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(54) Title: BIOPSY APPARATUS AND METHOD

(57) Abstract: A biopsy apparatus and method for taking internal tissue samples having an outer sleeve (10) with a cutting edge (15), a hollow needle (20) with a plurality of tissue ports (25) and a vacuum source that is in fluid communication with a vacuum mechanism that contains a plurality of vacuum sections (40) to direct and control the application of the vacuum. The hollow needle (20) contains a plurality of tissue ports (25) positioned for severing at least one tissue sample while a vacuum is applied through at least one vacuum section (40). The method for the biopsy apparatus includes positioning the apparatus at least partially within a tissue portion to be sampled, withdrawing the outer member (10), moving adjustable vacuum sections as required to open at least one tissue port (25), applying the vacuum, and moving the outer member (10) to simultaneously sever at least one tissue sample. The biopsy apparatus is capable of severing single tissue samples sequentially and multiple tissue samples simultaneously.

BIOPSY APPARATUS AND METHOD

BACKGROUND

1. Technical Field

The present disclosure relates to instruments and methods used for obtaining tissue samples. More particularly, the present disclosure relates to minimally invasive biopsy instruments and methods for obtaining tissue samples.

2. Background of Related Art

It is often necessary to sample tissue in order to diagnose and treat patients suspected of having cancerous tumors, pre-malignant conditions and other diseases or disorders. Typically, in the case of suspected cancerous tissue, when the physician establishes by means of procedures such as palpation, x-ray or ultrasound imaging that suspicious conditions exist, a biopsy is performed to determine whether the cells are cancerous. Biopsy may be done by an open or percutaneous technique. Open biopsy removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy on the other hand is usually done with a needle-like instrument and may be either a fine needle aspiration (FNA) or a core biopsy. In core biopsy, as the term suggests, a core or fragment tissue is obtained for histologic examination which may be done via frozen section or paraffin section.

The type of biopsy utilized depends in large part on the circumstances present with respect to the patient and no single procedure is ideal for all cases. Core biopsy, however, is extremely useful in a number of conditions and is being used more frequently.

Intact tissue from the organ or lesion is preferred by medical personnel in order to arrive at a definitive diagnosis regarding the patient's condition. In most cases only part of the organ or lesion need be sampled. The portions of tissue extracted must be indicative of the organ or lesion as a whole. In the past, to obtain adequate tissue from organs or lesions within the body, surgery was performed so as to reliably locate, identify and remove the tissue. With present technology, medical imaging equipment such as stereotactic x-ray, fluoroscopy, computer tomography, ultrasound, nuclear medicine and magnetic resonance imaging, may be used. These technologies make it possible to identify small abnormalities

even deep within the
body. However, definitive tissue characterization still requires obtaining adequate tissue samples to characterize the histology of the organ or lesion.

The introduction of stereotactic guided percutaneous breast biopsies offered alternatives to open surgical breast biopsy. With time, these guidance systems have become more accurate and easier to use. Biopsy guns were introduced for use in conjunction with these guidance systems. Accurate placement of the biopsy guns was important to obtain useful biopsy information because only one small core could be obtained per insertion at any one location. To sample the lesion thoroughly, many separate insertions of the instrument had to be made.

Biopsy procedures may benefit from larger tissue samples being taken, for example, tissue samples as large as 10 mm across. Many of the prior art devices required multiple punctures into the breast or organ in order to obtain the necessary samples. This practice is both tedious and time consuming.

One further solution to obtain a larger tissue sample is to utilize a device capable of taking multiple tissue samples with a single insertion of an instrument. Generally, such biopsy instruments extract a sample of tissue from a tissue mass by either drawing a tissue sample into a hollow needle via an external vacuum source or by severing and containing a tissue sample within a notch formed on a stylet. Such devices generally contemplate advancing a hollow needle into a tissue mass and applying a vacuum force to draw a sample into the needle and hold the same therein while the tissue is extracted.

A continuing need exists for percutaneous biopsy apparatus and methods which can reliably extract adequate biopsy sample(s) with a single insertion of the biopsy instrument.

SUMMARY

A biopsy apparatus is provided that employs a hollow tubular outer sleeve with a cutter and an inner hollow needle containing a plurality of tissue ports. Positioned within the needle is an adjustable vacuum shutter mechanism with at least one vacuum shutter section that translates to cover and exclude at least one tissue port from tissue sampling, provides a directionally oriented vacuum, and forms a tissue basket to retrieve tissue samples.

A biopsy method is provided wherein a biopsy apparatus, including a hollow tubular

outer sleeve with a cutter, an inner hollow needle containing a plurality of tissue ports, and at least one adjustable vacuum mechanism positioned within the needle that is in fluid communication with a vacuum source, is positioned at least partially within a suspect portion of tissue to be sampled from within a patient's body. The outer sleeve is withdrawn proximally to expose the plurality of needle tissue ports and, as required, at least one shutter section moved to open at least one tissue port. A vacuum is applied to the at least one open tissue port and at least one tissue sample is obtained.

The presently disclosed biopsy apparatus, together with attendant advantages, will be best understood by reference to the following detailed description in conjunction with the figures below.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the presently disclosed biopsy apparatus are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one embodiment of a biopsy apparatus having a multi-port needle with an adjustable vacuum shutter mechanism, constructed in accordance with the present disclosure;

FIG. 2 is a longitudinal cross-sectional view at 2-2 of a distal end of one embodiment of the embodiment of FIG. 1;

FIG. 3 is an axial cross-sectional view at 3-3 of one embodiment of the present disclosure as shown in FIG. 1; and

FIG. 4 is a perspective view of the distal end of an alternate embodiment of a biopsy instrument with an alternative adjustable vacuum shutter mechanism.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now in specific detail to the drawings in which like reference numerals identify similar or identical elements throughout the several views, and initially to FIG. 1, one preferred configuration of a biopsy apparatus 100 is shown. Biopsy apparatus 100 includes a tubular sleeve outer section 10, a multi-port hollow needle 20, and an adjustable vacuum shutter mechanism 30. Sleeve 10 includes a distal end 12 that contains a cutting edge 15 for severing tissue samples and a proximal end 14.

For purposes of clarity, only the details of the working distal ends 12, 22, 32, and 42 are illustrated in detail. The proximal ends 14, 24, 34, and 44 may be attached to a suitable handle or actuator to facilitate operation of biopsy apparatus 100. For example, biopsy apparatus 100 may include a housing wherein outer member 10, needle 20, and adjustable shutter mechanism 30 are housed. The housing may include suitable known driving and actuating mechanisms. In one embodiment penetrating member may be rapidly movable into position at the target tissue location by a suitable drive mechanism, such as, for example, potential energy devices, drive motors, pneumatic devices, or any other suitable drive mechanism.

Needle 20 includes a distal end 22 and a proximal end 24, wherein the distal end 22 and proximal end 24 define a central longitudinal axis "X" that is concentric with sleeve 10 and shutter mechanism 30. Needle 20 contains a plurality of tubular wall sections 26 that define a plurality of tissue ports 25 near distal end 22. Sleeve 10 may sever tissue samples by rotating or rotating and translating about the "X" axis over the outer circumference of needle 20 to cut tissue samples projecting into at least one open tissue port 25.

Vacuum shutter mechanism 30 is tubular in shape and has a distal end 32 and a proximal end 34. Shutter mechanism 30 employs a plurality of arcuately shaped slidingly adjustable vacuum shutter sections 40. Shutter sections 40 are translated about the "X" axis from proximal ends 44 to extend at least one distal end 42 to at least partially cover one tissue port 25 and thereby preclude the taking of a tissue sample from the at least partially covered tissue port 25. Each first side 46 defines multiple vacuum holes 45 on distal end 42 that are oriented towards at least one open tissue port 25 when the particular shutter section 40 is in a distally extended position. Shutter mechanism 30 is removably positioned in needle 20 and translates along the "X" axis for the retrieval of tissue samples.

Referring to FIG. 2, a longitudinal cross-section at 2-2 of FIG. 1 shows sleeve 10 of biopsy apparatus 100 with a sharpened circumferential cutting edge 15 which severs tissue samples independent of needle 20. Needle 20, translates and rotates about the "X" axis within sleeve 10. Vacuum shutter mechanism 30 translates with a fixed orientation within needle 20 remaining in fluid communication with a vacuum source (not shown). Shutter mechanism 30 and shutter sections 40 are translated distally and proximally about the "X" axis by an actuator (not shown) disposed at proximal end of shutter mechanism 30. The distal end of one shutter member 40 is shown covering a first tissue port 25 while a second tissue port 25 is shown open. Shutter sections 40 are slidingly engaged with the adjacent shutter section 40 and positioned by a retention mechanism (not shown) within shutter mechanism 30 that maintains the relationship of shutter sections 40 in combination with sliding engagement of shutter sections 40. Shutter sections 40 have a first side 46 that defines multiple directionally oriented holes 45 that are in fluid communication with a passageway 43 and the vacuum source. The vacuum source may contain a switching mechanism to select and fluidly connect at least one shutter section 40 with the vacuum source or, in an alternate configuration, it can contain multiple separate vacuum sources for each shutter section 40.

In FIG 3, a cross section at 3-3 of FIG. 2 shows needle 20 with three wall sections 26 defining three tissue ports 25, each covering an arc of approximately 120°. In this embodiment, shutter mechanism 30 contains three shutter sections 40 covering an arc of approximately 120° with a first side 46 and a second side 48. The vacuum drawn through passageway 43 and holes 45 of shutter section 40 augments the natural prolapse of tissue into any open tissue port 25 and thereby assists the ability of sleeve 10 to sever a larger tissue sample. Distally extended shutter section 40 contains second side 48 that is positioned to at least partially cover the adjacent tissue port 25. When at least one shutter section 40 is extended to at least partially cover the adjacent tissue port 25, it precludes the prolapse of a portion of tissue into the at least partially covered tissue port 25 and thus prevents the severing of tissue that is not desired. While one shutter section 40 is at least partially covering the adjacent tissue port 25, the plurality of directionally oriented vacuum holes of each shutter section 40 are aligned with the generally opposing open tissue port 25 to augment the prolapse of tissue therein. Distally extended shutter distal end 42 forms a concave shaped tissue basket 47 that in combination with vacuum holes 45, retains and transports tissue samples. The quantity, size, and shape of tissue ports 25 and vacuum shutter sections 40 are variables that are a function of the desired application of biopsy apparatus 100.

Referring now to FIG. 4, an alternative configuration of biopsy apparatus 200 includes an outer sleeve 210 having a cutting edge 215 on distal end 212 and a proximal end 214 aligned with the "X" axis. Cutting edge 215 severs at least one tissue sample by rotating and translating about the "X" axis.

Needle 220 is positioned concentrically within outer sleeve 210 and has a distal end 222 with a needle tip and a proximal end 224 that are aligned with the "X" axis. Tubular wall 226 forms a plurality of tissue ports 225 near distal end 222.

Vacuum mechanism 230 has a distal end 232 and a proximal end 234 formed by tubular wall 236. Vacuum mechanism 230 is rotatingly and slidingly positioned concentrically within needle 220 along the "X" axis and contains a vacuum passageway 233 and a plurality of vacuum through holes 237 near distal end 232. Vacuum mechanism 230 contains a tubular cylindrical wall 236 that defines a tissue port 235 that forms an arc that can range from approximately 90° to approximately 300° and covers at least one tissue port 225. Vacuum passageway 233 is defined within tubular wall 236 and is fluidly connected to both a vacuum source (not shown) and a plurality of vacuum holes 237 defined on the inside circumference of tubular wall 236. Vacuum holes 237 are directed towards open port 225 through tissue port 235 to augment the natural tissue prolapse into biopsy apparatus 200. The at least one severed tissue sample is retained within a tissue basket 239 formed by arcuate walls 236 in combination with the vacuum provided by holes 237. Vacuum mechanism 230 can then be rotated and additional tissue samples taken or withdrawn proximally through needle 220 with the at least one tissue sample.

With reference once again to FIGS 1-3, in operation biopsy apparatus 100 may be inserted by suitable known techniques, for example, by motor driver or spring fired mechanisms. Alternatively, biopsy apparatus 100 may be inserted manually. In either arrangement, biopsy apparatus 100 may be configured as a hand held apparatus or as part of a frame mounted device. An example of such a device is an image guided positioning apparatus such as a stereotactic imaging machine. Any suitable imaging modality may be used to guide biopsy apparatus to the target tissue.

Biopsy apparatus 100 is positioned at least partially within the tissue to be sampled with the tip of needle 20 extending from sleeve 10. Sleeve 10 is then withdrawn proximally to expose the plurality of tissue ports 25 and at least one vacuum section 40 distally extended to at least partially close the plurality of tissue ports 25. At least one vacuum section 40 is then withdrawn, as required, to open at least one tissue port 25, and a vacuum drawn through the distal end of vacuum sections 40. Sleeve 10 is extended distally by rotating or translating and rotating and severing a tissue sample. The tissue sample is retained by the at least one distally extended vacuum section 40 in combination with the vacuum applied through holes 45. The sample is withdrawn by proximally translating shutter mechanism 30 through needle 20. Vacuum sections 40 that are not extended are also envisioned as augmenting the sampling, retention, and withdrawal of tissue samples under different biopsy apparatus 100 applications. Alternatively, additional tissue samples can be taken with needle 20 in the same position by extending or withdrawing at least one sliding section 40 to change the quantity or location of the open tissue ports or changing both the quantity and location of the open tissue ports.

In a second method, biopsy apparatus 100 is positioned at least partially within a portion of tissue to be sampled with the tip of needle 20 extending from sleeve 10. Sleeve 10 is then withdrawn proximally to expose the plurality of tissue ports 25 and at least one shutter sliding section distal end 42 is extended distally to at least partially cover at least one tissue port 25. A vacuum is initiated at distal ends 42 to supplement the prolapse of tissue into tissue port 25 and sleeve 10 is rotated and translated about the "X" axis to sever at least one tissue sample. The tissue sample is retained on at least one distally extended sliding section 40 with the assistance of the vacuum provided by through holes 45. Shutter mechanism 30 is then withdrawn proximally to retrieve the sample. Vacuum sections 40 that are not extended are also envisioned as augmenting the sampling, retention, and withdrawal of tissue samples under different biopsy apparatus 100 applications. Alternatively, additional tissue samples can be taken with needle 20 in the same position by extending or withdrawing at least one sliding section 40 to change the combination of the quantity and location of open tissue ports 25.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, it is to be understood that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be affected therein by one skilled in the art without departing from the scope or spirit of the disclosure. All such changes and modifications are intended to be included within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A biopsy apparatus comprising:

a hollow needle defining a plurality of tissue ports;

a sleeve positionable relative to the hollow needle, the sleeve including a sharpened edge for cutting tissue; and

a plurality of vacuum members positioned within the needle, each of the plurality of vacuum members movable along a longitudinal axis between a proximal position and a distal position such that when in the distal position a particular vacuum member closes at least one tissue port and directionally transmits a vacuum from a source through the at least one vacuum member to at least one open needle tissue port to assist in drawing in at least one tissue sample.

2. The biopsy apparatus according to claim 1, wherein each of the plurality of vacuum members includes a plurality of vacuum holes formed along an inner surface thereof.

3. The biopsy apparatus according to claim 2, wherein the plurality of vacuum holes of each vacuum member are in fluid communication with a vacuum source.

4. The biopsy apparatus according to claim 3, wherein the plurality of vacuum holes of each vacuum member are in fluid communication, via a passageway, with a respective vacuum source.

5. The biopsy apparatus according to claim 4, wherein the hollow needle includes three tissue ports.

6. The biopsy apparatus according to claim 5, wherein each of the three tissue ports covers an arc of approximately 120°.

7. The biopsy apparatus according to claim 6, wherein the biopsy apparatus includes three vacuum members configured and adapted to cover a respective one of the three tissue ports.

8. The biopsy apparatus according to claim 1, wherein the biopsy apparatus further comprises a vacuum mechanism having a tubular cylindrical wall defining a tissue opening, the cylindrical wall forming an arc from approximately 90° to approximately 300°, wherein the vacuum mechanism includes a plurality of vacuum holes formed therein, which plurality of vacuum holes are in fluid communication with a vacuum source.

9. A method of taking internal tissue samples with a biopsy apparatus comprising the steps of:

positioning the biopsy apparatus at least partially within a tissue to be sampled, wherein the biopsy apparatus includes a cutting sleeve, a hollow needle having a tip for piercing and defining a plurality of tissue ports, and a plurality of adjustable vacuum shutter members configured and adapted to cover at least one of the plurality of tissue ports;

withdrawing the sleeve proximally to expose the plurality of tissue ports and the plurality of distally extended vacuum members at least partially positioned to cover the plurality of tissue ports;

adjusting at least one vacuum shutter member proximally to open at least one tissue port;

applying a vacuum from a vacuum source;

repositioning the sleeve to sever a first at least one tissue sample; and

transporting the tissue samples by withdrawing the adjustable vacuum shutter members proximally through the needle while the needle remains in the patient.

10. The method according to claim 9, further comprising the steps of:

adjusting the at least one vacuum member distally to close the at least one tissue port;

adjusting another of the at least one vacuum shutter member proximally to open another of the at least one tissue port;

applying a vacuum from a vacuum source; and

repositioning the sleeve to sever a second of the at least one tissue sample.

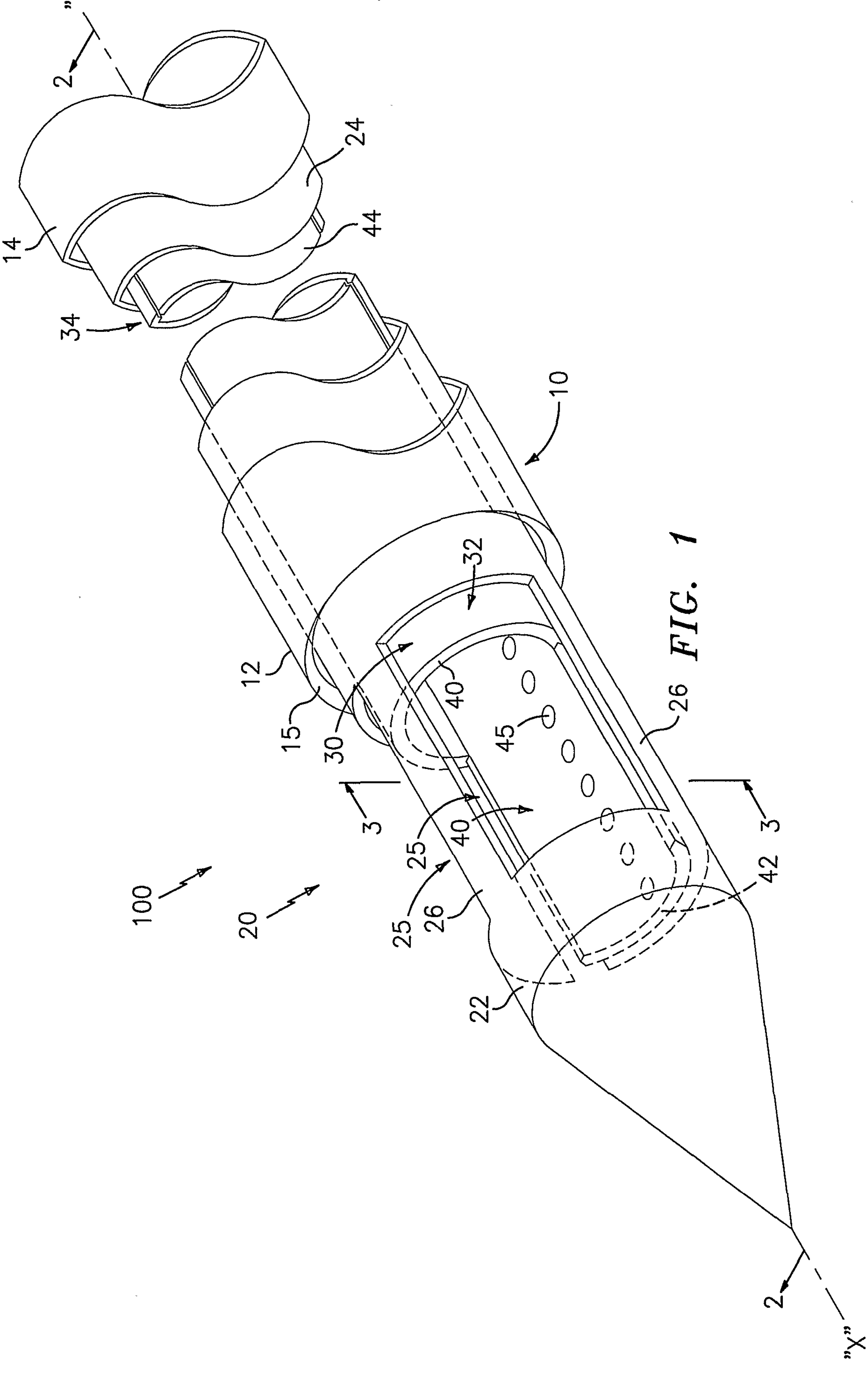

FIG. 1

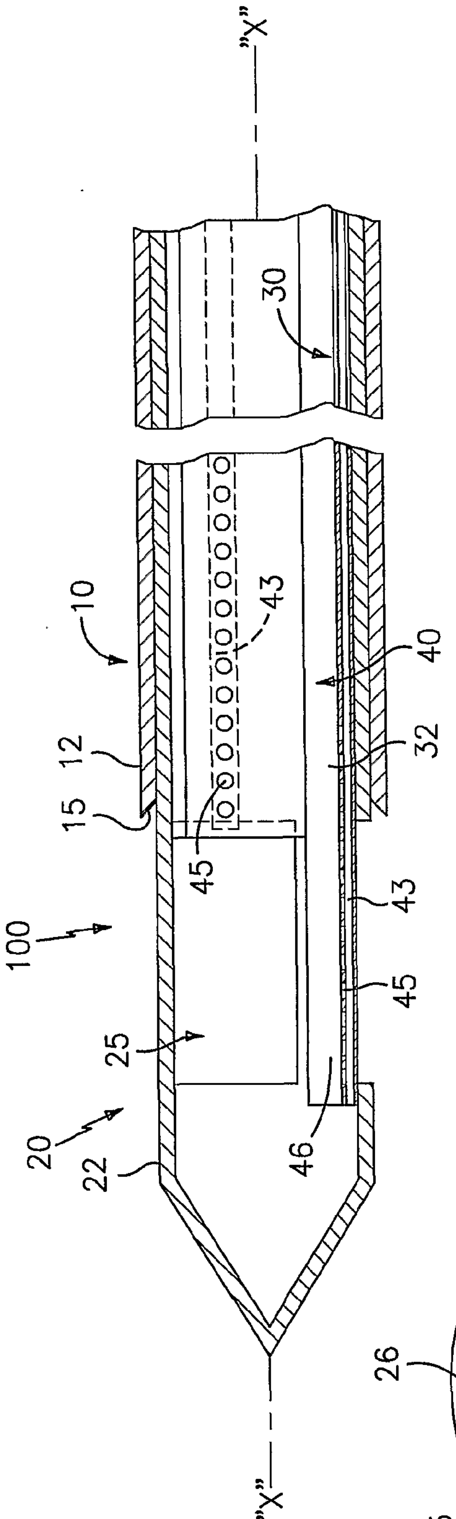
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FIG. 2

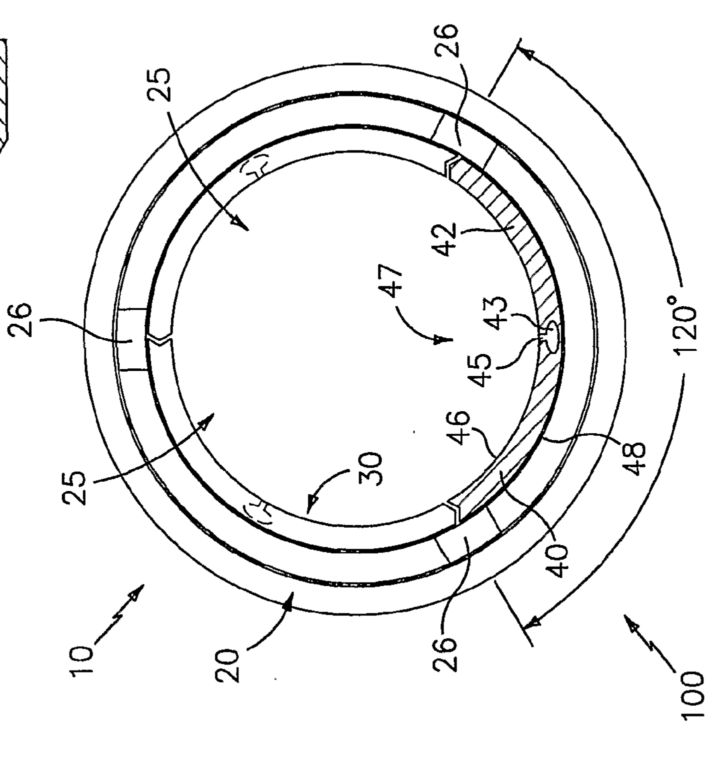
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FIG. 3

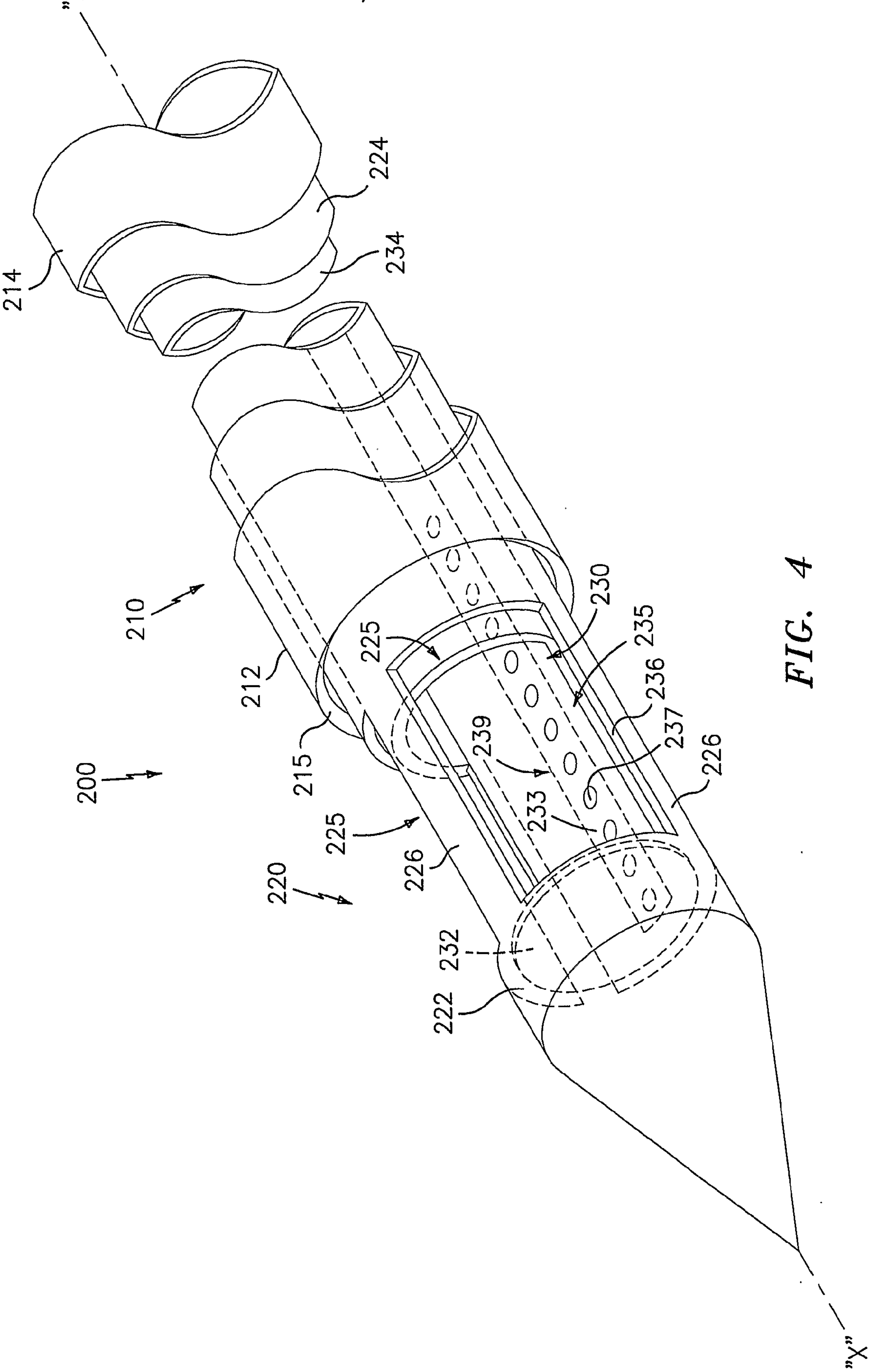
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FIG. 4