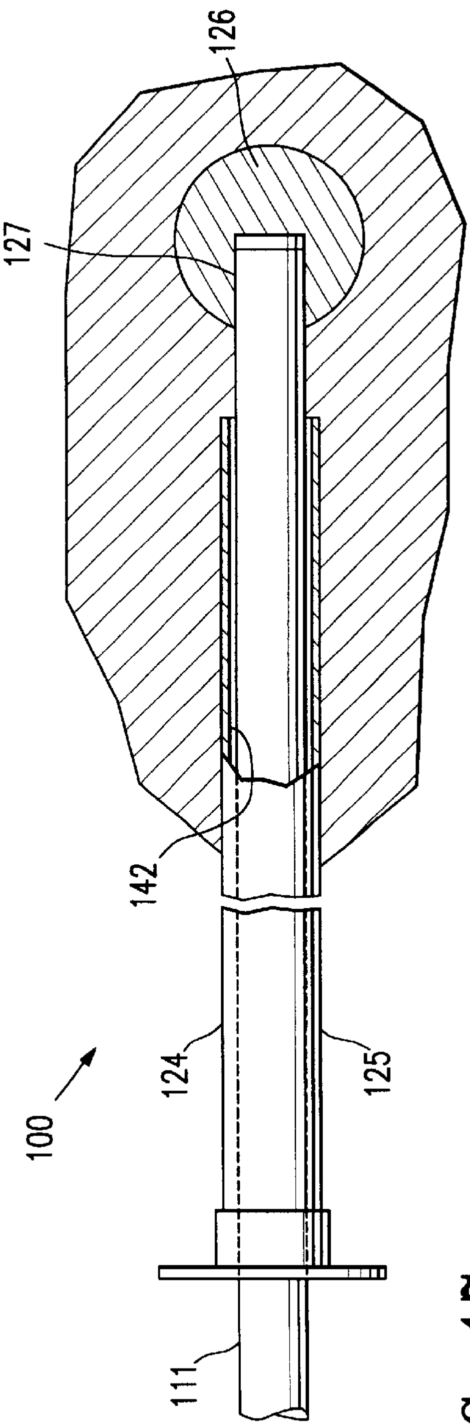
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FIG. 17

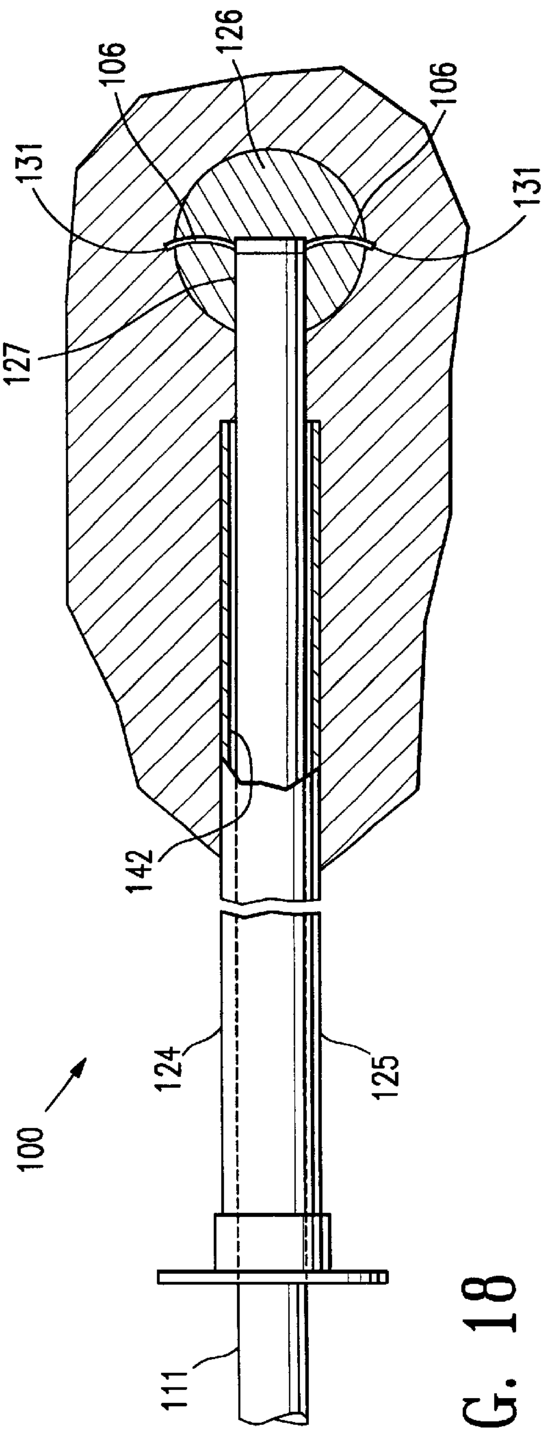
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FIG. 18

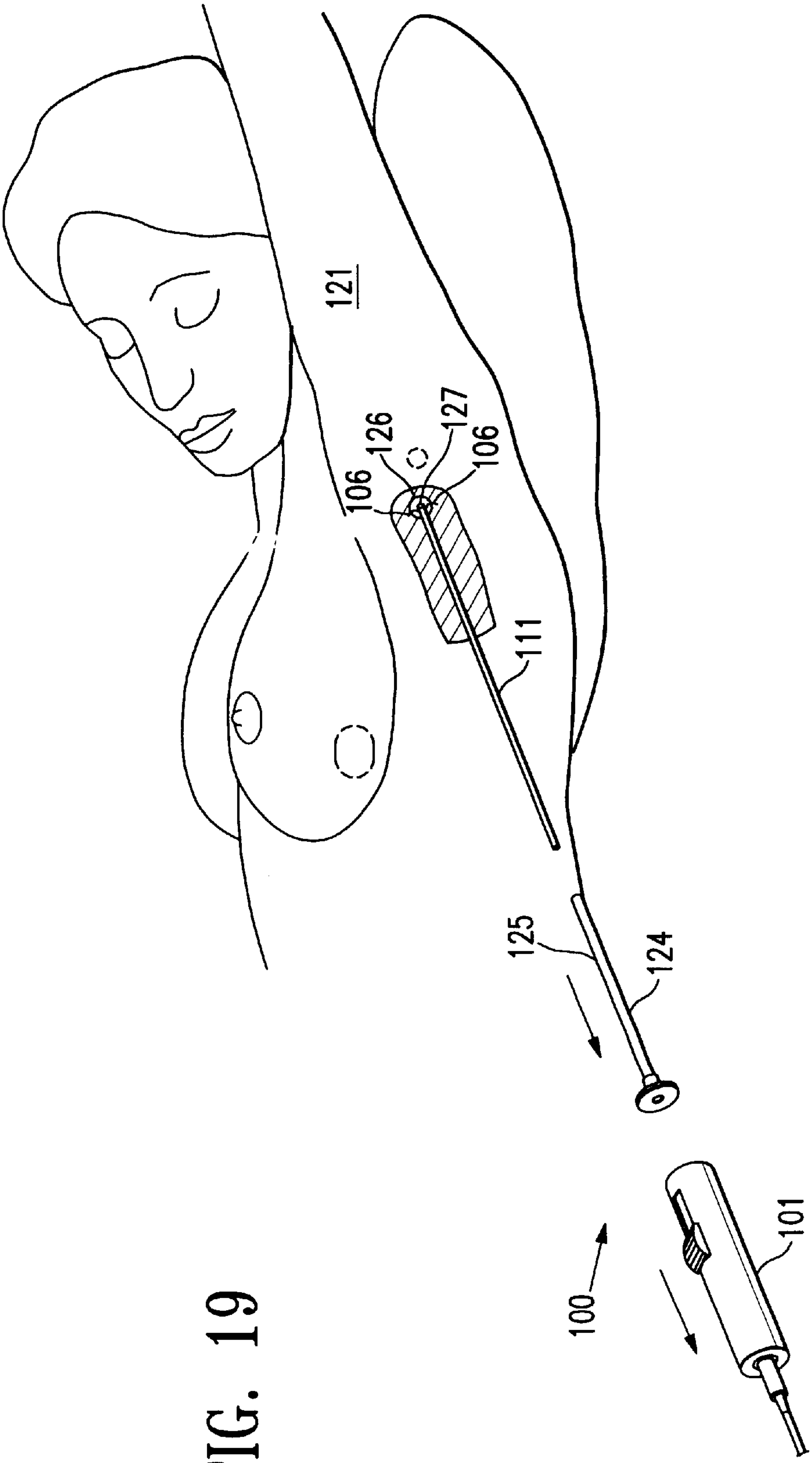
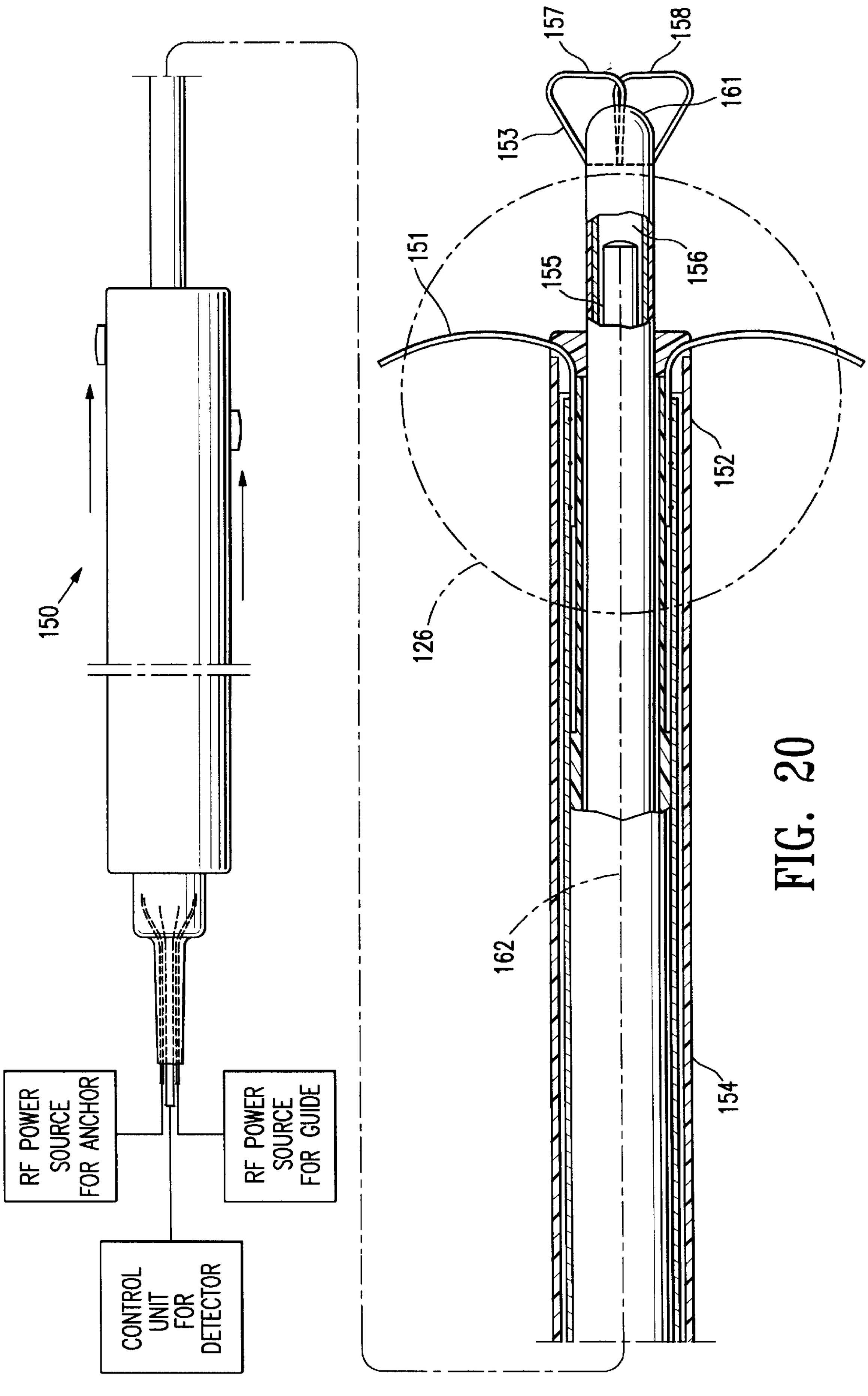


FIG. 19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RF POWER SOURCE FOR ANCHOR
RF POWER SOURCE FOR GUIDE
CONTROL UNIT FOR DETECTOR

FIG. 20

SENTINEL NODE LOCATION AND BIOPSY

RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 09/159,467, filed Sep. 23, 1998, now U.S. Pat. No. 6,261,241; and a continuation-in-part of Ser. No. 09/477,255, filed Jan. 4, 2000 now U.S. Pat. No. 6,471,700; and a continuation-in-part of Ser. No. 09/356,187, filed Jul. 16, 1999, now U.S. Pat. No. 6,312,429, which is a continuation-in-part of Ser. No. 09/146,185, filed Sep. 1, 1998, now U.S. Pat. No. 6,540,693, which is a continuation-in-part of Ser. No. 09/057,303, filed Apr. 8, 1998, now U.S. Pat. No. 6,331,166, which claims the benefit of provisional patent application Ser. No. 60/076,973, filed Mar. 3, 1998, all of which applications are hereby incorporated herein by reference in their entirety and from which priority is hereby claimed under 35 U.S.C. §§119(e) and 120.

BACKGROUND OF THE INVENTION

The invention relates to the field of medical devices and methods used in the treatment of diseases such as cancer which have the ability to metastasize within a patient's body. More specifically, the invention is directed to methods and devices for locating sentinel lymph nodes associated with a lesion site within a patient's body so that the sentinel lymph nodes may thereafter be selectively removed and analyzed to determine whether disease has spread from the primary lesion site to the sentinel lymph nodes. In the case of breast cancer patients, such methods and devices may eliminate the need for complete axillary lymph node dissection in patients who do not require such invasive and debilitating procedures.

With regard to breast cancer patients specifically, the determination of the severity of the disease or staging is frequently determined by the level of lymph node involvement in those lymph nodes which correspond to the primary cancer lesion site in the breast. The lymph nodes which correspond to the breast area are typically located in the armpit or axilla of the patient and are connected to the breast tissue of the patient by a series of lymph ducts. Other likely areas for sentinel nodes include inframammary and submammary locations and elsewhere in the patient's chest. The sentinel lymph nodes can be in fluid communication with other surrounding lymph nodes, however, lymph drainage from the lesion site will first flow to the sentinel lymph nodes. Thereafter, lymph fluid drainage may then continue on to lymph nodes surrounding the sentinel nodes.

Studies have shown that by the time a typical breast cancer lesion reaches the size of 1–2 cm, the cancer will have metastasized to at least one of the sentinel lymph nodes in about one third of patients. Malignant cells break off and drain through the lymph fluid ducts to the lymph nodes and will be apparent in excised lymph nodes if the malignant cells embed in the lymph node. In patients with more advanced disease, the likelihood of spread to sentinel nodes is higher as is the likelihood of spread of the disease to the lymph nodes surrounding the sentinel lymph nodes.

As discussed above, when a tumor lesion is under 1–2 cm, only about ⅓ of patients will have cancer cells in the corresponding lymph nodes, and in the patients where the disease has spread to the lymph nodes, it is often confined to the sentinel lymph nodes.

In the past, a breast cancer patient would normally have a complete axillary lymph node dissection as an adjunct to removal of the primary lesion in the breast. Thus, the patient's entire lymph node system in the armpit area is removed and biopsied to determine the stage of the cancer and what further treatment was required. However, as discussed above, when the lesion is under 1–2 cm, two thirds of the patients had no migration of cancer cells to the lymph nodes at all, and in others, cancer had only migrated to the sentinel lymph nodes. Thus, total axillary lymph node dissection in two-thirds of the cases were unnecessary. It should be noted that total axillary lymph node dissection can be an extremely painful and debilitating procedure for patients who often suffer from severe lymph edema as a result of the body's inability to channel the flow of lymph fluid once most or all of the lymph nodes have been excised.

Thus there is a need for methods and devices that can be used to determine the location of sentinel lymph nodes corresponding to a patient's primary lesion site, and a reliable and noninvasive means of accessing the sentinel lymph nodes to determine whether they are involved in the disease. If the sentinel lymph nodes are determined not to have cancer cells within them, then a total axillary lymph node dissection may be avoided.

It has been known to use radioactive materials or radiopharmaceuticals as localizing agents which can be injected into the area of a primary lesion to monitor the flow of the materials within the patients body using a variety of detectors. Radioactive material such as Technetium 99 m, Indium 111, Iodine 123 or Iodine 125 can be injected in a fluid into the site of a primary lesion and the migration of the radioactive material through lymph ducts to the patient's corresponding sentinel lymph nodes and other surrounding lymph nodes monitored. Although techniques exist to locate the sentinel lymph nodes of a patient with such radiopharmaceutical tagging, what has been needed are methods and devices to precisely locate and access the sentinel lymph nodes of the patient in a noninvasive manner so as to minimize trauma to the patient should it be determined that a total axillary node dissection is unnecessary.

SUMMARY OF THE INVENTION

The invention is directed generally to a method and system for locating and/or accessing specific target sites within the body of a patient. More specifically, the invention is directed to a method and system for locating and accessing a sentinel lymph node of a patient which corresponds to a lesion site within the patient's body.

In one embodiment of the invention, a radioactive material is injected into a patient's body near a primary lesion site or other site of interest within the patient. The approximate position of a sentinel lymph node is within the patient's body is determined by detecting radiation from the radioactive material accumulated within the sentinel lymph node with a radiation detector external to the patient's body. The sentinel lymph node can then be accessed with a cannula having an RF electrode disposed on a distal end of the cannula by activating the RF electrode to ablate tissue while passing the cannula into the patient's body until the distal end of the cannula is disposed adjacent the sentinel lymph node. Thus, access to a patient's sentinel lymph node corresponding to a lesion site is achieved with minimal trauma to the patient, requiring only a hypodermic injection at the lesion site and a channel through the patient's tissue from the outside surface of the skin to the sentinel node, the channel being no larger than the outside dimension of the cannula.

Once the distal end of the cannula is positioned adjacent the sentinel lymph node, an anchor device can be inserted through the cannula and into the sentinel lymph node. The distal end of the anchor device can then be secured to the sentinel lymph node. Once the distal end of the anchor device is secured to the lymph node, the patient can be transferred to a surgical suite and the lymph node surgically removed with the anchor device attached thereto. The anchor device is thus used as a locator for the sentinel lymph node during the surgical procedure.

In some embodiments of a method of the invention, a gamma camera is used to determine the approximate position of the sentinel lymph node within the patient's body prior to accessing the sentinel lymph node with the cannula assembly. Alternatively, a hand held radiation detecting wand or the like can be used to determine the approximate position of the sentinel lymph node within the patient's body. Once the approximate position of a sentinel lymph node is known, the skin of the patient can be marked with a visible mark above the location of the sentinel lymph node prior to accessing the sentinel lymph node with the cannula.

A cannula suitable for use with the method discussed above can have an outer hollow shaft having an inner lumen slidingly disposed about an inner shaft having an RF electrode disposed on the distal end of the inner shaft. The inner shaft can be withdrawn from the outer hollow shaft prior to insertion of the anchor device through the inner lumen of the outer hollow shaft to access a sentinel lymph node. The RF electrode can be an arcuate shaped wire spaced distally from a distal extremity of the distal end of the cannula whereby tissue is ablated along the length of the RF electrode and displaced by the distal end of the cannula as it is advanced through the tissue. Often it is desirable to image the cannula and sentinel lymph node with an ultrasound imaging system during insertion of the cannula into the patient's body.

The proximity of the distal end of the cannula to a radioactive or "hot" sentinel lymph node can be determined by inserting a radiation energy detector probe through the inner lumen of the hollow outer shaft of the cannula and detecting an amount of radiation energy emanating from the tissue along the longitudinal axis of the hollow outer shaft. The hollow outer shaft or the radiation energy detector within the outer hollow shaft can be manipulated while in the patient to detect the amount of radiation energy emanating from various portions of the tissue as they pass in front of the distal end of the radiation energy detector during the manipulation.

The relative amount of radiation detected from the various portions of tissue adjacent the longitudinal axis of the hollow outer shaft can be compared by a visual or audio signal or the like in order for the operator of the system to determine the position of the radiation energy detector where the maximum signal strength exists. The input of the radiation energy detector can be configured so as to maximize output signal strength when a hot sentinel lymph node is disposed directly distal of the distal end of the radiation energy detector. Thus, by maximizing the output signal, the operator can determine the precise location of a hot sentinel lymph node.

Once it is confirmed that the distal end of the outer hollow shaft of the cannula is disposed adjacent a hot sentinel node, the distal end of an anchor device can be inserted through the inner lumen of the outer hollow shaft and secured to the sentinel lymph node. The anchor device can be secured to the sentinel node by deploying at least one extension wire from the distal end of the anchor device into the sentinel lymph node. In addition, an outer extremity of the extension wires can be configured to emit RF energy during deployment of the extension wire so as to ablate tissue adjacent a distal end of the extension wire as it is being advanced through tissue during deployment. Ablation energy activation of the distal ends of the extension wires facilitates penetration of tissue during deployment of the extension wires.

An embodiment of an anchor device for locating a desired portion of tissue within a patient can have an elongate shaft with a proximal and distal end. At least one extension wire is disposed at the distal end of the elongate shaft having a withdrawn configuration and a deployed configuration extending from the distal end of the shaft. The anchor device may also include a deployment actuator disposed proximal of the distal end of the elongate shaft and configured to deploy the extension wire from a retracted configuration to an extended configuration. The deployment actuator of the anchor device can be configured to both extend the extension wires and activate RF energy to the extension wires. One embodiment of an anchor device may have markings spaced at predetermined intervals to delineate the diameter of extension of the extension wires.

In one embodiment of an anchor device, an RF electrode is disposed on the distal end of the elongate shaft configured to ablate and penetrate tissue in a manner similar to the RF electrode on the distal end of the cannula discussed above. An RF electrode on the distal end of the elongate shaft can be in the form of an arcuate wire spaced distally from the distal extremity of the distal end of the elongate shaft and optionally may lie in substantially the same plane as the longitudinal axis of the elongate shaft.

A radiation energy detector for locating the position of radioactive tissue within the body of a patient suitable for use with the methods discussed above can be an elongate shaft having a proximal end, a distal end and an outer transverse dimension of the distal end of up to about 4 mm. A detector body is disposed at the distal end of the elongate shaft which is collimated to receive radiation energy at an angle of up to about 30°, preferably about 10° to about 20° from a longitudinal axis of the elongate shaft. A detector body signal processor is coupled to the detector body. A handle assembly can be disposed at the proximal end of the elongate shaft of the radiation energy detector. The length of the elongate shaft is typically configured to access to a patient's tissue through an inner lumen of a cannula and can be about 5 to about 15 cm.

The detector body signal processor can be configured to emit an audible signal to a user of the detector which has an amplitude which increases logarithmically in relation to an increase in the amount of radiation energy being detected. Alternatively, the detector body signal processor can produce a visual signal to a user of the detector which is proportional in amplitude to the amount of radiation energy being detected.

These and other advantages of the invention will become more apparent from the following detailed description when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagrammatic view of a patient being injected with a radioactive material including monitoring of migration of the radioactive material from a lesion site to a sentinel node with a hand held radiation energy detector and a gamma camera.

FIG. **2** is a diagrammatic view of a medical procedure having features of the invention including ultrasonic imaging of insertion of a cannula with an RF electrode disposed on the distal end of the cannula.

FIG. **3** is a perspective view of a cannula with a two element RF electrode disposed on the distal end of the cannula with the RF electrode in an expanded state.

FIG. **4** is an elevational view in partial longitudinal section of a cannula with a two element RF electrode on the distal end in an expanded state.

FIG. **5** is an elevational view in partial longitudinal section of the cannula of FIG. **4** with the distal end of the inner shaft retracted into a hollow outer shaft and the RF electrode in a contracted state within the hollow outer shaft.

FIG. **6** is a schematic view of an outer hollow shaft of a cannula disposed within a patient with the inner shaft of the cannula withdrawn and the distal end of the outer hollow shaft adjacent a sentinel lymph node. A radiation energy detector probe is positioned for insertion into the outer hollow shaft of the cannula.

FIG. **7** is an elevational view in partial section of a radiation energy detector disposed within an outer hollow shaft of a cannula with the distal end of the radiation energy detector probe disposed adjacent a first sentinel lymph node and a second sentinel lymph node with the longitudinal axis of the outer hollow shaft and radiation energy detector probe substantially aligned with the center of the first sentinel lymph node.

FIG. **8** is a diagrammatic view of the distal end of a radiation energy detector probe disposed adjacent a first and second sentinel lymph node with the longitudinal axis of the detector probe substantially aligned with the center of the first sentinel lymph node and a phantom outline of the distal end of the radiation energy detector probe wherein the longitudinal axis thereof is substantially aligned with the center of the second sentinel lymph node.

FIG. **9** is a perspective view of an anchor device having features of the invention.

FIG. **10** is an elevational view in partial longitudinal section of an anchor device having features of the invention, wherein the extension wires at the distal end of the anchor device are in a retracted position.

FIG. **11** is an elevational view in partial section of the anchor device of FIG. **10** with the extension wires in an expanded position extending radially outward from a longitudinal axis of the anchor device.

FIG. **12** is a transverse cross sectional view of a handle assembly of the anchor device of FIG. **11** taken along lines **12—12** of FIG. **11**.

FIG. **13** is a transverse cross sectional view of the elongate shaft of the anchor device of FIG. **11** taken along lines **13—13** in FIG. **11**.

FIG. **14** is an end view in partial transverse cross section of the distal end of the anchor device of FIG. **11** taken along lines **14—14** of FIG. **11**.

FIG. **15** is a top view of the actuator switch of the anchor device of FIG. **11** in a fully forward distal position corresponding to full extension of the extension wires in an outward radial direction.

FIG. **16** is a schematic view of an anchor device being inserted into an outer hollow shaft of a cannula the distal end of which is disposed adjacent a sentinel lymph node.

FIG. **17** is an enlarged view in partial longitudinal section of the anchor device of FIG. **16** wherein the distal end of the anchor device is disposed within a sentinel lymph node of the patient with the extension wires in a retracted position.

FIG. **18** is an enlarged view in partial section of the anchor device of FIG. **16** wherein the distal end of the anchor device is disposed within a sentinel lymph node of the patient with the extension wires in an extended position wherein the extension wires have pierced and are mechanically secured to the sentinel lymph node.

FIG. **19** is a schematic view of an outer hollow shaft of a cannula and a handle assembly of an anchor device being removed from the patient proximally with the distal shaft of the anchor device remaining within the patient with the distal end of the anchor device secured to the sentinel lymph node with the extension wires.

FIG. **20** is an elevational view in partial section of an anchor device having features of the invention including extension wires which are radially extendable from the distal end of the anchor device, an expandable RF electrode on the distal end of the anchor device and a radiation detector probe disposed within an inner lumen of the anchor device and which is optionally axially moveable within the inner lumen of the anchor device.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** illustrates a patient **10** being injected with a radioactive material or radiopharmaceutical via a syringe **11** having a hypodermic needle **12** at a lesion site **13** within the patient's breast **14**. Monitoring of migration of the radiopharmaceutical **15** from the injection location **16** in or near the lesion site **13** to a sentinel node **17** is carried out with a hand held radiation energy detector **21** or alternatively a gamma camera **22**. The approximate position of the sentinel lymph node **17** is determined by detecting radiation from the radioactive material **15** accumulated within the sentinel lymph node **17** with the hand held radiation detector **21** or the gamma camera **22**. Radioactive material **15** such as Technetium 99 m, Indium 111, Iodine 123 or Iodine 125 can be injected in a fluid into the site of a primary lesion **13** and the migration of the radioactive material through lymph ducts to the patient's corresponding sentinel lymph nodes **17** and other surrounding lymph nodes observed.

By correctly timing the observation of the radiation energy signals coming from the patient's body after injection of the radioactive substance **15**, it is possible to locate the sentinel lymph nodes **17** corresponding to the lesion site **13**. The sentinel lymph nodes **17** corresponding to a given lesion site **13** or other site of interest within a patient's body are those lymph nodes to which lymph fluid emanating from the lesion site drains to first. As discussed above, the lymph nodes which correspond to the breast area are typically located in the armpit of the patient and are connected to the breast tissue **14** of the patient **10** by a series of lymph ducts. Lymph nodes of the axilla are approximately 1 to 2 cm in diameter and are approximately 1 to 5 inches deep in the tissue of the armpit area.

The sentinel lymph nodes **17** can be in fluid communication with other surrounding lymph nodes, however, lymph drainage from the lesion site **13** will first flow to the sentinel lymph nodes **17**. Thereafter, lymph fluid drainage may then continue on to lymph nodes surrounding the sentinel nodes **17**. Therefore, if a patient **10** is monitored or observed with a hand held radiation detector **21** or gamma camera **22** after the radioactive material **15** has migrated through the lymph ducts to the sentinel lymph nodes **17** but prior to dispersion of the radioactive material to the lymph nodes surrounding the sentinel nodes, an accumulation of radioactive material **15** will be observed in the sentinel lymph nodes **17**. These hot sentinel nodes **17** will be clearly distinguishable from surrounding non-radioactive lymph nodes using radiation energy detectors from outside the patient's body **10**, thus indicating an approximate position of nodes **17** in a non-invasive manner.

The hand held radiation energy detector **21** has a hand held probe **23** with a proximal end **24** and a distal end **25**, a control and display unit **26**, and an electrical conduit or cable **27** disposed between the control unit **26** and the hand held probe **23**. The control unit **26** can produce an audible or visual output that is commensurate with the amplitude of radiation energy signal being received at the distal end **25** of the hand held probe **23**. Typically, the hand held probe **23** will only detect radiation energy which impinges in a proximal direction upon the distal end **25** of the hand held probe **23** at some predetermined angle with respect to a longitudinal axis **31** of the hand held probe **23**. Thus, by manipulating the location and direction of the distal end **25** of the hand held probe **23**, the approximate location of the hot sentinel lymph nodes **17** within the patient **10** can be determined by maximizing the audio or visual signal generated by the control and display unit **26**.

The gamma camera **22** shown in FIG. **1** has a receiver unit **33**, a control unit **34** and a display **35**. Radiation energy emitted from the radioactive material **15** injected into the patient **10** travels through the tissue of the patient **10** to the receiver unit **33** which then generates an electrical signal at a location corresponding to the location of the radioactive material source in the patient **10**. The signal or hits from the radiation energy which impinges on the receiver **33** can be accumulated or stored such that the display **35** will show all hits received from the various portions of the receiver **33**. In this way, the relative location of radioactive material **15** in the patient's body **10** can be seen on the display and particularly locations in the patient's body **10** where radioactive material **15** has accumulated. The skin of the patient **10** can be marked with a visible mark above the location of the sentinel lymph node **17** to indicate the approximate position of the sentinel node **17** for future reference during the procedure.

Once the approximate position of the sentinel lymph nodes **17** of a patient **10** corresponding to a primary lesion site **13** is determined, an access device **36** may be used to reach tissue over the lymph nodes. This allows locating the sentinel nodes **17** with greater precision. FIG. **2** shows ultrasonic imaging of insertion of an access device **36** consisting of a cannula **37** having an RF electrode **41** disposed on the distal end **42** of the cannula **37**, an RF energy generator **43** in electrical communication with the RF electrode **41**, a cannula handle assembly **44** at a proximal end **45** of the cannula **37** and a ground pad **46** secured to and in electrical communication with the patient's body **10** and the RF generator **43**. The sentinel lymph node **17** is accessed by passing the cannula **37** with the RF electrode **41** energized to emit RF energy therefrom into the patient's body **10** until the distal end **42** of the cannula **37** is disposed adjacent the sentinel lymph node **17**.

The RF generator **43** for the RF electrode **41** can be any of a variety of standard electrosurgical units generating radiofrequency energy in a range of about 300 to about 6,000 kHz, specifically, about 350 to about 1,000 kHz. Power output for the RF generator **43** can be about 25 to about 150 watts, preferably about 75 to about 125 watts. The RF electrode **41** can be made of a variety of materials, including stainless steel, tungsten, nitinol and the like. The RF electrode material may have a cross section that is round, rectangular, oval or any other suitable configuration and generally has a transverse dimension of about 0.001 to about 0.015 inch, specifically about 0.006 to about 0.010 inch.

Because large arteries and nerves are generally located in the same area as the axillary lymph nodes of a patient **10** and could be compromised without an accurate and noninvasive access device **36**, ultrasonic imaging can be used while the cannula **37** is being inserted into the patient **10**. An ultrasonic imaging system **47** having a transducer **51**, transducer cable **52**, control unit **53** and display **54** is shown in FIG. **2**. The two sentinel lymph nodes **17** are imaged on the display **54**. The relative location of the target sentinel lymph node **17** and cannula **37** can be imaged and monitored during insertion of the cannula **37** to ensure accurate placement of the cannula and avoidance of sensitive anatomical features such as nerves and arteries. Because RF tissue ablation frequently interferes with ultrasonic imaging and the like, it may be desirable to use a system for reduction of such interference such as is taught by copending U.S. patent application Ser. No. 09/527,868, by Dabney et al., filed Mar. 17, 2000, which is hereby incorporated by reference herein in its entirety.

Referring to FIGS. **3–5** the cannula **37** is shown with a two element RF electrode **41** disposed on the distal end **42** of the cannula **37**. A outer hollow shaft **55** having an inner lumen **56** is slidingly disposed about an inner shaft **57** having the RF electrode **41** disposed on the distal end **61** of the inner shaft **57**. The RF electrode **41** has a first electrode element **62** and a second electrode element **63** which overlap at the intersection with the longitudinal axis **64** of the cannula **37** extending from the distal end **42**. This arrangement allows for the first and second electrode elements **62** and **63** to be expandable to an outer transverse dimension equal to or slightly greater than the circumference of the outer hollow shaft **55**. This enables easy insertion of the cannula assembly **37** into the patient **10** as the RF electrode **41** is activated and ablates tissue. The expandability and retractability of the RF electrode **41** allows the inner shaft **57** to be withdrawn from the outer hollow shaft **55** prior to insertion to provide access through the outer hollow shaft **55** to a sentinel lymph node **17** or other tissue area of interest within a patient **10**.

The RF electrode **41** is an arcuate shaped wire **65** spaced distally from a distal extremity **66** of the distal end **42** of the cannula **37**. When the electrode **41** is activated with RF energy, tissue is ablated along the length of the RF electrode **41** and displaced by the distal end **42** of the cannula **37** as it is advanced through the tissue. FIG. **4** shows the RF electrode **41** on the distal end **42** of the cannula **37** in an expanded state in which the transverse dimension of the RF electrode **41** as a whole is greater than the outer diameter of the outer hollow shaft **55**. In FIG. **5**, the distal end **61** of the inner shaft **57** of the cannula **37** is withdrawn into the inner lumen **56** of the hollow outer shaft **55** and the RF electrode **41** is in a contracted state within the inner lumen hollow outer shaft.

FIG. **6** shows an outer hollow shaft **55** of a cannula **37** disposed within a patient **10** with the inner shaft **57** of the cannula **37** withdrawn and the distal end **67** of the outer hollow shaft **55** adjacent a sentinel lymph node **17**. A radiation energy detector **71** having a signal processor unit **72**, a handle assembly **73** and a radiation detector probe **74** with a proximal end **75** and distal end **76** is positioned to have the distal end **76** of the radiation energy detector probe **74** inserted into the inner lumen **56** of the outer hollow shaft **55**. A cable **77** is in communication with the signal processor unit **72** and a proximal end **81** of the handle assembly **73**.

In FIG. **7**, the radiation energy detector probe **74** is shown disposed within the outer hollow shaft **55** of the cannula **37**. The distal end **76** of the radiation energy detector probe **74** is disposed adjacent a first sentinel lymph node **82** and a second sentinel lymph node **83** with a longitudinal axis **84** of the outer hollow shaft **55** and longitudinal axis **85** of the radiation energy detector probe **74** substantially aligned with the center **86** of the first sentinel lymph node **82**. The radiation energy detector probe **74** detects radiation energy emanating from the tissue along the longitudinal axis **85** of the probe **74** in a proximal direction relative to the probe. The hollow outer shaft **55** or the radiation energy detector probe **74** within the outer hollow shaft **55** can be manipulated, as shown in FIG. **8**, while in the patient **10** to detect the amount of radiation energy emanating from various portions of the tissue as they pass in front of the distal end **76** of the radiation energy detector probe **74** during the manipulation.

The amount of radiation detected from the various portions of tissue adjacent the longitudinal axis **84** of the hollow outer shaft **55** can be compared by observation of a visual or audio signal or the like generated by the signal processor unit **72** in order for the operator of the system to determine the position of the radiation energy detector probe **74** where the maximum signal strength exists. The input of the radiation energy detector probe **74** at the distal end **76** of the probe **74** can be configured or collimated so as to maximize output signal strength when a sentinel lymph node **17** emitting a relatively large amount of radiation ("hot" sentinel lymph node) is disposed directly distal of the distal end **76** of the radiation energy detector probe **74**. Thus, by maximizing the output signal from the signal processor unit **72**, the operator can determine the precise location of a hot sentinel lymph node **17** and effectively discriminate surrounding non-radioactive tissue and non-radioactive nodes.

In FIG. **8**, the longitudinal axis **85** of the detector probe **74** is substantially aligned with the center **86** of the first sentinel lymph node **82**. A phantom outline of the distal end of the radiation energy detector probe is also shown substantially aligned with the center **91** of the second sentinel lymph node **92** after manipulation of the distal end **76** of the radiation energy detector probe **74** from the proximal end **75** of the radiation energy detector probe **74** or the proximal end **93** of the outer hollow shaft **55** of the cannula **37**. The diameter of the elongate probe **74** of the radiation energy detector distal end can be about 1 to about 6 mm, specifically about 3 to about 5 mm, and more specifically about 4.0 to about 4.4 mm.

A detector body (not shown) is disposed within the distal end **76** of the elongate radiation energy detector probe **74** which is collimated to receive radiation energy at an angle of up to about 30°, preferably about 10° to about 20°, from a longitudinal axis **85** of the elongate radiation energy detector probe. The detector body can be designed to encompass the radiation emitted from a 1 cm node at a distance of 1 cm. The detector body can be configured or collimated to have enhanced reception of radiation energy from the distal end as opposed to side impingement of radiation energy. The detector body is coupled by the cable **77** to the signal processor unit **72**. The detector body can be configured to specifically detect gamma radiation or any other suitable form of radiation energy including alpha or beta radiation. The handle assembly **73** of the radiation energy detector **71** can have a preamplifier within it to increase the signal from the detector body to the signal processor unit **72**. The handle **73** typically has a diameter or transverse dimension of about 25–30 mm. The length of the radiation energy detector probe **74** is typically configured to access to a patient's tissue through an inner lumen of a cannula and can be about 5 to about 15 cm.

The signal processor unit **72** of the radiation energy detector **71** can be configured to emit an audible signal to a user of the detector which has an amplitude which increases logarithmically in relation to an increase in the amount of radiation energy being detected. Alternatively, the detector body signal processor unit **72** can produce a visual signal to a user of the detector which is proportional in amplitude to the amount of radiation energy being detected. The signal processor **72** has a display **95** with a digital readout of counts per second and total counts for given time period. The radiation energy detector **71** can typically detect radiation at useable levels from a hot lymph node from a distance of about 10 to about 12 cm, but is most accurate at a distance of about 2 to about 3 cm.

Referring to FIGS. **9–19**, an anchor device **100** and use thereof is shown. The anchor device **100** has a housing **101**, an inner conductor **102**, a main shaft **103** disposed within an inner lumen **104** of the inner conductor **102**, an actuator **105** coupled to the inner conductor **102** for extending the extension wires **106** and an RF energy generator **107** switchably coupled to the inner conductor **102** and elongate shaft **111** with a proximal end **112** and distal end **113**. At least one extension wire **106** is disposed within the distal end **113** of the elongate shaft **111** coupled to a distal end **114** of the inner conductor **102** and having a withdrawn configuration and a deployed configuration extending radially from the distal end **113** of the shaft **111**, or in some other suitable direction. A deployment actuator **105** is disposed proximal of the distal end **113** of the elongate shaft **111** and configured to deploy the extension wire **106** from a retracted configuration to an extended configuration.

Markings **115** on the housing **101**, as shown in FIG. **15**, may be spaced at predetermined intervals to delineate the diameter of extension of the at least one extension wire **106** by movement of actuator **105**. As shown in FIG. **16**, a first electrical conductor **116** can be electrically coupled to the inner conductor **102** and the RF energy generator **107** and a second electrical conductor **117** electrically coupled to the patient **121** as a ground plate **122** for the RF energy generator **107**. RF energy may be applied to the extension wires during deployment and extension thereof to aid in the advancement thereof through tissue. However, if RF energy is to be applied, the extension wires should be insulated along their lengths except for the distal tips thereof. The first electrical conductor **116** can be coupled to the extension wires **106** at the proximal end of the shaft **111** with a detachable coupler **123**.

The anchor device **100** is generally inserted through the outer hollow shaft **124** of a cannula **125** and into a sentinel lymph node **126**. The distal end **127** of the anchor device **100** is then secured to the sentinel lymph node **126**. Once the distal end **127** of the anchor device **100** is secured to the lymph node **126**, the patient **121** can be transferred to a surgical suite and the lymph node **126** surgically removed with the anchor device **100** attached thereto serving as a locating device.

In the embodiment of the anchor device shown in FIGS. **9-19**, the distal end **127** of the anchor device **100** can be secured to the sentinel lymph node **126** by deploying at least one extension wire **106** from the distal end **127** of the anchor device **100** into the sentinel lymph node **126** as shown in FIG. **18**. In addition, an outer extremity **131** of the extension wires **106** can be configured to emit RF energy during deployment of the extension wires so as to ablate tissue adjacent the outer extremities **131** of the extension wires **106** to facilitate advancement through tissue during deployment. Radial extension of the extension wires **106** from the anchor device **100** can be from about 1 to about 30 mm, specifically about 3 to about 25 mm, and more specifically about 5 to about 12 mm when deployed fully.

FIG. **10** shows the anchor device **100** where the extension wires **106** at the distal end **127** of the anchor device **100** are in a retracted position. A spring loaded electrical contact **132** is disposed within the coupler **123** disposed on the distal end **133** of first conductor **116**. The electrical contact **132** is slidingly and electrically coupled to a first conductor **116** which is secured to and in electrical communication with a proximal end **134** of the inner conductor **102**. The first conductor **116** is able to slide within the spring loaded contact **132** maintaining an electrical path between conductor **116** and inner conductor **102** while allowing axial translation of the inner conductor **102** relative to the coupler **123** and housing **101**.

Actuator switch **105** is mechanically coupled to inner conductor **102** and slidingly engaged in a slot **135** in the housing **101** with an abutment **136** extending radially from the slot **135** in the housing **101** to facilitate axial movement by the operator of the anchor device **100**. In FIG. **10** the actuator switch **105** and abutment **136** are in the most proximal position within the slot **135** which corresponds to the radially retracted position of the extension wires **106**. FIG. **11** shows the extension wires **106** in a radially expanded position extending radially outward from a longitudinal axis **137** of the anchor device **100** with the actuator switch **105** in its corresponding most distal forward position.

FIG. **15** shows a top view of the actuator switch **105** of the anchor device **100** in a fully forward distal position corresponding to full extension of the extension wires **106** in an outward radial direction as shown in FIG. **10**. Also in FIG. **15** the axial markings **115** can be more clearly seen with numerical designations which may correspond to the diameter or radius of the extension wires **106** at the distal end **127** of the anchor device **100**. In FIG. **16** the anchor device **100** is being inserted into an outer hollow shaft **124** of a cannula **125** the distal end **141** of which is disposed adjacent a sentinel lymph node **126**. The inner conductor **102** of the anchor device **100** is electrically coupled to a conductor **116** which is in turn electrically coupled to the RF generator **107**. A ground pad **122** is in electrical contact with the patient **121** and electrically coupled to the RF generator **107** with a second conductor **117**.

FIG. **17** shows the elongate shaft **111** of the anchor device **100** disposed within an inner lumen **142** of the hollow outer shaft **124** of the cannula **125**. The distal end **127** of the anchor device **100** disposed within a sentinel lymph node **126** in the tissue of the patient **121** with the extension wires **106** in a retracted position. In FIG. **18**, the extension wires **106** of the anchor device **100** have been extended into the sentinel lymph node **126** and mechanically secured thereto. In FIG. **19**, the outer hollow shaft **124** of the cannula **125** and housing **101** of the anchor device **100** are being removed proximally from the patient **121**. The elongate shaft **111** of the anchor device **100** remains within the patient **121** with the distal end **127** of the anchor device **100** secured to the sentinel lymph node **126** with the extension wires **106** in an extended position. Thereafter, the patient **121** may be taken to surgery to have the lesion excised or otherwise treated with the elongate shaft **111** of the anchor device **100** serving as a positive location means during the procedure.

In use during a typical procedure, radioactive material **15** is injected in patient's body **10** near a primary lesion site **13** or other site of interest within the patient **10**. The approximate position of a sentinel lymph node **17** within the patient's body **10** is determined by detecting radiation from the radioactive material **15** accumulated within the sentinel lymph node **17** with a radiation detector **21** or **22** external to the patient's body **10**. The sentinel lymph node **17** can then be accessed with a cannula **37** having an RF electrode **41** disposed on a distal end **42** of the cannula **37** by activating the RF electrode to ablate tissue while passing the cannula into the patient's body **10** until the distal end **42** of the cannula **37** is disposed adjacent the sentinel lymph node **17**.

Once the distal end **42** of the cannula **37** is positioned adjacent the sentinel lymph node **17**, the proximity of the distal end **42** of the cannula **37** to the sentinel lymph node **17** can be optimized by inserting a radiation energy detector probe **74** into an inner lumen of a hollow outer shaft **55** of the cannula **37** and manipulating a distal end **76** of the radiation energy detector probe **74** **50** as to positively identify the position of the targeted sentinel node **17** by maximizing radiation energy received by the radiation energy probe from the targeted sentinel node.

An anchor device **100** can then be inserted through the cannula **37** and into the sentinel lymph node **17**. The distal end **127** of the anchor device **100** can then be secured to the sentinel lymph node **17**. Once the distal end **127** of the anchor device **100** is secured to the lymph node **17**, the patient **10** can be transferred to a surgical suite and the lymph node **17** surgically removed with the anchor device **100** or a portion thereof attached thereto.

Referring to FIG. **20**, an alternative embodiment of an anchor device **150** is shown having features of the invention. The anchor device **150** has extension wires **151** which are radially extendable from the distal end **152** of the anchor device **150**, an expandable RF electrode **153** on the distal end **152** of an elongate shaft **154** of the anchor device **150** and a radiation detector probe **155** which is disposed within an inner lumen **156** of the anchor device **150** and which is optionally axially moveable within the inner lumen **156** of the anchor device **150**.

The RF electrode **153** is configured to ablate and penetrate tissue in a manner similar to the RF electrode **41** on the distal end **42** of the cannula **37** discussed above. The RF electrode **153** on the distal end **152** of the elongate shaft **154** is an arcuate wire having two separate electrode elements, a first electrode element **157** and a second electrode element **158**, spaced distally from a distal extremity **161** of the distal end **152** of the elongate shaft **154**. The RF electrode **153** of the embodiment shown lies in substantially the same plane as a longitudinal axis **162** of the elongate shaft **154** of the anchor device **150**.

In use during a typical procedure for this embodiment, radioactive material is injected into a patient's body near a primary lesion site or other site of interest within the patient. The approximate position of a sentinel lymph node within the patient's body is determined by detecting radiation from the radioactive material accumulated within the sentinel lymph node with a radiation detector external to the patient's body. The sentinel lymph node (shown in phantom in FIG. **20**) can then be accessed with the anchor device **150** having the RF electrode **153** disposed on a distal end **152** of the anchor device **150** by activating the RF electrode **153** to ablate tissue while passing the distal end **152** of the anchor device into the patient's body until the distal end **152** of the anchor device is disposed adjacent the sentinel lymph node.

Once the distal end **152** of the anchor device **150** is positioned adjacent the sentinel lymph node, the proximity of the distal end **152** of the anchor device to the sentinel lymph node can be optimized by manipulating the distal end of the anchor device so as to maximize signal output by the radiation energy detector **155** within the anchor device **150**. The distal end **152** of the anchor device **150** can be secured to the sentinel lymph node by the extension of extension wires **151** into the node. Once the distal end **152** of the anchor device **150** is secured to the lymph node, the patient can be transferred to a surgical suite and the lymph node surgically removed with the anchor device attached thereto.

While particular forms of the invention have been illustrated and described, it should be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A method of locating and accessing a sentinel lymph node of a patient which corresponds to a lesion site within the patient's body comprising:

a) injecting a radioactive material near the lesion site of the patient;

b) locating the approximate position of a sentinel lymph node within the patient's body by detecting radiation from the radioactive material accumulated within the sentinel lymph node with a radiation detector;

c) accessing the located sentinel lymph node with a probe assembly comprising an outer hollow cannula and a tissue penetrating multi-lobed electrode disposed on a distal end of the probe assembly by activating an RF power source connected to the electrode to cut through tissue while passing the probe assembly into the patient's body until the distal end of the probe assembly is disposed adjacent the located sentinel lymph node;

d) passing an anchor device through the cannula until a distal end thereof is disposed within the located sentinel lymph node; and

e) securing the distal end of the anchor device to the located sentinel lymph node by an outwardly extending anchoring member.

2. The method of claim **1** wherein the distal end of the anchor device is secured to the located sentinel lymph node by deploying a plurality of outwardly extending anchoring members from the distal end of the anchor device into the located sentinel lymph node.

3. The method of claim **2** wherein an outer extremity of at least one outwardly extending anchoring member is configured to emit RF energy and further comprising activating the outer extremity of at least one outwardly extending anchoring member to emit RF energy during deployment thereof.

4. The method of claim **1** wherein the outer hollow cannula comprises an inner lumen and a probe member which is slidably disposed within the inner lumen and which has said multi-lobed RF electrode disposed on the distal end of the probe member and wherein the method further comprises withdrawing the probe member from the inner lumen of the cannula and inserting an anchor device through the inner lumen of the cannula to access the located sentinel lymph node.

5. The method of claim **4** wherein the position of the distal end of the cannula adjacent to the located sentinel lymph node is confirmed by inserting a radiation energy detector through the inner lumen of the outer hollow cannula and detecting an amount of radiation energy emanating from the tissue along the longitudinal axis of the cannula and manipulating the cannula and or the radiation energy detector to detect the amount of radiation energy emanating from the tissue adjacent the longitudinal axis of the cannula and comparing the amounts of radiation detected from various portions of tissue.

6. The method of claim **1** wherein a gamma camera is used to determine the approximate position of the located sentinel lymph node within the patient's body prior to accessing the sentinel lymph node with the probe assembly.

7. The method of claim **1** wherein a hand-held radiation detecting wand is used to determine the approximate position of the located sentinel lymph node within the patient's body prior to accessing the sentinel lymph node with the probe assembly.

8. The method of claim **1** wherein the probe assembly and located sentinel lymph node are imaged with an ultrasound imaging system during insertion of the probe assembly into the patient's body.

9. The method of claim **1** further comprising surgically removing the located sentinel lymph node with the anchor device attached thereto and using the anchor device to locate the sentinel lymph node during the surgical procedure.

10. The method of claim **1** further comprising marking the skin of the patient with a visible mark above the location of the located sentinel lymph node prior to accessing the sentinel lymph node with the probe assembly.

11. The method of claim **1** wherein said multi-lobed RF powered electrode comprises a two-lobed RF electrode.

12. The method of claim **11** wherein the outer hollow cannula comprises an inner lumen, the probe assembly further comprises a probe member which is slidably disposed within said cannula inner lumen, and wherein the two-lobed RF electrode comprises a pair of arcuate shaped wire portions spaced distally from the distal end of the probe member whereby tissue is cut along the length of the RF electrode and displaced by the distal end of the probe member as the probe member is advanced through the tissue.

13. The method of claim **1** wherein said multi-lobed electrode comprises an expandable multi-lobed electrode.

14. The method of claim **13** wherein said expandable multi-lobed electrode comprises an expandable two-lobed electrode.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,638,234 B2
DATED : October 28, 2003
INVENTOR(S) : Burbank et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [63], **Related U.S. Application Data**, after “now Pat. No. 6,312,429,” delete “which is” and insert -- and --; and after “now Pat. No. 6,540,693,” delete “which is” and insert -- and --.

Signed and Sealed this

Twenty-fifth Day of May, 2004

JON W. DUDAS
Acting Director of the United States Patent and Trademark Office

专利名称(译)	Sentinel节点位置和活组织检查		
公开(公告)号	US6638234	公开(公告)日	2003-10-28
申请号	US09/727112	申请日	2000-11-29
[标]申请(专利权)人(译)	伯班克FRED ^ h LUBOCK PAUL		
申请(专利权)人(译)	伯班克FRED H. LUBOCK PAUL		
当前申请(专利权)人(译)	SENORX INC.		
[标]发明人	BURBANK FRED H LUBOCK PAUL		
发明人	BURBANK, FRED H. LUBOCK, PAUL		
IPC分类号	A61B17/00 A61B10/00 A61B18/14 A61B17/34 A61B19/00 G01T1/161 A61B10/02 A61N5/04 A61N5/10 A61B6/00 A61B18/18		
CPC分类号	A61B17/00491 A61B18/1477 A61B18/1482 A61B19/54 A61B10/0266 A61B10/02 A61B6/4258 A61B18/1487 A61B18/1815 A61B2010/0208 A61B2017/3488 A61B2018/00208 A61B2018/00273 A61B2018/00333 A61B2018/00577 A61B2018/00916 A61B2018/1407 A61B2018/1425 A61B2018/1475 A61B2019/5276 A61B2019/5404 A61B2019/5408 A61B2019/542 A61B90/39 A61B2090/378 A61B2090/3904 A61B2090/3908 A61B2090/392		
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摘要(译)

一种用于定位和接近患者的前哨淋巴结的方法和设备，所述患者的前哨淋巴结与患者的病变部位相关联。放射性药物注射在患者体内的病变部位处或附近。使用来自患者体外的γ相机或辐射能量检测器监测放射性药物的迁移和放射性药物在患者的前哨淋巴结中的累积。然后可以用套管接触前哨淋巴结，所述套管在套管的远端上具有RF能量电极，所述RF能量电极在插管插入期间被激活。一旦套管的远端定位在前哨淋巴结附近，就通过套管插入锚固装置。然后将锚定装置的远端定位在前哨节点中并固定到前哨节点以用作后续手术的定位器。