US 20160331254A1

(19) United States
(12) Patent Application Publication
(10) Pub. No.: US 2016/0331254 A1
(43) Pub. Date: Nov. 17, 2016
Tegg et al.

(54) NON-CONTACT ELECTRODE BASKET CATHETERS WITH IRRIGATION

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(21) Appl. No.: **15/155,277**

(22) Filed: **May 16, 2016**

Related U.S. Application Data

(63) Continuation of application No. 12/345,606, filed on Dec. 29, 2008, now Pat. No. 9,339,331.

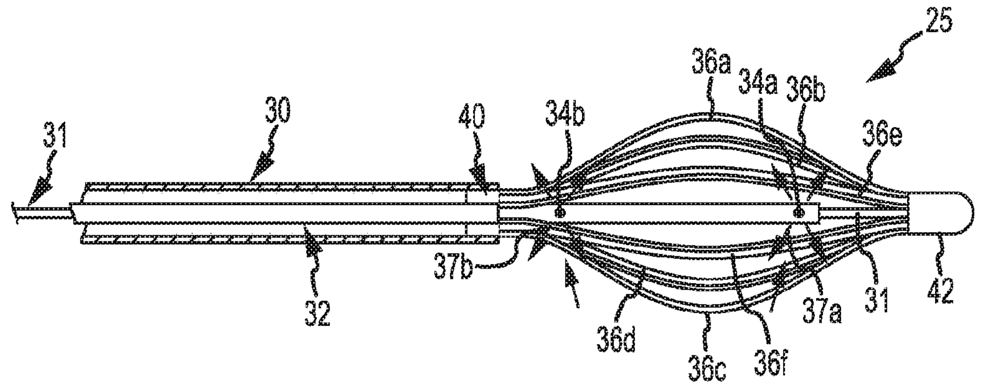
Publication Classification

(51) **Int. Cl.**
A61B 5/042 (2006.01)
A61B 18/14 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
CPC *A61B 5/042* (2013.01); *A61B 5/6858* (2013.01); *A61B 18/1492* (2013.01); *A61B 2018/00267* (2013.01)

(57) **ABSTRACT**

Catheter systems and methods are disclosed. An exemplary catheter includes an outer tubing housing and an inner fluid delivery tubing, the inner fluid delivery tubing having at least one fluid delivery port. The catheter also includes a deployment member movable axially within the inner fluid delivery tubing. A plurality of splines are each connected at a proximal end to the outer tubing and at a distal end to deployment member. A seal is provided between the outer tubing and the inner fluid delivery tubing. A gasket is provided between the deployment member and the inner fluid delivery tubing. Both the seal and the gasket are configured to prevent blood or other fluid from ingressing into the outer tubing.



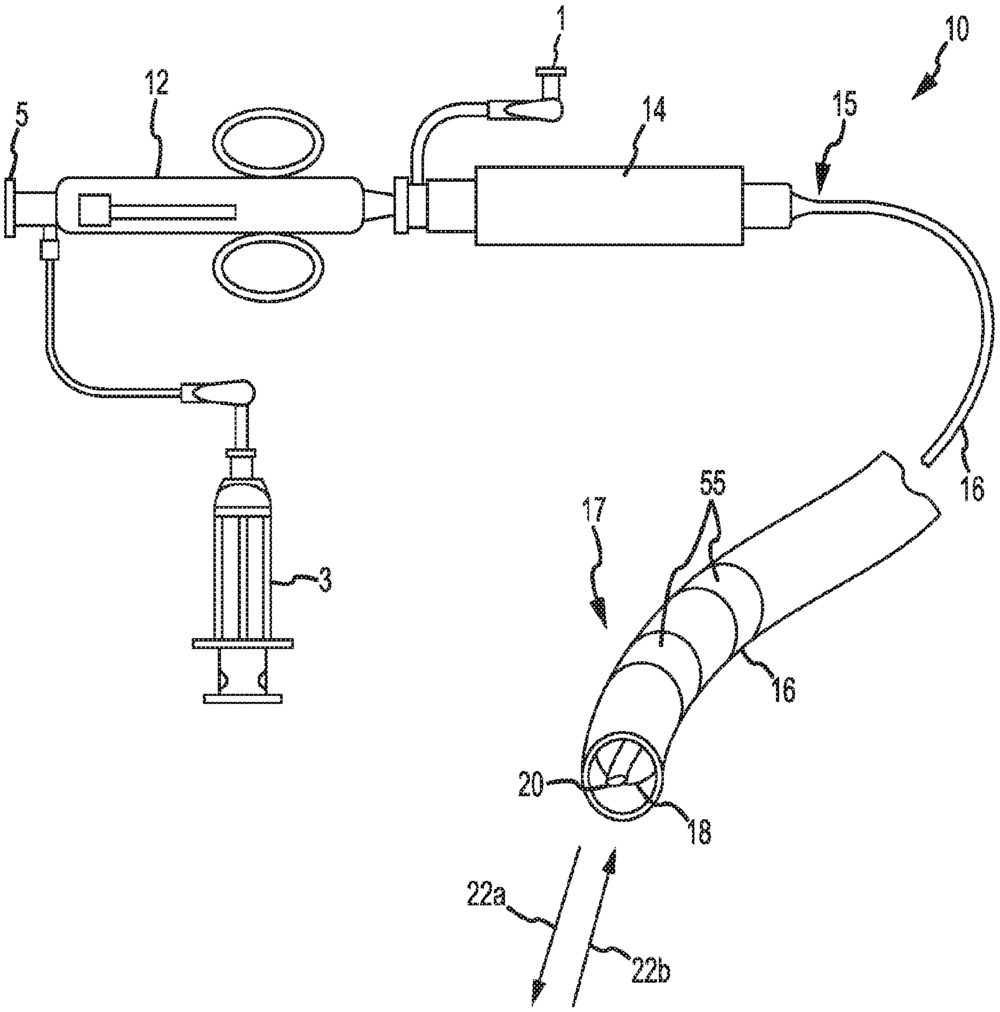


FIG.1

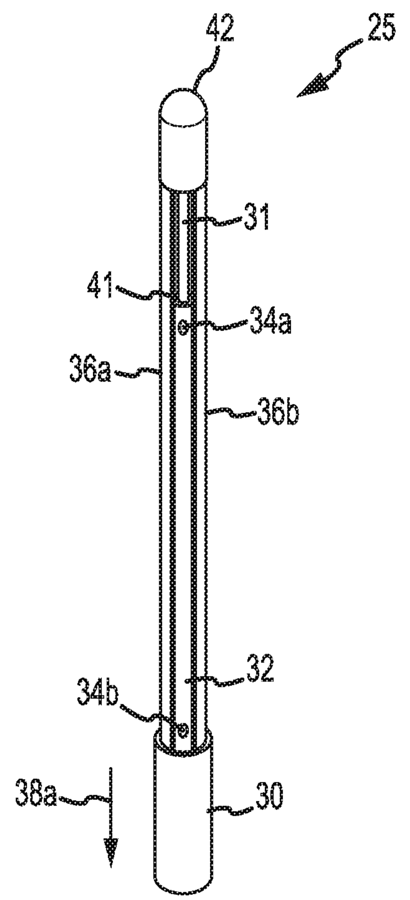


FIG.2a

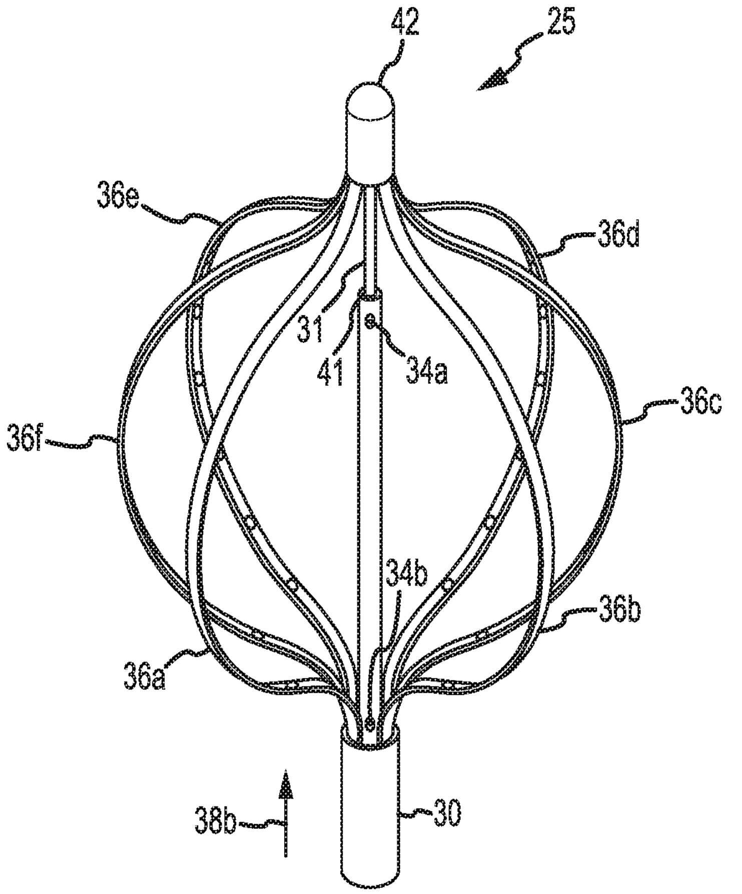


FIG.2b

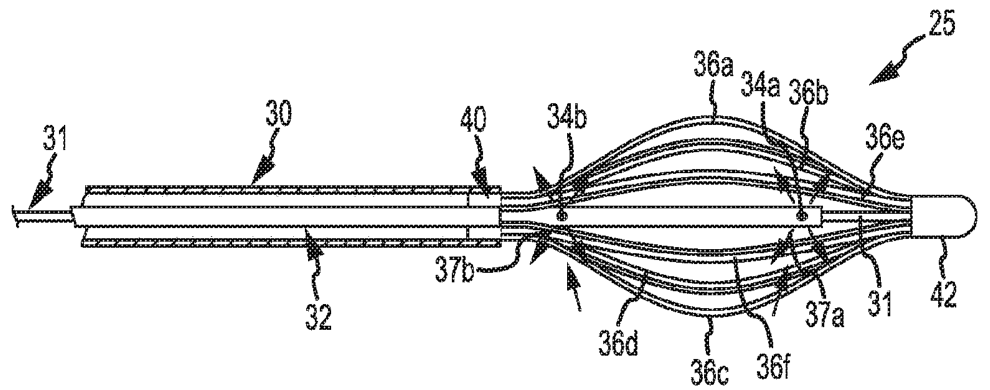


FIG.3a

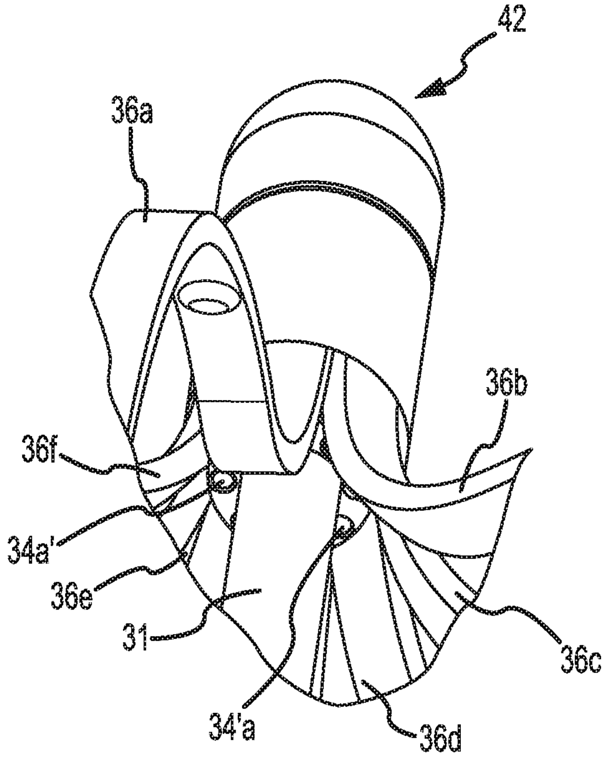


FIG.3b

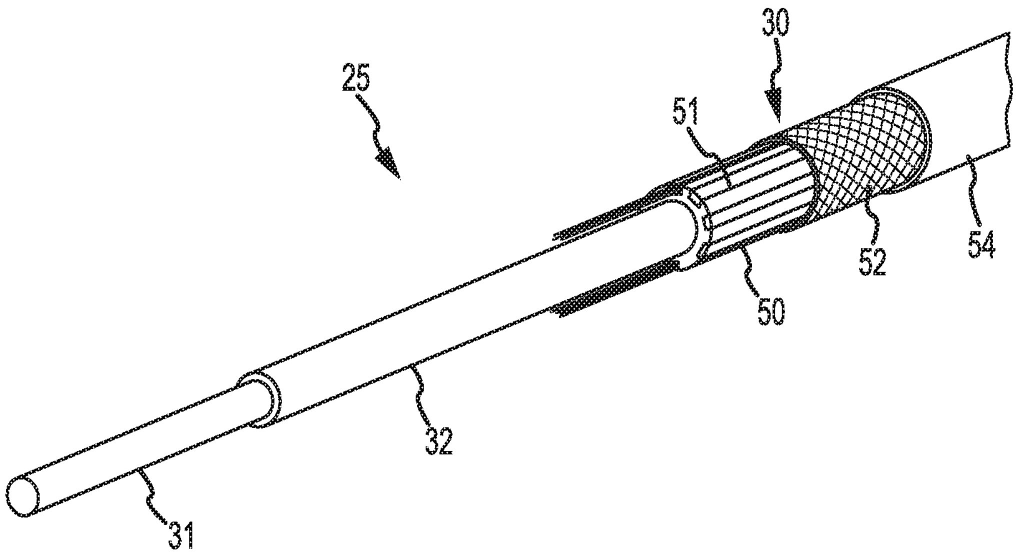


FIG.4

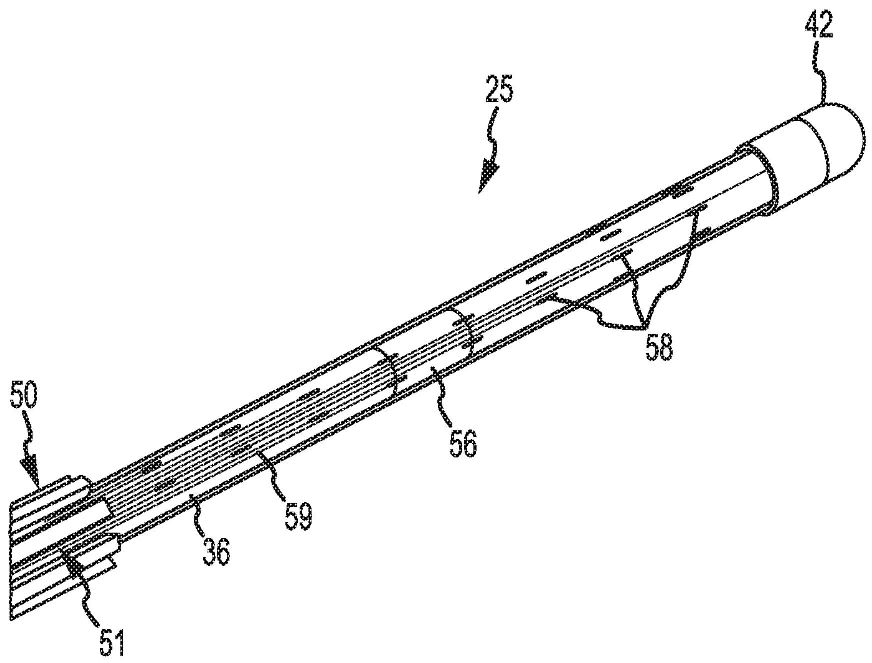


FIG.5a

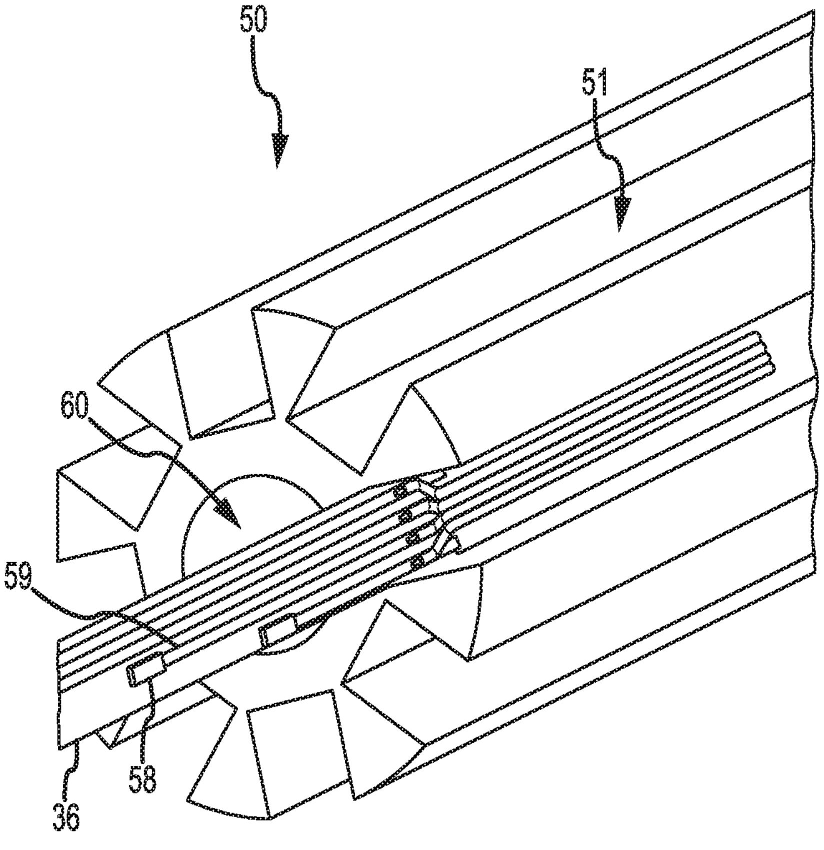


FIG.5b

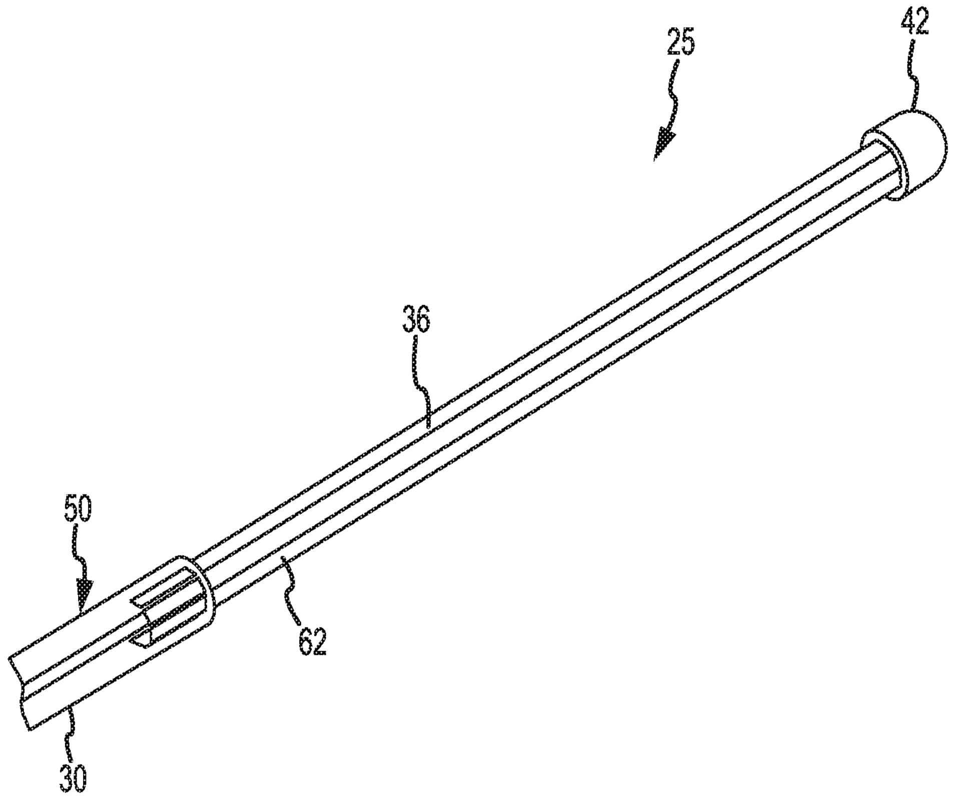


FIG.6

NON-CONTACT ELECTRODE BASKET CATHETERS WITH IRRIGATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 12/345,606, filed 29 Dec. 2008, now pending (the '606 application). The '606 application is hereby incorporated by reference as though fully set forth herein.

BACKGROUND OF THE INVENTION

[0002] a. Field of the Invention

[0003] The instant invention is directed toward non-contact electrode basket catheters with irrigation for delivering a fluid (e.g., an anticoagulant) during a medical procedure. In particular, the non-contact electrode basket catheter of the present invention may be used to deliver the fluid between splines of the basket catheter during medical procedures.

[0004] b. Background Art

[0005] Normal heart rhythm is between 60 and 100 beats per minute. Tachycardia is a fast heart rate (usually over 100 beats per minute) caused by disease or injury. Tachycardias may begin in the upper chambers of the heart (the atria) or the lower chambers of the heart (the ventricles). Some tachycardias are harmless, but other tachycardias are life threatening. Tachycardias can deteriorate to fibrillation, a disorder in which, the heart does not move enough blood to meet the needs of the body.

[0006] Atrial fibrillation (AF) is the most common abnormal heart rhythm. It is a very fast, uncontrolled heart rhythm that occurs when the upper chambers of the heart (the atria) try to beat so fast (between 350 and 600 times per minute) that they only quiver. Ventricular fibrillation (VF) occurs when the lower chambers of the heart (the ventricles) produce fast and erratic electrical impulses that fail to induce synchronous mechanical contraction, such that oxygenated blood is not circulated through the body. Fibrillation in the ventricles is a life-threatening arrhythmia demanding immediate treatment.

[0007] Before a tachycardia deteriorates to fibrillation, various procedures may be used to treat the heart tissue and reduce or altogether eliminate the occurrence of fibrillations. It is well known that treatment benefits may be gained by creating lesions in the heart tissue, which change the electrical properties of the tissue, if the depth and location can be controlled. For example, cardiac ablation techniques are known for forming lesions at specific locations in cardiac tissue to lessen or eliminate undesirable atrial fibrillations. Likewise, biologic and chemical agents may be delivered into infracted tissue in the lower chambers of the heart (the ventricles) to promote angiogenesis for the treatment of Ventricular Tachycardia (VT). Other procedures are also known for treating these and other ailments. Use of a particular procedure depends at least to some extent on the desired treatment, and may also depend on other considerations, such as tissue characteristics.

[0008] A basket catheter may be employed for ablation and other procedures (e.g., mapping) on the heart. The catheter system may include an outer catheter shaft also referred to as a "guiding introducer". The guiding introducer defines at least one lumen or longitudinal channel. A delivery sheath is fitted through the guiding introducer. To pre-position the sheath at the appropriate location in the heart, a dilator is first fitted through the sheath. In an example of a procedure within the left atrium, the sheath and the dilator are first inserted in the femoral vein in the right leg. The sheath and dilator are then maneuvered up to the inferior vena cava and into the right atrium. In what is typically referred to as a transseptal approach, the dilator is pressed through the interatrial septum between the right and left atria. A dilator needle may be used here to make an opening for the dilator to pass through. The dilator expands the opening sufficiently so that the sheath may then be pressed through the opening to gain access to the left atrium and the pulmonary veins. With the sheath in position, the dilator is removed and the basket catheter, needle, or other device (depending on the procedure) is fed into the lumen of the sheath and pushed along the sheath into the left atrium. When positioned in the left atrium, various mapping and/or ablation procedures, such as the ablation procedures described above, may be performed within the heart.

[0009] Several difficulties may be encountered, however, during these medical procedures using some existing basket catheters. For example, a slowing or stoppage of the flow blood may occur between the splines of the basket catheter, e.g., where the splines are attached to the catheter. This slowing or stoppage of the flow of blood may result in blood clot formation and may possibly lead to a thrombus. A thrombus may decrease blood flow or even completely cut off blood flow, resulting in heart attack or stroke. Indeed, the risk of thrombus formation in the heart continues to exist even after the basket catheter has been removed following the medical procedure.

[0010] Thus, there remains a need for irrigation of a basket catheter during a medical procedure.

BRIEF SUMMARY OF THE INVENTION

[0011] It is desirable to be able to deliver an anticoagulant such as a heparinized saline solution or other fluid in a basket catheter during various medical procedures, e.g., to reduce the risk of blood clot or thrombus formation. One effective way to prevent blood coagulation and thrombus formation is to irrigate the electrode with heparinized saline. It is further desirable to be able to seal a distal end of the catheter to prevent blood ingress into the catheter shaft during the medical procedure.

[0012] These and other objectives can be accomplished by the catheter systems and methods disclosed herein by providing a non-contact electrode basket catheter with irrigation. A seal may also be configured in the catheter system to reduce or altogether prevent blood ingress into the catheter shaft.

[0013] An exemplary non-contact electrode basket catheter with irrigation includes an outer tubing housing an inner fluid delivery tubing, the inner fluid delivery tubing having at least one fluid delivery port. The catheter also includes a deployment member movable axially within the inner fluid delivery tubing. A plurality of splines are each connected at a proximal end to the outer tubing and at a distal end to deployment member. The plurality of splines expand when the deployment member is moved in a first direction, and the plurality of splines collapse when the deployment member is moved in a second direction, the first direction being opposite the second direction. A seal is provided between the outer tubing and the inner fluid delivery tubing. A gasket is provided between the deployment member and the inner fluid delivery tubing. Both the seal and the gasket are configured to prevent blood or other fluid from ingressing into the outer tubing.

[0014] An exemplary catheter system comprises a delivery sheath, and a non-contact electrode basket catheter insertable through the delivery shaft. The basket catheter includes a plurality of splines operable to be moved by a deployment member between a deployed position and an undeployed position. The basket catheter also includes a fluid delivery tube housed within the basket catheter. The fluid delivery tube has at least one fluid delivery port for irrigating within the basket catheter between the plurality of splines to reduce clotting or thrombus formation. The basket catheter also includes a seal fixedly provided between the fluid delivery tube and an outer tube of the basket catheter. The seal preventing blood or fluid ingress into the outer tubing.

[0015] Another exemplary non-contact electrode basket catheter system with irrigation comprises a catheter shaft, and a basket catheter insertable through the catheter shaft. The basket catheter includes a fluid delivery tubing provided within an outer tubing, and a plurality of splines connected to the outer tubing and on one end and to a deployment member on an opposite end. The deployment member is operable to move the splines between an expanded configuration and a collapsed configuration. The basket catheter also includes fluid delivery means for irrigating within the basket catheter between the plurality of splines to reduce clotting or thrombus formation. The basket catheter also includes sealing means for stopping blood or fluid from ingressing into the catheter shaft.

[0016] An exemplary method comprises the steps of moving a deployment member axially within an inner fluid delivery tubing in a first direction to expand a plurality of splines of a non-contact electrode basket catheter, and moving the deployment member axially within the inner fluid delivery tubing in a second direction to collapse the plurality of splines. The method also comprises the steps of irrigating between the splines of the non-contact electrode basket catheter, and preventing fluid ingress into a catheter shaft.

[0017] The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] FIG. **1** is an isometric view of an exemplary embodiment of a catheter system.

[0019] FIG. **2***a*-*b* are isometric views of an exemplary embodiment of a non-contact electrode basket catheter with irrigation which may be implemented with the catheter system in

[0020] FIG. **1**, wherein (a) shows the basket portion of the catheter in a collapsed configuration, and (b) shows the basket portion of the catheter in an expanded configuration.

[0021] FIG. **3***a* is a cutaway isometric view of a distal portion of the basket catheter showing an exemplary configuration of distal fluid delivery ports. FIG. **3***b* is a close-up isometric view of a distal portion of the basket catheter showing an alternative configuration of the distal fluid delivery ports.

[0022] FIG. **4** is an isometric view of an exemplary basket catheter without the splines.

[0023] FIG. **5***a*-*b* are isometric views of the basket catheter of FIG. **4** with the base layer of the splines attached to show electrodes and electrode traces for the basket catheter. In FIG. **5***b*, the electrode traces are shown as the electrode traces may be fit into channels formed within interstitial spaces of the catheter shaft.

[0024] FIG. **6** is an isometric view of the basket catheter of FIG. **4** with an outer layer of the splines shown covering the electrodes and electrode traces in FIG. **5***a*.

DETAILED DESCRIPTION OF THE INVENTION

[0025] Several embodiments of a catheter system according to the present invention are depicted in the figures as the catheter system may be used for irrigation delivery of an anticoagulant, such as heparinized saline, or other fluid in a basket catheter during a medical procedure. In an exemplary embodiment, the basket catheter is a non-contact electrode basket catheter which may be used for ablation or other procedures (e.g., mapping). As described further below, the catheter of the present invention provides a number of advantages, including, for example, facilitating irrigation during the medical procedure to reduce blood clot or thrombus formation without blood ingress into the catheter shaft. The catheter system may also be used in difficult environments, such as in a beating heart.

[0026] Before continuing, it is noted that other components typical of catheter systems which are conventionally implemented for these and other medical procedures are not shown or described herein for purposes of brevity. Such components may nevertheless also be provided as part of, or for use with, the catheter system. For example, catheter systems commonly include or are used in conjunction with an ECG recording system, and/or various input and output devices. Such components are well understood in the medical devices arts and therefore further explanation is not necessary for a complete understanding of the invention.

[0027] FIG. **1** is an isometric view of an exemplary embodiment of a catheter system **10**. The catheter system **10** may include a handle **12** and connector **14** at the base or proximal end **15**. An outer catheter shaft also referred to as a "guiding introducer" **16** having a tubular body is connected to the connector **14** on the proximal end (e.g., illustrated by reference number **15** in FIG. **1**) of the catheter system **10**. As used herein and commonly used in the art, the term "proximal" is used generally to refer to components or portions of the catheter system **10**, such as the handle **12** and connector **14** that are located or generally orientated away from or opposite the heart or other target tissue when the catheter system **10** is in use. On the other hand, the term "distal" (e.g., illustrated in FIG. **1** by reference number **17**) is used generally to refer to components located or generally orientated toward the heart or other target tissue when the catheter system **10** is in use.

[0028] The guiding introducer **16** defines at least one lumen or longitudinal channel. A delivery sheath **18** is fitted through the guiding introducer **16**. In one implementation, the guiding introducer **16** and sheath **18** are fabricated from a flexible resilient material, and are preferably fabricated of materials suitable for use in humans, such as nonconductive polymers. Suitable polymers include those well known in the art, such as polyurethanes, polyether-block amides, polyolefins, nylons, polytetrafluoroethylene, polyvinylidene fluoride, and fluorinated ethylene propylene polymers, and other conventional materials. Some portions of the guiding introducer **16** and/or sheath **18** may be braided for enhanced stiffness.

[0029] In exemplary implementations, the guiding introducer **16** and sheath **18** are each about two to four feet long, so that they may extend from the left atrium through the body and out of the femoral vein in the right leg and be connected with various catheter devices such as the connector **14**, one or more fluid control valves **1-3**, and the like.

[0030] The sheath **18** is configured to receive and guide a device for carrying out the procedure (e.g., the basket catheter **25** shown in FIG. **2***a-b*) within the lumen to the target tissue. The sheath **18** is pre-positioned in the appropriate location in the heart prior to introduce a device. To pre-position the sheath **18** at the appropriate location in the heart, a dilator **20** is first fitted through the sheath **18**. In an example of a procedure within the left atrium, the sheath **18** and the dilator **20** are first inserted in the femoral vein in the right leg. The sheath **18** and dilator **20** are then maneuvered up to the inferior vena cava and into the right atrium. In what is typically referred to as a transseptal approach, the dilator **20** is pressed through the interatrial septum between the right and left atria. A needle may be used here to make an opening for the dilator **20** to pass through. The dilator expands the opening sufficiently so that the sheath **18** may then be pressed through the opening to gain access to the left atrium and the pulmonary veins. With the sheath **18** in position, the dilator **20** is removed and the basket catheter **25** (FIG. **2***a-b*) may be fed into the lumen of the sheath **18** and pushed along the sheath **18** into the left atrium. When positioned in the left atrium, various procedures (e.g., ablation and mapping procedures) may be performed within the heart tissue using the basket catheter.

[0031] Once the sheath **18** is pre-positioned in the appropriate location in the heart, the basket catheter **25** may be at least partially extended out from the lumen at the distal end **17** of the sheath **18** (e.g., in the direction illustrated by arrow **22***a*) so that the basket catheter **25** may be positioned adjacent the target tissue, and then expanded as illustrated in FIG. **2***b* for the medical procedure. The basket catheter **25** may also be collapsed as illustrated in FIG. **2***a*, and then retracted (e.g., in the direction of arrow **22***b*) before removing the catheter system **10** from the body.

[0032] Before continuing, it is noted that the catheter system **10** has been described as it may be inserted for procedures in the left atrium in the vicinity of or within the pulmonary veins of the heart. The catheter system **10**, however, is not limited to such procedures, and may be used for procedures involving other target tissue in other areas of the heart and body.

[0033] The following discussion will now be with reference to the basket catheter **25** shown in FIG. **2***a-b*. FIG. **2***a-b* are isometric views of an exemplary embodiment of a non-contact electrode basket catheter **25** with irrigation which may be implemented with the catheter system **10** in FIG. **1**, wherein (a) shows the basket portion of the catheter in a collapsed configuration, and (b) shows the basket portion of the catheter in an expanded configuration.

[0034] In these figures, an exemplary basket catheter **25** is shown as it may include an outer tubing **30** housing an inner fluid delivery tubing **32** and a deployment member **31**. The inner fluid delivery tubing **32** includes at least one fluid delivery port **34** within the splines **36** of basket catheter **25**. It is noted that two fluid delivery ports **34***a-b* and splines **36***a-b* are visible in FIG. **2***a*. In FIG. **2***b*, splines **36***a-f* are visible in FIG. **2***b*. However, the basket cathether **25** is not limited to any particular configuration (including number of splines or number or placement of ports), as will be readily understood by those having ordinary skill in the art after becoming familiar with the teachings herein.

[0035] Each spline **36** is connected at the proximal end of the splines **36** to the outer tubing **30**, and each spline **36** is connected at the opposite or distal end of the splines **36** to the deployment member **31**. The deployment member **31** is operable to be moved in a first direction (e.g., in the direction of arrow **38***a*) relative to the outer tubing **30** to expand the splines **36** to a deployed position, as shown in FIG. **2***b*. The deployment member **31** is also operable to be moved in a second direction (e.g., in the direction of arrow **38***b* in FIG. **2***b*) relative to the outer tubing **30** to collapse the splines **36** to an undeployed position, as shown in FIG. **2***a*.

[0036] The deployment member **31** may include a pull wire. For example. The deployment member **31** may be a solid stainless steel or Nitinol wire. Alternatively, the deployment member **31** may be a hollow tubing (or configured to house tubing). An embodiment wherein the deployment member **31** is a fluid delivery tubing is described in more detail below with reference to FIG. **3***b*. In either case, however, the deployment member **31** should be manufactured to be sufficiently stiff such that the deployment member **31** can be operated remotely (e.g., outside of the patient's body) to be moved in the directions illustrated by arrow **38***a* and **38***b* in FIG. **2***a-b* to expand and contract the splines **36**.

[0037] In any event, the basket catheter **25** may be inserted into the catheter shaft (e.g., sheath **18**) in its undeployed position as shown in FIG. **2***a* for placement in the patient's body (e.g., within a heart chamber). The basket catheter **25** may then be expanded to its deployed position as shown in FIG. **2***b* for a medical procedure within the patient's body. Following the procedure, the basket catheter **25** may again be collapsed to its undeployed position so that the basket catheter **25** may be withdrawn through the delivery sheath **18** of the catheter **10**.

[0038] In an exemplary embodiment, the deployment member **31** may be connected to port **5** on the handle **12** of catheter system **10** (in FIG. **1**). A handle portion may be operatively associated with the deployment member **31** in such a manner that movement of the handle is directly translated into movement of the deployment member **31**. Other embodiments of deployment systems are also contemplated and are not limited to the specific implementation described above. For example, the handle may be spring-loaded (not shown). The spring acts to bias the handle in a fully extended or pulled back position. Accordingly, a force must be applied to the handle in order to release the handle, and hence return the deployment member **31** toward its starting position. This may help ensure that the user does not leave the splines **36** of the basket in the expanded position as shown in FIG. **2***b* when attempting to remove the basket catheter **25** from the patient's body. This may also help ensure that the basket catheter **25** is not accidentally deployed during placement in the patient's body (doing so could cause unintended damage to tissue or other parts of the patient's body). Still other embodiments are also contemplated. For example, different mechanisms for controlling the distance the deployment member **31** can travel may also be implemented.

[0039] FIG. **3***a* is cut-away isometric view of a distal portion of the basket catheter **25** showing an exemplary configuration of distal fluid delivery ports **34**. Fluid delivery is illustrated by arrows **37***a* as the fluid may be delivered from ports **34***a* at the distal end of the fluid delivery tube **32**, and by arrows **37***b* from ports **34***a* as the fluid may be delivered from ports **34***b* at the proximal end of the fluid delivery tube **32**.

[0040] A seal **40** is also visible in FIG. **3***a*. The seal **40** may be manufactured of any suitable material. Seal **40** is provided between the inner fluid delivery tube **32** and the outer tubing **30**. For example, the seal **40** may be molded or bonded to the inner fluid delivery tube **32** and/or the outer tubing **30**. In an exemplary embodiment, the seal **40** may be oversized, e.g., having an inner diameter which is smaller than the outer diameter of the inner fluid delivery tubing **32** and having an outer diameter which is larger than the inner diameter of the outer tubing **30**. The specific diameters may vary depending on a number of design considerations, such as, the diameters of the inner fluid delivery tubing **32** and outer tubing **30**, or other components of the catheter **10**. Sizing the diameters in such a manner enables the seal **40** to provide a snug fit between the tubing **30** and **32** to prevent blood or other fluid from ingressing back within the catheter shaft.

[0041] It should also be noted that blood or other fluid may also be kept from ingressing back within the catheter shaft through the fluid delivery ports **34***a* and **34***b* by continuous fluid delivery at a positive pressure through these ports. In exemplary embodiments, it has been determined that fluid flow rates of 1 mL/m to 5 mL/m provide sufficient positive pressure so as to prevent blood or other fluid from ingressing through the fluid delivery ports **34***a* and **34***b*. However, these are merely exemplary, and specific flow rates may be determined for any of a wide variety of fluid delivery port configurations by those having ordinarily skill in the art after becoming familiar with the teachings herein.

[0042] A gasket **41** is visible in FIGS. **2***a* and **2***b*, and serves a similar purpose to the seal **40** in FIG. **3***a*. Specifically, the gasket **41** enables the deployment member **31** to be moved in the directions illustrated by arrows **38***a* and **38***b* to expand and collapse the splines **36**, while preventing blood or other fluid from ingressing back within the catheter shaft.

[0043] In an exemplary embodiment, the seal **40** and gasket **41** may be manufactured of an elastic polymer. However, the seal **40** and gasket **41** may be manufactured of any other suitable material as well, including but not limited to rubber, plastic, or metal.

[0044] FIG. **3***b* is a close-up isometric view of a distal portion **42** of the basket catheter **25** showing an alternative configuration of the distal fluid delivery ports **34***a*'. In this embodiment, the deployment member **31** may be a tubing (or house a tubing) fluidically connected on one end to a fluid source, and on the other end to the distal fluid delivery ports **34***a*' provided on the deployment member **31**. The distal fluid delivery ports **34***a*' may be fluidically connected to the same fluid source as the inner fluid delivery tubing **32** or to a separate fluid source. In any case, such an embodiment enables fluid delivery closer to the distal portion **42** of the basket catheter **25** even when the splines **36** are in an undeployed position (e.g., FIG. **2***a*).

[0045] Before continuing, it is noted that any configuration of the distal fluid delivery ports **34***a*' may be implemented and is not limited to the configuration (or number of ports) shown in FIG. **3***b*. Likewise, distal fluid delivery ports **34***a*' may be implemented with (in addition to) or without the fluid delivery ports **34***a* on inner fluid delivery tubing **32**.

[0046] Although the fluid delivery mechanisms and irrigation systems and methods described above may be implemented with any suitable basket catheter **25**, exemplary manufacture of a preferred embodiment of a non-contact electrode basket catheter will now be described with reference to FIG. **4**-**6**. FIG. **4** is an isometric view of an exemplary basket catheter **25** without the splines **36**. In FIG. **4**, the deployment member **31** is shown fitted within fluid delivery tubing **32**. The deployment member **31** may be a Nitinol wire which may be pre-bent to the desired shape. The deployment member **31** is configured for axial movement relative to the fluid delivery tubing **32**. The fluid delivery tubing **32** is in turn fitted within outer tube **30**. Outer tube **32** may comprise an inner shaft **50** which provides structural support and also has formed therein channels or interstitial spaces **51** for electrical wiring and/or fluid tubing (see, e.g., FIG. **5***b*). Outer tube **32** may also comprise a braided section **52** to contain the electrical wiring and/or fluid tubing within the interstitial spaces **51**, and a cover **54**.

[0047] It should be noted that although the section of the basket catheter **25** shown in FIG. **4** is depicted as having a circular cross-section, the cross-section may intentionally or unintentionally have a wide variety of cross-sectional configurations, and need not be circular. For example, manufacturing irregularities may result in different cross-sectional configurations. Or for example, different cross-sectional configurations (e.g., hexagonal, octagonal) may be intentionally selected to achieve desired properties. The particular configuration used will depend at least to some extent on design considerations. Exemplary design considerations may include, but are not limited to, the material and desired structural properties, the length, shape, and cross-sectional area. And of course, the design parameters may be different for various procedures or physician preferences.

[0048] FIG. **5***a*-*b* are isometric views of the basket catheter **25** of FIG. **4** with the base layer **56** of the splines **36** attached to show electrodes **58** and electrode traces **59** for the basket catheter. In an exemplary embodiment, the splines **36** are formed from sheets. The sheets can be formed of a suitable flexible material such as plastic (e.g., polyimide). Plastic-coated stainless steel sheets may also be used to provide additional rigidity. In any event, the sheets are formed with a plurality of longitudinally extending slits spaced transversely of the sheet. Longitudinally spaced apart electrodes **58** and corresponding electrode traces **59** are provided on the splines **36**.

[0049] The splines **36** may be formed by rolling the sheets onto a mandrel and then bonding the distal ends to the distal end **42** of the deployment member **51**, and on the proximal end to the outer tube **32**, e.g., within the channels **51**. The sheets form a flexible circuit and may include gold plated electrode tabs **58**.

[0050] In FIG. **5***b*, the electrode traces are shown as the electrode traces may be bonded so that the electrode traces **59** fit through the channels **51** of the outer tube **32**. The traces **59** may then be connected to electrical wiring and extend through the lumen of the catheter system **10**. The electrical wiring may convey electrical signals between the electrodes **58** and one or more control system (not shown). For example, the electrical signals may be used to control output of ablation electrodes, or for processing input from mapping electrodes for viewing by the user, (e.g., on an electrical monitoring device).

[0051] It is also noted that the fluid delivery tubing **32** may also extend through a channel **60** formed through the center of the outer tube **30**. Of course other designs for the inner shaft **50** of the outer tube **32** may also be implemented, as will be readily understood by those having ordinary skill in the art after becoming familiar with the teachings herein. For example the channel **60** need not maintain the inner fluid delivery tubing **32** in the center of outer tube **30**. It is only desired that the inner fluid delivery tubing **32** be maintained in a substantially constant position within the diameter of the outer tube **30** for uninterrupted flow of the fluid during the procedure.

[0052] FIG. **6** is an isometric view of the basket catheter **25** of FIG. **4** with an outer layer **62** of the splines **36** shown covering the electrodes **58** and electrode traces **59** in FIG. **5***a*. Accordingly, the splines **36** may form a non-contact electrode basket catheter. The outer layer **62** may also be used as an additional stiffener to protect the flexible circuit portion of the splines **36**.

[0053] It is noted that the various embodiments of catheter system **10** described above may also be implemented with a wide variety of different sensing means. These sensing means enable the catheter system **10** to be implemented for tissue contact assessment during the procedures, including contact with the tissue. For example, the catheter system **10** may include one or more piezoelectric sensor embedded in the splines **36**. The piezoelectric sensor generates electric signals in response to stresses caused by contact with the tissue. Radiopaque sensors may also be used. Still other exemplary sensing devices may include pressure, thermistor, thermocouple, or ultrasound sensors. In addition, more than one sensor or type of sensor may be implemented to provide additional feedback to the user. In any event, when the splines **36** are positioned in contact with and/or moved over a tissue, the sensors may be implemented to generate an electrical signal corresponding to stress caused by this contact and/or movement for tissue contact assessment.

[0054] It is noted that any suitable analog and/or digital device may also be implemented for outputting data of electrical signals generated by the sensor(s) to a user. In addition, the electrical signals may be further characterized using a suitable processing device such as, but not limited to, a desktop or laptop computer. Such processing device may be implemented to receive the voltage signal generated by the contact assessment sensor(s) and convert it to a corresponding contact condition and output for the user, e.g., at a display device, an audio signal, or tactile feedback or vibrations on the handle of the catheter. In any event, circuitry for conveying output of the piezoelectric sensor to a user in one form or another may be readily provided by those having ordinary skill in the electronics arts after becoming familiar with the teachings herein.

[0055] Although several embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this invention. References are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations as to the position, orientation, or use of the invention. In addition, various combinations of the embodiments shown are also contemplated even if not particularly described. Changes in detail or structure, such as but not limited to combinations of various aspects of the disclosed embodiments, may be made without departing from the spirit of the invention as defined in the appended claims.

1-27. (canceled)

28. A catheter, comprising:

an outer tubing housing;

a plurality of splines configured to deploy from a linear configuration to an expanded configuration; and

flexible electronic circuitry extending along a length of the plurality of splines, wherein the flexible electronic circuitry is configured to conform to the shape of the splines as the splines are deployed.

29. The catheter of claim **28**, further comprising a plurality of electrodes disposed along the length of the plurality of splines, and communicatively coupled to the flexible electronic circuitry, and wherein the electrodes are configured to conduct one or more of the following: anatomy mapping, electrophysiological mapping, temperature measuring, cardiac pacing, and myocardial tissue ablation.

30. The catheter of claim **29**, wherein the plurality of splines, the flexible electronic circuitry, and the electrodes are encapsulated in an outer layer that is thermally and electrically conducting, the outer layer is configured to prevent direct contact between the electrodes and myocardial tissue within a cardiac muscle during at least one of therapy and diagnostic procedure, and to structurally stiffen the deployed basket catheter.

31. The catheter of claim **28**, further including a plurality of fluid delivery ports positioned at a distal end of the basket catheter, the fluid delivery ports configured to provide irrigation to the plurality of splines.

32. The catheter of claim **28**, further including an inner shaft, within the outer tubing, with a plurality of interstitial spaces that extend along the length of the inner shaft, and wherein each of the interstitial spaces mate with a proximal end of one of the plurality of splines, each of the interstitial spaces being configured to minimize the torsional bending moment of the mated spline in response to a force being exerted upon the basket.

33. The catheter of claim **29**, further including electrical leads that are disposed along the length of the interstitial space within the inner shaft and in conjunction with the flexible electronic circuitry communicatively couple the electrodes to controller circuitry at a proximal end of the outer tubing.

34. The catheter of claim **28**, further including an inner fluid delivery tubing within the outer tubing, and a deployment member axially movable within the inner fluid delivery tubing; wherein:

the distal end of the deployment member is coupled to a distal end of the splines; and

the splines are configured to expand axially outward in response to the motion of the deployment member in a first direction, and collapse axially inward in response to the motion of the deployment member in a second direction, the second direction being opposite the first direction.

35. The catheter of claim **28**, further including

an inner fluid delivery tubing within the outer tubing;

a seal disposed between the outer tubing and the inner fluid delivery tubing; and a gasket disposed at an end of the inner fluid delivery tubing between the deployment member and the inner fluid delivery tubing, wherein both the seal and the gasket are configured to prevent blood or other fluid from ingressing into the outer tubing and the inner fluid delivery tubing.

36. The catheter of claim **35**, wherein the seal is maintained in a fixed position relative to the outer tubing and the inner fluid delivery tubing.

37. The catheter of claim **35**, wherein the seal has an inner diameter smaller than an outer diameter of the inner fluid delivery tubing, and wherein the seal has an outer diameter larger than an inner diameter of the outer tubing.

38. The catheter of claim **35**, further including:

a deployment member axially movable within the inner fluid delivery tubing; and

a distal end of the deployment member connected to each of the plurality of splines, wherein the deployment member extends through the gasket, and is configured to be moveable through the gasket to expand and collapse the plurality of splines.

39. A catheter comprising:

a catheter shaft;

an expandable structure coupled to a distal end of the catheter shaft, the expandable structure configured to assume expanded and non-expanded configurations;

a fluid dispersion member including a plurality of fluid delivery ports at proximal and distal ends of the expandable structure, the fluid delivery ports configured to direct irrigation fluid toward the expandable structure;

a fluid delivery lumen extending a length of the catheter shaft and coupled to the fluid delivery ports, wherein the fluid delivery lumen is configured to distribute fluid from a reservoir disposed at a proximal end of the catheter shaft to the fluid delivery ports; and

flexible electronic circuitry extending along a length of the expandable structure, the flexible electronic circuitry configured to conform to the shape of the expandable structure as the expandable structure assumes the expanded and the non-expanded configurations.

40. The catheter of claim **39**, further including a plurality of electrodes disposed along the length of the expandable structure, and communicatively coupled to the flexible electronic circuitry, and wherein the electrodes are configured to conduct one or more of the following: anatomy mapping, electrophysiological mapping, temperature measuring, cardiac pacing, and myocardial tissue ablation.

41. The catheter of claim **40**, wherein the expandable structure, the flexible electronic circuitry, and the electrodes are encapsulated in an outer layer that is thermally and electrically conductive, the outer layer being configured to prevent direct contact between the electrodes and tissue during at least one of therapy and diagnostic procedure, and to structurally stiffen the deployed expandable structure.

42. The catheter of claim **40**, further including an inner shaft, within the catheter shaft, the inner shaft including a plurality of interstitial spaces that extend along a length of the inner shaft, and wherein each of the interstitial spaces mate with a proximal end of the flexible electronic circuitry.

43. The catheter of claim **42**, further including electrical leads that communicatively couple the flexible electronic circuitry and the electrodes to a handle of the catheter, and run the length of the interstitial space within the inner shaft.

44. The catheter of claim **39**, further including a central lumen, and wherein the plurality of fluid delivery ports are circumferentially dispersed around the central lumen.

45. The catheter of claim **39**, wherein the expandable structure includes a plurality of splines.

46. The catheter of claim **45**, further including a plurality of electrodes, wherein the splines are fabricated with the flexible electronic circuitry and the electrodes are disposed along the length of the splines and communicatively coupled to the flexible electronic circuitry, and wherein the electrodes are configured to conduct one or more of the following: anatomy mapping, electrophysiological mapping, temperature measuring, cardiac pacing, and myocardial tissue ablation.

47. A catheter comprising:

an elongate element, including a catheter shaft and a distal portion disposed at a distal end of the catheter shaft;

a plurality of electrodes distributed axially and circumferentially along the distal portion, the electrodes configured to conduct at least one of therapy and diagnostic operation;

a plurality of flexible electronic circuits that extend along an exterior surface of the distal portion; and

one or more conductors extending along a length of the catheter shaft.

48. The catheter of claim **47**, wherein the flexible electronic circuitry and the electrodes are encapsulated in an outer layer that is thermally and electrically conductive, the outer layer being configured to prevent direct contact between the electrodes and tissue during the at least one of therapy and diagnostic procedure, and to structurally stiffen the distal portion.

49. The catheter of claim **47**, wherein the at least one of therapy and diagnostic operation includes one or more of the following: anatomy mapping, electrophysiological mapping, temperature measuring, cardiac muscle pacing, and myocardial tissue ablation.

50. The catheter of claim **47**, further including an electrode controller disposed at a proximal end of the catheter shaft, the electrode controller configured to simultaneously control the plurality of electrodes and thereby conduct the at least one of therapy and diagnostic operation, and wherein the electrode controller is communicatively coupled to each of the plurality of electrodes via the flexible electronic circuits and the conductors.

51. The catheter of claim **28**, further comprising a deployment member axially movable within the inner fluid delivery tubing, and wherein a distal end of the deployment member is coupled to a distal end of the splines.

52. The catheter of claim **28**, wherein the plurality of splines are further configured to be formed by rolling sheets onto a mandrel, and bonding distal ends of the plurality of splines to a distal end of the deployment member and within one of a plurality of channels extending into a proximal end of the outer tube.

53. The catheter of claim **28**, wherein the flexible electronic circuitry is integral to the plurality of splines.

54. The catheter of claim **29**, wherein the plurality of electrodes are gold plated electrodes.

55. The catheter of claim **40**, wherein the plurality of electrodes are gold plated electrodes.

56. The catheter of claim **47**, wherein the plurality of electrodes are gold plated electrodes.

57. The catheter of claim **28**, wherein distal ends of the plurality of splines are anchored to one another, and proximal ends of the splines are anchored by the outer tubing, thereby forming an orb shape as the splines are deployed in the expanded configuration.

* * * * *

专利名称(译)	非接触式电极篮导管带灌溉		
公开(公告)号	[US20160331254A1](US20160331254A1)	公开(公告)日	2016-11-17
申请号	US15/155277	申请日	2016-05-16
[标]申请(专利权)人(译)	圣犹达医疗用品电生理部门有限公司		
申请(专利权)人(译)	ST.犹达医疗用品，房颤DIVISION，INC.		
当前申请(专利权)人(译)	ST.犹达医疗用品，房颤DIVISION，INC.		
[标]发明人	TEGG TROY T STEHR RICHARD E		
发明人	TEGG, TROY T. STEHR, RICHARD E.		
IPC分类号	A61B5/042 A61B18/14 A61B5/00		
CPC分类号	A61B5/042 A61B5/6858 A61B18/1492 A61B2018/00267 A61B2018/00577 A61B2018/00642 A61B2218/002 A61B2018/00351 A61B2018/00839 A61B2017/00867 A61B2018/00214 A61B2090/065 C08L2201/12		
外部链接	Espacenet　USPTO		

摘要(译)

公开了导管系统和方法。示例性导管包括外管道壳体和内流体输送管道，内流体输送管道具有至少一个流体输送端口。导管还包括在内部流体输送管内可轴向移动的展开构件。多个花键各自在近端连接到外管并且在远端连接到展开构件。在外管和内流体输送管之间提供密封。在展开构件和内部流体输送管之间提供垫圈。密封件和垫圈都构造成防止血液或其它流体进入外管。