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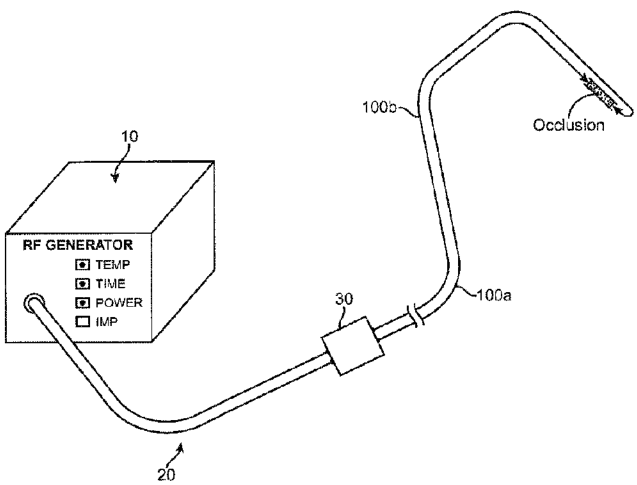


(57) Abrégé/Abstract:
An energy delivery and imaging catheter includes a dilating catheter having a distal end, a proximal end, and a guidewire shaft comprising a guidewire lumen. The dilating catheter is configured along at least part of its length to enable advancement of the dilating catheter through a narrow blood vessel by twisting or turning the dilating catheter. An electrode configured to perform ablation within an occluded vessel is on the distal end of the dilating catheter. One or more conductive wires, covered by an insulating sheath, transmit radiofrequency energy to the electrode from an external radiofrequency energy source. A transducer configured to perform ultrasound imaging is disposed on the distal end of the dilating catheter. One or more conductive wires transmit a signal from the transducer to an external ultrasound source.

Abstract

An energy delivery and imaging catheter includes a dilating catheter having a distal end, a proximal end, and a guidewire shaft comprising a guidewire lumen. The dilating catheter is configured along at least part of its length to enable advancement of the dilating catheter through a narrow blood vessel by twisting or turning the dilating catheter. An electrode configured to perform ablation within an occluded vessel is on the distal end of the dilating catheter. One or more conductive wires, covered by an insulating sheath, transmit radiofrequency energy to the electrode from an external radiofrequency energy source. A transducer configured to perform ultrasound imaging is disposed on the distal end of the dilating catheter. One or more conductive wires transmit a signal from the transducer to an external ultrasound source.

ENERGY DELIVERY AND IMAGING CATHETER

Field of the Invention

This invention relates generally to dealing with occlusions of the lumen and more specifically to apparatus and methods for crossing severe or total chronic occlusions of lumens in the body using radiofrequency energy.

Description of the Related Art

Chronic total occlusion (CTO) is the complete blockage of a vessel and usually has serious consequences if not treated in a timely fashion. The blockage could be due to atheromatous plaque or old thrombus. One of the common procedures for treating CTOs of the coronary arteries is percutaneous transluminal coronary angioplasty (PTCA). During a PTCA procedure, a small incision is, typically, made in the groin. A guiding catheter over a guide wire is introduced into the femoral artery and advanced to the occlusion. Frequently, with gentle maneuvering, the guidewire is able to cross the occlusion. Then, a balloon-tipped angioplasty catheter is advanced over the guide wire to the occlusion. The balloon is inflated, separating or fracturing the atheroma. Some of the common steps involved in the PTCA procedure are the simultaneous injection of a contrast agent in the contra-lateral vessel, getting backup force or stabilization for a guide wire (which could invoke additional personnel to handle the catheter), puncturing the plaque, drilling or rotating the guide wire to push it through the dense plaque, etc. Because of the stiff resistance sometimes offered by dense plaque, one could be forced to use stiff wires. Occasionally, the wires could puncture the vessel wall calling for remedial measures.

The most common percutaneous coronary intervention (PCI) failure mode for CTOs is inability to successfully pass a guidewire across the lesion into the true lumen of the distal vessel. To date, there is no consensus on how best to treat CTO after attempts with conventional guidewires have failed. Different strategies and specific devices for CTOs have been developed including the subintimal tracking and reentry with side branch technique, parallel wire technique, IVUS guided technique, retrograde approach, etc.

Mechanical and energy based techniques have also been proposed for passing guidewires through hard calcified occlusions, such as mechanical cutting or oscillation and laser or ultrasound or radiofrequency (RF) energy ablation. Most of these devices work by locally applying energy at the tip of the guidewire or catheter device to cause ablation of the occlusion, which is carefully carried out to create a channel through the occlusion. Once a channel is created, the guidewire is used to guide the balloon catheter in place.

RF energy is widely used to coagulate, cut or ablate tissue. In both modalities, monopolar and bipolar, conductive electrodes contact the tissue to be treated. In the monopolar mode, the active electrode is placed in contact with the tissue to be treated and a return electrode with a large surface area is located on the patient at a distance from the active electrode. In the bipolar mode, the active and return electrodes are in close proximity to each other bracketing the tissue to be treated. Sometimes an array of electrodes is used to provide better control over the depth of penetration of the RF field and hence control over the temperatures to which the tissue is heated. There are many disadvantages with each mode. For example, in the monopolar arrangement, because of the large physical separation between the electrodes there are frequent reports of local burning at the electrode sites. This would clearly be undesirable where one of the electrodes will be inside a blood vessel. The other serious issue is the likelihood of forming blood clots. The tissue that is in contact with the electrodes can be coagulated or ablated. In the case of the electrodes being present inside a blood vessel the chances of forming dangerous blood clots is quite high.

In an attempt to overcome the issues described above, various device and electrode configurations are described in the following patents. US Patent Numbers 5,366,443 and 5,419,767 describe the use of RF electrodes on a catheter to cross a lesion. These patents describe a bipolar electrode assembly at the distal tip of a catheter that is in contact with the occlusion, and patentees claim that application of RF energy ablates the occlusion and renders the occlusion susceptible for the guidewire to penetrate. This method has the drawback that careful tracking of the occlusion and the ablation process is necessary to avoid trauma to the vessel walls or healthy tissue, since the possibility of short-circuiting of current through healthy tissue instead of the occlusion is high. US Patent Number 5,419,767 overcomes this limitation to a certain extent through the use of a multiple electrode array. However, this device requires a channel to be pre-created through the occlusion so that the device can be passed through a guidewire traversing this channel, which is not always easy.

US Patent Number 5,514,128 to Hillsman et al. describes a laser catheter device that enables ablation of an occlusion in the vasculature. This system has similar drawbacks to the ones described above-need for a guidance system, potential for healthy tissue to be ablated, complexity (and hence cost) of the device, etc.

One major problem with the existing devices is the potential for the ablation energy to damage the walls of the vasculature, in the absence of a mechanism to track the orientation and position of the energy delivery member. Several devices exist in the prior art that address the issue of tracking and steering of the energy delivery element. US Patent Number 6,911,026 to Hall et al. describes a magnetic steering and guidance system to direct an ablation device that delivers RF energy at the tip in a unipolar configuration where the return electrode is placed externally in contact with the body or in a bipolar configuration where the return electrode is a ring surrounding the central wire electrode.

US Patent Number 6,416,523 to Lafontaine discusses a mechanical cutting device where the guidance is provided by measuring impedance of the tissue in contact. The guidance system senses the difference in impedance between the stenotic tissue and the vessel wall and directs the cutting element to the occlusion.

However, none of these alternate strategies have provided satisfactory results for the most challenging of the CTOs. In case of hard calcified occlusions, the revascularization procedure can be tedious and time consuming. Therefore, there is a need for improved methods of ablating or disrupting the occlusive material that are safe, efficacious and fast. It would be beneficial to have alternate techniques and devices that would recanalize a CTO without the shortcomings of the current techniques.

CTOs that are hard to recanalize, either because of the tortuous anatomy of the diseased vessel, or because the proximal end of the stenosis is too hard for the guide wire to penetrate, or other characteristics of the CTO that would make the standard procedure vulnerable to failure would benefit from newer approaches to recanalize CTOs. Recently a combined antegrade-retrograde approach has been proposed for recanalizing chronic occlusions (US Application Serial Number 11/706,041). The method disclosed in the co-pending application would benefit from the use of energy for crossing CTOs.

SUMMARY OF THE INVENTION

Various methods and devices are provided to overcome some of the commonly encountered problems in treating chronic total occlusions. One aspect of this invention is to provide a method and systems for successfully recanalizing an occluded vessel by advancing, in combination, guidewires in an antegrade and retrograde fashion to the occlusion and applying RF energy between the proximal and distal ends of the occlusion. The RF energy application across the occlusion is accomplished using a bipolar arrangement, where one electrode is located on the antegrade guidewire and the other electrode that makes up the bipolar arrangement is located on the retrograde guidewire.

In one aspect, the present invention discloses a method of recanalizing an occluded vessel comprising advancing in an antegrade fashion a first longitudinal member through a proximal end of an occlusion, advancing in a retrograde fashion a second longitudinal member through a distal end of the occlusion, applying RF energy between the distal ends of the antegrade and retrograde guidewires, ablating the tissue locally, and creating a channel through which a guidewire could be advanced. In another embodiment, the retrograde guidewire could have a deployable capture mechanism at its distal end and upon deployment could snare the antegrade guidewire.

In another aspect, this invention relates to a catheter assembly for recanalizing an occluded vessel comprising an antegrade longitudinal member with a distal end containing an RF electrode and a retrograde longitudinal member with a distal end containing a second RF electrode; and the proximal end of the catheter assembly connected to an RF generator. Additionally, a temperature measuring element could be disposed on the distal ends of the antegrade or retrograde longitudinal member. The RF generator could also be programmed to treat the tissue for a pre-set time or until a set condition has been reached. One such condition could be till the occlusion has reached a pre-determined temperature. Another condition could be the impedance of the occlusion.

In another aspect, the invention is a kit for recanalizing occluded vessels comprising one or more of the following: an antegrade guidewire, a retrograde guidewire, a dilating device, a capture device and an injection catheter, wherein at least one of these devices contains at least one electrode. Additionally, the proximal ends of this device are configured to be coupled with an RF generator.

Other aspects of the invention include methods corresponding to the devices and systems described above.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention has other advantages and features which will be more readily apparent from the following detailed description of the invention and the appended claims, when taken in conjunction with the accompanying drawings, in which:

Figure 1 is a schematic showing an RF generator connected to the longitudinal members.

Figure 2 shows the features of the longitudinal members.

Figures 3A and 3B show the steps involved in recanalizing a CTO using bipolar RF and combined antegrade and retrograde approach.

Figure 4 shows an example embodiment of a longitudinal member comprising an embolic protection mechanism.

Figures 5 A-C show a longitudinal member structurally configured along at least part of the length of the catheter to enable advancement or alignment of the longitudinal member through a narrow diameter blood vessel or occlusion.

DETAILED DESCRIPTION

Although the detailed description contains many specifics, these should not be construed as limiting the scope of the invention but merely as illustrating different examples and aspects of the invention. It should be appreciated that the scope of the invention includes other embodiments not discussed in detail above. Various other modifications, changes and variations which will be apparent to those skilled in the art may be made in the arrangement, operation and details of the method and apparatus of the present invention disclosed herein without departing from the scope of the invention as described here.

The present embodiments combine the use of RF energy delivered through antegrade and retrograde members for recanalizing occluded lumens, particularly chronic total occlusions. The methods and systems described herein recanalize difficult to cross occlusions by taking advantage of an antegrade and retrograde approach to establish a bipolar electrode arrangement across the occlusion. This approach minimizes the potential of the vessel wall becoming perforated or injured, as may otherwise occur in a conventional bipolar RF treatment approach, where both RF electrodes are on the same side of the occlusion. Because the electrodes are distributed on opposite sides of the occlusion, the tissue that is ablated by the RF treatment (i.e., the occlusion) is well contained between the electrodes. This also allows the user to localize the treatment to the occlusion.

As disclosed in the co-pending US Patent Application Serial Number 11/706,041 by the same inventors, in the controlled antegrade and retrograde tracking (CART) technique the retrograde approach takes advantage of an intercoronary channel. Such a channel may be an epicardial channel, an inter-atrial channel, an intra-septal channel (also referred to as septal collateral), or a bypass graft. The basic concept of the CART technique is to create a channel through an occlusion, preferably with limited dissections, by approaching the occlusion both antegradely and retrogradely.

While the combined antegrade and retrograde approach has been effective in crossing difficult to cross lesions, it has been observed that using energy, for example RF energy, to ablate or alter the tissue in a controlled fashion is beneficial in crossing hard to cross lesions.

Such controlled energy deployment is achieved using a bipolar arrangement of the electrodes, where one electrode is located on the antegrade element and the other electrode that constitutes the bipolar arrangement is located on the retrograde element. These electrodes can also be referred to as the return and active electrodes. They are also referred to as the anode and cathode, respectively. The electrodes could also be arranged in an array (multiple electrodes), where the electrode arrangement provides better control over the depth of penetration of the RF field and thereby provides the ability to control the tissue temperature.

Figure 1 shows a system for recanalizing occluded vessels using RF energy. The system comprises longitudinal members **100a** and **100b** for delivering RF energy to an occlusion. As indicated in Figure 1, longitudinal member **100a** serves as an antegrade member and longitudinal member **100b** serves as a retrograde member. An RF generator 10 (also referred to as a controller) serves as the source of RF energy to be provided to longitudinal members **100a** and **100b**. Longitudinal members **100a** and **100b** may be guidewires, catheters, micro-catheters, or dilating catheters. In a preferred embodiment, longitudinal members **100a** and **100b** are guidewires. Thus, while in the following description the term "guidewire" is used to refer to a longitudinal member **100a** or **100b**, it is understood that the term "guidewire" as used herein is intended to include any other type of longitudinal member.

To provide RF energy from the RF generator **10** to the guidewires **100a** and **100b** a pigtail **20** connects at its proximal end to the RF generator **10** and terminates at its distal end in a connector **30**. Connector **30** is a standard connector that couples the input and output signals of the RF generator **10** to the guidewires **100a** and **100b**.

Guidewires **100a** and **100b** are configured to have sufficient torsional rigidity and longitudinal flexibility to advance through an occlusion, and to align their electrodes in a direction away from the vessel wall, towards the other longitudinal member, or any combination thereof.

As shown in Figure 2, the antegrade and retrograde guidewires **100a** and **100b** have conductive electrodes **105a** and **105b**, respectively, at their distal ends. In one embodiment, the electrodes **105a** and **105b** are located on one side of their respective guidewires **100a** and **100b**, thereby providing the operating physician with the freedom to allow the electrode-free side of the guidewire to touch the vessel wall (if needed) while still directing the RF energy away from the vessel wall. Additionally, this allows the configuration to direct the RF energy away from the vessel wall, thereby minimizing potential RF injury to the vessel wall. In one embodiment, one or more of the guidewires comprises a plurality of electrodes arranged in an array.

Conductive wires (not shown) connect the electrodes **105a** and **105b** to connector **30** to deliver RF energy from the RF generator **10** to the electrodes **105a** and **105**. The exterior of the guidewires are covered by non-conductive layers **115a** and **115b**, respectively, that sandwich the conductive wires between the guidewires and the non-conductive layers. In one embodiment, the non-conductive layers **115a** and **115b** comprise a sheath or a coating.

In one embodiment, and as further shown in Figure 2, the guidewires **100a** and **100b** comprise temperature measuring elements **110a** and **110b** at the distal tip of the antegrade and retrograde guidewires, respectively. In one embodiment, the temperature measuring elements **110a** and **110b** comprise thermocouples or thermistors that are connected to the connector **30**. In another embodiment, pressure measuring elements are placed on the distal ends of the guidewires to detect a change in pressure upon activation of the RF energy.

RF generator **10** is configured to allow the user to set a maximum temperature, a treatment time period, a level of RF power, or a combination of these control parameters. The treatment time period indicates the period of time over which the RF energy will flow between the electrodes. The maximum temperature setting serves as a threshold temperature for the tissue that is in contact with the electrodes, and the RF generator **10** can be set to reduce or shut off power to one or both electrodes when one or more of the temperature measuring elements **110a** and **110b** indicate a tissue temperature at or near the threshold.

In one embodiment, the generator **10** is capable of measuring the impedance of the tissue between the two electrodes **105a** and **105b**. Based on the type of the occlusion (i.e., the nature of the calcified material), the user can choose the appropriate combination of temperature, treatment time, and the amount of RF energy to be provided to the tissue to achieve a safe and effective treatment. Alternatively, the treatment may proceed with the user manually controlling the parameters during the recanalization procedure, with the user treating the occlusion until recanalization is achieved.

The sequence of the recanalization treatment steps are illustrated in Figures 3A and 3B. As shown in diagram A of Figure 3A, the antegrade guidewire **100a** and retrograde guidewire **100b** are advanced to the proximal and distal ends **310a** and **310b** of the occlusion **310**, respectively. This can be accomplished using standard angioplasty techniques. As described in the above referenced co-pending US Patent Application Serial Number 11/706,041, the retrograde guidewire can be advanced to the distal end of the occlusion **310b** using collaterals such as the septals.

Once the user has confirmed that the guidewires **100a** and **100b** are in contact with the occlusion **310** and are not touching the vessel wall **300**, the RF treatment is initiated.

Alternatively, the guidewires are advanced as deep into the occlusion as possible to minimize the distance between the electrodes and, consequently, minimize the length of the ablation zone. Confirmation that the guidewires **100a** and **100b** are in an appropriate position can be generated by impedance measurements and/or by using any of the standard imaging techniques employed during interventional procedures, such as fluoroscopy or intravascular ultrasound (IVUS), in which transducers are placed on the distal ends of the guidewire. When using tissue impedance measurements, the calcified occlusion **310** generally exhibits significantly higher impedance than the vessel wall **300**. If an impedance measurement indicates a low impedance value, it is likely that one or both guidewires are in contact with the vessel wall **300**, and appropriate repositioning of the guidewires may be warranted.

Upon initiating the recanalization RF treatment, the occlusion **310** is ablated from the ends **310a** and **310b** of the occlusion **310** to the interior of the occlusion **310**, as shown in Figure 3A diagram B. The user then slowly and carefully advances one or both guidewires **100a** and **100b** until a channel or path is created in the occlusion **310**, as shown in Figure 3A diagram C. As shown in Figure 3A, the antegrade guidewire **100a** may be kept stationary and the retrograde guidewire **100b** may be advanced through the occlusion **310**. Once a channel has been created, the retrograde guidewire **100b** may be withdrawn and the antegrade guidewire **100a** may be advanced through the occlusion **310**, as shown in Figure 3A diagram D, and standard interventional procedures, such as balloon angioplasty, can be performed. Alternatively, the retrograde guidewire **100b** can be kept stationary during the RF treatment and the antegrade guidewire **100a** can be advanced through the occlusion **310**. This is illustrated in Figure 3B diagrams A - D.

Optionally, the catheter comprises a means for removing or withdrawing debris resulting from the RF ablation. For example, a mechanism could be provided to capture and retrieve the debris, or a suction device could be provided to actively remove the debris near the ablation area. Examples of such embolic protection mechanisms are disclosed in the above referenced co-pending US Patent Application Serial Number 11/706,041. Figure 4 shows an example embodiment of a longitudinal member **400** comprising an embolic protection mechanism **410**. The embolic protection mechanism **410** comprises filter, mesh, net, or similar element, for capturing and retrieving ablation debris. As another example, the embolic protection may comprise a balloon for occluding the vessel and preventing the debris from circulating, and for subsequent aspiration of the debris through a longitudinal member. As another example, if a sheath is provided, such sheath may also be configured to be or to include a debris capture and retrieval mechanism or a suction device. In one embodiment, a longitudinal member may be retracted, and the remaining sheath may be used as a capture and retrieval mechanism or a suction device to remove ablation debris. In another embodiment, the longitudinal member comprises an ablating wire housed in the lumen of a dilating catheter. Upon ablation, the ablating wire may be retracted and the dilating catheter may be used to remove the debris. Alternatively, the system comprises a separate catheter to provide suction, or otherwise capture and remove the debris from the ablation site.

Optionally, the device may be coupled to an electrocardiogram (EKG) machine to aid in timing energy emissions. For example, the rate of blood flow through the coronary arteries typically varies during the cardiac cycle. During systole when the heart is contracting, flow through the arteries is generally lower than during diastole. In one embodiment, energy emission is timed during diastole, for example using an algorithm to detect the R-wave of an EKG, and energy emission is timed to occur when flow is highest, thereby maximizing the cooling effect provided by blood flow and consequently minimizing the heat exposure to the vessel. Additionally, coronary artery dimensions can vary during the cardiac cycle and energy emission can similarly be timed to take advantage of this fact.

Optionally, the device comprises a mechanism for detecting or estimating the distance between the electrodes, and for decreasing the amount of delivered RF energy as the distance between the electrodes decreases, thereby minimizing potential RF injury to the vessel wall.

In another embodiment, the device is an ablation catheter comprising a longitudinal member having a distal end, a proximal end, and a guidewire shaft there-between comprising a guidewire lumen. The longitudinal member is a dilating catheter and is structurally configured along at least part of the length of the catheter to enable advancement or alignment of the longitudinal member through a narrow diameter blood vessel or occlusion. Advancement is achieved, for example, by turning or twisting the longitudinal member. Figures 5A-C show such an embodiment of the present invention. For example, as shown in Figure 5A, the longitudinal member **500** may comprise a helical exterior **501** that advances through the vessel and dilates the vessel as the member is being twisted or rotated. Helical exterior **501** comprises a plurality of grooves **502** carved into the outer body of the longitudinal member **500**. The distal tip of longitudinal member 500 optionally comprises a radiopaque marker **510**. An electrode **520** is located at or near the distal end of the catheter. Another example is shown in Figure 5B, the cross section of which is shown in Figure 5C. The longitudinal member **550** may comprise a plurality of wires **551** and **552** wound around a liner **565**. In one embodiment, the wires **551** and **552** comprise at least two different diameters. Longitudinal member **550** optionally terminates at a marker **570**. An electrode **580** is located at or near the distal end of the longitudinal member **550**. The ablation catheter additionally and optionally comprises conductive wires for transmitting energy between the electrode and an external energy source. Alternatively, the plurality of wires may be configured to act as the electrode or conductive wires. Additionally and optionally, the catheter comprises an insulating sheath **560** which is optionally retractable.

The guidewires and electrodes may be made from any one or more suitable materials as is commonly known in the art. Examples of such suitable materials include stainless steel, Nitinol, Elgiloy, platinum, iridium, tantalum, titanium, cobalt, chromium, or any combinations thereof. In one embodiment, one or more of the guidewires may be made of a polymer, with an electrically conductive core for transmitting electrical energy to the respective electrodes.

While the above embodiments refer to the use of RF energy for the purpose of ablation, it should be noted that other energy modalities may be used as well, for example ultrasound energy. In one embodiment, one or more longitudinal members of the recanalization systems of the present invention comprise one or more ultrasound transducers, instead of or in addition to RF electrodes. The ultrasound transducers provide ultrasound energy for ablating an occlusion. In one embodiment, both the antegrade and the retrograde longitudinal members comprise ultrasound transducers and ablate the lesion from an antegrade as well as a retrograde direction. Other energy modalities could include microwave and laser. It should be noted that the combined antegrade and retrograde energy delivery techniques described above could also be used as an adjunct technique to crossing CTOs in combination with using conventional methods. The technique could be used to sufficiently soften or weaken the occlusion, thereby allowing a guidewire or catheter to cross the occlusion.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. An energy delivery and imaging catheter comprising:

a dilating catheter having a distal end, a proximal end, and a guidewire shaft comprising a guidewire lumen, wherein the dilating catheter is configured along at least part of its length to enable advancement of the dilating catheter through a narrow diameter blood vessel by twisting or turning the dilating catheter;

an electrode on the distal end of the dilating catheter, the electrode configured to perform ablation within an occluded vessel;

one or more first conductive wires coupled to the electrode for transmitting radiofrequency energy to the electrode from an external radiofrequency energy source, wherein the one or more conductive wires coupled to the electrode are covered by an insulating sheath;

a transducer disposed on the distal end of the dilating catheter, the transducer configured to perform ultrasound imaging; and

one or more second conductive wires coupled to the transducer for transmitting a signal from the transducer to an external ultrasound source.

2. The catheter of claim 1, wherein the dilating catheter is configured to have a helical exterior.

3. The catheter of claim 1, wherein the dilating catheter comprises a plurality of wires.

4. The catheter of claim 3, wherein the plurality of wires comprise at least two different diameters.

5. The catheter of claim 3, wherein the plurality of wires are configured to be electrodes or conductive wires.

6. The catheter of claim 1, wherein the dilating catheter has a tapered configuration along at least a part of its length between the distal end and the proximal end.

7. The catheter of claim 1, wherein the insulating sheath runs along the entire length of the dilating catheter.

Date Reçue/Date Received 2021-01-15

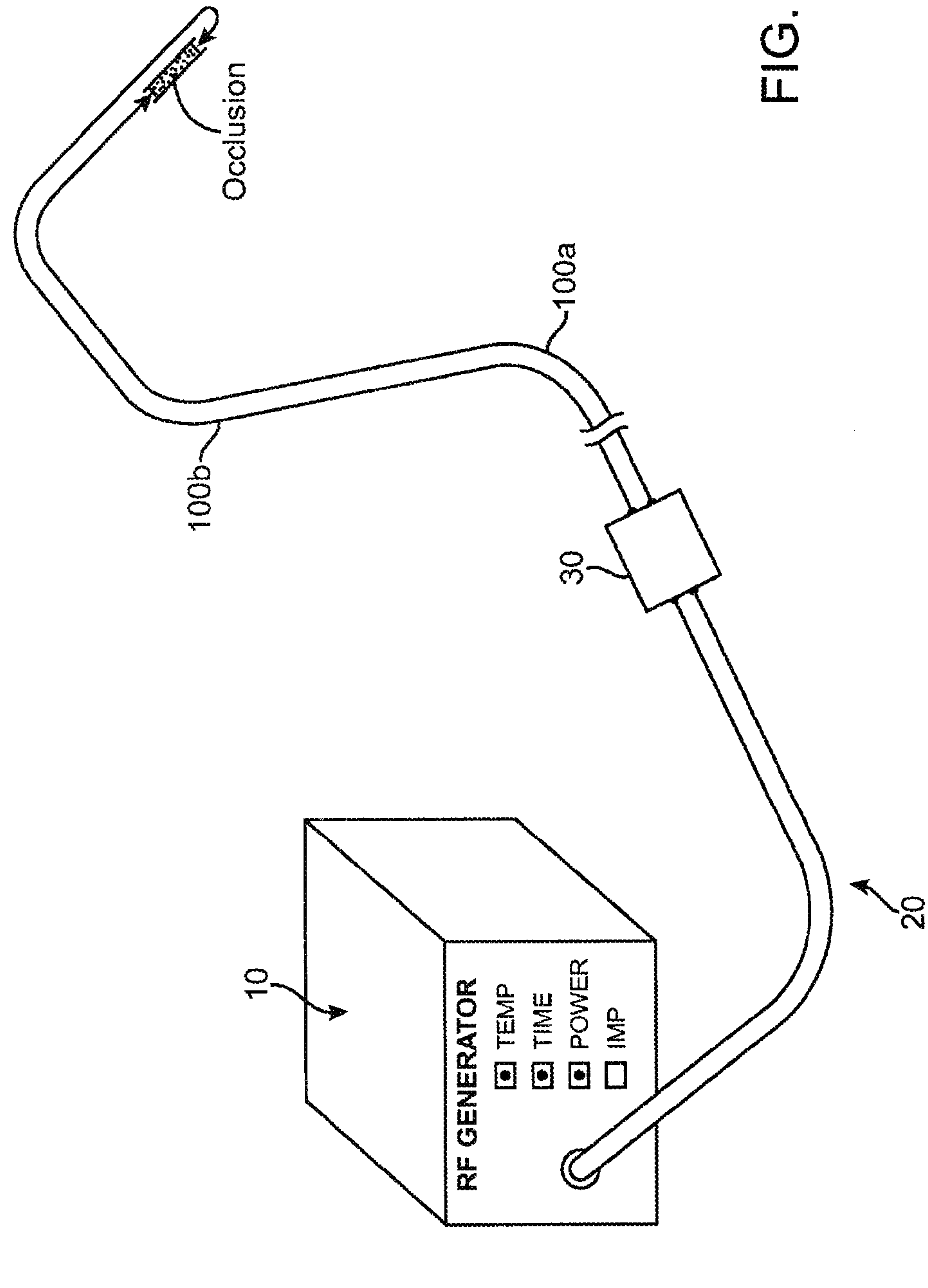

Occlusion
100a
100b
30
20
10
RF GENERATOR
TEMP
TIME
POWER
IMP

FIG. 1

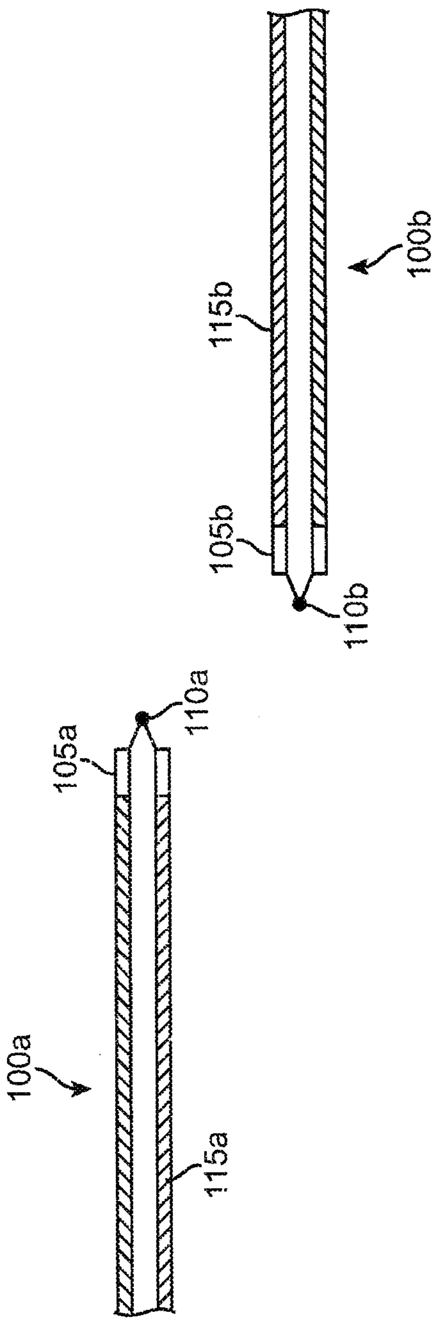


FIG. 2

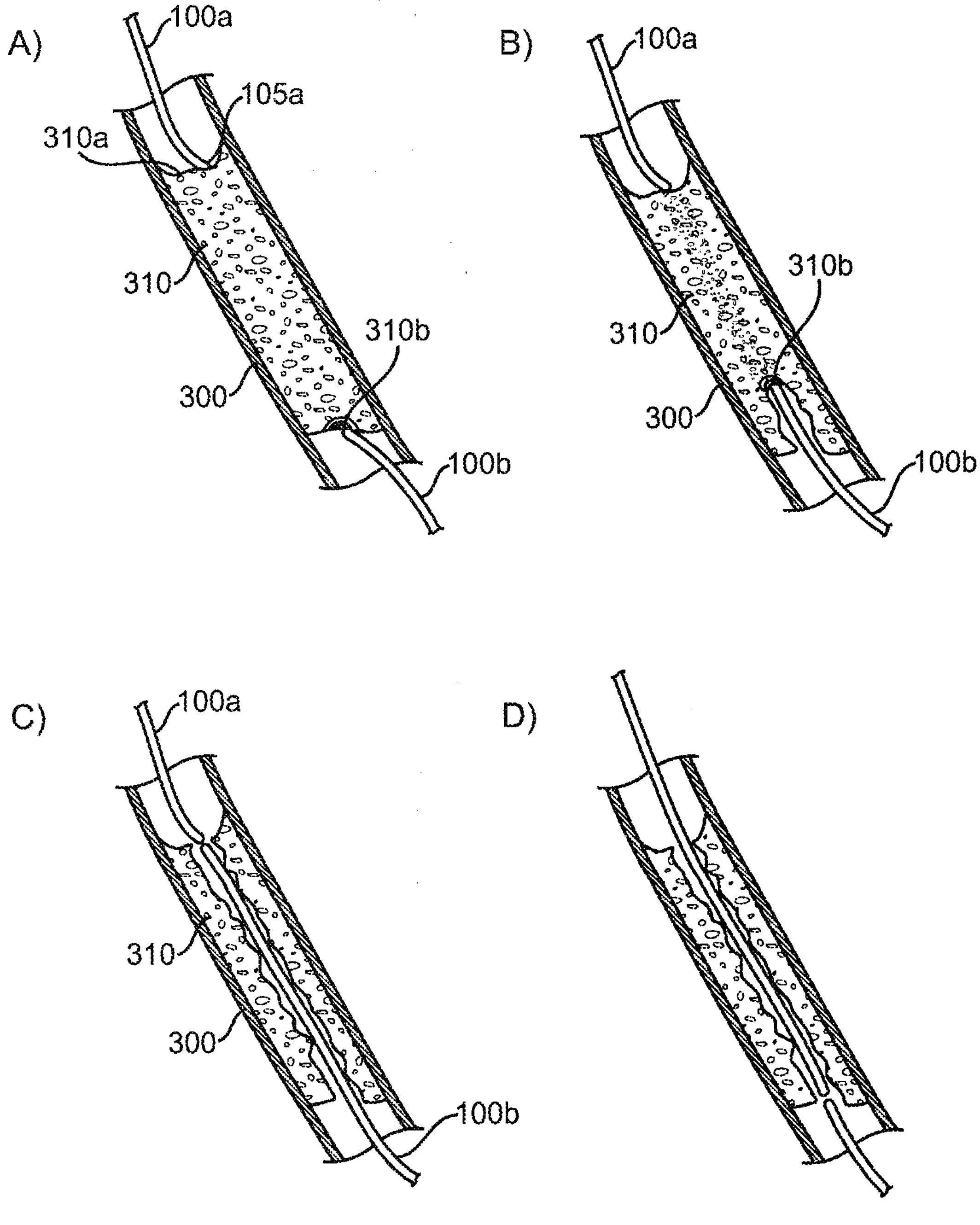
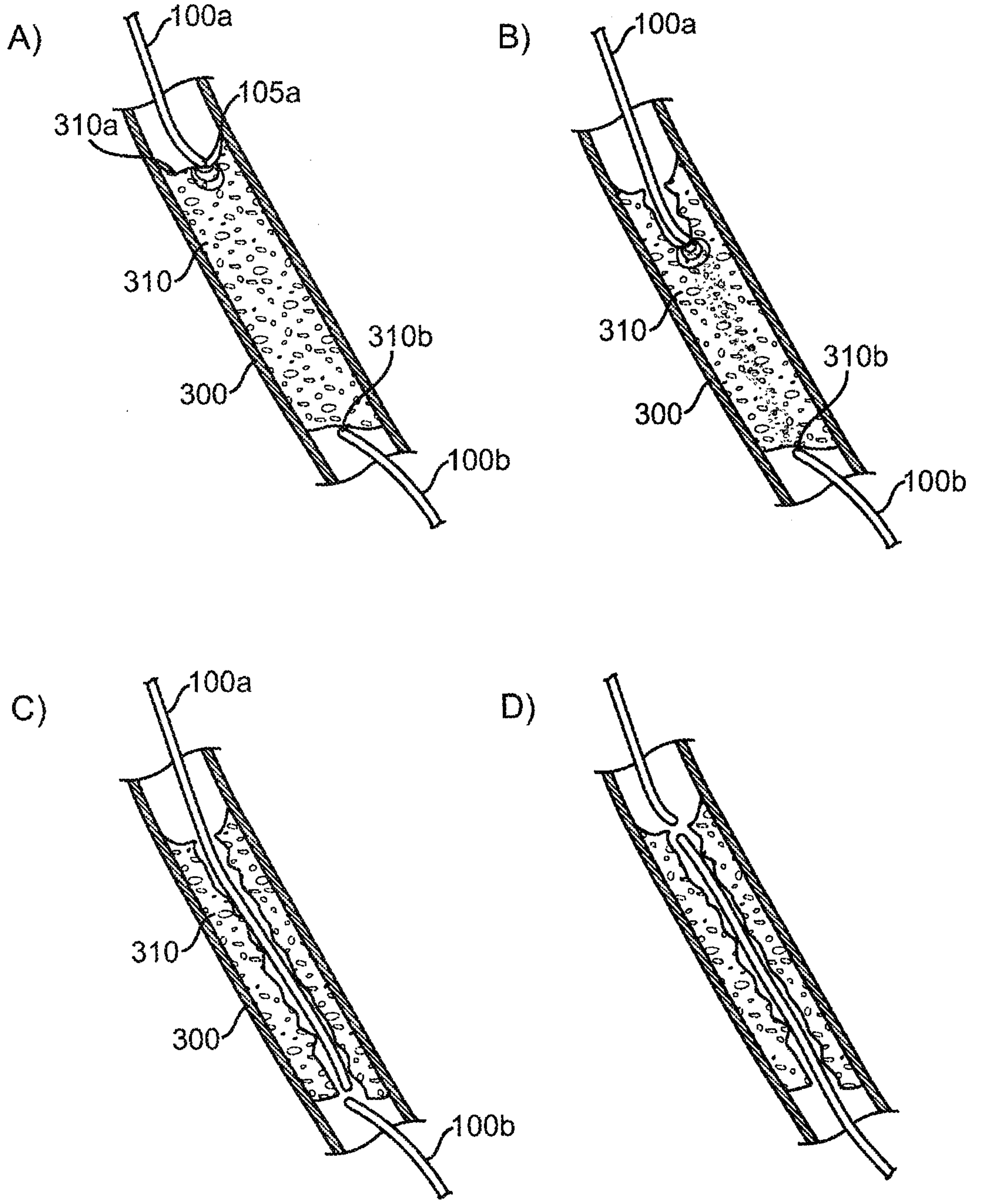

A)
100a
105a
310a
310
310b
300
100b
B)
100a
310b
310
300
100b
C)
100a
310
300
100b
D)

FIG. 3A


A)
100a
105a
310a
310
310b
300
100b
B)
100a
310
310b
300
100b
C)
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310
300
100b
D)

FIG. 3B

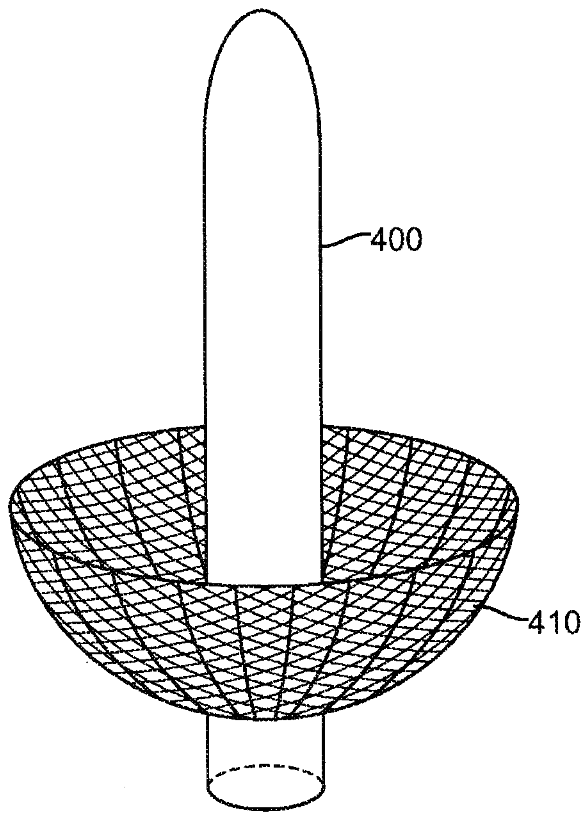


FIG. 4

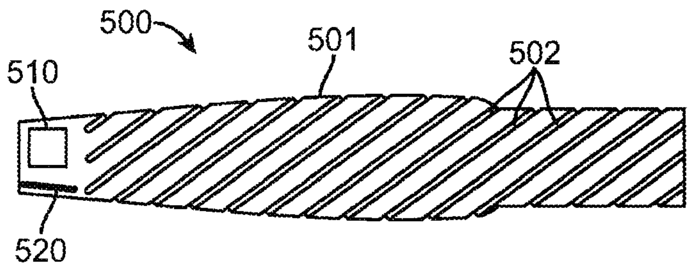


FIG. 5A

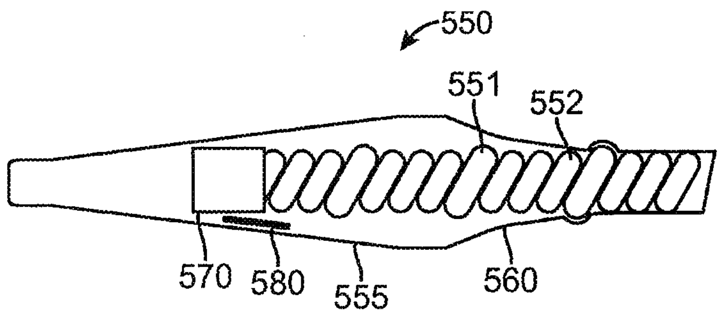


FIG. 5B

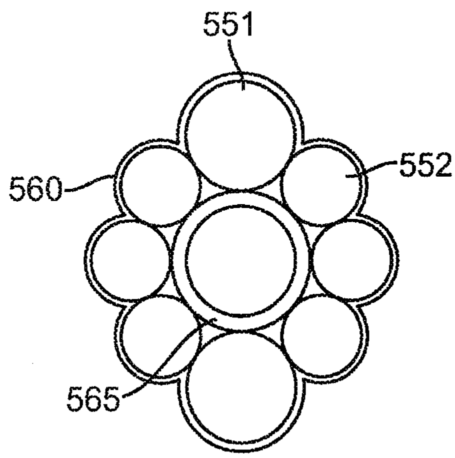
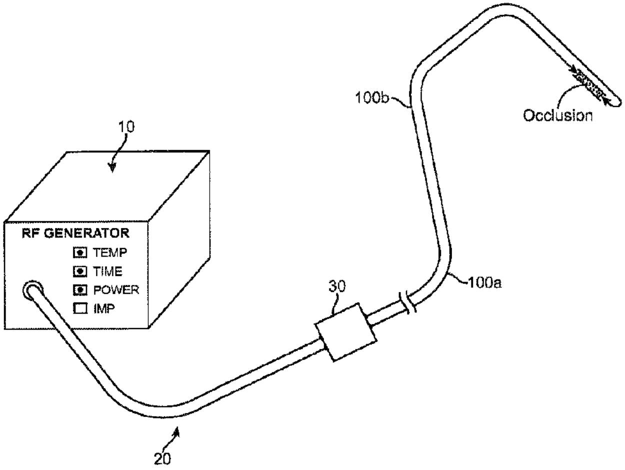


FIG. 5C


10
RF GENERATOR
TEMP
TIME
POWER
IMP
20
30
100a
100b
Occlusion