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

(75) Inventors: Jack W. Moorman, Los Gatos, CA (US); M. Elizabeth Bush, Fremont, CA (US)

> Correspondence Address: LYON & LYON LLP **633 WEST FIFTH STREET SUITE 4700** LOS ANGELES, CA 90071 (US)

(73) Assignee: Vivant Medical, Inc., Portola Valley, CA

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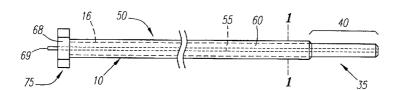
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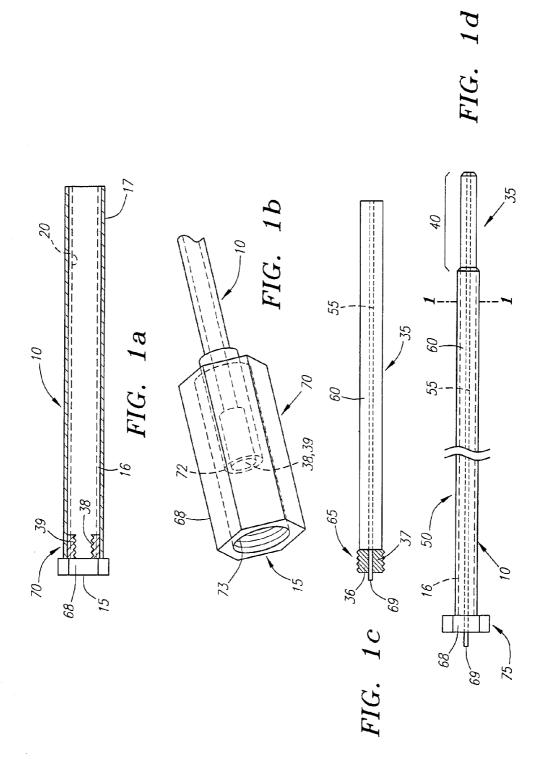
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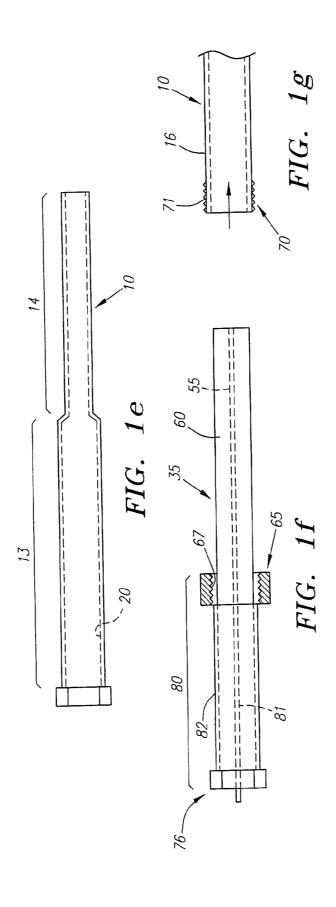
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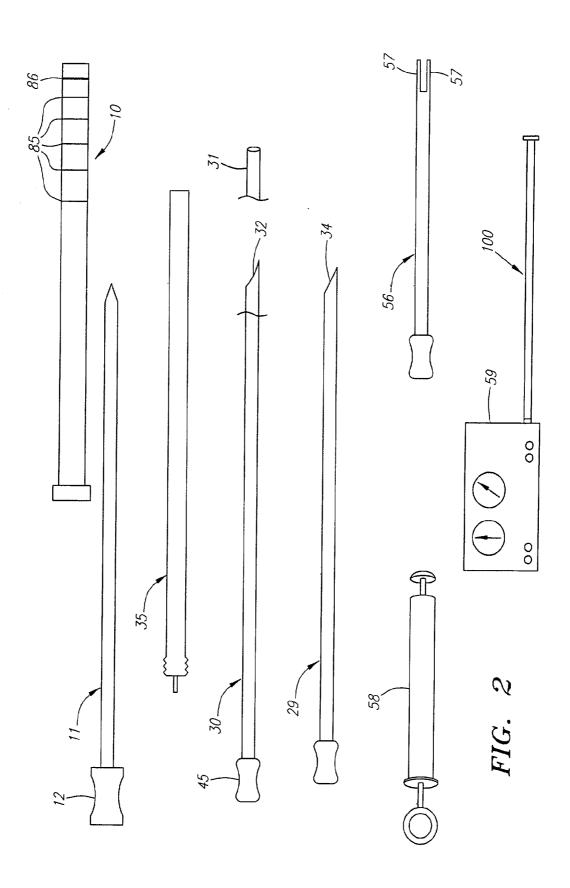
#### ABSTRACT (57)

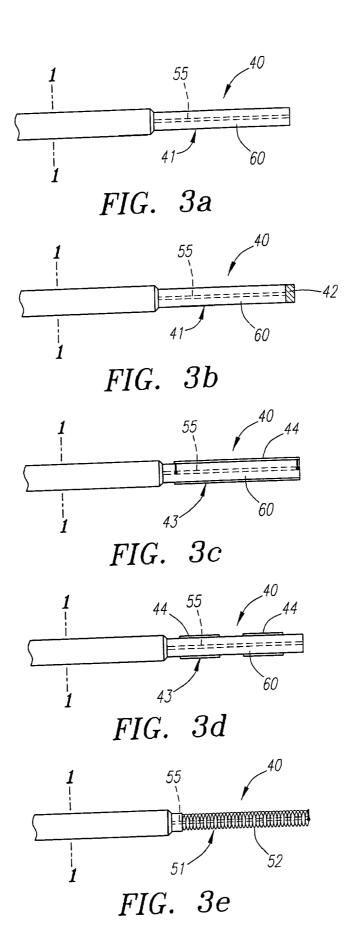
A modular biopsy, ablation and track coagulation needle apparatus is disclosed that allows the biopsy needle to be inserted into the delivery needle and removed when not needed, and that allows an inner ablation needle to be introduced and coaxially engaged with the delivery needle to more effectively 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.











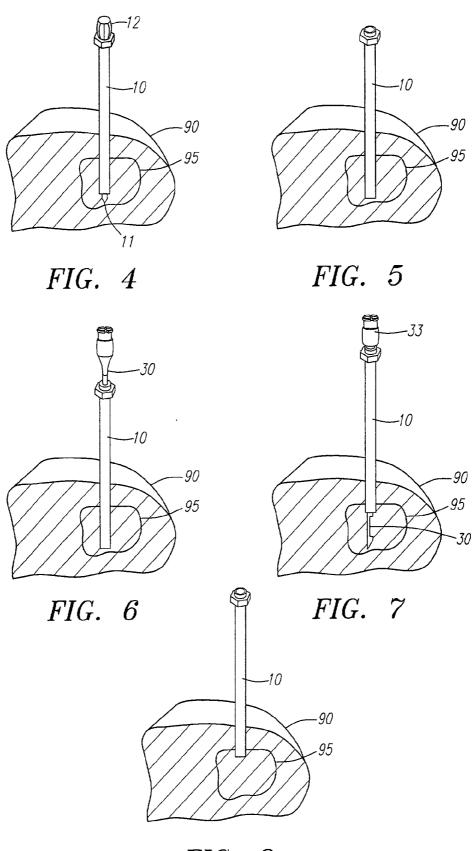


FIG. 8

100

-90

.95

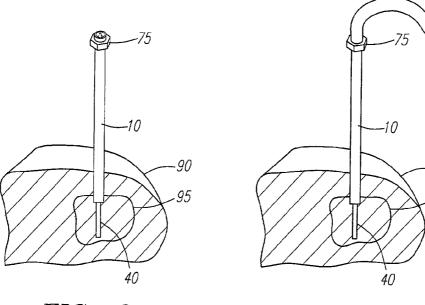


FIG. 9

FIG. 10

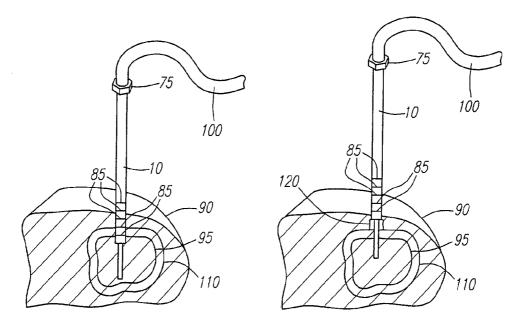
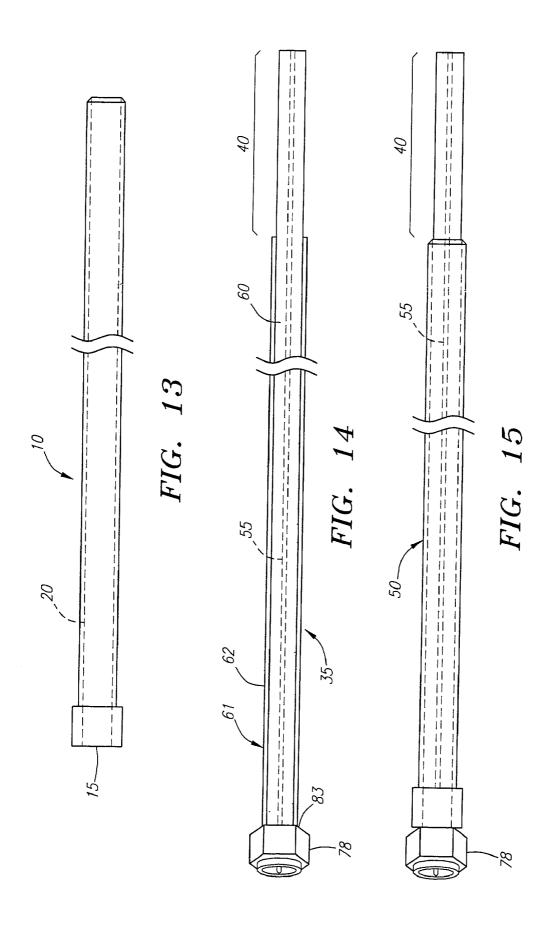


FIG. 11

FIG. 12



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

#### FIELD OF THE INVENTION

[0001] 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

[0002] 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.

[0003] Outside the U.S., primary liver cancer (hepatocellular carcinoma) accounts for one of the largest cancerrelated 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.

[0004] 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.

[0005] 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.

[0006] 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 non-resectable 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.

[0007] 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 improve-

ments 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.

[0008] 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.

[0009] 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

[0010] 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.

[0011] 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.

[0012] 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 distall projection of either the biopsy needle or the ablation needle may extend beyond the distall end of the delivery needle. The distall 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.

[0013] 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.

[0014] 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.

[0015] 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.

[0016] 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.

[0017] 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.

[0018] 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.

[0019] 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.

[0020] 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

[0021] FIG. 1a 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.

[0022] FIG. 1b is an isometric view of the proximal end of the hollow delivery needle of FIG. 1a.

[0023] FIG. 1c 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.

[0024] FIG. 1d is a side view of a modular needle apparatus wherein the ablation needle of FIG. 1b is connected to the delivery needle of FIG. 1a.

[0025] FIG. 1e is a side view of the delivery needle wherein a distal portion is narrower in diameter than the remainder of the delivery needle.

[0026] FIG. If 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.

[0027] FIG. 1g is a side view of a delivery needle wherein the first connector comprises a threaded portion at its proximal end.

[0028] FIG. 2 is a side view of a tissue biopysing and ablating system including the hollow delivery needle of FIG. 1a and the ablation needle of FIG. 1c.

[0029] FIG. 3a is a side view of an open-tip monopole antenna according to one embodiment of the invention.

[0030] FIG. 3b is a side view of a dielectric or metal tip monopole antenna according to one embodiment of the invention.

[0031] FIG. 3c is a side view of a dipole antenna according to one embodiment of the invention.

[0032] FIG. 3d is a side view of a dipole antenna according to one embodiment of the invention.

[0033] FIG. 3e is a side view of a helical coil antenna according to one embodiment of the invention.

[0034] FIG. 4 is a side view illustrating the delivery needle with an obturator inserted into a tumor.

[0035] FIG. 5 is a side view of the delivery needle inserted into a tumor with the obturator withdrawn.

[0036] FIG. 6 is a side view of the biopsy needle inserted into the delivery needle.

[0037] FIG. 7 is a side view of the delivery needle withdrawn slightly so as to expose the tip of the biopsy needle.

[0038] FIG. 8 is a side view of the delivery needle inserted into a tumor with the biopsy needle withdrawn.

[0039] FIG. 9 is a side view of the ablation needle inserted into the delivery needle so as to form the microwave antenna

[0040] FIG. 10 is a side view of a flexible coaxial extension cable connected to the modular needle apparatus of FIG. 9.

[0041] FIG. 11 is a side view of the microwave antenna ablating the tumor.

[0042] FIG. 12 is a side view of the microwave antenna ablating the insertion track.

[0043] 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.

[0044] 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.

[0045] 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

[0046] Turning now to FIGS. 1a 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. 1a through 1g, 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. 1a). 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.

[0047] 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. 1d.

[0048] 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:

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

[0049] where Z is the characteristic impedance,  $\epsilon$  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  $\Omega$ . The value of  $\epsilon$  is typically between 1 and 10, for example, the  $\epsilon$  of PTFE is 2.1.

[0050] 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,  $\delta$ . The skin depth in meters is given by the following equation:

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

[0051] where  $\omega=2\pi$  frequency (in Hz),  $\mu$  is the permeability (or rate of absorption) of the very conductive metal in henrys/ meter, and  $\sigma$  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

[0052] 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. 1a through 1c, 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.

[0053] 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.

[0054] In an alternative embodiment, first and second connectors 70 and 65, illustrated in FIGS. 1f and 1g, 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. 1e, 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.

[0055] 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.

[0056] 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.

[0057] Turning now to FIGS. 3a through 3e, 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. 3a and 3b 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. 3a, 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. 3b. 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.

[0058] Alternatively, the distal projection of the ablation needle 35 may form a dipole antenna 43 as illustrated in FIGS. 3c and 3d. 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. 3c or may be electrically isolated from it as shown in FIG. 3d.

[0059] 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.

[0060] 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. 1a) 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 ( $\delta$ ) as described herein. Outer conductor 62 preferably is protected by an outer coating of a material such as a fluoropolymer or parvlene. 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. 3a through 3c. 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.

[0061] 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.

[0062] 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.

[0063] 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.

[0064] 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.

[0065] 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. 1a and 1c. 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.

[0066] 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. 1a-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.

[0067] 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.

[0068] 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.

[0069] 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 comprising a conducting material, said delivery needle having an open proximal end and an open distal end with a lumen extending therebetween, said delivery needle having a first connector, said delivery needle extending longitudinally from said first connector to said open distal end a first predetermined distance; and
  - an ablation needle comprising a center conductor circumferentially surrounded by a dielectric material, said ablation needle further comprising a second connector, said ablation needle extending longitudinally a second predetermined distance from the second connector to a distal end wherein said second predetermined distance is greater than said first predetermined distance whereby said ablation needle forms a distal projection extending beyond the distal end of said delivery needle when said first and second connectors are connected, said distal projection forming a microwave antenna, and wherein the ablation needle and the delivery needle form a coaxial transmission line when the first and second connectors are connected wherein said coaxial transmission line electrically couples to said microwave antenna.
- 2. The kit of claim 1 wherein said second connector of said ablation needle comprises an inner portion of a coaxial connector, and wherein said first connector of said delivery needle 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.
- 3. The kit of claim 2 wherein said inner and said outer portions are adapted to threadably engage each other.
- 4. The kit of claim 1 wherein said ablation needle further comprises a proximal coaxial extension wherein a center conductor of said proximal coaxial extension electrically couples to said center conductor of said ablation needle, and wherein an outer conductor of said proximal coaxial extension ends distally in said second connector.
- 5. The kit of claim 4 wherein said first connector and said second connector are adapted to threadably engage each other.
- **6**. 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.
- 7. The kit of claim 1 wherein said delivery needle is at least partially surrounded with a layer of electrically and/or thermally insulating material.
- **8**. The kit of claim 7 wherein said insulating material is chosen from the group consisting of fluoropolymer, polyethylene and parylene.
- 9. The kit of claim 1 wherein said delivery needle has a proximal portion having a first diameter and a distal portion

- having a second diameter, and wherein said first diameter is greater than said second diameter.
- 10. The kit of claim 1, wherein said delivery needle is equal to or narrower in diameter than approximately 17 gauge.
- 11. The kit of claim 1, wherein said delivery needle is equal to or narrower in diameter than approximately 18 gauge.
- 12. 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.
- 13. The kit of claim 12 wherein said biopsy needle comprises:
  - an outer cannula; and
  - a stylet, wherein said stylet is adapted to be slidably disposed within said cannula.
- 14. The kit of claim 13, wherein stylet has a matched point, said matched point matching a distal end of said outer cannula.
- 15. The kit of claim 12 wherein said biopsy needle is 20 to 23 gauge.
- **16**. The kit of claim 12 wherein said biopsy needle is 20 to 21 gauge.
- 17. The kit of claim 12 wherein said biopsy needle has a lumen having a diameter greater than 0.017 of an inch.
- **18**. The kit of claim 12 wherein said biopsy needle has a lumen having a diameter at least 0.022 of an inch.
- 19. The kit of claim 1 wherein said dielectric material is selected from the group consisting of a fluoropolymer, polyethylene, ceramic and silicone.
- **20**. The kit of claim 19 wherein said dielectric comprises polytetrafluoroethylene.
- 21. The kit of claim 1 wherein the distal end of said delivery needle is flat.
- 22. The kit of claim 1 wherein said first connector comprises a first contact electrically coupled to said conducting material of said delivery needle, and wherein said second connector comprises a second contact electrically coupled to said center conductor wherein said second connector further comprises a connector dielectric material surrounding a portion of said second contact.
- 23. The kit of claim 22, further comprising connector dielectric material lining a portion of said first contact.
- **24**. 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 lumen 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 wherein 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 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.
- 25. The kit of claim 24 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.
- **26**. The kit of claim 24 wherein said microwave antenna is chosen from the group consisting of a monopole antenna, a dipole antenna, and a helical coil antenna.
- 27. The kit of claim 24 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.
- 28. The kit of claim 24 wherein said ablation needle further comprises a proximally located stop adapted to engage a proximal end of said delivery needle.
- 29. The kit of claim 25 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.
- **30**. The kit of claim 25, wherein said transmission line comprises an outer conductor having a thickness of 1 to 10 times the skin depth.
- **31**. The kit of claim 25 further comprising a protective coating at least partially coating said outer conductor.
- **32**. The kit of claim 31 wherein said protective coating comprises a material selected from the group consisting of fluoropolymer or parylene.
  - 33. A system for ablation of tissue, comprising:
  - an elongated delivery needle comprising a conducting material, said delivery needle having an open proximal end and an open distal end with a lumen extending therebetween, said delivery needle having a first connector, said delivery needle extending longitudinally from said first connector to said open distal end a first predetermined distance;
  - an ablation needle comprising a center conductor circumferentially surrounded by a dielectric material, said
    ablation needle further comprising a second connector,
    said ablation needle extending longitudinally a second
    predetermined distance from the second connector to a
    distal end wherein said second predetermined distance
    is greater than said first predetermined distance
    whereby said ablation needle forms a distal projection
    extending beyond the distal end of said delivery needle
    when the first and second connectors are connected,
    said distal projection forming a microwave antenna,
    and wherein the ablation needle and the delivery needle
    form a coaxial transmission line when first and second
    connectors are connected wherein said coaxial transmission line electrically couples to said microwave
    antenna, and
  - a microwave energy source, wherein said coaxial transmission line is adapted to electrically couple to said microwave energy source.
- **34**. The system of claim 33 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.
- **35**. The system of claim 34, wherein said biopsy needle comprises:
  - a cannula; and
  - a stylet adapted to be slidably disposed within said cannula.
- **36**. The system of claim 33 further comprising an assembly tool for aiding the connection of the first and second connectors.
- **37**. A method of ablating abnormalities in a tissue, the method comprising the steps of:
  - (a) providing a system for ablation of tissue comprising:
    - an elongated delivery needle comprising a conducting material, said delivery needle having an open proximal end and an open distal end with a lumen extending therebetween, said delivery needle having a first connector, said delivery needle extending longitudinally from said first connector to said open distal end a first predetermined distance;
    - an ablation needle comprising a center conductor circumferentially surrounded by a dielectric material, said ablation needle further comprising a second connector, said ablation needle extending longitudinally a second predetermined distance from the second connector to a distal end wherein said second predetermined distance is greater than said first predetermined distance whereby said ablation needle forms a distal projection extending beyond the distal end of said delivery needle when the first and second connectors are connected, said distal projection forming a microwave antenna, and wherein the ablation needle and the delivery needle form a coaxial transmission line when the first and second connectors are connected wherein said coaxial transmission line electrically couples to said microwave antenna;
    - a microwave energy source, wherein said coaxial transmission line is adapted to electrically couple to said microwave energy source;
  - (b) introducing the distal end of the delivery needle into tissue in a predetermined area;
  - (c) inserting the distal end of the ablating needle into the lumen of the delivery needle through said open proximal end of said delivery needle;
  - (d) advancing the ablating needle until said first and second connectors are adjacent one another;
  - (e) connecting said first and second connectors whereby said coaxial transmission line is formed;
  - (f) coupling said microwave energy source to said coaxial transmission line; and
  - (g) ablating the tissue in the predetermined site by delivering microwave energy to said microwave antenna through said coaxial transmission line.
- **38**. The method of claim 37 wherein said step (b) comprises percutaneously introducing the distal end of the delivery needle into the tissue.

- **39**. The method of claim 37 wherein said step (b) comprises laparoscopically introducing the distal end of the delivery needle into the tissue sample.
- **40**. The method of claim 37 wherein said step (b) comprises introducing the distal end of the delivery needle into the tissue sample through an open surgical incision.
- **41**. The method of claim 38, further comprising the step of:
  - (h) discontinuing the delivery of microwave energy to said microwave antenna after said ablating step.
- **42**. The method of claim 41, further comprising the steps of:
  - (i) disconnecting said first and second connectors; and
  - (j) withdrawing said ablation needle from said lumen of said delivery needle.
- **43**. The method of claim 37 wherein said step (b) forms an insertion track, said method further comprising the steps of:
  - (k) partially withdrawing said delivery needle and said ablation needle after said ablating step; and
  - (1) ablating the insertion track.
- **44**. The method of claim 37, further comprising the steps of:
  - (m) providing 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 disposable within said lumen of said delivery needle;

- (n) inserting the distal end of the biopsy needle into the lumen of the delivery needle through the open proximal end of said delivery needle, said step (n) occurring prior to said step (c) of inserting the distal end of the ablating needle into the lumen of the delivery needle;
- (o) sampling a tissue sample with the biopsy needle; and
- (p) removing the biopsy needle with the tissue sample from the delivery needle.
- **45**. The method of claim 44 wherein said step (b) occurs while said biopsy needle is inserted into the lumen of the delivery needle.
- 46. The method of claim 37 wherein said delivery needle has a proximal portion having a first diameter and a distal portion having a second diameter, and wherein said first diameter is greater than said second diameter, and wherein said step (b) comprises introducing only the distal portion into an affected organ.
- **47**. The method of claim 44 further comprising the steps of
  - (q) providing an additional biopsy needle; and
  - (r) repeating said steps (n) through (p) following said step (g).
- **48**. The method of claim 37, further comprising the step of:
  - (s) providing an assembly tool, wherein said step (e) comprises connecting the first and second connectors using the assembly tool.

\* \* \* \* \*



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		
公开(公告)号	US20020058932A1	公开(公告)日	2002-05-16
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[标]申请(专利权)人(译)	VIVANT医疗		
申请(专利权)人(译)	VIVANT MEDICAL , INC.		
当前申请(专利权)人(译)	COVIDIEN LP		
[标]发明人	MOORMAN JACK W BUSH M ELIZABETH		
发明人	MOORMAN, JACK W. BUSH, M. ELIZABETH		
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### 摘要(译)

公开了一种模块化的活检,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被移除,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。

