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- (54) **Title:** INTRAVASCULAR DEVICES, SYSTEMS, AND METHODS HAVING A RADIOPAQUE PATTERNED FLEXIBLE TIP

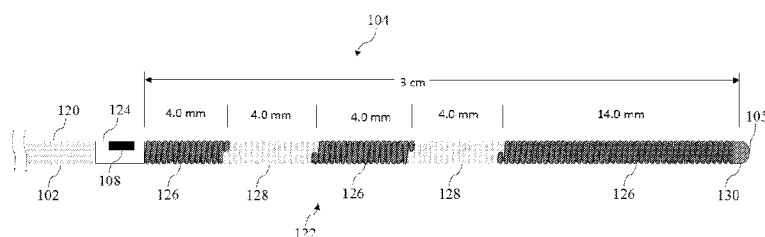


Fig. 2

- (57) **Abstract:** Intravascular devices, systems, and methods are disclosed. In some instances, the intravascular device is a guide wire (100) with distal tip element (104) having a radiopaque marker (126) pattern. For example, in some implementations a sensing guide wire includes a flexible elongate member (102); a sensing element (108) coupled to the flexible elongate member; a flexible tip element (104) coupled to and extending distally from the sensing element, the flexible tip element having a first radiopaque section (126), a second radiopaque section (126), and a non-radiopaque section (128) positioned between the first and second radiopaque sections. Methods of making, manufacturing, and/or assembling such intravascular devices and associated systems are also provided.



Intravascular devices, systems, and methods having a radiopaque patterned flexible tip

TECHNICAL FIELD

The present disclosure relates to intravascular devices, systems, and methods. In some embodiments, the intravascular devices are guide wires that include a distal tip element having a radiopaque marker pattern.

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BACKGROUND OF THE INVENTION

Heart disease is very serious and often requires emergency operations to save lives. A main cause of heart disease is the accumulation of plaque inside the blood vessels, which eventually occludes the blood vessels. Common treatment options available to open up the occluded vessel include balloon angioplasty, rotational atherectomy, and intravascular stents. Traditionally, surgeons have relied on X-ray fluoroscopic images that are planar images showing the external shape of the silhouette of the lumen of blood vessels to guide treatment. Unfortunately, with X-ray fluoroscopic images, there is a great deal of uncertainty about the exact extent and orientation of the stenosis responsible for the occlusion, making it difficult to find the exact location of the stenosis. In addition, though it is known that restenosis can occur at the same place, it is difficult to check the condition inside the vessels after surgery with X-ray.

A currently accepted technique for assessing the severity of a stenosis in a blood vessel, including ischemia causing lesions, is fractional flow reserve (FFR). FFR is a calculation of the ratio of a distal pressure measurement (taken on the distal side of the stenosis) relative to a proximal pressure measurement (taken on the proximal side of the stenosis). FFR provides an index of stenosis severity that allows determination as to whether the blockage limits blood flow within the vessel to an extent that treatment is required. The normal value of FFR in a healthy vessel is 1.00, while values less than about 0.80 are generally deemed significant and require treatment.

Often intravascular catheters and guide wires are utilized to measure the pressure within the blood vessel, visualize the inner lumen of the blood vessel, and/or otherwise obtain data related to the blood vessel. To date, guide wires containing pressure sensors, imaging elements, and/or other electronic, optical, or electro-optical components

have suffered from reduced performance characteristics compared to standard guide wires that do not contain such components. For example, the handling performance of previous guide wires containing electronic components have been hampered, in some instances, by the limited space available for the core wire after accounting for the space needed for the conductors or communication lines of the electronic component(s), the stiffness of the rigid housing containing the electronic component(s), and/or other limitations associated with providing the functionality of the electronic components in the limited space available within a guide wire.

Further, a problem with existing pressure and flow guide wires is that the coil(s) defining the distal tip of the device can be fragile and prone to unwanted bending or kinking. In that regard, the small diameter and high flexibility of the coil(s) limits the structural integrity that can be provided. Further, the rigid nature of the sensor housing adjacent to the coil(s) causes additional stress to be applied to the coil(s) during use, especially when traversing complex vasculature with many curves and turns. As a result, the handling and performance of the guide wires can be reduced because of the limitations of the coil(s). Further, in some implementations the tip coil is formed of a radiopaque material to allow the device to be identified during a procedure using fluoroscopy. However, a solid radiopaque tip coil provides little to no indication of the relative orientation of the device and, therefore, can make it difficult for the medical personnel and/or other medical processing systems to correlate the current location of the device with other information or images of the vessel.

Accordingly, there remains a need for intravascular devices, systems, and methods that include one or more electronic, optical, or electro-optical components and have improved visualization characteristics under fluoroscopy.

SUMMARY OF THE INVENTION

The present disclosure is directed to intravascular devices, systems, and methods that include a guide wire having a distal tip element having a radiopaque marker pattern.

In some implementations, a sensing guide wire is provided that includes a flexible elongate member; a sensing element coupled to the flexible elongate member; a flexible tip element coupled to and extending distally from the sensing element, the flexible tip element having a first radiopaque section, a second radiopaque section, and a non-radiopaque section positioned between the first and second radiopaque sections. The sensing

element is a pressure sensor in some instances. The guide wire can also include a flow sensor coupled to a distal end of the flexible tip element. The first radiopaque section can be positioned adjacent a sensor housing in which the sensing element is disposed. The first and second radiopaque sections can each be defined by a coil formed of a radiopaque material, such platinum, tungsten, gold, or other suitable material. Also, the non-radiopaque section can be defined by a coil formed of a non-radiopaque material, such as stainless steel or other suitable material. Each of the first and second radiopaque sections and the non-radiopaque section can have equal lengths. In some instances, the first and second radiopaque sections are welded to the non-radiopaque section. The flexible tip element can have an outer diameter of approximately 0.014", 0.018", 0.035", or other size. In some instances, the coils defining the flexible tip element have a pitch of approximately .00295" and/or are formed from a wire having an diameter of approximately 0.0026". The flexible tip element has a length of approximately 3 cm in some implementations, with the first and second radiopaque sections each having a length between 2 mm and 6 mm and the non-radiopaque section having a length between 2 mm and 12 mm.

In some implementations, a method of forming a sensing guide wire is provided that includes coupling a sensing element to a distal portion of a flexible elongate member; and coupling a flexible tip element to the sensing element such that the flexible tip element extends distally from the sensing element, the flexible tip element having a first radiopaque section, a second radiopaque section, and a non-radiopaque section positioned between the first and second radiopaque sections.

Additional aspects, features, and advantages of the present disclosure will become apparent from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

Illustrative embodiments of the present disclosure will be described with reference to the accompanying drawings, of which:

FIG. 1 is a diagrammatic, schematic side view of an intravascular device according to an embodiment of the present disclosure.

FIG. 2 is a diagrammatic, schematic side view of a distal portion of the intravascular device of Fig. 1 according to an embodiment of the present disclosure.

FIG. 3 is a diagrammatic, schematic side view of a connection of adjacent coil components according to an embodiment of the present disclosure.

FIG. 4 is a diagrammatic, schematic side view of a connection of adjacent coil components according to another embodiment of the present disclosure.

FIG. 5 is a fluoroscopic image of an intravascular device incorporating a radiopaque patterned tip coil according to an embodiment of the present disclosure.

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DETAILED DESCRIPTION OF THE EMBODIMENTS

For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It is nevertheless
10 understood that no limitation to the scope of the disclosure is intended. Any alterations and further modifications to the described devices, systems, and methods, and any further application of the principles of the present disclosure are fully contemplated and included within the present disclosure as would normally occur to one skilled in the art to which the disclosure relates. In particular, it is fully contemplated that the features, components, and/or
15 steps described with respect to one embodiment may be combined with the features, components, and/or steps described with respect to other embodiments of the present disclosure. For the sake of brevity, however, the numerous iterations of these combinations will not be described separately.

As used herein, “flexible elongate member” or “elongate flexible member”
20 includes at least any thin, long, flexible structure that can be inserted into the vasculature of a patient. While the illustrated embodiments of the “flexible elongate members” of the present disclosure have a cylindrical profile with a circular cross-sectional profile that defines an outer diameter of the flexible elongate member, in other instances all or a portion of the flexible elongate members may have other geometric cross-sectional profiles (*e.g.*, oval,
25 rectangular, square, elliptical, etc.) or non-geometric cross-sectional profiles. Flexible elongate members include, for example, guide wires and catheters. In that regard, catheters may or may not include a lumen extending along its length for receiving and/or guiding other instruments. If the catheter includes a lumen, the lumen may be centered or offset with respect to the cross-sectional profile of the device.

30 In most embodiments, the flexible elongate members of the present disclosure include one or more electronic, optical, or electro-optical components. For example, without limitation, a flexible elongate member may include one or more of the following types of components: a pressure sensor, a flow sensor, a temperature sensor, an imaging element, an optical fiber, an ultrasound transducer, a reflector, a mirror, a prism, an ablation element, an

RF electrode, a conductor, and/or combinations thereof. Generally, these components are configured to obtain data related to a vessel or other portion of the anatomy in which the flexible elongate member is disposed. Often the components are also configured to communicate the data to an external device for processing and/or display. In some aspects, 5 embodiments of the present disclosure include imaging devices for imaging within the lumen of a vessel, including both medical and non-medical applications. However, some embodiments of the present disclosure are particularly suited for use in the context of human vasculature. Imaging of the intravascular space, particularly the interior walls of human vasculature can be accomplished by a number of different techniques, including ultrasound 10 (often referred to as intravascular ultrasound ("IVUS") and intracardiac echocardiography ("ICE")) and optical coherence tomography ("OCT"). In other instances, infrared, thermal, or other imaging modalities are utilized.

The electronic, optical, and/or electro-optical components of the present disclosure are often disposed within a distal portion of the flexible elongate member. As used 15 herein, "distal portion" of the flexible elongate member includes any portion of the flexible elongate member from the mid-point to the distal tip. As flexible elongate members can be solid, some embodiments of the present disclosure will include a housing portion at the distal portion for receiving the electronic components. Such housing portions can be tubular structures attached to the distal portion of the elongate member. Some flexible elongate 20 members are tubular and have one or more lumens in which the electronic components can be positioned within the distal portion.

The electronic, optical, and/or electro-optical components and the associated communication lines are sized and shaped to allow for the diameter of the flexible elongate member to be very small. For example, the outside diameter of the elongate member, such as 25 a guide wire or catheter, containing one or more electronic, optical, and/or electro-optical components as described herein are between about 0.0007" (0.0178 mm) and about 0.118" (3.0 mm), with some particular embodiments having outer diameters of approximately 0.014" (0.3556 mm), approximately 0.018" (0.4572 mm), and approximately 0.035" (0.889 mm). As such, the flexible elongate members incorporating the electronic, optical, and/or electro- 30 optical component(s) of the present application are suitable for use in a wide variety of lumens within a human patient besides those that are part or immediately surround the heart, including veins and arteries of the extremities, renal arteries, blood vessels in and around the brain, and other lumens.

“Connected” and variations thereof as used herein includes direct connections, such as being glued or otherwise fastened directly to, on, within, etc. another element, as well as indirect connections where one or more elements are disposed between the connected elements.

5 “Secured” and variations thereof as used herein includes methods by which an element is directly secured to another element, such as being glued or otherwise fastened directly to, on, within, etc. another element, as well as indirect techniques of securing two elements together where one or more elements are disposed between the secured elements.

Referring now to Fig. 1, shown therein is a portion of an intravascular device
10 100 according to an embodiment of the present disclosure. In that regard, the intravascular device 100 includes a flexible elongate member 102 having a distal portion 104 adjacent a distal tip 105 and a proximal portion 106 adjacent a proximal end 107. A component 108 is positioned within the distal portion 104 of the flexible elongate member 102 proximal of the distal tip 105. Generally, the component 108 is representative of one or more electronic,
15 optical, or electro-optical components. In that regard, the component 108 is a pressure sensor, a flow sensor, a temperature sensor, an imaging element, an optical fiber, an ultrasound transducer, a reflector, a mirror, a prism, an ablation element, an RF electrode, a conductor, and/or combinations thereof. The specific type of component or combination of components can be selected based on an intended use of the intravascular device. In some instances, the
20 component 108 is positioned less than 10 cm, less than 5, or less than 3 cm from the distal tip 105. In some instances, the component 108 is positioned within a housing of the flexible elongate member 102. In that regard, the housing is a separate component secured to the flexible elongate member 102 in some instances. In other instances, the housing is integrally formed as a part of the flexible elongate member 102.

25 The intravascular device 100 also includes a connector 110 adjacent the proximal portion 106 of the device. In that regard, the connector 110 is spaced from the proximal end 107 of the flexible elongate member 102 by a distance 112. Generally, the distance 112 is between 0% and 50% of the total length of the flexible elongate member 102. While the total length of the flexible elongate member can be any length, in some
30 embodiments the total length is between about 1300 mm and about 4000 mm, with some specific embodiments have a length of 1400 mm, 1900 mm, and 3000 mm. Accordingly, in some instances the connector 110 is positioned at the proximal end 107. In other instances, the connector 110 is spaced from the proximal end 107. For example, in some instances the connector 110 is spaced from the proximal end 107 between about 0 mm and about 1400

mm. In some specific embodiments, the connector 110 is spaced from the proximal end by a distance of 0 mm, 300 mm, and 1400 mm.

The connector 110 is configured to facilitate communication between the intravascular device 100 and another device. More specifically, in some embodiments the connector 110 is configured to facilitate communication of data obtained by the component 108 to another device, such as a computing device or processor. Accordingly, in some embodiments the connector 110 is an electrical connector. In such instances, the connector 110 provides an electrical connection to one or more electrical conductors that extend along the length of the flexible elongate member 102 and are electrically coupled to the component 108. In some embodiments the electrical conductors are embedded within a core of the flexible elongate member. In other embodiments, the connector 110 is an optical connector. In such instances, the connector 110 provides an optical connection to one or more optical communication pathways (*e.g.*, fiber optic cable) that extend along the length of the flexible elongate member 102 and are optically coupled to the component 108. Similarly, in some embodiments the optical fibers are embedded within a core of the flexible elongate member. Further, in some embodiments the connector 110 provides both electrical and optical connections to both electrical conductor(s) and optical communication pathway(s) coupled to the component 108. In that regard, it should be noted that component 108 is comprised of a plurality of elements in some instances. The connector 110 is configured to provide a physical connection to another device, either directly or indirectly. In some instances, the connector 110 is configured to facilitate wireless communication between the intravascular device 100 and another device. Generally, any current or future developed wireless protocol(s) may be utilized. In yet other instances, the connector 110 facilitates both physical and wireless connection to another device.

As noted above, in some instances the connector 110 provides a connection between the component 108 of the intravascular device 100 and an external device. Accordingly, in some embodiments one or more electrical conductors, one or more optical pathways, and/or combinations thereof extend along the length of the flexible elongate member 102 between the connector 110 and the component 108 to facilitate communication between the connector 110 and the component 108. In some instances, at least one of the electrical conductors and/or optical pathways is embedded within the core of the flexible elongate member 102, as described in U.S. Provisional Patent Application No. 61/935,113, filed February 3, 2014, which is hereby incorporated by reference in its entirety. Generally, any number of electrical conductors, optical pathways, and/or combinations thereof can

extend along the length of the flexible elongate member 102 between the connector 110 and the component 108, embedded in the core or not. In some instances, between one and ten electrical conductors and/or optical pathways extend along the length of the flexible elongate member 102 between the connector 110 and the component 108. The number of communication pathways and the number of electrical conductors and optical pathways extending along the length of the flexible elongate member 102 is determined by the desired functionality of the component 108 and the corresponding elements that define component 108 to provide such functionality.

Referring now to Figs. 2-4, shown therein are aspects of the intravascular devices of the present disclosure that include a distal tip coil having a radiopaque marker pattern. Referring initially to Fig. 2, shown therein is a diagrammatic, schematic side view of the distal portion 104 of the intravascular device 100 according to an embodiment of the present disclosure. As shown, the distal portion 104 includes a proximal flexible element 120 and a distal flexible element 122 on each side of a housing 124 containing component 108. A proximal core member extends through the proximal flexible element 120. Similarly, a distal core member extends through the distal flexible element 122. In some implementations, the proximal and distal core members are an integral component (i.e., the proximal core member extends through the housing 124 to define core member 128). Generally, the core members are sized, shaped, and/or formed out of particular material(s) to create a desired mechanical performance for the distal portion 104 of the intravascular device 100. In that regard, in some instances the distal core member is coupled to a shaping ribbon. For example, in some particular implementations the distal core member is coupled to a shaping ribbon utilizing a multi-flat transition as described in U.S. Provisional Patent Application No. 62/027,556, filed July 22, 2014, which is hereby incorporated by reference in its entirety.

The proximal and distal flexible elements 120, 122 can include any suitable flexible element, including coils, polymer tubes, and/or coil-embedded polymer tubes. In the illustrated embodiment the proximal flexible element 120 is a coil and the distal flexible element 122 is defined by a series of alternating radiopaque coils 126 and non-radiopaque coils 128. In that regard, the non-radiopaque coils 128 are less radiopaque than coils 126 such that the coils 128 are readily distinguishable from the coils 126 under fluoroscopy or other imaging techniques. Fig. 5 illustrates an example of such imaging contrast between the coils 126 and the coils 128. Accordingly, it is understood that the coils 126 and the coils 128 are both radiopaque to varying degrees in order to create such identifiable contrast. As a result, the use of radiopaque and non-radiopaque in the present disclosure is understood to be an

indication of the relative radiopacity of the coils 126 and 128 to one another and not necessarily an indication of an absolute measurement of the radiopacity of the coils 126 and 128.

A solder ball 130 or other suitable element is secured to the distal end of the distal flexible element 122. As shown, the solder ball 130 defines the distal tip 105 of the intravascular device 100 with an atraumatic tip suitable for advancement through patient vessels, such as vasculature. In some embodiments, a flow sensor is positioned at the distal tip 105 instead of the solder ball 130.

The distal portion 104 of the intravascular device 100—as well as the proximal portion 106 and the flexible elongate member 102—may be formed using any suitable approach so long as the distal flexible element 122 defines a radiopaque marker pattern in accordance with the present disclosure. Accordingly, in some implementations the intravascular device 100 includes features similar to the distal, intermediate, and/or proximal sections described in one or more of U.S. Patent No. 5,125,137, U.S. Patent No. 5,873,835, U.S. Patent No. 6,106,476, U.S. Patent No. 6,551,250, U.S. Patent Application No. 13/931,052, filed June 28, 2013, U.S. Patent Application No. 14/135,117, filed December 19, 2013, U.S. Patent Application No. 14/137,364, filed December 20, 2013, U.S. Patent Application No. 14/139,543, filed December 23, 2013, U.S. Patent Application No. 14/143,304, filed December 30, 2013, and U.S. Provisional Patent Application No. 61/935,113, filed February 3, 2014, each of which is hereby incorporated by reference in its entirety.

As shown in Fig. 2, the radiopaque coils 126 form blocks of greater radiopacity or radiodensity with respect to the non-radiopaque coils 128. As such, the radiopaque coils 126 are recognizable in resulting x-ray, fluoroscopy, or other images. In that regard, the alternating pattern of radiopaque coils 126 and non-radiopaque coils 128 can be utilized to determine a relative orientation of the distal flexible element 122 and, thereby, the guide wire 100 within a vessel. To this end, essentially any pattern of radiopaque and non-radiopaque sections can be utilized. Depending on a particular use of the guide wire a different pattern or different size pattern may be desirable. In that regard, it is understood the radiopaque and non-radiopaque sections can have constant spacings, variable spacings, and/or combinations thereof. In some embodiments, each of the radiopaque sections has a length ranging from 1.0 mm to 20.0 mm, from 1.0 mm to 5.0 mm, from 2.0 mm to 4.0 mm, or otherwise. Similarly, each of the non-radiopaque sections can have a length ranging from 1.0 mm to 20.0 mm, from 1.0 mm to 5.0 mm, from 2.0 mm to 4.0 mm, or otherwise. In the

illustrated embodiment, the distal flexible element 122 has an overall length of approximately 3 cm that is defined by two 4 mm radiopaque coils 126, two 4 mm non-radiopaque coils 128, and one 14 mm radiopaque coil 126 extending distally from the sensor housing 124 in an alternating pattern, as shown.

5 In the illustrated embodiment, the radiopaque sections are defined by a stack of radiopaque coils 126 formed by and/or coated with a radiopaque material, while the non-radiopaque section are formed by a stack of non-radiopaque coils 128 formed by a non-radiopaque material (or at least a material less radiopaque than that forming the radiopaque sections). As shown in Figs. 3 and 4, the radiopaque coils 126 are coupled to the non-
10 radiopaque coils 128 at weld points 132. Fig. 3 shows an implementation where the ends of the coils 126 and 128 are abutted or at least placed in very close proximity and welded in place. Fig. 4 shows an implementation where the ends of the coils 126 and 128 are spaced apart from one another (e.g., by $1/16^{\text{th}}$ of a circumference of the coils or more) and welded in place. It is understood that additional welds beyond the particular welds 132 shown in Figs. 3
15 and 4 may be used to achieve and maintain a desired coil alignment and/or tensile. In this regard, the separate coils 126 and 128 can be assembled such that they perform similar to a coil wound as a single unit. It is recognized that any pattern of radiopaque and non-radiopaque sections is possible by choosing coils of desired lengths, though more markers require more welds. Further, such an approach provides a very distinct transition between the
20 radiopaque and non-radiopaque sections. Further still, this multi-section approach can be used for the distal tip of the intravascular device that extends distally from a sensing element. In that regard, the need for markers proximal to a sensing element, which are often not desired by physicians, can be eliminated while still providing sufficient marker data to allow co-registration of the location of the intravascular device and, in particular, the sensing
25 element.

Both the radiopaque and non-radiopaque coils 126 and 128 retain the ability to flex. As a result, the radiopaque sections may have greater lengths and resultant visibility in the images than traditional rigid, metallic marker bands without adversely affecting the flexibility of the intravascular device. Thus, the distal flexible element 122 remains capable
30 of curving/bending with the intravascular device 100 as it traverses through tortuous anatomy without causing the inadvertent kinking and/or trauma that can be caused by rigid marker bands.

In the illustrated embodiments, the radiopaque coils 126 and the non-radiopaque coils 128 have substantially similar outer diameters, pitches, and wire diameters.

For example, in one implementation of a 0.014" guide wire, the coils 126 and 128 each have an outer diameter of 0.0139" with a 0.00295" pitch using a 0.0026" diameter wire, with the radiopaque coils 126 being formed from a radiopaque material (e.g., platinum/tungsten, etc.) and the non-radiopaque coils 128 being formed from a less radiopaque material (e.g., 304V stainless steel, etc.). The outer diameter, pitch, and/or wire diameter can be selected to achieve desired mechanical properties of the intravascular device. For 0.014" outer diameter intravascular devices, the coils 126 and 128 can have outer diameters between .0130" and .0145", pitches between .0022" and .0044", and wire diameters between .0020" and .0040". For 0.018" outer diameter intravascular devices, the coils 126 and 128 can have outer diameters between .0170" and .0185", pitches between .0022" and .0044", and wire diameters between .0020" and .0040". For 0.035" outer diameter intravascular devices, the coils 126 and 128 can have outer diameters between .0260" and .0355", pitches between .0022 and .0066", and wire diameters between .0020" and .0060". In other embodiments, the radiopaque coils 126 and the non-radiopaque coils 128 may have different outer diameters, pitches, wire diameters, and/or other parameters.

The patterned radiopaque distal flexible element 122 allows co-registration of the location of the intravascular device 100 with other diagnostic techniques, such as external and internal imaging. For example, in some instances the patterned radiopaque distal flexible element 122 is utilized to define a pattern of radiopaque marker elements identifiable by an image processing system. For example, a repeating pattern of radiopaque marker sections with known spacings can be identified using image processing techniques. Benefits of utilizing such an approach include: pressure wires having this patterned tip will be pushed past the lesion of interest and not get in the way of stent markers and can be utilized to identify the exact location of the sensor based on the location of the sensor housing relative to the radiopaque marker pattern.

Referring now to Fig. 5, shown therein is a fluoroscopic image 140 of an intravascular device incorporating a patterned radiopaque distal flexible element according to an embodiment of the present disclosure. The image 140 shows the distinct contrast between the radiopaque coils 126 and the non-radiopaque coils 128 that allows the location and orientation of the device to be determined by the physician and/or other medical processing equipment.

Guide wires of the present disclosure can be connected to an instrument, such as a computing device (e.g. a laptop, desktop, or tablet computer) or a physiology monitor, that converts the signals received by the sensors into pressure and velocity readings. The

instrument can further calculate Coronary Flow Reserve (CFR), Fractional Flow Reserve (FFR), instant wavefree ratio (iFR), or other calculated measurements and provide the readings and calculations to a user via a user interface. In some embodiments, a user interacts with a visual interface to view images associated with the data obtained by the intravascular devices of the present disclosure. Input from a user (e.g., parameters or a selection) are received by a processor in an electronic device. The selection can be rendered into a visible display.

Persons skilled in the art will also recognize that the apparatus, systems, and methods described above can be modified in various ways. Accordingly, persons of ordinary skill in the art will appreciate that the embodiments encompassed by the present disclosure are not limited to the particular exemplary embodiments described above. In that regard, although illustrative embodiments have been shown and described, a wide range of modification, change, and substitution is contemplated in the foregoing disclosure. It is understood that such variations may be made to the foregoing without departing from the scope of the present disclosure. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the present disclosure.

CLAIMS:

1. A sensing guide wire, comprising:
a flexible elongate member;
a sensing element coupled to the flexible elongate member;
a flexible tip element coupled to and extending distally from the sensing
5 element, the flexible tip element having a first radiopaque section, a second radiopaque
section, and a non-radiopaque section positioned between the first and second radiopaque
sections.
2. The guide wire of claim 1, wherein the sensing element is a pressure sensor.
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3. The guide wire of claim 2, further comprising a flow sensor coupled to a distal
end of the flexible tip element.
4. The guide wire of claim 1, wherein the first radiopaque section is adjacent a
15 sensor housing in which the sensing element is disposed.
5. The guide wire of claim 1, wherein the first and second radiopaque sections
are each defined by a coil formed of a radiopaque material.
- 20 6. The guide wire of claim 5, wherein the radiopaque material is selected from
the group consisting of platinum, tungsten, and gold.
7. The guide wire of claim 5, wherein the non-radiopaque section is defined by a
coil formed of a non-radiopaque material.
25
8. The guide wire of claim 7, wherein the non-radiopaque material is selected
from the group consisting of stainless steel, MP35N, and nitinol alloys.

9. The guide wire of claim 7, wherein each of the first and second radiopaque sections and the non-radiopaque section having an equal length.

10. The guide wire of claim 7, wherein the first and second radiopaque sections
5 are welded to the non-radiopaque section.

11. The guide wire of claim 7, wherein the flexible tip element has an outer diameter of approximately 0.014", 0.018", or 0.035".

10 12. The guide wire of claim 11, wherein the coils have a pitch of approximately 0.0295".

13. The guide wire of claim 11, wherein the coils are formed from a wire having a diameter of approximately 0.0026".

15 14. The guide wire of claim 11, wherein the flexible tip element has a length of approximately 3 cm.

15. The guide wire of claim 14, wherein the first and second radiopaque sections
20 each have a length between 2 mm and 6 mm and the non-radiopaque section has a length between 2 mm and 12 mm.

16. A method of forming a sensing guide wire, the method comprising:
coupling a sensing element to a distal portion of a flexible elongate member;

25 and
coupling a flexible tip element to the sensing element such that the flexible tip element extends distally from the sensing element, the flexible tip element having a first radiopaque section, a second radiopaque section, and a non-radiopaque section positioned between the first and second radiopaque sections.

30 17. The method of claim 16, wherein the sensing element is a pressure sensor.

18. The method of claim 17, further comprising coupling a flow sensor to a distal end of the flexible tip element.

19. The method of claim 16, wherein coupling the flexible tip element to the sensing element includes positioning the first radiopaque section is adjacent a sensor housing in which the sensing element is disposed.

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20. The method of claim 16, wherein the first and second radiopaque sections are each defined by a coil formed of a radiopaque material.

21. The method of claim 20, wherein the radiopaque material is selected from the group consisting of platinum, tungsten, and gold.

10

22. The method of claim 20, wherein the non-radiopaque section is defined by a coil formed of a non-radiopaque material.

23. The method of claim 22, wherein the non-radiopaque material is selected from the group consisting of stainless steel, MP35N, and nitinol alloys.

15

24. The method of claim 22, wherein each of the first and second radiopaque sections and the non-radiopaque section having an equal length.

20

25. The method of claim 22, further comprising welding the first and second radiopaque sections to the non-radiopaque section.

26. The method of claim 22, wherein the flexible tip element has an outer diameter of approximately 0.014", 0.018", or 0.035".

25

27. The method of claim 26, wherein the coils have a pitch of approximately .00295".

28. The method of claim 26, wherein the coils are formed from a wire having a diameter of approximately 0.0026".

30

29. The method of claim 26, wherein the flexible tip element has a length of approximately 3 cm.

30. The method of claim 29, wherein the first and second radiopaque sections each have a length between 2 mm and 6 mm and the non-radiopaque section has a length between 2 mm and 12 mm.

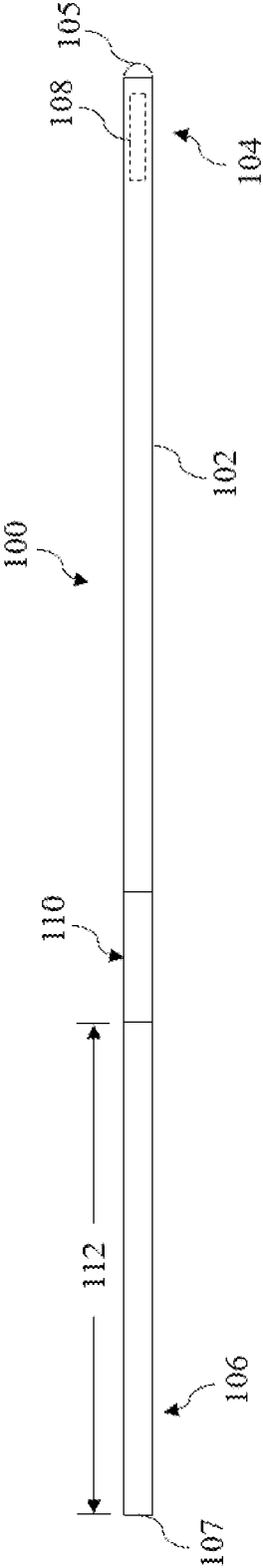


Fig. 1

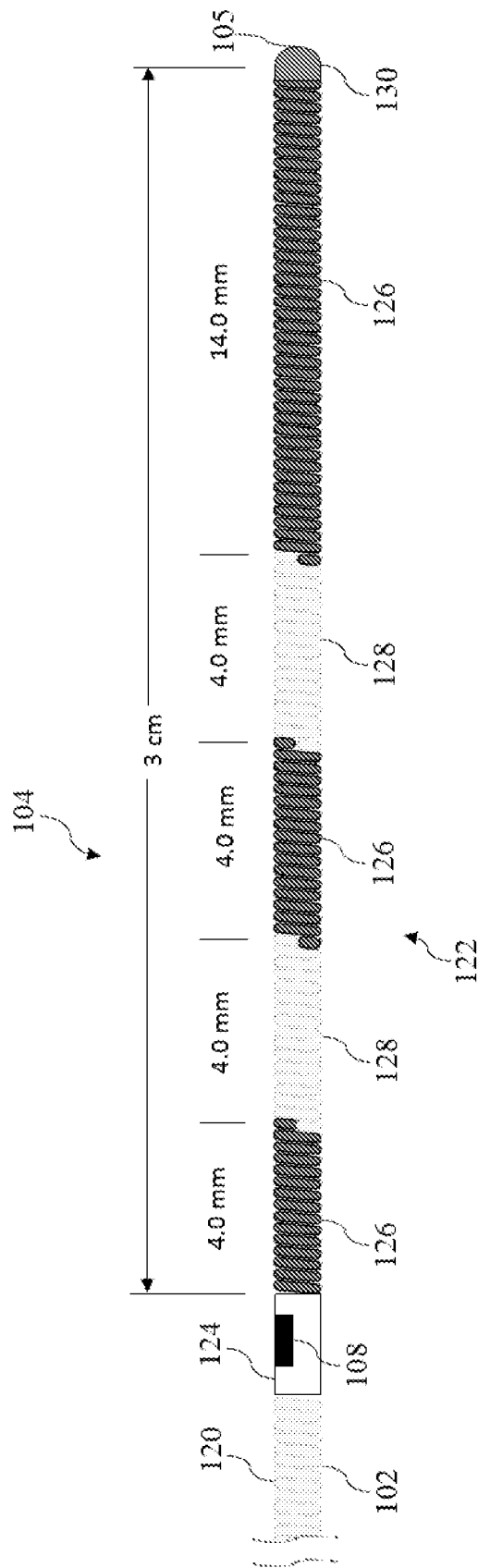


Fig. 2

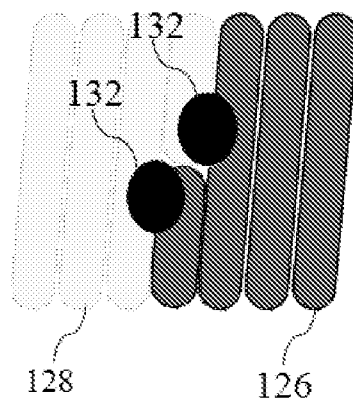


Fig. 3

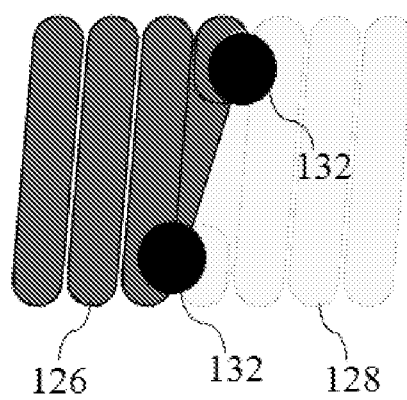


Fig. 4

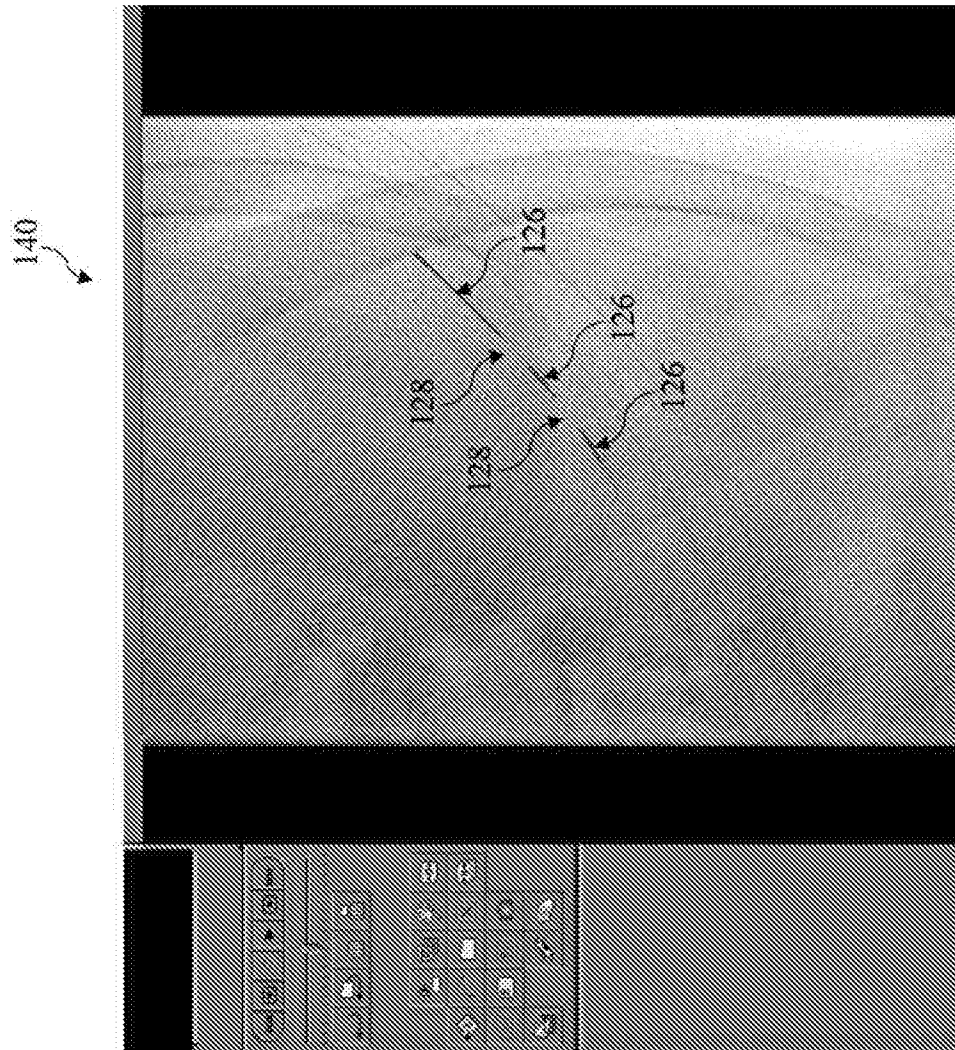


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2015/058457

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/00 A61B5/0215
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Y	----- US 2014/005543 A1 (BURKETT DAVID H [US]) 2 January 2014 (2014-01-02) paragraph [0065]; figure 6	1-30
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Further documents are listed in the continuation of Box C.



See patent family annex.

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

18 April 2016

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INTERNATIONAL SEARCH REPORT

International application No

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A	US 2005/065434 A1 (BAVARO VINCENT P [US] ET AL) 24 March 2005 (2005-03-24) paragraph [0042] -----	1-30
E	WO 2016/030804 A2 (KONINKL PHILIPS NV [NL]; VOLCANO CORP [US]) 3 March 2016 (2016-03-03) page 19, last paragraph; figure 2 -----	1-30

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