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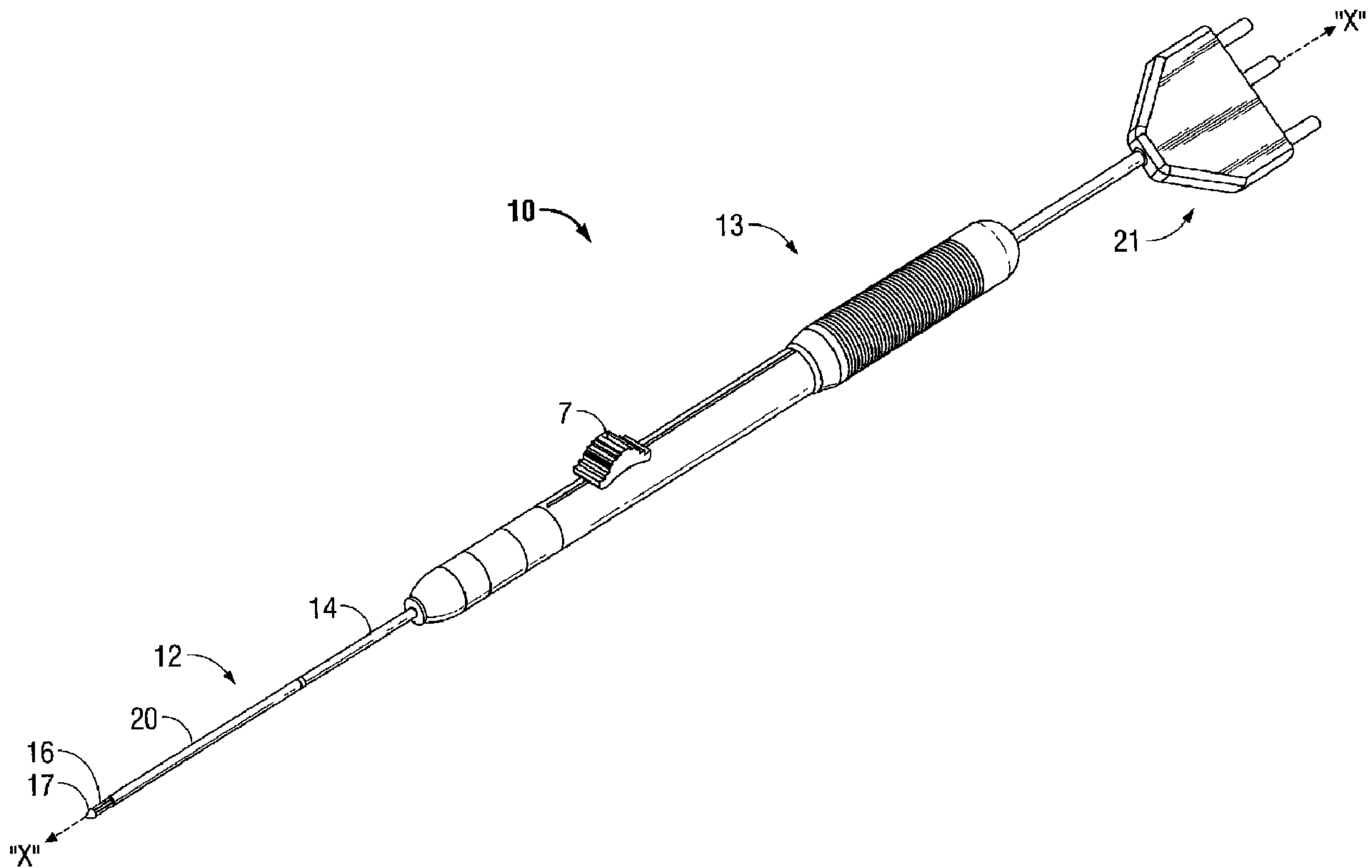
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(54) Titre : SYSTEME ET METHODE PERMETTANT DE REALISER UNE INTERVENTION ELECTROCHIRURGICALE A L'AIDE D'UN APPAREIL D'ABLATION MUNI D'UN DISPOSITIF D'IMAGERIE INTEGRE
(54) Title: SYSTEM AND METHOD FOR PERFORMING AN ELECTROSURGICAL PROCEDURE USING AN ABLATION DEVICE WITH AN INTEGRATED IMAGING DEVICE



(57) **Abrégé/Abstract:**

An ablation device includes an antenna assembly having a radiating portion configured to deliver energy from a power source to tissue. The radiating portion has an outer conductor and an inner conductor. The inner conductor is disposed within the outer conductor. The device also includes an imaging device operably coupled to the radiating portion. The imaging device is configured to generate imaging data corresponding to tissue proximate the radiating portion of the antenna assembly.

ABSTRACT

An ablation device includes an antenna assembly having a radiating portion configured to deliver energy from a power source to tissue. The radiating portion has an outer conductor and an inner conductor. The inner conductor is disposed within the outer conductor. The device also includes an imaging device operably coupled to the radiating portion. The imaging device is configured to generate imaging data corresponding to tissue proximate the radiating portion of the antenna assembly.

**SYSTEM AND METHOD FOR PERFORMING AN
ELECTROSURGICAL PROCEDURE USING AN ABLATION
DEVICE WITH AN INTEGRATED IMAGING DEVICE**

BACKGROUND

1. *Technical Field*

[0001] The present disclosure relates to energy-based apparatuses, systems and methods. More particularly, the present disclosure is directed to a system and method for performing an electrosurgical procedure using an ablation system including an integrated imaging device.

2. *Background of Related Art*

[0002] In the treatment of diseases such as cancer, certain types of cancer cells have been found to denature at elevated temperatures (which are slightly lower than temperatures normally injurious to healthy cells.) These types of treatments, known generally as hyperthermia therapy, typically utilize electromagnetic radiation to heat diseased cells to temperatures above 41°C, while maintaining adjacent healthy cells at lower temperatures where irreversible cell destruction will not occur. Other procedures utilizing electromagnetic radiation to heat tissue also include ablation and coagulation of the tissue. Such microwave ablation procedures, e.g., such as those performed for menorrhagia, are typically done to ablate and coagulate the targeted tissue to denature or kill the tissue. Many procedures and types of devices utilizing electromagnetic radiation therapy are known in the art. Such microwave therapy is typically used in the treatment of tissue and organs such as the prostate, heart, liver, lung, kidney, and breast.

[0003] One non-invasive procedure generally involves the treatment of tissue (e.g., a tumor) underlying the skin via the use of microwave energy. The microwave energy is able to

non-invasively penetrate the skin to reach the underlying tissue. However, this non-invasive procedure may result in the unwanted heating of healthy tissue. Thus, the non-invasive use of microwave energy requires a great deal of control.

[0004] Presently, there are several types of microwave probes in use, e.g., monopole, dipole, and helical. One type is a monopole antenna probe, which consists of a single, elongated microwave conductor exposed at the end of the probe. The probe is typically surrounded by a dielectric sleeve. The second type of microwave probe commonly used is a dipole antenna, which consists of a coaxial construction having an inner conductor and an outer conductor with a dielectric junction separating a portion of the inner conductor. The inner conductor may be coupled to a portion corresponding to a first dipole radiating portion, and a portion of the outer conductor may be coupled to a second dipole radiating portion. The dipole radiating portions may be configured such that one radiating portion is located proximally of the dielectric junction, and the other portion is located distally of the dielectric junction. In the monopole and dipole antenna probe, microwave energy generally radiates perpendicularly from the axis of the conductor.

[0005] The typical microwave antenna has a long, thin inner conductor that extends along the axis of the probe and is surrounded by a dielectric material and is further surrounded by an outer conductor around the dielectric material such that the outer conductor also extends along the axis of the probe. In another variation of the probe that provides for effective outward radiation of energy or heating, a portion or portions of the outer conductor can be selectively removed. This type of construction is typically referred to as a "leaky waveguide" or "leaky coaxial" antenna. Another variation on the microwave probe involves having the tip formed in a

uniform spiral pattern, such as a helix, to provide the necessary configuration for effective radiation. This variation can be used to direct energy in a particular direction, e.g., perpendicular to the axis, in a forward direction (i.e., towards the distal end of the antenna), or combinations thereof.

[0006] Invasive procedures and devices have been developed in which a microwave antenna probe may be either inserted directly into a point of treatment via a normal body orifice or percutaneously inserted. Such invasive procedures and devices potentially provide better temperature control of the tissue being treated. Because of the small difference between the temperature required for denaturing malignant cells and the temperature injurious to healthy cells, a known heating pattern and predictable temperature control is important so that heating is confined to the tissue to be treated. For instance, hyperthermia treatment at the threshold temperature of about 41.5°C generally has little effect on most malignant growth of cells. However, at slightly elevated temperatures above the approximate range of 43°C to 45°C, thermal damage to most types of normal cells is routinely observed. Accordingly, great care must be taken not to exceed these temperatures in healthy tissue.

[0007] In the case of tissue ablation, a high radio frequency electrical current in the range of about 500 MHz to about 10 GHz is applied to a targeted tissue site to create an ablation volume, which may have a particular size and shape. The targeted tissue site is observed prior to the application of energy thereto to ensure accurate placement of the ablation device (e.g., microwave antenna) relative to the targeted tissue site. Typically, observation is facilitated through scanned data obtained through use of imaging devices such as CT, MRI, PET, or other tomographic or X-ray devices. However, images obtained using such scanning techniques

before, during, or after an electrosurgical procedure, such as tissue ablation, are obtained from outside the patient and, therefore, are often lacking in quality due to distortions and the limitations of two-dimensional imaging.

SUMMARY

[0008] According to an embodiment of the present disclosure, an ablation device includes an antenna assembly having a radiating portion configured to deliver energy from a power source to tissue of a patient. The radiating portion has an outer conductor and an inner conductor. The inner conductor is disposed within the outer conductor. The device also includes an imaging device operably coupled to the inner conductor. The imaging device is configured to generate imaging data corresponding to tissue proximate the radiating portion of the antenna assembly.

[0009] According to another embodiment of the present disclosure, a microwave ablation system includes an antenna assembly configured to deliver energy from a power source to tissue of a patient and an introducer having a distal end configured to penetrate tissue. The introducer has a lumen disposed coaxially therein at least partially along its length. The lumen is configured to receive the antenna assembly therein. The system also includes an imaging device disposed on the introducer configured to provide imaging data to a processing unit corresponding to tissue proximate the introducer. The processing unit is configured to generate an image based on the imaging data.

[0010] According to another embodiment of the present disclosure, a method for performing an electrosurgical procedure includes the steps of positioning an ablation device including an imaging device proximate a desired tissue site of a patient and imaging the desired

tissue site to generate corresponding imaging data. The method also includes the steps of generating a display of the desired tissue site based on the imaging data and re-positioning the ablation device proximate the desired tissue site based on the display. The method also includes the step of supplying energy from an energy source to the ablation device for application to the desired tissue site.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Various embodiments of the present disclosure are described herein with reference to the drawings wherein:

[0012] Fig. 1 is a perspective view of a microwave ablation device in accordance with an embodiment of the present disclosure;

[0013] Figs. 2A and 2B are schematic views of the microwave ablation device of Fig. 1 connected to a generator according to various embodiments of the present disclosure;

[0014] Fig. 2C is a cross-sectional view taken along section line 2C-2C of Figs. 2A and 2B;

[0015] Figs. 3A and 3B are enlarged side views of the microwave ablation device of Fig. 1 according to various embodiments of the present disclosure; and

[0016] Figs. 4A and 4B are perspective views of an introducer for use with the microwave ablation device of Fig. 1.

DETAILED DESCRIPTION

[0017] Particular embodiments of the present disclosure are described hereinbelow with reference to the accompanying drawings. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail. In the discussion that follows, the term “proximal” will refer to the portion of a structure that is closer to a user, while the term “distal” will refer to the portion of the structure that is farther from the user.

[0018] Generally, the present disclosure relates to the use of an ablation device having an integrated imaging device, such as an ultrasound transducer adapted to generate image data by generating sound waves within the ultrasound frequency range toward a desired imaging site and subsequently receiving echoing of such sound waves from the desired imaging site. The ability to radially visualize target tissue before, during, and/or after an ablation procedure in three dimensions allows a user to accurately place the ablation device within the target tissue and, further, to monitor ablation progress.

[0019] An ablation device (e.g., a microwave ablation device) in accordance with the present disclosure is referred to in the figures as reference numeral 10. While a microwave ablation device is described herein, it is contemplated that the present disclosure may also be used in connection with other types of ablation devices and other instruments, such as introducers. Such ablation devices may include an antenna and/or an electrode.

[0020] Referring initially to Fig. 1, ablation device 10 includes an antenna 12 and a handle portion 13. Antenna 12 includes a shaft or feedline 14 having an inner conductor 16 and an outer conductor 20, which defines a longitudinal axis X-X. Outer conductor 20 may be, for

example, an introducing structure (e.g., needle) configured to pierce and/or penetrate tissue. A power transmission cord 21 is shown and connects ablation device 10 to a suitable electrosurgical generator 22 (see Figs. 2A and 2B). Additionally, an actuation element 7 is illustrated in Fig. 1 in accordance with various embodiments of the present disclosure. Actuation element 7 is operably coupled to inner conductor 16 and movable along a track 9 disposed at least partially along the length of handle portion 13 to move inner conductor 16 relative to outer conductor 20. More specifically, distal actuation of actuation element 7 along track 9 deploys or extends inner conductor 16 from outer conductor 20 and proximal actuation of actuation element 7 along track 9 retracts inner conductor 16 within outer conductor 20.

[0021] As seen in Fig. 2A, inner conductor 16 includes a distal tip 17 and is extendable from outer conductor 20. Several types of inner conductors 16 may be used in connection with the disclosed ablation device 10, including an inner conductor configured to deploy substantially in-line with outer conductor 20 (e.g., Fig. 2A) and an inner conductor configured to deploy in a curved orientation (e.g., Fig. 2B) along a curvilinear path to define an ablation region 29. In the illustrated embodiments of Figs. 2A and 2B, a proximal end of feedline 14 includes a coupler 18 that electrically couples antenna 12 to generator 22 via power transmission cord 21.

[0022] In some embodiments, distal tip 17 allows for insertion of antenna 12 into tissue with minimal resistance. In those cases where the antenna 12 is inserted into a pre-existing opening, distal tip 17 may be rounded or flat.

[0023] As shown in Fig. 2C, feedline 14 may be in the form of a coaxial cable. Portions of feedline 14 may be formed of outer conductor 20 surrounding inner conductor 16. Each of inner conductor 16 and/or outer conductor 20 may be made of a suitable conductive metal that

may be semi-rigid or flexible, such as, for example, copper, gold, or other conductive metals with similar conductivity values. Alternatively, portions of each inner conductor 16 and outer conductor 20 may also be made from stainless steel that may additionally be plated with other materials, e.g., other conductive materials, to improve conductivity or decrease energy loss.

[0024] With continued reference to Fig. 2C, feedline 14 of antenna 12 is shown including a dielectric material 28 surrounding at least a portion of a length of inner conductor 16 and outer conductor 20 surrounding at least a portion of a length of dielectric material 28 and/or inner conductor 16. That is, dielectric material 28 is interposed between inner conductor 16 and outer conductor 20, to provide insulation therebetween and is comprised of any suitable dielectric material.

[0025] With reference to Figs. 3A and 3B, antenna 12 may be embodied having a straight probe configuration of radiating portion 12, as shown in Fig. 3A, or a loop probe configuration of radiating portion 12, as shown in Fig. 3B. In either scenario, radiating portion 12 includes a lumen 26 defined coaxially therethrough and at least partially along the length thereof. Disposed within lumen 26 is an imaging device 30 adapted to image a desired ablation area. An electrical lead 31 electrically connects imaging device 30 to a processing unit 24 configured to process data generated by imaging device 30 for representation on a display (see, e.g., Figs 2A, 2B). Although not shown entirely in the accompanying figures, lead 31 is connected to processing unit 24 and extends therefrom through handle assembly 13 and lumen 26 to connect to imaging device 30. Processing unit 24 may include a processor operably coupled with a memory (not shown) that stores suitable image processing software executable as programmable instructions by the processor to cause processing unit 24 to generate an image based on imaging data

received from imaging device 30. Processing unit 24 may be a stand-alone device or may be incorporated within generator 22. Imaging device 30 may be, for example, an ultrasound transducer adapted to generate and receive sound waves to generate imaging data corresponding to the tissue area surrounding radiating portion 12. In other embodiments, imaging device 30 may be, for example, a CAT scan device, a PET scan device, an X-ray device, an MRI device, or other tomographic or X-ray device utilized to generate imaging data corresponding to the desired ablation area.

[0026] Imaging device 30 may be fixedly mounted within lumen 26 (e.g., via adhesive, fastener, etc.) or may be slidably disposed within lumen 26 such that imaging device 30 may be moved proximally and distally within lumen 26 and/or rotated about longitudinal axis X-X of radiating portion 12 to facilitate 360 degree and/or radial imaging of surrounding tissue along the entire length of inner conductor 16. This configuration of imaging device 30 makes three-dimensional imaging of the desired tissue site possible. With this purpose in mind, ablation device 10 may also be rotated 360 degrees by the user to achieve three-dimensional imaging of the desired tissue site.

[0027] In another embodiment shown in Figs. 4A and 4B, imaging device 30 may be used in conjunction with an introducer 50 to facilitate placement of radiating portion 12 relative to an ablation area or a tumor "T". Introducer 50 includes a shaft 52 extending from a proximal hub 54 to a distal end 58, and a lumen 56 disposed coaxially through shaft 52 from proximal hub 54 distally toward distal end 58 through at least a portion of the length of shaft 52. Distal end 58 may be tapered to allow for insertion of introducer 50 into tissue with minimal resistance. Shaft 52 is inserted into tissue of a patient "P" until distal portion 58 of shaft 52 is positioned adjacent

to or within an ablation area of tissue, e.g., tumor "T", as shown in Figs. 4A and 4B. Imaging device 30 is utilized to image the area surrounding distal portion 58 of shaft 52 to ensure that introducer 50 is properly placed relative to the ablation area. More specifically, imaging data relating to the ablation area is received and processed by processing unit 24 for viewing by the surgeon. Based on the generated imaging data, the user may maneuver or re-position the introducer 50 within the patient "P", if necessary, to ensure accurate position of distal portion 58 of shaft 52 relative to tumor "T" before ablation thereof. As illustrated by rotational arrow "A" of Fig. 4A, introducer 50 may be rotated about the longitudinal axis of shaft 52 such that imaging device 30 may be rotated 360 degrees to completely image the ablation area.

[0028] Once introducer 50 is desirably positioned, ablation device 10 may then be inserted within lumen 56 while maintaining the position and orientation of shaft 52 within patient "P". Ablation device 10 is advanced distally within lumen 56 such that radiating portion 12 of device 10 is adjacent to or within tumor "T". The length of radiating portion 12 may be configured to fit within shaft 52 such that a proximal end of handle portion 13 and proximal hub 54 contact one another in a lock-fit manner (not explicitly shown). During and/or after an ablation procedure, the ablation area may be imaged to enable the user to monitor the progress and/or completeness of the ablation.

[0029] In the illustrated embodiment of Figs. 4A and 4B, imaging device 30 is shown without electrical lead 31 to illustrate that imaging device 30 may be configured to communicate imaging data to processing unit 24 wirelessly from within patient "P". As such, an electrical lead (e.g., lead 31) connecting imaging device 30 to processing unit 24 may not be necessary to effect proper and intended implementation of any of the embodiments disclosed herein.

[0030] In use, energy (e.g., microwave energy) generated by generator 22 in close proximity to imaging device 30 may cause interference with image data generated by imaging device 30 during an imaging procedure. In this scenario, imaging device 30 and generator 22 may be configured, in certain embodiments, to automatically operate in mutual exclusion relative to one another. More specifically, generator 22 continuously receives and processes an imaging signal generated by imaging device 30 (e.g., wirelessly) and/or processing unit 24 that continuously indicates in real-time whether or not an imaging procedure is currently being performed by imaging device 30. Based on the generated signal, generator 22 terminates energy output during an imaging procedure and continues energy output while no imaging procedure is being performed by the imaging device 30. In this manner, imaging procedures and electrosurgical procedures (e.g., microwave ablation) may be performed in close proximity and essentially during the same procedure or operation without adverse effects (e.g., image distortion) to the imaging process caused by interference from the output of generator 22.

[0031] Those skilled in the art will appreciate that imaging device 30 and/or processing unit 24 include suitable circuitry (e.g., processor, memory, a/d converter, etc.) configured to generate the imaging signal as output and, further, that generator 22 includes suitable circuitry configured to receive and process the imaging signal as input. In some embodiments, processing unit 24 and/or ablation device 10 may include buttons, switches, actuators, or the like, configured to activate or deactivate imaging device 30 and/or to generate a signal to generator 22 indicating the activation, suspension, and/or termination of an imaging procedure.

[0032] While several embodiments of the disclosure have been shown in the drawings and/or discussed herein, it is not intended that the disclosure be limited thereto, as it is intended

that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of particular embodiments. For example, it should be understood that any of the above disclosed embodiments may be configured such that imaging device 50 generates a logic low to indicate an imaging procedure is currently being performed and, vice-versa, a logic high may indicate that no imaging procedure is currently being performed. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. An ablation device, comprising:
an antenna assembly having a radiating portion configured to deliver energy from a power source to tissue of a patient; and
an imaging device coupled to the radiating portion and configured to generate imaging data corresponding to the tissue.
2. An ablation device according to claim 1, wherein the radiating portion includes outer conductor and an inner conductor extending therethrough, the inner conductor disposed within the outer conductor.
3. An ablation device according to claim 2, wherein the inner conductor is configured to deploy from the outer conductor into the tissue.
4. An ablation device according to claim 1, wherein the imaging device is selected from the group consisting of ultrasound transducers, CAT scan devices, MRI devices, and PET scan devices.
5. An ablation device according to claim 1, wherein the imaging device is movable relative to the radiating portion to generate three-dimensional image data of tissue surrounding the radiating portion.

6. An ablation device according to claim 1, wherein a lumen is defined coaxially through at least a portion of the radiating portion, the imaging device disposed within the lumen.

7. An ablation device according to claim 1, wherein the imaging device is configured to communicate the imaging data to a processing unit adapted to generate a display based on the imaging data.

8. An ablation device according to claim 7, wherein the imaging device is configured to communicate the imaging data to the processing unit wirelessly.

9. An ablation device according to claim 1, wherein the antenna assembly includes a straight probe configuration.

10. An ablation device according to claim 1, wherein the antenna assembly includes a loop probe configuration configured to deploy in a curved orientation along a curvilinear path to define an ablation area.

11. A microwave ablation system, comprising:
an antenna assembly configured to deliver energy from a power source to tissue of a patient;

an introducer having a distal end configured to penetrate tissue and having a lumen disposed coaxially therein at least partially along the length thereof and configured to receive the antenna assembly therein; and

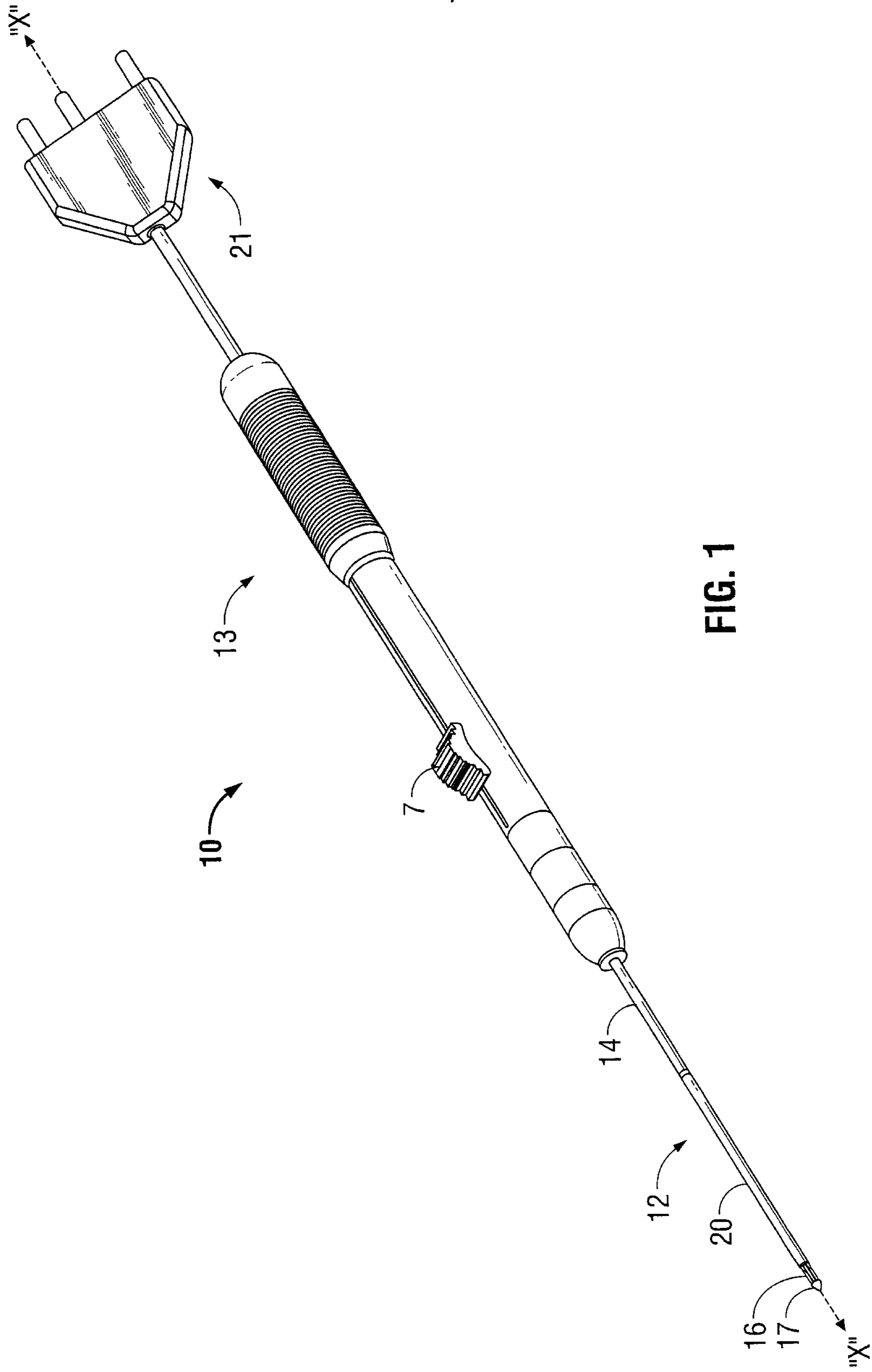
an imaging device disposed on the introducer and configured to provide imaging data to a processing unit corresponding to tissue proximate the introducer.

12. A microwave ablation system according to claim 11, wherein the imaging device is selected from the group consisting of ultrasound transducers, CAT scan devices, MRI devices, and PET scan devices.

13. A microwave ablation system according to claim 11, wherein the introducer is placed relative to the tissue based on the imaging data.

14. A microwave ablation system according to claim 11, wherein the introducer is rotatable 360° about a longitudinal axis thereof to facilitate radial imaging of tissue proximate the introducer.

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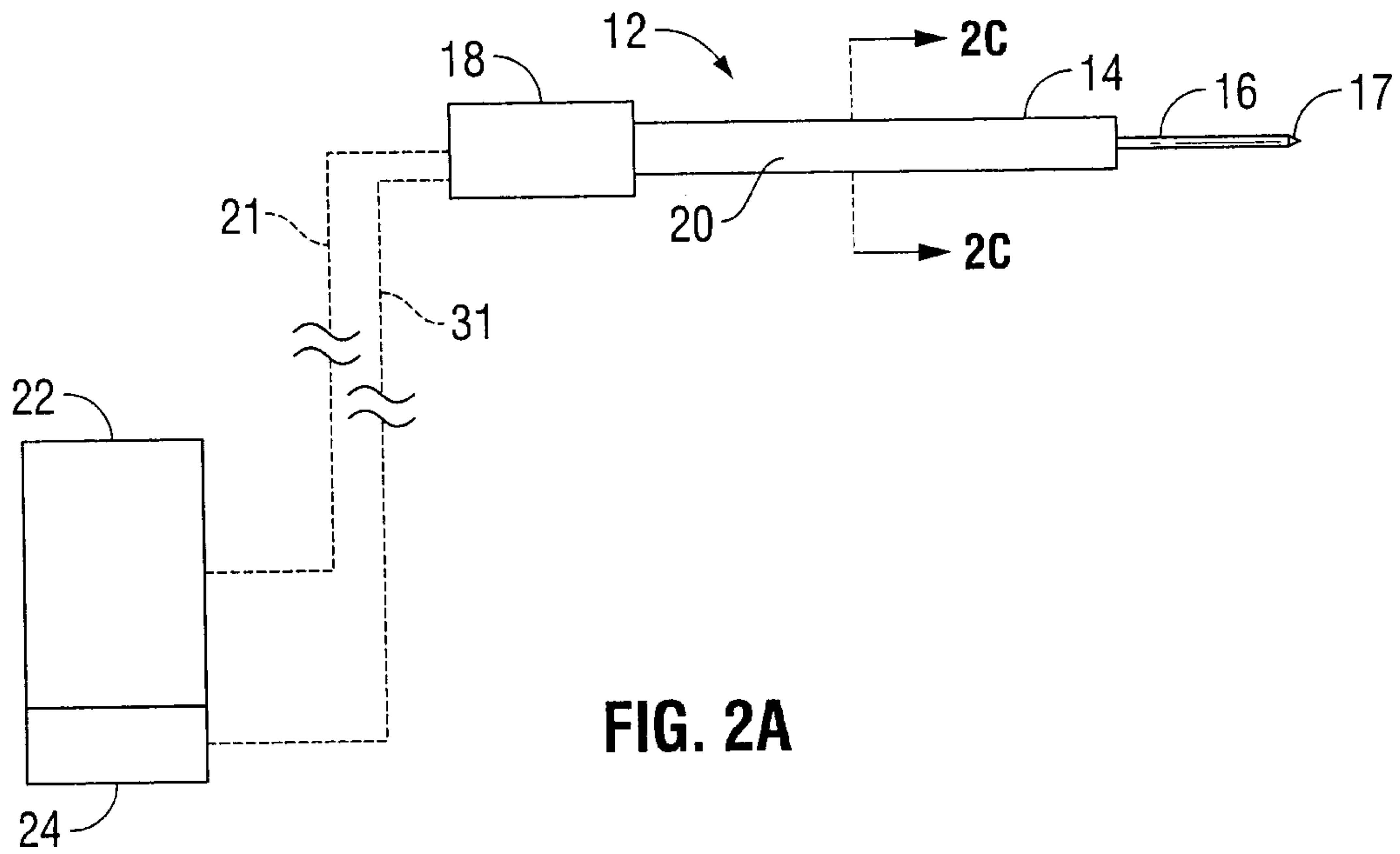


FIG. 2A

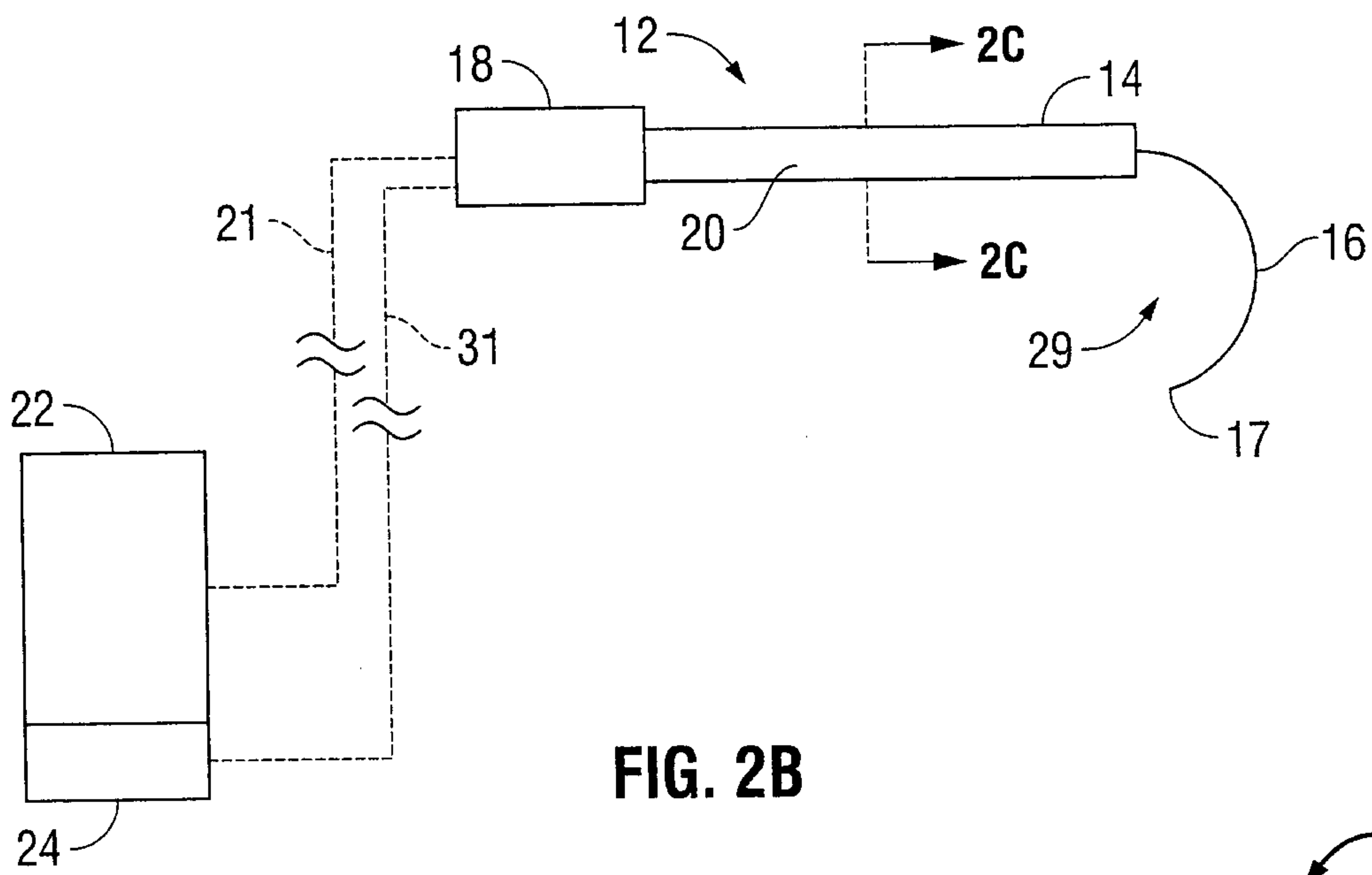


FIG. 2B

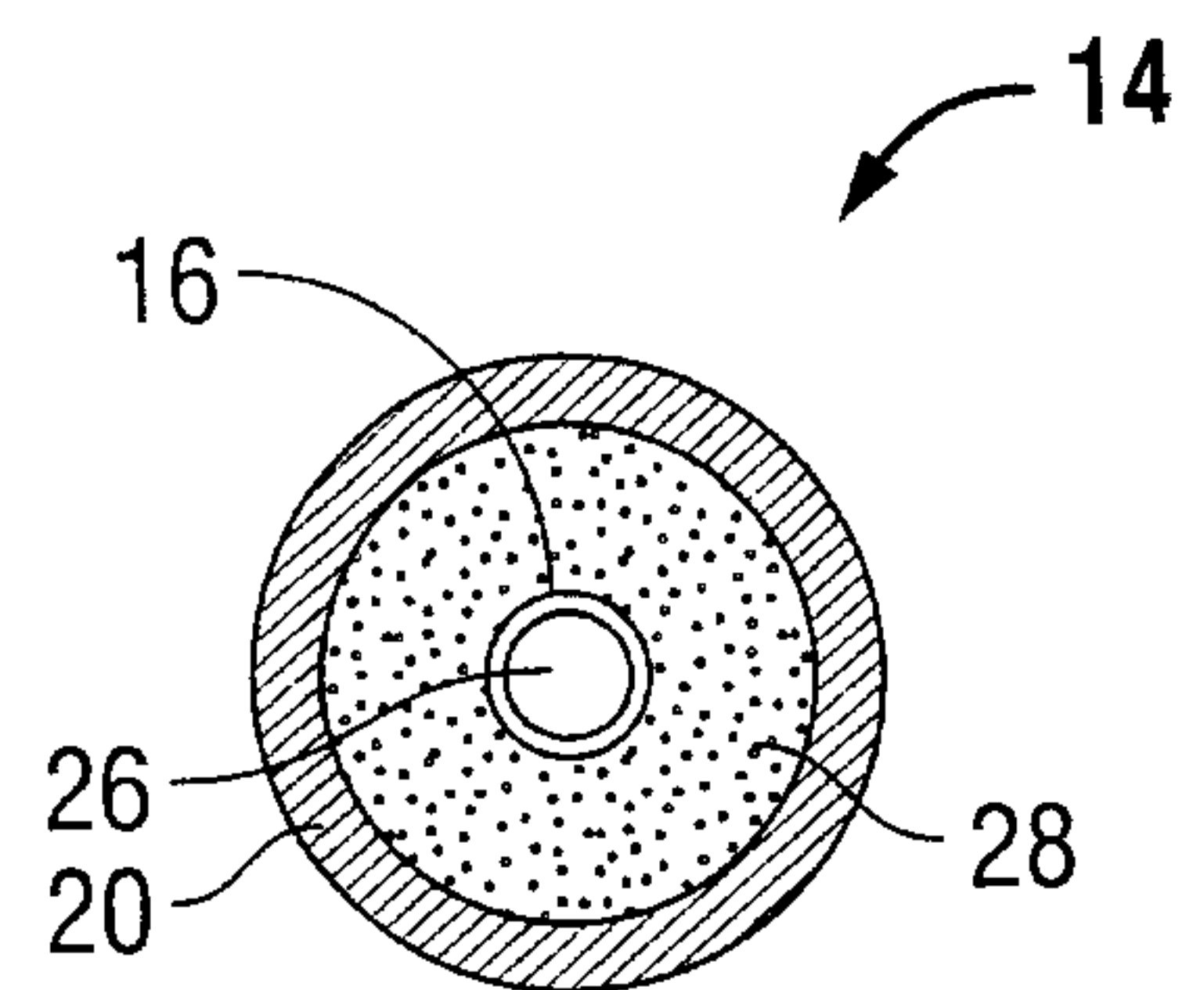


FIG. 2C

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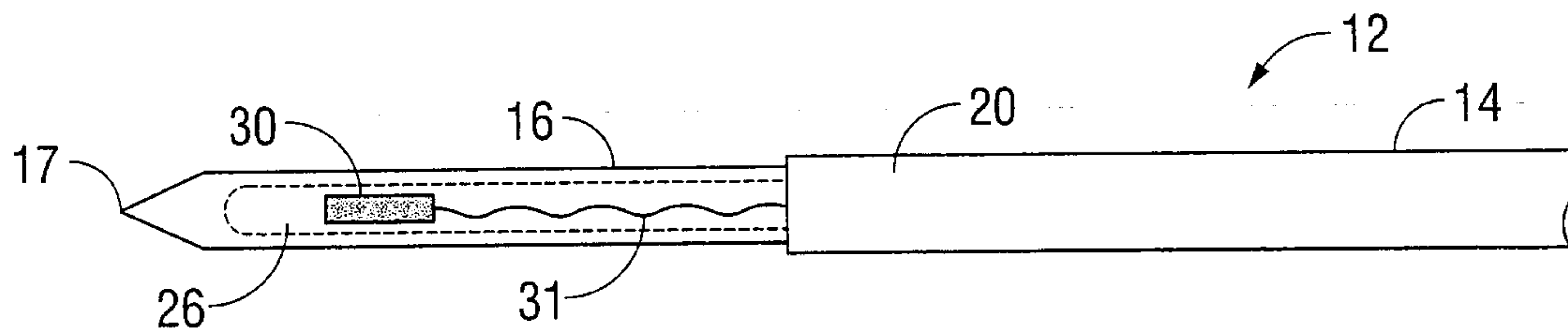


FIG. 3A

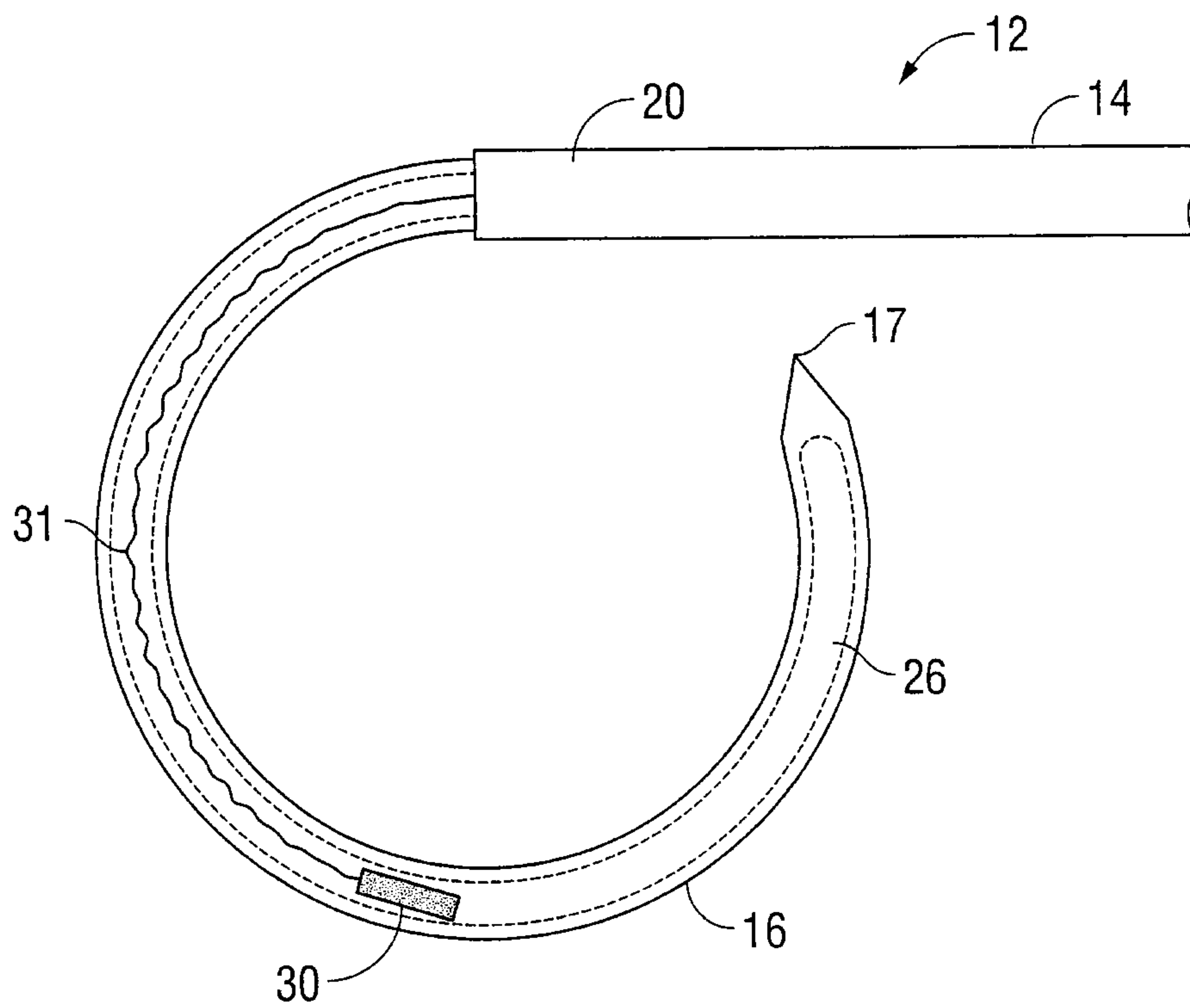


FIG. 3B

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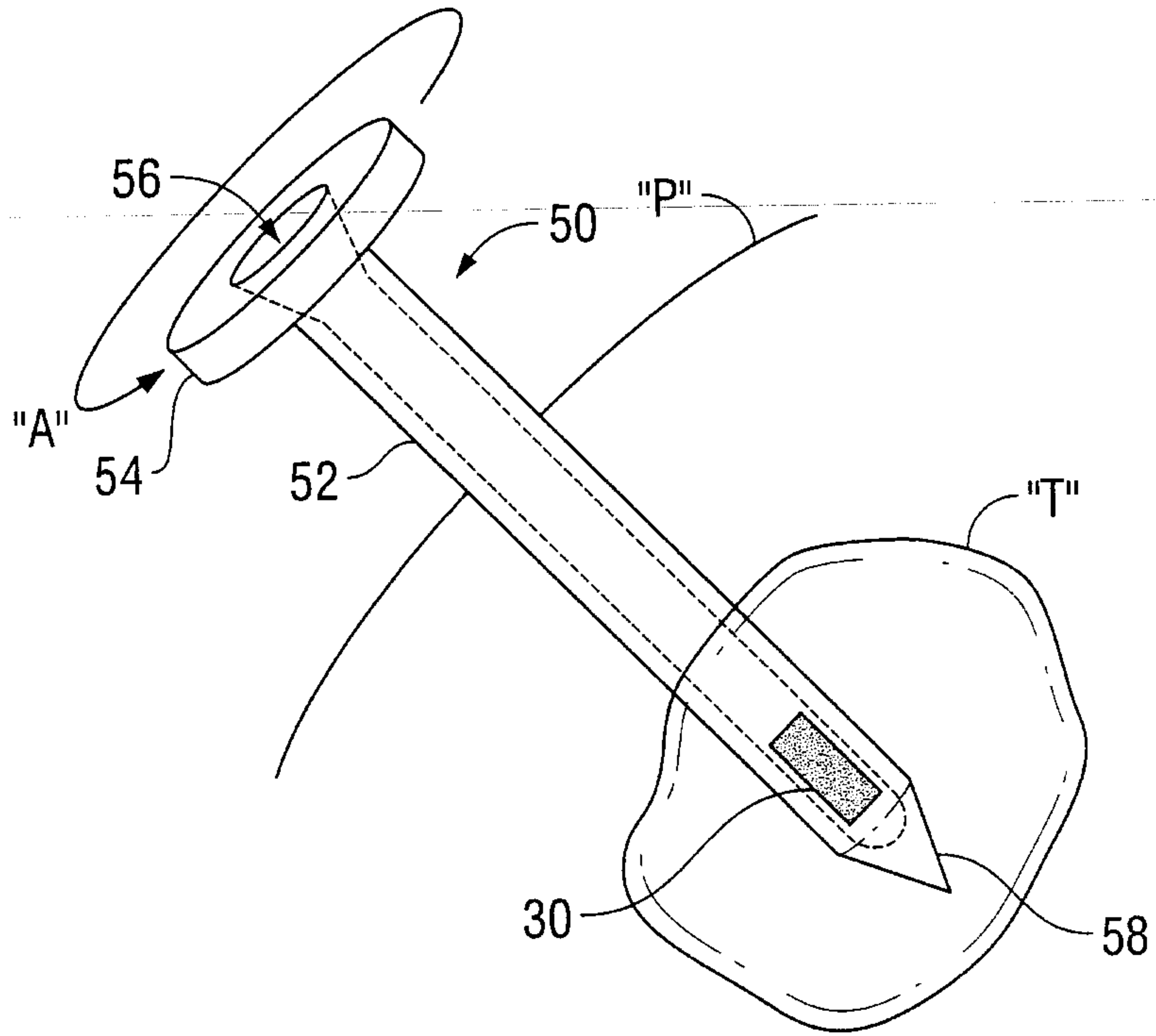


FIG. 4A

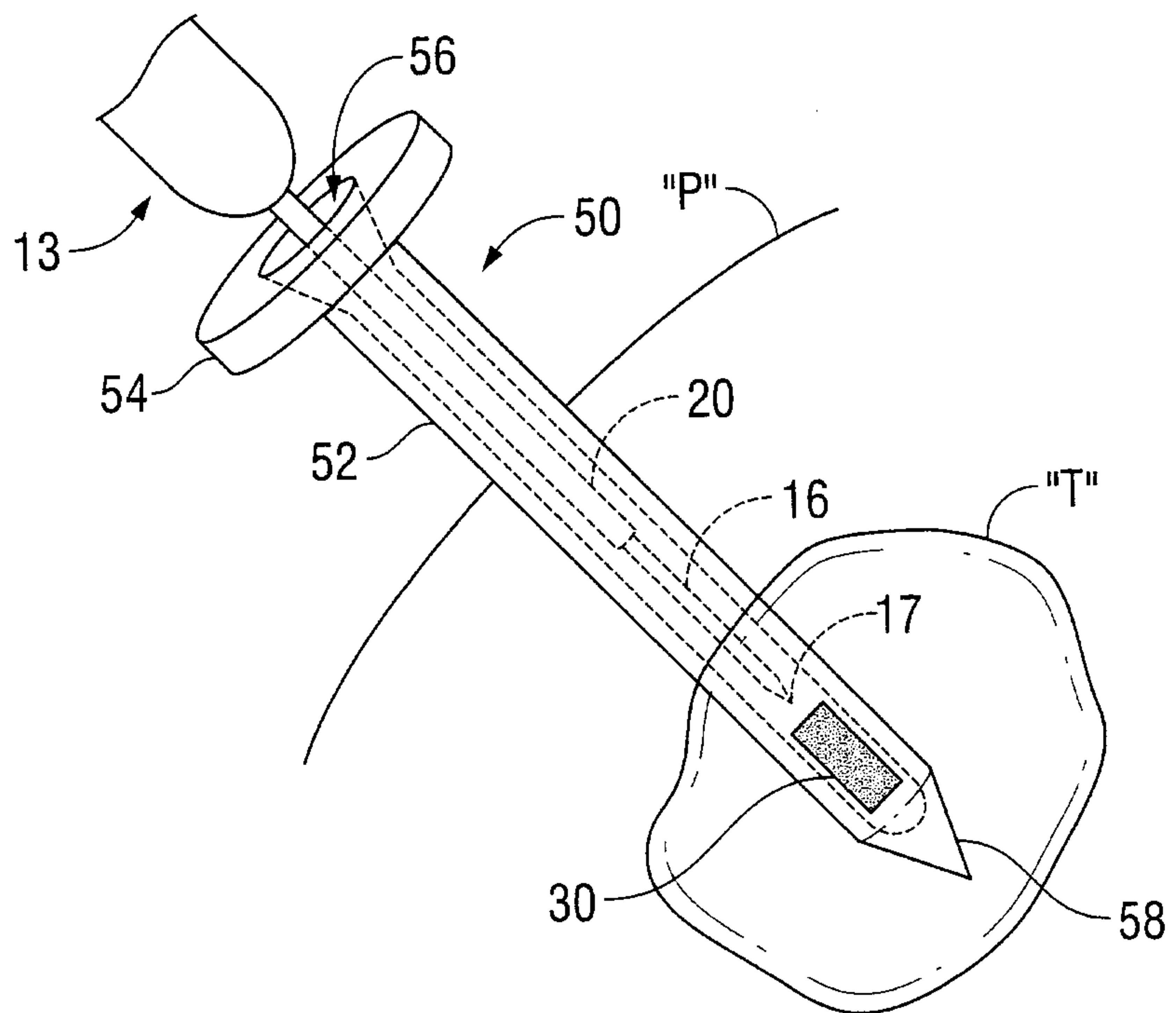


FIG. 4B

