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Gibson et al.

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(54) **MEANS FOR SECURING A CATHETER INTO A VESSEL**

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(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 14/192,478, filed on Feb. 27, 2014, now Pat. No. 9,345,416, which is a continuation of application No. 13/186,192, filed on Jul. 19, 2011, now abandoned.

(60) Provisional application No. 61/386,281, filed on Sep. 24, 2010.

(51) **Int. Cl.**

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A61B 5/00	(2006.01)
A61M 25/04	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/042*** (2013.01); ***A61B 5/0422*** (2013.01); ***A61B 5/6853*** (2013.01); ***A61B 5/6858*** (2013.01); ***A61M 25/04*** (2013.01)

(58) **Field of Classification Search**

CPC A61B 5/042; A61B 5/0422

USPC 600/374

See application file for complete search history.

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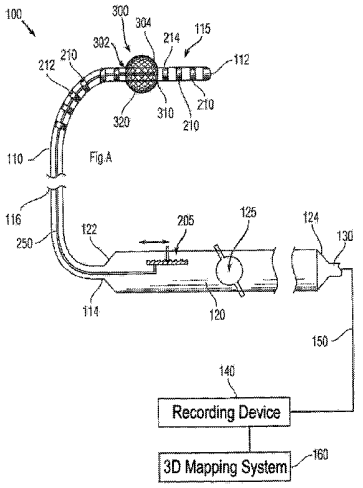
(57) **ABSTRACT**

An electrophysiology catheter, e.g., a coronary sinus catheter, for insertion into a cardiac vessel, such as the coronary sinus, includes a handle and a catheter shaft coupled at one end to the handle. The catheter shaft has a distal end and an anchor is associated with the catheter shaft and is movable between a deployed position and a collapsed position. In the deployed position, the anchor extends radially outward from an outer surface of the catheter shaft for contacting a wall and temporarily anchoring the catheter shaft within the coronary sinus. The catheter also includes an actuator for causing deployment and collapsing of the anchor upon manipulation of the actuator.

19 Claims, 10 Drawing Sheets



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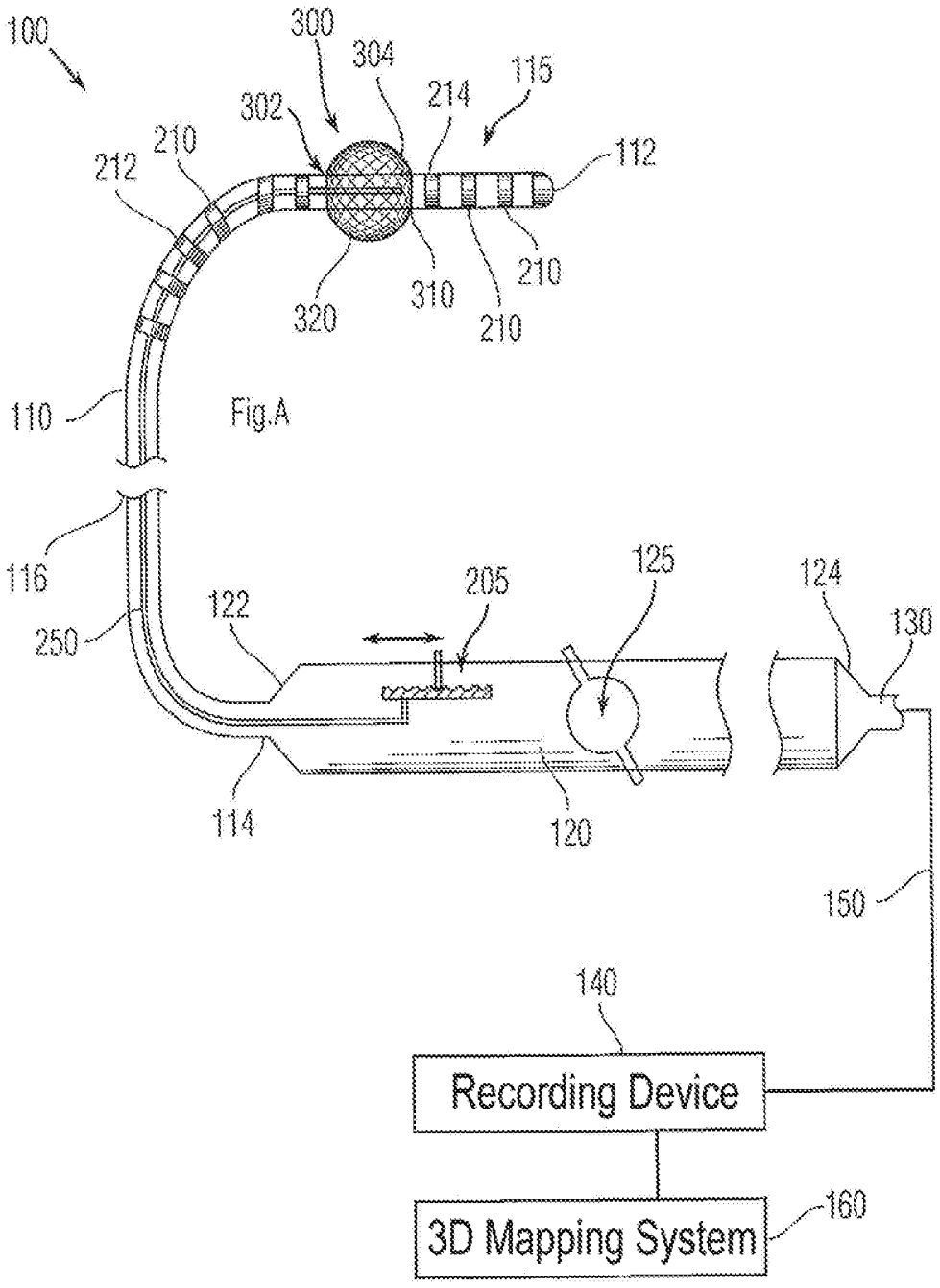

100
300
304
115
302
214
212
210
112
210
320
310
210
110
Fig.A
116
125
124
205
122
130
250
114
120
150
140
Recording Device
3D Mapping System
160

Fig. 1

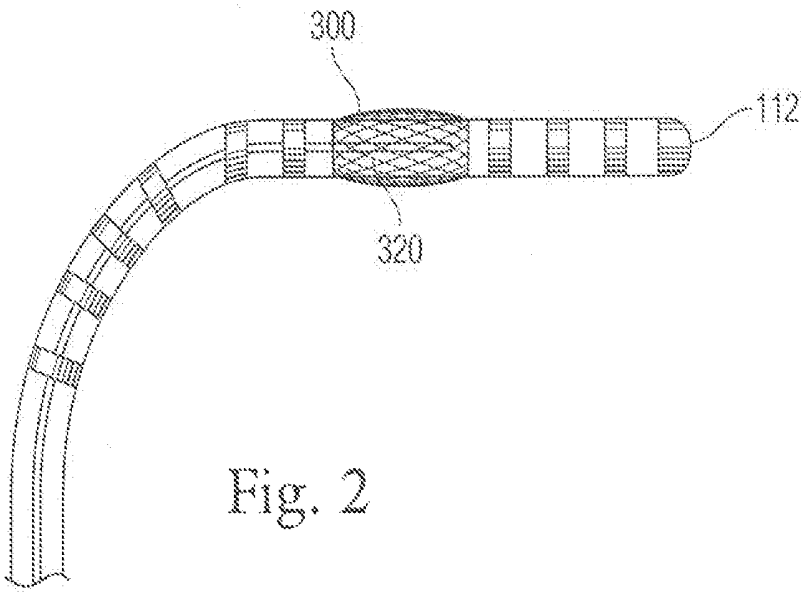


Fig. 2

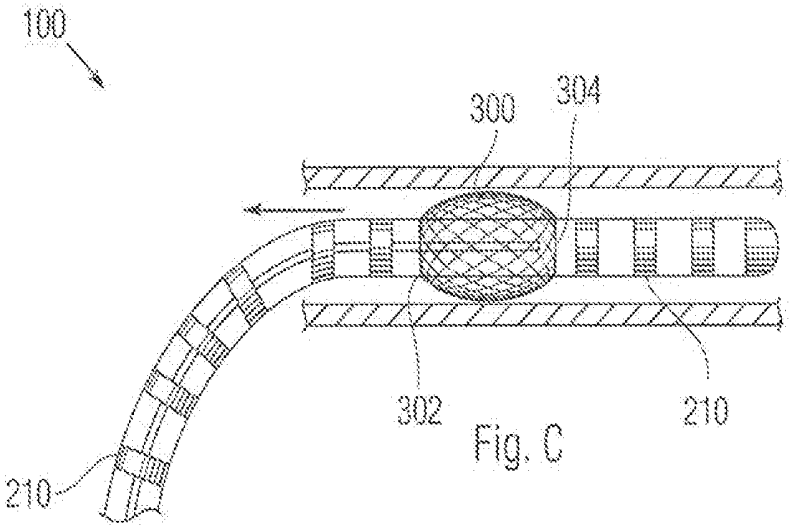


Fig. C

Fig. 3

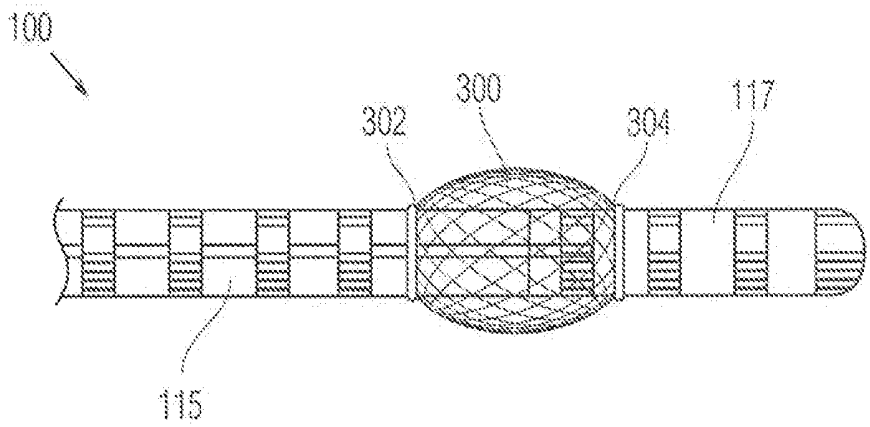


Fig. 4

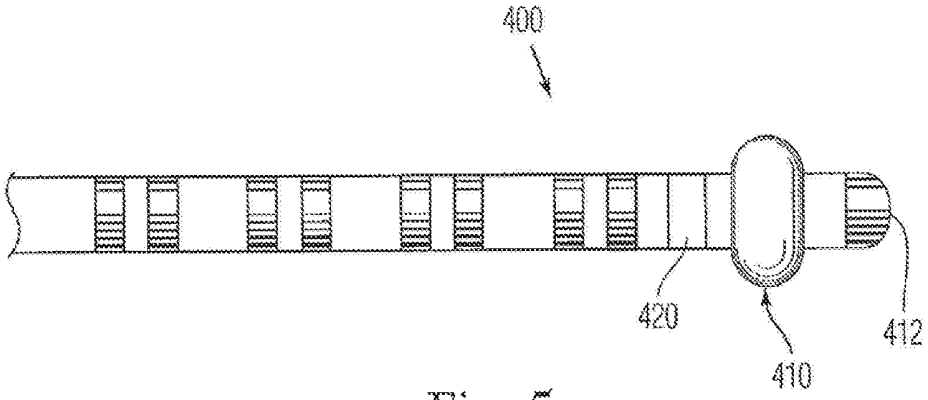
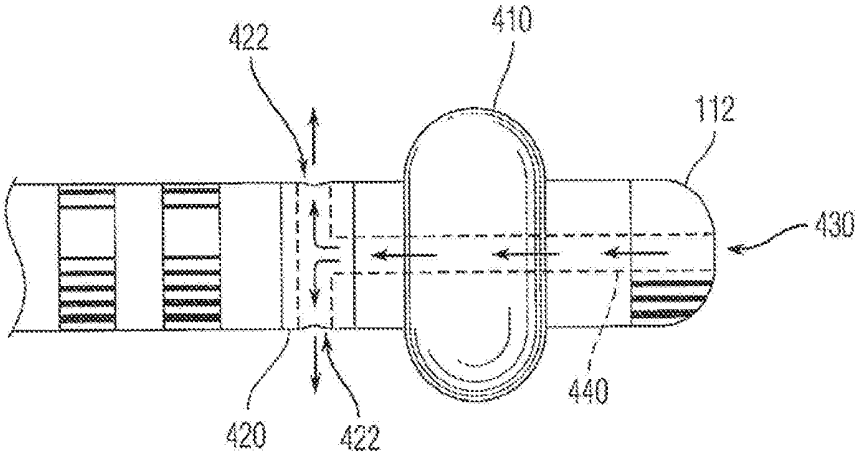


Fig. 5



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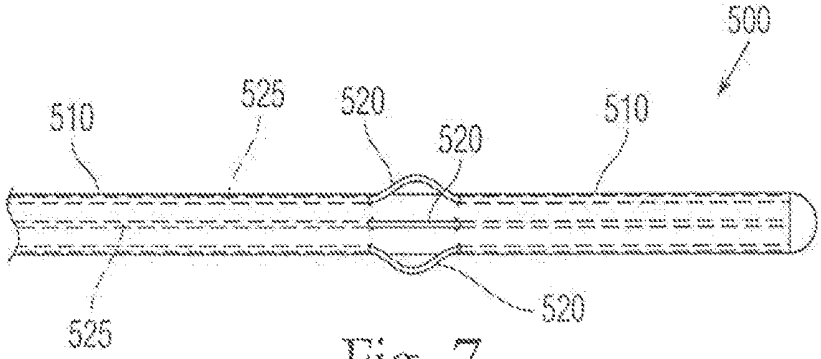


Fig. 7

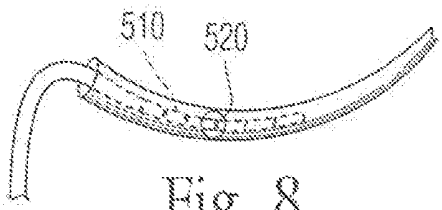


Fig. 8

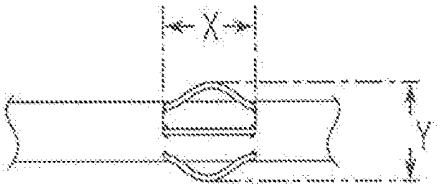


Fig. 10

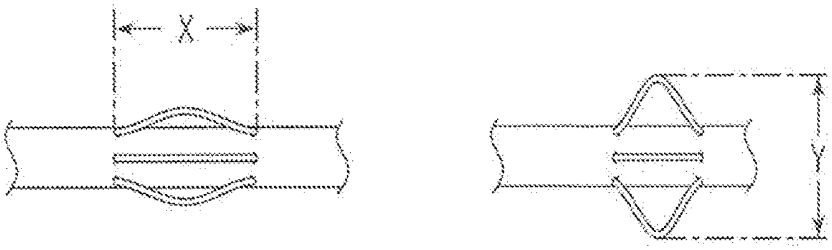
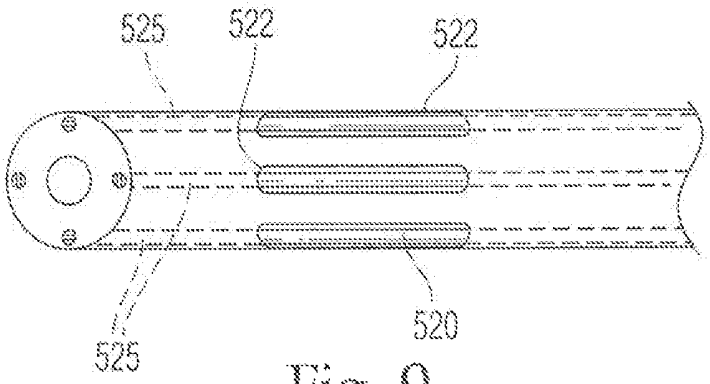


Fig. 11



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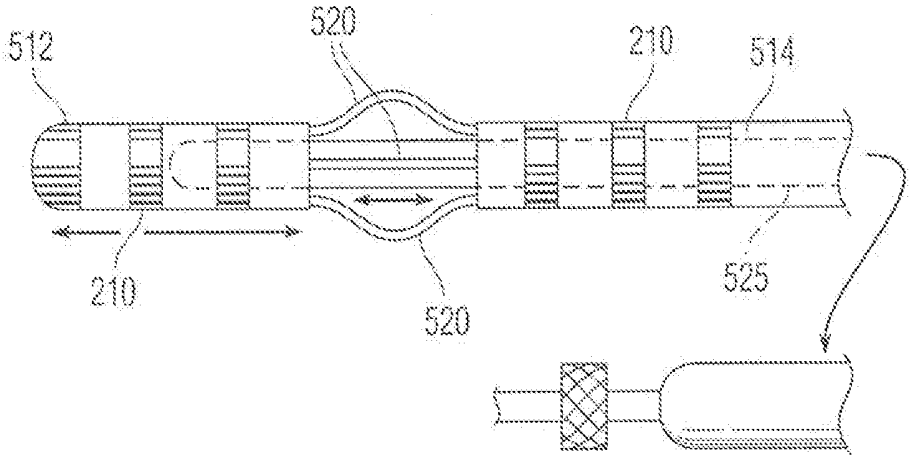


Fig. 12

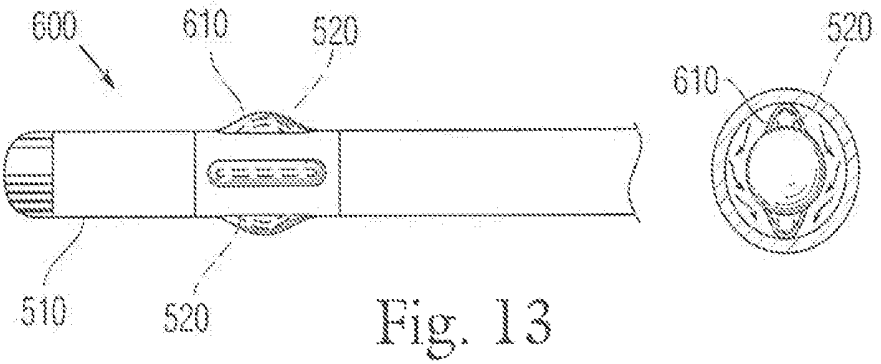


Fig. 13

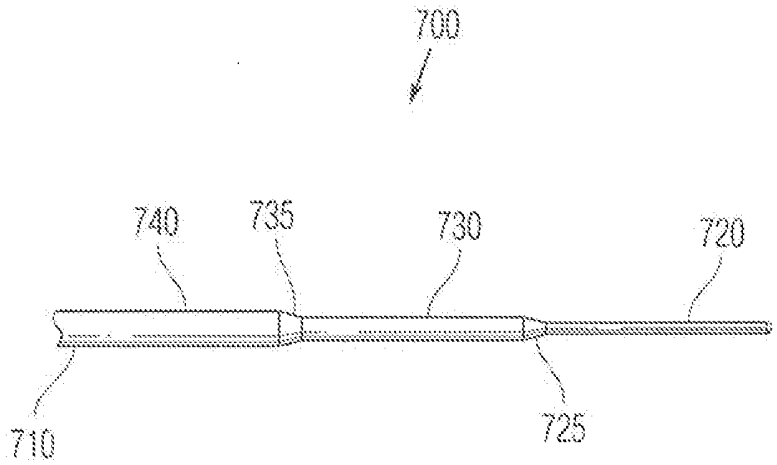


Fig. 14

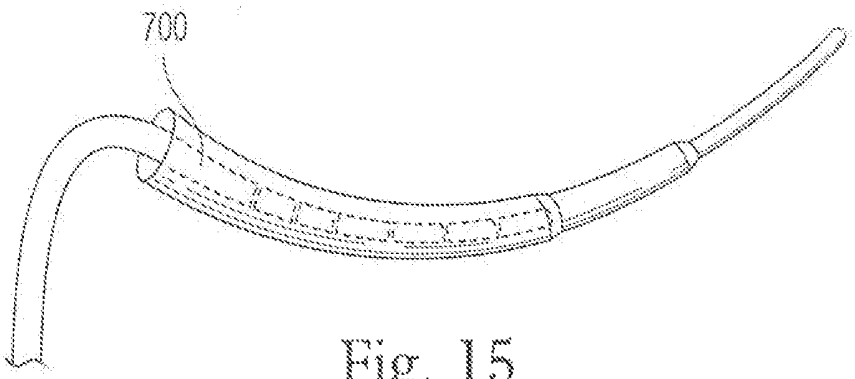


Fig. 15

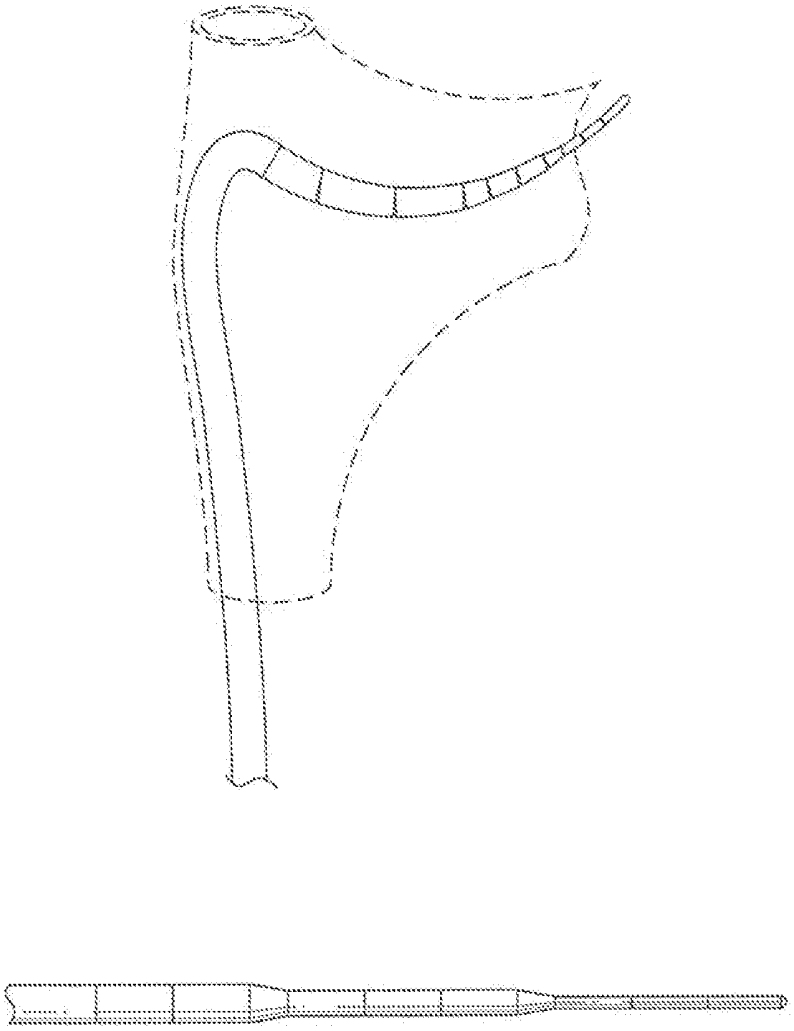


Fig. 16

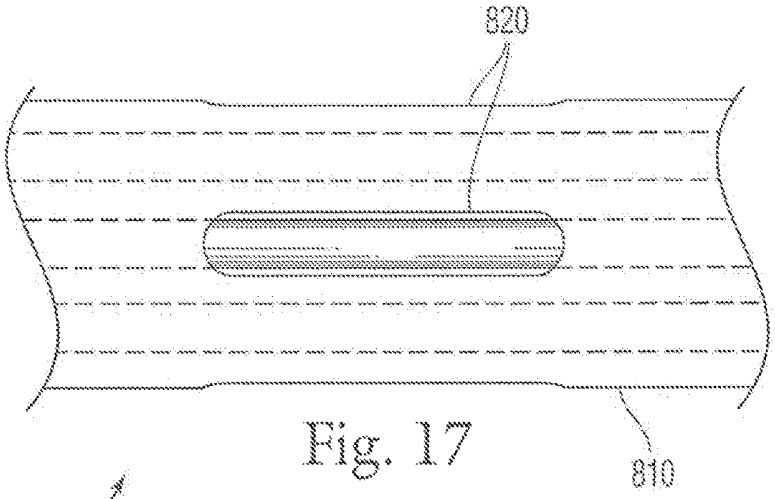
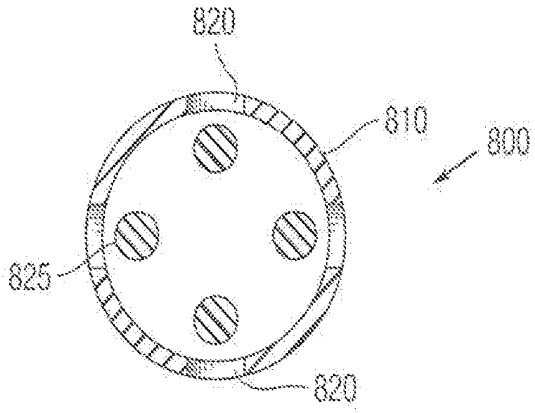


Fig. 17



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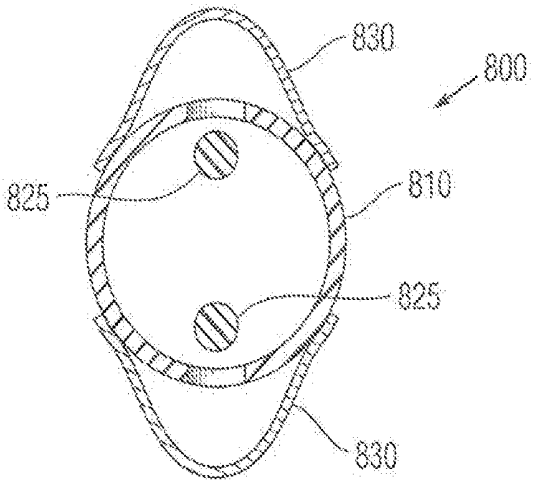

Fig. 19

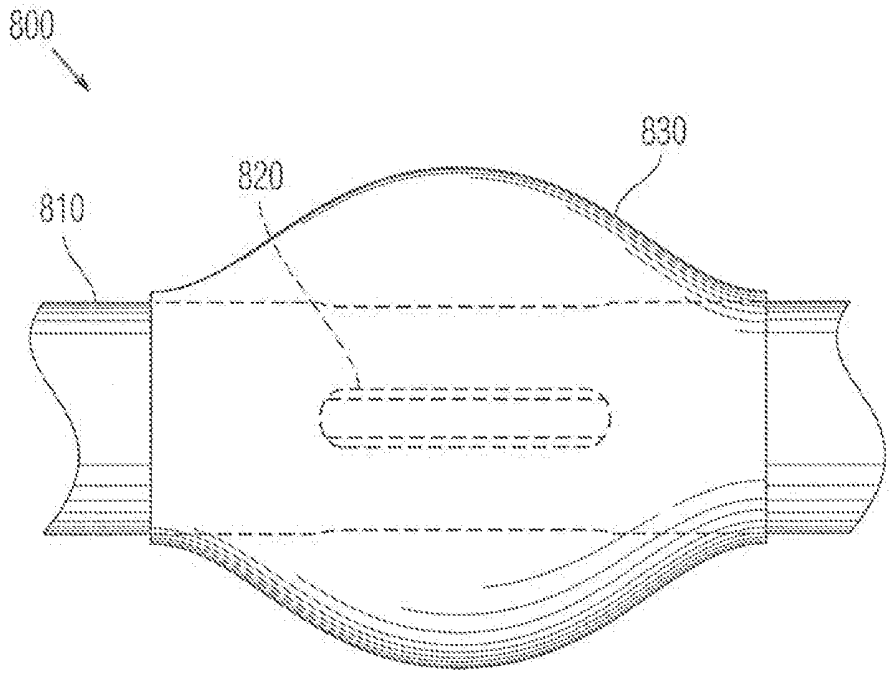

Fig. 20

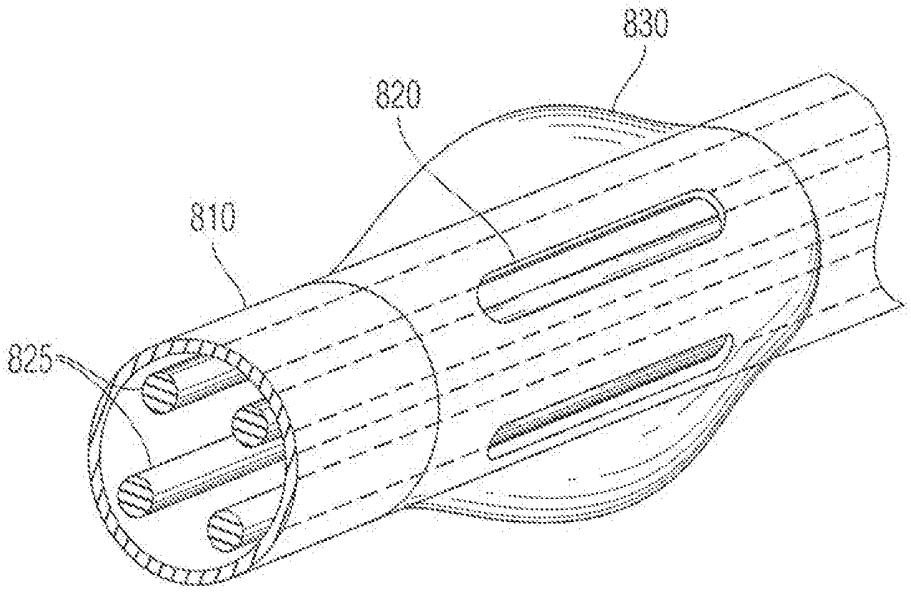

Fig. 21

MEANS FOR SECURING A CATHETER INTO A VESSEL

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. application Ser. No. 14/192,478, filed Feb. 27, 2014, now U.S. Pat. No. 9,345,416, which is a continuation of U.S. application Ser. No. 13/186,192, filed Jul. 19, 2011, now abandoned, which claims priority to Provisional Application No. 61/386,281, filed Sep. 24, 2010, all of which are herein incorporated by reference in their entirety

TECHNICAL FIELD

The present invention relates medical equipment, and in particular, to an electrophysiology catheter, such as a coronary sinus catheter, that includes an actuatable mechanism for anchoring the catheter at a desired location.

BACKGROUND

The human heart is a very complex organ, which relies on both muscle contraction and electrical impulses to function properly. The electrical impulses travel through the heart walls, first through the atria and then the ventricles, causing the corresponding muscle tissue in the atria and ventricles to contract. Thus, the atria contract first, followed by the ventricles. This order is essential for proper functioning of the heart. The coronary sinus is a collection of veins joined together to form a large vessel that collects blood from the myocardium of the heart. It delivers deoxygenated blood to the right atrium in conjunction with the superior and inferior vena cava. The coronary sinus opens into the right atrium, between the inferior vena cava and the auriculo-ventricular opening. It returns the blood from the heart, and is protected by a semicircular fold of the lining membrane of the auricle, the coronary valve.

An indwelling positioned coronary sinus catheter is used as a reference site for electrophysiology studies due to its tubular shape and anatomical positioning on the atrioventricular groove (AV) groove. Catheters are inserted into the coronary sinus ostium and advanced distally to provide both left sided (most distal) and right sided (most proximal) signals. Because the coronary sinus is located in the AV groove, the signals uniquely show both atrial and ventricular activity. The current state of the art CS catheter uses ten (10) poles for recording signals throughout the coronary sinus. Because these catheters are stationary they make a good choice for a timing reference when performing a mapping procedure while a second or third catheter is in the chambers of the heart. They are also used as location or position references with 3D mapping systems such as Velocity™, NAVX™ sold by St. Jude Medical or the CARTO XP and CARTO3 systems sold by BioSense-Webster division of Johnson and Johnson.

Unfortunately, current coronary sinus catheters suffer from a number of disadvantages and in particular, physicians have reported that the coronary sinus catheter can move during the electrophysiology procedure and, when it does, there will be a change in the reference signal. This creates inaccuracies in maps and makes comparisons from one map to another very difficult. There is therefore a need for an improved coronary sinus catheter that overcomes the disadvantages associated with the conventional coronary sinus catheter.

SUMMARY

According to one embodiment, an electrophysiology catheter, such as a coronary sinus catheter, for insertion into a cardiac vessel, such as a coronary sinus, includes a handle and a catheter shaft coupled at one end to the handle. The catheter shaft has a distal end and an anchor is associated with the catheter shaft and is movable between a deployed position and a collapsed position. In the deployed position, the anchor extends radially outward from an outer surface of the catheter shaft for contacting a wall and temporarily anchoring the catheter shaft within the coronary sinus. The catheter also includes an actuator for causing deployment and collapsing of the anchor upon manipulation of the actuator.

The anchor can be in the form of a wire mesh structure and the actuator is operatively coupled to the mesh using a mechanical attachment or link member. The link can be in the form of a flexible elongated mandrel that extends within the catheter shaft and is coupled at one end to the actuator and at an opposite end is connected to a slidable collar that is disposed about the outer surface of the catheter shaft. A proximal end of the wire mesh structure can be fixedly attached to the catheter shaft and a distal end of the wire mesh structure can be attached to a collar such that when the collar moves in a proximal direction, the distal end of the wire mesh structure moves in a proximal direction and the wire mesh structure is deployed by extending radially outward relative to the catheter shaft. Conversely, a distal end of the wire mesh structure can be fixedly attached to the catheter shaft and a proximal end of the wire mesh structure can be attached to the collar such that when the collar moves in a distal direction, the proximal end of the wire mesh structure moves in a distal direction and the wire mesh structure is deployed by extending radially outward relative to the catheter shaft.

The anchor can also be in the form of a plurality of splines that are disposed within an interior of the catheter shaft and project through openings formed in the catheter shaft when in the deployed position. Each spline is disposed within a lumen that is formed within the catheter shaft and the splines are operatively coupled to the actuator such that movement of the actuator is translated into the splines moving between the deployed position in which the splines extend through the openings and extend radially outward from the catheter shaft and the collapsed position in which the splines lie within the lumens.

In yet another embodiment, an electrophysiology catheter, such as a coronary sinus catheter for insertion into a cardiac vessel, such as a coronary sinus, includes a handle and a catheter shaft coupled at one end to the handle. The catheter shaft has a distal end and an inflatable balloon is disposed along an outer surface of the catheter shaft in a location proximal to the distal end. The balloon is inflatable between a deployed position and a collapsed position. In the deployed position, the balloon extends radially outward from the outer surface of the catheter shaft for contacting a wall and temporarily anchoring the catheter shaft within the coronary sinus. The catheter also includes an actuator for causing deployment and collapsing of the anchor upon manipulation of the actuator.

The catheter shaft has an entrance port formed at the distal end that forms an entrance into a conduit that passes within the shaft beneath the inflatable balloon and at least one exit port that is formed proximal to the balloon and in communication with the conduit such that the entrance port is formed on one side of the inflatable balloon and the exit port

is formed on the other side of the inflatable balloon. When the inflatable balloon is fully deployed, blood flows into the entrance port through the conduit and out the exit port. The balloon can be ovoid in shape in one implementation.

It will be appreciated that in the various embodiments disclosed herein, the anchoring mechanism does not occlude fluid (e.g., blood) flow within the vessel when the catheter is in the deployed position.

Various arrangements are disclosed that can be combined and still be within the scope of the present disclosure. These and other aspects, features and advantages shall be apparent from the accompanying Drawings and description of certain embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view of an electrophysiology catheter (e.g., a coronary sinus catheter) with an anchor mechanism according to a first exemplary embodiment of the present invention;

FIG. **2** is a local side view of a distal end of the catheter shaft of the catheter of FIG. **1** showing the anchor in a collapsed position;

FIG. **3** is a side view of the catheter of FIG. **1** within the coronary sinus with the anchor in a deployed position;

FIG. **4** is a side view of an electrophysiology catheter (e.g., a coronary sinus catheter) with an anchor mechanism according to a second exemplary embodiment of the present invention;

FIG. **5** is a side view of an electrophysiology catheter (e.g., a coronary sinus catheter) with an anchor mechanism according to a third exemplary embodiment of the present invention;

FIG. **6** is a local side view of the catheter shaft of the catheter of FIG. **5** showing blood flow when the distal anchor is deployed;

FIG. **7** is a side view of an electrophysiology catheter (e.g., a coronary sinus catheter) with an anchor mechanism according to a fourth exemplary embodiment of the present invention;

FIG. **8** is a side view of the catheter of FIG. **7** in the coronary sinus with the distal anchor deployed;

FIG. **9** is an end and side view of the catheter of FIG. **7** showing windows through which anchor elements are deployed;

FIG. **10** is side view showing the two dimensions of the anchor;

FIG. **11** shows methods of increasing the projection of the anchor elements;

FIG. **12** is a side view of an electrophysiology catheter (e.g., a coronary sinus catheter) with an anchor mechanism according to a fifth exemplary embodiment of the present invention;

FIG. **13** illustrates side and end views of an electrophysiology catheter (e.g., a coronary sinus catheter) catheter with an anchor mechanism according to a sixth exemplary embodiment of the present invention;

FIG. **14** is a side view of an electrophysiology catheter (e.g., a coronary sinus catheter) with a tapered shaft according to an exemplary embodiment of the present invention;

FIG. **15** is a side view of the catheter of FIG. **14** inserted into the coronary sinus;

FIG. **16** shows a tapered tipstock used in combination with a conventional proximal shaft;

FIG. **17** is a side view of an electrophysiology catheter (e.g., a coronary sinus catheter) with an anchor mechanism according to another embodiment of the present invention;

FIG. **18** is a cross-sectional view of an anchor mechanism in a collapsed state;

FIG. **19** is a cross-sectional view of an anchor mechanism in a deployed state;

FIG. **20** is side view of the anchor mechanism in the deployed state; and

FIG. **21** is a perspective view of the catheter of FIG. **18**.

DETAILED DESCRIPTION

In accordance with a first embodiment of the present invention, shown in FIGS. **1-3**, a coronary sinus (CS) catheter **100** is provided. The catheter **100** has a shaft portion **110**, a control handle **120** and a connector portion **130**. The catheter **100** is preferably part of a catheter system and when the catheter **100** is used in a mapping application, the catheter **100** can be operatively coupled to a recording device **140** via a cable **150** or the like. Signals coming from the catheter **100** can be processed and delivered to the recording device **140**. In addition, the catheter system can include and be connected to a 3D mapping system **160**.

It will also be understood that the catheter **100** can be part of a catheter system that can include an energy source that is operatively connected to the connector portion **130**, as by cable **150**, for selectively delivering energy to one more portions of the catheter. It will be appreciated that the energy source and the recording device **140** can be incorporated into a single unit.

As illustrated, the catheter shaft portion **110** includes a distal end **112** and an opposite proximal end **114** that joins the control handle **120**. The shaft portion **110** is a hollow structure that includes at least one lumen to allow routing of different members, such as wires, etc., along the length of the shaft portion **110**. The catheter shaft portion **110** includes an outer surface **116**. As shown in FIG. **1**, the distal end **112** includes a distal tip that can have a rounded shape.

Similarly, the control handle **120** includes a first end **122** and an opposing second end **124** with the first end **122** being the end of the control handle **120** that is joined to the shaft portion **110**. The second end **124** is the end that joins to the connector portion **130**. The control handle **120** can have any number of different shapes and is designed to be held by the operator during the procedure and further can provide accessible control features that permit control and/or operation of the catheter **100**.

For example, the catheter **100** can be a steerable device. For example, a distal tip portion **115** of the catheter shaft portion **110** can be deflected by a mechanism that is incorporated within the control handle **120**. The control handle **120** can include a rotatable thumbwheel and/or a slide actuator which can be used by a user to deflect the distal end of the catheter. In FIG. **1**, a steering mechanism is generally indicated at **125**. The thumbwheel (or any other suitable actuating device) is connected to one or more pull or push wires which extend through shaft portion **110** and are connected to the distal end of the catheter at an off-axis location, whereby tension applied to one or more of the pull wires causes the distal portion of the catheter to curve in a predetermined direction or directions. U.S. Pat. Nos. 5,383,852; 5,462,527 and 5,611,777, which are hereby incorporated by reference in their entirety, illustrate various embodiments of control handle that can be used for steering the catheter **100**.

The catheter **100** includes one or more electrodes and preferably includes a plurality of electrodes **210** that are disposed along the length of the shaft portion **110**. The electrodes **210** can be in the form of recording electrodes

when the catheter **100** is used as part of a mapping application. In the illustrated embodiment, the electrodes **210** are divided into two groups and in particular, the electrodes **210** are divided into a first set **212** of electrodes and a second set **214** of electrodes. The second set **214** of the electrodes are located in the distal tip portion **115** and one of the electrodes in the second set **214** is located at the distal end **112** (a tip electrode). The number of electrodes in the first set **212** can be the same or different than the number of electrodes in the second set **214**. When the catheter **100** is used in a mapping application, the electrodes **210** are operably connected to the recording device **140** and/or 3D mapping system **160**. As previously mentioned, it is also within the scope of the present invention that the catheter **100** can be used in an ablation application in which case the electrodes **210** are operatively connected to an energy source to allow energy to be delivered to selected electrodes. The electrodes **210** can be in the form of electrode bands.

In accordance with the present invention, the catheter **100** includes a mechanism for anchoring the shaft portion **110** in a desired location (coronary sinus) during the electrophysiology procedure by deployment of an anchor **300**. In particular, the mechanism is a user actuatable mechanism that causes the anchor **300** to be either deployed or to be collapsed (return the anchor to a normal operating position). The mechanism includes an actuator **205** that is accessible to the user and is designed so that upon manipulation of the actuator **205**, the anchor **300** is either moved to a deployed position or is withdrawn and moved to a collapsed position.

The actuator **205** is preferably disposed within the control handle **120**; however, other locations are possible for placement of the actuator **205**. It will also be appreciated that any number of different types of actuator designs can be used including a slide actuator, a thumbwheel, etc.

In the illustrated embodiment, the actuator **205** is a slide actuator that is slid linearly to cause the anchor **300** to change its position and in particular, to cause the anchor **300** to either deploy or to be placed back into a collapsed position. The slide actuator **205** is operatively coupled to the anchor **300** such that the sliding action of the actuator **205** is translated into a change in the position (condition) of the anchor **300** (e.g., anchor **300** deploys and radially expands so as to provide a structure that anchors the catheter **100** in place, or conversely, anchor **300** radially contracts and is returned to a collapsed state. FIG. **1** shows the anchor **300** in its deployed position and FIG. **2** shows the anchor **300** in its collapsed position.

Any number of different techniques and mechanisms can be used to mechanically couple the actuator **205** to the anchor **300** to cause a translation of the movement of the actuator **205** into the desired radial expansion and radial contraction of the anchor **300**. In one embodiment, a mechanical attachment member or link member in the form of a mandrel **250** is coupled to both the anchor **300** and the actuator **205** and is constructed so that it can withstand the normal movements of the catheter **100** including the selected bending of a portion of the catheter shaft **110**. For example, the anchor **300** can have a proximal end **302** and an opposing distal end **304** that is closer to the distal end **112** of the catheter shaft **110**. The proximal end **302** of the anchor **300** is fixed relative to the catheter shaft **110**, while the distal end **304** is an adjustable end in that it can move relative to the catheter shaft **110** or vice versa.

Any number of different members can be used to couple the mandrel **250** to the distal end **304** of the anchor **300** to allow controlled movement of the distal end **304** both relative to the catheter shaft **110** and the proximal end **302**. For example, a coupling member **310**, such as a slide ring or collar can be used and disposed about the outer surface of the catheter shaft **110**. The coupling member **310** is movable relative to the catheter shaft **110** and is coupled to the distal end **304** of the anchor **300** such that movement of the coupling member **310** (due to movement of the mandrel **250**) is translated into movement of the anchor **300** in the desired direction.

The coupling member **310** can even travel in one or more channels formed in the outer surface of the catheter shaft **110** to control the movement of the coupling member **310**. For example, a pin and groove mechanism can be employed between the coupling member **310** and the catheter shaft **110**.

The mandrel **250** can be constructed using methods that are identical or similar to those previously disclosed by the current assignee for a mesh or sliding electrode catheter. For example, see U.S. Pat. No. 7,727,229 and U.S. patent application publication No. 2007/0129717, each of which is hereby incorporated by reference in its entirety. The mandrel **250** can thus be an elongate structure that has one end that is coupled to the coupling member **310** and another end that is coupled to the actuator **205**. Alternatively, the catheter shaft **110** can include a dedicated lumen formed therein along at least a length thereof for containing the mandrel **250**. In this manner, the mandrel **250** can be both mechanically and electrically isolated from the recording wires and other electrical components that are in communication with the electrodes **210**.

In yet another embodiment, the mandrel **250** can be used intentionally as a conductor to carry electrical signals from selected areas of the anchor **300** which in this case can function as a recording electrode. It will further be appreciated that separate electrical wires can be routed to select sections (e.g., wires) of the anchor **300** (e.g., a wire mesh) to facilitate recording signals.

In the illustrated embodiment, the anchor **300** is located between the first set of electrodes **212** and the second set of electrodes **214**; however, this is merely one exemplary location for the anchor **300** and the anchor **300** can thus be located anywhere along the catheter shaft **110** that allows the anchor **300** to perform the intended function. Typically, the anchor **300** will be located adjacent or proximate electrodes since anchoring of the catheter shaft **110** is desirable in the region where electrodes are present to permit the electrodes to perform their intended function. In the case of a coronary sinus catheter, the electrodes are recording electrodes. However, in other catheter designs, the electrodes **210** can be constructed specially as mapping or ablation electrodes. Depending upon the application, electrodes **210** are optimally placed relative to the location of the anchor **300** and typically, as previously mentioned, electrodes are located both proximal and distal to the anchor **300**.

The anchor **300** can take any number of different forms so long as the structure can be deployed and collapsed relative to the catheter shaft and permits conventional catheter functions and operations to be performed. In particular, since the anchor **300** is designed to hold the catheter shaft **110** in placed within a vessel (e.g., coronary sinus), the anchor arrangement cannot obstruct fluid flow (e.g., blood flow) within the vessel. In one embodiment, the anchor **300** is in the form of a mesh structure, such as a braided mesh structure, that is disposed about the outer surface of the catheter shaft **110** and can be moved between both collapsed and deployed positions, as previously described. It will also be appreciated that the anchor **300** can be locked in positions that are between the fully collapsed position and the fully

deployed position. The anchor **300** can thus be in the form of a plurality of interlaced filaments **320**, such as wires that form a braided wire mesh. The filaments are flexible and capable of being expanded radially outwardly from catheter shaft **110**. The filaments **320** can be formed of metallic elements having relatively small cross sectional diameters, such that the filaments can be expanded radially outwardly. The filaments may be round, having a dimension on the order of about 0.001-0.030 inches in diameter. Alternatively, the filaments may be flat, having a thickness on the order of about 0.001-0.030 inches, and a width on the order of about 0.001-0.030 inches. The filaments can be formed of Nitinol type wire. Alternatively, the filaments may include non-metallic elements, or non-metallic elements woven with metallic elements, with the non-metallic elements providing support to or separation of the metallic elements. A multiplicity of individual filaments **320** can be provided in braided mesh structure **300**, for example up to 300 or more filaments **320**. It will be appreciated that the aforementioned dimensions and description is merely exemplary for a mesh structure according to one embodiment and other structures and other dimensions are equally possible so long as the intended catheter functions and operations can be performed.

As mentioned herein, in some embodiments, the anchor **300** can be formed of wire filaments (wires) and the filaments **320** can be electrically isolated from each other by an insulation coating. This insulation coating may be, for example, a polyimide type material. A portion of the insulation on the outer circumferential surface of the braided conductive member is removed. This allows each of the filaments to facilitate recording signals. Alternatively, specific filaments **320** can be permitted to contact each other to form a preselected grouping of filaments **320**.

Each of the filaments **320** can be helically wound under compression about the catheter shaft **110**. As a result of this helical construction, select movement of the anchor **300** causes radial expansion of the anchor **300** and in particular, the radial expansion of the portions of filaments **320** that results in the deployment of the anchor **300**.

As mentioned herein, proximal end **302** of the braided wire mesh **300** can be fixed relative to the catheter shaft **110** while the distal end **304** of the braided wire mesh **300** is attached to the sliding coupling member **310**. When the coupling member **310** is moved in a proximal direction, the distal end **304** of the wire mesh **300** is drawn towards the proximal end **302** and this results in a radial expansion of the wire mesh **300**. The coupling member **310** is moved proximally due to proximal movement of the mandrel **250** within the catheter shaft **110**. (The converse arrangement can have the mesh expand by moving the coupling member in a distal direction).

When the anchor **300** is positioned between two sets of electrodes, the sets of electrodes are placed to allow for movement of the anchor **300** between the collapsed and deployed positions. In the collapsed position, the distal end **304** of the anchor **300** is closest to the more distally located electrodes (e.g., the second set **214** of electrodes) and when the anchor **300** is deployed, the spacing between the distal end **304** of the anchor **300** and the electrode set is greater. The wire mesh structure of the anchor **300** permits fluid to flow therethrough and thus, when the catheter **100** is placed in a vessel (e.g., the coronary sinus), fluid (e.g., blood) can flow through the wire mesh and its flow is not obstructed as it flows about the catheter **100**.

Now referring to FIGS. **1-3**, a method of using the catheter **100** as a coronary sinus catheter and for advancing the catheter **100** within the coronary sinus are described. The catheter **100** is advanced by inserting the distal end **112** of the catheter shaft **110** into the coronary sinus (vessel) while the anchor **300** is in the collapsed position as shown in FIG. **2**. Once the catheter **100** is in an optimal location within the coronary sinus, the anchor **300** is deployed by manipulating the actuator **205** to cause the mandrel **250** to move in a proximal direction, thereby causing the coupling member **310** to likewise move in a proximal direction. This movement of the mandrel **250** and the coupling member **310** is directly translated into the radial expansion of the anchor **300**. FIG. **3** shows the anchor **300** in a deployed position within the coronary sinus.

As discussed herein, the anchor **300** is designed to locate and hold the catheter **100** in its desired location within the coronary sinus by applying outward radial pressure to the vessel wall. Blood flows past the deployed wire mesh **300** due to its open wire construction. The deployment mechanism can be reversed in the design to optimize contact and safe deployment and collapse.

This can be achieved by reversing the anchor point from the proximal end **302** to the distal end **304** and attaching the mandrel actuation mechanism to the proximal end **302**. In this configuration, a push on the mandrel **250** deploys the wire mesh **300** (anchor) and collapse the wire mesh **300** against the catheter shaft **110**.

The actuator **205** also preferably includes a lock mechanism that permits the actuator **205** to be locked in place and prevent inadvertent movement of the anchor **300**. For example, when the anchor **300** is fully deployed to position and retain the catheter **100** in its desired position, the actuator **205** can be locked to prevent inadvertent movement of the catheter **100** due to a change in the deployment status of the anchor **300**. Similarly, the actuator **205** can be placed into a locked position when the anchor **300** is not deployed (collapsed state).

In one other embodiment, the catheter shaft **110** can be constructed such that when the coupling member **310** is moved to cause the radial expansion of the anchor **300**, an electrode (e.g., a ring electrode, etc.) is exposed.

In yet another embodiment that is illustrated in FIG. **4**, a telescoping catheter shaft design can be used for deploying and collapsing the anchor **300**. In this embodiment, the catheter shaft **110** includes a first main section **115** and a second sliding section **117** that is coupled to the main section **115** and slidable relative thereto. The second sliding section **117** represents the distal end section of the catheter **100** and is disposed relative to the main section **115** so that the sliding section **117** can be moved relative to the main section **115** in both proximal and distal directions. In FIG. **4**, the sliding section **117** is disposed about a portion of the outer surface of the main section **115**. The sliding section **117** is coupled to the mandrel **250** (not shown) so that movement of the mandrel **250** in the proximal and distal directions is translated into proximal and distal movement of the sliding section **117**.

The proximal end **302** of the anchor **300** (e.g., a wire mesh) is fixedly attached to the first main section **115** of the catheter shaft **110**, while the distal end **304** of the anchor **300** is fixedly attached to the sliding section **117**. When the sliding catheter section **117** is moved in a proximal direction, the anchor **300** is deployed (expands radially outward). Conversely, when the sliding catheter section **117** is moved in a distal direction, the anchor **300** is collapsed due to the flattening out of the anchor **300** along the catheter shaft **110**.

In this embodiment, the catheter shaft **110** is thus formed of two sections with one movable relative to the other one to cause a change in the position of the anchor **300**.

Now referring to FIGS. **5** and **6**, another mechanism for temporarily anchoring or fixing a catheter **400** within a vessel, such as a coronary sinus, is shown. The catheter **400** is similar to catheter **100** and therefore like elements are numbered alike. The catheter shaft **100** includes a distal tip at the distal end **112**. The distal tip can be in the form of a recording electrode or the distal tip can be free of a recording electrode. Proximal to the distal tip **112** is an anchor in the form of an inflatable balloon **410**, such as an inflation balloon, that can be inflated so as to extend radially outward from the catheter shaft **110**. As described herein the inflation balloon **410** can have any number of different shapes and can have any number of different sizes. One preferred shape is ovoid. The inflation balloon **410** can be inflated using conventional techniques including delivering a fluid, including a liquid or gas, to the inflation balloon **410** using a fluid conduit (e.g., a lumen formed in the catheter shaft) or the like that is routed internally through the catheter shaft and is in communication with the interior of the balloon **410**. The inflation of the balloon **410** can be preferably accomplished using controls that are part of the control handle **120** or alternatively, an actuator that is either a part of or separate from the catheter can be used. For example, a syringe or the like or other type of device that holds a fluid can be used to inject fluid into the balloon **410** as by injecting the fluid within one or more inflation lumens that are formed in the catheter shaft and in fluid communication with the interior of the balloon **410**. The actuator of the present invention can thus be thought of as any mechanism that is configured to cause the anchor to deploy and/or collapse.

Proximal to the inflation balloon **410**, a first port hub **420** is formed in the catheter shaft **110** and in addition, proximal to the inflation balloon **410**, recording electrodes **210** are disposed along the length of the catheter shaft **110**. The catheter shaft **110** includes an entrance port **430** at the distal tip **112** of the catheter shaft **110** from which a conduit **440**, such as a shunt tube, runs through the center of the inflation balloon **410**, within the catheter shaft, to the proximal port hub **420**. In the proximal port hub **420**, there are 1 or more exit ports **422** that are in communication with the entrance port **430** via the shunt tube **430**. It will further be appreciated that in some embodiments, the shunt tube **430** can be eliminated due to the construction of the balloon itself, such as when an ovoid shaped balloon is used or a balloon with a non-occluding shape is used.

As with the previous embodiments, the catheter **400** typically includes a steering mechanism and in particular, the catheter **400** can include one or more catheter steering cables (not shown) that can or cannot be anchored to the port hub **420**, or the steering cables can pass through the hub **420** to anchor at the distal tip **112**.

As with the other embodiments and in contrast to conventional designs, the catheter **400** of the present invention includes a mechanism for temporarily anchoring itself within the vessel (e.g., coronary sinus). The catheter **400** can thus be used as a common coronary sinus diagnostic catheter. Once inserted into the coronary sinus, the inflation balloon **410** is inflated using conventional techniques such as filling the balloon **410** with a fluid or air. The inflation of the balloon **410** results in the catheter **400** being anchored within the coronary sinus in a desired position for added stability and to help prevent the catheter **400** from popping out or otherwise moving within the coronary sinus.

Since blood flows through the coronary sinus, the catheter **400** is designed to accommodate such blood flow. More specifically, blood is allowed to bypass the inflation balloon **410** by first flowing through the entrance port **430** and flowing through the shunt tube **440** to the one or more exit ports **422** through which the blood exits the catheter shaft **110**. FIG. **6** shows the flow of blood within the catheter shaft **110**. Since the shunt tube **440** runs through the inflation balloon **410**, within the shaft, blood can flow in an unimpeded manner even when the inflation balloon **410** is fully inflated and in contact with the walls of the coronary sinus.

Now referring to FIGS. **7-11**, another embodiment of the present invention is illustrated for temporarily securing a catheter **500** within a vessel, such as the coronary sinus. The catheter **500** is similar to the other catheters disclosed herein and therefore, like elements are numbered alike. The catheter **500** includes an elongated catheter shaft **510**. As with the other embodiments, the catheter **500** has both a deployed state for temporarily securing and holding the catheter **500** in a desired position and location within the vessel (e.g., coronary sinus) and a collapsed state. In this embodiment, the catheter **500** includes a plurality of deployable splines **520**. As shown in the figures, when the splines **520** are deployed, the splines **520** move radially outward from the catheter shaft **510** for intimately contacting the walls of the vessel.

In one embodiment, each spline **520** is disposed within a lumen **525** that extends along a length of the catheter shaft **510**. In the illustrated embodiment, there are four lumens **525** that contain four splines **520** (e.g., the lumens and splines can be oriented 90 degrees relative to one another). A length of each lumen **525** is exposed along the outer surface of the catheter shaft **110**. In other words, the splines **520** are accessible within these exposed lumen sections which can be thought of as being windows **522** formed along the catheter shaft **510**. These openings or windows **522** formed within and along the catheter shaft **510** permit the radial expansion (outward radial movement) of the splines **520** and this translates into the splines **520** being moved into contact with the vessel wall (i.e., wall of the coronary sinus).

The location of the splines **520** can vary to coincide with the vessel dimensions and it will be appreciated that the use of splines **520** allows for blood flow to only be minimally restricted (an important consideration in typical coronary sinus applications). The amount of the projection (radial outward movement—diameters) of the spline **520** can be varied by lengthening the degree of exposure of the splines **520** (e.g., increase the length of the window formed within the catheter shaft **510**) and/or lengthening the stroke of the exposed splines **520**. This is generally shown in FIGS. **10-11**, where x is equal to the length of the exposed spline **520** (variable radius or the catheter) and y is equal to the stroke of the spline **520** (e.g., the amount of projection). By altering one or more of these parameters, the overall diameter of the catheter shaft **510** can be varied.

Varying the "y" dimension can be achieved using a number of different mechanisms including a push/pull deployment mechanism to control the spline deployment or spline retraction (collapse).

The splines **520** can be actuated using any number of different techniques where movement of one member, such as an actuator in the handle control section, is translated into the splines **520** either being deployed by expanding radially outward from the catheter shaft or collapsing as by laying flat within the lumens **525**. For example, a handle mechanism can be used and include a control in which the splines **520** can be moved forward and rearward within the catheter

shaft **510** to cause the deployment and/or collapse of the splines **520**. The handle mechanism thus can drive the movement of the splines **520**. A dual control handle can be provided if steering is needed as previously described herein.

The splines **520** can be in form of an elongated filament, such as an elongated wire, that is disposed within the lumen **525**. However, other materials can be used so long as the splines **520** can be deployed and placed into a collapsed position.

FIG. **12** shows an alternative embodiment where the catheter shaft **510** includes a distal end section **512** that is slidable relative to a main shaft section **514**. In this embodiment, one end of the spline **520** is attached to the slidable end section **512**, while the other end of the spline **520** is attached to the main section **514**. As a result, movement of the end section **512** relative to the main section **514** causes a change in the position of the spines **520**. For example, the proximal movement of the end section **512** relative to the main section **514** can cause the splines **520** to project radially outward and into contact with the vessel wall for locally anchoring the catheter **500** within the vessel (e.g., coronary sinus). Alternatively, a pushing (movement of the main section **512** relative to the end section **514**) can cause deployment of the splines **520**. The actuation (deployment) of the splines **520** can be controlled at the control handle portion of the catheter **500**. In this embodiment, the catheter shaft **510** can be thought of as being of a telescoping type.

The splines **520** can be actuated using any number of different techniques where movement of one member, such as an actuator in the handle control section, is translated into the splines **520** either being deployed by expanding radially outward from the catheter shaft or collapsing as by laying flat within the lumens **525**.

The splines **520** can be in form of an elongated filament, such as an elongated wire, that is disposed within the lumen **525**.

In yet another embodiment, as shown in FIG. **13**, a catheter **600** is provided and is similar to the other embodiments disclosed herein with the exception that each spline **520** is covered with a membrane **610** that can readily flex and contract as a result of the movement of the underlying spline **520**. The flexible membrane **610** is disposed over a respective spline **520** and is deployed by the spline **520** as shown in the end view of FIG. **13**. FIG. **13** shows blood flow around the catheter **600** and shows how the splines **520** anchor and hold the catheter **600** in place within the vessel (e.g., coronary sinus).

The advantages of this embodiment are that this design prevents exposed splines **520** and thus avoids any issues that are attributable to having exposed splines **520** present. At the same time, blood flow is still permitted in the embodiment where the splines **520** lie in a single plane as is the case when the splines **520** are oriented 180 degrees apart. The splines **520** can be a metal, a plastic, etc., and can be flat wire, round wire, etc.

Now referring to FIGS. **14-15**, a catheter **700** according to another embodiment is shown. The catheter **700** is of a tapered design in that a shaft **710** of the catheter **700** has a tapered construction. In the illustrated embodiment, the catheter shaft **710** has three distinct regions, namely, a first region **720**, a second region **730**, and a third region **740**. The first region **720** represents a distal end (distal tip) of the catheter shaft **710** and the third region **740** is the most proximal region with the second region **730** being located between the first and third regions **720**, **740**. A first taper **725** is formed between the first and second regions **720**, **730** and a second taper **735** is formed between the second and third regions **730**, **740**. The dimensions of the catheter shaft **700** decrease along its length from the proximal end to the distal end and in particular, the first region **720** has the smallest diameter, the third region **740** has the largest diameter and the second region **730** has diameter between the first and third regions **720**, **740**.

A tapered tip (e.g., two or more tapered regions) facilitates a closer geometry match to the coronary sinus morphology as the surgeon spans the right to left side of the heart during the procedure. In other words, the coronary sinus is typically not of a constant diameter and is better described as having a tapered construction itself. The catheter shaft **710** thus provides the benefit of deeper coronary sinus penetration. A tapered profile can also provide a means to secure the device within the vessel (e.g., coronary sinus). More specifically, the larger diameter portion (e.g., third region **740**) of the catheter shaft **710** can become slightly wedged in the coronary sinus as the larger diameter region of the catheter shaft meets a narrower transition within the coronary sinus (vessel).

A tapered transition allows for the ability to maintain an existing transition relationship with a shaft that mates with the larger proximal end, which aides in processing and mechanical properties for traversing the coronary sinus with a strengthened proximal segment. Proximal support of the curve is better for advancement into the coronary sinus versus a device that fails to include the tapered section. FIG. **16** shows a tapered tip stock in the form of the tapered tip of the present invention used in combination with a conventional catheter shaft that has a uniform diameter.

It will be appreciated that the coronary sinus catheter shaft can include a combination of the above described features, including but not limited to the inclusion of an anchor in a distal region of a catheter shaft that has a tapered construction as described herein. In some applications the inclusion of an anchor (e.g., deployable mesh, deployably splines, inflatable balloon, etc.) along a tapered catheter shaft can provide improved results in that the tapered shaft permits the catheter to be disposed further within the coronary sinus and allow deployment of the anchor at an optimal location to anchor the entire catheter. It will also be appreciated that it is also within the scope of the invention that two different anchors (of same type or different types) can be utilized.

FIGS. **17-21** illustrate an electrophysiology catheter (e.g., coronary sinus catheter) **800** according to another embodiment. The catheter **800** includes an elongated shaft **810** similar to the other catheters disclosed herein. It will be understood that the catheter **800** can include the same features of the catheter **100** shown in FIG. **1** including one or more control mechanisms that are part of a handle, etc. and can be operatively connected to other equipment, such as the recording device **140** and/or the 3D mapping system **160**. For ease of illustration, FIGS. **17-21** only show a portion of the catheter shaft **810**. The catheter shaft **810** can be of a single lumen type or of a multi lumen type. FIGS. **17-21** illustrate a multi lumen type. In accordance with the invention, the catheter shaft **810** has one or more (preferably two or more) windows **820** formed in the catheter shaft **810**. The windows **820** can be elongated slots formed in the shaft **810**. FIG. **18** shows four windows **820** and FIG. **19** shows two windows **820**. The windows **820** are preferably formed opposite (180 degrees one another since this permits the anchor to contact the vessel in two opposite points (locations); however, they can be located in positions that are not directly opposite one another.

Each window **820** of the catheter shaft **810** is in fluid communication with at least one lumen **825** that is formed in the shaft **810**. Each window **820** can have its on respective lumen **825** formed in the catheter shaft in which case each window **820** is in fluid communication with a respective lumen **825** or one lumen **825** can be in communication with two or more windows **820**.

An inflatable member **830** is disposed about the catheter shaft **810** in covering relation to the windows **820**. In other words, the inflatable member **830** covers the windows **820**. In one embodiment, the inflatable member **830** is a balloon, such as an ovoid shaped balloon that is disposed about the shaft **810**. In this embodiment, the balloon is a continuous structure about the outer surface of the catheter shaft. However, it will also be appreciated that the inflatable member **830** can be formed of one or more sections of flexible material that expands when a fluid force is applied thereto and collapses when the fluid force is removed. In other words, each window **820** can be covered with a single piece or section of a material that has inflatable characteristics (e.g., balloon like material) and the regions between the windows **820** can be entirely free of the expandable material. In this embodiment, the pieces of expandable material are bonded or otherwise attached to the outer surface of the catheter shaft along the periphery of the respective window **820**.

When an inflation fluid, such as a gas (air) or liquid, flows through the lumen(s) **825**, the fluid flows through the window(s) that is fluidly connected to the lumen and into the inflatable member **830** for inflation thereof. Alternatively, in the embodiment where sections or pieces of material are individually disposed over each window or the embodiment where the balloon is bonded to the catheter shaft in regions between the catheter shaft, the fluid force of the fluid flowing through the window against the piece of material causes the radial expansion of the material locally above the window. For example, the inflatable member **830** is at least locally inflated in the areas of the windows **820**. This is shown in FIGS. **18** and **19**. As shown in FIG. **21**, the inflatable member **830** can be bonded or otherwise secured to the catheter shaft **810** in areas surrounding the windows **820** so as to prevent inflation of the member **830** in areas that are not overlying a window **820**. As a result, the inflation characteristics are influenced and controlled by the shape of the window **820** and in the case of two or four windows, the resulting inflated structure can be thought of as being two or four elongated inflated sections (i.e., balloon splines) that overlie the window **820**.

It will be understood that the fluid (e.g., blood) can flow around the balloon splines and thus, fluid flow (e.g., blood flow) is not occluded. In other words, in regions where the inflatable member **830** is bonded to the catheter shaft **810** or in regions of the shaft **810** where the inflatable member **830** is absent, fluid flows freely along the catheter shaft **810** since the balloon splines are absent in these regions.

As with the other embodiments, the catheter **800** can be a coronary sinus catheter that is used in the coronary sinus.

In addition, it will be appreciated that the catheters described herein are configured so that the anchor element can be partially deployed in that it can be deployed in a position between the fully collapsed position and the fully deployed position. Partial deployment may be desired in a narrower coronary sinus, etc. Partial deployment is possible in both the mechanically actuated anchor structures, such as the mesh, splines, etc., as well as the embodiments where the anchor is an inflatable member, such as a balloon in which case the balloon is only partially inflated.

Example

In accordance with the present invention, a catheter according to one of the embodiments is inserted into the coronary sinus by first inserting a distal end of the catheter into the coronary sinus. The catheter is inserted with the anchor being in a collapsed position or state. The catheter is continually advanced within the coronary sinus and the position of the catheter can be monitored until the catheter is in a target area of the coronary sinus. When the catheter is being used as part of a mapping application, the target area can be a location where the mapping electrodes of the catheter are in locations where mapping signals are to be detected. Once the catheter is in a desired location within the coronary sinus where a mapping application is to be performed, the anchor is then deployed. In its deployed position, the anchor locally anchors the catheter within the coronary vessel by applying a radially outward force against the vessel wall. However, as discussed herein, the embodiments of the present invention do not occlude blood flow and therefore, blood flows around the deployed anchor. Once the mapping application is completed, the anchor can then be collapsed and the catheter is moved in the opposite direction resulting in the catheter shaft being removed from the coronary sinus.

While the invention has been described in connection with certain embodiments thereof, the invention is capable of being practiced in other forms and using other materials and structures. In particular, features of different embodiments can be combined, for example, to have splines or covered splines on a taper-tipped catheter, and so on. Accordingly, the invention is defined by the recitations in the claims appended hereto and equivalents thereof.

We claim:

1. A catheter for insertion into a cardiac vessel, the catheter comprising:

a handle; and

a catheter shaft coupled at one end to the handle, the catheter shaft having a tapered tip positioned at a distal region of the catheter shaft, an anchor coupled to the tapered tip, and a plurality of windows,

wherein the tapered tip includes: a distal region, a middle region, a proximal region, a first taper between the distal region and the middle region, and a second taper between the middle region and the proximal region;

wherein the anchor comprises a plurality of splines each configured to extend radially outward from the catheter shaft through one of the plurality of windows such that the anchor contacts a wall of the cardiac vessel and temporarily anchors the catheter shaft within the cardiac vessel.

2. The catheter of claim **1**, wherein a diameter of the distal region is less than a diameter of the middle region, and wherein the diameter of the middle region is less than a diameter of the proximal region.

3. The catheter of claim **2**, wherein the distal region, the middle region, and the proximal region each extend along the catheter shaft at a length that is greater than a length of either the first or second taper.

4. The catheter of claim **1**, wherein a distal end of the tapered tip is hemispherical shaped.

5. The catheter of claim **1**, wherein the anchor includes a recording electrode.

6. The catheter of claim **1**, further comprising:

an actuator for causing deployment and collapsing of the anchor within the cardiac vessel.

7. The catheter of claim 6, wherein the actuator is a slide actuator disposed within the handle and coupled to an elongated mandrel, wherein a sliding action of the actuator is translated through the mandrel to the anchor being moved between a deployed position and a collapsed position.

8. The catheter of claim 6, further including an actuator lock mechanism for locking the actuator in first and second positions that correspond respectively to the anchor being in a fully deployed position and a fully collapsed position.

9. The catheter of claim 1, wherein the anchor is positioned within the tapered tip.

10. The catheter of claim 1, wherein each of the plurality of splines is coupled to an actuator.

11. The catheter of claim 10, wherein the actuator and the plurality of splines are coupled to a collar slidable along the catheter shaft to deploy or collapse the plurality of splines.

12. The catheter of claim 11, wherein the actuator is coupled to, and actuated by, the handle.

13. The catheter of claim 1, wherein each of the plurality of splines is an elongated filament.

14. The catheter of claim 1, further comprising:

a plurality of electrodes that are disposed along the catheter shaft, wherein the anchor is disposed between a first set of the plurality of electrodes and a second set of the plurality of electrodes.

15. The catheter of claim 14, wherein the plurality of electrodes are recording electrodes.

16. The catheter of claim 1, wherein each of the plurality of splines is covered by a membrane.

17. The catheter of claim 1, wherein each of the plurality of splines includes two splines disposed 180 degrees from each other along the catheter shaft.

18. The catheter of claim 1, wherein each of the plurality of windows is an elongated slot.

19. The catheter of claim 1, further comprising a balloon disposed along the catheter shaft to cover each of the plurality of windows.

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专利名称(译)	用于将导管固定到血管中的装置		
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摘要(译)

用于插入心脏血管（例如冠状窦）的电生理学导管，例如冠状窦导管，包括手柄和在一端连接到手柄的导管轴。导管轴具有远端，并且锚固件与导管轴相关联，并且可在展开位置和折叠位置之间移动。在展开位置，锚从导管轴的外表面径向向外延伸，用于接触壁并将导管轴暂时固定在冠状窦内。导管还包括致动器，用于在操纵致动器时引起锚的展开和收缩。