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Moorman et al.

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(54) **MODULAR BIOPSY AND MICROWAVE ABLATION NEEDLE DELIVERY APPARATUS ADAPTED TO IN SITU ASSEMBLY AND METHOD OF USE**

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(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61B 18/18**

(52) **U.S. Cl.** **606/41**; 606/33; 600/562; 607/101

(58) **Field of Search** 600/562–572; 606/33, 34, 35, 41, 46; 607/96, 98, 99, 100, 101

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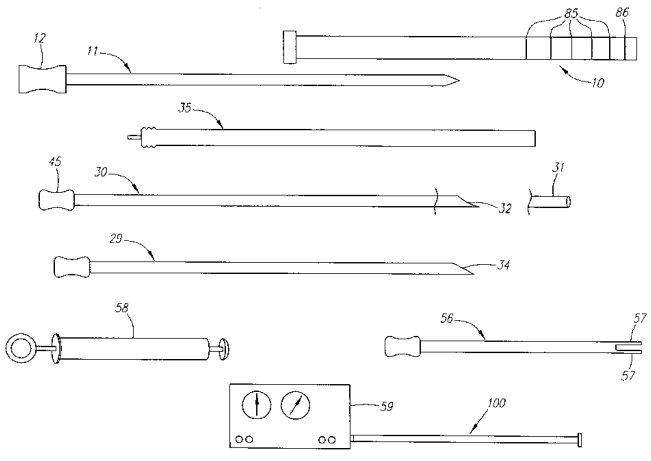
(57) **ABSTRACT**

A modular biopsy, ablation and track coagulation needle apparatus is disclosed that allows the biopsy needle to be inserted into the delivery needle and removed when not needed, and that allows an inner ablation needle to be introduced and coaxially engaged with the delivery needle to more effectively biopsy a tumor, ablate it and coagulate the track through ablation while reducing blood loss and track seeding. The ablation needle and biopsy needle are adapted to in situ assembly with the delivery needle. In a preferred embodiment, the ablation needle, when engaged with the delivery needle forms a coaxial connector adapted to electrically couple to an ablating source. Methods for biopsying and ablating tumors using the device and coagulating the track upon device removal are also provided.

29 Claims, 7 Drawing Sheets



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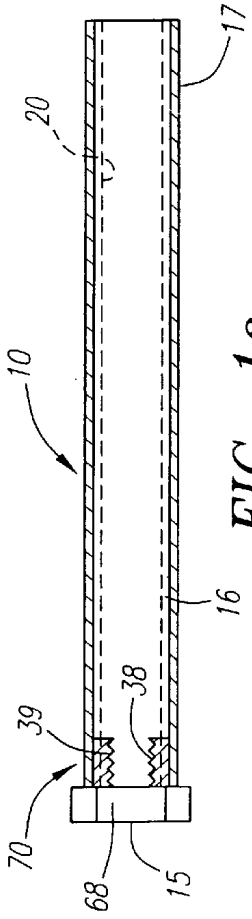

FIG. 1a

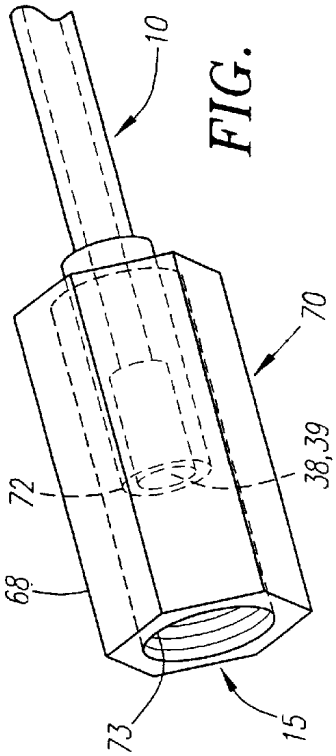

FIG. 1b

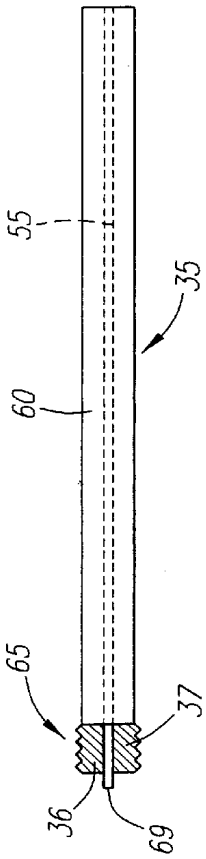

FIG. 1c

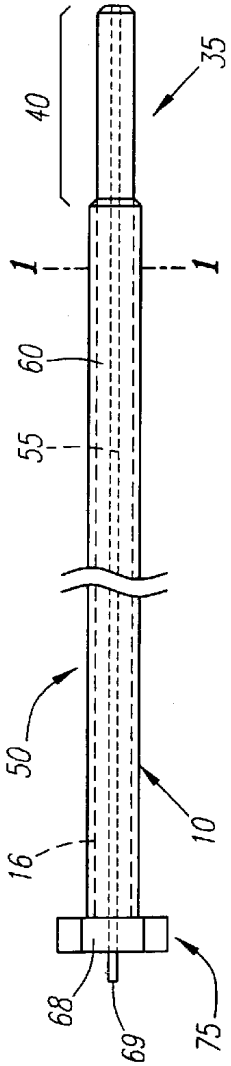

FIG. 1d

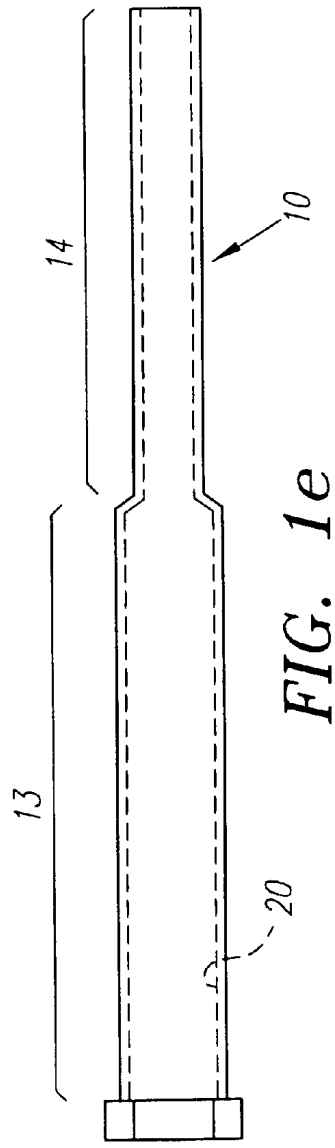

FIG. 1e

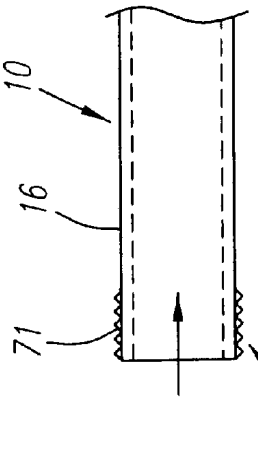

FIG. 1g

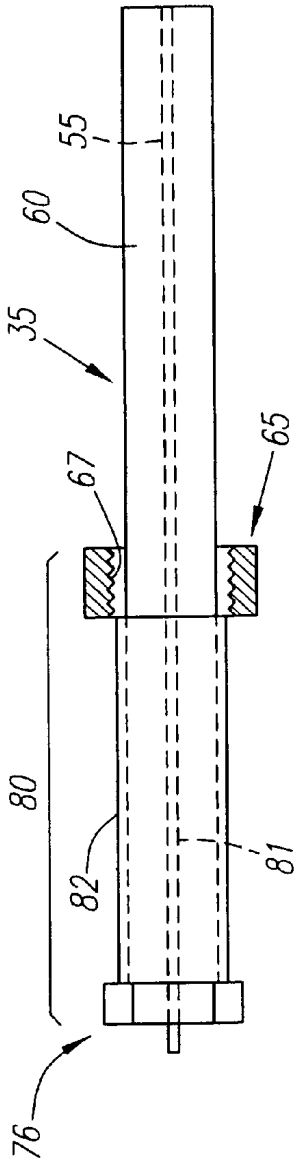

FIG. 1f

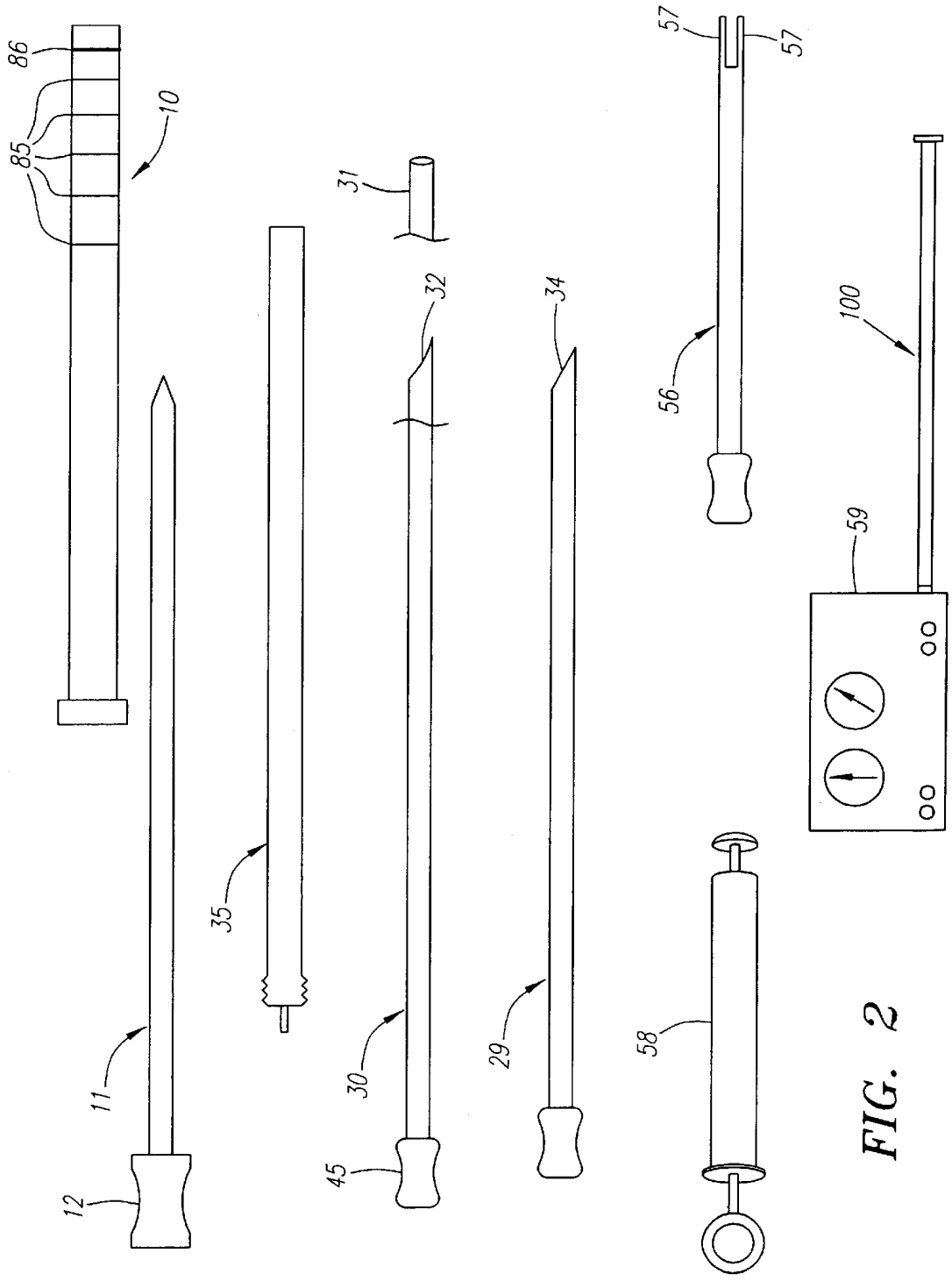

FIG. 2

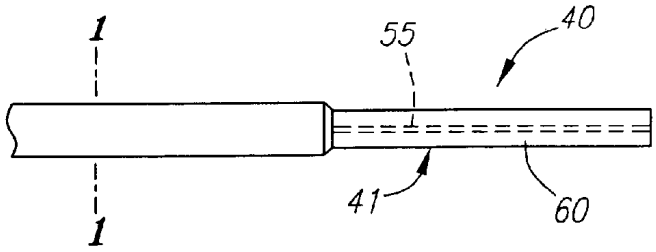

FIG. 3a

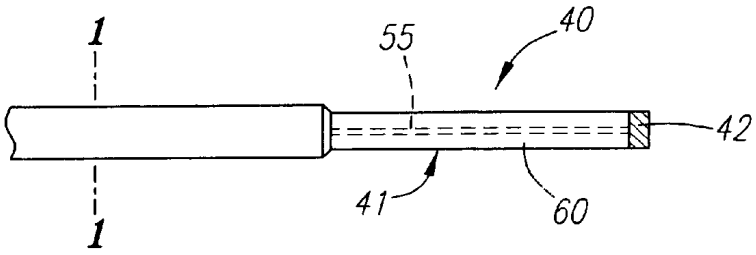

FIG. 3b

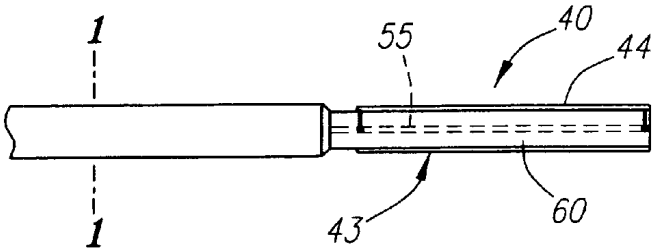

FIG. 3c

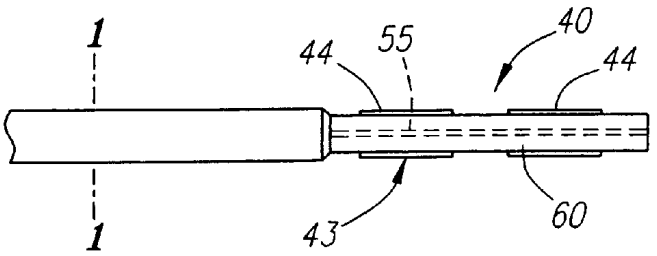

FIG. 3d

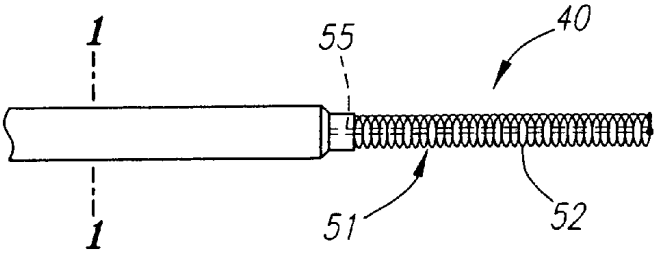

FIG. 3e

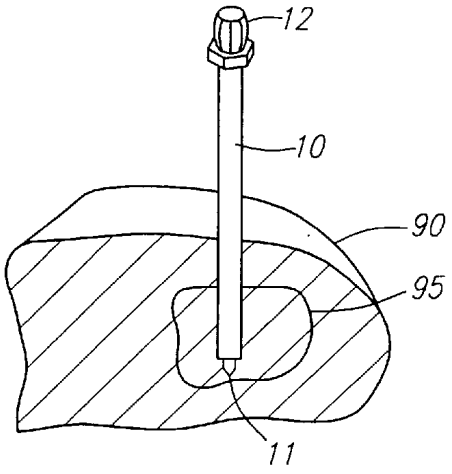

FIG. 4

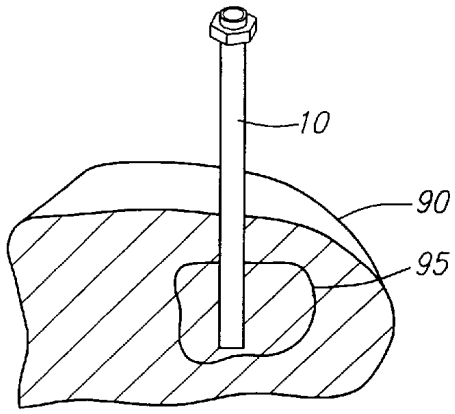

FIG. 5

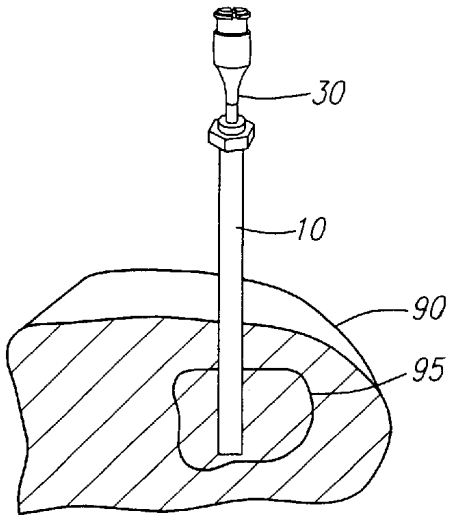

FIG. 6

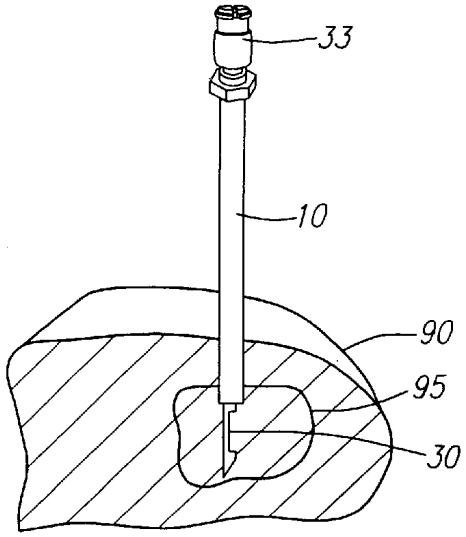

FIG. 7

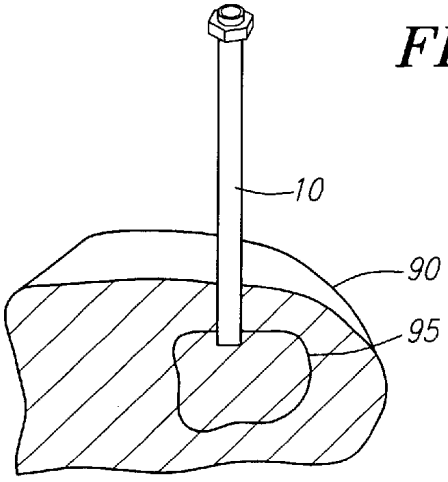

FIG. 8

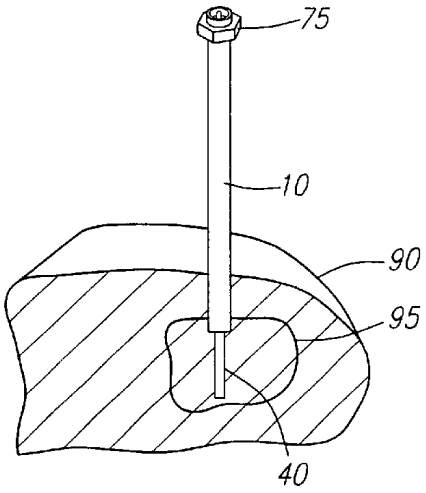

FIG. 9

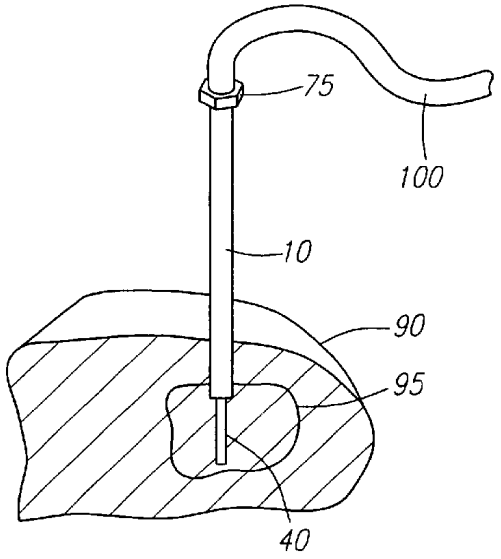

FIG. 10

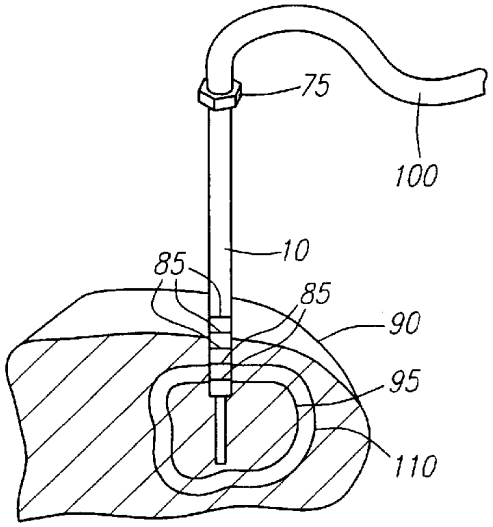

FIG. 11

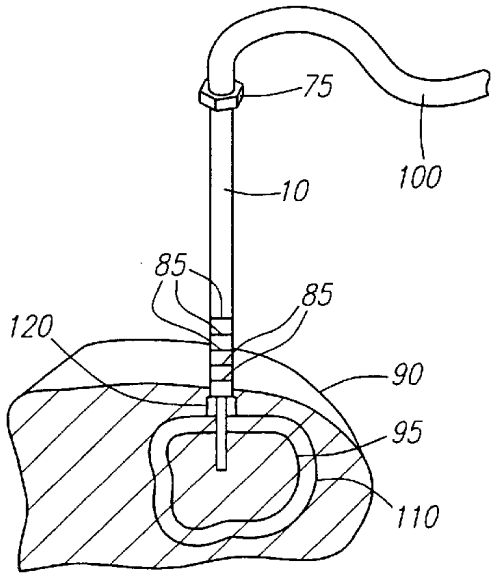

FIG. 12

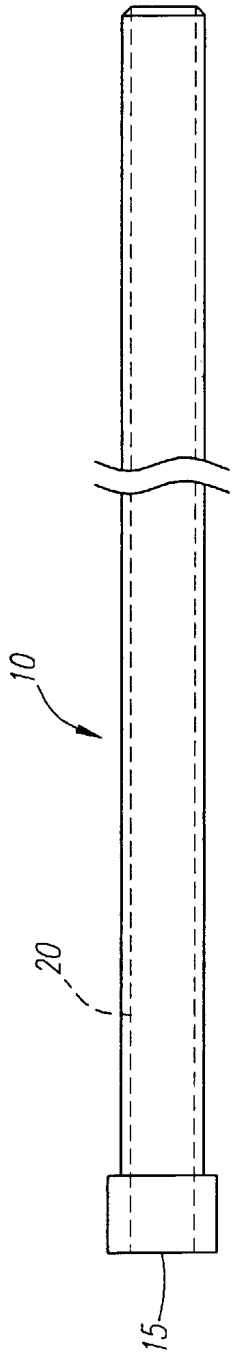

FIG. 13

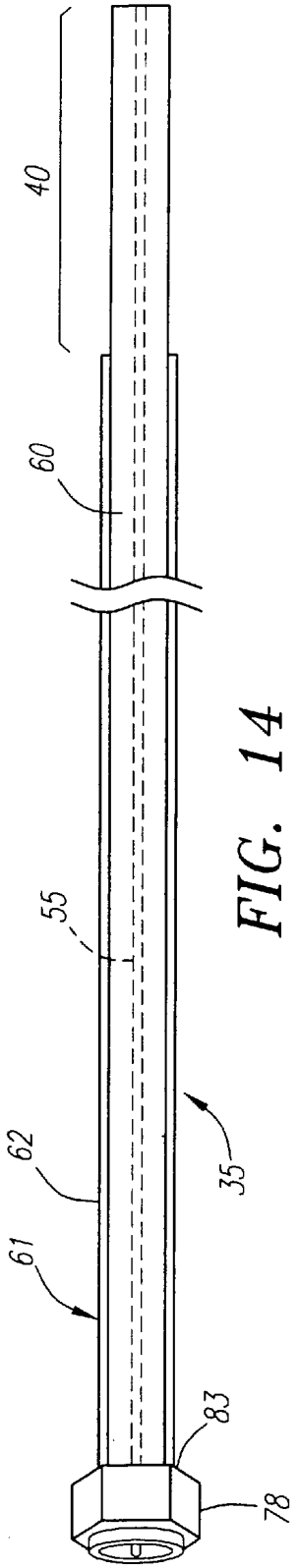

FIG. 14

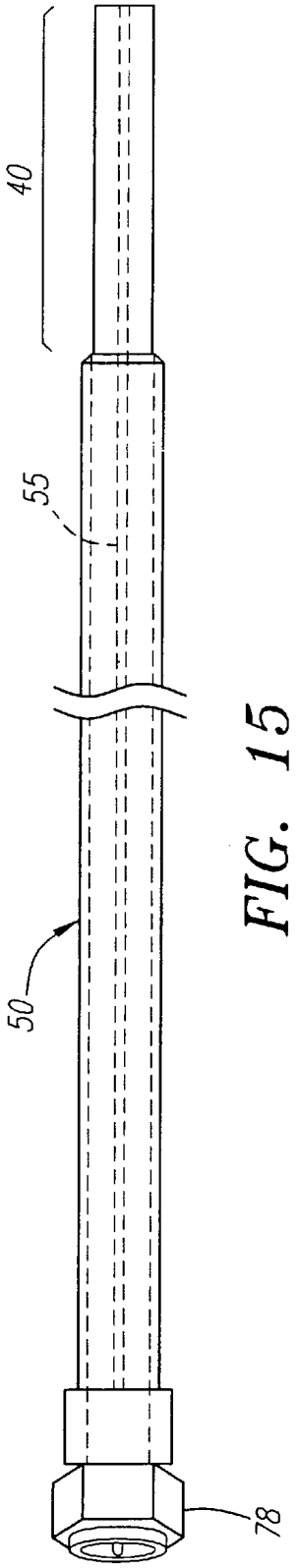

FIG. 15

MODULAR BIOPSY AND MICROWAVE ABLATION NEEDLE DELIVERY APPARATUS ADAPTED TO IN SITU ASSEMBLY AND METHOD OF USE

This application is a Divisional of application Ser. No. 09/336,371, filed Jun. 17, 1999, issued on Oct. 23, 2001 as U.S. Pat. No. 6,306,132.

FIELD OF THE INVENTION

The present invention relates generally to a modular biopsy, ablation and delivery needle apparatus that allows a biopsy needle to be inserted into a delivery needle, and, absent the biopsy needle, allows an inner ablation needle to be introduced and engaged with the delivery needle to form a microwave antenna. The present invention also relates to methods for biopsying and ablating tumors and coagulating the insertion track using the modular apparatus.

BACKGROUND OF THE INVENTION

In the U.S., the lifetime chance of developing an invasive cancer is 46% for men and 38% for women. Cancer is the second leading cause of death in the U.S. and is a major cause of death worldwide. In the U.S. in 1998, there were an estimated 564,800 deaths due to cancer with 1,228,600 new cases of invasive cancer diagnosed. Over 40% of the deaths are associated with primary and metastatic liver cancer.

Outside the U.S., primary liver cancer (hepatocellular carcinoma) accounts for one of the largest cancer-related mortalities in the world (about 1,250,000 per year) in adults. In Japan, liver cancer is the third most common cause of death in men.

Of the over 1 million newly diagnosed U.S. cancer patients each year, hundreds of thousands will develop liver cancer during the course of the disease. For liver metastases that result in or are associated with death, estimates vary but are conservatively estimated at more than 230,000 annually in the U.S. Numerous studies of colorectal carcinoma have shown that liver metastasis is the primary determinant of patient survival.

Patterns of metastasis can be explained in part by the architecture of the circulatory system. Cancers in the intestine and many other tissues often colonize the liver first because the liver contains the first downstream capillary bed. It is estimated that 131,600 new cases of colorectal cancer were detected in 1998 and that 98,000 of them will eventually have liver involvement. Due to a lack of treatment options and the likelihood of recurrence, the American Joint Committee on Cancer projects that less than 1% of the patients diagnosed with nonresectable liver metastasis will be alive in 5 years.

Unfortunately, except for the small number of patients who have a form of cancer that can be surgically resected, there is no effective treatment. Therapies for nonresectable tumors include chemotherapy, radiation, transcatheter arterial embolization, chemoembolization and cryotherapy. Of particular interest are the percutaneous ablative techniques using ethanol, acetic acid, hot saline solution, laser, radiofrequency (RF), microwave, gene therapy and focused ultrasound.

Recent improvements in computed tomography (CT), ultrasound imaging and magnetic resonance imaging (MRI) have enabled physicians to detect tumors at an earlier stage and to locate them more precisely. These improvements have increased the use of laparoscopic and percutaneous

procedures. As a result, RF, microwave, and cyroprobe devices have been developed to be used in the treatment of preselected sites. A number of problems exist with respect to these currently available devices. For example, cyroprobes generally require laparotomy because of their relatively large diameter, precluding a simpler, less traumatic approach. RF ablation relies on electrical conduction to deliver energy to tissues away from an RF ablation electrode. As tissue adjacent to the RF ablation electrode becomes desiccated or charred, the impedance increases, thereby limiting conduction through the desiccated or charred tissue. In addition, scar tissue, blood vessels or other tissue inhomogeneity within the ablation site may alter the conduction path of the RF current. Microwave coagulation therapy (MCT), however, destroys the diseased tissue though propagation of electromagnetic waves from a microwave antenna. Because the energy is deposited into the tissue away from the antenna without relying solely on conduction currents, little or no charring occurs with microwave coagulation therapy as compared to RF ablation methods. Furthermore, any charring that might occur does not affect energy deposition patterns to the extent that it would for RF ablation methods because energy can be propagated beyond any charred tissue since conduction through the charred tissue is not required. Therefore, microwave antennas can ablate tissue with little or no charring and with little or no alteration of their energy deposition patterns (typically measured by a specific absorption rate (SAR)) by tissue inhomogeneities. Despite the advantages offered by MCT, a need in the art exists for small-diameter microwave antennas that can precisely follow the biopsy needle track.

This need in the art is particularly acute in liver surgery. For instance, excessive bleeding and bile leakage during surgical procedures within the liver are common. Not surprisingly, large instruments are more traumatic than smaller ones. Furthermore, attempts at biopsy and thermotherapy of tumors can result in seeding of the carcinoma along the track during instrument removal and additional bleeding along the track. Localizing the tumor site can also be a problem and can result in additional trauma and bleeding, for instance, when a biopsy tool is used to sample and localize the tumor and subsequently the thermotherapy device is reinserted to treat the tumor.

Accordingly, there is a need for a small diameter delivery device that can facilitate the biopsy and ablation of a tumor through a single protected puncture site without the need to withdraw the device from the puncture site during biopsying and ablation. Further, there is a need for a device that can efficiently ablate the track during removal to reduce bleeding and the chances of track seeding.

SUMMARY OF THE INVENTION

The present invention is directed to a modular biopsy and microwave ablation needle and delivery apparatus adapted for in situ assembly, biopsy and ablation of tumors in tissues, and ablation of the track upon removal of the apparatus. More particularly the apparatus is adapted to the biopsy and ablation of tumors in solid organs that have a propensity to bleed, for instance, the liver. The present invention also relates to methods for the biopsy and ablation of tumors using the modular biopsy and microwave ablation needle and delivery apparatus.

Generally, a modular needle apparatus for performing biopsy and ablation of tissue abnormalities through a puncture site comprises an elongated hollow delivery needle, a biopsy needle, and an ablation needle. The hollow delivery

needle extends longitudinally a first predetermined distance from an open proximal end to an open distal end, with a lumen extending therebetween. The lumen may accommodate either the biopsy needle or the ablation needle inserted through the open proximal end. The distal end of the delivery needle may be sharpened to pierce tissue. Alternatively or additionally, an obturator may be inserted within the lumen of the delivery needle to stiffen the delivery needle and provide a sharp tip to facilitate piercing tissue. As yet another alternative, the biopsy needle acts as the obturator of the delivery needle, and the biopsy needle and delivery needle are inserted into tissue as a unit. In that case, the biopsy needle itself serves to stiffen the assembly and provide a sharp point for piercing tissue. The biopsy needle may be of any type known in the art and may comprise a single piece, two pieces, or more.

Both the biopsy needle and the ablation needle are longer than the first predetermined distance such that when either the biopsy needle or the ablation needle is inserted into the proximal port and distally displaced within the lumen of the delivery needle, a distal projection of either the biopsy needle or the ablation needle may extend beyond the distal end of the delivery needle. The distal projection of the ablation needle is adapted to form a microwave antenna. The microwave antenna may comprise one of many forms known in the art, for example, a monopole, a dipole or a helical coil antenna.

In a preferred embodiment, the delivery needle has a first connector adapted to connect to a second connector of the ablation needle when the ablation needle is inserted within the lumen of delivery needle. The ablation needle comprises a center conductor circumferentially surrounded by a dielectric material, and the delivery needle comprises a conducting material wherein the combination of the delivery needle, the dielectric material and the center conductor comprise a coaxial transmission line when the first and second connectors are connected. The delivery needle thus comprises the outer conductor of the coaxial transmission line and the inner conductor of the ablation needle comprises the inner conductor of the coaxial transmission line. The ablation needle extends longitudinally a second predetermined distance from the second connector wherein the second predetermined distance is greater than the first predetermined distance whereby the ablation needle forms the distal projection extending beyond the distal end of the delivery needle when the first and second connectors are connected. The distal projection of the ablation needle forms the microwave antenna that is coupled to the coaxial transmission line.

The first connector of the delivery needle and the second connector of the ablation needle may comprise various embodiments. For example, in a preferred embodiment of the invention, the second connector of the ablation needle forms an inner portion of a coaxial connector. The first connector of the delivery needle forms an outer portion of a coaxial connector wherein the outer portion and the inner portion are adapted to couple together to form a coaxial connector. When so formed, the coaxial connector is electrically coupled to the coaxial transmission line.

In another embodiment of the invention, the ablation needle further comprises a proximal coaxial extension wherein a center conductor of the proximal coaxial extension electrically couples to the center conductor of the ablation needle. An outer conductor of the proximal coaxial extension ends distally in the second connector wherein the outer conductor of the coaxial extension is electrically coupled to the delivery needle when the first and second connectors are connected. The second connector may comprise, for example, a threaded portion. The delivery needle ends proximally in the first connector wherein the first connector comprises a threaded portion such that the threaded portions are adapted to threadably engage each other. Thus, the proximal coaxial extension electrically couples to the coaxial transmission line when the first and second connectors are connected. The proximal coaxial extension ends proximally in a coaxial connector for coupling to a microwave power source.

In another embodiment of the invention, the delivery needle and the ablation needle are not adapted to form a transmission line. Instead, the transmission line is contained within the ablation needle. The delivery needle extends longitudinally a first predetermined distance from an open proximal end to an open distal end, with a lumen extending therebetween as described generally above. The ablation needle extends longitudinally a third predetermined distance from a distal end wherein the third predetermined distance is greater than the first predetermined distance whereby the ablation needle forms a distal projection extending beyond the distal end of the delivery needle when the ablation needle is distally displaced within the lumen of the delivery needle. The distal projection of the ablation needle forms the microwave antenna. The remainder of the ablation needle comprises a transmission line that couples to the microwave antenna. The microwave antenna may be a dipole, a monopole or a helical coil antenna.

For the embodiments described herein, the biopsy needle, which may be an aspirating or a coring type, extends distally from its proximal end a fourth predetermined distance wherein the fourth predetermined distance is greater than the first predetermined distance. The biopsy needle may comprise a cannula and a stylet adapted to be disposed within the cannula. The stylet may include a matched point wherein the matched point matches a distal end of the cannula.

A tissue biopysing and ablating system for ablating abnormalities in tissue is also described. The tissue ablation system includes the one of the previously described modular needle embodiments. In a specific embodiment, the system includes the modular needle apparatus wherein the first connector of the delivery needle forms an outer portion of a coaxial connector and the second connector of the ablation needle forms an inner portion of a coaxial connector. The system further comprises a microwave energy source for coupling to the modular needle apparatus.

Methods of ablating tissue are also described. First, an ablation system as described herein is provided. Then, the distal end of the delivery needle is introduced into a tissue sample in a predetermined area. Next, the distal end of the ablating needle is inserted into the lumen of the delivery needle through the open proximal end, and the ablating needle is then advanced until the first and second connectors are adjacent one another. Next, the first and second connectors are connected. Then, a coaxial connector of the modular needle apparatus is electrically coupled to a coaxial connector of the microwave energy source. Microwave energy may then be delivered to the microwave antenna, thus ablating the tissue abnormality in the predetermined area. In other embodiments, the steps of inserting a biopsy needle into the delivery needle, biopsying the tissue, and removing the biopsy needle with a tissue sample precede or follow the step of inserting the ablation needle. In other embodiments, the step of ablating the insertion track upon removal of the modular needle apparatus follows the ablating step.

Additional objects and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1***a* is a side view of a hollow delivery needle wherein the first connector comprises an outer portion of a coaxial connector according to one embodiment of the invention.

FIG. **1***b* is an isometric view of the proximal end of the hollow delivery needle of FIG. **1***a*.

FIG. **1***c* is a side view of an ablation needle wherein the second connector comprises an inner portion of a coaxial connector according to one embodiment of the invention.

FIG. **1***d* is a side view of a modular needle apparatus wherein the ablation needle of FIG. **1***b* is connected to the delivery needle of FIG. **1***a*.

FIG. **1***e* is a side view of the delivery needle wherein a distal portion is narrower in diameter than the remainder of the delivery needle.

FIG. **1***f* is a side view of an ablation needle further comprising a proximal coaxial extension wherein the second connector comprises a threaded portion at the distal end of an outer conductor of the proximal coaxial extension.

FIG. **1***g* is a side view of a delivery needle wherein the first connector comprises a threaded portion at its proximal end.

FIG. **2** is a side view of a tissue biopysing and ablating system including the hollow delivery needle of FIG. **1***a* and the ablation needle of FIG. **1***c*.

FIG. **3***a* is a side view of an open-tip monopole antenna according to one embodiment of the invention.

FIG. **3***b* is a side view of a dielectric or metal tip monopole antenna according to one embodiment of the invention.

FIG. **3***c* is a side view of a dipole antenna according to one embodiment of the invention.

FIG. **3***d* is a side view of a dipole antenna according to one embodiment of the invention.

FIG. **3***e* is a side view of a helical coil antenna according to one embodiment of the invention.

FIG. **4** is a side view illustrating the delivery needle with an obturator inserted into a tumor.

FIG. **5** is a side view of the delivery needle inserted into a tumor with the obturator withdrawn.

FIG. **6** is a side view of the biopsy needle inserted into the delivery needle.

FIG. **7** is a side view of the delivery needle withdrawn slightly so as to expose the tip of the biopsy needle.

FIG. **8** is a side view of the delivery needle inserted into a tumor with the biopsy needle withdrawn.

FIG. **9** is a side view of the ablation needle inserted into the delivery needle so as to form the microwave antenna.

FIG. **10** is a side view of a flexible coaxial extension cable connected to the modular needle apparatus of FIG. **9**.

FIG. **11** is a side view of the microwave antenna ablating the tumor.

FIG. **12** is a side view of the microwave antenna ablating the insertion track.

FIG. **13** is a side view of the delivery needle not adapted to form a coaxial transmission line in combination with the ablation needle according to one embodiment of the invention.

FIG. **14** is a side view of the ablation needle not adapted to form a coaxial transmission line in combination with the delivery needle according to one embodiment of the invention.

FIG. **15** is a side view of a modular needle apparatus wherein the ablation needle of FIG. **14** is inserted within the lumen of the delivery needle of FIG. **13** according to one embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning now to FIGS. **1***a* through **2** and **13** through **15**, various embodiments of the modular needle apparatus are illustrated. In each of these embodiments, the modular needle apparatus includes a hollow delivery needle **10** having a proximal port **15** opening into a lumen **20** which extends through the delivery needle **10** to its distal end. The lumen **20** is sized to accommodate alternately a biopsy needle **30** and an ablation needle **35**. Both the biopsy needle **30** and the ablation needle **35** are longer than the delivery needle **10** such that when either is inserted into the proximal port **15**, a distal projection may extend from the distal end of the delivery needle **10**. In this fashion, the biopsy needle **30** may obtain a tissue sample. In addition, the distal projection of the ablation needle **35** forms a microwave antenna **40** for performing tissue ablation. In certain embodiments, illustrated in FIGS. **1***a* through **1***g*, inserting the ablation needle **35** into the lumen **20** of the delivery needle **10** forms a coaxial transmission line **50** which supplies power to the microwave antenna **40**. In such embodiments, the delivery needle **10** comprises a conductive material that functions as the outer conductor **16** of the coaxial transmission line **50**, while a center conductor **55** of the ablation needle **35** circumferentially surrounded by dielectric material **60** acts as the center conductor and dielectric of the coaxial transmission line **50**. Delivery needle **10** preferably further comprises a jacket **17** of electrically and/or thermally insulating material such as parylene or Teflon® which at least partially surrounds outer conductor **16** (shown in FIG. **1***a*). Delivery needle **10** may have a flat or a sharpened distal end. As used herein, a "flat" distal end indicates a bevel of 90° as described in Andriole et al., Biopsy Needle Characteristics Assessed in the Laboratory, Radiology 148: 659–662, September 1983, the contents of which are hereby incorporated by reference.

In an alternate embodiment, illustrated in FIGS. **13** through **15**, the microwave antenna **40** couples to a transmission line **61** contained entirely within the ablation needle **35** such that the delivery needle **10** has no electrical transmission function, although it may provide additional shielding and/or act as an insulator. Thus, in these embodiments, the delivery needle **10** and the ablation needle **35** do not couple together to create the coaxial transmission line **50** of FIG. **1***d*.

It is to be noted that by coupling the delivery needle **10** with the ablation needle **35** to create the coaxial transmission line **50** feeding the microwave antenna **40**, the largest diameter that must enter the tissue may be kept very small, preferably of 17 gauge or higher, and more preferably 18 gauge or higher. As used herein, "gauge" shall refer to the outer diameter of a needle unless otherwise indicated. For such embodiments, the ablation needle **35** comprises a center conductor **55** circumferentially surrounded by a dielectric material **60**. The dielectric material **60** may comprise a ceramic material, a fluoropolymer such as polytetrafluoroethylene (PTFE) or expanded PTFE, polyethylene (PE), silicone or other suitable materials. The dielectric material **60** is sized to fill the lumen **20** of the delivery needle **35**. The diameter of the center conductor **55** and the inner diameter of the outer conductor **16** are chosen according to the equation:

$$Z=(138/(\epsilon)^{1/2})log_{10}(D/d)$$

where Z is the characteristic impedance, ϵ is the dielectric constant of the dielectric material **60**, D is the inner diameter

of outer conductor **16**, and d is the diameter of center conductor **55**. Typically, Z is chosen to be 50 Ω. The value of ϵ is typically between 1 and 10, for example, the ϵ of PTFE is 2.1.

In addition, to promote efficient conduction along the coaxial transmission line **50**, the inner surface of outer conductor **16** of the delivery needle **10** may be coated with a layer of very conductive metal such as Ag, Au, Cu or Al preferably to a thickness of at least the skin depth, or depth of penetration, δ. The skin depth in meters is given by the following equation:

$$\delta=\mathrm{Sqrt}(2/(\omega\mu\sigma))$$

where $\omega=2\pi$ frequency (in Hz), μ is the permeability (or rate of absorption) of the very conductive metal in henrys/meter, and σ is the conductance in mhos/meter. Similarly, the base metal forming the center conductor **55** in the ablation needle **35** may be coated with a layer of a very conductive metal preferably to a thickness of at least the skin depth.

To complete the coaxial transmission line **50**, the ablation needle **35** and the delivery needle **10** are coupled together using a first connector **70** on the delivery needle **10** and a second connector **65** on the ablation needle **35**. The first and second connectors **70** and **65** may be implemented in many different ways. For example, in a preferred embodiment, illustrated in FIGS. **1***a* through **1***c*, the first connector **70** on the delivery needle **10** comprises an outer contact **72** for a coaxial connector **75** at the proximal end of the delivery needle **10**. Similarly, the second connector **65** on the ablation needle **35** comprises an inner contact **69** for coaxial connector **75** at the proximal end of the ablation needle **35**. The second connector **65** on the ablation needle **35** further comprises a connector dielectric material **36** surrounding a portion of inner contact **69**. Additional connector dielectric material **39** may optionally line a portion of the lumen of outer contact **72**. First and second connectors **70** and **65** are adapted to connect together to form a coaxial connector **75** after the ablation needle **35** is inserted in the proximal port **15** of the delivery needle and distally displaced to bring the connectors **65** and **70** into contact. The adaptations on the connectors **65** and **70** may comprise a number of embodiments. For example, as shown, external threads **37** may be provided in the connector dielectric material **36** and internal threads **38** may be provided in the connector **70** to allow second connector **65** to threadably engage first connector **70**. In such an embodiment, a suitable assembly tool **56** for use in threadably engaging connectors **65** and **70** is illustrated in FIG. **2**. The assembly tool **56** includes tabs **57** for engaging slots (not illustrated) in the dielectric material **36** of the second connector **65**. To complete assembly, a clinician would distally displace the ablation needle **35** within the lumen **20** of the delivery needle **10** until the threads **37** and **38** contact each other. The clinician would then insert the tabs **57** of the assembly tool **56** into the slots of the dielectric material **36** and rotate the assembly tool **56** to threadably engage threads **37** and **38**, completing the formation of the coaxial connector **75**.

Those of ordinary skill in the art will appreciate the numerous ways in which connectors **65** and **70** may engage one another to form coaxial connector **75**. For example, rather than using threads **37** and **38**, a latching mechanism using biased tabs engaging matching grooves may be employed. Regardless of the manner in which connectors **65** and **70** connect together, the result is that the inner contact **69** of the coaxial connector **75** electrically couples to the center conductor **55** of the ablation needle **35**. Similarly, the outer contact **72** electrically couples to the outer conductor **16** of delivery needle **10**. As used herein, "electrically coupled" shall indicate a coupling capable of conducting current at microwave frequencies. In this fashion, a microwave power source (not illustrated) coupled to the coaxial connector **75** will transmit energy through the coaxial transmission line **50** to the microwave antenna **40**. First connector **70**, and therefore coaxial connector **75**, further comprises a nut **68** having internal threads **73** or other mechanical means for insuring firm connection between the coaxial connector **75** and a flexible coaxial cable coupled to the microwave power source. Nut **68** freely rotates about delivery needle **10**.

In an alternative embodiment, first and second connectors **70** and **65**, illustrated in FIGS. **1***f* and **1***g*, the ablation needle **35** further comprises a proximal coaxial extension **80**. A center conductor **81** of the coaxial extension **80** is electrically coupled to the center conductor **55** in the ablation needle **35**. The coaxial extension **80** includes an outer conductor **82** that ends distally in the second connector **65**. The coaxial extension **80** ends proximally in coaxial connector **76**. The delivery needle **10** ends proximally in the first connector **70** such that when the first and second connectors **70** and **65** and connected, the outer conductor **82** of the coaxial extension **80** is electrically coupled to the outer conductor **16** of the delivery needle **10**. In this fashion, microwave energy coupled to the coaxial connector **76** electrically couples to the coaxial transmission line **50** through the coaxial extension **80**. The first connector **70** may comprise threads **71** on the outer surface of the outer conductor **16**. Similarly, the second connector may comprise threads **67** on the inner surface of the outer conductor **82** wherein threads **71** and **67** are adapted to threadably engage one another. Those of ordinary skill in the art will appreciate that alternate means such as the biased tabs and matching grooves previously described may be used instead of threads **71** and **67**. Regardless of whether the ablation needle **35** and the delivery needle couple together to create the coaxial transmission line **50**, to minimize trauma and bleeding, particularly in organs like the liver that tend to bleed, the delivery needle **10** is preferably 17 gauge or higher. However, as illustrated in FIG. **1***e*, although the delivery needle **10** may have a distal portion **14** that is 17 gauge or higher, a proximal portion **13** of the delivery needle **10** may be thicker in diameter, for example, 12 gauge or less. Only the distal portion **14** would penetrate sensitive tissue such as the liver; the proximal portion **13** may either not penetrate the body at all (as in an open surgical procedure) or may penetrate only skin and muscle such as during a percutaneous procedure. The added diameter in the proximal portion **13** allows the proximal portion of the coaxial transmission line **50** to have a larger diameter and therefore be less lossy. The larger diameter also helps to improve rigidity in the proximal portion **13**. Furthermore, in some embodiments such as those of FIGS. **13–15**, it allows greater maneuverability of the biopsy and ablation needles through delivery needle **10**. It is to be noted that as the outer diameter of delivery needle **10** changes from that in proximal portion **13** to the diameter of distal portion **14**, the diameter of lumen **20** also may change accordingly. In addition, the outer diameter of the dielectric material **60** of ablation needle **35** would change accordingly to create the coaxial transmission line **50**.

Turning now to FIG. **2**, the hollow delivery needle **10** may include an obturator **11** adapted to be slidably disposed within the lumen **20**. The obturator **11** includes a proximal handle **12**. With the obturator **11** inserted in the lumen **20** through the proximal port **15**, the handle **12** acts as a stop,

engaging the proximal port **15** on the delivery needle **35** and preventing further distal displacement of the obturator **11**. Thus, the obturator may provide additional support for the delivery needle and assist in piercing tissue, particularly for hard tumors. To reach liver tumors, the delivery needle **10** may extend distally 15 to 20 centimeters from the proximal port **15**. The delivery needle **10** may have a jacket **17** of an insulating material such as parylene or Teflon® on its outer surface.

The biopsy needle **30** may be of either an aspirating or coring type as is well known in the art. Note that the biopsy needle **30** may have a proximal handle **45**. When the biopsy needle is inserted into the proximal port **15** of the delivery needle **10**, the proximal handle **45** abuts against the proximal port **15**, preventing further distal displacement within the lumen **20**. The biopsy needle **30** may have a blunt distal end **31** or a sharpened distal end **32**. In addition, the biopsy needle **30** may further comprise a stylet **29** having a matched point **34** to aid in strengthening or stiffening the biopsy needle **30** and assist piercing tissue with the needle **30**. The biopsy needle **30** is preferably 20 to 23 gauge and most preferably 20 to 21 gauge. The lumen of the biopsy needle **30** is preferably greater than 0.017" and most preferably at least 0.022". The biopsy needle **30** may be inserted into the lumen **20** of delivery needle **10** and both inserted into tissue as a unit such that the biopsy needle **30** acts as an obturator **11**. Use of either a biopsy needle **30** or the obturator **11** in this way allows the delivery needle **10** to have a flat distal end, lessening trauma to internal organs from movements of the delivery needle **10** during exchange of the biopsy needle **30** and the ablation needle **35**.

Turning now to FIGS. **3***a* through **3***e*, the microwave antenna **40**, formed by the distal projection of the ablation needle **35**, may take any of several well-known forms in the art. For example, FIGS. **3***a* and **3***b* illustrate embodiments in which the microwave antenna comprises a monopole antenna **41** as described by Labonte et al., "Monopole Antennas for Microwave Catheter Ablation," *IEEE Trans. Microwave Theory Tech.*, vol. 44, no. 10, pp. 1832–1840, October 1996, the contents of which are hereby incorporated by reference. In such embodiments, the distal projection of the ablation needle comprises the previously described center conductor **55** surrounded by the dielectric material **60**. If, as illustrated in FIG. **3***a*, the center conductor **55** extends to the distal end of the distal projection, thereby contacting tissue when in use, the monopole antenna **41** is referred to as an open-tip monopole antenna. In other embodiments, a tip **42** prevents the center conductor **55** from directly contacting tissue as illustrated in FIG. **3***b*. If the tip **42** comprises a dielectric material, the monopole antenna **41** is referred to as a dielectric-tip monopole. If the tip **42** comprises a metallic material, the monopole antenna **41** is referred to as a metal-tip monopole.

Alternatively, the distal projection of the ablation needle **35** may form a dipole antenna **43** as illustrated in FIGS. **3***c* and **3***d*. In such embodiments, the distal projection of the ablation needle **35** comprises the center conductor **55** and surrounding dielectric material **60** as previously described. In addition, the distal projection of the ablation needle includes an outer conductor **44** forming one or more sections of coaxial transmission line in combination with the center conductor **55**. This outer conductor **44** is electrically isolated from the delivery needle **10**. It may be electrically coupled to the center conductor **55** as shown in FIG. **3***c* or may be electrically isolated from it as shown in FIG. **3***d*.

In yet another embodiment, the distal projection of the ablation needle **35** may form a helical coiled antenna **51**. The helical coiled antenna **51** comprises the center conductor **55** and surrounding dielectric material **60** as previously described. In addition, the center conductor **55** has an extension that forms coils **52** about the dielectric material **60**. The coils **52** are electrically isolated from the delivery needle **10**. Stauffer et al., (1995) Interstitial Heating Tech. In: Seegenschmiedt et al. (eds.), *Thermoradiotherapy and Thermochemotherapy*, vol. 1, Springer, pp. 279–320 provide additional discussion of suitable dipole **43** and helical coil antennas **51**, the contents of which is hereby incorporated by reference.

Turning now to FIGS. **13** through **15**, an alternate embodiment of the present invention in which the ablation needle **35** and the delivery needle **10** do not couple together to create the coaxial transmission line is illustrated. The hollow delivery needle **10** possesses a proximal port **15** opening into a lumen **20** which extends through the delivery needle **10** to an open distal end as described previously. In addition, the delivery needle **10** preferably has a jacket of an insulating material such as parylene or Teflon® at least partially surrounding its outer surface (illustrated in FIG. **1***a*) or may be formed completely of a nonconductive material such as plastic. The delivery needle **10** is preferably 17 gauge, more preferably 18 gauge or higher. The ablation needle **35** is longer than the delivery needle **10** such that when the ablation needle **35** is inserted into the proximal port **15** and displaced until a stop **83** located on the ablation needle **35** engages the proximal port **15**, a distal projection of the ablation needle **35** will extend from the distal end of the delivery needle **10**. The distal projection of the ablation needle is adapted to form a microwave antenna **40**. The ablation needle **35** includes a transmission line to couple to the microwave antenna **40**. In the embodiment illustrated in FIG. **14**, the transmission line in the ablation needle **35** comprises a coaxial transmission line **61**. However, other types of transmission lines as known in the art may be used in ablation needle **35**. To form the coaxial transmission line **61**, the ablation needle **35** includes the center conductor **55** and surrounding dielectric material **60** as previously described. In addition, the ablation needle **35** includes an outer conductor **62** that circumferentially surrounds the dielectric material **60** to complete the coaxial transmission line **61**. This outer conductor **62** extends distally from a coaxial connector **78** to the microwave antenna **40** and preferably comprises a highly conductive metal of a thickness of 1 to 10 times the skin depth (δ) as described herein. Outer conductor **62** preferably is protected by an outer coating of a material such as a fluoropolymer or parylene. Because ablation needle **35** includes the complete coaxial transmission line **61** and coaxial connector **78**, the delivery needle **10** requires no electrical connector, and need merely end in the proximal port **15** through which the ablation needle **35** is inserted. The ablation needle **35** is distally displaced within the lumen **20** of the delivery needle **10** until the stop **83**, here provided by the coaxial connector **78**, prevents further distal displacement by contacting the proximal end of the delivery needle **10**. In addition to acting as a stop **83**, the coaxial connector **78** may be modified to connect to the proximal end of the delivery needle **10** through appropriate connectors (not illustrated). When the ablation needle **35** is displaced to contact the stop **83** with the proximal end of the delivery needle **10**, the distal projection of the ablation needle **35** extends beyond the distal end of the delivery needle **10**. This distal projection forms a microwave antenna **40**. The microwave antenna **40** may be a monopole **41**, dipole **43** or helical coil **51** as previously described and illustrated in FIGS. **3***a* through **3***c*.

If center conductor **55** and outer conductor **62** are not comprised of a highly conductive metal, the center conductor **55** and the inner surface of the outer conductor **62** may be coated with a highly conductive metal to a thickness as previously described. To minimize trauma during insertion and ablation, the delivery needle **10** is preferably 17 gauge or higher, more preferably 18 gauge or higher.

As an alternative embodiment, instead of the coaxial connector **78**, the delivery needle **10** may include a connector (not illustrated) comprising an outer portion of a coaxial connector and the ablation needle **35** may include a connector (not illustrated) comprising an inner portion of a coaxial connector. When the connectors are connected, the resulting coaxial connector is electrically coupled to the coaxial transmission line **61**. In such an embodiment, the outer portion of the coaxial connector would have to electrically couple to the outer conductor **62** of the ablation needle **35**.

It is to be noted that, regardless of the particular type of microwave antenna **40** implemented, the present invention provides advantages over prior art microwave antennas. In the present invention, the biopsy needle **30** and the delivery needle **10** may have already formed an insertion track before the microwave antenna **40** is inserted into an ablation site. Because the microwave antenna **40** may follow the existing insertion track, the microwave antenna **40** may possess a flat distal end. Prior art MCT microwave antennas typically had a sharpened distal end so that these antennas could be inserted into an ablation site. The SAR pattern of a microwave antenna **40** may be altered depending upon whether a flat or sharpened distal end is utilized. Thus, the present invention allows a clinician more control of the SAR patterns needed for a particular therapy.

Whether the ablation needle **35** and the delivery needle **10** are coupled to create the coaxial transmission line **50** or the ablation needle **35** includes the coaxial transmission line **61**, the present invention will provide a variety of microwave antennas **40** which are inserted into a tumor through the lumen **20** of the delivery needle **10**. The delivery needle **10** and the microwave antenna **40** together follow an insertion track in the body. The microwave antenna **40** may take a number of forms as previously described. Each of the forms, such as the monopole **41**, has an effective antenna length which represents the longitudinal extent of tissue ablated by the microwave antenna **40** in the insertion track. The effective antenna length may depend upon the antenna design, the expected insertion depth, the expected amount of tissue perfusion, the expected duration and power of energy deliver, the frequency of the microwave power source, and additional factors. Tumors, such as liver tumors, can "seed" an insertion track as the microwave antenna **40** is withdrawn from the tumor. Therefore, it is beneficial to ablate the insertion track during withdrawal to kill any tumor cells displaced along the insertion track which would otherwise (potentially) act as "seeds" for future tumors. Moreover, track ablation helps to stem hemorrhage from the insertion track. After performing ablation of a tumor, the microwave antenna **40** may be withdrawn approximately an effective antenna length. Ablation would then be performed again, thus performing ablation in the insertion track without gaps and without excess overlap between successive ablations so as to kill displaced tumor cells while minimizing excess damage to the insertion track. Because only a small area surrounding the insertion track need be ablated, and to minimize damage to healthy tissue during track ablation, the clinician may decrease the diameter of the field of the antenna and/or lengthen the field to speed track ablation time. These alterations to microwave field diameter and length may be made by decreasing the power or frequency of the microwave power source. In addition or alternatively, the antenna field may be altered by changing the physical dimensions of the microwave antenna **40** by, for example, proximally or distally displacing the ablation needle **35** within the lumen **20** of the delivery needle **10**.

To assist coupling a microwave power source to the microwave antenna **40**, the coaxial connector **75**, **76** and **78** as used in the various embodiments described herein may comprise a standard coaxial connector such as an SMA connector. Alternatively, the coaxial connector may be a coaxial connector of a custom design for ease of assembly.

The present invention also includes a system for biopsy and ablation of tumors. The system comprises a modular needle apparatus in one of the various embodiments as described herein. An example system is illustrated in FIG. **2**. This system includes the delivery needle **10** and ablation needle **35** of FIGS. **1***a* and **1***c*. Also included is an obturator **11**, a biopsy needle **30** and a stylet **29** with a matched point **34** for the biopsy needle **30**. A syringe **58** is shown for coupling to the biopsy needle **30** during aspiration of a tissue sample. As discussed herein, an assembly tool **56** aids the connection of the ablation needle **35** and the delivery needle **10**. The system would further comprise a microwave power source **59** for coupling to the modular needle apparatus by connecting to the coaxial connector **75**. The microwave power source will preferably generate microwave energy in the frequency range of 0.3 to 3.0 GHz. More preferably, the microwave antenna **40** and the microwave power source are adapted to operate at 0.915 or 2.45 GHz. The particular frequency or frequency range generated by the microwave power source will affect the SAR pattern of the microwave antenna **40**. The clinician may thus adjust the microwave power source to generate a desired SAR pattern as required by a particular tumor.

The present invention includes methods of biopsy and ablation using the disclosed modular needle apparatus. Turning now to FIGS. **4–12**, a method of biopsy and ablation is illustrated using the modular needle apparatus as shown in FIGS. **1***a–1c*. As discussed herein, this embodiment creates the coaxial transmission line **50** after connecting together connector **65** on the ablation needle **35** to connector **70** on the delivery needle **10**. As illustrated in FIG. **3**, the delivery needle has an obturator **11** in the lumen **20** to stiffen the delivery needle **35** and assist piercing of tissue. Preferably, a percutaneous procedure is performed. If, however, a laparoscopic procedure is performed, the delivery needle **10** may be introduced through a trocar (not illustrated). Moreover, in an open surgical procedure, the delivery needle would enter tissue through an incision rather than entering percutaneously. The clinician may monitor the procedure with an imaging device such as MRI or ultrasound to guide the insertion of the delivery needle **10** into a patient until the delivery needle **10** is suitably positioned with respect to a tumor **95** located within the liver **90**. Such a suitable position will depend upon the shape and position of the tumor **95** and the SAR pattern of the particular microwave antenna **40** used. Having inserted the delivery needle **10** properly with respect to the tumor **95**, the clinician may withdraw the obturator **11** as illustrated in FIGS. **4** and **5**. The clinician is now ready to perform a biopsy of the tumor **95** using a biopsy needle **30** inserted through the lumen **20** of the delivery needle **10**. The clinician may perform this biopsy in a number of ways. For example, the biopsy needle **30** may be distally displaced within the lumen **20** until the distal end of the biopsy needle protrudes from the delivery needle **10**

into the tumor **95**. Alternatively, as illustrated in FIG. **6**, the clinician may distally displace the biopsy needle within the lumen **20** until the distal end of the biopsy needle is proximally adjacent the distal end of the delivery needle **10**. The clinician then exposes the distal end of the biopsy needle to the tumor **95** so that a tissue sample may be taken by proximally withdrawing the delivery needle **10** with respect to the biopsy needle **30** as illustrated in FIG. **7**.

As an alternative to the steps shown in FIGS. **4–7** as described thus far, biopsy needle **30** may be introduced with delivery needle **10** as a unit, and would appear as in FIG. **7**. In that case, biopsy needle **30** preferably has a stiffening stylet **29** with a matched point **34** to aid in piercing tissue, particularly hardened tumors. To further aid in stiffening the biopsy needle **30**, the biopsy needle **30** would preferably have a diameter very close to the inner diameter of delivery needle **10**. The biopsy stylet **29** is then removed so that a biopsy can be taken. In either case, the biopsy needle **30** preferably comprises a luer-type fitting **33** on its proximal end. A syringe (illustrated in FIG. **2**) is attached to fitting **33** and suction is applied to draw tissue into biopsy needle **30**.

After drawing a tissue sample into biopsy needle **30**, the biopsy needle **30** is withdrawn from the lumen **20** of the delivery needle **10** as illustrated in FIG. **8**. The clinician may optionally perform an additional biopsy, either at this point or following an ablation using the same or a different biopsy needle **30**. Should the biopsy result indicate that the tumor **95** requires ablation, the clinician proceeds to insert the ablation needle **35** into the lumen **20** of the delivery needle **10**. (Alternatively the clinician need not wait for the result). As described previously, the clinician distally displaces the ablation needle **35** within the lumen **20** until the second connector **65** on the ablation needle **35** is coupled to the first connector **70** on the delivery needle **10**. In this fashion, a coaxial connector **75** is formed as illustrated in FIG. **9** so that microwave power source may be coupled through the coaxial transmission line **50** to the microwave antenna **40**. Note that the insertion of the microwave antenna **40** into the tumor **95** does not require removal of the delivery needle **10**. Thus, the clinician need not have to reinsert the delivery needle after a biopsy, avoiding the uncertainties of trying to align the delivery needle **10** with the previously formed insertion track. Furthermore, because the microwave antenna **40** follows the insertion track left by the biopsy needle **30**, the microwave antenna **40** need not have a sharpened distal end. However, the present invention also contemplates methods wherein the clinician performs ablation before or in lieu of performing a biopsy or in a slightly different location than the biopsy site. In such an embodiment of the invention, the microwave antenna **40** would preferably have a sharpened distal end because the microwave antenna **40** will not be following a biopsy needle track. Turning now to FIG. **10**, the clinician couples a microwave power source to the coaxial connector **75** through, e.g., a flexible coaxial cable **100**. At this point the clinician may begin ablating the tumor **95**. As illustrated in FIG. **11**, the ablation continues until the area of ablated tissue **110** is larger than the tumor, thus insuring that the entire tumor **95** is destroyed. Finally, as illustrated in FIG. **12**, the clinician may perform track ablation as previously described. The clinician partially withdraws the delivery needle **10** before performing another ablation. Repeated partial withdrawal and ablation steps are performed to completely ablate the insertion track.

Many widely differing embodiments of the present invention may be constructed without departing from the spirit and scope of the present invention. Therefore, it should be understood that the present invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the present invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.

What is claimed is:

1. A modular needle kit for biopsy and ablation through a puncture site, comprising:

an elongated delivery needle of 17 gauge or higher having an open proximal end and an open distal end with a humen extending therebetween, said delivery needle extending longitudinally a first predetermined distance, and

an ablation needle comprising a transmission line, said transmission line extending longitudinally a second predetermined distance wherein the second predetermined distance is greater than the first predetermined distance whereby said ablation needle forms a distal projection extending beyond the distal end of said delivery needle when said ablation needle is distally and detachably displaced within the lumen of said delivery needle, and wherein said distal projection comprises an extension of a conductor of said transmission line, said extension of said conductor forming a microwave antenna electrically coupled to said transmission line.

2. The kit of claim **1** wherein said transmission line comprises a coaxial transmission line and said extension of said conductor comprises an extension of a center conductor of said coaxial transmission line.

3. The kit of claim **1** wherein said microwave antenna is chosen from the group consisting of a monopole antenna, a dipole antenna, and a helical coil antenna.

4. The kit of claim **1** further comprising a biopsy needle, said biopsy needle extending a third predetermined distance from a proximal handle to a distal end wherein said third predetermined distance is greater than said first predetermined distance, said biopsy needle formed to be slidably disposed within said lumen of said delivery needle.

5. The kit of claim **1** wherein said ablation needle further comprises a proximally located stop adapted to engage a proximal end of said delivery needle.

6. The kit of claim **2** wherein said ablation needle further comprises an inner portion of a coaxial connector, and wherein said delivery needle further comprises an outer portion of said coaxial connector wherein said inner portion and said outer portion are adapted to engage each other to form said coaxial connector, and wherein said coaxial connector electrically couples to said coaxial transmission line.

7. The kit of claim **2** wherein said transmission line comprises an outer conductor having a thickness of 1 to 10 times the skin depth.

8. The kit of claim **2** further comprising a protective coating at least partially coating said outer conductor.

9. The kit of claim **8** wherein said protective coating comprises a material selected from the group consisting of fluoropolymer or parylene.

10. A method of treating a region of tissue, comprising:

advancing a distal end of an elongate delivery device into a tissue region of interest, the delivery device having a length with a lumen defined therewithin, wherein an insertion track is created within tissue along the length of the delivery device;

advancing a biopsy needle within the lumen such that a distal end of the needle protrudes from the distal end of the delivery device into the region of interest;

withdrawing a sample of tissue from the region of interest via the distal end of the needle;

advancing an elongate microwave ablation device which is detachable from the delivery device within the lumen such that a distal end of the ablation device protrudes from the distal end of the delivery device into the region of interest; and

ablating the region of interest and the insertion track of tissue with the ablation device while withdrawing both the elongate delivery device and the ablation device from the region of interest.

11. The method of claim **10** wherein the elongate delivery device is advanced percutaneously into the tissue region of interest.

12. The method of claim **10** wherein the elongate delivery device is advanced laparoscopically into the tissue region of interest.

13. The method of claim **10** further comprising advancing an obturator within the lumen past the distal end of the delivery device for piercing the tissue region of interest prior to advancing the biopsy needle within the lumem.

14. The method of claim **13** wherein the obturator is advanced within the lumen until a stop disposed on a proximal end of the obturator halts the advancement of the obturator.

15. The method of claim **10** wherein the elongate delivery device is advanced into the tissue region of interest through a trocar.

16. The method of claim **10** wherein advancing the biopsy needle within the lumen comprises displacing the biopsy needle distally within the lumen such that the distal end of the biopsy needle is adjacent to the distal end of tire delivery device.

17. The method of claim **10** wherein withdrawing the sample of tissue comprises aspirating the sample through a needie lumen defined within the biopsy needle.

18. The method of claim **17** wherein the sample is aspirated via a syringe connected in fluid communication with a proximal end of the needle lumen.

19. The method of claim **10** wherein withdrawing a sample of tissue comprises withdrawing multiple samples of tissue from the region of interest via the distal end of the needle.

20. The method of claim **10** wherein withdrawing a sample of tissue comprises withdrawing multiple samples of tissue from the region of interest via a plurality of additional biopsy needles.

21. The method of claim **10** wherein ablating the region of interest and the insertion track of tissue comprises applying microwave energy via a microwave antenna.

22. The method of claim **10** wherein ablating the region of interest and the insertion track of tissue comprises applying microwave energy to the region of interest within a first ablation field having a first diameter and further applying microwave energy to the insertion track of tissue within a second ablation field having a second diameter.

23. The method of claim **10** wherein the elongate delivery device and the ablation device are withdrawn incrementally through the insertion track.

24. The method of claim **10** wherein the elongate delivery device and the ablation device are withdrawn continually through the insertion track.

25. The method of of claim **10** further comprising readvancing the distal end of the elongate delivery device into the tissue region of interest and further advancing at least an additional biopsy needle within the lumen and withdrawing at least one additional sample of tissue from the region of interest.

26. A method of treating a region of tissue, comprising:

advancing a distal end of an elongate delivery device into a tissue region of interest, the delivery device having a length with a lumen defined therewithin, wherein an insertion track is created within tissue along the length of the delivery device;

advancing an elongate microwave ablation device which is detachable from the delivery device within the lumen such that a distal end of the ablation device protrudes from the distal end of the delivery device into the region of interest;

ablating the region of interest and the insertion track of tissue with the ablation device while withdrawing the ablation device from the region of interest;

advancing a biopsy needle within the lumen such that a distal end of the needle protrudes from the distal end of the delivery device into the region of interest; and

withdrawing a sample of tissue from the region of interest via the distal end of the needle.

27. The method of claim **26** further comprising advancing an obturator within the lumen past the distal end of the delivery device for piercing the tissue region of interest prior to advancing the elongate microwave ablation device within the lumen.

28. The method of claim **26** further comprising readvancing the elongate microwave ablation device within lumen such that the distal and of the ablation device protrudes from the distal end of the delivery device into the region of interest.

29. The method of claim **28** further comprising reablating the region of interest and the insertion track of tissue with the ablation device while withdrawing both the elongate delivery device and the ablation device from the region of interest.

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专利名称(译)	模块化活组织检查和微波消融针输送装置适于原位组装和使用方法		
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摘要(译)

公开了一种模块化活组织检查，消融和轨道凝固针装置，其允许活检针插入输送针并在不需要时移除，并且允许内消融针被引入并且与输送针同轴地接合以更有效地活检肿瘤，消融并通过消融凝固轨道，同时减少失血和跟踪播种。消融针和活检针适于与输送针原位组装。在优选实施例中，消融针在与输送针接合时形成适于电连接到消融源的同轴连接器。还提供了使用该装置对肿瘤进行活组织检查和消融以及在移除装置时凝结轨道的方法。