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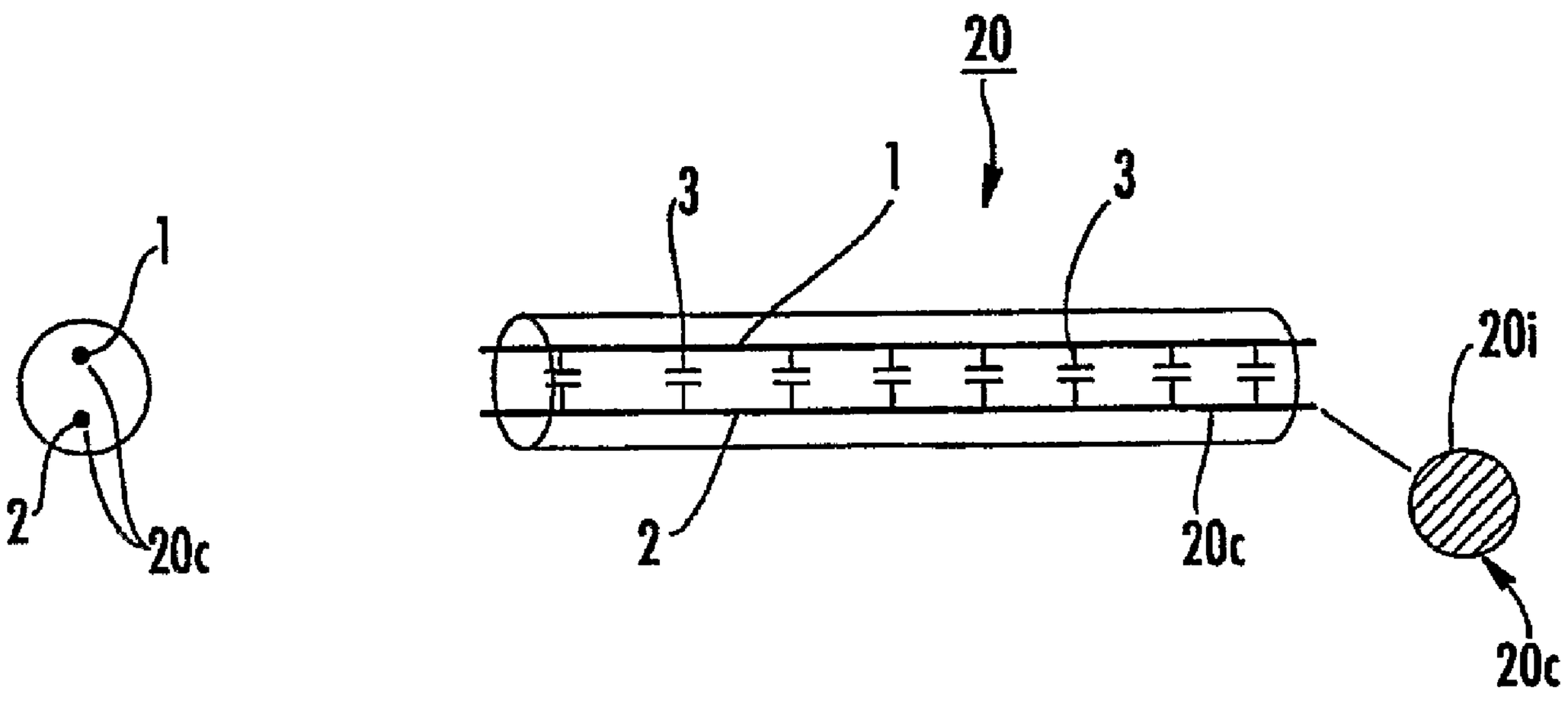
(54) **Titre : SYSTEMES DE DERIVATION A IMPEDANCE ELEVEE COMPATIBLES AVEC DES SYSTEMES IRM ET PROCEDES ASSOCIES**
(54) **Title: MRI-SAFE HIGH IMPEDANCE LEAD SYSTEMS AND RELATED METHODS**



(57) **Abrégé/Abstract:**
Some embodiments are directed to MRI/RF compatible medical interventional devices. A plurality of spaced apart high impedance circuit segments are configured to have a high impedance at a high range of radiofrequencies and a low impedance at a low range of frequencies The high impedance circuit segments may comprise co-wound coiled inductors and can reduce, block or inhibit RJ-transmission along the lead system (20) during exposure to RF associated with a high-Held magnet MRI systems, while permuting passage of low frequency physiologic signals, treatments and/or stimuli The devices can include at least one electrode

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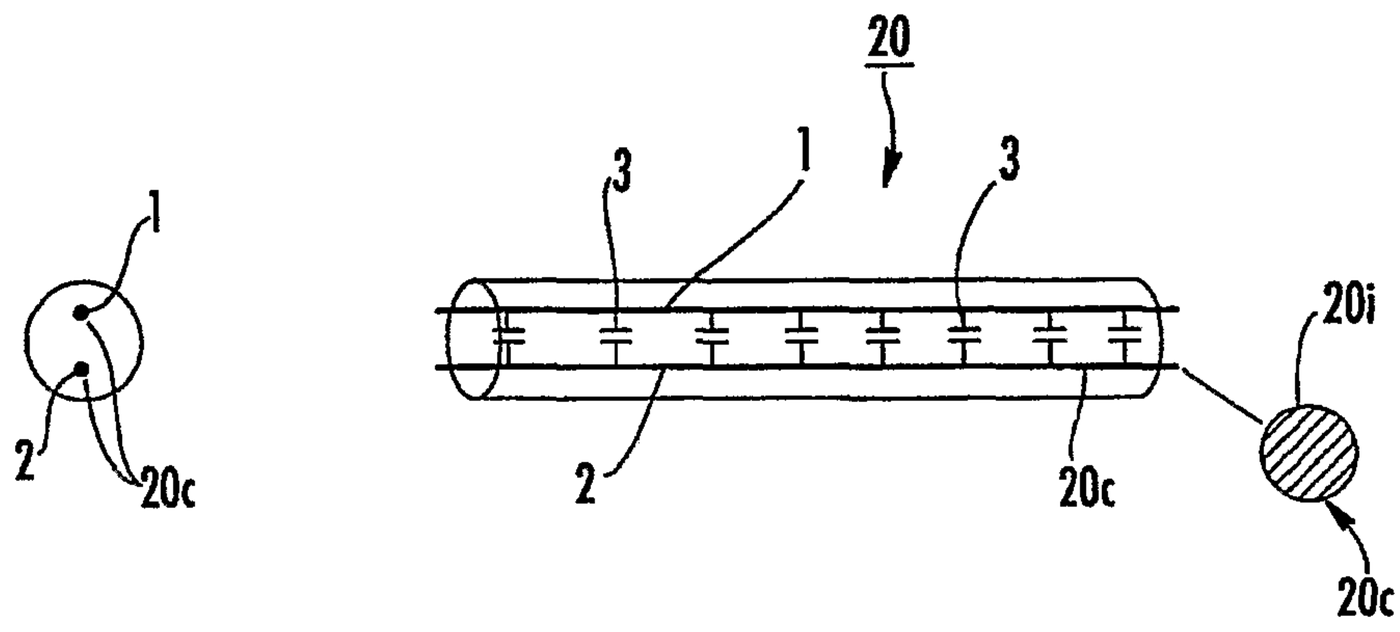
(54) Title: MRI-SAFE HIGHII IMPEDANCE LEADSYSTEMS



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MRI-SAFE HIGH IMPEDANCE LEAD SYSTEMS AND RELATED METHODS

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MRI-SAFE HIGH IMPEDANCE LEAD SYSTEMS AND RELATED METHODS

FIELD OF THE INVENTION

[0002] The present invention relates to interventional medical leads and may be particularly suitable for MRI compatible implantable devices such as cardiac pacing devices and Deep Brain Stimulation ("DBS") and/or sympathetic nerve chain stimulation leads.

BACKGROUND OF THE INVENTION

[0003] When patients implanted with deep brain stimulation (DBS) or cardiac pacing (CP) lead systems are exposed to external Radio Frequency (RF) fields, local tissue damage around the electrodes of these leads can occur as has been reported by various researchers. *See, e.g.,* Baker et al., *Neurostimulation systems: assessment of magnetic field interactions associated with 1.5- and 3-Tesla MR systems*, J Magn Reson Imaging 2005;21(1):72-77; Bhidayasiri et al., *Bilateral neurostimulation systems used for deep brain stimulation: in vitro study of MRI-related heating at 1.5 T and implications for clinical imaging of the brain*; Magn Reson Imaging 2005;23(4):549-555; Rezai et al., *Neurostimulators: potential for excessive heating of deep brain stimulation electrodes during magnetic resonance imaging*. J Magn Reson Imaging 2001;14(4):488-489; Chou et al., *RF heating of implanted spinal fusion stimulator during magnetic resonance imaging*, IEEE Trans Biomed Eng 1997;44(5):367-373; and Luechinger et al., *In vivo heating of pacemaker leads during magnetic resonance imaging*, Eur Heart J 2005;26(4):376-383; discussion 325-377.

[0004] There are several external RF sources such as, for example, RF

exposure during MRI or during RF diathermy. Local tissue damage during RF diathermy procedures in patients with implanted deep brain stimulator lead systems has also been reported. RF/microwave diathermy treatments can use leads that employ an alternating current to cauterize tissue. The diathermy alternating current delivered during the therapy can be in the range of between about 1KHz-350 MHz (believed to be typically at about 27.5 MHz). In certain situations, the lead system may undesirably act as an antenna, receiving and depositing current in localized tissue where the leads are exposed, thereby potentially increasing the specific absorption rate (SAR) (a way of measuring the quantity of radiofrequency (RF) energy that is absorbed by the body).

[0005] RF heating of tissue in close proximity to long conductors (such as metallic wires) in an MRI environment has also been reported in literature. Local tissue damage can be caused by RF deposition in the tissue that is in close proximity to the linear conductors or electrodes of the lead system, when patients with implanted leads or interventional devices are placed in an external RF field. This RF heating mechanism may be explained as follows. During an MRI scan, the transmit RF field creates a voltage along the long linear conductors (individual or part of any interventional device) or the conductors/filers of the DBS and cardiac pacing lead systems. Currents are then created through the conductors and into the surrounding tissue. Where the current emerges from the distal tip of the device (or adjacent to the electrode in the case of an implantable lead), it can be concentrated and can cause heating and subsequent tissue damage.

[0006] In view of the foregoing, there remains a need for alternative medical lead configurations.

SUMMARY OF EMBODIMENTS OF THE INVENTION

[0007] Some embodiments of the present invention provide therapeutic lead systems that can exhibit high impedance during exposure to RF (high frequencies).

[0008] The lead systems can be used with interventional devices and may be acutely placed *in vivo* or chronically implantable and can include one or more stimulating, ablating and/or recording electrode. The lead systems may be particularly suitable for implantable lead systems for IPGs (implantable pulse generators), cardiac

defibrillators, cardiac pacing (CP), neurostimulation (peripheral, deep brain, or spinal), EP catheters, guidewires, and the like, for leads used in heat-sensitive regions in the body.

[0009] The lead systems may be implantable, MRI compatible multi-purpose lead systems with at least one stimulating/pacing electrode and may optionally be configured to provide an internal MRI receive antenna.

[0010] In some embodiments, the lead systems can include a plurality of high impedance sections or segments spaced along the length of the lead. The high impedance sections can be configured as RF traps that inhibit flow of induced RF current at the high impedance frequency/frequencies, whereby current is inhibited from heating tissue adjacent to one or more electrodes, thus reducing the likelihood of and/or preventing RF-current induced tissue damage. The RF traps can be configured to allow physiological and stimulation signals to pass through (typically in the kHz range). Thus, the RF trap can trap only the high frequencies of interest to which the traps are tuned.

[0011] Embodiments of the invention describe different methods of creating high impedance RF traps using the components of an implantable lead system or a medical device. The RF traps may be incorporated in long metallic components to render them safe to use in an MRI environment.

[0012] The lead systems may include supplemental high impedance circuits for the shield in combination with the high impedance configurations for conductors.

[0013] Some embodiments are directed to interventional devices and/or implant devices comprising metal or metallic components.

[0014] In particular embodiments, a lead can be a relatively long implantable lead having a length in the body of greater than 10 cm. The at least one electrode can be a plurality of electrodes with at least one being a recording and/or a recording and stimulating and/or ablating electrode.

[0015] Some embodiments are directed to MRI/RF compatible medical interventional devices. The devices include an implantable elongate lead system having at least a first and a second electrode, each associated with a respective first and second axially extending conductor. A plurality of axially spaced apart capacitors are disposed between the first and second axially extending conductor along at least major portion of a

length of the lead system to define a plurality of high impedance circuit segments whereby the lead system has a high impedance over a target range of (typically a high range) of radiofrequencies and a low impedance over another range of low electromagnetic frequencies (such as audio-frequencies or frequencies in the kHz or lower ranges, including DC at around 0 Hz).

[0016] The high impedance circuit segments may be configured to inhibit RF transmission along the lead system during exposure to RF associated with a high-field magnet MRI system.

[0017] Other embodiments are directed to MRI compatible device/lead systems that include: (a) an implantable lead system elongate lead having at least a first and a second electrode, each associated with a respective first and second axially extending conductor; and (b) a high impedance surface band gap structure disposed about the first and second conductors.

[0018] The surface band gap structure may include a primary shield and secondary and tertiary segmented shields which are intermittently connected to the primary shield, whereby the high impedance surface reduces or blocks RF propagation.

[0019] Other embodiments are directed to an MRI compatible device that includes: (a) an implantable lead system elongate lead having at least a first and a second electrode, each associated with a respective first and second axially extending conductor, wherein a plurality of spaced apart capacitors are disposed between the first and second axially extending conductors along at least major portion of a length of the lead system to define a plurality of high impedance circuit segments; and (b) a high impedance band gap surface formed along at least a major length of the lead system. The lead system has a high impedance at a high range of radiofrequencies and a low impedance at a low range of frequencies.

[0020] Still other embodiments are directed to MRI compatible implantable pulse generators (IPG). The IPG's include: (a) an implantable housing; (b) a high impedance decoupling circuit disposed in the housing; (c) at least one implantable lead in communication with the decoupling circuit and configured with a length that extends from the housing to a target treatment site; (d) at least one implantable electrode in communication with the lead; and (e) a controller in the implantable housing, the

controller configured to selectively activate the decoupling circuit to provide a high impedance to the lead at high radiofrequencies and a low impedance at a low radiofrequencies.

[0021] In particular embodiments, the controller is remotely controllable to activate the decoupling circuit to provide the high impedance.

[0022] The high impedance circuits and/or circuit segments may comprise inductors. Inductors and capacitors can be formed form conducting leads and a dielectric substrate and can be configured to reduce, block or inhibit RF transmission along the lead system during exposure to RF associated with a high-field magnet MRI system, while permitting passage of low frequency physiologic signals, treatments and/or stimuli.

[0023] The lead may be a flexible lead and the at least one electrode can be a plurality of spaced apart electrodes. The lead can include a plurality of conductors held in a core of the lead, a respective one for each electrode.

[0024] Some embodiments are directed to MRI safe lead systems that include: (a) an elongate flexible body with at least one conductor; (b) at least one electrode in communication with the at least one conductive lead; and (c) a plurality of high impedance segments axially spaced apart along a length of the lead system. The at least one conductive lead has a plurality of axially spaced apart coiled segments and a plurality of linear segments residing between adjacent coiled segments. The high impedance segments include: (a) a coiled conductive lead segment defining an inductor; (b) a dielectric over the coiled conductive lead segment; (c) a conductive shield over the dielectric with the dielectric residing between the inductor and the conductive shield, wherein the conductive lead is electrically coupled to the shield at a proximal end portion of the coiled segment; and (d) a capacitor at a distal end of the coiled conductive lead segment electrically connecting the conductive lead and the shield. The high impedance segments are configured to provide an impedance that is greater than about 450 Ohms at a target RF frequency associated with an MRI system.

[0025] Some embodiments are directed to MRI-safe lead systems that include: (a) an elongate flexible body with a plurality of conductors, the body having distal and proximal portions, the conductors each having a plurality of axially spaced apart coiled segments, each coiled segment defining an inductor; (b) at least one electrode residing at

the distal portion of the flexible body in communication with at least one of the conductors; and (c) a plurality of high impedance segments axially spaced apart along a length of the lead. The high impedance segments include: (i) a plurality of coiled conductor segments residing at a common axially extending segment of the flexible body, at least one coiled lead segment for each of the conductors; (ii) a dielectric insulator covering the plurality of coiled conductor segments at the common axial segment; and (iii) a conductive shield at the common axial segment disposed over the dielectric insulator with the dielectric insulator residing between the coiled segments and the conductive shield. A single one of the plurality of conductors is electrically coupled to the conductive shield at a proximal end portion of the common axial segment.

[0026] Some embodiments are directed to MRI-safe lead systems that include an elongate flexible body with a plurality of conductors and at least one high impedance segment with opposing proximal and distal portions. The at least one high impedance segment is configured so that at least one of the conductors has (a) a first individually coiled segment that is proximate to but axially apart from the coiled segments of different leads, and (b) a second coiled segment that is co-wound with at least one other conductor coiled segment. A conductive shield resides over the first lead first and second coiled segments and an insulating material resides between the shield and the first and second coiled segments. The at least one lead with the individual and co-wound coiled segments is in electrical communication with the shield at a proximal portion of the high impedance segment.

[0026a] According to another aspect, there is provided an MRI/RF compatible medical device, comprising: an implantable elongate lead having at least a first electrode, a second electrode, a first axially extending conductor, and a second axially extending conductor, the first electrode electrically coupled to the first axially extending conductor and the second electrode electrically coupled to the second axially extending conductor, wherein, at each of a plurality of intermediate locations along a length of the elongate lead, at least one of a plurality of spaced apart capacitors is disposed between the first and second axially extending conductors to define a plurality of high impedance circuit segments, each high impedance circuit segment comprising at least a portion of the first axially extending conductor, at least a portion of the second axially extending conductor, and at least one of the

plurality of spaced apart capacitors disposed between the portion of the first axially extending conductor and the portion of the second axially extending conductor, whereby the lead has a high impedance at a target range of high radiofrequencies and a low impedance at low frequencies.

[0026b] According to a further aspect, there is provided an MRI compatible device comprising: an elongate lead having at least a first and a second electrode, each associated with a respective first and second axially extending conductor, wherein a plurality of spaced apart capacitors are disposed between the first and second axially extending conductors along at least major portion of a length of the lead to define a plurality of high impedance circuit segments; and a high impedance surface band gap structure formed along at least a major length of the lead, wherein the surface band gap structure comprises a primary shield and secondary and tertiary segmented shields which are intermittently connected to the primary shield, whereby the high impedance surface reduces or blocks RF propagation; wherein the lead has a high impedance at a high range of radiofrequencies and a low impedance at a low range of frequencies.

[0027] Other systems, methods, and/or computer program products according to embodiments of the invention will be or become apparent to one with skill in the art upon review of the following drawings and detailed description. It is intended that all such additional systems, methods, and/or computer program products be included within this description, be within the scope of the present invention, and be protected by the accompanying claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] Figures 1A and 1B are schematic illustrations of high impedance lead systems according to embodiments of the present invention.

[0029] **Figures 2A-2B** are schematic illustrations of examples of multi-electrode lead systems with an IPG, which may include high impedance circuits or segments to provide a high impedance operation at selected RF frequencies according to embodiments of the present invention.

[0030] **Figures 3A** and **3C** are schematic diagrams that illustrate a lead system with electrodes and capacitors disposed therealong according to embodiments of the present invention. **Figure 3A** illustrates a linear system and **Figure 3C** illustrates a wound/coiled system.

[0031] **Figures 3B** and **3D** are schematic cross-sectional views of the systems shown in **Figures 3A** and **3B**, respectively.

[0032] **Figure 4** is a schematic diagram that illustrates three conductors, three electrodes and capacitors disposed between conductor pairs according to embodiments of the present invention.

[0033] **Figures 5A** and **5B** are schematic diagrams of other multi-electrode high impedance leads according to embodiments of the present invention.

[0034] **Figure 6** is a schematic illustration of an implantable pulse generator with a high impedance operation according to embodiments of the present invention.

[0035] **Figures 7** and **8** are data charts/graphs of a coiled parallel inductor pair in a frequency range of between 1-150MHz.

[0036] **Figures 9** and **10** are data charts/graphs of a coiled parallel inductor similar to that shown with respect to **Figures 7** and **8**, but modified with capacitors to provide higher impedance according to embodiments of the present invention.

[0037] **Figure 11** is a schematic illustration of the parallel inductors and capacitors used to provide the data of **Figures 9** and **10** according to embodiments of the present invention.

[0038] **Figure 12** is a graph of a sample loss of an open circuit for a frequency range of about 1- 150 MHz.

[0039] **Figure 13A** is a schematic illustration of an electrode lead system with a high-impedance surface shield according to other embodiments of the present invention.

[0040] **Figure 13B** is a section view of the lead system shown in **Figure 13A** illustrating shielding and conductor configurations according to embodiments of the present invention.

[0041] **Figure 13C** is a cross-sectional view of the lead system shown in **Figure 13B**.

[0042] **Figure 14** is a schematic illustration of a lead system with RF chokes that may be combined with one or more of the high impedance configurations shown and/or described herein according to embodiments of the present invention.

[0043] **Figure 15A** is a schematic illustration of an RF trap that can be used to form a high impedance segment on a lead according to embodiments of the invention.

[0044] **Figure 15B** is a schematic illustration of the RF trap shown in **Figure 15A** with the addition of a capacitor connecting the shield and the conductor according to some embodiments of the invention.

[0046] **Figure 16** is a schematic illustration of a long lead with a plurality of axially spaced apart RF traps along a length of a conductor or lead according to embodiments of the invention.

[0047] **Figure 17** is a schematic illustration of a lead system with RF traps having co-wound conductors in a common shield according to embodiments of the invention.

[0048] **Figure 18A** is a partial cutaway side view of a multi-lead system with an RF trap having co-wound conductors/filars according to some embodiments of the invention.

[0049] **Figure 18B** is a cross-section view taken along lines **18B-18B** in **Figure 18A**.

[0050] **Figure 18C** is a schematic line illustration of the embodiment shown in **Figure 18A**.

[0051] **Figure 19A** is a partial cutaway side view of a multi-lead system with an RF trap having co-wound conductors/filars with capacitors connecting the respective

leads to the conductive shield at two locations according to some embodiments of the invention.

[0052] **Figure 19B** is a cross-section view taken along lines **19B-19B** in **Figure 19A**.

[0053] **Figure 19C** is a schematic line illustration of the embodiment shown in **Figure 19A**.

[0054] **Figure 20A** is a partial cutaway side view of a multi-lead system with an RF trap having co-wound conductors/filars with less than all the leads/conductors in electrical contact with the shield according to some embodiments of the invention.

[0055] **Figure 20B** is a cross-section view taken along lines **20B-20B** in **Figure 20A**.

[0056] **Figure 21A** is a partial cutaway side view of a system with an RF trap having conductors coiled both separately and co-wound according to some embodiments of the invention.

[0057] **Figure 21B** is a cross-section view taken along lines **21B-21B** in **Figure 21A**.

[0058] **Figure 21C** is a schematic line illustration of the embodiment shown in **Figure 21A**.

[0059] **Figure 22** is a graph of impedance (Ohms) versus frequency (MHz) for the embodiment shown in **Figures 21A** and **21B**.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0060] The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. It will be appreciated that although discussed with respect to a certain embodiment, features or operation of one lead system embodiment can apply to others.

[0061] In the drawings, the thickness of lines, layers, features, components and/or regions may be exaggerated for clarity and broken lines illustrate optional features or operations, unless specified otherwise. In addition, the sequence of operations (or steps) is not limited to the order presented in the claims unless specifically indicated otherwise. It will be understood that when a feature, such as a layer, region or substrate, is referred to as being "on" another feature or element, it can be directly on the other element or intervening elements may also be present. In contrast, when an element is referred to as being "directly on" another feature or element, there are no intervening elements present. It will also be understood that, when a feature or element is referred to as being "connected" or "coupled" to another feature or element, it can be directly connected to the other element or intervening elements may be present. In contrast, when a feature or element is referred to as being "directly connected" or "directly coupled" to another element, there are no intervening elements present. Although described or shown with respect to one embodiment, the features so described or shown can apply to other embodiments.

[0062] Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and this specification and should not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[0063] The term "high radiofrequency" or "high RF" refers to RF frequencies that are at or above about 1 MHz, and includes radiofrequencies in the range of about 1MHz to about 256 MHz. Embodiments of the present invention configure devices so as to have high impedance circuit segments or a high impedance circuit at high RF and low impedance circuit segments or circuit at DC or low frequency (at a kHz or less frequency or frequency range), *i.e.*, at frequencies used for treatment such as stimulation or ablation. For example, for 1.5T, 3.0T and 6.0T systems, the respective frequencies are 64 MHz, 128 MHz and 256 MHz. The frequencies of the different MRI systems are well known to those of skill in the art. The devices can be configured to have high impedance at several

of the radiofrequencies associated with high-field magnet MRI systems, such as systems with magnets above about 1.0T, such as about 1.0T, 1.5T, 2.0T, 3.0T, 4.0T, 5.0T, 6. 0T and 9.0T, typically between about 1T to 15T.

[0064] The term "high impedance" means an impedance sufficiently high to inhibit, block or eliminate flow of RF-induced current at a target frequency range(s). The impedance has an associated resistance and reactance as is well known to those of skill in the art. Some embodiments provide an impedance of at least about 300 Ohms, typically between about 400 Ohms to about 600 Ohms, such as between about 450 Ohms to about 500 Ohms, while other embodiments provide an impedance of between about 500 Ohms to about 1000 Ohms. Embodiments of the invention configure lead systems that provide sufficiently high-impedance at frequencies associated with a plurality of different conventional and future magnetic field strengths of MRI systems, such as at least two of 1.5T, 2.0T, 2.5T, 3.0T, 9.0T, and the like, allow for safe use in those environments (future and reverse standard MRI system compatibility).

[0065] The term "tuned" means that a parallel resonant circuit with inductive and capacitive characteristics defined by certain components and configurations has a high impedance at one or more target frequencies, typically including one or more MRI operating frequencies.

[0066] The term "coiled segment" refers to a conductive lead (trace, wire or filar) that has a coiled configuration. The term "co-wound segments" means that the affected leads, conductors, wires and/or filars can be substantially concentrically coiled at different radii, one above the other, or concentrically coiled closely spaced at substantially the same diameter. The term "co-wound" is used to describe structure and is not limiting to how the structure is formed (*i.e.*, the coiled segments are not required to be wound concurrently or together, but may be so formed). The terms "conductive element", "conductive lead" and "conductors" are used interchangeably and refer to a conductive path that connects target components (such as, for example, a stimulation source and an electrode) and can include one or combinations of a metallic trace, a wire, a flex circuit, a filar(s), or other conductive configuration. As such, the conductors or conductive elements include long linear and/or non-linear conductors that can be formed with one or more of discrete wires, flex circuits, filars (bi, quadra or other winding), or by

plating, etching, deposition, or other fabrication methods for forming conductive electrical paths.

[0067] Embodiments of the present invention can be configured to for any desired internal region of the body or object. The object can be any object, and may be particularly suitable for animal and/or human subjects. Some embodiments can be sized and configured for brain stimulation, typically deep brain stimulation. Some embodiments can be configured to stimulate a desired region of the sympathetic nerve chain and/or the spinal cord. Some lead or implantable devices can be configured for cardiac intervention. Other embodiments may be directed to other anatomical structures, organs or features including deep tissue, lumens, and the like. For example, the systems of the present invention may be configured for treatment of gastrointestinal, urinary, or other body regions. Some embodiments provide devices configured for intraluminal or intratissue penetration. Some embodiments provide devices for acute or chronic implantation.

[0068] Examples of known stimulation treatments and/or target body regions are described in U.S. Patent Nos. 6,708,064; 6,438,423; 6,356,786; 6,526,318; 6,405,079; 6,167,311; 6539,263; 6,609,030 and 6,050,992.

[0069] Generally stated, the extent to which the lead system or the long conductor couples with the external RF is a function of length of the lead system or the conductor, the insulation thickness over it and its arrangement in the RF field *e.g.* looping, etc. Typically, lengths shorter than quarter wavelength (at the applied RF frequency) do not couple with the external RF fields, displaying reduced RF deposition and lower local temperature rise in tissue adjacent to them. Also, typically, increasing the insulation thickness can reduce the coupling and RF deposition in the adjacent tissue.

[0070] Long wires, conductors and lead systems couple to external RF to different extents at different frequencies. The extent of RF deposition in the tissue depends on the extent of resonation, *i.e.*, the coupling at that frequency. Linear conductors/wires act as linear antennas. Lead systems which have more than one long conductor act as linear antennas, where each individual conductor acts as an antenna and two or more conductors in combination with each other act as antennas too. This creates

a RF coupling pattern having the lead system couple at multiple/different frequencies. DBS and cardiac pacing leads may comprise about 8 (and may include more or less) long conductors and electrodes. In particular embodiments, one, some or all of the conductors can act as antennas individually and in combination with each other.

[0071] Internal and external imaging coils used in MRI can be decoupled during RF transmit by the scanner. This can inhibit local heat deposition in the tissue adjacent to the coils. The decoupling mechanism can create a high impedance circuit so that these coils do not couple with the transmitted RF, thus eliminating any tissue damage. *See*, Yoda K., *Decoupling technique for transmit coils in NMR spectroscopy and imaging*,. NMR Biomed 1990;3(1):27-30; and Buchli et al., *Increased RF power absorption in MR imaging due to RF coupling between body coil and surface coil*, Magn Reson Med 1989; 9(1):105-112.

[0072] Similarly, standing wave formation on long coaxial cables may be attenuated by incorporating balun circuits or RF chokes at various locations on the shield of coaxial cables. *See*, Atalar et al., U.S. Patent No. 6,284,971, entitled, *Enhanced Safety Coaxial Cables*. *See also*, Ladd *et al.*, *Reduction of resonant RF heating in intravascular catheters using coaxial chokes*, Magn Reson Med 2000; 43(4): 615-619. *See also*, PCT Application Serial No., PCT/US2005/028116, filed August 9, 2005, entitled, *Implantable MRI Compatible Stimulation Leads and Antennas and Related Systems and Methods*. Generally stated, this application describes incorporating RF chokes on DBS and CP lead systems.

[0073] **Shielding linear conductors can inhibit RF deposition on them. This shielding can be continuous, discontinuous, or may be achieved by multiple methods, to list a few, *e.g.*, insulating conductors with polymers filled with conducting metals doped for conductivity.**

[0074] Referring now to the figures, in some embodiments as shown in **Figures 1A** and **1B**, a high impedance lead assembly **20** can employ at least one conductor **20c**, shown as two conductors **1, 2** which may be coiled (**Figure 1B**) and/or reside parallel (**Figure 1A**) to each other, or be configured with combinations of both,

and that are operational over a relatively wide range of frequencies. These long conductors **20c** can have a metal core and are typically insulated from each other along their length and may be surrounded by a polymeric dielectric **20i**. At intermediate locations, the two conductors **1, 2** can be connected by capacitors **3**. The combination of the length of the conductors **1** and **2** (which can also form inductors) and the capacitors **3** can be configured to create a high impedance circuit(s). This circuit can be configured so that it does not tune to a target range of RF frequencies, including for example, frequencies ranging from about 1 MHz to 250 MHz, creating high impedance circuit segments, thus reducing the extent of coupling in this frequency range. In operation, the circuit has high impedance to high RF, but has low resistance to DC, or low frequency RF (KHz), which is the stimulation frequency. This principle may be applied to designing RF/MRI-safe devices and/or lead systems for CP leads, DBS leads, spinal cord stimulation leads, etc.

[0075] The capacitors **3** can be regularly spaced or irregularly spaced. The capacitors **3** may have the same or different capacitance from each other.

[0076] Lead systems **20** can comprise a plurality of electrodes and conductors, such as between about 2 to about 10 conductors, typically at least about 4. In some embodiments, the lead systems can include about 8 conductors. The conductor axial lengths (linear and/or coiled) can range from about 10 to 200 cm, with a thin insulator layer on the conductors and with a polymeric dielectric insulator layer over it.

[0077] Design of conventional known lead systems with multiple electrodes 100_1-100_4 and conductors **20c** are shown in **Figures 2A-2B**. *See also*, U.S. Patent Application Publication No. 2005/0222647.

[0078] Referring to **Figures 3A** and **3B**, at a distal end portion of the lead system **20**, the conductors **20c** can be connected to electrodes $\mathbf{100_1}$, $\mathbf{100_2}$, which, in position, can be in contact with target tissue. The conductors **20c** run along the length of the lead system and are terminated by connecting to electrodes $\mathbf{100_1}$ and $\mathbf{100_2}$ at the distal end. At the proximal end these conductors are connected to the pulse generator (IPG). The conductors are typically made of stainless steel or other conducting non-ferromagnetic material. The concepts described herein can be implemented in creating a

high impedance lead system for multi-electrode leads such as those shown in **Figures 2A-2E**.

[0079] In some embodiments, as shown in **Figures 3A**, two (straight/linear) parallel conductors **8** and **9** are connected to each other at intermediate locations by capacitors **10** along the length of the lead system to form high impedance sections. The capacitors **10** can be semiconductor-based discrete products or can be otherwise provided, such as using coatings of metal oxides, *e.g.* tantalum oxide, and the like at discrete certain locations so as to connect the two conductors **8, 9** at desired locations.

[0080] **Figure 3B,** similar to **Figure 3A,** illustrates two parallel conductors but as wound conductors **1, 2** with spaced capacitors **3** in communication therewith and two respective electrodes $\mathbf{100_1}$, $\mathbf{100_2}$.

[0081] In embodiments that employ more than two conductors **20c**, more than one high impedance circuit can be formed with different conductor pairs. For example, as shown in **Figure 4**, where there are three electrodes $\mathbf{100_1}$, $\mathbf{100_2}$, $\mathbf{100_3}$ and three conductors **20c**, labeled as elements, **8, 9,** and **12,** respective capacitors **10** can be disposed between conductor pairs (**8, 12** or **12, 9**, as shown). Also, one conductor **20c** may be used in combination with two conductors to form two separate high impedance circuits.

[0082] In some embodiments, the lead systems **20** can conduct DC or a low frequency AC (KHz), typical of stimulation current. The conductors **20c** may be made of any suitable (MRI compatible and/or non-ferromagnetic) conducting material and/or metal, *e.g.*, Nitinol, Cobalt-Chromium alloy, MP35N alloy, gold, silver, platinum, platinum-iridium alloy, stainless steel, copper and other non-ferromagnetic materials, which will not cause a susceptibility artifact in MRI or magnetically react to the magnetic field in an MRI scanner environment. DC conductivity is a bulk phenomenon and RF conductivity is a skin depth phenomenon. The RF conductivity of the lead system may be reduced by using composite wire (a conductor or wire formed of a combination of different conductive materials) such as by using a resistive metal such as tungsten, MP35N or Nitinol wire on the outside and with a conductive core formed of gold, silver or copper or other metals. This may reduce RF transmission along the length of the lead system, thus reducing the amount of RF that may be deposited in the tissue. Further,

these leads made of composite wires (with a resistive outer layer and conductive core) can have an insulator coating on the outer surface and may be connected by capacitors to form high impedance RF circuits along the length of the lead system as described above with respect to **Figures 1-4**.

[0083] **Figures 5A** and **5B** illustrate lead systems formed with high impedance segments of two or more insulated conductors **20c** with any single conductor and/or a composite conductor structure having a polymeric layer **13** over them. As shown, the leads may be further shielded by a polymeric dielectric material with metal or conductive particulates **13c** (**Figure 5A**) dispersed therein to shield/deflect external RF. In some embodiments, the polymeric dielectric or insulation **13c** over the conductors **20c** may be filled/dispersed or mixed with another high dielectric constant material, *e.g.*, titanium dioxide, etc., to regulate the impedance between (two or more) conductors.

[0084] Also, or alternatively, conductive shielding **325** as a continuous or discontinuous conductor layer (braided, coated, etc) may be applied over the conductors **20c** of the lead system as shown in **Figure 5B**. An insulating polymeric material **13** may reside between the conductors $\mathbf{20c_1}$, $\mathbf{20c_2}$ and the shield **325**. A polymer outer layer **21** may encase the lead system **20**.

[0085] In some embodiments, as shown in **Figure 14**, RF chokes **64rf**, as described in PCT Application Serial No., PCT/US2005/028116, filed August 9, 2005, entitled, *Implantable MRI Compatible Stimulation Leads and Antennas and Related Systems and Methods*, may be incorporated over these high impedance segments or leads to further prevent formation of standing RF waves.

[0086] In some embodiments, as shown in **Figure 6**, an IPG **102** can have a lead system **20** with multiple conductors **20c** that connect distal electrodes **100**. The IPG may optionally include a decoupling circuit **200** which can be incorporated in an implanted housing of the IPG **102** and/or in a connector or portion of the IPG lead assembly (a connector or end portion of the lead assembly rather than the housing itself). The IPG **102** can include a power source **102b**, such as a battery. The circuit **200** can be in communication with a digital controller **121** that can programmatically activate the circuit **200** (and/or deactivate the circuit **200**). The lead system **20** may optionally be arranged as an antenna described earlier with two or more capacitor sets per antenna.

[0087] Implantable IPGs can be used with other lead system configurations (*see, e.g.*, **Figures 15-22**). The lead system can be transformed to a high impedance lead (and/or antenna) by activating the decoupling circuit **200** to a short circuit, before an MRI scan or exposure to external RF. This activation can create a high impedance circuit with the capacitors and inductor assembly in the lead body making the lead electrically invisible to the external RF thus reducing coupling with the RF. The decoupling may comprise a single or multiple circuits tuned to different frequencies and can be programmed to be activated accordingly. The activation and/or adjustment to different RF frequency and/or deactivation can be carried out by a wireless command sent to the IPG. The activation may be carried out internally (automatically) in response to detection of an RF signal.

[0088] Some lead systems **20** of the instant invention can be configured so that one or more conductors behave as inductors or comprise inductive components. The inductors can be provided by coiled conductor (wire) segments, flexible dielectric substrates, or other inductor configurations. In some embodiments, at high frequency, capacitors can act as shorts and may not, by themselves, give sufficiently high impedance. Thus, the lead systems **20** can include inductors that cooperate with the capacitors. The leads or conductors of the systems can have high impedance at high frequency and low impedance at low frequency by configuring the conductors (wires/leads) to behave as inductors.

[0089] In some embodiments, at least one conductor **20c** of the lead system **20** comprises a wound coil segment of the at least one conductor to define a coil inductor. In particular embodiments, the coil inductor may be wound to encase other another conductor(s) of the lead system. The coil inductor can be formed as substantially an entire length of a first conductor or as a smaller portion of the conductor. The capacitors can connect sections of the coil inductor and a second conductor.

[0090] **Figures 7** and **8** are graphs of data associated with a 12 cm long coiled inductor pair open at both ends when loaded in saline. The conductors are 32 AWG magnet wire closely wound on a 0.020 inch mandrel. The graph shows an X-axis frequency sweep from 1.0 to 150 MHz. The two-conductor assembly tunes at different frequencies to different extents as represented by the arrows in **Figure 8**.

[0091] **Figures 9** and **10** illustrate the same parallel inductors as described above (**Figures 7** and **8**) with 0.5 pF capacitors placed at about 2.5 cm apart at 5 locations. The return loss is flatter and higher than -8 db for all frequencies. It is contemplated that this loss can be further reduced (closer to zero) in an optimized design.

[0092] **Figure 11** is a schematic diagram of the parallel inductors with the inductor coil **1** being the wider outside strip and the inductor coil **2** being the inner strip (slightly thinner). The 0.5 pF inductors (**3, 4**) are shown positioned between the two inductors **1, 2** to create a high impedance system at the frequency range or ranges of interest.

[0093] **Figure 12** is a graph of a sample return loss of an open circuit for a frequency range of between about 1-150MHz.

[0094] **Figure 13A** illustrates another embodiment of an MRI/RF safe lead system with an IPG connector **22** and IPG electrical connections **23**. As shown, the lead system **20** includes a plurality of electrodes **100**, respective conductors/wires **20c**, a primary shielding **33,** a segmented secondary shielding **34**, segments /inductors **35**, and a segmented tertiary shield **36.** The segments/inductors **5** connect the secondary **34** and tertiary shield **36** to the primary shield **33**. The lead system **20** and/or the conductors **20c** of the lead system are shielded by one or more layers of shield arrangements as shown in **Figure 13A**. This creates a high impedance surface and inhibits RF coupling of the lead system and any formation and/or transmission of a standing wave. This may be defined as a "3-D RF band gap structure" **39** which is an RF open circuit, while being a DC (and/or potentially a low frequency AC) short circuit. This structure can include a thin, typically two-dimensional, pattern of capacitive and inductive elements, which act as miniature parallel resonant circuits which block RF propagation.

[0095] In some embodiments, the conductors **20c** can be coiled individually or co-wound, or combinations of each. At one end portion, typically a proximal end portion of the segment, the conductors **20c** can be selectively connected to the high impedance shield directly or indirectly in a capacitor which act as an RF open and low frequency (DC) open circuit.

[0096] **Figure 13B** illustrates an exemplary axial sectional view of the device shown in **Figure 13A**. **Figure 13C** is a cross-sectional view. As shown, a polymer

dielectric insulating overcoating **21** can be applied to the lead system **20**. As also shown, dielectric/insulation layers **46, 48, 40** may be disposed intermediate the shielding layers **33** (primary shield), **34** (segmented secondary shield), and **36** (segmented tertiary shield). The conductors **20c** extend to connector **22** and electrical connections **23** to the IPG or other stimulation, ablation or recording device. Capacitors **24** (**Figure 13A**) are not required according to some embodiments of the present invention, as the segmented shielding configurations and inductor lead configuration may provide suitable impedance at high frequency.

[0097] **Figure 14** illustrates an electrode arrangement with RF chokes **64rf** that can be used with high impedance circuits/segments and configurations described and/or shown herein. Each electrode **100** is typically in communication with at least one of the insulated conductors **20c**. At the proximal end of the lead support body **20**, the conductors **20c** are connected to a connector **22** with electrical connections **23** so as to be connected to the implantable signal generator **102** or to an external circuit, such as an interface circuit **40** during MRI guided lead/cable placement. The lead support body **20** need not be able to provide MRI signals (*i.e.*, it can optionally be configured with an MRI receive antenna). These insulated conductors **20c** are typically covered with a polymeric insulator sleeve **61** and a conducting material is cylindrically layered to form the first shielding layer **62** over the insulator. This shielding **62** may be terminated proximal to the electrodes **100** and, in this embodiment, may not be in electrical contact with the conductors and/or the electrodes. A second insulator/polymeric/dielectric layer **63** further insulates this shielding **62** to form multi-core coaxial type cable system, with an impedance that is typically between about 10-100 ohms. The RF chokes **64rf** can be integrated or built into the shielding **64** in the form of a second shielding, which is not continuous and has multiple sections each $\lambda/4$ or less in length. As shown in **Figure 14**, at the proximal end, each section or segment **64s** is connected to the primary shielding **62**, and the distal end may not be electrically connected to the primary shielding **62**, or is connected with a capacitance **164** in between the primary and secondary shielding **62, 64**, respectively. A top insulator/polymeric layer **65** can be used to insulate the body **20b**, except for the electrodes **25**.

[0098] As shown by the axial arrow in **Figure 14**, the MRI active portion of the antenna **35** may extend between a location where the primary shield **62** terminates and the first electrode $\mathbf{25_1}$. However, other antenna **35** configurations may also be used. As shown, the second shield layer **64** comprises a plurality of axially spaced apart RF chokes **64rf**. The term "RF chokes" refers to a shielding layer configuration that provides an electrical length of less than or equal to $\lambda/4$ (from the perspective of external electromagnetic waves) to inhibit the formation and/or propagation of RF induced current or standing waves in an AC (alternating current, *e*.g., diathermy applications) or RF exposure environment. The physical length that provides the electrical wavelength may vary depending on the materials used in fabricating the catheter or lead system support body (such as dielectric constant) and the magnetic field in which it is used. In some embodiments, the lead system **20** has a physical length that is greater than 10 cm, typically between about 20 cm to about 150 cm. In some embodiments, the implantable lead segment **50** can also include RF chokes **64rf** formed along target regions or along substantially the entire implantable length. In the embodiment shown in **Figure 14**, the RF chokes **64rf** comprise a plurality of disconnects of the shield **64** and/or discrete electrically isolated second shield segments. In other embodiments, the RF chokes **64rf** can include a series of axially spaced apart Balun circuits or other suitable circuit configurations. *See, e.g.*, U.S. Patent No. 6,284,971, for additional description of RF inhibiting coaxial cable that can inhibit RF induced current.

[0099] As shown in **Figure 14**, the second shield layer **64** may be coupled to the first shielding layer **62** at opposing ends of the segments **64s**. As shown, one end (typically the proximal end portion) of the disconnected segment **64s** is directly coupled to the shielding layer **62** and the other end (typically the distal end portion) is capacitively coupled to the first shielding layer **62.** Each segment **64s** may be configured to engage the first shield layer **62** in the same manner or in an opposing different electrical manner (not shown).

[0100] **Figures 15A-15B** illustrate lead systems **20** with at least one high impedance segment **300** with associated axially spaced apart proximal and distal portions, **300p, 300d**, respectively. The high impedance segment **300** can be described as an RF

trap that includes a conductor **20c** being coiled to define an inductor **310** within a conductive shield **325** and with an insulator/dielectric material **330** between the inductor **310** and shield **325**. The conductor **20c** can be in electrical communication with the conductive shield **325** at one end (shown in **Figure 15A** as the proximal end portion **300p**) of the high impedance segment **300**.

[0101] The implantable lead system can include multiple high impedance sections or segments **300** along the length of the lead. The high impedance sections or segments are created by arranging the components of the medical device, *i.e.*, the conductor, etc. as an RF trap. These high impedance RF traps inhibit the flow of induced RF current (at the frequency to which the RF trap is tuned) and prevent it from heating tissue adjacent to the electrodes, thus minimizing or preventing RF induced tissue damage. Since the physiological and stimulation signals are at low frequencies (KHz range), the RF trap allows the lower frequency signal(s) to go through, trapping only the higher frequencies of interest to which the traps are tuned.

[0102] As shown in **Figure 15A**, the conductor **20c** can be in electrical communication with the shield at the distal portion of the high impedance segment **300** via a tuning capacitor **340**. The high impedance segment **300** (*e.g.*, RF trap) can be tuned to a MRI frequency. The segment **300** can also be configured so that the conductor **20c** at the proximal end portion of the segment **300p** is connected to the shield **325** via a capacitor **360**. Different high impedance segments **300** may be tuned to different MRI frequencies (*i.e.*, 64 MHz and 128 MHz or other standard operating frequencies of commercial MRI scanners). The impedance of the segment **300** can be at least 400 Ohms, typically greater than about 450 Ohms. The at least one high impedance segment **300** can be placed at between about 0.1-12 cm from the electrode(s) **100**. The lead **20c** can be configured with a straight segment **311** that merges into the coiled segment **310**.

[0103] In operation, the RF trap **300** with the shield **325**, inductor **310** and tuning capacitor **340** form a high impedance parallel resonant circuit at the desired frequency to block RF currents along the conductor. The tuning capacitor can include one or more of a discrete capacitor **340** (**Figure 15A**) and/or stray capacitance **350** (**Figure 15B**) between the inductor **310** and the shield **325**.

[0104] **Figure 15B** illustrates that the high impedance segment **300** may

include stray capacitance **350** that resides between the conductive shield **325** and the inductor **310** through the insulator/dielectric **330**. The stray capacitance **350** and/or the discrete capacitor **340** can be used to tune the RF trap to a high-impedance at a desired frequency (range), typically between 1MHz to 250MHz. Another capacitor **360** may also be used at the opposing end of the segment **300** to form an RF short (not shown). The high impedance segment **300** can be tuned to achieve high impedance at desired frequencies by varying the length of the trap structure, thereby increasing or decreasing the total capacitance and inductance until the resonant condition is met at the desired frequency. Different segments **300** along a lead length **20** can be tuned to a different (typically MHz) frequency.

[0105] As shown in **Figure 16**, a conductive lead **20c** can include a plurality of high impedance segments **300** that can be positioned along the length of the lead system **20** at regular or irregular intervals, but typically so that the spacing provides an electrical length of less than about $\lambda/4$ therebetween. The RF traps **300** are placed less $\lambda/4$ apart, where λ is the wavelength in the medium of the operating frequency, to electrically break the long conductor into multiple sections.

[0106] **Figure 17** illustrates that a plurality of conductors **$20c_1$, $20c_2$, $20c_3$** can be co-wound (see element **310c**) and reside within a common flexible shield **325.** Each conductor **$20c_1$, $20c_2$, $20c_3$** can be electrically connected to the shield **325** at a proximal portion thereof, directly or indirectly, such as using a respective capacitor **360** as shown. The capacitor **360** can provide an RF short. The high impedance segments **300** (RF traps) are placed less than a $\lambda/4$ apart from each other at the desired frequency.

[0107] When multiple high impedance segments **300** (using, for example RF traps) are incorporated over the length of a device such that the distance between two adjacent traps is less than one-quarter wavelength, this effectively breaks the long conductor into multiple sections, each shorter than a quarter wavelength. The RF current induced on a conductor is a function of length of the conductor at the RF frequency, and when the conductor is shorter than a quarter wavelength, the RF current induced is not large enough and may not cause undue RF deposition RF induced-treating of the tissue.

[0108] For a bare copper wire $\lambda/4$ in a physiological medium, the length has been measured at about ~ 8 cm at 64 MHz (1.5T) and 4 cm at 128 MHz (3T). For

implantable leads where the conductors are insulated with a polymeric layer of about or > 0.001 inches thick, and have an electrode exposed to tissue, the temperature change in the tissue adjacent to the electrode due to RF deposition is measured to be less than 1°C at length less than 15 cm at 1.5T (64 MHz frequency). When a high impedance segment or section **300** (using one or more RF traps) is incorporated in the length of the conductor **20c**, the section **300** can be positioned such that the distal end of the trap **300d** is less than 15 cm from one or more of the electrodes **100** and the impedance can be greater than about 450 Ohms at a target MRI frequency, in order to reduce RF deposition induced heating at the electrodes (less than 1°C). Thus, in some embodiments, multiple segments **300** with impedance of about or greater than 450 Ohms (at 64 MHz) are placed at distances less than 15 cm apart on a long conductor, which can make the conductor **20c** safe to use in MRI at 1.5T. Similarly if these segments **300** have an impedance of about or greater than 450 Ohms at 128 MHz and are placed <10 cm apart (Length ~ $\lambda/4$ at 128 MHz, or 3T MRI frequency), it can effectively reduce the extent of heating at the electrode in a 3T MRI environment.

[0109] Different designs of high impedance segments **300** along the length of the leads for multi-conductor lead systems with electrodes are described herein. Such high impedance segments **300** can be placed along the length (less than $\lambda/4$ length apart from each other) of the lead **20** to reduce RF deposition at the electrodes **100** and inhibit undue tissue damage.

[0110] **Figures 18A-18C** illustrate a high impedance segment **300** with four co-wound conductors/filars **$20c_1$-$20c_4$** and a shield **325** placed over the co-wound conductors **310c** which is connected to the conductors **$20c_1$-$20c_4$** at the proximal end of the trap **300p** via respective capacitors **360**. The capacitor **360** can have a relatively large capacitance sufficient to act as an RF short and a DC and low frequency (Hz, kHz) open circuit. The connection **370** can be via a metallic trace, small wire or other connection from a linear segment **311** of the conductor **20c** to the shield **325** as the conductor **20c** merges into a coiled segment **310**. A polymeric outer layer **21** can be provided over the shield **325**. The lead system **20** can be a flexible lead system and the dielectric material **330** can be provided as a flexible material.

[0111] As shown in **Figures 18A** and **18B**, for a lead **20** comprising one or

more insulated filars/conductors **20c**, the filars/conductors **20c** can have a straight section **311** followed by a coiled section **310** that forms the inductor. The coiled section **310** may be co-wound with another filar/conductor. A dielectric/insulator **330** can be placed on the coiled section **310** and a shield **325** can be placed on the co-wound conductors separated by the dielectric **330** between them. As shown, at the proximal end portion of the coil **310**, the shield **325** is connected (via trace or wire **370**) to each conductor **$20c_1$-$20c_4$** by a capacitor **360** which acts as an RF short at high frequencies and a DC and low frequency open circuit.

[0112] Although the tuning capacitor **340** is shown in various embodiments at a distal portion of the segment **300d** and the RF short and low frequency open circuit capacitor **360** is shown at the proximal portion **300p**, the reverse orientation may also be used. Also, alternating or different orientations can be used along a length of the lead system **20**.

[0113] The length of the shielded co-wound segment **300** is such that a high impedance (typically greater than about 450 Ohms) is created at the distal end of the segment **300d** between the shield **325** and the conductor(s) **20c** at one or more frequencies. Typically, at least one frequency is an MRI frequency, such as about 64 MHz. This high impedance segment **300** created by shielded coiled conductors/inductors, with the shield **325** electrically connected to the conductors **20c** at the proximal end portion of the segment **300p**, inhibits RF current from flowing along the length of the lead **20**. One or more of such segments **300s**, tuned to one or more RF frequencies, may be incorporated along the length of the lead. The length of each segment **300** may be between about 0.1-200 cm, typically between about 1-200 cm, and more typically between about 6 cm to about 15 cm.

[0114] **Figures 18A, 18B, 19A** and **19B** illustrate a high impedance segment **300** with four conductors **$20c_1$-$20c_4$**. The conductors **$20c_1$-$20c_4$** may comprise filars that have a straight section **311** and a coiled section **310**. The straight section **311** may be between about 0-15 cm long and a respective coiled section may be between about 1-150 cm long. An insulator/dielectric material **330** with dielectric constant >1 separates the conductors **20c** (coiled and straight sections, **310, 311**) and the shield **325** is placed over the insulated conductors **$20c_1$-$20c_4$**. The high impedance section **300** may be between

about 1-150 cm long.

[0115] In the embodiments shown in both **Figures 18A** and **19A**, at the proximal end of the high impedance section **300p**, the shield **325** is connected to the conductors **20c** via capacitors **360**, typically having a value between about 100pF to 10000 μF, using a trace or thin wire **370** to facilitate the connection. This capacitor **360** creates an RF short at high frequencies and a low frequency and DC open circuit and inhibits the stimulation current from getting shorted in the shield **325**. The diameter of the lead system **20** can be between about 0.10-19 mm, typically between about 0.5-6 mm, and can be varying in different sections of the lead. The lead **20** may be substantially flat, elliptical, circular, rectangular, or square in cross-sectional shape.

[0116] **Figures 19A-19C** illustrate a lead system **20** with at least one high impedance segment **300** similar to that shown in **Figures 18A** and **18B,** but with the conductors **20c** connected to the shield **325** via capacitors **340**, **360** at both a distal and proximal end portion **300d, 300p** of the high impedance segment **300**. At one end, for example, the proximal end as shown, the capacitances **360** are large, representing an RF short circuit at high frequency but low frequency open circuit at low frequencies. At the other end, the capacitances **340** are adjusted so that the inductance-shield-capacitance combination forms a high impedance circuit. The inductance and the capacitance are adjusted such that the high impedance segment **300** is tuned to a high impedance at desired frequency or frequencies, where one of these frequencies is an MRI frequency. This design can control the length of the segment **300** (RF trap) to a desired length, such as, for example, less than $\lambda/4$ (< 10 cm at the desired frequency in physiological medium). A high impedance segment **300** is tuned to a desired frequency by adjusting the values of the parallel resonant circuit created by the RF trap capacitors **360** (and **350** shown in **Figure 15B,** where used) and the inductance of the coiled filars **310**. This configuration can adjust the length of the segment **300** (RF trap) and the impedance at a RF frequency of interest. One or more segments **300** tuned to one or more MRI frequencies can be placed along the length of the lead **20**.

[0117] Again, it is noted that in some embodiments, at one end, either the distal or proximal end, the capacitances of the capacitor(s) **360** are sufficiently large to represent an RF short at high frequency but a low frequency open circuit at low

frequency. At the opposing other end, the capacitances **340** are adjusted (tuned) so that the inductance-shield-capacitance combination forms the high impedance.

[0118] **Figures 20A** and **20B** show a high impedance segment **300** with an RF trap with a single one of the four (**20c$_1$-20c$_2$**) conductors **20c** connected to the shield **325** at a proximal portion of the segment **300p**. Multiple segments **300** with RF traps similar to the one shown can be placed along the length of the lead **20** and a single different one or pairs or other combinations of the conductors **20c** can be serially connected to the shield **325** per different RF trap location, so that each conductor **20c** has been connected to the shield **325** at least once before it reaches an electrode **100**.

[0119] The high impedance segment **300,** shown in **Figures 20A-20C**, includes a plurality of co-wound conductors **20c$_1$-20c$_2$**, wherein only one conductor is connected to the shield **325** at a time. The shield **325** is connected to only one conductor per segment **300** (via a capacitor or directly). In a long lead, the series of segments **300** can be incorporated along the length of the lead **20** and each segment **300** can be designed such that the each conductor **20c** is connected to the shield **325** at least once over the length of the lead. In this lead design, the number of segments **300** along the length of the lead **20** can at least equal the number of conductors **20c** in the lead.

[0120] **Figures 21A-21C** illustrate a high impedance segment **300** with an RF trap having conductors **20c** coiled in two different manners: a co-wound segment **375** and a discretely coiled segment **380** (shown as four discrete segments **380$_1$, 380$_2$, 380$_3$, 380$_4$,** one for each conductor **20c$_1$-20c$_4$**) under the same shield **325**. The segment **375** can be described as having a common co-wound configuration at a common axially extending location. However, one or more of the conductors **20c** can be co-wound with one or more other conductors for substantially the entire length of the segment **300** without having an individual or discrete coiled segment **380** in the high impedance segment **300** (*i.e.,* can be co-wound with less than all of the conductors) at a portion of the length of the segment **300**

[0121] The shield **325** can be connected to at least one of the conductors **20c** at the proximal end **300d** directly or indirectly. As shown, a connection **370** connects each conductor **20c$_1$-20c$_4$** via respective capacitors **360** to the shield **325**. Although not shown, one or more of the conductors **20c** may be connected to the shield **325** at a distal

end of the segment **300** via a capacitor **340**.

[0122] The length of the individual coiled inductors may not be the same on all conductors and is a function of location with respect to other inductors in the segment **300** of the RF trap. This arrangement can be used to create a high impedance at the distal end of the RF trap at one or more frequencies (both in MHz) as shown in **Figure 22**. One or both of these frequencies is an MRI frequency.

[0123] The length of each individual coiled section **380** and co-wound section **375** can be 0.1-5.0 cm depending on the diameter of the coiled inductor. The spacing between the individually coiled inductors $\mathbf{380_1}$ - $\mathbf{380_4}$ may be between about 0.1-2 cm. This configuration allows a high impedance segment to generate high impedance at a plurality of MHz frequencies, where at least one frequency is an MRI frequency as shown in **Figure 22**.

[0124] In some embodiments, the conductors or other metallic components of the lead systems **20** may include one or more of: Nitinol, Cobalt- Chromium alloy, MP35N alloy, gold, silver, copper, platinum, platinum-iridium alloy, and other non ferromagnetic materials which will not cause a susceptibility artifact in MRI or magnetically respond to a high field magnet associated with MRI scanners.

[0125] Polymeric components can comprise polyurethane, fluorinated ethylene copolymer (FEP, ETFE), PTFE (Teflon), Nylon, PEBAX, polyethylene, polypropylene, and the like. As discussed above, the polymer may be filled with a metallic powder or other fillers.

[0126] The conductive shield material may be metallic or conductive non-metallic and may be braided, coiled or deposited over the insulation layer **330** over the inductors **325**. The capacitors **340, 360** may comprise semiconductor chip capacitors. Although the exemplary materials are described with respect to embodiments described in **Figures 15-22**, the same materials can be used with respect to other embodiments described herein.

[0127] **Figure 22** is a graph of impedance vs. frequency characteristics for the embodiment of the lead system **20** shown in **Figures 21A** and **21B**. High impedance is observed at two frequencies. The impedance and frequency are a function of individual inductors and spacing between them. It is contemplated that the design can be configured

to generate high impedance at a plurality of frequencies in the MHz range, allowing the lead system or device to be compatible with two or more different field strength MRI scanners (*i.e.*, 1.5T and at least one other higher field system such as a 2.0T, 3.0T or even 9.0T system).

[0128] Embodiments of the invention can be configured to reduce heating at an end of the shield **325** at the distal portion **300d** of the high impedance segment (RF trap) **300**. The impedance of the RF trap is a function of the inductance of the inductor and the capacitance between the shielded inductor. To achieve impedance > 450 Ohms on an inductor of small diameter (typically less than about 1 mm) with more than one conductor **20c** co-wound, the length of the segment **300** (RF trap) may sometimes exceed 15 cm. The lead system **20** can be configured with supplemental high impedance segments **300** similar to those described herein with respect to the conductors, or RF chokes, balun circuits and the like may be incorporated on or in the shield **325**. Alternatively, or additionally, discrete tubular resistors may be incorporated on or into the shield **325** to inhibit RF deposition at the distal ends of the shield. Alternatively or additionally, a thickness of the outer insulator/polymer layer **21** can be increased to reduce the likelihood of undue RF deposition at the distal end of the shield.

[0129] In the drawings and specification, there have been disclosed embodiments of the invention and, although specific terms are employed, they are used in a generic and descriptive sense only and not for purposes of limitation, the scope of the invention being set forth in the following claims. Thus, the foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. In the claims, means-plus-function clauses, where used, are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures. Therefore, it is to be understood that the foregoing is illustrative of the present invention and is not to be construed as limited to the specific embodiments disclosed, and that

modifications to the disclosed embodiments, as well as other embodiments, are intended to be included within the scope of the appended claims. The invention is defined by the following claims, with equivalents of the claims to be included therein.

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CLAIMS:

1. An MRI/RF compatible medical device, comprising:

an implantable elongate lead having at least a first electrode, a second electrode, a first axially extending conductor, and a second axially extending conductor, the first electrode electrically coupled to the first axially extending conductor and the second electrode electrically coupled to the second axially extending conductor, wherein, at each of a plurality of intermediate locations along a length of the elongate lead, at least one of a plurality of spaced apart capacitors is disposed between the first and second axially extending conductors to define a plurality of high impedance circuit segments, each high impedance circuit segment comprising at least a portion of the first axially extending conductor, at least a portion of the second axially extending conductor, and at least one of the plurality of spaced apart capacitors disposed between the portion of the first axially extending conductor and the portion of the second axially extending conductor, whereby the lead has a high impedance at a target range of high radiofrequencies and a low impedance at low frequencies.

2. A device according to claim 1, wherein the high impedance circuit segments are configured to reduce or eliminate electronic coupling of the lead to external RF.

3. A device according to claim 1, wherein the high impedance circuit segments are configured to reduce or eliminate transmission of induced RF along the length of the lead.

4. A device according to claim 2, wherein the lead comprises three axially spaced apart electrodes and a respective first, second and third conductor, and wherein some of the capacitors are arranged to extend between the first and second conductors and others are arranged to extend between the second and third conductors.

5. A device according to claim 4, wherein the capacitors between the first and second conductors are axially offset from the capacitors between the first and third conductors.

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6. A device according to claim 1, wherein at least one of the first and second conductors defines an inductor that is in electrical communication with at least two of the capacitors.

7. A device according to claim 1, wherein the spaced apart capacitors are substantially regularly spaced apart axially.

8. A device according to claim 1, wherein at least some of the spaced apart capacitors are axially spaced apart at irregular intervals from the others over the length of the lead.

9. A device according to claim 1, wherein the components of the lead are formed from non-magnetic materials.

10. A device according to claim 1, wherein the high impedance circuit segments are configured to inhibit RF transmission along the lead during exposure to RF associated with a high-field magnet MRI system.

11. A device according to claim 10, wherein the high impedance circuit segments include at least one inductor distributed along at least a major portion of a length of at least one of the conductors.

12. A device according to claim 11, wherein the at least one inductor comprises a coil inductor defined by a wound coil segment of the at least one conductor.

13. A device according to claim 12, wherein the coil inductor is wound to encase other conductors of the lead.

14. A device according to claim 12, wherein the coil inductor is substantially an entire length of the at least the first conductor, and wherein the spaced capacitors connect segments of the coil and the second conductor.

15. A device according to claim 11, wherein the first and second conductors have a respective length, and wherein portions of the length of the first and second conductors disposed axially between the spaced apart capacitors comprise inductors.

16. A device according to claim 1, further comprising an electrically insulating biocompatible coating disposed over an external surface of the lead.

17. A device according to claim 11, wherein the values of the capacitances and at least one inductance associated with the lead define a high impedance over the RF range of between about 1-150 MHz and a low impedance at frequencies less than about 50 kHz.

18. An MRI compatible device comprising:

an elongate lead having at least a first and a second electrode, each associated with a respective first and second axially extending conductor, wherein a plurality of spaced apart capacitors are disposed between the first and second axially extending conductors along at least major portion of a length of the lead to define a plurality of high impedance circuit segments; and

a high impedance surface band gap structure formed along at least a major length of the lead, wherein the surface band gap structure comprises a primary shield and secondary and tertiary segmented shields which are intermittently connected to the primary shield, whereby the high impedance surface reduces or blocks RF propagation;

wherein the lead has a high impedance at a high range of radiofrequencies and a low impedance at a low range of frequencies.

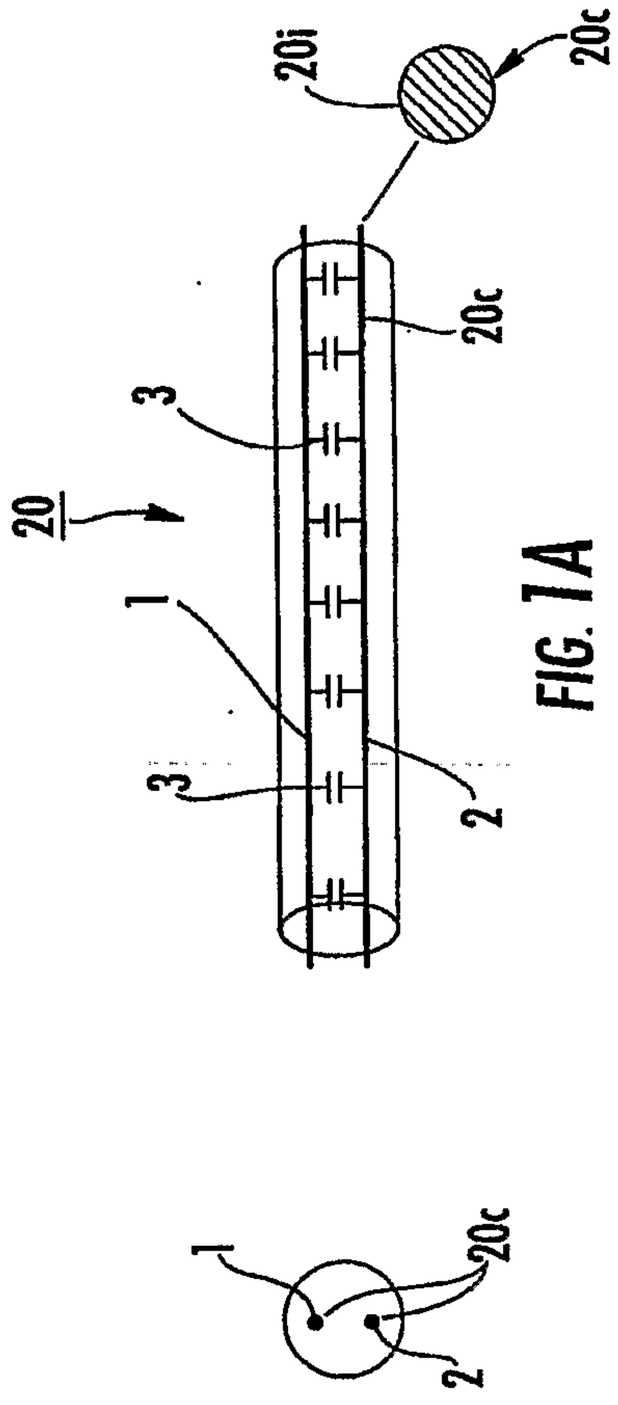


FIG. 1A

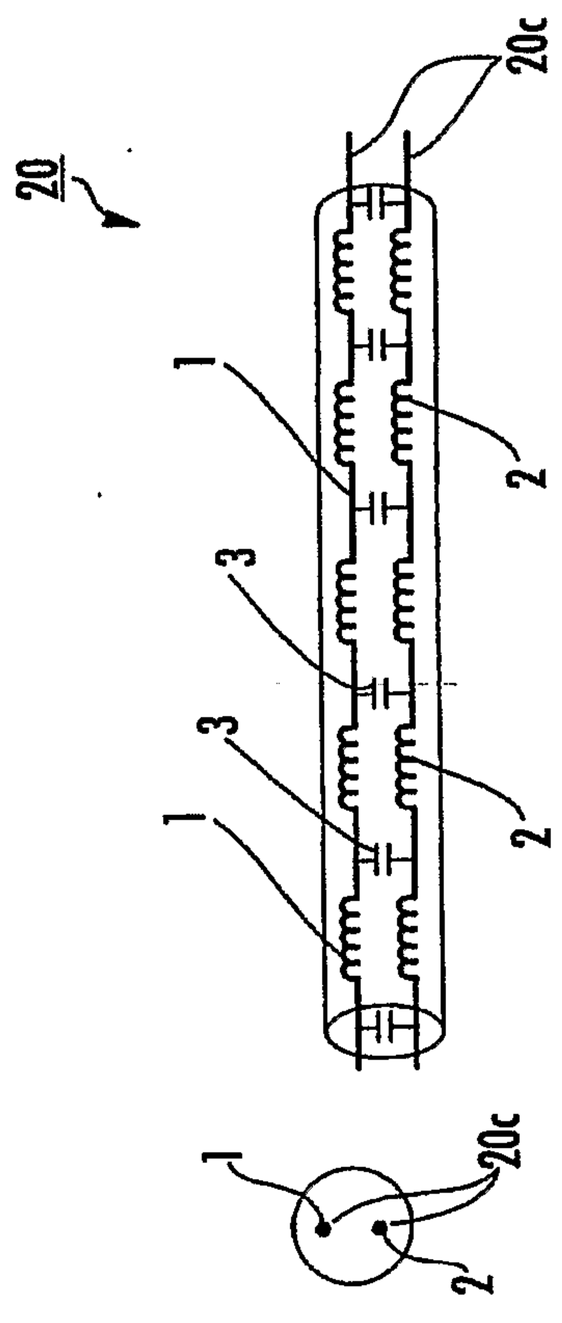


FIG. 1B

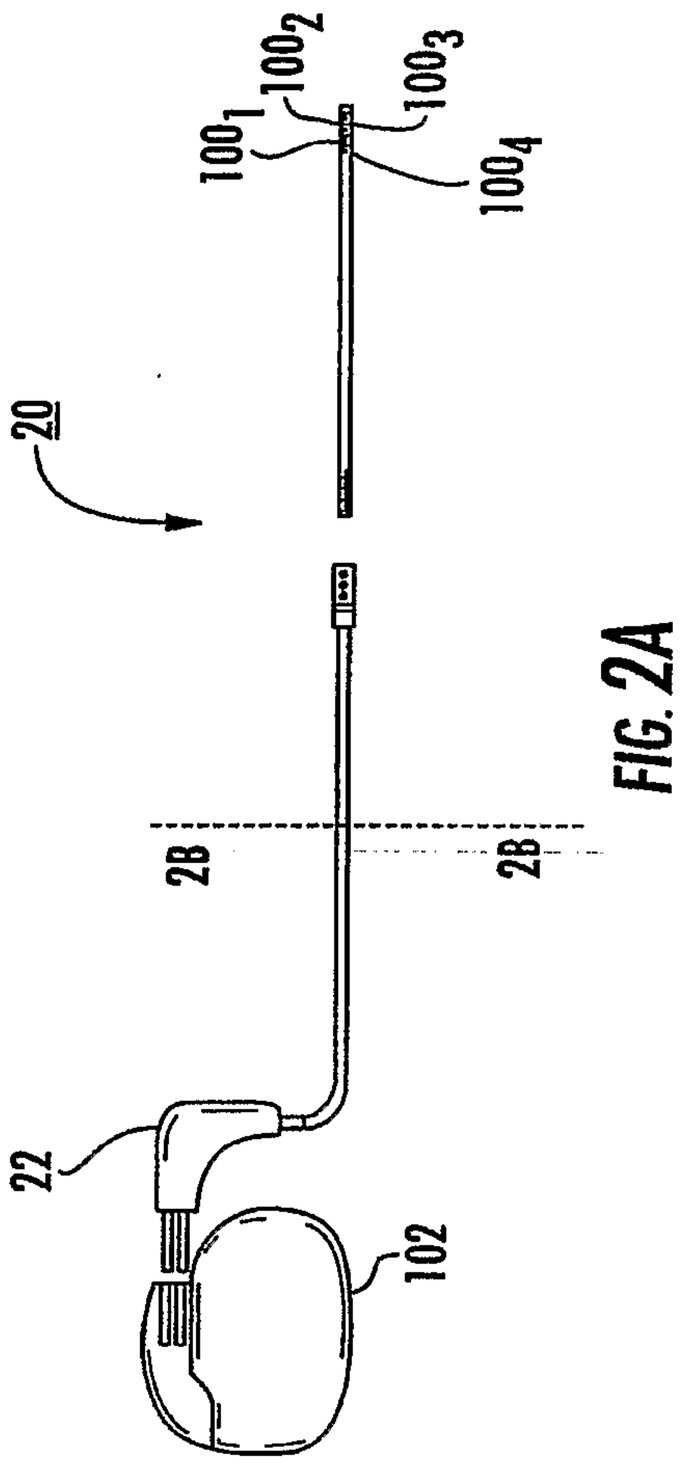


FIG. 2A

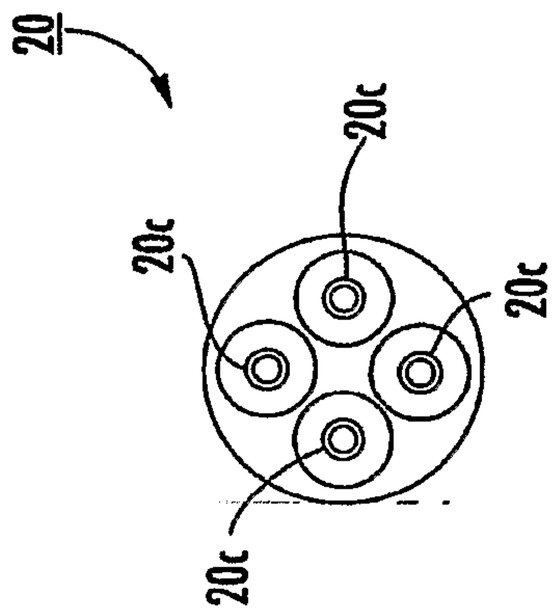


FIG. 2B

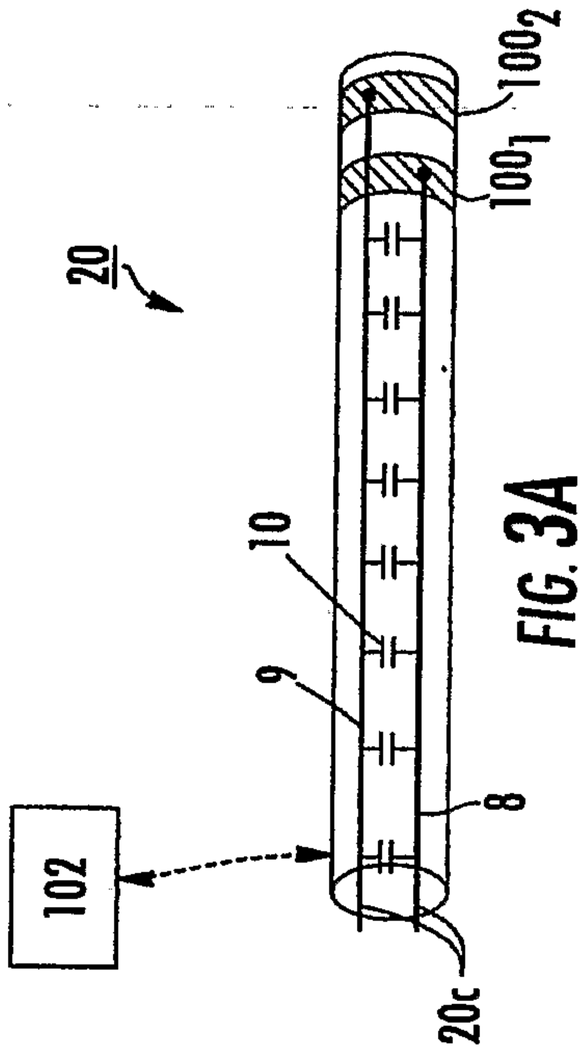


FIG. 3A

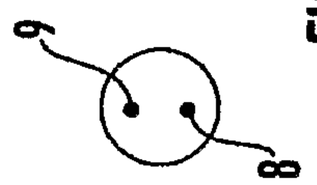


FIG. 3B

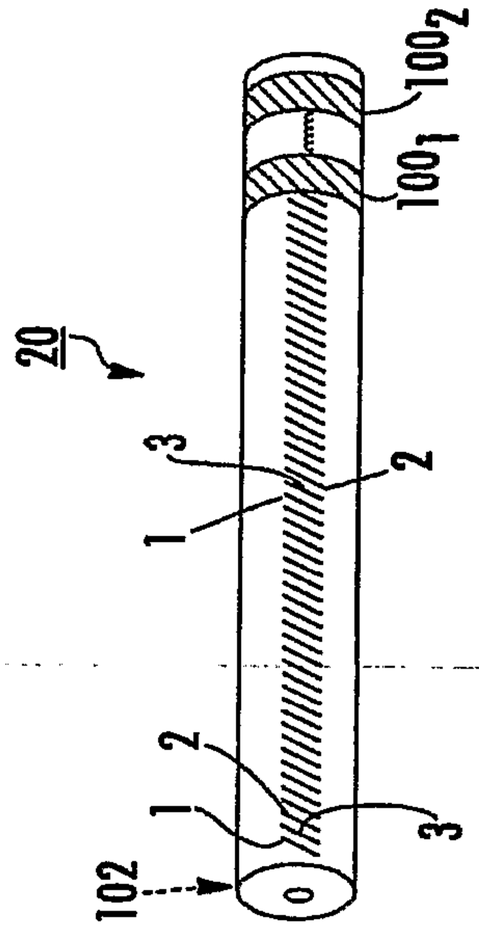


FIG. 3C

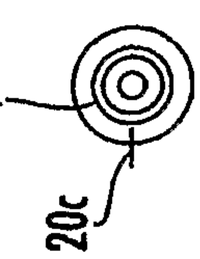


FIG. 3D

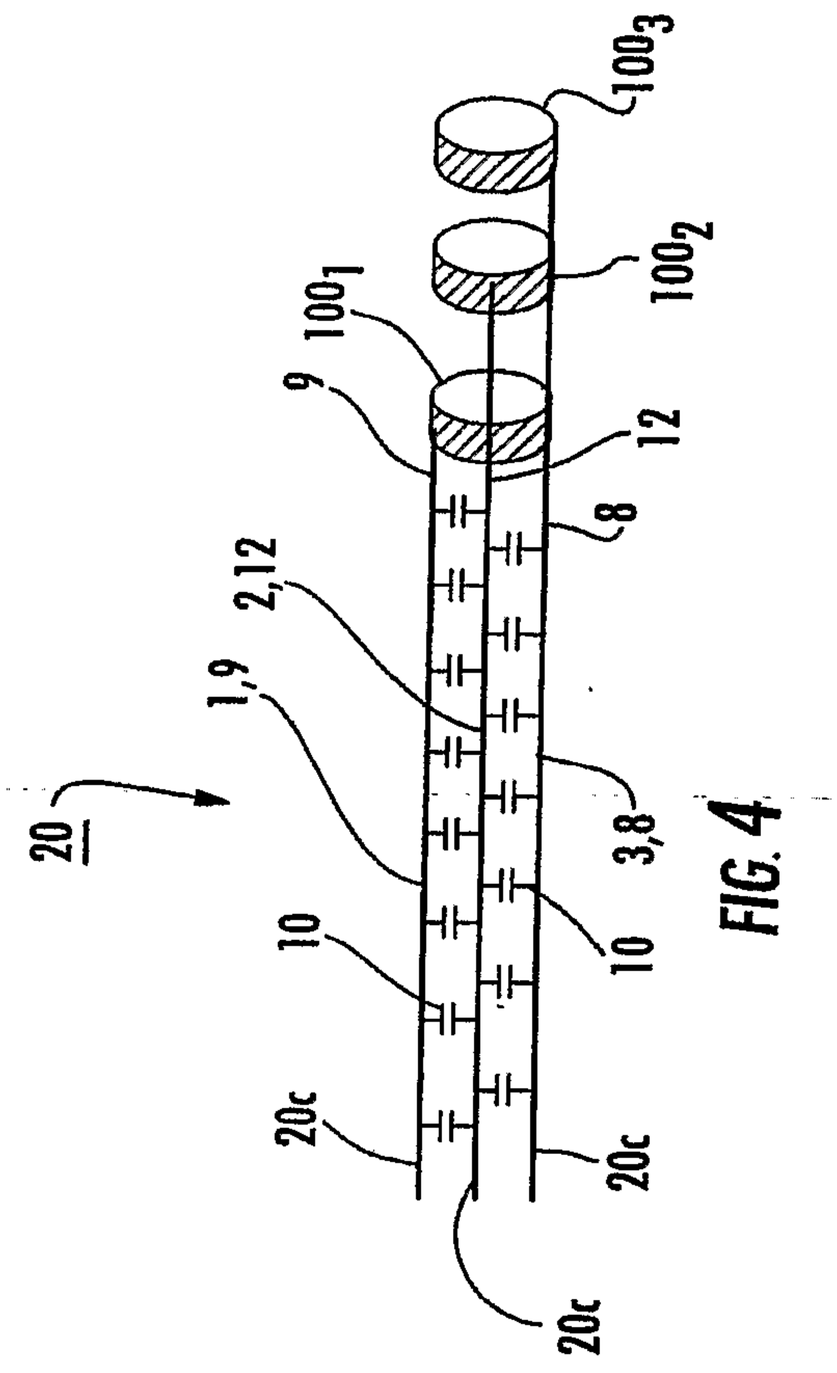


FIG. 4

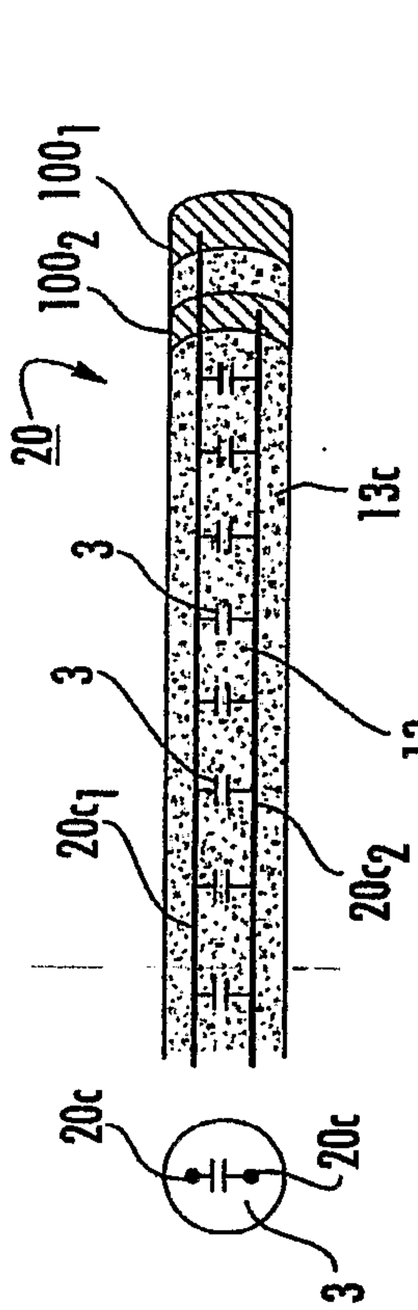

100_1
100_2
20
13c
3
13
$20c_1$
$20c_2$
20c
20c
3

FIG. 5A

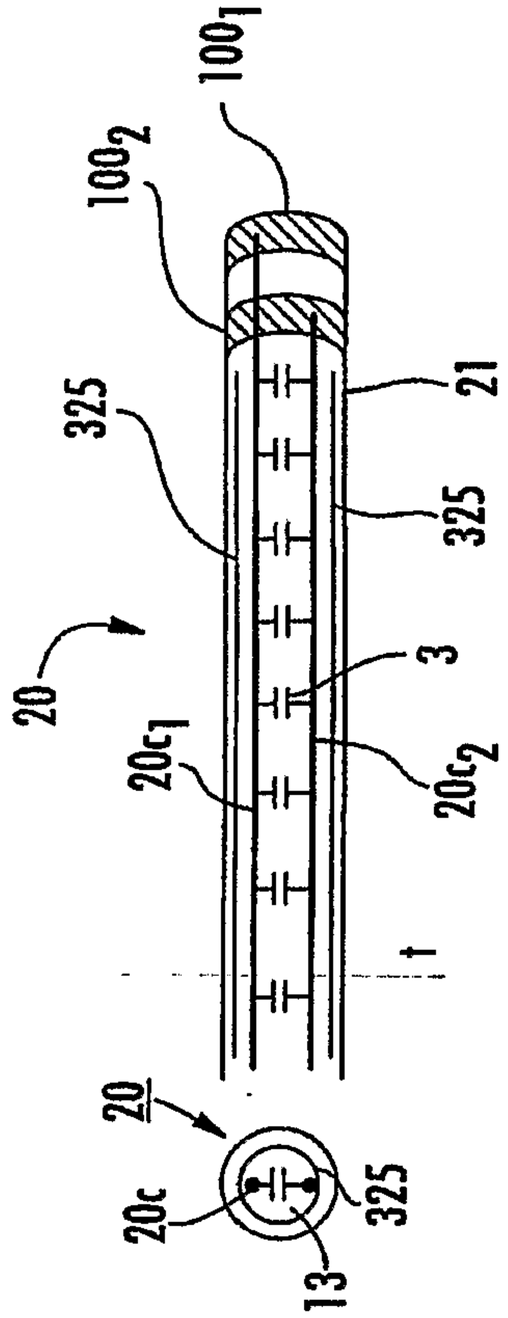

100_1
100_2
325
21
325
20
3
$20c_1$
$20c_2$
t
20
20c
325
13

FIG. 5B

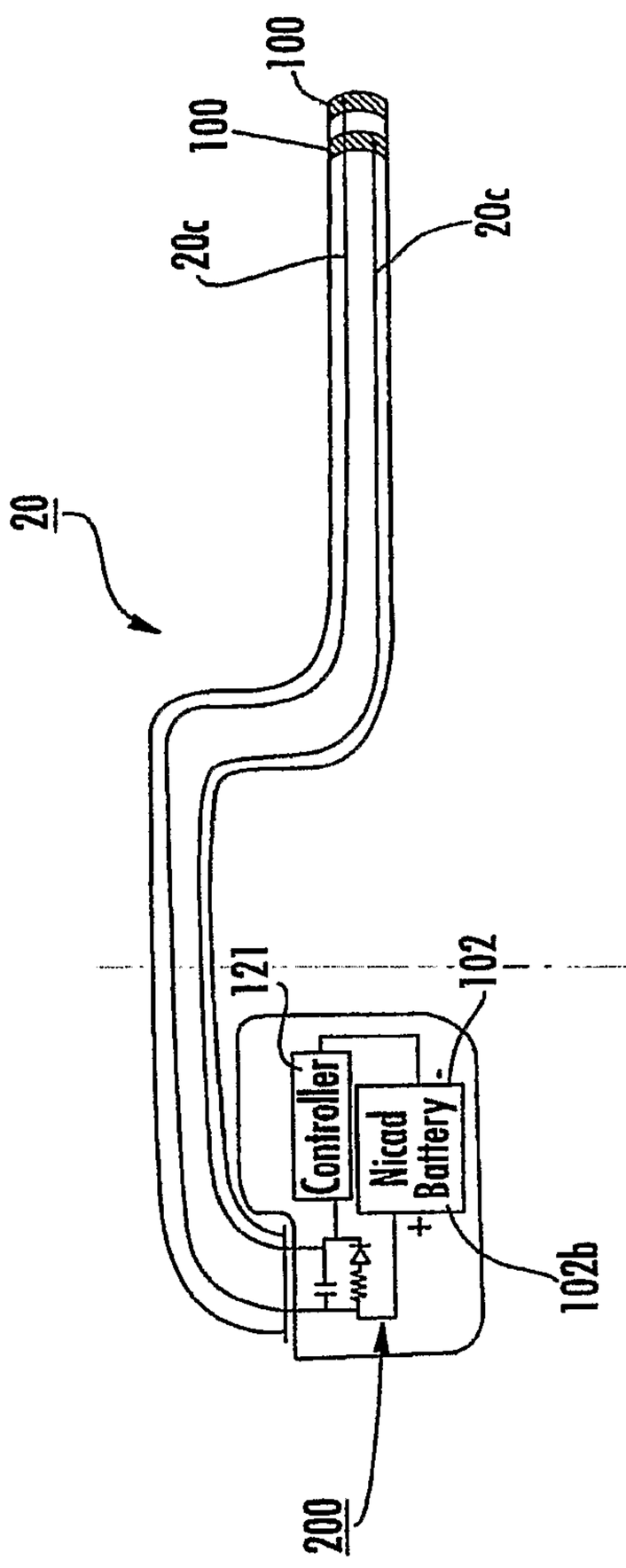


FIG. 6

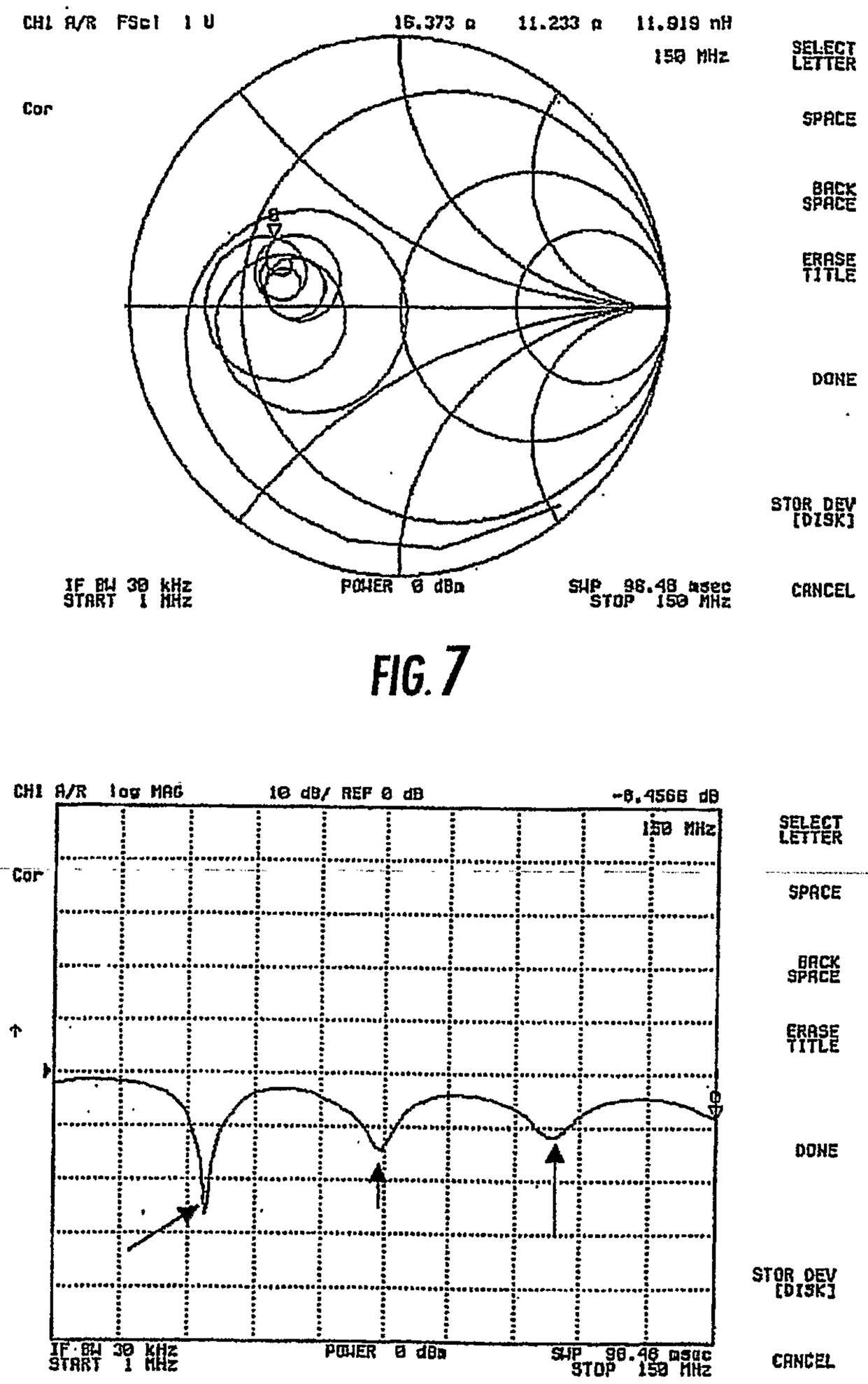


FIG. 7

FIG. 8

Smith Chart and Return Loss for a 12 cm long coiled inductor pair open at both ends when loaded in saline.

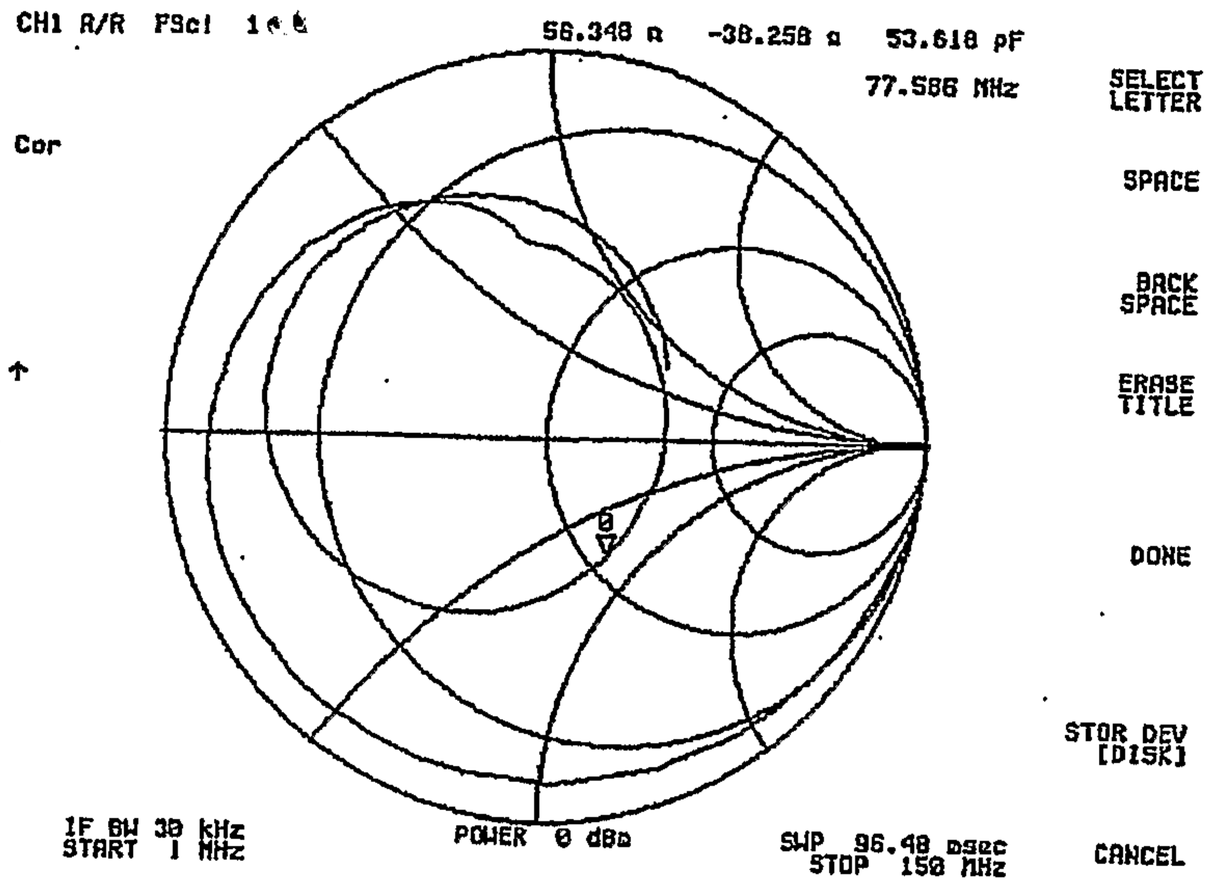
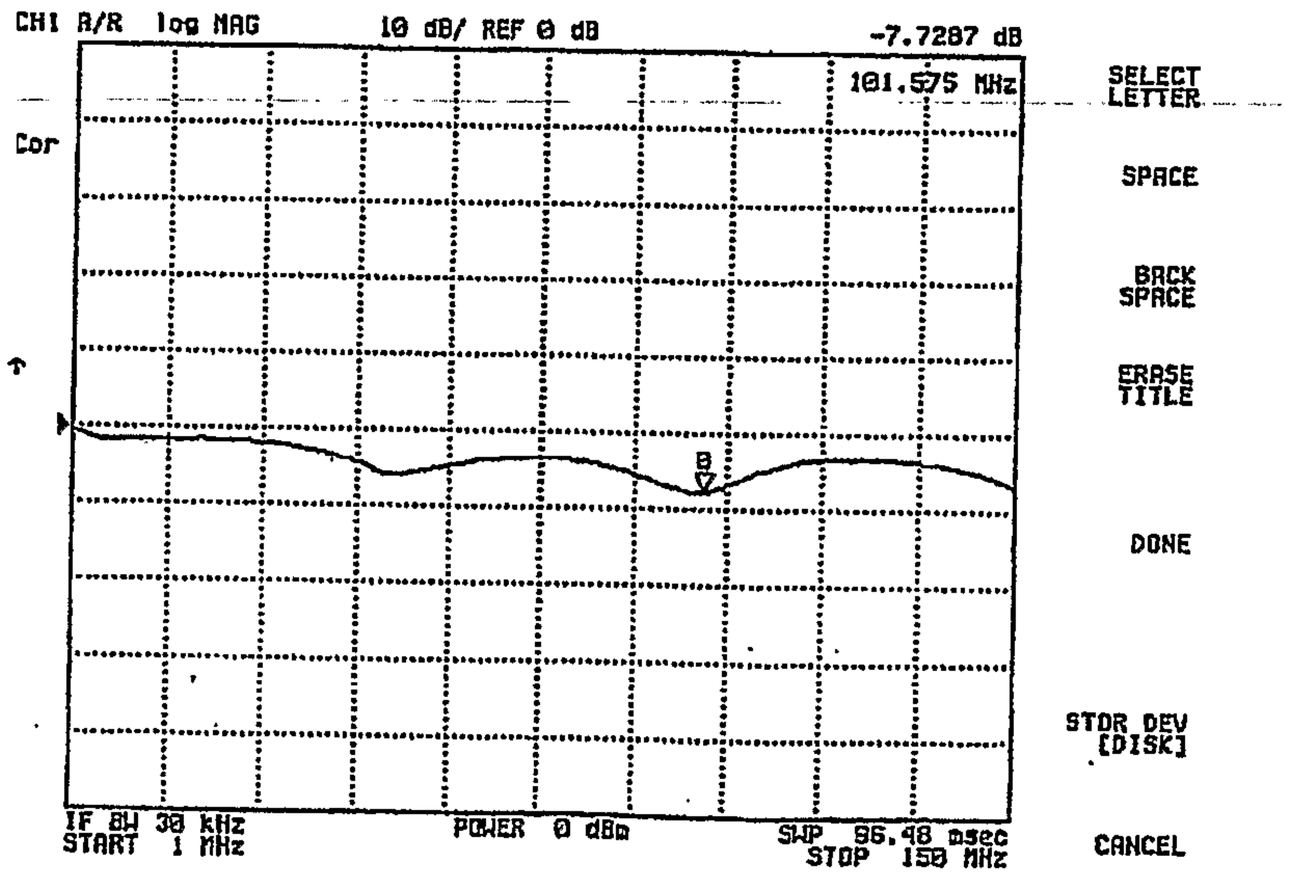


FIG. 9



Same parallel inductors as above with 0.5 pF capacitors places 2.5 cm apart at 5 locations. The return loss is flatter and higher than -8 dB for all frequencies.

FIG. 10

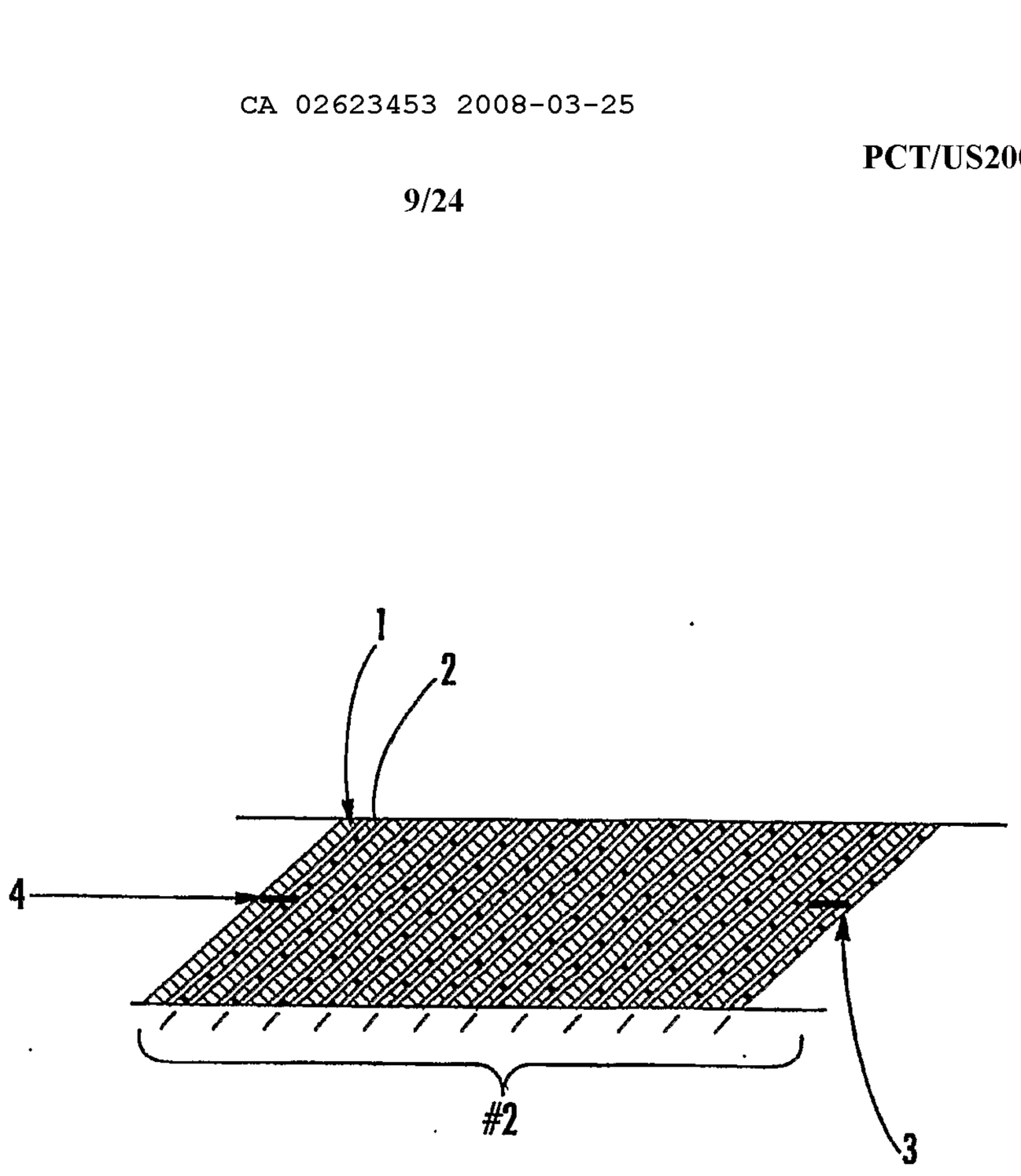
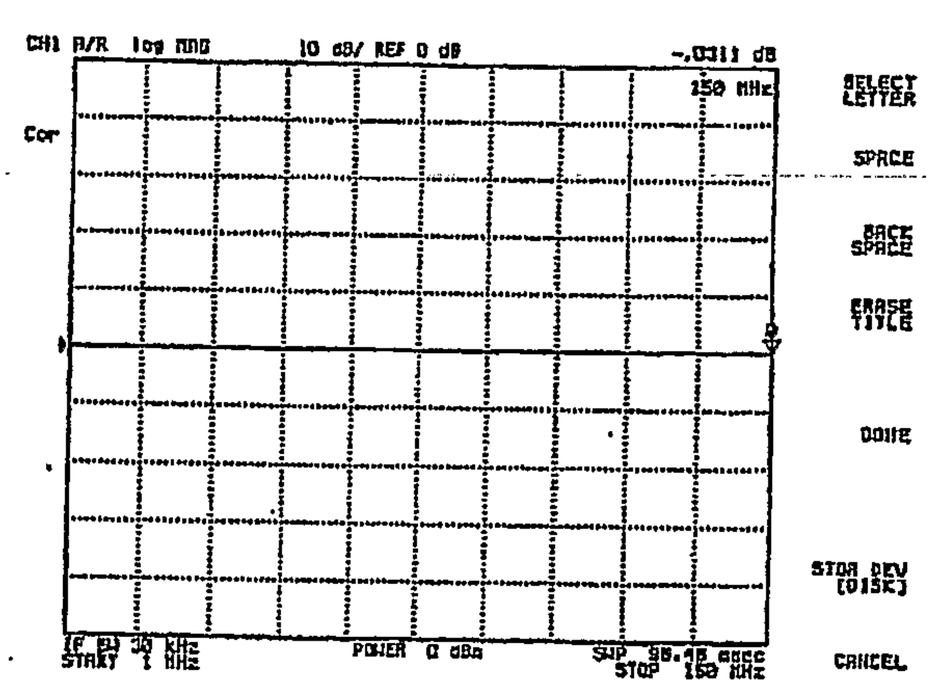


FIG. 11



Sample return loss of an open circuit for a frequency range of 1-150 MHz.

FIG. 12

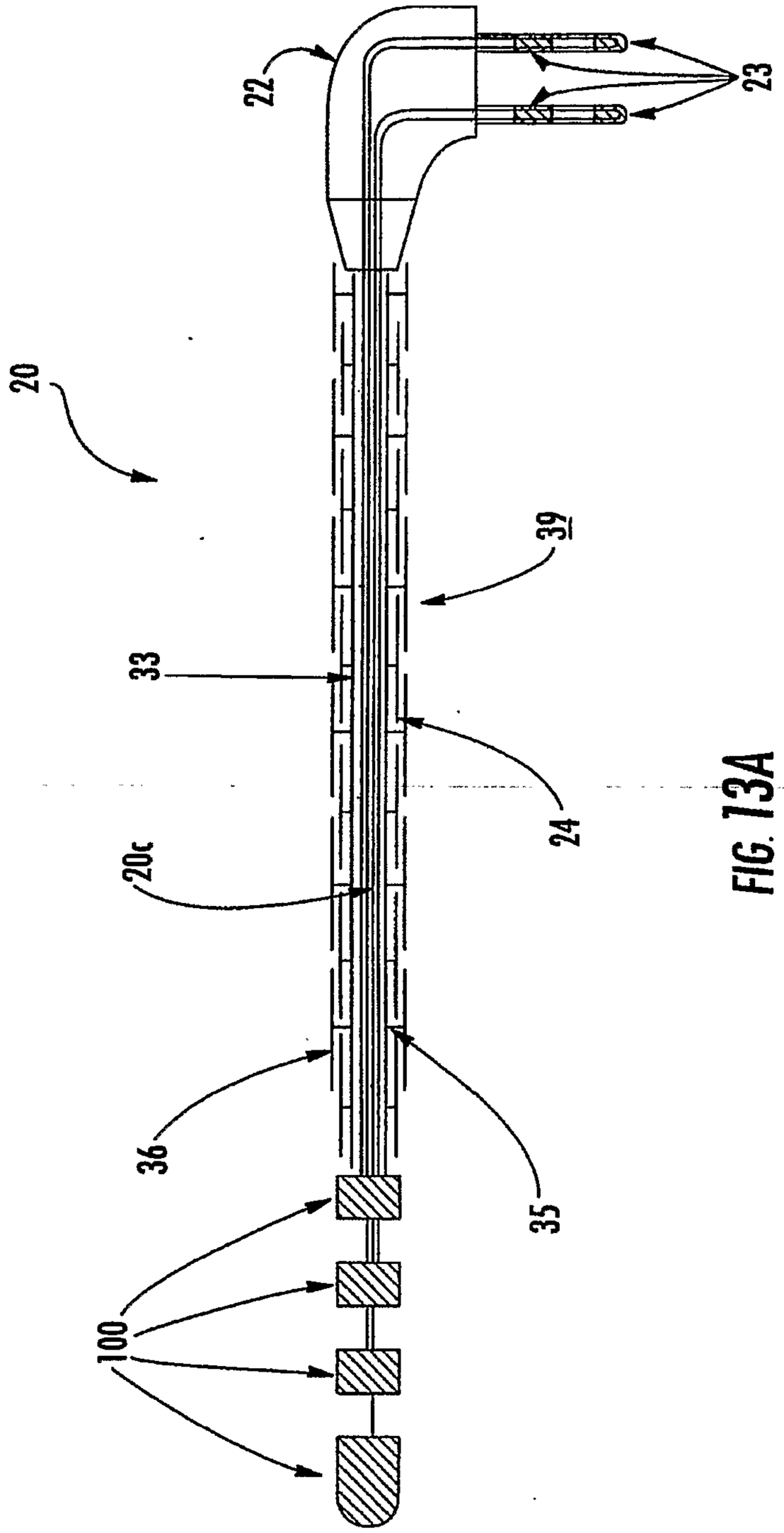


FIG. 13A

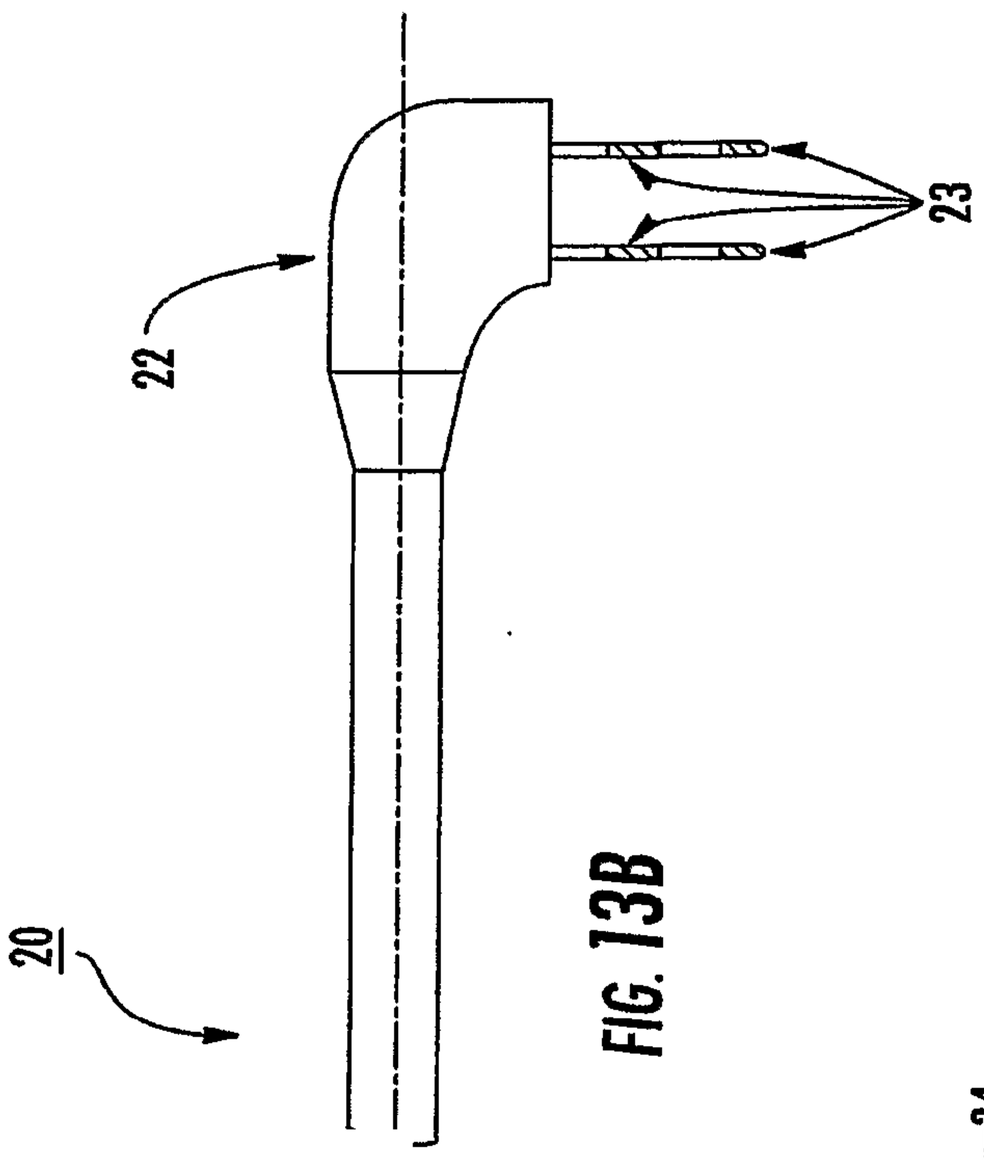


FIG. 13B

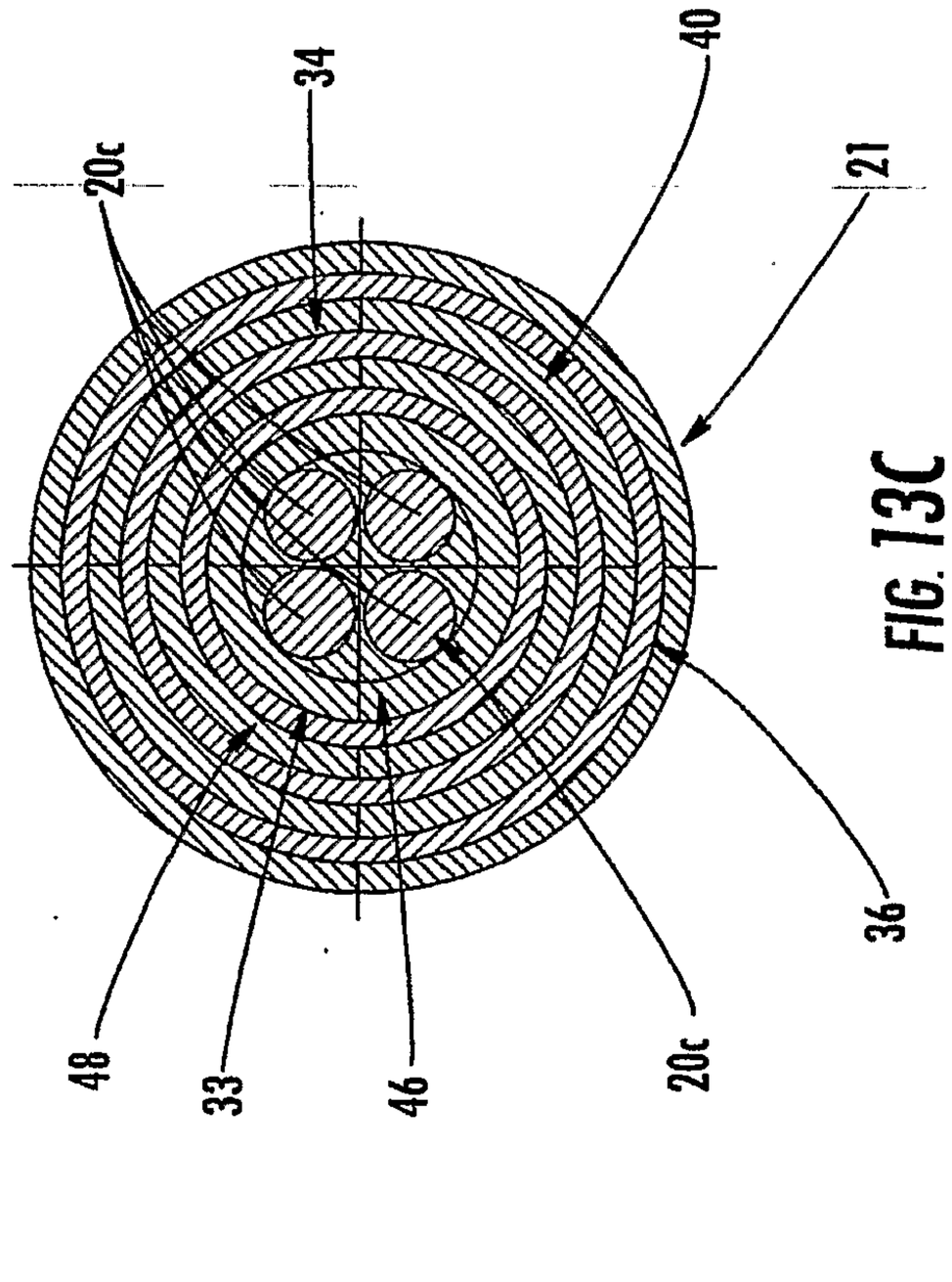


FIG. 13C

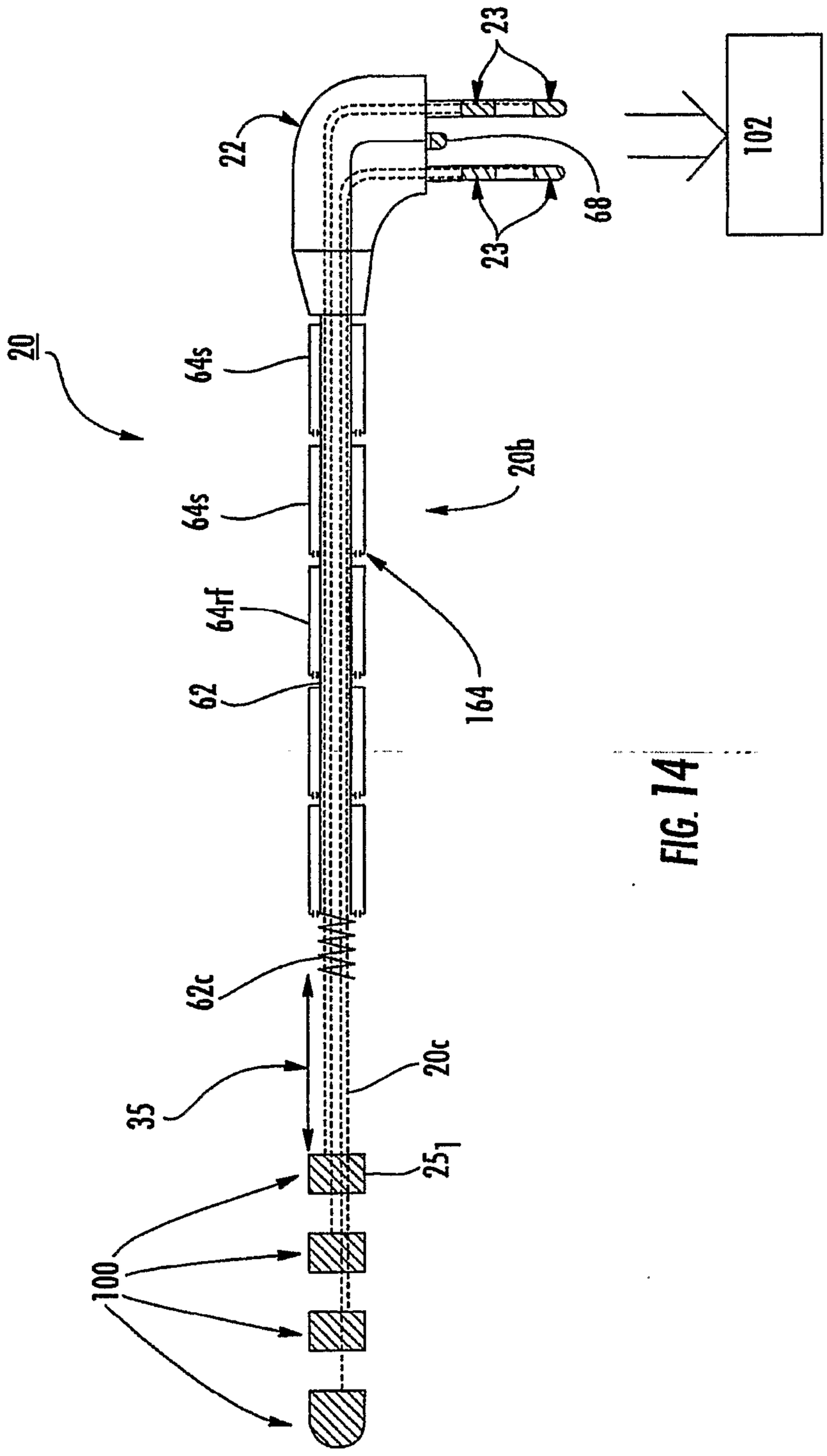


FIG. 14

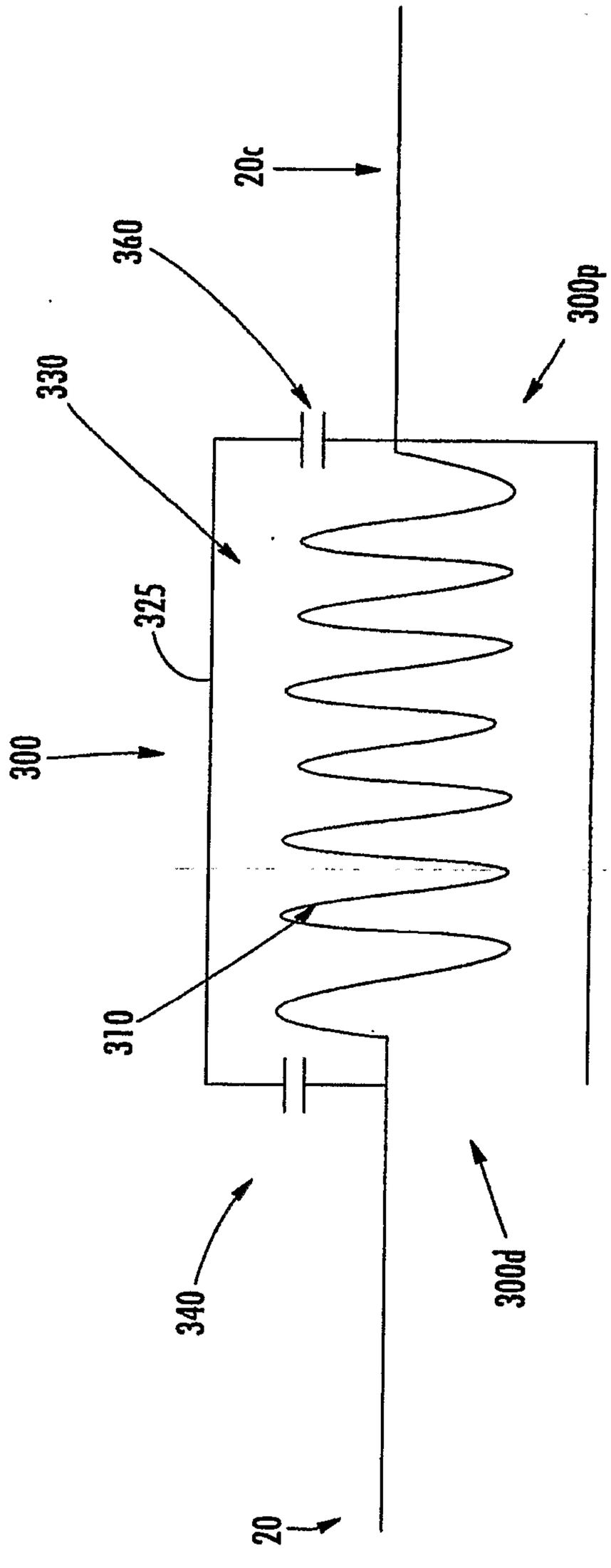


FIG. 15A

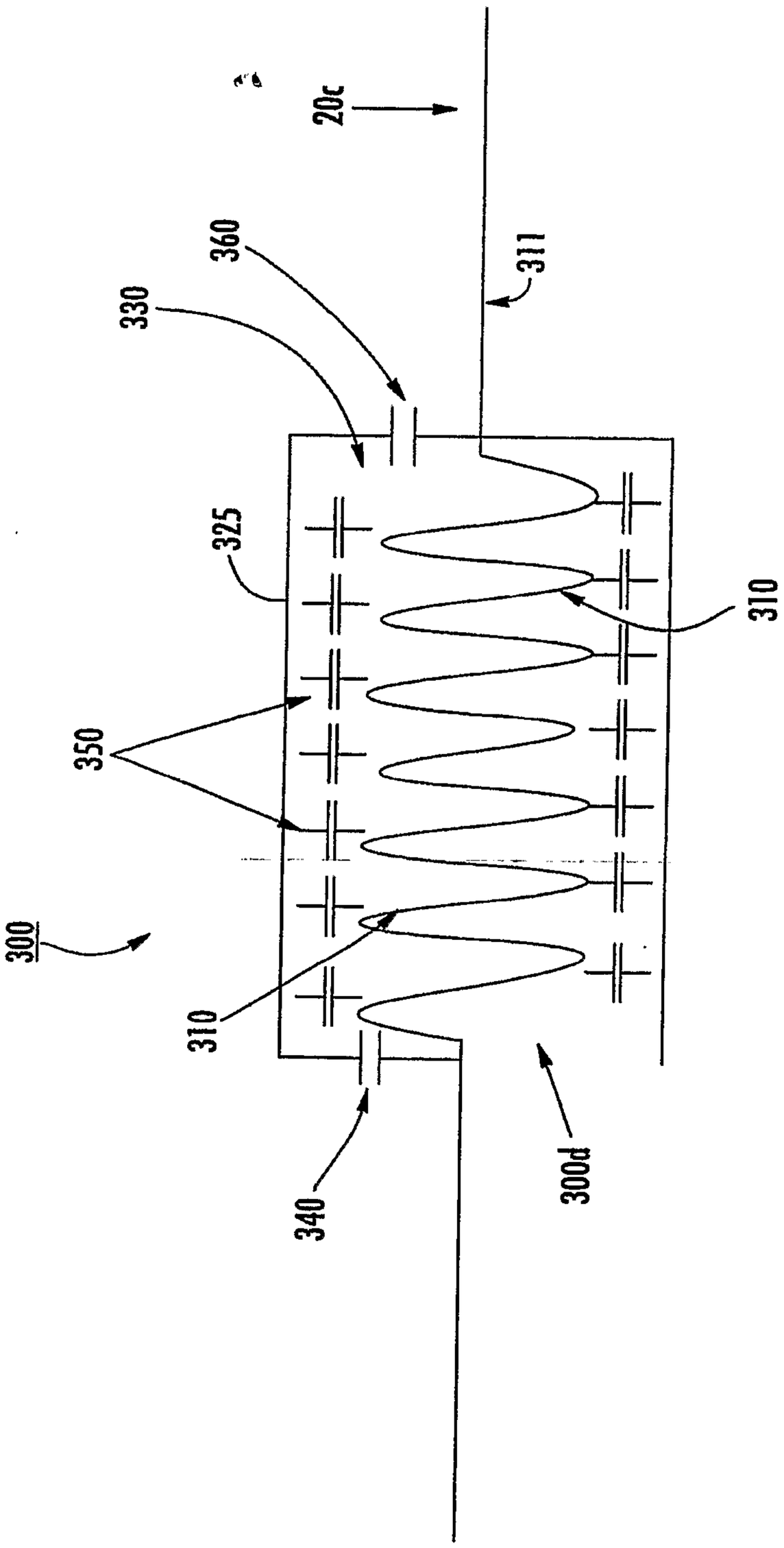


FIG. 15B

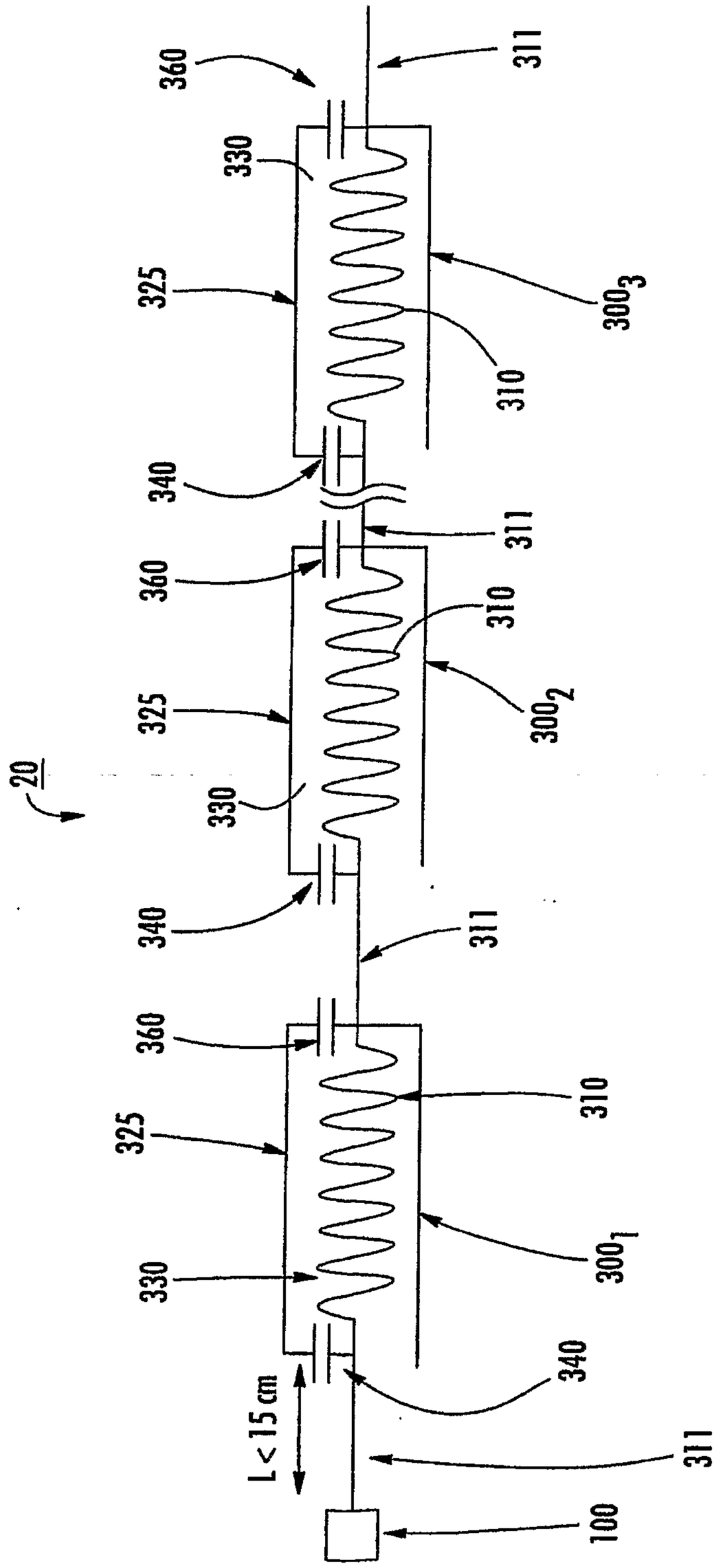

20
360
311
330
325
300_3
310
340
311
360
310
325
300_2
330
340
311
360
310
325
330
300_1
340
15 cm
L<15
311
100

FIG. 16

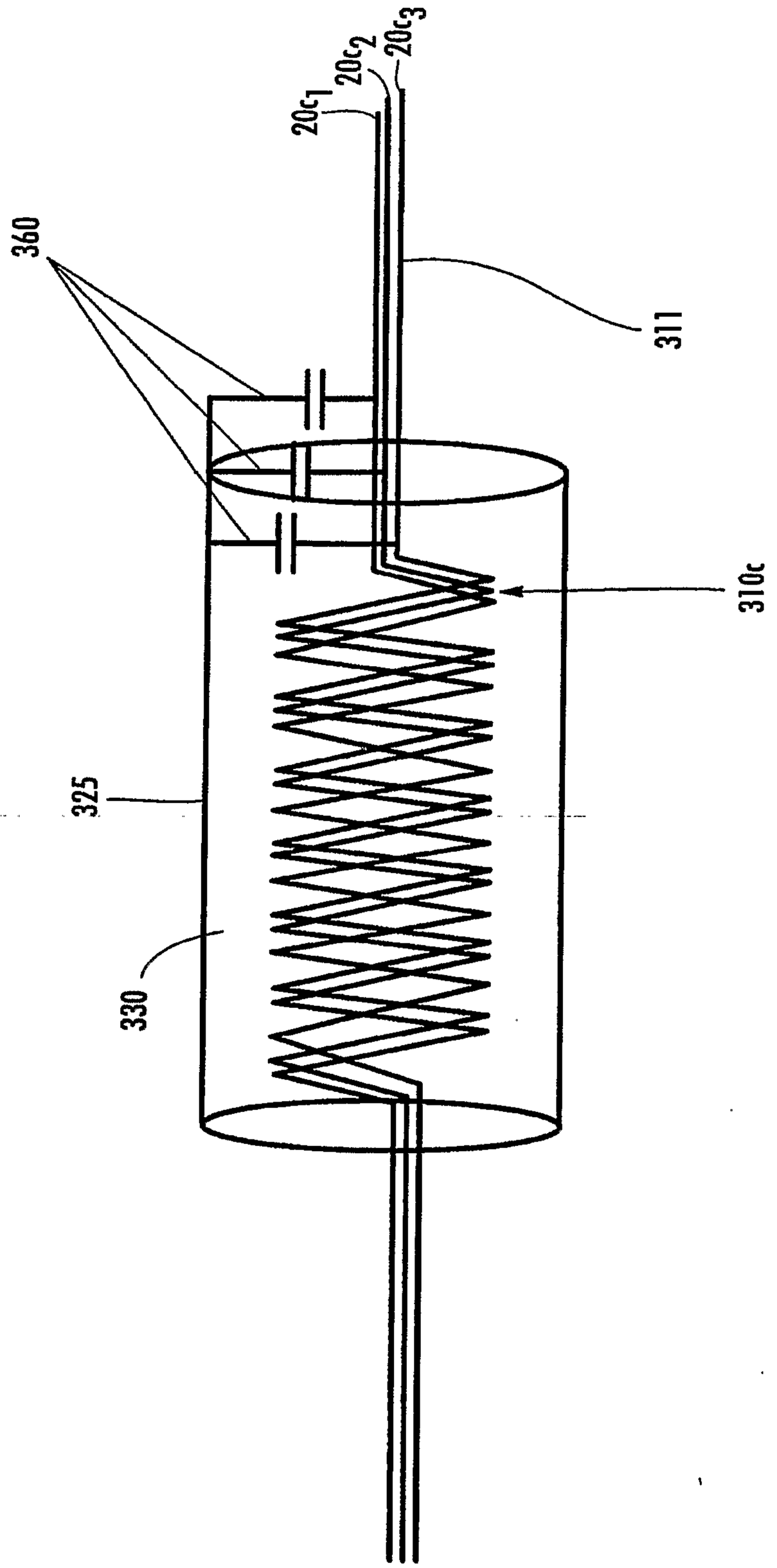


FIG. 17

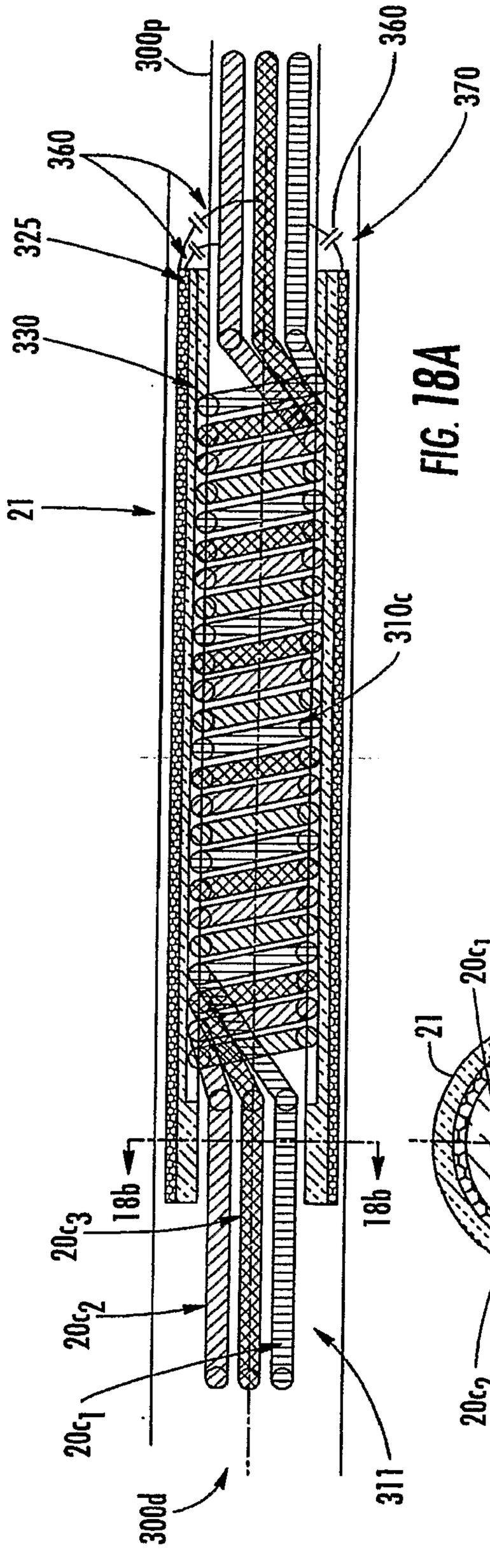


FIG. 18A

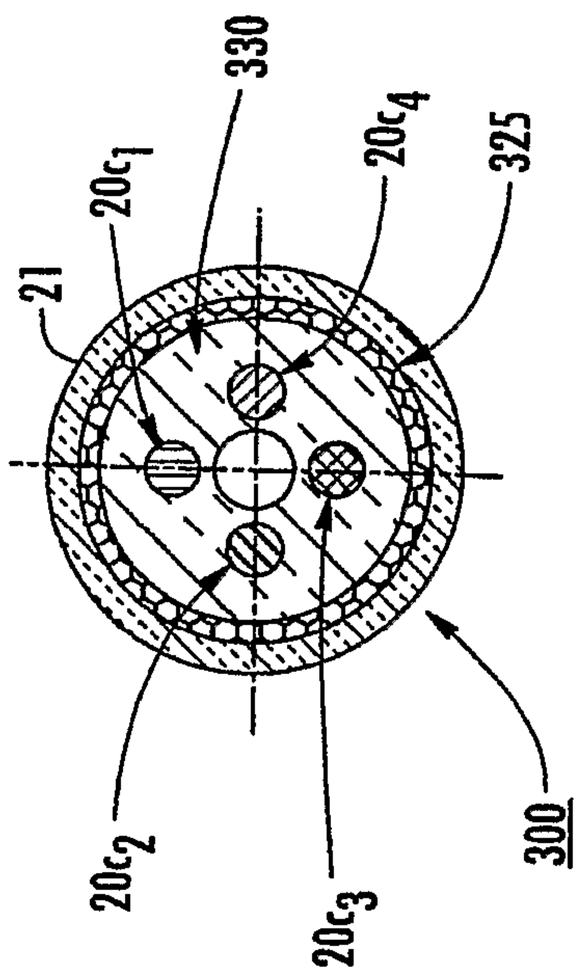


FIG. 18B

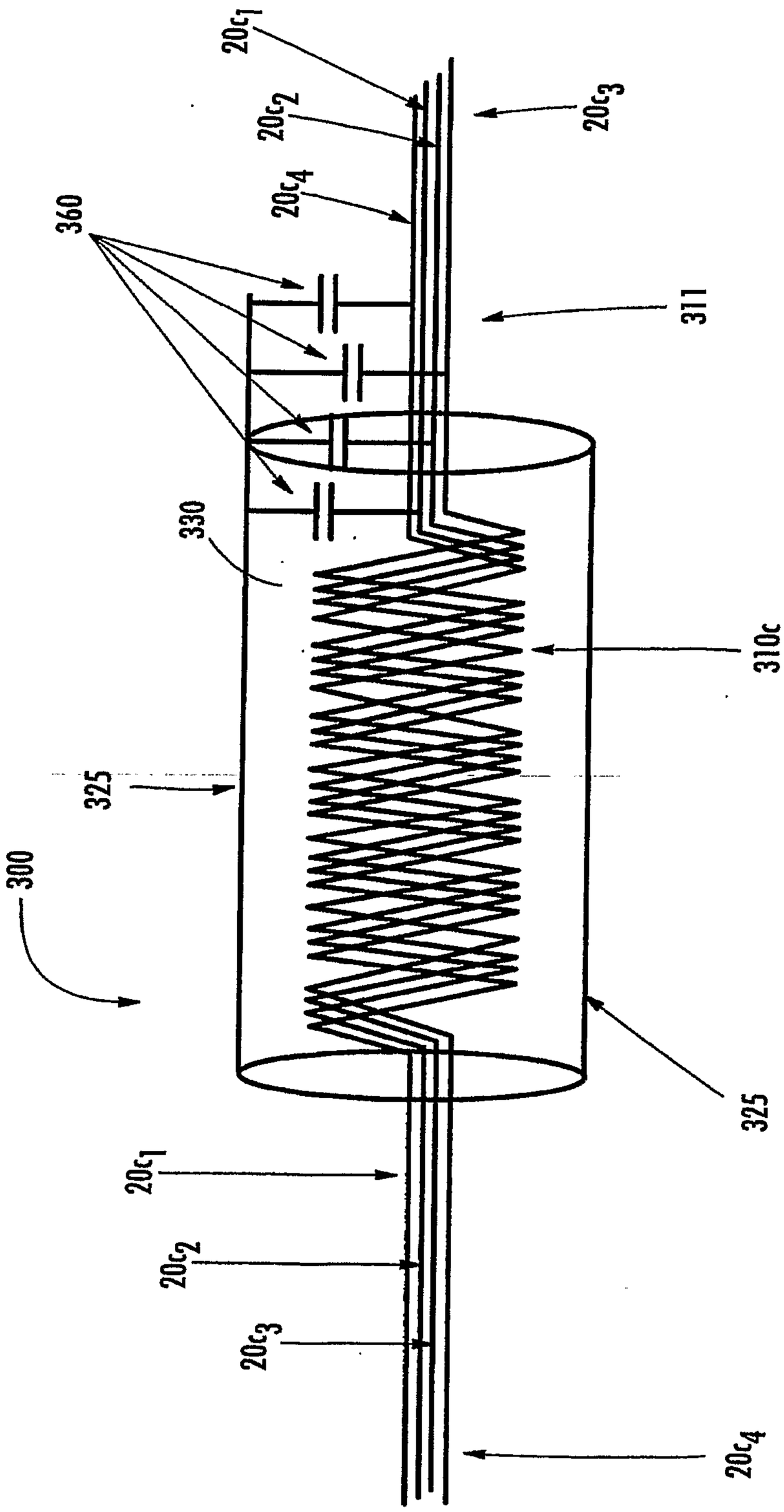

20c1
20c2
20c3
20c4
360
311
330
310c
325
300
325
20c1
20c2
20c3
20c4

FIG. 18C

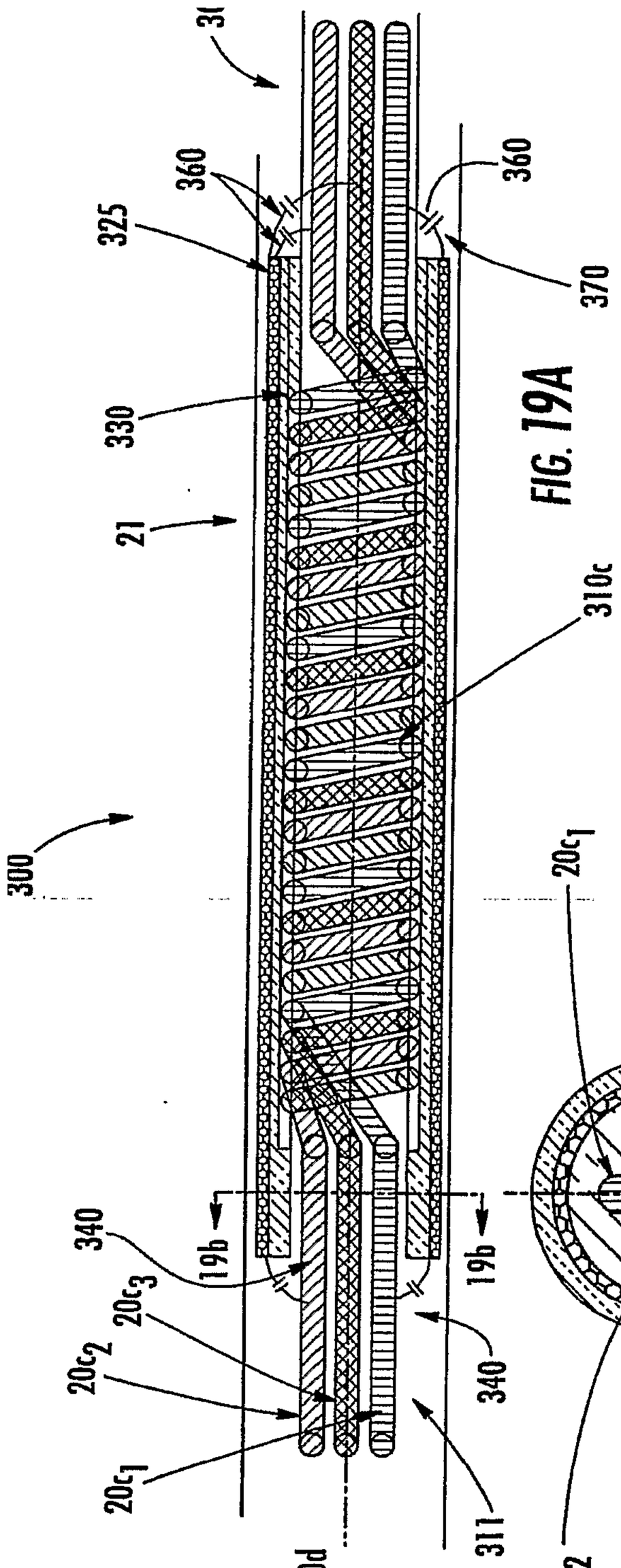


FIG. 19A

FIG. 19B

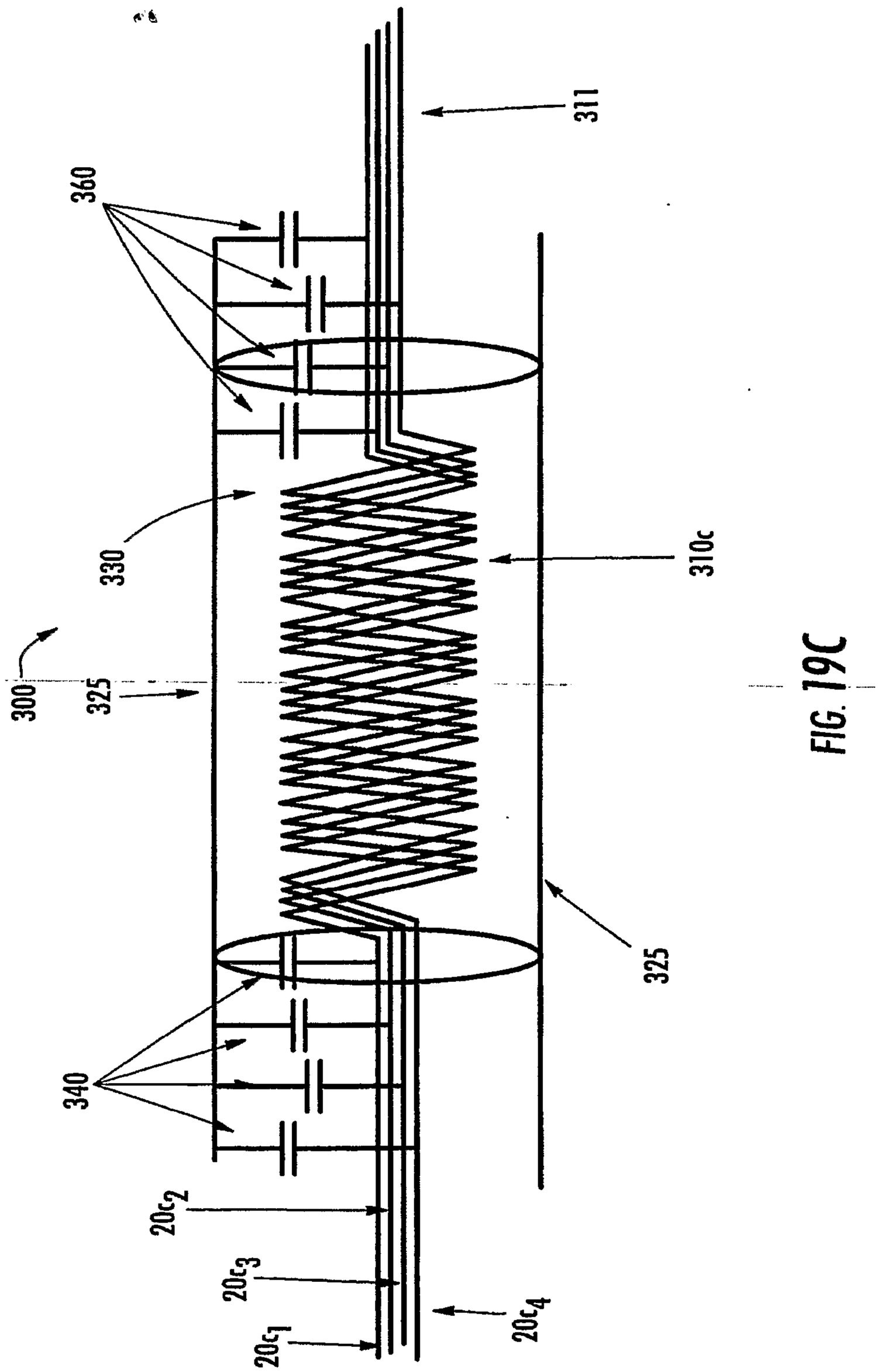


FIG. 19C

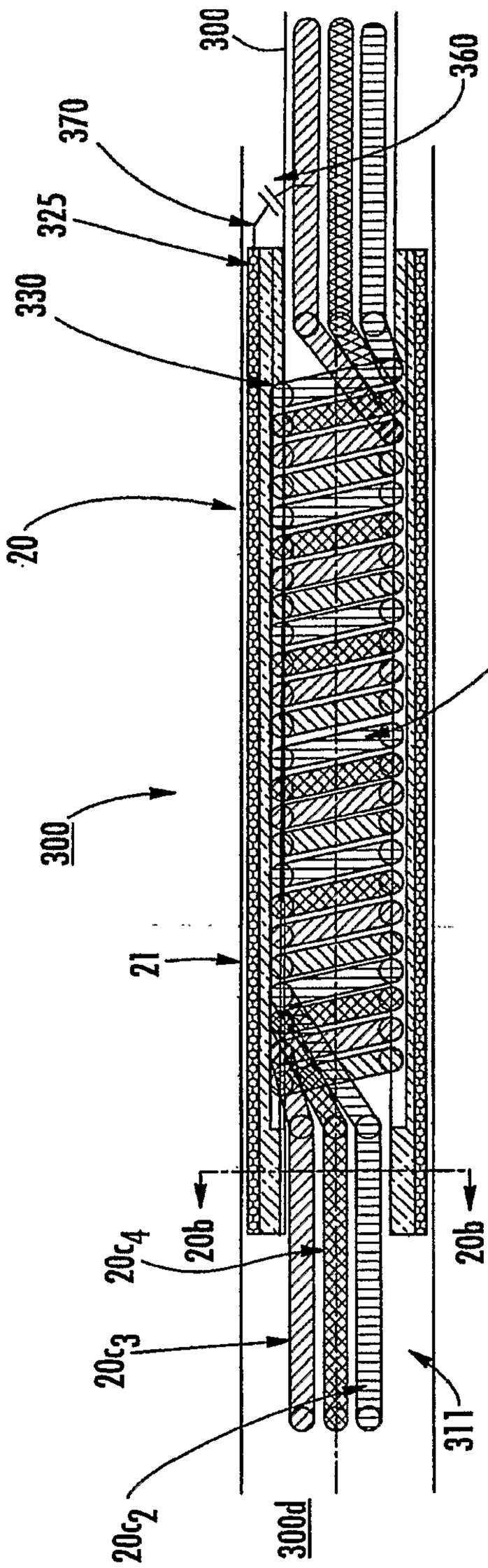


FIG. 20A

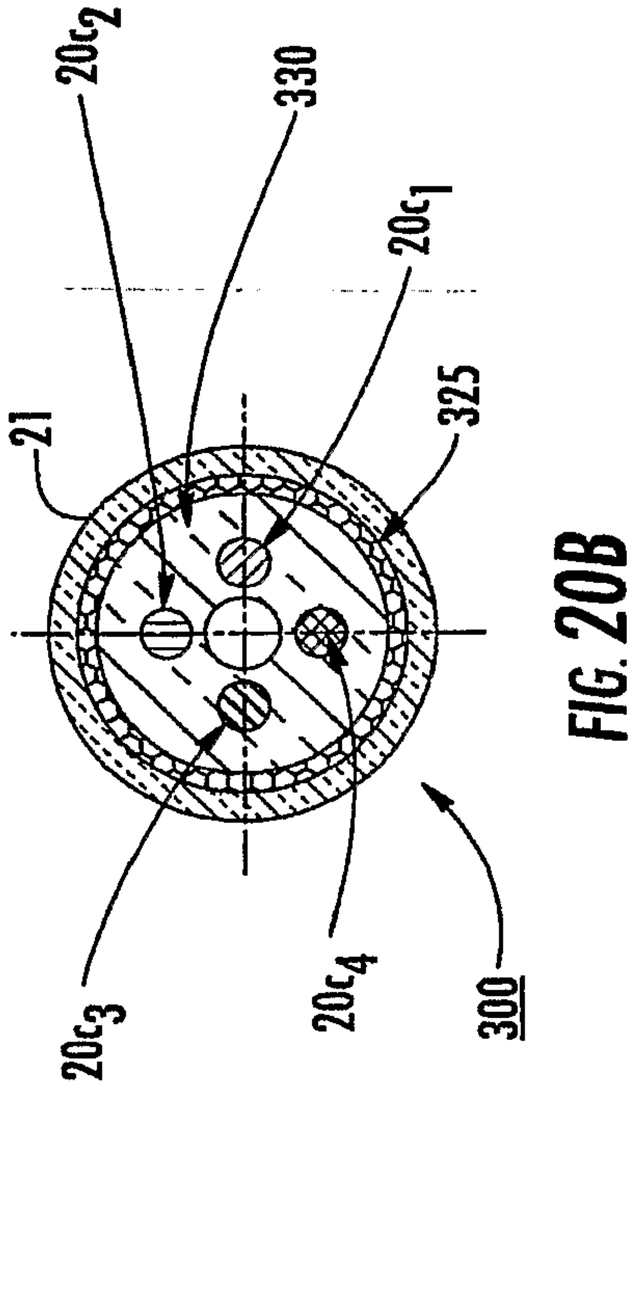


FIG. 20B

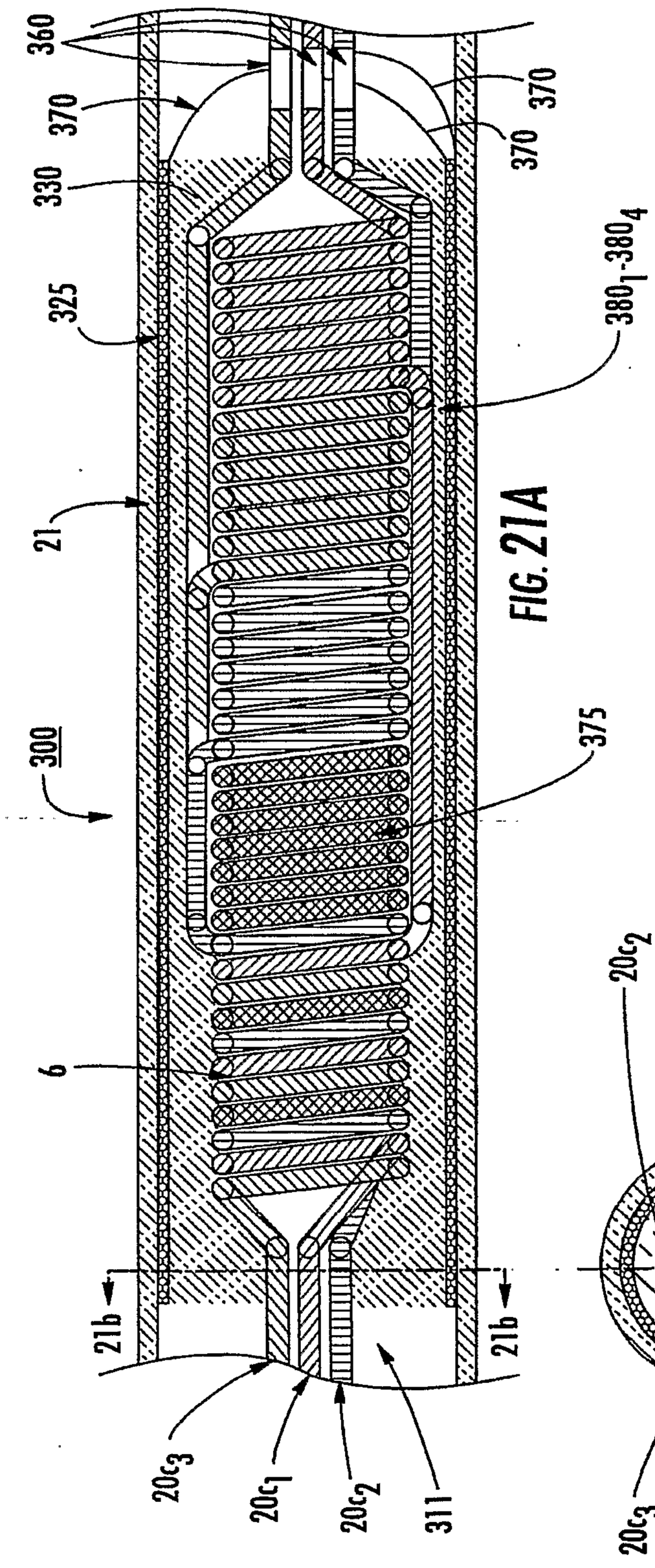


FIG. 21A

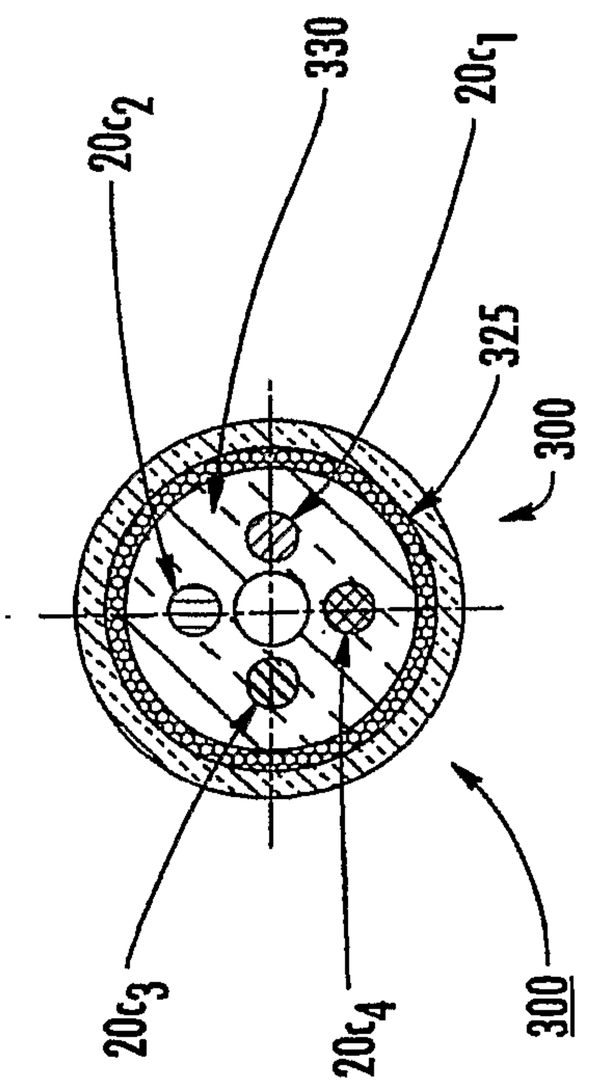


FIG. 21B

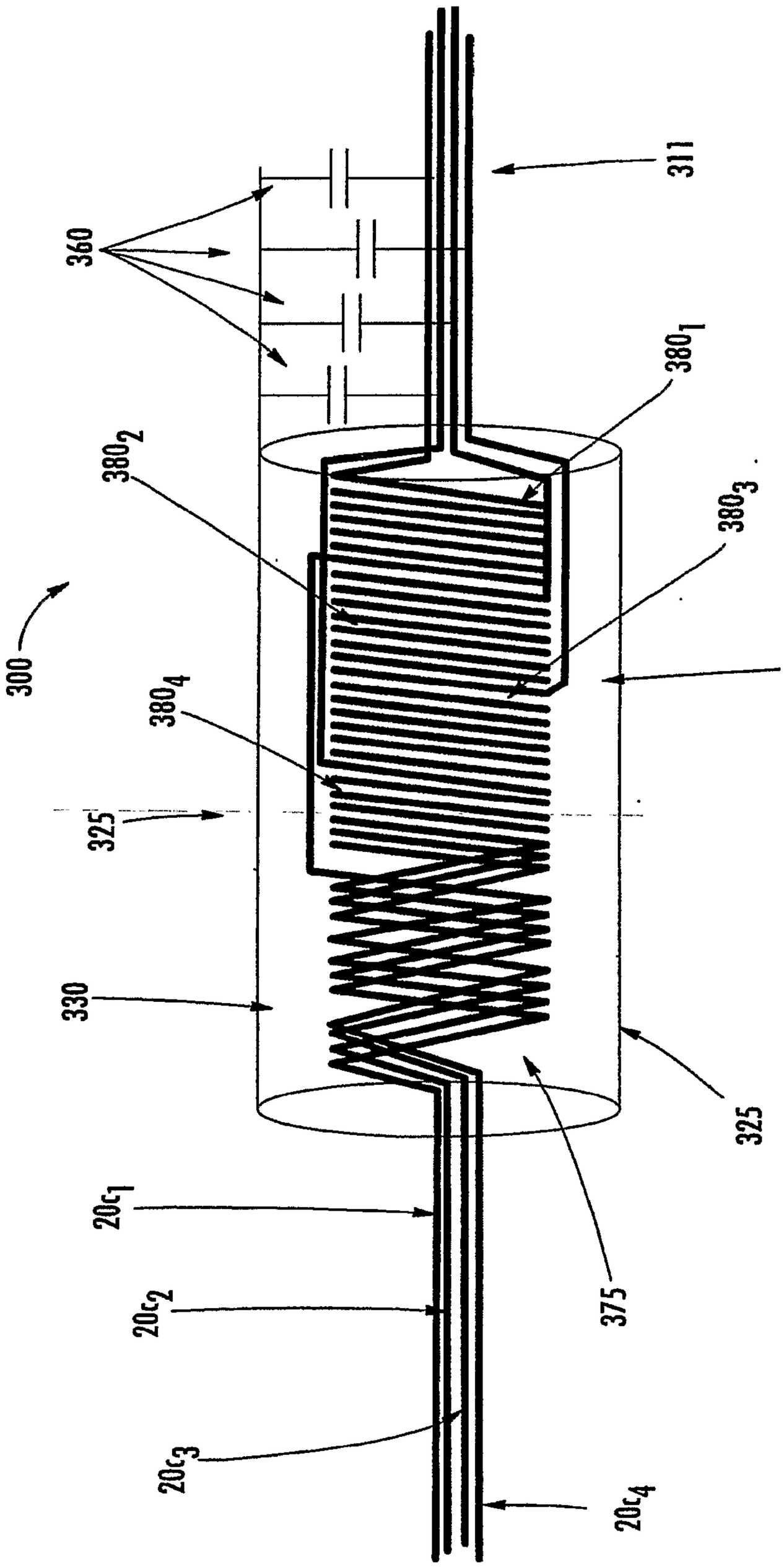

311
360
380_1
380_2
380_3
300
380_4
310c
325
330
325
$20c_1$
375
$20c_2$
$20c_3$
$20c_4$

FIG. 21C

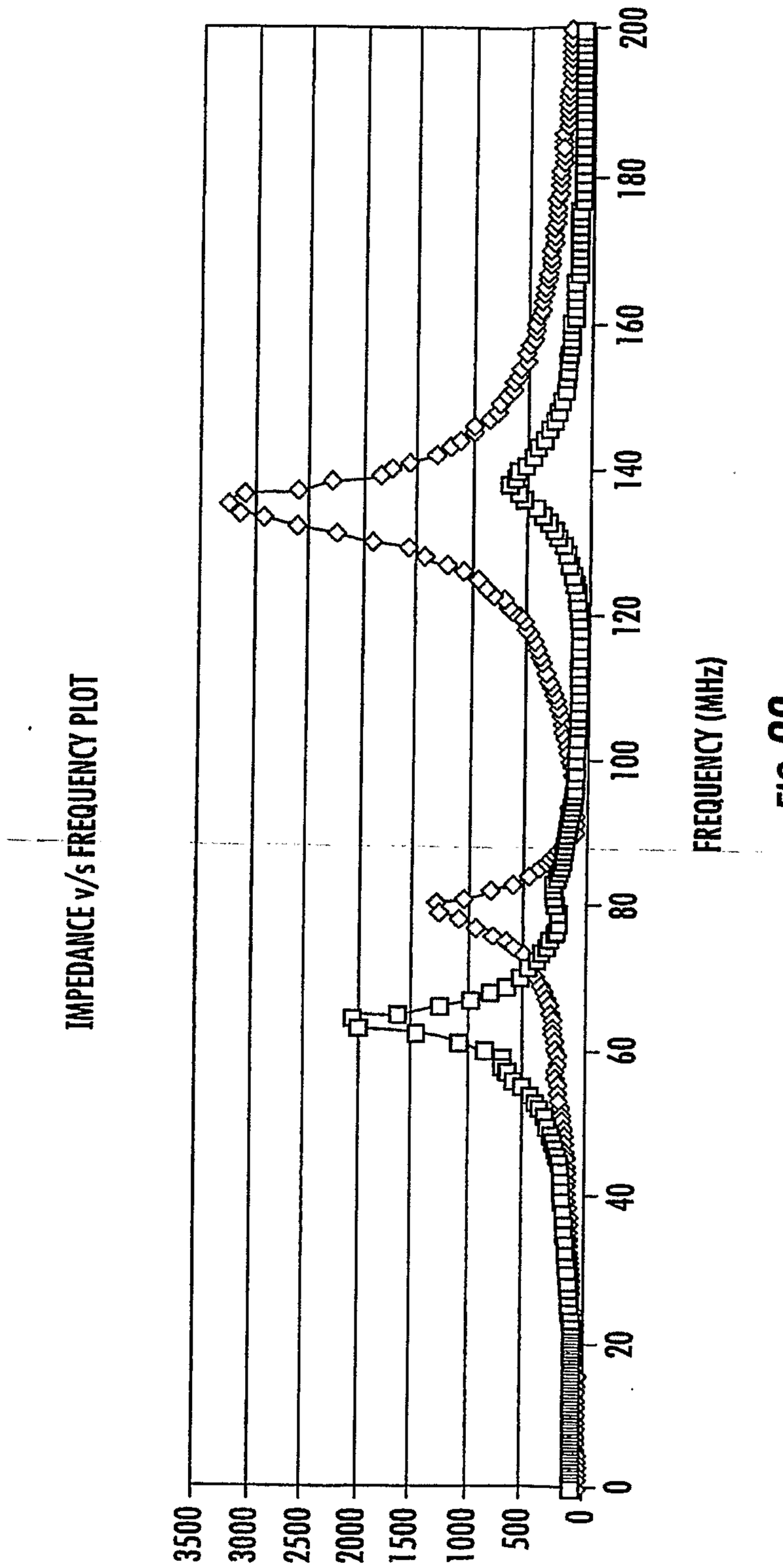
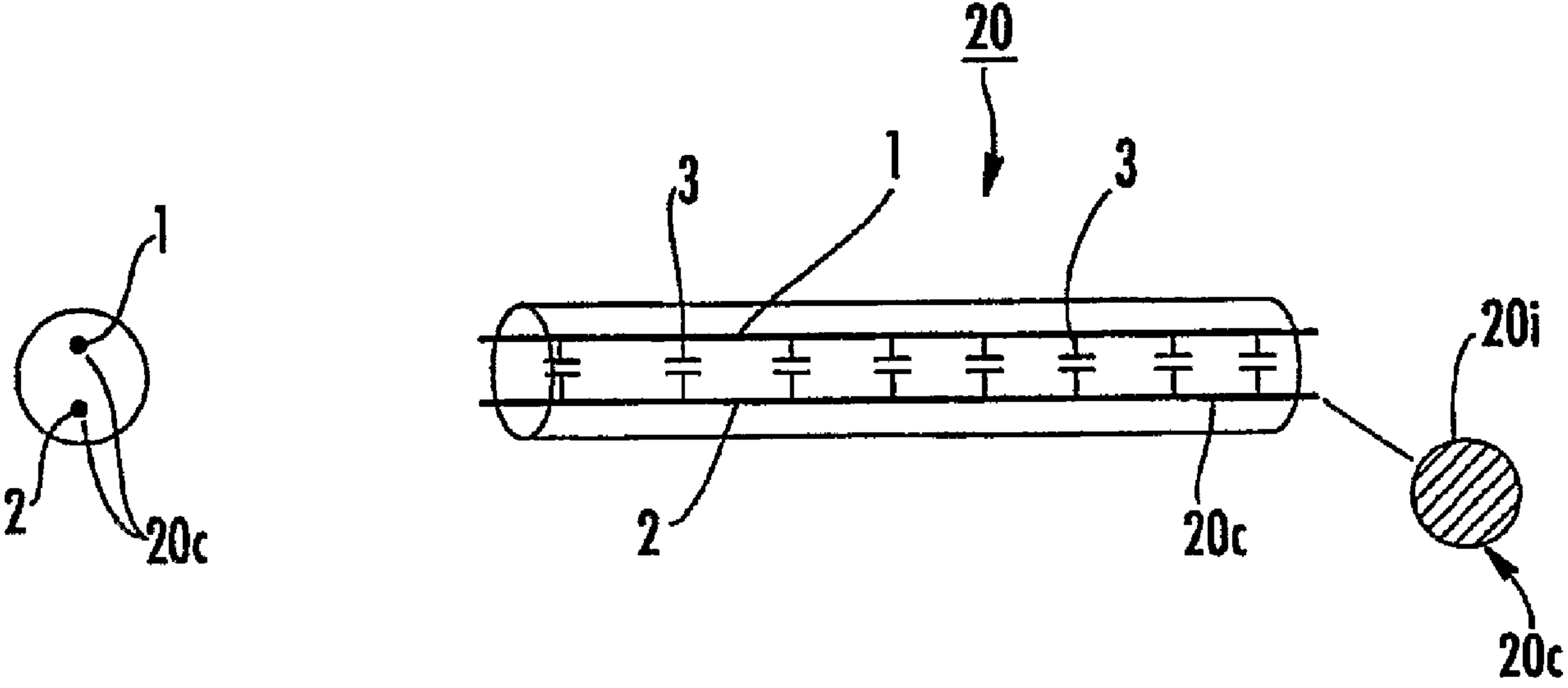

IMPEDANCE v/s FREQUENCY PLOT
IMPEDANCE (ohms)
3500
3000
2500
2000
1500
1000
500
0
0
20
40
60
80
100
120
140
160
180
200
FREQUENCY (MHz)

FIG. 22


20
1
3
3
20i
2
20c
20c