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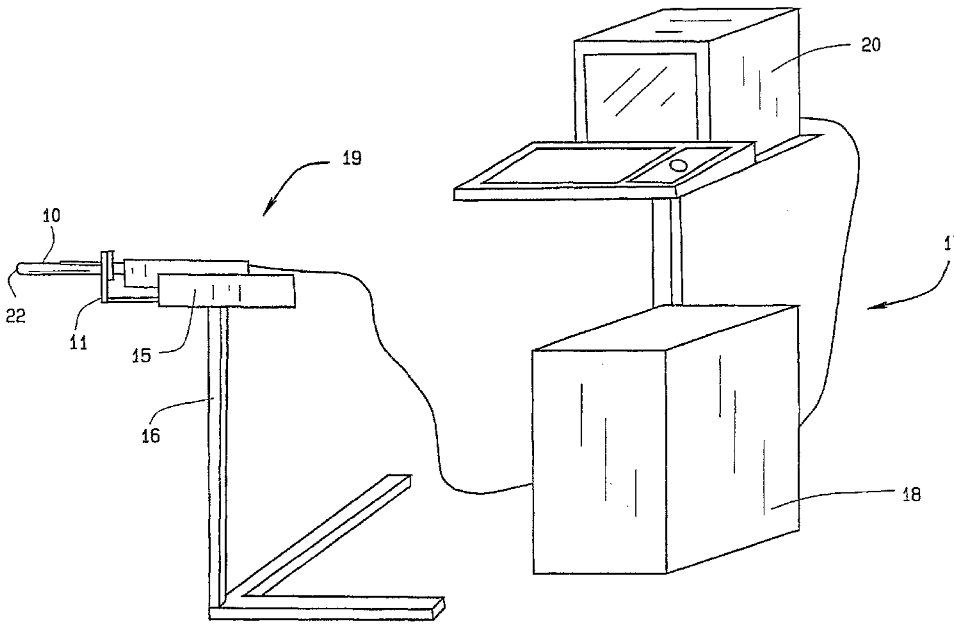
(54) Title: TARGETED BIOPSY DELIVERY SYSTEM



(57) **Abstract:** This invention relates generally to the targeting and biopsy of tissue for medical purposes, and more particularly to a targeted biopsy system which allows planning of tissue to be sampled, targeting of specific areas of tissue in reference to the plan, capturing the tissue sample and recording the source location of the tissue sample, particularly for use in collecting tissue samples from the prostate gland. A further purpose of this invention is to provide a targeted treatment system which allows planning of tissue to be treated, targeting of specific areas of tissue in reference to the plan, and delivering the treatment to the targeted tissue.

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TARGETED BIOPSY DELIVERY SYSTEM

Technical Field

Prostate health is a significant concern for men over the age of fifty. If prostate cancer is suspected from either a physical examination or because of a Prostate Specific Antigens test, a biopsy is performed to collect tissue samples from the prostate for evaluation by a pathologist. Prostate tumors are small growths scattered about the prostate. For this reason, a physician will take multiple tissue samples from different areas of the prostate, typically between 9 and 18 samples.

Background Art

The normal procedure for obtaining biopsy samples with ultrasound guidance is called Transrectal Ultrasound (TRUS) Guided Prostate Biopsy. An end-fire ultrasound probe is used, which generates a pie-shaped image plane. Some end-fire probes are manufactured with a biopsy needle channel, which passes through the body of the probe at an angle, such that a biopsy needle set inserted through the biopsy needle channel exits the channel at a slight angle relative to the body of the probe. Most probes require a needle set guide tube to be affixed to the probe body, such that a needle set placed through the guide tube parallels the axis of the probe and the needle set can be extended beyond the end of the probe. In use for both, the physician inserts the ultrasound probe into the rectum, and moves the probe around until the specific area of the prostate to be sampled is identified. The physician then bends the probe upward, pointing the biopsy needle channel or biopsy needle set guide at the targeted area of the prostate. A needle set is inserted into and through the needle channel or guide, pushed through the rectum wall and into the prostate.

Standard coring biopsy needles sets are made from substantially rigid, coaxially aligned, stainless steel wire and tubing. They are comprised of two basic components; an inner solid wire stylet with specimen notch and a hollow outer cutting cannula. Once the needle set is correctly positioned relative to the area of tissue to be sampled, the inner stylet is quickly advanced under spring loaded or similar pressure into the prostate tissue. The tissue to be sampled then "prolapses" into stylet's sample notch cutout. Almost instantaneously the outer cutting cannula quickly advances, also under spring loaded pressure, which serves to sever and capture the tissue that had prolapsed into the stylet notch. The needle set is then removed from the tissue/patient so that the tissue sample can be extracted from the needle set and evaluated for the presence of cancer. The physician then moves the probe around within the rectum to identify the next area of the prostate to be sampled, and the process is repeated. As noted, between 9 and 18 samples are typically taken from different areas of the prostate.

Existing biopsy methods suffer from a number of disadvantages. Because the probe must be physically moved about within the rectum by hand to identify and target the different areas of the prostate, it is difficult for physicians to precisely targeted biopsy sample locations, often causing the need for additional samples to be taken. Further, if a sample seems to confirm cancer, it is difficult for the physician to accurately know where in the prostate the sample was taken from, and so difficult to re-biopsy the same tissue location to confirm the cancer.

A number of systems or devices have been proposed for the purpose of better targeting biopsies. Batten, et al, (5,398,690) discloses a slaved biopsy device, analysis apparatus, and process. In Batten, an ultrasound device is inserted into the male urinary tract through the penis, with the biopsy and treatment device inserted transrectally. Chin, et al, (6,179,249) discloses an ultrasound guided therapeutic and diagnostic device. Chin is a flexible ultrasound device used for laproscopic surgery. Lin (6,261,234) disclosed a method and apparatus for ultrasound imaging with biplane instrument guidance. Lin's ultrasound device uses two transducers to create two image planes, and has a biopsy needle guide which directs a biopsy needle at the intersection of the imaging planes. Burney, et al (6,447,477) discloses surgical and pharmaceutical site access guide and methods. Burney shows a biopsy device in which a thick needle with side exit ports is inserted into the targeted tissue. Biopsy needles are then inserted into the thick needle, exiting out the side to take samples. Further, a number of systems have specified the use of flexible biopsy needle kits.

However, all of these inventions suffer from a number of disadvantages. All require specialized equipment, and do not make use of existing ultrasound systems and technology. All require the movement of the imaging device, making it more difficult to plan and target areas of the prostate for biopsy. Further, the flexible biopsy needles called out either require heating or additional force to cause them to fire, and are impractical for use with established prostate biopsy procedures and existing biopsy needle set firing devices.

Therefore, users would benefit from a biopsy system to allow a biopsy to be planned prior to the tissue sampling, to allow the biopsy needle to be precisely inserted into a targeted area and which is able to record the precise location from which the tissue sample is collected while the imaging device remains stationary. Users would also benefit from a flexible needle set which may be easily "fired" while in a curved position. Further, users would benefit from a means of precisely delivering a treatment to a targeted area of an organ or tissue mass.

Summary Of The Invention

It is the principal object of this invention to provide a device and method for precisely planning, undertaking and recording a multi-sample biopsy of a targeted tissue mass such as a prostate, improving physicians' ability to diagnose cancer.

Another object of the invention is to allow a biopsy plan to be formulated identifying the specific quadrants and areas of the prostate to be sampled.

Another object of the invention is to allow this biopsy plan to be saved as a reference point.

Another object of the invention is to allow a physician to adjust the biopsy needle guide to allow the physician to precisely insert the needle into the tissue at the planned location.

Another object of the invention is to allow a physician to monitor the needle set as it is inserted into the tissue, to verify that the needle is in the planned location.

Another object of the invention is to provide a biopsy needle guide which can be affixed to or associated with existing side-imaging transrectal ultrasound probes.

A further object of the invention is to allow the transrectal ultrasound probe to remain stationary while the biopsy samples are gathered from different areas of the prostate, thereby improving the accuracy of the procedure.

A further object of the invention is to allow the probe to remain stationary while the needle guide is moved longitudinally along the probe and is also rotated around the probe.

A further object of the invention is to provide a needle set guide which can redirect the needle set such that the needle set can be curved while still maintaining the freedom of movement to allow the firing and collecting of tissue samples.

A further object of the invention is to provide a biopsy needle set that may be redirected at an angle and further maintains its ability to be fired and so collect the tissue samples.

An object of an alternative embodiment of the invention is to allow a treatment plan to be formulated identifying the specific areas of tissue or an organ to be treated.

A further object of an alternative embodiment of the invention is to allow this treatment plan to be saved as a reference point.

Another object of an alternative embodiment of the invention is to allow a physician to precisely insert a needle or treatment delivery means into the tissue at the planned location.

Another object of the invention is to allow a physician to monitor the needle or treatment delivery method as it is inserted into the tissue, to verify that the needle or treatment delivery method is in the planned location.

These and other objects, advantages and features are accomplished according to the devices and methods of the following description of the preferred embodiment of the invention.

As noted the present invention relates to a biopsy targeting system for use with ultrasound imaging devices, and particularly for use in sampling prostate tissue. The biopsy targeting system consists of a redirecting biopsy needle guide which works in conjunction with a side-view or end-fire transrectal ultrasound probe, a cooperating software program which can be loaded and operated on a computer controlled ultrasound system, and a bendable needle set.

In use, the transrectal ultrasound probe is placed in the cradle of a stabilizer. The redirecting needle guide positioning assembly is also affixed to the cradle. The physician then advances and adjusts the cradle to allow the transrectal probe to be inserted into the rectum of a patient. The physician generates an ultrasound image while positioning the probe to insure that the patient's prostate is viewable within the viewing area of the probe. Once the probe is correctly positioned, the physician then locks the probe in place in the stabilizer.

With the transectal probe in place, the physician initiates a full 3D scan of the prostate. The multiple image slices are captured by the ultrasound system. The physician then looks through these saved images, to identify possible problem areas of the prostate and further to decide which areas of the prostate to sample. Typically, physicians collect 9 to 18 tissue samples from different areas of the prostate. As part of this process, the physician is able to use the software program to project potential needle path lines onto the images of the prostate. These paths are shown as lines in views parallel to the needle path and as circles where the paths pierce the image plane. Each possible path is described by the positional settings of the redirecting needle guide. When the physician identifies a specific area to be sampled, the physician moves a projected needle path line to intersect the planed area to be biopsied. The physician continues to evaluate the prostate and target additional areas for sampling, again saving projected needle paths for each planned sample. Further, if the physician does not identify any possible problem areas, but wishes to take a standard biopsy, the physician can use a range of default setting on the computer program to project between 9 and 18 projected needle paths with a standard distribution throughout the prostate.

Once the biopsy is planned, the physician initiates the biopsy. All of the needle paths for a given longitudinal image are displayed on the ultrasound monitor. The display shows the coordinates of the planned needle paths which correlate to the positional setting of the redirecting needle guide. The physician then advances and/or rotates the redirecting needle guide to the correlating coordinates for the first planned needle path. The physician then inserts a flexible biopsy needle kit into the redirecting needle guide's needle insertion point. The needle set is advanced by hand through the needle set channel, including through the redirecting curve within the needle guide. This redirecting curve causes the needle to exit the needle guide, within the rectum of the patient, at an angle relative to the transrectal probe. The physician pushes the needle guide through the tissue of the rectal wall and into the prostate, monitoring the progress of the needle on the ultrasound system and insuring that the actual path of the needle matches the planned needle path being projected on the image. When the biopsy needle set has achieved the correct depth of penetration, the physician uses a standard biopsy firing gun to "fire" the needle set, causing the stylet and cannula to quickly extend in sequence, cutting and capturing a slice of prostate tissue in the specimen notch of the needle set. Because the specimen notch is substantially longer than in standard biopsy needles and the cannula body is flexible, the needle set is very flexible and able to be fired even though bent. The specimen notch is extended to the curved portion of the needle set within the redirecting needle set guide, allowing the stylet to be quickly moved in reference to the cannula without binding. With the needle still in the prostate, the physician saves the ultrasound image(s) on the computer program, creating a permanent record of the biopsy tissue location. The physician then removes the biopsy needle with captured tissue sample. Once removed, the cannula is retracted from the stylet, allowing the tissue sample to be placed into a tissue specimen dish. The physician then advances or moves the redirecting biopsy needle guide to the next planned needle path location, and repeats the procedure.

Brief Description Of The Drawings

FIG. 1 is a perspective view of targetable biopsy system in conjunction with an ultrasound imaging system and stabilizer.

FIG. 2 is a perspective view of the redirecting needle set guide mounted on a side-imaging transrectal ultrasound probe.

FIG 3 is a side view of the redirecting needle set guide mounted on a side-imaging transrectal ultrasound probe, showing the guide positioning assembly.

FIG. 4 is a planning software interface displayed on the monitor.

FIG. 5 is a schematic of the biopsy planning process.

FIG. 6 is a schematic of the biopsy procedure.

FIG. 7 is a side view of an embodiment of the targetable biopsy guide.

FIG. 8 is a side cutaway view of an embodiment of the targetable biopsy guide designed to be manufactured with an insertable metal tube.

FIG. 9 is a side cutaway view of an alternative embodiment of the targetable biopsy guide.

FIG. 10 is a side cutaway view of an alternative embodiment of the targetable biopsy guide with an enlarged bend channel.

FIG. 11 shows a side view of a biopsy stylet with extended specimen notch.

FIG. 12 shows a side view of an alternative embodiment of the stylet with dual extended specimen notches.

FIG. 13 shows a side view of an alternative embodiment of the stylet with a tiered specimen notch.

FIG. 14 shows a side view of an alternative embodiment of the stylet with multiple notches to facilitate bending

FIG. 15 shows a side view of an embodiment of the cannula in which the cannula tube has been ground down along its length to leave a flexible spine.

FIG. 16 shows a side view of an embodiment of the cannula in which the cannula tube has been spiral-cut along its length to facilitate bending of the cannula.

FIG. 17 shows a side view of an alternative embodiment of the cannula in which the tip of the cannula tube is uncut while the body of the cannula tube has been spiral-cut.

FIG. 18 shows a side view of an alternative embodiment of the cannula in which sections of the cannula tube alternate between cut and uncut.

FIG. 19 shows a side view of an embodiment of the cannula in which the cannula tube is encased in flexible tubing.

FIG. 20 shows a perspective view of an embodiment of the flexible needle set.

FIG. 21 is a side view of the traditional method of taking a prostate biopsy with a biopsy needle channel.

FIG. 22 is a side view of the bendable needle and biopsy targeting system mounted on a side-fired probe taking a biopsy.

FIG. 23 is a side view of the redirecting guide with a flexible needle set inserted and extending out of the guide such that the needle set is bent by the needle set channel bend.

Parts Numbers

Rectum	1
Prostate	2
redirecting guide	10
alternative redirecting guide	10A
positioning assembly	11
targeting software system	12
flexible needle set	13
cradle	15
stabilizer	16
ultrasound system	17
ultrasound system CPU	18
side view transrectal probe	19
monitor	20
probe tip	22
probe imaging window	23
guide body	30
needle set channel	31
needle set insertion point	32
needle set exit point	33
front body guide extensions	34A, 34B
imaging cutout	35
needle set channel bend	36
enlarged bend channel	37
insertable metal tube	38
rotational adjustment collar	40
fixed collar	41
longitudinal slides	42

longitudinal position controller	43
needle path location registry	50
needle path lines	51
needle path dots	52
flexible stylet	60
flexible cannula	61
tip	62
extended specimen notch	63
stylet body	64
cutting tip	65
cannula body	66
counter bore and taper	67
bending notches	70
tiered specimen notch	71
segmented specimen notch	72
removable needle set guide insert	75
stylet hub	76
cannula hub	77
strip	78
depth markings	79
cannula sheath	81
spiral cut	82
non-spiral cut portion	83
beveled edge	84
Biopsy attachment angle selector and display	201
Biopsy attachment depth selector and display	202
needle path coordinates display	204

window	
Finished with Biopsy Planning button	206
Remove selected biopsy location from plan button	207
Add selected biopsy location to plan button	208
Select pre-planned template	209
Sagittal image plane selector	210
Transverse image plane selector	211
Transverse image display	212
Sagittal Image display	213

Best Mode for Carrying Out the Invention

As seen in FIG. 1, the targeted biopsy system is comprised of a redirecting guide 10, positioning assembly 11, targeting software system 12 (loaded on CPU 18) and flexible needle set 13 (best seen in FIG. 20). The positioning assembly 11 is affixed to cradle 15, which is a part of stepper and stabilizer 16. Working in conjunction with the targeted biopsy system is ultrasound system 17, which is comprised of ultrasound system CPU 18, side view transrectal probe 19 and monitor 20. Side view transrectal probe is comprised of probe tip 22 and probe imaging window 23. As seen in FIGS. 2 and 7, the redirecting guide 10 consists of guide body 30, needle set channel 31, needle set insertion point 32, and needle set exit point 33, front body guide extensions 34A and 34B, imaging cutout 35. As seen in FIG 10, needle set channel 31 may be provided with enlarged bend channel 37. As seen in FIG 8, the redirecting guide 10 may be provided with insertable metal tube 38. In an alternative embodiment, the redirecting guide may contain one or more pathways may be used for insertion of the biopsy needle kit. The redirecting guide may be comprised of a movable device such that the opening through which the needle kit exits may be moved relative to the opening into which the biopsy needle kit is placed. In a further alternative embodiment, the redirecting guide may straighten a previously curved biopsy needle kit such that the biopsy needle kit re-curve when leaving the redirecting guide.

As best seen in FIG. 3, positioning assembly 11 is comprised of rotational adjustment collar 40, fixed collar 41, longitudinal slides 42 and longitudinal position controller 43.

As best seen in FIG. 4, targeting software system 12 is comprised of transverse image display 212, Sagittal Image display 213, longitudinal projected needle path 51 and transverse projected needle path 52, in addition to various controls.

As best seen in FIG. 20 flexible needle set 13 consists of flexible stylet 60 and flexible cannula 61. Stylet 60 may be affixed to stylet hub 76, with cannula 61 affixed to cannula hub 77. Further, cannula 61 may be provided with depth markings 79. As seen in FIG. 11, the preferred Flexible stylet 60 consists of tip 62, extended specimen notch 63 and stylet body 64. As seen in FIG 12, an alternative preferred Flexible stylet 60 consists of tip 62 and segmented specimen notches 72a and 72b. Alternative embodiments of flexible stylet 60, as seen in FIGS. 13 and 14, contain bending notches 70 and tiered specimen notch 71.

As seen in FIG 19, the preferred embodiment of cannula 61 consists of cutting tip 65, cannula body 66 and cannula sheath 81. The cannula sheath may have beveled edges. As seen in FIG 15, a portion of the body of flexible cannula 61 has been removed. As seen in FIG 16, cannula body 66 may be provided with spiral cut 82 to facilitate bending. As seen in FIG 17, in an alternative embodiment of cannula 61, cannula body 66 may be provided with non-spiral cut portion 83 at cutting tip 65, to facilitate the straight entry of the cannula into the tissue. As seen in FIG 18, in a further alternative embodiment of cannula 61, cannula body 66 may be provided with non-spiral cut portions 83 interspersed with spiral cuts 82. In an alternative embodiment of flexible cannula 61 consists of a cutting tip inserted into the flexible cannula body.

It should be noted that both the stylet cannula can be made from a range of flexible materials, including combinations of one or more materials, to facilitate the bendability. This may include traditional materials used in medical devices, such as stainless steel, as well as materials such an nitinol®. Furthermore, the cannula design may mirror the stylet, such that portion or portions of the metal cannula tube are removed to create a metal component which has a metal cutting tip, a long spine consisting of only a portion of the cannula wall in the flexible part of the cannula and then the full tubular cannula. Furthermore, the machine cannula may be partially or wholly incased in a cannula sheath, which may be plastic or some other material.

FIG. 21 shows a biopsy being performed using the standard method, using an end-fire ultrasound probe with a biopsy needle channel. The probe is inserted into the rectum, and then angled upward until the probe tip is pointed at the desired portion of the prostate. A needle set is then inserted through the biopsy needle channel guide into the prostate 2.

In use of the preferred embodiment of the invention, as seen in FIGS. 1 and 22, side view transrectal probe 19 is mounted on the cradle 15 of a stabilizer 16. Redirecting guide 10 is also mounted on the cradle 15, such that guide body 30 sits atop probe tip 22. As seen in FIG. 2, front body extensions 34a and 34b partially wrap around probe tip 22 to help maintain the guide body 30 on the probe tip 22. The cradle 15 is moved forward, with the probe tip 22 inserted into patient's rectum 1. Probe tip 22 is generating ultrasound images, which are displayed on monitor 20. The physician uses this image to insure that the entirety of prostate 2 is viewable by probe imaging window 23. Once the probe tip 22 is correctly positioned, the physician locks in place cradle 15.

The biopsy planning process is illustrated in FIG. 5. A representative display of the biopsy information to the user is shown in FIG 4.The process begins with the planning software obtaining a set of volumetric data 101. The volumetric data consists of two sets of sampled images. One set is of longitudinal images sampled at a regular angular spacing, and the other is a set of transverse images sampled at regular depth spacing. If only one of the two sets is available, one may be interpolated from the other. The physician starts the planning process by pressing button 203 to satisfy step 102 of FIG 4. For 103, the planning system overlays a series of lines 51 a, b, c, etc. and dots 52 a, b, c, etc. on the images in panes 212 and 213. These lines and dots represent the available needle paths selectable with controls 40 and 43, and show where the needle intersects with image planes. Each line and dot combination is labeled with a coordinate 50 corresponding to a unique pair of setting for controls 40 and 43. The user can review the stored images using controls 210 and 211 to change the image viewed. For 104, the user can "simulate" the effect of controls 40 and 43 using on-screen controls 201 and 202 to adjust the selected needle path. The current path is displayed by changing the color of the appropriate line and dot (51 and 52, respectively). The user adds a specific needle path to the biopsy plan (105) by selecting button 208. Each time a path is selected, a record is placed into needle path coordinates display window 204 showing the coordinates of the path. The user may also remove a specific path from the plan by selecting button 207. When the plan is complete, the user clicks on the button 206 to send the planning process (106).

Once the biopsy planning process has been completed, the physician or technician may then proceed with the biopsy procedure, to complete the series of precision located biopsy's to be taken through the usage of this instrument. For example, as can be noted in FIG. 6, once a biopsy procedure has been completed, the physician then determines whether any more biopsies are needed, and where the biopsy locations may be determined. This can be seen at 301. If no additional biopsies are required, this is the end of the procedure. If additional biopsies are considered as needed, the physician then adjusts the redirection of the guide 10, and the longitudinal controller 40, to mass the desired biopsy coordinates, as provided upon the scanner. This can be noted at 302. Then, the user inserts a needle set 13 into the channel 32, to prepare for additional biopsies. The physician then inserts the needle into the patient, moving the needle in and out to adjust for depth, as determined by the scanner, as can be seen at 304. Then, the physician can determine if the needle tip is at the correct depth, at 305. If it is not, then the physician may move the needle and adjust its depth further. If it is, the physician then fires the needle of the biopsy instrument, as at 306. Then the physician removes the needle set 13 from the patient, having taken the biopsy as required. Then, the tissue sample is removed from the biopsy needle notch, for further analysis by the lab. This can be noted at 308. When this is completed, this concludes the conduct of biopsies upon the patient.

As alternative to the procedure in FIG 4, preplanned biopsy selection menu 209 allows the user to select a pre-determined needle pattern, typically 9-12 needle paths, without having to select each needle path manually. The needle paths generated could need to be adjusted for the specific size of the organ. The size of the organ can be input by various means. The planning process allows the physician to modify the needle paths as needed and to approve that they are correct.

Projected needle paths 51a, 51b, etc, include needle path location registry 50, which indicate the horizontal and rotational position of the needle path in reference to the probe. Working from the saved biopsy plan, displayed in 204, the physician rotates redirecting guide 10 using rotational adjustment collar 40, and then advances the redirecting guide using longitudinal position controller 40, both of which have position information which correlates to the needle path location registry 50. As seen in FIG. 18, the physician inserts flexible needle set 13 into needle set insertion point 32 and into needle set channel 31. When the needle set 13 reaches needle set channel bend 36, the needle set 13 is redirected at an angle away from the axis of probe tip 22. Needle set 13 exits needle set exit point 33. Because of imaging cutout 35, the physician is able to see the needle set in the ultrasound image as it exits exit point 33, allowing the physician to insure that the needle set 13 is in the path marked by projected needle path 51a. The physician monitors the depth of the needle set 13 as it is pushed through the rectum wall and into the prostate 2. Once the desired depth is reached, the physician stops inserting the needle set 13. Using a standard biopsy gun, the needle set 13 is “fired”. This causes flexible stylet 60 to rapidly advance a short distance, such that tissue from the prostate two prolapses into extended specimen notch 63. Almost instantaneously flexible cannula 61 quickly advances, also under spring loaded pressure or other motivational means, which serves to sever and capture the tissue that had prolapsed into the extended specimen notch 63. Because the extended specimen notch 63 extends to the point where flexible needle set 13 is bent in needle set channel bend, the stylet and cannula are able to fire without the two pieces binding together, allowing the specimen to be effectively captured. The physician then removes the flexible needle set 13 with the captured specimen. The specimen is removed from the flexible needle set, and the physician then resets the redirecting guide to the coordinates of the next saved projected needle path 51b. The process is repeated until the physician has captured all of the samples as planned using the targeting software system 12.

FIG. 23 provides a side cut-away view of the redirecting guide with a flexible needle set inserted and extending out of the guide such that the extended specimen notch is bent by the needle set channel bend.

In an alternative embodiment of the invention, the invention is used to plan and perform a targeted treatment of an organ or tissue mass. With the device in place, the process begins with the planning software obtaining a set of volumetric data. The planning system overlays a series of needle path lines and needle path dots on the images in panes 212 and 213, which represent the available needle paths with coordinates that match the coordinates on rotational adjustment collar 40 and longitudinal position controller 43 of positioning assembly 11. The user selects specific needle paths, which are saved the treatment plan. Preplanned treatment selections allow the user to select a pre-determined needle pattern without having to select each needle path manually.

Working from the saved treatment plan, the physician rotates redirecting guide using rotational adjustment collar, and then advances the redirecting guide using longitudinal position controller, both of which have position information which correlates to the needle path location registry. The physician then inserts a flexible needle set or treatment delivery means into needle set insertion point 32 and into needle set channel 31. When the needle set or treatment delivery means reaches the needle set channel bend, the needle set or treatment delivery method is redirected at an angle away from the axis of probe tip 22. Needle set 13 exits needle set exit point 33. Because of imaging cutout 35, the physician is able to see the needle set or treatment delivery method in the ultrasound image as it exits exit point 33. The physician monitors the depth of the needle set or treatment delivery method as it is pushed into the targeted organ or tissue mass. Once the desired depth is reached, the physician is able to undertake the preferred activity. This may include using the delivery means to inject a solid, gas or liquid material or other treatment apparatus into the targeted organ or tissue mass. Further, the physician may insert an organism into the targeted organ or tissue mass. The material may be deposited and left in the targeted organ or tissue mass. Further, material previously deposited may be removed. The use of the deposited material may be as a treatment, a marker, or other uses. Further, the delivery means may be used to apply energy to a targeted organ or tissue mass, including but not limited to heat, cold, light and radiation. Once the treatment or marking is delivered, the physician then removes the flexible needle set or treatment delivery method, and then resets the redirecting guide to the coordinates of the next saved projected needle path. The physician has the option of saving the image of the treatment needle in the targeted organ or tissue mass, to record the location of the treatment as delivered. The process is repeated until the physician has treated or marked all of the targeted areas of the organ or tissue mass.

Claims

What is claimed is:

1. A targetable biopsy system comprising:

a flexible biopsy needle kit;

a redirecting biopsy needle guide;

an imaging means;

a biopsy planning and recording means;

such that a specific area of tissue may be accurately targeted for tissue collection.

2. The device of claim 1 whereby said flexible biopsy kit is comprised of:

a flexible stylet containing an extended specimen notch;

a flexible cannula;

3. The device of claim 1 whereby said stylet and said cannula are manufactured with a pre-formed curve

4. The device of claim 1 whereby said stylet and said cannula are manufactured from flexible material such as nitinol ® or plastic.

5. The device of claim 1 whereby said stylet and said cannula are manufactured without a pre-formed curve.

6. The device of claim 1 whereby said stylet is assembled from two or more sections each made of materials with different properties to improve the flexibility.

7. The device of claim 1 whereby said cannula is assembled from two or more sections each made of materials with different properties to improve the flexibility.

8. The device of claim 1 whereby the length of said specimen notch is increased to improve the flexibility of the stylet.

9. The device of claim 1 whereby multiple specimen notches are used to improve the flexibility of the stylet.

10. The device of claim 1 whereby the depth of the specimen notches varies to improve the flexibility of the stylet.

11. The device of claim 1 whereby said redirecting biopsy needle guide is comprised of:

an opening into which a biopsy needle kit may be inserted;

an opening through which a portion of the biopsy needle kit exits;

a means of redirecting said biopsy needle kit such that the portion of the biopsy needle kit which has exited the biopsy needle guide is angled relative to the portion of said biopsy needle kit which has not been inserted into said biopsy needle guide.

a means of positioning the redirecting biopsy needle guide relative to an ultrasound imaging device which remains fixed.

12. The device of claim 1 whereby said means of redirecting the biopsy needle physically bends a previously straight biopsy needle kit.

13. The device of claim 1 whereby said means of redirecting straightens a previously curved biopsy needle kit such that the biopsy needle kit re-curve when leaving the redirecting means.

14. The device of claim 1 whereby said means of redirecting is comprised of one or more static angled or curved channels.

15. The device of claim 1 whereby said means of redirecting straightens is comprised of a movable device such that the opening through which the needle kit exits may be moved relative to the opening into which the biopsy needle kit is placed.

16. The device of claim 1 whereby said redirecting biopsy needle guide is affixed to or associated with an ultrasound or imaging system.

17. The device of claim 1 whereby said redirecting biopsy needle guide may selectively positioned or rotated relative to the imaging portion of the imaging means.

18. The device of claim 1 whereby said redirecting biopsy needle guide is provided with demarcations or other indications of position relative to the imaging portion of the imaging means.

19. The device of claim 1 whereby said imaging means records the position of the biopsy sample.

20. The device of claim 1 whereby said imaging means may include a biopsy plan specifying the preferred locations of the biopsies relative to the position of the imaging portion of the imaging means.

21. The device of claim 1 whereby said redirecting biopsy needle guide may be positioned or rotated relative to the imaging portion of the imaging consistent with the planned biopsy locations of the biopsy plan.

22. A biopsy needle kit comprising:

a flexible stylet containing an extended specimen notch;

a flexible cannula.

23. The device of claim 22 whereby said stylet and said cannula are manufactured with a pre-formed curve from flexible material such as nitinol ® or plastic or other suitably flexible material.

24. The device of claim 22 whereby said stylet and said cannula are manufactured without a pre-formed curve.

25. The device of claim 22 whereby said stylet is assembled from two or more sections each made of materials with different properties to improve the flexibility.

26. The device of claim 22 whereby said cannula is assembled from two or more sections each made of materials with different properties to improve the flexibility.

27. The device of claim 22 whereby the length of said specimen notch is increased to improve the flexibility of the stylet.

28. The device of claim 22 whereby the cross section of said stylet is reduced for a portion of the length of the stylet to improve the flexibility of the stylet.

29. The device of claim 22 whereby the cross section of said stylet alternates between areas where the cross section is reduced and areas where the cross section is not reduced to improve the flexibility of the stylet.

30. The device of claim 22 whereby the cannula is spiral cut to improve flexibility.

31. The device of claim 22 whereby the body of the cannula is spiral cut but the tip of the cannula body is not.

32. The device of claim 22 whereby the body of the cannula alternates between spiral cut portions and non-spiral cut portions.

33. A redirecting biopsy needle guide comprising:

an opening into which a biopsy needle kit may be inserted;

an opening through which a portion of the biopsy needle kit exits;

a means of redirecting said biopsy needle kit such that the portion of the biopsy needle kit which has exited the biopsy needle guide is angled relative to the portion of said biopsy needle kit which has not been inserted into said biopsy needle guide.

34. The device of claim 33 whereby said means of redirecting the biopsy needle physically bends a previously straight biopsy needle kit.

35. The device of claim 33 whereby said means of redirecting straightens a previously curved biopsy needle kit such that the biopsy needle kit re-curve when leaving the redirecting means.

36. The device of claim 33 whereby said means of redirecting is comprised of one or more static angled or curved channels.

37. The device of claim 33 whereby said means of redirecting is comprised of a movable device such that the opening through which the needle kit exits may be moved relative to the opening into which the biopsy needle kit is placed.

38. The device of claim 33 whereby said biopsy needle guide may be affixed to or associated with an ultrasound or imaging system.

39. The device of claim 33 whereby said biopsy needle guide may selectively positioned or rotated relative to the imaging portion of the ultrasound or imaging system.

40. A targeted medical deliver mechanism comprising:

a flexible delivery means;

a flexible cannula;

a redirecting cannula guide;

Whereby the cannula can be inserted into specific area of tissue and said delivery means can be inserted through the cannula to said specific area of tissue.

41. The device of claim 40 whereby said delivery means deposits a material in said specific area of tissue.

42. The device of claim 40 whereby said delivery means deposits and removes a material in said specific area of tissue.

43. The device of claim 40 whereby said delivery means removes a previously-deposited material in said specific area of tissue.

44. The device of claim 41 whereby said material may be a solid, liquid or gas.

45. The device of claim 42 whereby said material may be a solid, liquid or gas.

46. The device of claim 43 whereby said material may be a solid, liquid or gas.

47. The device of claim 43 whereby said material may be organic.

48. The device of claim 43 whereby said material may be a living organism.

49. The device of claim 40 whereby said delivery means is used to apply energy to said specific area of tissue.

50. The device of claim 49 whereby said energy may be heat, cold, visible or non-visible radiation.

51. A biopsy planning and recording means comprising:

means of receiving and displaying images generated by the imaging means;

means of projecting needle image path information onto said displayed images;

means of recording projected needle path locations

means of recording actual needle path locations

52. The device of claim 51 whereby said biopsy and planning means can project a line which correlates with a needle path.

53. The device of claim 51 whereby said biopsy and planning means can project a dot which correlates to the intersection of the needle path with the imaging plane.

54. The device of claim 51 whereby said projected needle image path information can be positioned relative to a landmark of the scanned organ or tissue mass.

55. The device of claim 51 whereby said projected needle image path information can be correlated to the redirecting guide positioning selection.

56. The device of claim 51 whereby said biopsy and planning means can be used to simulate the insertion of a needle into the targeted organ or tissue mass.

57. The device of claim 51 whereby said received images can be used to build a graphical representation of the targeted organ or tissue mass showing the positions of the projected and actual needle paths relative to the targeted organ or tissue mass.

58. The device of claim 51 whereby said recording projected and actual needle paths can be recorded to an external medium or transmitted to an external location.

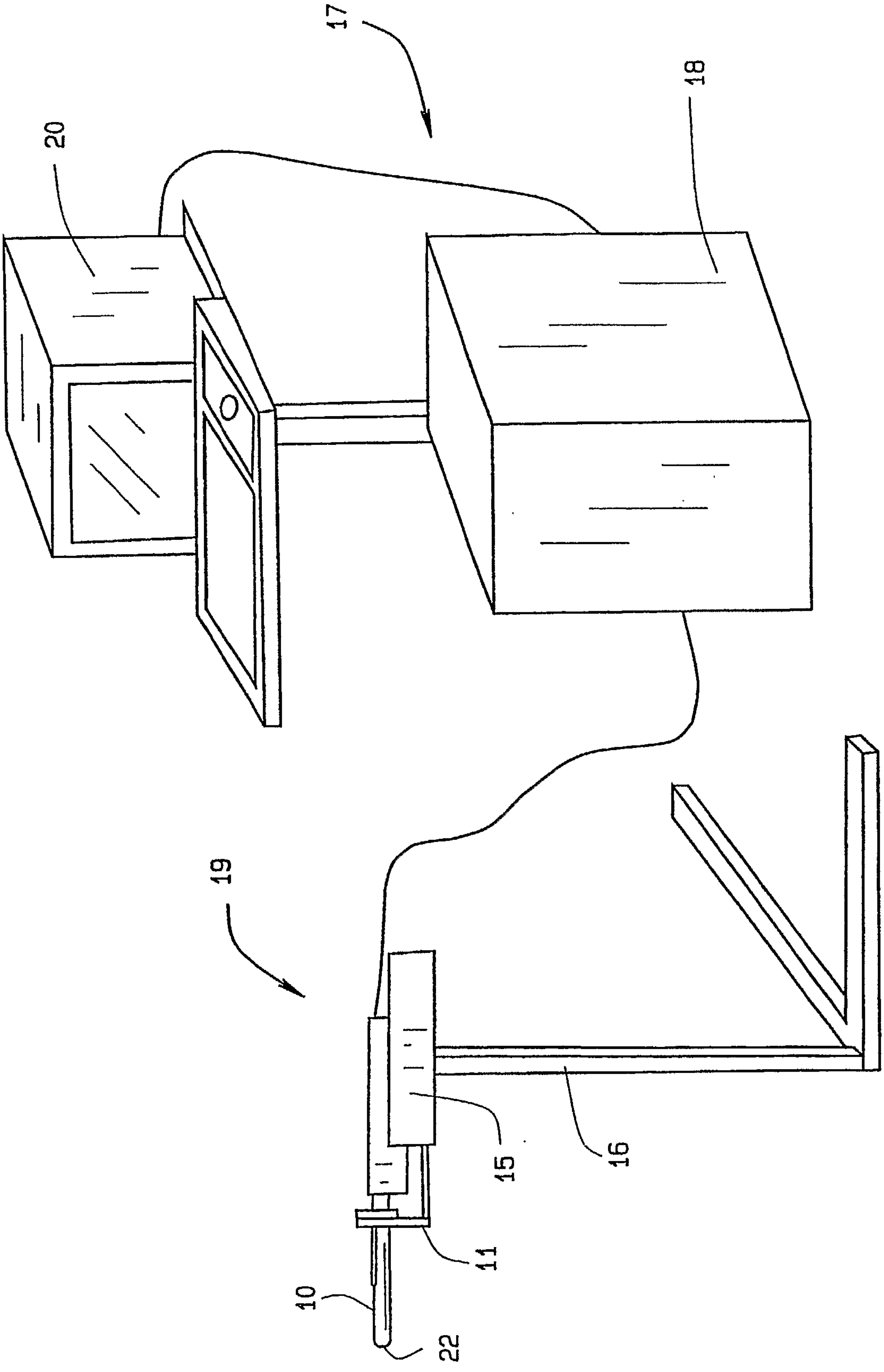

FIG. 1

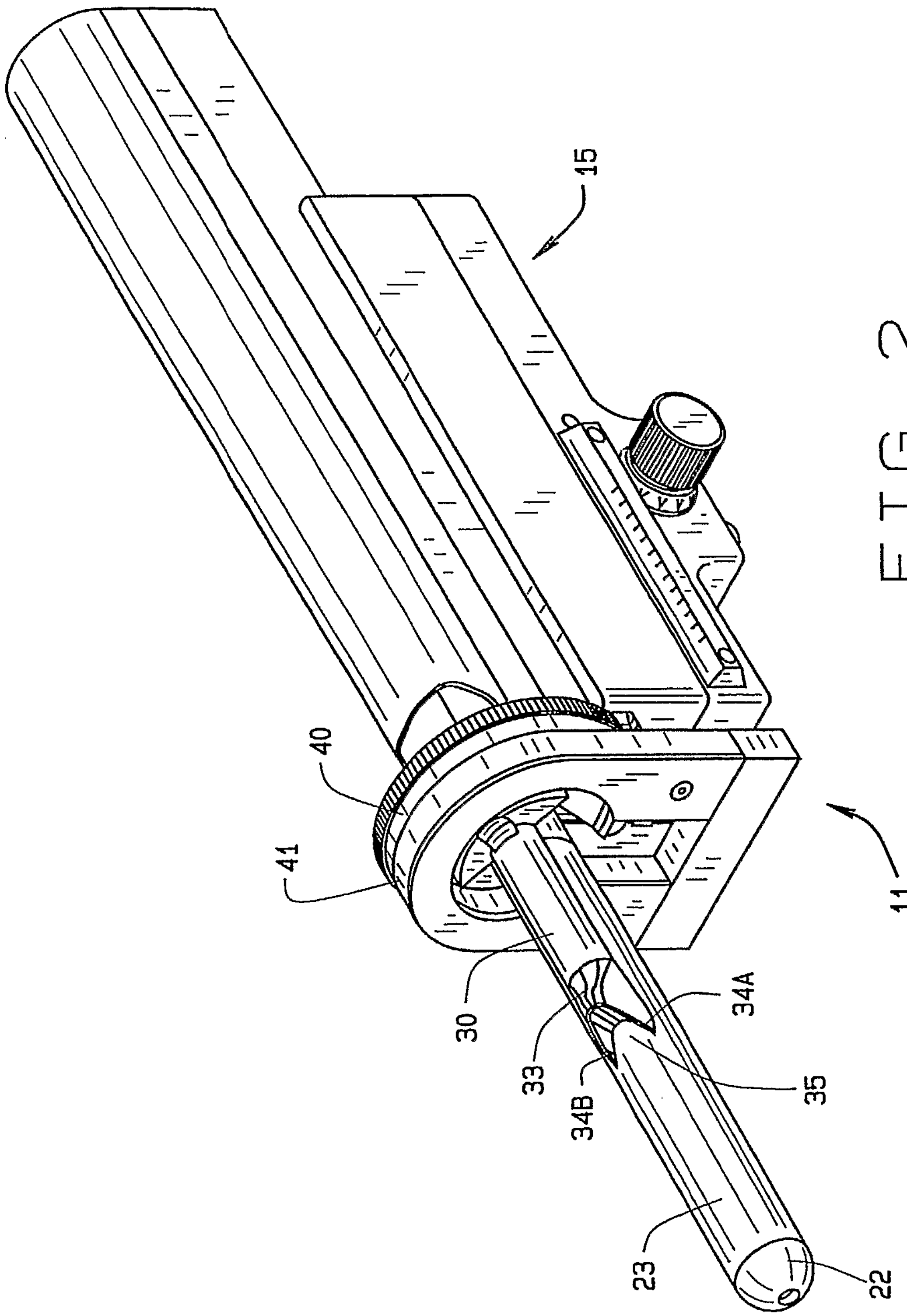

FIG. 2

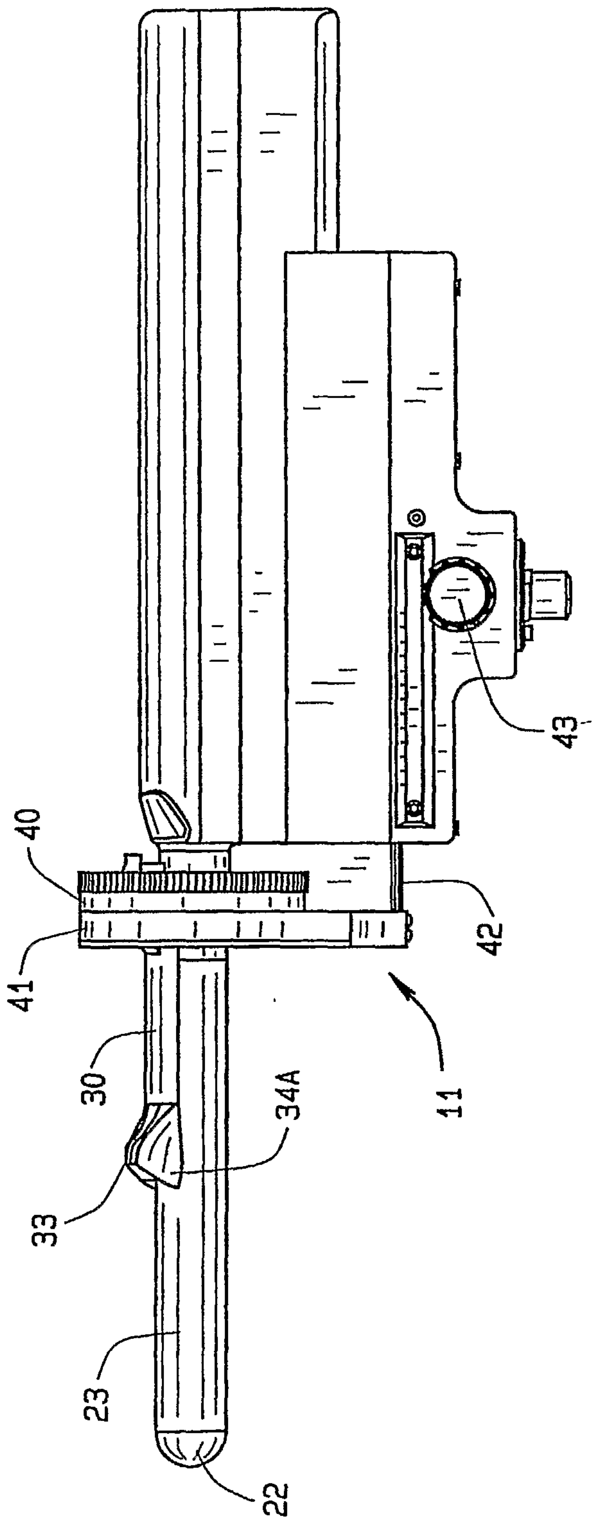

FIG. 3

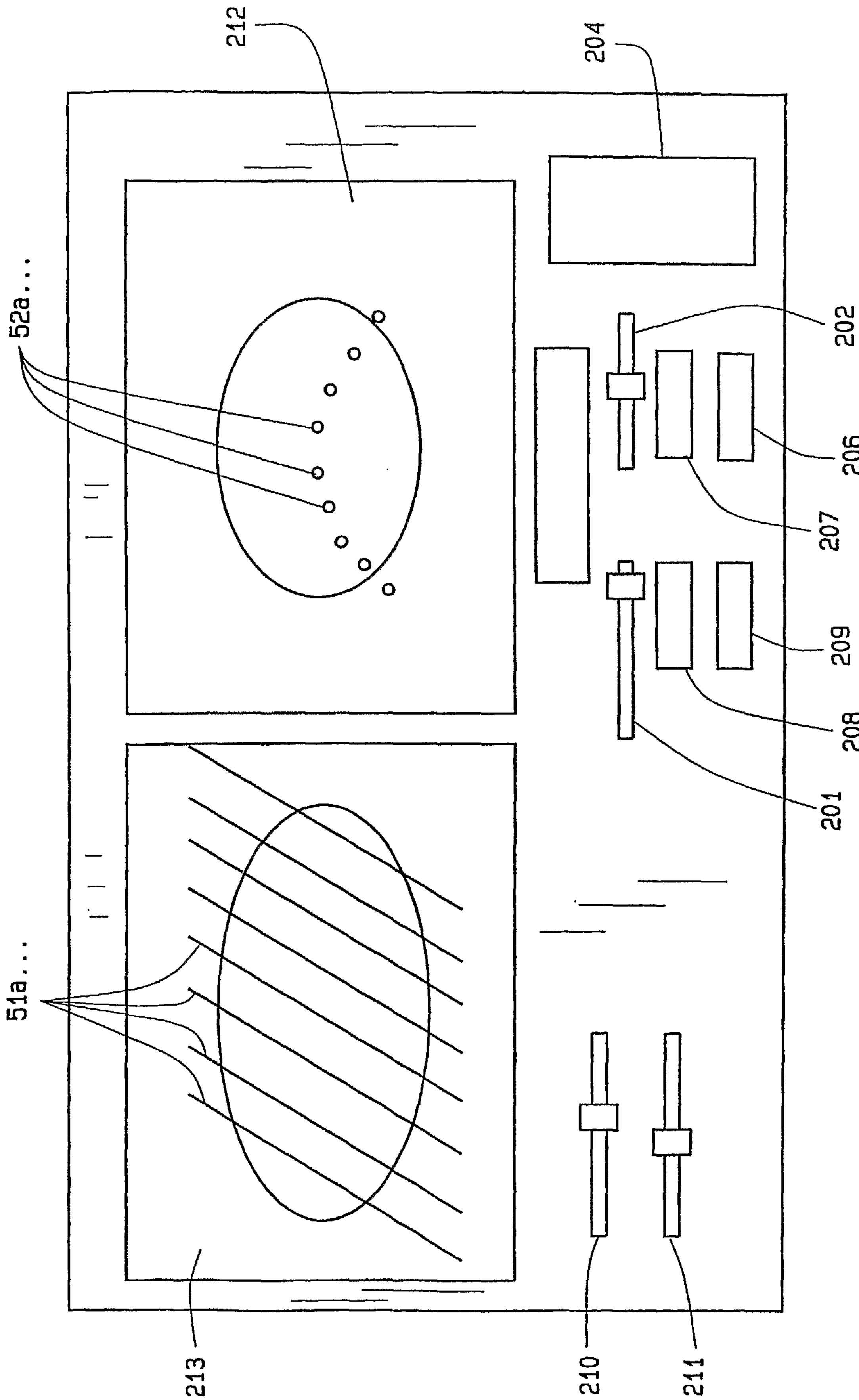

FIG. 4

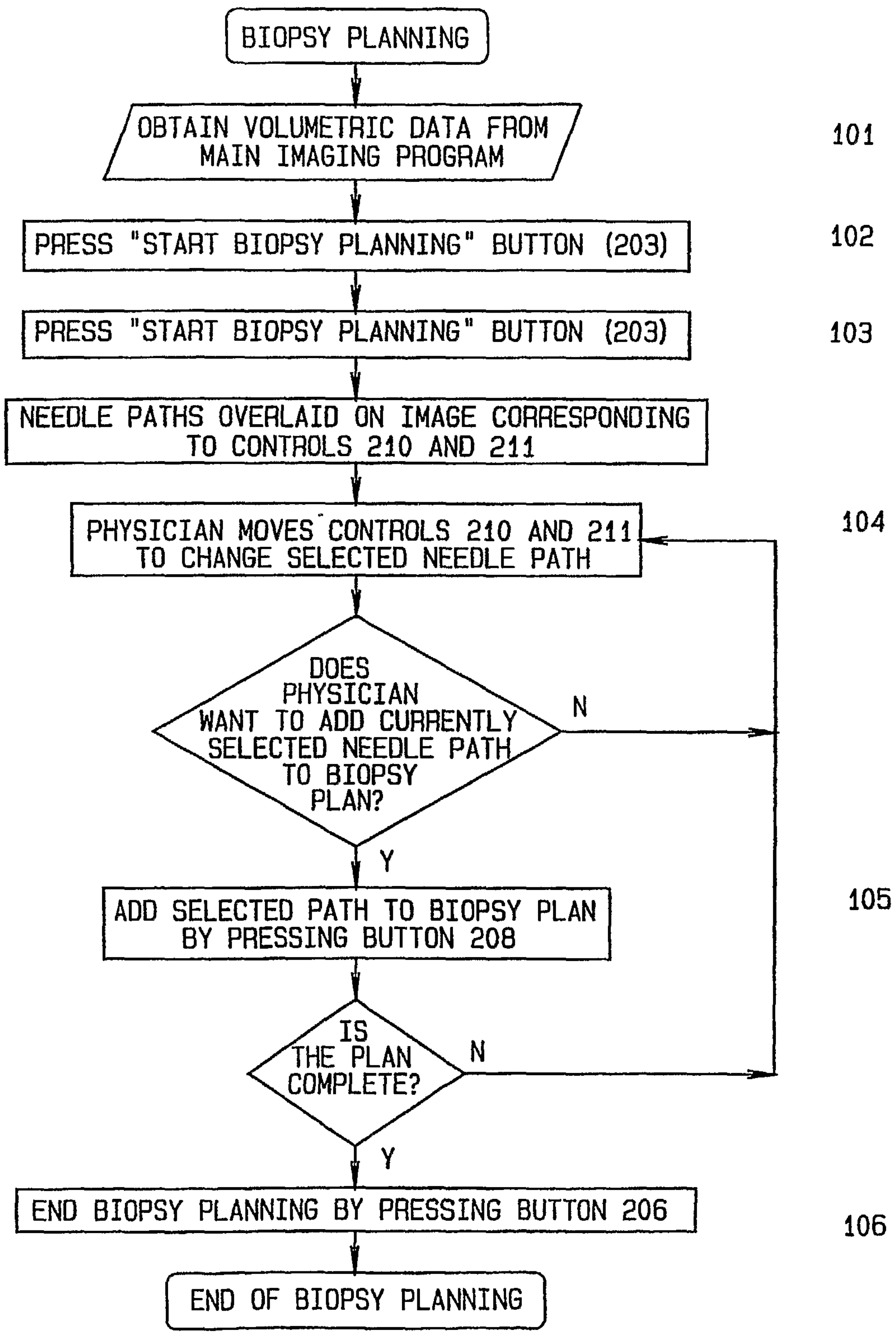
BIOPSY PLANNING
OBTAIN VOLUMETRIC DATA FROM MAIN IMAGING PROGRAM
101
PRESS "START BIOPSY PLANNING" BUTTON (203)
102
PRESS "START BIOPSY PLANNING" BUTTON (203)
103
NEEDLE PATHS OVERLAID ON IMAGE CORRESPONDING TO CONTROLS 210 AND 211
PHYSICIAN MOVES CONTROLS 210 AND 211 TO CHANGE SELECTED NEEDLE PATH
104
DOES PHYSICIAN WANT TO ADD CURRENTLY SELECTED NEEDLE PATH TO BIOPSY PLAN?
N
Y
ADD SELECTED PATH TO BIOPSY PLAN BY PRESSING BUTTON 208
105
IS THE PLAN COMPLETE?
N
Y
END BIOPSY PLANNING BY PRESSING BUTTON 206
106
END OF BIOPSY PLANNING

FIG. 5

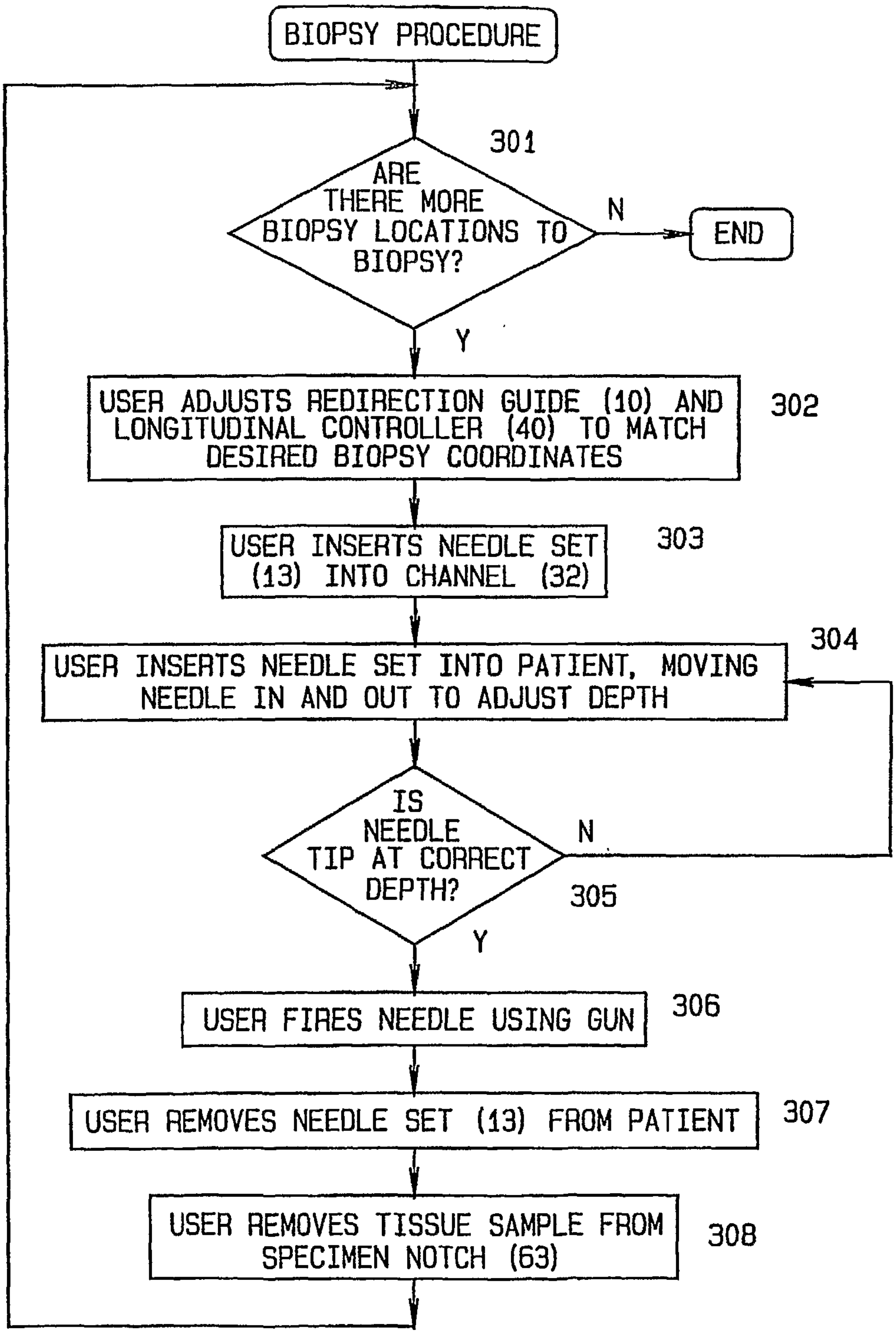
BIOPSY PROCEDURE
301
ARE THERE MORE BIOPSY LOCATIONS TO BIOPSY?
N
END
Y
USER ADJUSTS REDIRECTION GUIDE (10) AND LONGITUDINAL CONTROLLER (40) TO MATCH DESIRED BIOPSY COORDINATES
302
USER INSERTS NEEDLE SET (13) INTO CHANNEL (32)
303
USER INSERTS NEEDLE SET INTO PATIENT, MOVING NEEDLE IN AND OUT TO ADJUST DEPTH
304
IS NEEDLE TIP AT CORRECT DEPTH?
N
305
Y
USER FIRES NEEDLE USING GUN
306
USER REMOVES NEEDLE SET (13) FROM PATIENT
307
USER REMOVES TISSUE SAMPLE FROM SPECIMEN NOTCH (63)
308

FIG. 6

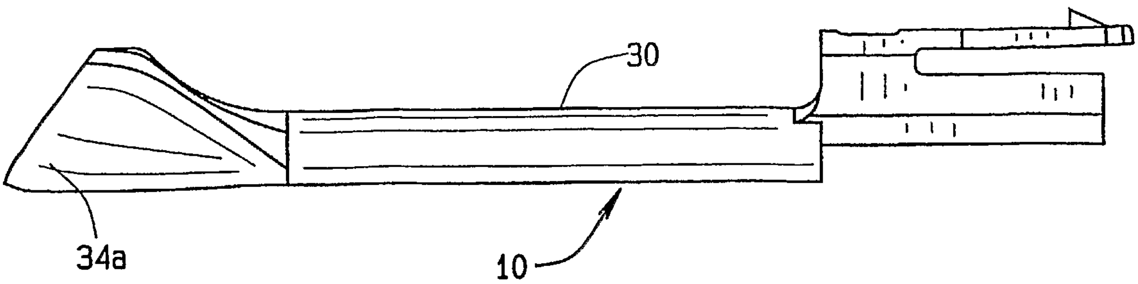

FIG. 7

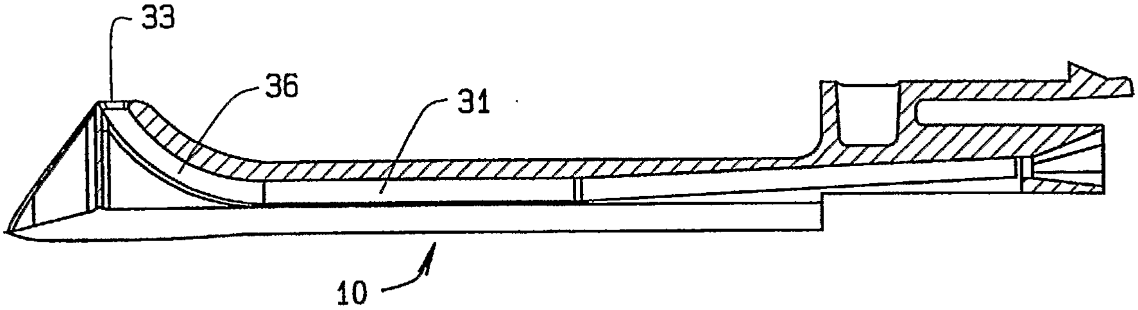

FIG. 8

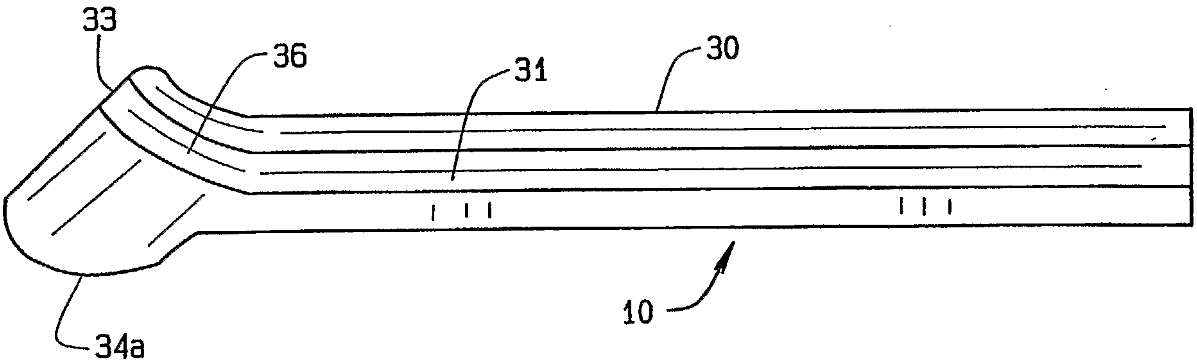

FIG. 9

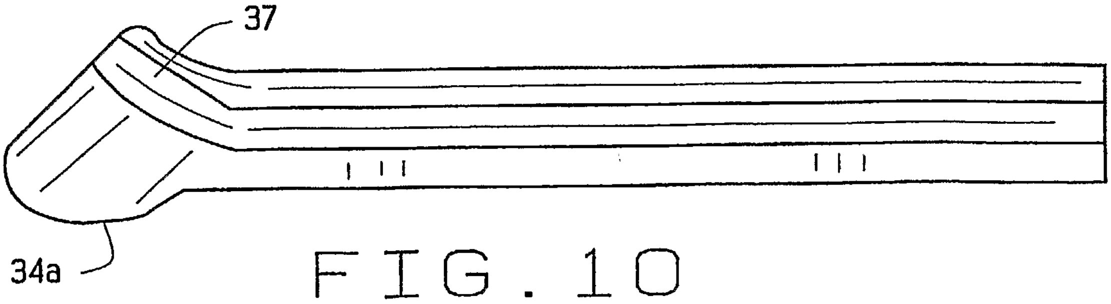

FIG. 10

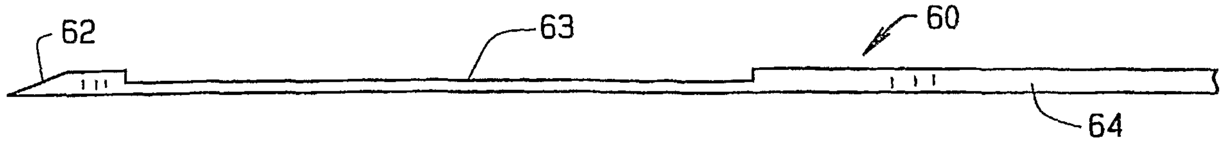

FIG. 11

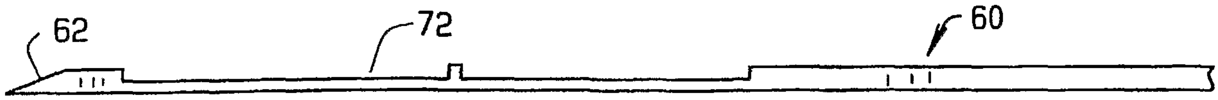

FIG. 12

FIG. 13

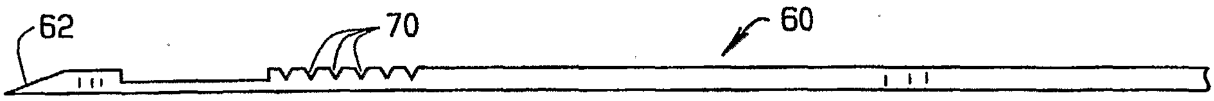

FIG. 14

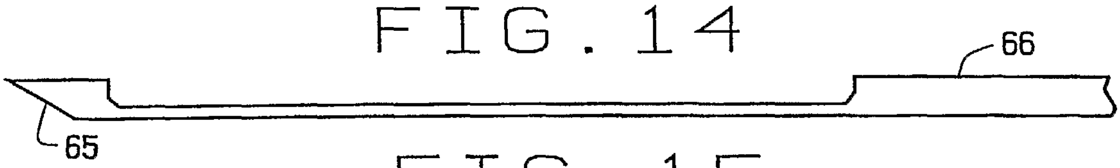

FIG. 15

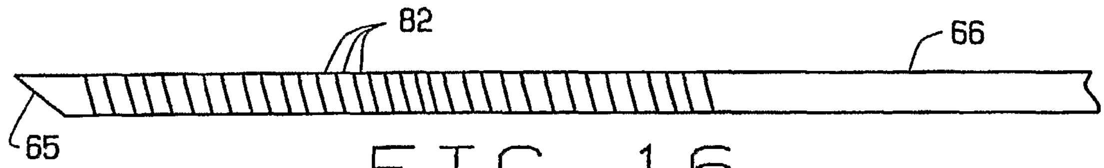

FIG. 16

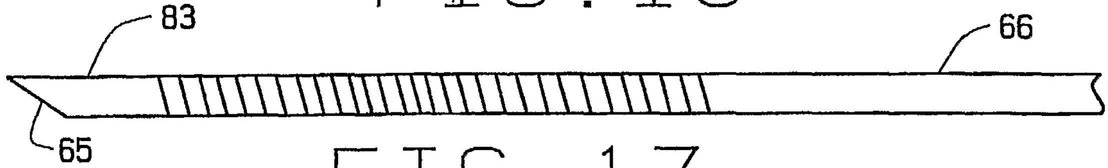

FIG. 17

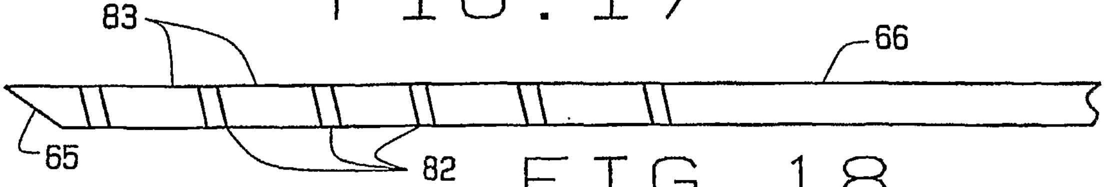

FIG. 18

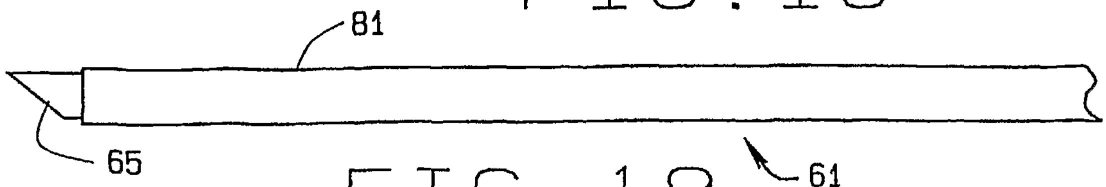

FIG. 19

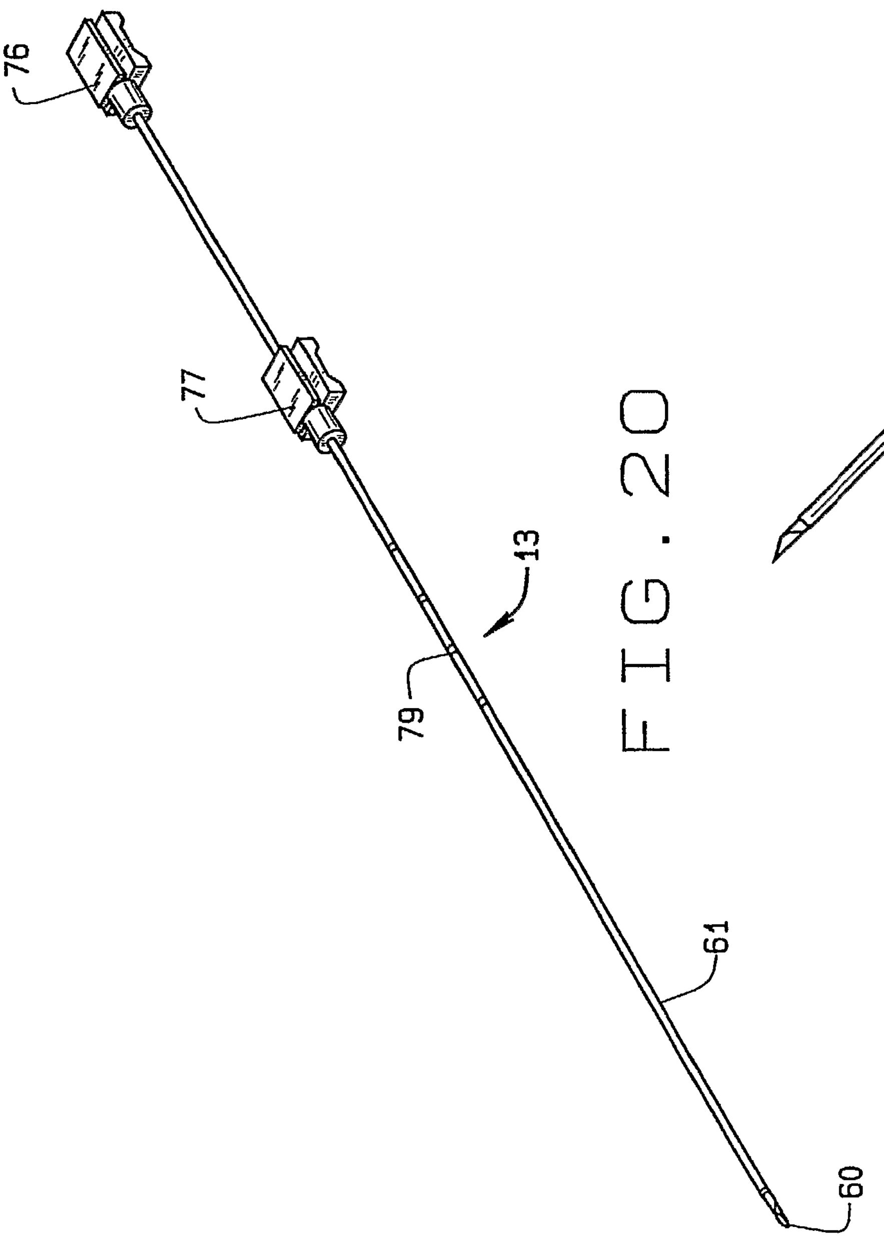

FIG. 20

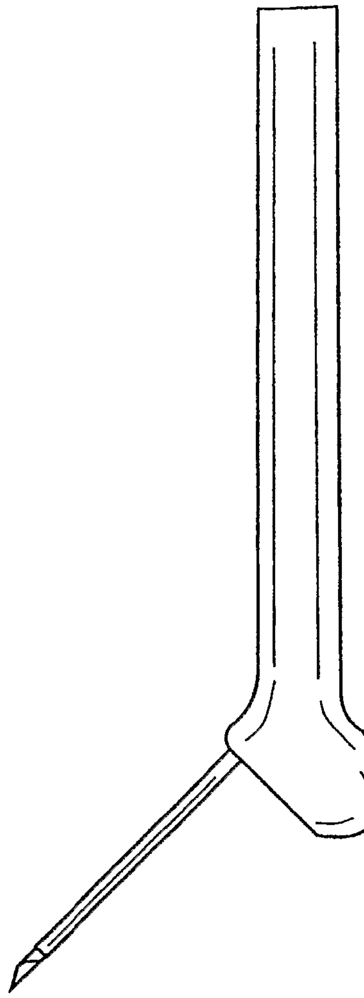

FIG. 23

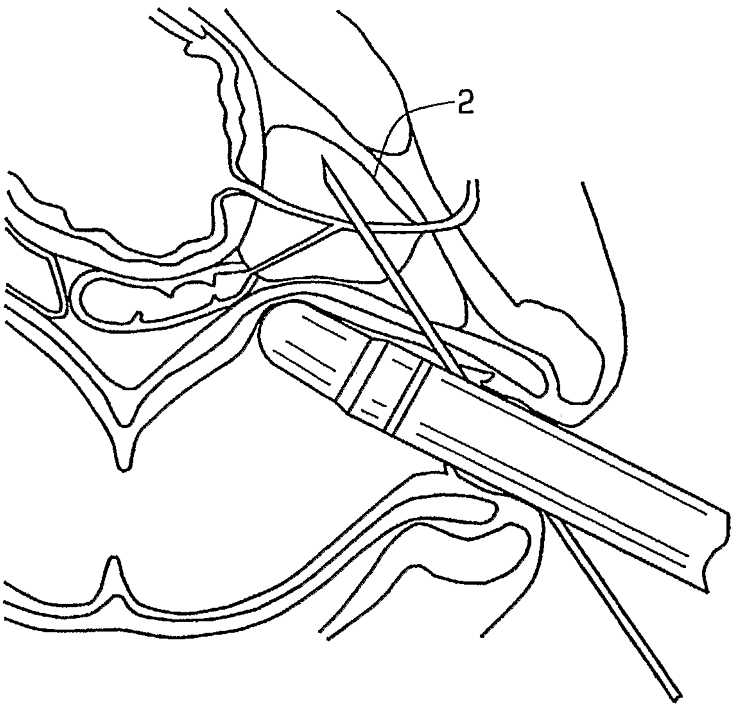

FIG. 21

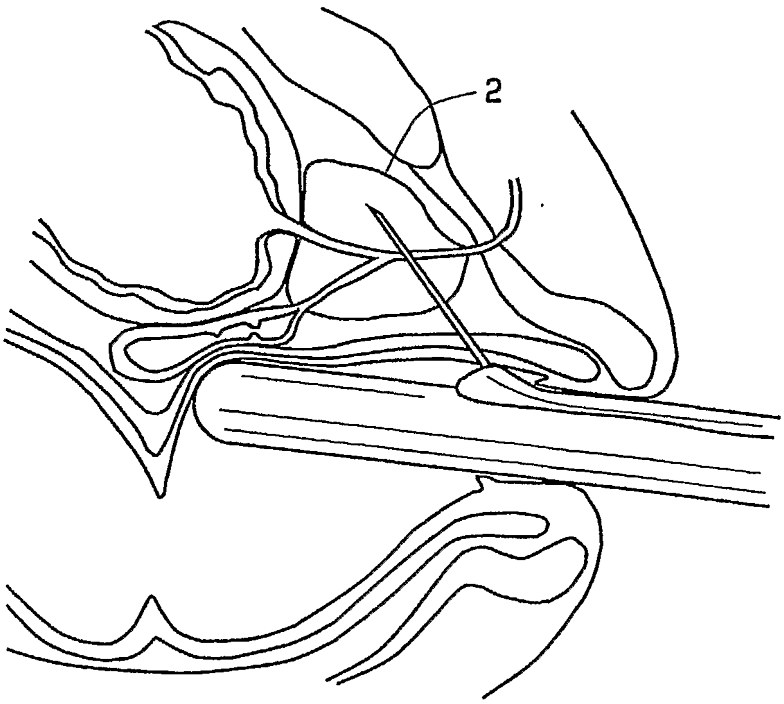

FIG. 22

patsnap

专利名称(译)	有针对性的活组织检查系统		
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申请号	EP2005744025	申请日	2005-05-04
申请(专利权)人(译)	Envisioneering的有限责任公司		
当前申请(专利权)人(译)	Envisioneering的有限责任公司		
[标]发明人	TAYLOR JAMES D OLSEN BRUCE LEWIS STEPHEN		
发明人	TAYLOR, JAMES, D. OLSEN, BRUCE LEWIS, STEPHEN		
IPC分类号	A61B10/00 A61B1/00 A61B8/00 A61B8/14 A61B17/34 A61B10/02 A61B17/00 A61B17/122 A61B17/32 A61B19/00		
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优先权	10/842652 2004-05-10 US		
其他公开文献	EP1765178A4 EP1765178B1		
外部链接	Espacenet		

摘要(译)

本发明一般涉及用于医学目的的组织的靶向和活组织检查，更具体地涉及一种靶向活组织检查系统，其允许对要采样的组织进行计划，针对该计划针对特定组织区域，捕获组织样本并记录组织样品的来源位置，特别是用于收集来自前列腺的组织样品。本发明的另一个目的是提供一种靶向治疗系统，其允许计划待治疗的组织，参照计划靶向组织的特定区域，并将治疗递送至靶组织。