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Catheter Shaft Having Highly Resilient Rubber Member and Method of Manufacture

Abstract

Catheter shaft assemblies that include a rubber member and a ring electrode mounted to induce radial deformation of the rubber member to inhibit loss of interference fit of the ring electrode, and related methods of fabrication, are disclosed. A catheter shaft assembly includes an elongate tubular inner layer, a first rubber member, an elongate outer layer, and one or more ring electrodes. The first rubber member is disposed on an exterior surface of the elongate tubular inner layer. The elongate outer layer covers an exterior surface of the first rubber member or the elongate tubular inner layer. The one or more ring electrodes are attached to and encircle the elongate outer layer or the first rubber member. Each of the ring electrodes induces a radial hyperelastic deformation of the first rubber member that inhibits loss of an interference fit of the ring electrode.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATION DATA [0001] The present application is a Continuation of PCT/US2023/035534 filed Oct. 19, 2023; which claims the benefit of U.S. Provisional Application No. 63/417,925 filed Oct. 20, 2022; the full disclosures which are incorporated herein by reference in their entirety for all purposes.

FIELD OF DISCLOSURE
[0002] This disclosure relates generally to an elongate catheter-based cardiovascular medical device and related components. More particularly, this disclosure relates to an elongate shaft portion of the device for the installation and securement of multiple ring electrodes on the shaft.
BACKGROUND
[0003] Elongate catheter-based cardiovascular medical devices, such as electrophysiology (EP) catheters, can be used in a variety of diagnostic and/or therapeutic procedures to diagnose and/or correct medical conditions such as atrial arrhythmias, including for example, ectopic atrial tachycardia, atrial fibrillation, and atrial flutter. Arrhythmias can produce a variety of medical conditions including irregular heart rates, loss of synchronous atrioventricular contractions, and stasis of blood flow in a chamber of a heart, which can lead to a variety of other symptomatic and asymptomatic ailments and even death. The catheters can include multiple ring-shaped electrodes (or simply ring electrodes or electrodes) fixedly coupled to an elongate shaft portion configured to achieve these diagnostic and/or therapeutic purposes. For example, some electrodes can be configured to transmit electrical signals from the heart anatomy for diagnostics (e.g., cardiac mapping), while other electrodes can be configured to impart resistive heating or irreversible electroporation for therapeutics.
[0004] Radiofrequency (RF) ablation therapy can be conventionally used to treat various medical conditions. For example, RF ablation therapy may be used to treat cardiac arrhythmias. It is believed that the primary cause of atrial arrhythmia is stray electrical signals within the left or right atrium of the heart. An ablation catheter can be used to impart ablative energy (e.g., radiofrequency energy, electroporation, cryoablation, lasers, chemicals, high-intensity focused ultrasound, etc.) to create a lesion in the abnormal cardiac tissue, such that any undesirable electrical pathways within the heart can be potently limited or prevented.
[0005] Electroporation is a non-thermal ablation technique in which an electric field is applied to tissue to induce pore formation in cellular membranes. The electric field from electrode(s) can be applied in a pulse train of relatively short duration pulses that last, for example, from a nanosecond to several milliseconds. When electroporation is applied to tissue in an in vivo setting, the cells in the tissue are subjected to a trans-membrane potential to induce the pore formation in the cellular membranes. Electroporation may be reversible (i.e., the induced pores are temporarily formed) or irreversible (i.e., the induced pores remain open and induce cellular destruction). In the field of cardiovascular diseases, irreversible electroporation can be used to induce cell destruction in the abnormal cardiac tissues that may cause any undesirable electrical pathways within the heart, thereby achieving similar, and possibly superlative, therapeutics to conventional RF ablation.
[0006] As an elongate medical device configured to provide an access to the heart anatomy and conduct relevant medical procedures (e.g., RF ablation, irreversible electroporation, cardiac mapping, etc.), a cardiovascular catheter generally consists of multiple shaft sections, including a proximal shaft section, a deflectable shaft section, and a distal functional shaft section (or

alternatively referred as electrode shaft section) disposed at, and adherently interconnected to, the distal end of the deflectable shaft section. The proximal shaft section of an elongate catheter is generally coupled with a handle and adherently interconnected with the deflectable shaft of the catheter. Typically, the deflectable shaft section of the catheter contains a pull ring disposed at its distal end and one or more pull wires coupled to the pull ring, wherein the pull wire(s) passes through the proximal shaft section and then coupled to an activating mechanism residing within the handle. Therefore, steering forces imposed at the handle can be effectively transmitted through the proximal shaft section to properly deflect or curve the deflectable shaft section in different orientations, such that the functional (or electrode) shaft section, including various related functional components (e.g., electrodes, sensors, etc.), can be desirably positioned within the heart anatomy for intended medical procedures. Examples of catheters with different shaft sections, in particular distal electrode shaft sections comprising ring electrodes, are disclosed in U.S. Pat. Nos. 5,524,337; 5,855,552; 6,032,061; and 7,914,515 which are incorporated herein in their entirety by reference.

BRIEF SUMMARY

[0007] The present disclosure relates to catheters used during medical procedures such as, for example, diagnostic and therapeutic procedures to detect and/or correct medical conditions such as atrial arrhythmias (e.g., ectopic atrial tachycardia, atrial fibrillation, and atrial flutter). In many embodiments, a catheter includes an elongate electrode shaft section comprising one or more rubber members for improved securement of one or more electrodes to the elongate electrode shaft section. When electrodes (e.g., ring electrodes) are radially reduced in dimensions (e.g., via mechanical swaging) to encircle the shaft, the rubber members of the electrode shaft section under compression, compared to other layers of the electrode shaft section made of a different material e.g., thermoplastic polymers, will exhibit some long-term, hyperelastic material strains with minimal compression sets of material to be able to impart some long-lasting, high push-back forces against the electrodes for effectively maintaining the interference fits between the electrodes and the shaft. For example, the electrode shaft section has a composite tubular structure comprising multiple layers with same or different material properties. The one or more electrodes can be secured in place due to push-back radial forces/pressure from layers of the electrode shaft section. However, the layers of the electrode shaft section will exhibit decaying or time-evolving loss of the push-back radial force against the electrodes due to viscoelastic behavior of polymer (e.g., permanent set, stress relaxation, etc.). To enhance securement of the electrodes, the catheter shaft assembly herein is provided with the one or more members made of a highly resilient rubber or thermosetting elastomer in addition to other layers made of same or different thermoplastic polymer(s), including thermoplastic elastomers. The rubber members advantageously imparts the electrode shaft section with the high material resiliency and hyperelasticity with minimal compression set, while the other thermoplastic layers provides good manufacturability for the incorporation of the rubber member(s) into the shaft via thermal fusion bonding or melt reflow. In some embodiments, the electrode shaft section onto which ring electrodes are mounted can be disposed at, and adherently interconnected to, the distal end of a deflectable shaft section, such that the electrode shaft section, along with the deflectable shaft section, can be articulated to navigate through a tortuous path through a patient's vasculature. Advantageously, one or more rubber members of the electrode shaft section can sustain higher material strains and stresses for securely holding the electrodes in place during operation.

[0008] Thus, in one aspect, a catheter shaft assembly is described. The catheter shaft assembly includes an elongate tubular inner layer, a first rubber member disposed on an exterior surface of the elongate tubular inner layer, an elongate outer layer that covers an exterior surface of the first rubber member or the elongate tubular inner layer, and one or more ring electrodes attached to and encircling the elongate outer layer or the first rubber member, wherein each of the ring electrodes induces a radial hyperelastic deformation of the first rubber member that inhibits loss of an interference fit between the ring electrode and the elongate outer layer or the first rubber member. In some embodiments, the first rubber member encircles and extends along a first length of the elongate tubular inner layer.

[0009] In many embodiments, the elongate tubular inner layer is made of a thermoplastic or thermoplastic elastomer material. The thermoplastic or thermoplastic elastomer material of the elongate tubular inner layer has a durometer of greater than Shore D40. For example, the thermoplastic or thermoplastic elastomer material of the elongate tubular inner layer has a durometer in the range of Shore D60 to D85. In many embodiments, the outer layer is made of a thermoplastic or thermoplastic elastomer material. In some embodiments, the thermoplastic or thermoplastic elastomer material of the outer layer is the same as that of the elongate tubular inner layer. In some embodiments, the thermoplastic or thermoplastic elastomer material of the outer layer is different from that of an elongate tubular inner layer and has a durometer of less than Shore D60. In many embodiments, the first rubber member has a durometer equal to or less than Shore A65. The first rubber member is formed of a silicone rubber compound. In some embodiments, the first rubber member is chemically treated to impart chemical compatibility with at least one of the elongate tubular inner layer and the elongate outer layer.

[0010] In many embodiments, the elongate tubular inner layer has the same length as the elongate outer layer. In many embodiments, the first rubber member is elongated, and has a length equal to or shorter than the elongate tubular inner layer or the elongate outer layer. The first rubber member can be disposed between the elongate tubular inner layer and the elongate outer layer.

[0011] In some embodiments, the catheter shaft assembly further includes a second rubber member. Each of the first rubber member and the second rubber member has a length equal to or longer than a ring electrode of the one or more ring electrodes. The first rubber member is longitudinally spaced apart from the second rubber member along the elongate tubular inner layer. The catheter shaft assembly further includes a third rubber member having a length equal to or longer than a ring electrode of the one or more ring electrodes. The first, second, and third rubber members are longitudinally spaced apart from each other at equal distances or varying distances.

[0012] In some embodiments, the catheter shaft assembly further includes a second rubber member and a third rubber member. The first rubber member, the second rubber member, and the third rubber member are circumferentially distributed and spaced apart along the length of the elongate tubular inner layer. Each of the one or more ring electrodes induces a radial hyperelastic deformation on each of the first rubber member, the second rubber member, and the third rubber member that inhibits loss of the interference fit between each of the ring electrodes and the elongate outer layer, the first rubber member, the second rubber member, or the third rubber member. In some embodiments, the catheter shaft assembly further includes a fourth rubber member, a fifth rubber member, and a sixth rubber member. The first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, and the sixth rubber member are circumferentially distributed and spaced apart along the first length of the elongate tubular inner layer. Each of the one or more ring electrodes induces a radial hyperelastic deformation of each of the first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, and the sixth rubber member that inhibits loss of the interference fit between the one or more ring electrodes and the elongate outer layer, the first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, or the sixth rubber member.

[0013] In some embodiments, at least one of the first rubber member and the second rubber member comprises a protruding portion shaped to enhance coupling with the elongate outer layer. For example, the first rubber member comprises a protruding portion shaped to enhance coupling with the outer layer or the elongate tubular inner layer. In some embodiments, the first rubber member is a tubular rubber member comprising at least one longitudinally oriented through slot or holes for facilitating melt flow-induced space filling and thermal fusion bonding of the elongate tubular inner layer, the outer layer, and the first rubber member.

[0014] In many embodiments, the catheter shaft assembly further includes a first electrode wire electrically connected to the first ring electrode. For example, the first rubber member includes a first electrode wire hole through which the first electrode wire extends. In some embodiments, the first rubber member further includes a potting hole configured to accommodate injection of a potting adhesive through the potting hole into a lumen defined by the elongate tubular inner layer.

[0015] In many embodiments, the catheter shaft further includes a metallic braided layer that is longitudinally disposed over the exterior surface of the elongate tubular inner layer and under an interior surface of the first rubber member.

[0016] In another aspect, a method of manufacturing a catheter shaft is described. The method involves forming a tubular inner thermoplastic layer, forming a first shaft assembly by placing or optionally in situ forming a first rubber member on an exterior surface of the tubular inner thermoplastic layer, forming a second shaft assembly by placing an outer thermoplastic layer over the first shaft assembly, forming a bonded catheter shaft by thermal-fusion bonding between the inner and outer thermoplastic layers to affix the first rubber member in position within the second shaft assembly; and attaching a first ring electrode to the bonded catheter shaft so that the first ring electrode induces a radial hyperelastic deformation of the first rubber member that inhibits loss of an interference fit between the first ring electrode and the bonded catheter shaft. In many embodiments, the first rubber member encircles and extends along a first length of the bonded catheter shaft. The first rubber member has a durometer equal to or less than Shore A65. The first rubber member is made of a silicone rubber compound.

[0017] In many embodiments, forming the first shaft assembly comprises placing or optionally in situ forming a plurality of discrete rubber members on the exterior surface of the tubular inner thermoplastic layer so that the discrete rubber members are circumferentially distributed and spaced apart along a first length of the tubular inner thermoplastic layer, wherein the plurality of discrete rubber members comprises the first rubber member. In some embodiments, one or more of the discrete rubber members include a protruding portion shaped to enhance coupling of the discrete rubber member with the outer thermoplastic layer.

[0018] In some embodiments, forming the first shaft assembly involves applying an adhesive to (e.g., temporarily affix the plurality of the pre-formed discrete rubber members onto) the exterior surface of the inner thermoplastic layer. The adhesive, when cured, is thermoplastic in nature. The adhesive includes a cyanoacrylate adhesive comprising at least one of: a cyanoacrylate monomer or oligomer.

[0019] In many embodiments, the thermal-fusion bonding comprises melting and reflowing the tubular inner thermoplastic layer and the outer thermoplastic layer of the second shaft assembly under radial compressive pressure. Forming the bonded catheter shaft further includes placing a heat-shrinkable tube over the outer thermoplastic layer prior to heating the second shaft assembly. In some embodiments, the method further involves pre-treating the first rubber member with one or more silane coupling agent to impart chemical compatibility with at least one of the inner thermoplastic layer or the outer thermoplastic layer e.g., to enhance melt adhesion of the inner and outer thermoplastic layers with the first rubber member.

[0020] In many embodiments, attaching a first ring electrode to the bonded catheter shaft comprises swagging the first ring electrode onto the bonded catheter shaft using a swaging die.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate one or more embodiments and, together with the description, explain these embodiments. The accompanying drawings have not necessarily been drawn to scale. Any values dimensions illustrated in the accompanying graphs and figures are for illustration purposes only and can or cannot represent actual or preferred values or dimensions. Where applicable, some or all features cannot be illustrated to assist in the description of underlying features.

[0022] FIG. **1** is a catheter, in accordance with some embodiments of the present disclosure.

[0023] FIG. **2**(*a*) is an example catheter shaft portion including example rubber member for electrode shaft section of the catheter of FIG. **1** in a longitudinally exploded view.

[0024] FIG. **2**(*b*) shows a cross-section view of the electrode shaft section of FIG. **2**(*a*).

[0025] FIG. **2**(*c*) is an enlarged portion of the cross-section of FIG. **2**(*b*)

[0026] FIG. **2**(*d*) illustrates example forces acting on an electrode of the electrode shaft section.

[0027] FIG. **2**(*e*) illustrates example forces acting on electrode shaft section layers underneath the electrode of FIG. **2**(*d*).

[0028] FIG. **2**(*f*) illustrates a rubber member with slots.

[0029] FIG. **2**(*g*) illustrates a rubber member with holes.

[0030] FIG. **3** is another example catheter shaft portion including another example rubber member for an electrode shaft section of the catheter of FIG. **1** in a longitudinally exploded view and in a cross-section view.

[0031] FIG. **4** is another example catheter shaft portion including another example rubber member for an electrode shaft section of the catheter of FIG. **1** in a longitudinally exploded view and in a cross-section view.

[0032] FIG. **5** is an electrode shaft section showing electrodes coupled to the shaft of the catheter of FIG. **1**.

[0033] FIG. **6** is a longitudinal-section view of the electrode shaft section showing electrodes coupled to the shaft of the catheter of FIG. **5**.

[0034] FIG. **7** is an enlarged view of the longitudinal-section view of FIG. **6** showing different layers of the electrode shaft section including a rubber member.

[0035] FIG. **8** illustrates different shaft sections of another catheter similar to the catheter shown in FIG. **1**.

[0036] FIG. **9** illustrates an electrode shaft section of the catheter of FIG. **8** without a rubber member.

[0037] FIG. **10** is a graph illustrating relaxation behavior of some compressive material stress over time for different polymer materials under a given compression.

[0038] FIG. **11** is method of manufacturing the electrode shaft section of the catheter of FIG. **1** including a rubber member.

[0039] FIG. **12** is another example method of manufacturing an intimately bonded distal shaft assembly comprising an integral electrode shaft section of the catheter of FIG. **1** including a rubber member.

[0040] FIG. **13** is a schematic and block diagram of an electrophysiology catheter system for RF ablation or electroporation therapy that can include the catheter of FIG. **1**.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0041] The description set forth below in connection with the appended drawings is intended as a description of various embodiments of the disclosed subject matter and is not necessarily intended to represent the only embodiment(s). In certain instances, the description includes specific details for the purpose of providing an understanding of the disclosed embodiment(s). However, it will be apparent to those skilled in the art that the disclosed embodiment(s) can be practiced without those specific details. In some instances, well-known structures and components can be shown in block diagram form in order to avoid obscuring the concepts of the disclosed subject matter.

[0042] The present disclosure provides a catheter suitable for use in the human vasculature for known medical procedures, such as cardiac ablation, cardiac mapping, irreversible electroporation, etc. For purposes of description and explaining the concepts, the present disclosure will be described in connection with ring electrodes that are mounted on a distal shaft section of the catheter e.g., via mechanical swaging. The distal shaft section with electrodes of the catheter herein comprises one or more highly resilient, rubber members, which will, upon instant compressive deformation imposed by the swaging of the electrodes, be able to sustain some counteractive, elastic push-back force against the electrode(s) to tightly secure the interference fit (e.g., pressed fit or friction fit) between the electrodes and the shaft for a long term. It is contemplated, however, that the described features may be incorporated into any number of catheters or introducers as would be appreciated by one of ordinary skill in the art.

[0043] Referring now to the figures, in which like reference numerals refer to the same or similar features in the various views, FIG. **1** shows a catheter **100** with a handle **110**, in accordance with many embodiments. The catheter **100** includes an elongate shaft **120** comprising a distal shaft section **250** onto which electrodes **112** are mounted e.g., via mechanical swaging. In many embodiments, the proximal end **201** of the distal shaft section **250** can be adherently attached to the distal end **201**A of a deflectable shaft section **200** of the catheter **100**. The distal shaft section **250** has a distal end **202** that may be adherently attached to other functional shaft sections (for example, for adopting an ablation tip & assembly and for accommodating sensors), such that the distal shaft section with electrodes, when integrated with the other functional shaft sections, may be alternatively identified as a distal functional shaft assembly (FSA) **270** of the catheter **100** (FIG. **7**). A proximal portion **100**A of the proximal shaft section **150** is coupled to a handle **110**. The handle **110** is configured and operable to selectively curve the deflectable shaft section **200** together with the distal shaft section **250** with electrodes and other applicable functional shaft sections. For example, the deflectable shaft section **200**, along with the distal shaft section **250**, is configured to be selectively deflected in either of two directions as illustrated to accommodate navigation of the elongate shaft **120** through a patient's vasculature and/or positioning/orientation of the distal shaft section **250** of the catheter **100** within the heart anatomy during a medical procedure.

[0044] In many embodiments, the elongate shaft **120** has a composite, hollow shaft structure. The elongate shaft **120** includes various shaft sections with varying mechanical properties (e.g., stiffness, rigidity, flexibility, etc.), and/or may contain different electrical and functional components or assemblies, such as conductors or wires, magnetic sensors, optical force sensors, etc. The elongate shaft **120** can be made of same or different materials to collectively achieve a desired mechanical performance for a particular shaft section of the catheter **100**. According to the present disclosure, the distal shaft section **250** or at least a portion of the distal shaft section **250**, includes one or more rubber members configured to provide improved securement of electrodes **112**. For example, the distal shaft section **250** comprises an elongate tubular shaft structure (e.g., see FIGS. **2**(*a*)-**2**(*g*)-**4**), in which one or more rubber members or other hyperelastic member (e.g., **220**, **320**, **420**) are disposed over an inner layer **210** or between an inner layer **210** (e.g., made of thermoplastic material) and an outer layer **230** (e.g., made of thermoplastic material). In many embodiments, one or more electrodes **112** are mounted to compressively encircle the distal shaft section **250** via mechanical swaging, so as to form the interference fit or pressed fit between the electrodes **112** and the distal shaft section **250**. Swaging-induced hyperelastic compressive material strains within the distal shaft section **250** comprising the one or more rubber members can make the distal shaft section **250** effectively sustain a counteractive push-back force against the electrode(s) that inhibits the loss of an interference fit between the one or more ring electrodes and the distal shaft section **250**. A hyperelastic material such as thermosetting elastomer or rubber is a material that respond elastically even when they are subjected to large deformations. The material shows both a nonlinear material behavior as well as large shape changes. Hyperelastic material can be characterized by large elastic deformations of order of 100 to 700% which are largely recoverable, i.e., the initial shape can be almost completely (e.g., more than 95% of the initial shape) recovered when load is removed. Example structure and configuration of the one or more rubber members or other hyperelastic material for the distal shaft section **250** are further discussed with respect to FIGS. **2**(*a*)-**2**(*g*) through FIG. **4**.

[0045] FIGS. **2**(*a*)-**2**(*g*) illustrates an example construction of a portion **250**A of a distal shaft section **250** with electrodes comprising at least one rubber member for the elongate shaft **120** of the catheter **100**. The distal shaft section **250** or one or more portion (e.g., **250**A) thereof includes one or more rubber members configured to provide improved securement of the electrodes **112** (e.g., ring electrodes) to the shaft of the distal shaft section **250**. In the illustrated embodiment, the elongate distal shaft section **250** includes an elongate tubular inner layer made of thermoplastic polymer material, i.e., an inner layer **210**, a tubular rubber member **220**, and a tubular outer layer **230**. The tubular rubber member **220** extends along a length equal to or slightly shorter than the length of the distal shaft section **250**, while the inner and outer layers **210** and **230** extend the full length of distal shaft section. In some embodiments, the elongate distal shaft section **250** with electrodes comprises the tubular layers **210**, **220**, and **230** in same or different thicknesses and has its inner and outer thermoplastic layers made of the same or different thermoplastic polymer materials. Accordingly, the inner layer **210** and the outer layer **230** can be interchangeably referred as the inner thermoplastic layer **210** and the outer thermoplastic layer **230**, respectively, without limiting the scope of the present disclosure.

[0046] In many embodiments, the distal shaft section **250** includes the inner thermoplastic layer **210** and the outer thermoplastic layer **230** that are chemically similar or compatible to each other but may have the same or different mechanical properties of polymer and where the tubular rubber member or layer **220** is adherently sandwiched between the thermoplastic layers **210** and **230**. For example, the outer thermoplastic layer **230** can be made of a thermoplastic elastomer material having a durometer of less than Shore D40 (e.g., poly(ether block amide) copolymers, poly(ether-co-ester) copolymers, thermoplastic polyurethanes, thermoplastic olefins, olefinic thermoplastic vulcanizates, and the like), while the inner thermoplastic layer **210** can be made of a thermoplastic elastomer or thermoplastic having a durometer of greater than Shore D50, preferably greater than Shore 70D (e.g., nylons, polyesters, poly(bisphenol A carbonate), polyolefins, polysulfone, etc.). The tubular rubber member **220** can be made of a highly resilient rubber material having a durometer from Shore A40 to Shore A90 and good thermal stability of material, e.g., silicone rubber. The electrodes **112** can be made of 90Pt:10Ir.

[0047] In some embodiments, each of the inner thermoplastic layer **210**, the tubular rubber member **220**, and the outer thermoplastic layer **230** may have same longitudinal lengths. In some embodiments, the inner thermoplastic layer **210**, the tubular rubber member **220**, and the outer thermoplastic layer **230** may have different longitudinal lengths. For example, the inner thermoplastic layer **210** and the outer thermoplastic layer **230** may have same longitudinal lengths and are axially extended to the full length of the distal shaft section **250** (e.g., a length between the proximal end **201** and the distal end **202**). The tubular rubber member **220** may have a shorter longitudinal length than the thermoplastic layers **210** and **230**, such that two thermoplastic layers **210** and **230** are integrally adhered together where the tubular rubber member or layer **220** is absent at and near two opposite ends **201** and **202** of the distal shaft section **250**.

[0048] In some embodiments, there may be more than one tubular rubber members **220** longitudinally disposed along the distal shaft section **250**, each of which has a length equal to, or slightly longer than, the length of the corresponding ring electrodes, such that the individual tubular rubber members **220** can be longitudinally disposed and fully encapsulated by the thermoplastic layers **210** and **230** having an elongate tubular structure to form different shaft portions where electrodes are to be mounted, while the thermoplastic layers **210** and **230** can be intimately adhered to each other where the tubular rubber members **220** or electrodes **112** are absent.

[0049] In many embodiments, the inner thermoplastic layer **210** extends longitudinally e.g., between the proximal end **201** and the distal end **202** of the elongate distal shaft section **250**. The inner thermoplastic layer **210** may further extend longitudinally up to the entire deflectable shaft section **200**, or even continuously extend to the proximal shaft section **150** (i.e., the entire length of an elongate shaft **120**).

[0050] In many embodiments, the inner thermoplastic layer **210** includes a center lumen to accommodate various electrical components for catheter **100** (e.g., conductors to electrodes and leading conductive wires to sensors, etc.), and/or functional assemblies (e.g., assemblies associated with magnetic positioning sensor, optical force sensor, etc.), and/or other accessory components (e.g., pull wires, irrigation fluid tube, and etc.) as required to perform a medical procedure. Some functional assemblies, e.g. sensor assemblies, include shell-like sensor holders that are made of high-performance engineering polymer materials like polysulfone, polyetherimide, poly(ether ether ketone), etc.) may make direct contact with the interior surface of the inner thermoplastic layer **210**, such that the inner thermoplastic layer **210** of the distal shaft section **250** is largely supported and strengthened to prevent any radial clasping when the electrodes **112** are forcibly swaged to impose radial compression force against the distal shaft section **250**.

[0051] The tubular rubber member **220** is placed or optionally in situ formed over the inner thermoplastic layer **210** that may be further internally strengthened or supported (by relatively rigid shell-like sensor holders). The tubular rubber member **220** is flexible and tightly fits on an exterior surface of the inner thermoplastic layer **210**. The outer thermoplastic layer **230** tightly fits on the exterior surface of the tubular rubber member **220**. The tubular rubber member **220** can be adherently integrated with the thermoplastic layers **210** and **230** such that there is no relative movement between each other. For example, the relative disposition of the layers **210**, **220**, and **230** is shown in FIG. **2**(*b*). FIG. **2**(*b*) illustrates a cross-section view taken along a section line A-A in FIGS. **2**(*a*), and **2**(*c*) shows an enlarged portion A′ of the cross-section. FIGS. **2**(*b*) and **2**(*c*) show an interior surface of the tubular rubber member **220** is intimately integrated with the exterior surface of the inner thermoplastic layer **210**. Further, the exterior surface of the tubular rubber member **220** is intimately integrated with the interior surface of the outer thermoplastic layer **230**. The integral thickness of the distal shaft section comprising the layers **210**, **220**, and **230** with the electrode **112** can be configured to maintain a desired outer diameter comparable to that of the deflectable shaft section **200** or the elongate shaft **120** to facilitate insertion and retraction through blood vessels within a patient. For example, FIGS. **2**(*b*) and **2**(*c*) illustrate relative thickness and diameters of the inner thermoplastic layer **210**, the tubular rubber member **220**, and the outer thermoplastic layer **230**. In particular, an outer thermoplastic layer **230** can be very thin and made of a thermoplastic elastomer material that is considerably softer than the inner thermoplastic layer **210**. Thus, advantageously, the rubber member **220** can largely retain its high hyperelastic material deformation to effectively provide push-back forces, via the thinner and softer thermoplastic outer layer **230**, against an electrode **112**, while the inner layer **210** would only bear a small material deformation to dissipate or become unrecoverable over time, thereby electrodes can be securely coupled against the push-back forces in the long term.

[0052] Unlike the inner and outer thermoplastic layers **210** and **230**, the tubular rubber members **220** cannot be re-shaped or re-processed by heating. Hence, in many embodiments, the tubular rubber members **220** as shown in FIGS. **2**(*a*)-**2**(*g*) have a particular structural feature of e.g., at least one elongate slots **225** (see FIG. **2**(*f*)) or multiple holes **227** (see FIG. **2**(*g*)) through the wall of the rubber members **220**. The slots **225** and holes **227** may be staggered formation, evenly distributed, or other geometric formation without limiting the scope of the present disclosure. When subjected to heating, the inner and outer thermoplastic layers **210** and **230** can reflow through the slots or holes and be reshaped to encapsulate the rubber members **220** intimately and adherently within the distal shaft section **250** as an integral entity.

[0053] In many embodiments, the tubular rubber member **220** extend longitudinally e.g., between the proximal end **201** and the distal end **202**, or a portion therebetween. For example, the tubular rubber member **220** can have a longitudinal length defined by a distance between end electrodes **112** e.g., a distal electrode and a proximal electrode. The tubular rubber member **220** may be shorter in length than the inner thermoplastic layer **210** and/or the outer thermoplastic layer **230**.

[0054] In some embodiments, the tubular rubber member **220** has a continuous length extending along the distal shaft section **250**. In some embodiments, multiple pieces of the tubular rubber member **220** may be longitudinally spaced from each other. For example, the distal shaft section **250** may include one or more tubular rubber members **220**, each rubber member disposed at a longitudinal location along the distal shaft section **250** that corresponds to a particular electrode of the electrodes **112** (e.g., as shown in FIG. **7**). For example, a first tubular member may be disposed at a first longitudinal location of the distal shaft section **250** where a first electrode of the electrodes **112** is mounted, a second tubular member may be disposed at a second longitudinal location of the distal shaft section **250** where a second electrode of the electrodes **112** is mounted, etc. Each of these tubular rubber members **220** may have a longitudinal length comparable to or slightly longer than a corresponding electrode to be mounted along the distal shaft section **250** e.g., by mechanical swaging.

[0055] The tubular rubber member **220** can largely sustain the swaging-induced hyperelastic material strains and associated compressive material stresses for a considerably longer duration of time than other thermoplastic layers of the distal shaft section **250**. The tubular rubber member **220** facilitates improved securement of the electrode **112** by providing the long-lasting push-back forces against the electrode **112** in response to the hyperelastic material strains and stresses within the shaft portion **250**A, at which the electrode **112**, when mounted, imposes constant compressive deformation on the shaft **250**A. The tubular rubber element **220** has a short relaxation time of material and can swiftly attain its steady state of stress relaxation with minimal permanent set (e.g., minimal unrecoverable or viscous or inelastic material strains), such that the shaft portion **250**A at the steady state can still counteractively impart a hyperelastic push-back force against the electrode **112** to maintain an interference fit between the electrodes **112** and the distal shaft section **250**.

[0056] Mechanical swaging is a forging or cold-working process, during which the diameters of an electrode **112** are forcibly, “permanently” reduced by applying a rotary die, thus resulting in some compressive material strains in the hoop (or circumferential) direction (“h”) and in the radial direction (“r”) and the associated compressive material stresses (σ.sub.r and σ.sub.h) within various constituent components (i.e., the layers **210**, **220**, and **230**) of the shaft portion **250**A. FIGS. **2**(*d*) and **2**(*e*) show the schematic, free-body force diagrams for the electrode **112** and the shaft portion **250**A of the distal shaft section **250** comprising the rubber member **220**, the inner thermoplastic layer **210**, and a skin-like, flexible outer thermoplastic layer **230** over the exterior surface of the rubber member **220**.

[0057] At and after mechanical swaging, the swaging-mounted electrode **112** will impose a radial compressive force (cf) that circumferentially distributes on the exterior surface of the shaft portion **250**A, which will relax or decay with time because some compressive material strains are inelastic (i.e., unrecoverable) in nature or the associated compressive material stresses (i.e., σ.sub.h and σ.sub.r) within the continuum comprised of various constituent layers of the shaft portion **250**A will relax towards steady strained/stressed states. In many embodiments, the inner thermoplastic layer **210** is made of a rigid thermoplastic polymer or thermoplastic elastomer having a considerably higher material hardness than the rubber member **220** made of an elastomeric thermosetting or crosslinked polymer material and also the outer thermoplastic layer **230**.

[0058] Hence, when a radial compressive force (cf) applied on the shaft portion **250**A, the rubber member **220**, as compared to other constituent thermoplastic layers **210** and **230** within the continuum of the shaft portion **250**A, will qualitatively experience a much higher material strain that is hyperelastic in nature because of the highly resilient, elastomeric mechanical properties of the rubber material, including a small compression set (<5% to 30%) and a significantly short characteristic time (τ) of stress relaxation of material. In contrast, the swaging-induced compressive material strains within the inner thermoplastic layer **210** of the shaft portion **250**A are relatively small in magnitude and viscoelastic (or more viscous or plastic) in nature. Therefore, the swaging-induced material strains within the layer **210** tend to become unrecoverable and eventually take a high compression set (e.g., >50% to nearly 100%), and the associated material stresses within the layer **210** will decay with time. In contrast, the swaging-induced, relatively large hyperelastic material strains tend to recover and will not ever decay to none, and neither will the associated material stresses in relaxation towards the steady strained/stressed state of material, within the rubber member **220**, thanks to low compression set and fast stress relaxation characteristics of the rubber material (e.g., <5 to 30%), such that the rubber member(s) **220** with the shaft portion **250**A can counteractively impose a sustainable push-back force (pf) against the electrode(s) **112** at any portions of the shaft portion **250**A where electrode(s) is mounted.

[0059] As shown in FIG. **2**(*d*), the shaft portion **250**A, as a free body subjected to the only radial compressive force (cf) imposed by the electrode(s) **112**, can be in force balance on its own, provided that the inner tubular thermoplastic layer **210** is mechanically strong to support and contain the rubber member **220** within the distal shaft section **250** (e.g., without any material failure or structural collapsing). Alternatively, the distal shaft section **250** may experience some additional radial force (sf) externally imposed by any components/assemblies that reside within the center lumen of the distal shaft section **250** (e.g., sensor holders). This radial force (cf) may advantageously provide a mechanical support to the distal shaft section **250** to prevent any possible structural collapsing when the shaft portion **250**A is externally subjected to any swaging-induced radial compressive force (cf). Again, the shaft portion **250**A, as a free body subjected to both radial compressive forces in opposite directions (cf and sf), are in force balance on its own. Following Newton's third law, the push-back force (pf) (against electrodes **112**) is equal to the “relaxing” compressive force (cf) (against the shaft portion **250**A) in magnitude but opposite in direction. The electrode **112** has substantially higher rigidity than the polymer materials of the shaft portion **250**A. As such, the electrode **112**, as a free body, is externally subjected to only “relaxing” push-back force (pf) that is circumferentially distributed on the interior surface of the electrode **112**, can be in balance on its own without causing material creeping or expansion. Under the “relaxing” but highly sustainable radial compressive force (pf), there is a highly sustainable static frictional force (F or F′) against the electrode(s) **112**. That is, whenever the electrode **112** tends to become loose with respect to the shaft portion **250**A in any directions (e.g., clockwise or counterclockwise, etc.), a counteracting static frictional force (F or F′) in an opposite direction will spontaneously appear to secure the interference fit, which is also commonly known as friction fit, for inhibiting any movement of the electrode **112** with respect to the shaft portion **250**A or the distal shaft section **250** of the catheter **100**.

[0060] Additionally or alternatively, a braided layer **213** woven of metal material or other rigid material to provide structural rigidity and resilience. The braided layer **213** can be alternatively referred as metallic braided layer **213**, without limiting the scope of the present disclosure. For example, the braided layer **213** may be multiple stainless-steel wires woven in some pattern that partly extend along the distal shaft section **250** from the deflectable shaft section **200** to provide additional structural rigidity and resiliency for the distal shaft section **250** (in FIG. **1**). The metallic braided layer **213** may be disposed underneath the tubular rubber member **220** or between the inner thermoplastic layer **210** and the tubular rubber member **220**.

[0061] FIG. **3** illustrates another example construction of the distal shaft section **250**, in particular a shaft portion **250**B. The shaft portion **250**B has one or more than one rubber members that are non-tubular (e.g., having an arc-shape) unlike a tubular rubber member of the shaft portion **250**A in FIGS. **2**(*a*)-**2**(*g*)). Other layers e.g., **210** and **230** can be same as layers of the shaft portion **250**A. In the illustrated embodiment, in FIG. **3**, the shaft portion **250**B of the distal shaft section **250** can include one or more longitudinally extending discrete rubber members (e.g., **320**, **321**, **322**). The discrete rubber members (e.g., **320**, **321**, **322**) can advantageously ensure secured attachment of the electrodes **112** in the same manner as the tubular rubber member **220** (in FIGS. **2**(*a*)-**2**(*g*)). For example, the discrete rubber members **320-322** provides the push-back forces in a similar manner as discussed with respect to FIGS. **2**(*a*)-**2**(*g*) above. Example structure and distribution of the discrete rubber members can be seen in a cross-section view B-B in FIG. **3**(*b*) and an enlarged view of a portion B′ in FIG. **3**(*c*).

[0062] In the illustrated embodiment, in FIG. **3**(*b*), the distal shaft section **250** includes the inner thermoplastic layer **210**, a group or set of discrete rubber members **320**, **321**, and **322** (for example, used in place of the tubular rubber member **220** in FIGS. **2**(*a*)-**2**(*g*)), and the outer thermoplastic layer **230**. Additionally or alternatively, the metallic braided layer **213** may be included in the composite shaft structure of a distal shaft section **250**. The group of the discrete rubber members **320**, **321**, and **322** may be longitudinally disposed at individual location corresponding to each ring electrodes along a length of the distal shaft section **250** or longitudinally extended for a length equal to or slightly less than the distal shaft section **250**. The discrete rubber members **320**, **321**, and **322** in a group are circumferentially spaced apart from each other. For example, a first rubber member **320** is circumferentially spaced from a second rubber member **321** and a third rubber member **322**. In many embodiments, the rubber members **320**, **321**, and **322** are evenly spaced over an exterior surface of the inner thermoplastic layer **210**. An arcuate arc length (AL) (see FIG. **3**(*c*)) of each of the discrete rubber members **320-322** can be the same so that equal amount of the push-back forces can be applied to the electrode **112** at different angular positions corresponding to the discrete rubber members **320-322**. The push-back forces from the rubber members **320-322** disposed at locations corresponding to the electrodes will be similar to that shown in FIG. **2**(*b*). However, along a circumferential arc-length portion between the discrete rubber members **320-322**, the distal shaft section **250** comprises the inner and outer thermoplastic layers **210**, **230**, which will experience a slow relaxation of the push-back forces over time. These push-back forces from the layers may tend to eventually disappear because swaging-induced compressive material strains may become as permanent sets. Advantageously, the discrete rubber members **320-322** will be able to sustain the swaging-induced material strains and associated material stresses, thus imposing the desired push-back forces for the long-term securement of the electrodes **112** against the distal shaft section **250** or its portion **250**B comprising the highly resilient rubber members.

[0063] FIG. **4** illustrates an example construction of the distal shaft section **250**, in particular a shaft portion **250**C. The shaft portion **250**C has one or more than one rubber members that are non-tubular (e.g., having an arc-shape) unlike a tubular rubber member of the shaft portion **250**A in FIGS. **2**(*a*)-**2**(*g*)). The electrode shaft section **250** comprising the shaft portion **250**C in FIG. **4** has similar construction as the distal shaft section **250** comprising the shaft portion **250**B of FIG. **3**, except that there are a group of six, instead of three, discrete rubber members in place of a tubular rubber member **220** for a shaft portion **250**A of FIGS. **2**(*a*)-**2**(*g*). It can be understood that the present disclosure is not limited by a number of discrete rubber members in a group and any appropriate number (e.g., 2, 3, 4, 5, 6, or more) of the rubber members for the group may be employed. Again, the discrete rubber members **420-425** in FIG. **4** can advantageously ensure secured attachment of the electrodes **112** in the same manner as the discrete rubber members **320-322** in FIG. **3**. For example, the discrete rubber members **420-425** provide the sustainable long-term push-back forces in a similar manner as discussed with respect to FIG. **3** above. Example structure and distribution of the discrete rubber members **420-425** can be seen in a cross-section view C-C in FIG. **4**(*b*) and an enlarged view of a portion C′ in FIG. **4**(*c*).

[0064] In the illustrated embodiment, in FIG. **4**(*c*), a discrete rubber member (e.g., **420**) has protruding portions (or side profiles) **401** and **402**. The protruding portions **401** and **402** may be wing-like features formed at two opposite ends of the discrete rubber member **420**. The protruding portions **401** and **402** create spaces to be filled by the polymer material of the thermoplastic layers **230** and/or **210**. For example, the outer thermoplastic layer **230** can melt and spread around the protruding portions **401** and **402** to securely integrate the rubber member **420** to the outer thermoplastic layer **230**.

[0065] In the illustrated embodiment, in FIG. **4**(*b*), the elongate distal shaft section **250** includes the inner thermoplastic layer **210**, six discrete rubber members **420-425**, and the outer thermoplastic layer **230**. Additionally or alternatively, the metallic braided layer **213** may be included in the distal shaft section **250** comprising a shaft portion **250**C. The group of the six discrete rubber members **420-425** extends along a length equal to or slightly longer than the length of a corresponding electrode **112** and are circumferentially spaced apart from each other. In many embodiments, the rubber members **420-425** are evenly spaced over an exterior surface of the inner thermoplastic layer **210**. Each of the discrete rubber members **420-425** has an arc shape. An arcuate length of each of the discrete rubber members **420-425** can be same so that equal amount of push-back forces can be applied to the electrode **112** at different angular positions corresponding to the discrete rubber members **420-425**. In some embodiments, such a shaft portion **250**C longitudinally extend to a length equal to or slightly shorter than the distal shaft section **250**. In some embodiments, there may be multiple shaft portions **250**C longitudinally disposed along the length of the distal shaft section **250**, while other shaft portions between individual shaft portions **250**C may include the inner thermoplastic layer **210** and the outer thermoplastic layer **230** without any rubber members **420** to **425** (see FIG. **7**) disposed therebetween.

[0066] It can be understood the present disclosure illustrates three and six discrete rubber members configuration in FIG. **3** and FIG. **4**, respectively, by way of examples. The present disclosure is not limited a number of rubber members. The elongate distal shaft section **250** can include 2, 3, 4, 5, 6, or more discrete rubber members that extend longitudinally. Also, the longitudinal length of each of the discrete rubber members can be sufficient to continuously extend underneath all electrodes **112** or may further extend to be equal to the distal shaft section **250**.

[0067] In many embodiments, referring to FIG. **5** through FIG. **7**, another example configuration of one or more rubber members disposed in the distal shaft section **250** of catheter shaft **120** is discussed. FIG. **5** illustrates an assembled view and FIG. **6** illustrates a longitudinal-section view of the elongated shaft assembly **120** including a distal shaft section **250** onto which the electrodes **112** are mounted. The deflectable shaft section **200** is configured for steering the elongate shaft **120** through tortuous vasculature to deliver the distal shaft section **250** at a desired location within the heart anatomy of a patient.

[0068] In some embodiments, the distal shaft section **250** may be manufactured together with other functional shaft sections (e.g., a shaft section **253** for adopting an ablation tip & assembly and another shaft section **254** for accommodating and encircling sensor(s), etc.), thus forming a distal FSA **270** comprising the distal shaft section **250** on which electrodes are mounted. The distal FSA **270** is coupled to the deflectable shaft section **200**, which is in turn coupled to the proximal shaft section **150**, thus forming an elongate catheter shaft **120**. In some embodiments, one or more layers e.g., the inner thermoplastic layer **210** and/or the metallic braided layer **213** may be continuously formed of the deflectable shaft section **200**.

[0069] FIG. **7** illustrates an enlarged view of cross-section portion D (shown in FIG. **6**) of the elongated shaft assembly **120** showing detailed structure and components in the distal shaft section **250** and the distal portion **201**A of the deflectable shaft section **200**. To impart various essential diagnostic and/or therapeutic functionality of an EP catheter, other shaft sections, such as a tip-fitting shaft section **253**, a moisture-barrier shaft section **254**, may be disposed at the distal front of the distal shaft section **250**. The tip-fitting shaft section **253** is configured to distally receive a tip assembly (e.g., an assembly containing an ablation tip) used for a medical procedure, e.g., RF ablation, irreversible electroporation, etc. The moisture-barrier shaft section **254** is disposed between the tip-fitting shaft section **253** and the distal shaft section **250** to prevent moisture from entering the lumen of the moisture-barrier shaft section **254** where an optical sensor resides. The distal shaft section **250** is disposed between the moisture-barrier shaft section **254** and the deflectable shaft section **200**. In many embodiments, a distal shaft section **250** may be seamlessly integrated, distally with a moisture-barrier shaft section **254**, and proximately with a deflectable shaft section **200**, as an integral entity via thermal fusion bonding or melt reflow.

[0070] In the illustrated embodiments, the distal shaft section **250** includes one or more shaft portions **750**A, **750**B or **750**C with one or more rubber members (e.g., tubular rubber member of FIGS. **2**(*a*)-**2**(*g*) and/or a group of discrete rubber members of FIG. **3** or **4**). Additionally, features may also be included to facilitate electrical connections and/or adhesion. For example, the distal shaft section **250** comprising the shaft portion **750**A, **750**B and **750**C includes a plurality of discrete tubular rubber members (e.g., **720-722**) axially or longitudinally spaced from each other. An individual tubular rubber member or an individual group of the discrete tubular rubber members (e.g., **720-722**) encircles and extends along a respective length of the ring electrodes **112**. For example, a first tubular rubber member **720** or a first group of discrete rubber members **720** extends underneath a first ring electrode **112**, a second tubular rubber member **721** or a second group of discrete tubular rubber members **721** extends underneath a second ring electrode **112**, and a third tubular rubber member **722** or a third group of discrete rubber members **722** extends underneath a third ring electrode **112**, etc. The ring electrodes **112**, when mounted on the distal shaft section **250**, will reduce the outer diameter of the distal shaft section **250** to cause some hyperelastic material strains and the associated compressive material stresses within the rubber member(s) of the distal shaft section **250** comprising the shaft portions **750**A, **750**B, and/or **750**C.

[0071] Other elongational shaft portions without any rubber members (e.g., **271** and **272**) may be largely absent of any swaging-induced material strains & stresses and can retain a constant outer diameter. As such, the outer diameter of the distal shaft section **250** may vary from a shaft portion to another. In many embodiments, the outer shaft diameter for a shaft portion **750**A, **750**B and/or **750**C that comprises one or more rubber members **220** is equal to, or slightly larger than, other shaft portion such as portion **280** that does not contain any rubber members **220**, such that after the electrode(s) is mounted by mechanical swaging, there is a smooth transition in the shaft diameters Between different shaft portions along the distal shaft section **250**.

[0072] In some embodiments, at least one of the longitudinally-space rubber member **720-722** includes an electrode-wire hole, e.g., **730**, **731**, and **732**, configured to accommodate routing of an electrode-wire (e.g., similar to wires **855** in FIG. **9**) coupled with a respective ring electrode of the one or more ring electrodes **112**. The electrode-wire hole **730**, **731**, and **732** can be a through hole extending from an inner surface of the inner thermoplastic layer **210** to an exterior surface of the outer layer **230** or the rubber member **220**. For example, the discrete tubular rubber members **720-722** include electrode wire hole **730-732**, respectively, to electrically couple an electrode wire and route the wire through a lumen **265** of the elongate shaft **120** and the handle **110** where the wire is integrated with an electrode harness or connector **130** (FIG. **1**). For example, an electrode-wire (e.g., wire **855** in FIG. **9**) may be coupled with an electrode **112** by welding and strung through the center lumen **265** of the elongate shaft **120** until the handle **110** (see FIG. **1** and FIG. **13**), and then coupled with an electrical connector **130** leading to a catheter system (e.g., see FIG. **13**)

[0073] In some embodiments, distal shaft section **250** includes at least one adhesive potting hole **740** configured to accommodate the injection of a potting adhesive through the potting hole **740**. In some embodiments, the potting hole **740** may be located in a portion (e.g., **280**A or **280**B) of the distal shaft section **250** between adjacent electrodes **112** where no rubber member **220** is present. For example, an adhesive potting hole **740** is located between the first tubular rubber member (or the first group of discrete rubber members) **720** and the second tubular rubber member (or the second group of discrete rubber members) **721**. The potting hole **740** provides an access from the exterior surface of the distal shaft section **250** to an internal center lumen **265**A of the distal shaft section **250**. Through the potting hole **740**, a potting adhesive can be injected into any spaces unoccupied by components within the lumen **265**A of the distal shaft section **250** and in situ cured. The cured adhesive fixes various components (e.g., electrode-wires, a tip assembly component, sensors, etc.) disposed within the lumen **265**A of the distal shaft section **250** in position to result in a solid, relatively rigid core that can mechanically strengthen the distal shaft section **250** for preventing the distal shaft section **250** from collapsing when the distal shaft section **250** is subjected to a radial compressive deformation or force (cf) upon mechanically swaging one or more electrode(s) **112**. In some embodiments, a rigid core of the inner layer **210** can span approximately from a proximal end of the moisture-barrier tubular section **254** (where the optical force sensor resides) to the proximal end **201** of the distal shaft section **250** (or the distal end of the deflectable shaft section **201**A) where a pull ring **261** resides.

[0074] Additionally, the distal shaft section **250** can include a braided shaft portion **252** and an unbraided shaft portion **251**. The braided shaft portion **252** includes a metallic braided layer **213** circumferentially disposed over the exterior surface of an inner thermoplastic layer **210**, while the unbraided section **251** does not include a metallic braided layer. In the illustrated embodiment, the metallic braided layer **213** of the distal shaft section **250** may extend proximally through the deflectable shaft section **200** or even an elongate shaft **120** to provide a smooth, reinforced and intimate integration with the deflectable shaft section **200**. The unbraided shaft portion **251** of the distal shaft section **250** extends distally to effect an intimate and smooth integration with the tubular moisture-barrier shaft section **254** and the tip-fitting shaft section **253**.

[0075] As illustrated in FIGS. **6** and **7**, the deflectable shaft section **200** of the elongate shaft **120** internally includes components used for deflecting the distal FSA **270** comprising a distal shaft section **250** and/or other functional shaft sections (such as a tip-fitting shaft section **253** and a moisture-barrier shaft section **254**, etc.). For example, the pull ring **261** is internally disposed at the distal end of the deflectable shaft section **200** and coupled with a pair of pull wires **262** and **263**. The pull wires **262** and **263** extend proximally through the deflectable shaft section **260**, the proximal shaft section **150**, and then coupled with a steering mechanism that resides within the handle **110** (see FIG. **1**).

[0076] Referring to FIGS. **8** and **9**, another catheter **800** including a distal shaft section **850** where electrodes **112** are mounted and the deflectable shaft section **200** is illustrated. The catheter **800** include several sections similar to the catheter **100** except for the distal shaft section **850**. The distal shaft section **850**, unlike the distal shaft section **250** comprising at least one shaft portion **750**A, **750**B and/or **750**C, does not include any rubber member extending underneath the electrodes **112**. As such, the distal shaft section **850** of the catheter **800** would have different mechanical responses to swaging-induced material strains and stresses compared to the distal shaft section **250** of the catheter **100**. In the illustrated embodiment, the distal shaft section **850** includes an elongate tubular inner thermoplastic layer **810** (e.g., similar to the inner thermoplastic layer **210** of the catheter **100**) and an elongate tubular outer thermoplastic layer **830** (e.g., similar to the outer thermoplastic layer **230** of the catheter **100**) with an optional metallic braided layer **840** (e.g., similar to the braided layer **213** of the catheter **100**). The electrode **112** are mounted onto the distal shaft section **850** comprised of the elongate tubular inner thermoplastic layer **810** and the outer thermoplastic layer **830** by swagging. However, the swaging-induced material strains within the thermoplastic layers **810** and **830** of the distal shaft section **850** are largely unrecoverable or inelastic in nature and tend to "permanently" take some compression sets of >50% up to nearly 100%, because the distal shaft section **850** does not have one or more hyperelastic rubber members. As a result, the distal shaft section **850** cannot effectively retain the push-back force (pf) but may even decay to none, because of large loss of any recoverable material strains within the distal shaft section **850**. While the catheter **100** including the distal shaft section **250** having the hyperelastic rubber members is highly resilient compared to the distal shaft section **850**, as such advantageously the swaging-induced material strains within the rubber members **220** of the distal shaft section **250** are largely recoverable and will continues to provide push-back forces (pf) for secured engagement of the electrodes **112** over a long period of time (see FIG. **2**(*d*)). The mechanical properties and behavior of the distal shaft section **850** versus the distal shaft section **250** are further discussed with respect to FIG. **10** below.

[0077] When a distal shaft section (e.g., **250**) is radially compressed by mechanical swaging, certain material strains and associated material stresses are induced and will decay and relax with time because of different inherent viscoelastic properties of material for various constituent layers (e.g., **210**, **220**, and **230**) of the distal shaft section (e.g., **250**). FIG. **10** is an example graph illustrating the relaxation of a compressive material stress (y-axis) that is associated with the decaying of a swaging-induced material strain over time (x-axis) for different polymer materials of the distal shaft section **250**, including a hyperelastic rubber material (e.g., a first curve **1001**), a thermoplastic elastomer material (e.g., a second curve **1002**), and a thermoplastic material (e.g., a third curve **1003**), respectively. Each stress relaxation curve may have, or infinitely approach, a plateau or stabilized value at a different rate of stress relaxation. For example, when subjected to an initial compressive material deformation or strain (ε.sub.0), a hyperelastic rubber material can exhibit a quicker stress relaxation than a thermoplastic elastomer material, which in turn shows a faster rate of stress relaxation than a thermoplastic material with time (t). As a result, the hyperelastic rubber material (e.g., rubber members **220**) can quickly achieve its steady state with retaining a high plateau value of material stress associated with a minimal compression set (i.e., a high recoverable material strain). By comparing the steady states for the polymer materials of different types subjected to a certain initial material strain (ε.sub.0), the stress relaxation curves (e.g., **1001**, **1002**, **1003**) illustrated in FIG. **10** indicate that the rubber material (i.e., curve **1001**) can well retain a higher compressive stress and strain (in order words, experience less compression set) than the thermoplastic elastomer material (i.e., curve **1002**) at a shorter period of time. In contrast, the rigid, thermoplastic polymer or plastic material may only approach a steady or plateau state of stress relaxation towards zero over a very long period of time and can only retain a minimal material stress and strain because of its high compression set of material of >50 to nearly 100%.

[0078] Due to the hyperelastic nature of the underlying rubber members **220**, the distal shaft section **250** of an elongate shaft **120** can largely retain the swaging-induced material strains and stresses to continuously impart a high push-back force or pressure (pf) onto the electrode **112**, under which the swaged electrode tends to be intimately secured via an interference fit (e.g., friction fit) with the distal shaft section **250**.

[0079] An extent of stress relaxation towards a steady stressed state largely depends on polymer type, and this can be alternatively characterized by the inherent compression set of material. For example, a rigid thermoplastic polymer material generally has a very low yield strain (e.g., less than 10%), such that when subjected to a given compressive deformation, the material tends to fail and exhibit 100% compression set (e.g., permanent deformation). In contrast, a thermoplastic elastomer material has a relatively higher yield strain (e.g., greater than 10%), and can undertake relatively high compressive deformation, such that when subjected to a specific compressive deformation, the material is able to attain a steady stressed state and exhibit a finite compression set of less than 100% (i.e., a recoverable material strain upon unloading). In particular, as compared to thermoplastics and thermoplastic elastomer materials, thermosetting elastomers (or simply rubbers) possess characteristic material hyperelasticity without definitive yield strain of material to likely exhibit considerably lower compression sets of <<100% (e.g., 30% or less) with much less temperature dependence, because of material's chemically cross-linked network structure. For example, silicone thermosetting elastomers or silicone rubbers are suitable for applications at high pressures and temperature variations, because of material's excellent hyperelasticity and very low compressions sets that are largely independent of environmental conditions at high temperatures up to 250° C. The suitable rubber material, in particular silicone rubber, can be selected for the one or more rubber members (e.g., **220**, **320-322**, **420-425**) for the distal shaft section **250** of an elongate shaft **120** in view of material's compression set. A lower compression set of the one or more tubular rubber members (e.g., **220**, **320-322**, **420-425**) provides higher hyperelasticity, and higher tendency that the one or more rubber members (e.g., **220**, **320-322**, **420-425**) will be able to continuously retain the higher push-back forces for the distal shaft section **250**.

[0080] The term "compression set" discussed herein can be understood as follows. Suppose that a (rubber) material is variably loaded to maintain a certain amount of compressive deformation or strain (ε.sub.0) at a specific temperature and then released free after a certain length of time, the compression set of material is measured as the percentage of how much this specific compressive strain (ε.sub.0) would not be able to recover, namely the unrecoverable (i.e., inelastic or viscous) material strain (ε.sub.v), but be “set” permanently. By definition per ASTM D395, the compression set (c) of a rubber material can be readily characterized in terms of a recoverable or elastic material strain (ε.sub.e) that can be readily measured after the material has been constrained at a constant material strain (ε.sub.0) at a specific temperature for a certain length of time and then released free. That is, c=(1−ε.sub.e/ε.sub.0)×100% where ε.sub.0=ε.sub.e+ε.sub.v.

[0081] The decaying or time-evolving loss of the push-back radial pressure of the shaft **250** against the swaged electrode **112** due to the stress relaxation behavior of the polymeric shaft material(s) would eventually reach, or tend to reach, a steady stressed state as the unrecoverable material strain tends to become “permanently” set after a certain period of time. For securement of the electrode **112** to the distal shaft section **250**, such a steady push-back radial pressure of the shaft **250** must be nonzero, but sufficiently high to provide a reliable securement of the electrodes **112** and also a good sealing capacity against any possible fluid migration into the inside of the elongate shaft **120**, including the distal shaft section **250**. In other words, the shaft material(s) under the fixed, swaging-induced radial compressive strain (ε.sub.0) must have a relatively low permanent strain (ε.sub.v<<ε.sub.0), e.g., a lower compression set (c<<100%), such that the shaft material(s) would still be capable of largely recovering or bounce-back to original free states, thus imparting a sufficiently high bounce-back or resilient radial pressure against the electrodes **112**.

[0082] Referring back to FIG. **10**, stress relaxation behaviors under a given compressive deformation at a temperature is qualitatively represented. A rubber material may be able to attain a high, nonzero stress plateau (or the push-back pressure) with a very low compression set, whereas a thermoplastic material relaxes very slowly, and relevant retaining stress (or the push-back pressure) tends to largely disappear over time. Depending on the chemically cross-linked network structures and chemical characteristics, various rubber materials may have different thermophysical stability of material and material resiliencies or compression sets. Accordingly, the rubber members (e.g., **220**, **320**, **420**) may be made of high resilient silicone rubbers because of material's outstanding thermo-physical stability and very low compression sets less than 30% at elevated temperatures up to 250° C.

[0083] Therefore, for reliable securement of multiple swaged electrodes **112** on the distal shaft section **250** of an elongate shaft **120**, the present disclosure selects composite structure made of a combination of rubber material and thermoplastic polymers (including thermoplastic elastomer materials). For example, the one or more rubber members (e.g., **220**, **320-322**, **420-425**) are made of highly resilient elastomeric material(s), e.g., thermosetting silicone rubbers, nitrile butadiene rubbers (NBR), natural rubbers, etc., in combination with the inner and outer thermoplastic layers (e.g., **210** and **230**) made of thermoplastic polymers including thermoplastic elastomers, e.g., nylons, polyesters, poly(bisphenol A carbonate), polysulfone, poly(ether imide), poly(ether block amide) copolymers, poly(ether-co-ester) block copolymers, thermoplastic polyurethanes, styrenic copolymers, thermoplastic olefinic elastomers, etc. The rubber material imparts the elongate shaft assembly **120** with the high material resiliency and hyperelasticity, while the thermoplastic polymers provides the distal shaft section **250** of an elongate shaft **120** ease of manufacturability via thermal fusion bonding or melt reflow.

[0084] Molecularly, thermoplastic polymer materials are largely linear polymers comprised of very long polymer chains with or without relatively short branches, whereas thermosetting rubbers (or simply rubbers) are network polymers comprised of chemically cross-linked molecular segments or polymer chains. Because of their differences in polymer structure, rubbers have the outstanding thermo-physical stability of material, and importantly, low compression sets (or high resiliency) at ambient and elevated temperatures of interest (for example, ≤60° C.) during the life cycle of medical devices, such as terminal EO sterilization, thermal cycling for simulating extreme climatic conditions, accelerated aging, etc.

[0085] Based on the solid-state structures of material, thermoplastics and thermoplastic elastomers can be classified as semi-crystalline and amorphous polymers, which exhibit the characteristic, critical solid-state thermal transition temperatures of material, e.g., melting temperatures for semi-crystalline polymers or glass transition temperatures for amorphous polymers. Because of such thermally induced thermal transition from a solid to a liquid state, each of thermoplastics and thermoplastic elastomers can be repeatedly shaped or formed at some elevated temperatures above the characteristic, critical thermal transition temperature of material by means of melt processes (e.g., melt extrusion, melt reflow, etc.). However, unlike thermoplastics and thermoplastic elastomers, rubber materials, including silicone rubbers, do not have any melt processability. A rubber material, supplied as a reactive liquid or liquid-like polymer system, can be only shaped or formed once, then followed by the underlying chemical conversion (e.g., curing) into a permanent thermosetting solid rubber material via an underlying cure reaction of the material. Because of its chemically cross-linked structure of material that remains permanent under certain thermal conditions (i.e., thermo-physical stability of material), a rubber material generally has a significantly higher resiliency than a thermoplastic polymer or a thermoplastic elastomer material.
[0086] Accordingly, as an example, the elongate tubular inner thermoplastic layer **210** can be made of relatively rigid thermoplastic or thermoplastic elastomer materials, while the outer thermoplastic layer **230**, if any, can be made of same as, or softer thermoplastic or thermoplastic elastomer material than, the inner thermoplastic layer **210**. The rubber members (e.g., **220**, **320**, **420**) of the distal shaft section **250** are preferably made of a highly resilient, temperature-invariant rubber having a relatively low compression set of less than 30%, preferably less than 10%. Preferably, the rubber members (e.g., **220**, **320**, **420**) are made of silicone rubbers that impart good adhesion to the inner and outer thermoplastic layers (e.g., **210** and **230**). In some embodiments, the surfaces of the rubber members (e.g., **220**, **320**, **420**) are chemically activated or treated by means of organosilane coating or plasma treatment. As an example, for the distal shaft section **250** of an elongate shaft **120** shown in FIGS. **2**(*a*)-**2**(*g*), the inner thermoplastic **210** and the outer thermoplastic layer **230** are premade of thermoplastic or thermoplastic elastomer material having a relatively high material hardness (e.g., >Shore 70D; Pebax® 7233SA01, Pebax® 7033SA01, Rilsan® BESNO nylon 11, Rilsan® AESNO nylon 12, Pellethane® 2363-75D, or equivalent) and relatively low material hardness (e.g., Shore D35; Pebax® 3522 SA01, Pellethane® 2363-90AE, etc.) by means of melt extrusion, respectively.
[0087] Referring back to FIG. **1** and FIG. **8**, the catheters **100** and **800**, which are similarly constructed of various shaft assemblies but differ in their respective distal shaft sections **250** and **850** only, are described herein, respectively. For example, like the catheter **800**, the catheter **100** can be configured as an elongate electro-anatomic electrophysiology (EP) catheter structurally comprised of at least three shaft sections that are seamlessly integrated as an integral entity via thermal fusion bonding or melt reflow: a proximal shaft section (e.g., **150**), a deflectable shaft section (e.g., **200**), and a distal shaft section (e.g., **250**). The distal shaft section **250** of the catheter **100** can be manufactured by forming and integrating with some other functional shaft sections, such as a tubular moisture-barrier shaft sections **254**, and/or a tip-fitting shaft section **253**, etc., to result in a distal FSA **270** of the catheter **100**.
[0088] The proximal shaft section **150** of the catheter **100** is configured to provide column strength and torqueability for a deflectable EP catheter. For this purpose, the proximal shaft section **150** has a tubular composite structure composed of an inner polymer layer, an intermediate braided layer woven of multiple threads of thin metallic wires (e.g., stainless steel) in pattern, and an outer polymer layer. The metallic braided layer is fully embedded between the inner and outer polymer layer extruded of the same or two different thermoplastic polymer materials. For example, the inner and outer polymer layers of the proximal shaft section **150** can be pre-extruded of a thermoplastic polymer material that has a relatively high material durometer of greater than or equal to Shore D70, and then integrated with the metallic braided layer via common thermal fusion bonding or

melt reflow techniques that are known of the art.

[0089] The deflectable shaft section **200** of the catheter **100** is configured to impart distal deflectability (or steerability) for enabling an elongate catheter **100** to pass through the tortuous vasculature and have desired geometric configurations for easy accesses to the targeted sites within the heart anatomy. Accordingly, the deflectable shaft section **200** includes multiple interconnected tubular shaft sections, each of which may have different column flexibilities or rigidities. To enhance column stability for the purpose of preventing column collapsing when forcibly deflected, the deflectable shaft section **200** may also have a similar composite shaft structure to that of the proximal shaft section **150**. Hence, the deflectable shaft section **200** may be considered as a flexible variant or extension to the proximal shaft section **150**. In particular, the deflectable shaft section **200**, compared to the proximal shaft section **150**, similarly comprises an elongate tubular inner polymer layer and an intermediate metallic braided layer, but differently includes an outer polymer layer in multiple interconnected tubular sections made of various chemically compatible thermoplastic elastomer materials with varying material flexibilities or durometers ranging from Shore 25D to Shore 75D. The deflectable shaft section **200** can be structurally integrated with the proximal shaft section **150** by means of reflow or thermal fusion bonding to result in a proximal-deflectable shaft assembly (PDA) of the catheter **100**.

[0090] The deflectable shaft section **200** has a pull ring (e.g., **261**) affixed in position at its distal end. A pair of pull wires (e.g., **262**, **263**) welded onto the pull ring are properly strung through the internal channels of the PDA to be coupled with the manual deflecting mechanism residing within the handle (e.g., **110**).

[0091] As an integral assembly, the premade PDA can have the intermediate metallic braided layer protrude beyond its distal end for some distance. This extended metallic braided layer can be disposed beneath the inner thermoplastic layer **210** but over the rubber member(s) **220** to form a distal shaft section **250**. As such, the distal shaft section **250** can have an unbraided portion (e.g., **251**) be distally integrated or interconnected with other unbraided tubular sections, such as a moisture-barrier tubular section **254**, a tip-fitting tubular section **253**, etc., to result in a distal FSA **270**. On the other hand, the distal shaft section **250** can have a braided portion (e.g., **252**) to impart a good structural continuity and smooth transition proximally with the pre-made PDA (e.g., **150** and **200**).

[0092] The distal FSA **270** of the catheter **100** for an electro-anatomical contact force, irrigation RF ablation catheter (e.g., Tacticath® SE or Tactiflex® SE contact force irrigation ablation catheter) provides a tubular shaft section for fitting to an ablation electrode tip (e.g., the tip-fitting shaft section **253**), through which the tip functional assembly (TFA) can be inserted and disposed into a center lumen (e.g., **265**A) of the distal FSA **270**. The ablation tip can be adhesively affixed in position into the tip-fitting shaft section **253** of the distal FSA **270**. For example, the tip-fitting shaft section **253** is configured to couple the TFA comprising multiple functional elements as required for accomplishing advanced EP therapeutic and/or diagnostic procedures, and may include a tip (ablation) electrode, an irrigation tube, a thermocouple, an optical force sensor, a magnetic positioning sensor, and other accessory components (e.g., potting adhesive, magnetic sensor cage, conductors, etc.).

[0093] Also, the distal FSA **270** of the catheter **100** may also provide a highly flexible, moisture-barrier tubular shaft section **254**, which circumferentially encapsulates an optical force sensor disposed within the center lumen **265**A of the distal FSA **270** and prevents any penetration of moisture through the moisture-barrier shaft section **254**. These tip-fitting shaft section **253** and the moisture-barrier tubular shaft section **254** are located and structurally integrated together with the distal shaft section **250**) by means of thermal fusion bonding or melt reflow.

[0094] FIG. **11** is a flow chart of an example method **1100** for manufacturing a catheter shaft. The method **1100** can be implemented in following steps **1101**, **1102**, **1103**, and **1104**. Step **1101** involves forming an inner layer, an outer layer, and optionally a rubber member, respectively. In many embodiments, the inner layer is an inner thermoplastic layer having an elongated tubular shape, which can be formed by melt (or tubing) extrusion. Similarly, the outer layer may have an elongated tubular shape, which may be formed by melt or tubing extrusion. In many other embodiments, a rubber member is formed of a (liquid or paste-like) rubber compound, where the rubber compound is shaped by a mold and then thermally press-cured within the hot mold at an elevated cure temperature for a duration of time.

[0095] Step **1102** involves placing an inner layer (over a mandrel) and then forming a first shaft assembly by placing a rubber member on an exterior surface of the inner layer. In some embodiments, part of step **1101** (i.e., forming a rubber member) may be delayed until step **1102**, in which forming a first shaft assembly involves in situ forming a rubber member that is intimately bondable to the exterior surface of the inner layer. Further in some embodiments, step **1101** for forming the rubber member or step **1102** for in situ forming the rubber member for the first shaft assembly involves post-curing at a predetermined temperature for a specified time period in an effort to optimally enhance material resiliency or hyperelasticity of the rubber member. For example, post-curing of the rubber member formed (or in situ formed) of a silicone rubber compound involves heating the “standalone” rubber member (or the first shaft assembly) at a temperature between 110° C. to 180° C. for a time period between 1 hours to 4 hours. In many embodiments, the rubber member as formed in step **1101** or in situ formed in step **1102** may be surface treated to improve its chemical compatibility with the inner and/or outer layers.

[0096] In some embodiments, the rubber member includes a tubular rubber member (e.g., **220** in FIGS. **2**(*a*)-**2**(*g*) or **720-711** in FIG. **7**) that encircles and extends along a first length of the inner thermoplastic layer (e.g., **210** in FIGS. **2**(*a*)-**2**(*g*)). In some embodiments, one or more tubular rubber members (e.g., **220** in FIGS. **2**(*a*)-**2**(*g*) or **720-711** in FIG. **7**) may be longitudinally spaced on the exterior surface of the inner thermoplastic layer (e.g., **210**). In some embodiments, forming the first shaft assembly involves placing, or in situ forming, a plurality of discrete rubber members (e.g., a group or set of rubber members **320-322** in FIG. **3** or **420-425** in FIG. **4**) on the exterior surface of the inner thermoplastic layer (e.g., **210**) so that the discrete rubber members are circumferentially distributed and spaced apart along the inner thermoplastic layer. In some embodiments, at least one of the plurality of discrete rubber members comprises protruding portions (e.g., the protruding portions **401** and **402** in FIG. **4**) that protrude circumferentially from a perimeter of the discrete rubber member. Each extension is configured to enhance coupling of the discrete rubber member with at least one of the outer layer and the inner thermoplastic layer.

[0097] Step **1103** involves forming a second shaft assembly by placing an outer layer over the first shaft assembly. In many embodiments, the outer layer and/or the inner layer are made of same or different thermoplastic material. For example, the thermoplastic material of the outer layer and/or the inner thermoplastic layer has a durometer of greater than Shore D40, and the range of Shore D60 to D85. In some embodiments, the outer thermoplastic layer has a different durometer from that of the inner thermoplastic layer and preferably has a durometer of less than Shore D60. The one or more rubber members have a durometer equal to or less than Shore A65 (e.g., silicone rubber). As per the examples discussed with respect to FIGS. **2-4**, and FIG. **7**, the inner layer **210** and the outer layer **230** can be formed of same or different thermoplastic material, the one or more rubber members (e.g., **220**, **320-322**, **420-425**, or **720-722**) can be formed and then disposed, or in situ formed, on exterior surface of the inner layer **210**, and the outer layer **230** can be disposed over the rubber members. Furthermore, the inner layer **210**, the rubber members **220**, and the outer layer **230** can be made integral by thermal fusion bonding e.g., by melting and reflowing the inner and outer thermoplastic layers.

[0098] In many embodiments, the step **1102** of forming the first shaft assembly further involves applying an adhesive to temporarily affix the rubber members (that are pre-formed in step **1101**) onto the exterior surface of the inner thermoplastic layer. Preferably the adhesive when cured is thermoplastic in nature. For example, the adhesive comprises cyanoacrylate adhesives based on a cyanoacrylate monomer or oligomer.

[0099] In many embodiments, the step **1104** of forming the catheter shaft involves thermal-fusion bonding process to form an integral shaft. For example, an integral catheter shaft can be formed by melting and reflowing the inner thermoplastic layer and the outer thermoplastic layer of the second shaft assembly under radial compressive pressure. In some embodiments, the heating involves placing a heat-shrinkable tube over the outer layer to apply a temperature in a predetermined temperature range (e.g., 200° to 250° C.).

[0100] Step **1105** involves attaching one or more ring electrodes (e.g., a first ring electrode) to bonded catheter shaft (e.g., by mechanical swaging) so that each of the ring electrodes induces a radial hyperelastic deformation of the rubber members to inhibit loss of an interference fit between the first ring electrode and the catheter shaft. For example, as discussed with respect to FIGS. **2-4**, and FIG. **7**, the electrodes **112** can be attached to the exterior surface of the outer layer **230** by mechanical swagging that induces radial elastic deformation of the rubber members (e.g., **220**, **320-322**, **420-425**, or **720-722**).

[0101] In many embodiments, attaching the one or more electrodes during subsequent assembling process of the catheter **100** involves swagging the one or more electrodes onto the distal shaft section **250** of the catheter **100** to induce radial hyperelastic or recoverable deformation of the one or more rubber members while the one or more rubber members induces a push-back pressure against the one more or electrodes to securely retain an effective interfere or friction fit of the electrode(s) **112** onto the distal shaft section **250** for a prolonged period of time.

[0102] In some embodiments, the method **1100** can be further integrated into a manufacturing process of a catheter (e.g., **100**) that includes additional shaft sections. For example, the catheter **100** including the distal FSA **270** (e.g., comprising a distal shaft section **250**) can be manufactured and adherently interconnected with a pre-made PDA (e.g., **150** and **200**) as an integral entity, by means of thermal fusion bonding (e.g., melt reflow). FIG. **12** is an illustrative flow chart of an example method **1200** for manufacturing the catheter **100** including the distal FSA **270** comprising an integral distal shaft section **250** on which electrodes are to be mounted. Method **1200** starts with two preparation steps, including step **1201**: preparing the pre-made PDA (e.g., **150** and **200**) for manufacturing a distal FSA (e.g., **270**) and step **1202**: preparing various building components of the distal FSA (e.g., **270**) including a distal shaft section (e.g., **250**) on which electrodes are to be mounted.

[0103] In some embodiments, step **1201** may involve coupling a pair of pull wires (e.g., **262** and **263**) to the pull-ring **261** by laser welding, and then disposing the pull wires assembly through the center lumen of the pre-made PDA (e.g., **200** and **150**). The pull ring **261** can be situated inside and adhesively affixed to the distal end of an integral, premade PDA, as illustrated in FIGS. **7** and **9**. In addition, an intermediate metallic braided wire distally extending from the PDA (e.g., **213**) can be stripped and cleaned by means of laser ablation or other chemical and/or physical techniques, and then cut in a length equal to the braided shaft portion **252** (e.g., in FIG. **7**) of the distal shaft section **250**.

[0104] In some embodiments, at step **1202**, the inner thermoplastic layer **210** of the distal shaft section **250** may be pre-extruded of a relatively rigid thermoplastic polymer or thermoplastic elastomer material in a continuous tubing form and cut in tubular sections, each having a length equal to the length of the distal shaft section **250**. Similarly, the outer thermoplastic layer **230** of the distal shaft section **250** may be pre-extruded of the same as, or relatively softer than, thermoplastic polymer or thermoplastic elastomer material than, that of the inner layer **210** in a continuous tubing form and cut in tubular sections, each having a length equal to, or slightly less than, a length comparable to that of the distal shaft section **250**. The rubber member(s) **230** may be pre-made of a reactive liquid/paste-like rubber compound via liquid/paste rubber extrusion, reactive injection molding, reactive compression molding, or liquid casting, etc. commonly known of the art for rubber processing. Post-curing the rubber member(s) at a proper high cure temperature may be

necessary for enhancing material resiliency and hyperelasticity.
[0105] The method **1200** further utilizes a non-stick PTFE-coated shaft-forming mandrel proximally conforming to the distal end of a premade PDA. The proximal end of such a shaft-forming mandrel has an outer diameter conforming to the inner diameter of the center lumen of the PDA at the distal end of the PDA where the pull ring **216** is adhesively affixed.
[0106] Accordingly, method **1200** further includes step **1203** that involves placing the shaft-forming mandrel, by which the proximal portion of the mandrel is inserted and snugly fitted to the center lumen of the PDA until the proximal end of the mandrel is snugly in contact with the pull ring **261** of the PDA (e.g., **150** and **200**).
[0107] To make the distal FSA **270** comprising the distal shaft section **250** that is intimately adhered to and integrated with the premade PDA of the catheter **100**, method **1200** can include multiple steps e.g., steps **1204** to **1207**.
[0108] Step **1204** involves setting up or assembling an unbonded distal shaft section **250**, during which the inner thermoplastic layer (e.g., **210**) is disposed over the shaft-forming mandrel, optionally followed by disposing the pre-stripped or bare metallic braid layer (e.g., **213**). The groups of the rubber member(s) **220**, each in specified sizes, along with the outer thermoplastic layer **230**, are sequentially introduced and disposed over the metallic braided layer (e.g., **213**) or over the inner layer (e.g., **210**).
[0109] Step **1205** involves setting up an unbonded FSA. For example, a premade moisture-barrier tubular section and the tip-fitting tubular section can be longitudinally inserted over the non-stick mandrel, one by one, to attach to the distal end of the unbonded distal shaft section **250**, thus resulting in the unbonded distal FSA **270**. The unbonded distal FSA **270** is then fully encapsulated by a high-temperature heat shrink tube (e.g., PTFE heat shrink tube).
[0110] Step **1206** involves forming a bonded FSA **270** comprising the integral distal shaft section **250** that is also adherently interconnected with the pre-made PDA (e.g., **150** and **200**) by means of thermal fusion bonding or melt reflow at a high temperature (e.g., >180 to 250° C.) in a convective oven. Oven heating will make all the thermoplastic polymer materials of the unbonded FSA **270** (including the inner & outer thermoplastic layers (e.g., **210**) of the unbonded distal shaft section **250**, the moisture-barrier tubular section **254**, and the tip-fitting shaft section **253**, etc.,) melt and reflow to fill up any unoccupied spaces within the distal FSA **270** under radial inwards pressure exerted by the outmost heat shrink tube, thereby forming the bonded distal FSA **270** comprising the integral distal shaft section **250** that is in turn, adherently interconnected with the premade PDA as an elongate catheter shaft **120**.
[0111] After thermal fusion bonding or melt reflow, step **1207** involves finishing the bonded FSA **270** for subsequent assembling of the catheter **100**. For example, the heat shrink tube is removed from the resultant FSA **270**, followed by placing ring electrodes **112** onto the integral distal shaft section **250** and inserting the TFA into the tip-fitting shaft section **253**, stringing various elongate components coupled to the ring electrodes **112** (e.g., conductive wires **855**) and to the TFA (e.g., conductive wires of sensors and thermocouple wires, irrigation tube, etc.) through the center lumen of the integral, interconnected catheter shaft **120**, adhesively attaching the TFA to the tip-fitting section **253** of the distal FSA **270**, and affixing the TFA in position within the center lumen of the distal FSA **270** by applying a potting adhesive through the adhesive-potting holes **700**, etc. Finally, the ring electrodes **112** are affixed onto the integral distal shaft section **250** in position by mechanical swaging.
[0112] According to the above embodiments, relevant manufacturing methods for various shaft designs for the distal shaft section **250** of the FSA **270** of catheter **100** is further discussed with some examples as follows:
EXAMPLE #1
[0113] For the shaft designs shown in FIG. **3**, FIG. **4** and FIG. **7**, the inner thermoplastic layer **210** pre-extruded of nylon 12 (or PA12) is introduced onto a shaft-forming mandrel. Optionally, the

layer **210** is at least partially covered by the braided metallic layer **213** extending from the premade integral PDA (see FIG. **8**). Then, a plurality of the rubber members (e.g., **320-322** or **420-425**) press-made of a silicone rubber compound (e.g., Momentive Tufel III 92656) and various tubular sections of the outer thermoplastic layer **230** pre-extruded of Pebax® 3533 SA01 PEBA copolymer resin are alternately applied over the metallic braided layer **213** (FIG. **7**) or the inner thermoplastic layer **210**. Herein, the plurality of arc-like rubber members (e.g., discrete rubber members **320-322** or **420-425**) are circumferentially and evenly disposed over the inner thermoplastic layer **210** or the metallic braided layer **213**, and temporarily affixed in position by sparingly using an instant cyanoacrylate (CA) adhesive (e.g., Loctite 4011). The resultant, unbonded distal shaft section **250**, along with other thermoplastic functional shaft components (e.g., tip-fitting shaft section **253**, moisture-barrier shaft section **254**, etc.) of the distal FSA **270**, is circumferentially covered by a high-temperature heat-shrinkable tube (e.g., PTFE heat shrink tube), and then heated to a high temperature of about 220° C. to 250° C. for about 10 to 15 minutes, thus forming a bonded distal FSA comprising the integral distal shaft section **250**. During heating that effects the thermal fusion bonding or melt reflow within all the thermoplastic components of the distal shaft section **250**, all the rubber members (e.g., the discrete rubber members **320-322** or **420-425**) would largely remain geometrically intact because of material's inherent chemically cross-linked network structure or thermosetting, while the cured CA instant adhesive (for temporarily affixing the rubber members) would be able to melt and mix with the polymer melts, thus imparting melt adhesion of the rubber members with the rest of thermoplastic polymers (e.g., the inner thermoplastic (PA12) layer **210** and the outer thermoplastic (Pebax 3533 SA01) layer **230**) within the distal shaft section **250**. The cured CA adhesive is chemically comprised of linear poly(ethyl cyanoacrylate), which is a typical amorphous thermoplastic polymer having a critical solid-state thermal transition or glass transition temperature of about 125° C. During heating, the cured CA adhesive is able to reflow or be reshaped, while without affecting the formation of the integral distal shaft section **250** comprising various rubber members **220**.

[0114] In many embodiments, the highly resilient rubber members are premade of a silicone rubber compound (e.g., Momentive Tufel III 92656) by means of an applicable reactive liquid process (e.g., reactive liquid extrusion, reactive liquid injection molding, reactive liquid casting, etc.), which includes a process step of oven/press curing (e.g., at 177° C. for 10 minutes). A post-forming thermal cure process, e.g., post-cure, at 177° C. for 2 hours, may be optionally performed to improve crosslink density of material and thus enhance material's resiliency or hyperelasticity (e.g., the push-back forces) and optimally minimize material's compression set. The resultant silicone rubber material used for the rubber members has a material durometer of Shore A65, and a very low compression set of about 14% as tested in accordance with ASTM D-395.

[0115] To facilitate the heating-induced thermal fusion bonding of the two polyamide-based thermoplastic polymers (e.g., nylon 12 and Pebax 3533 SA01) for the inner and outer thermoplastic layers (e.g., **210** and **230**), all the rubber members (e.g., discrete rubber members **320-322** or **420-425**) as formed above are chemically pre-treated to impart chemical compatibility with polyamides (e.g., nylon 12 and Pebax 3533SA01 PEBA copolymer) by either conventional physical methods known in the art (e.g., plasma surface treatment, etc.) or by a chemical method with use of a diluted coating solution comprising one or more organosilane coupling agents at a concentration of about 2 to 5%. Relevant technology & processes for organosilane treatment of silicone rubber in improving material's chemical compatibility with thermoplastic polymers like nylons, PEBAs, and TPUs, etc., are described in "*Silane Coupling Agents, Connecting Across Boundaries*" Gelest Inc., 2014 and U.S. Pat. No. 12,017,056, which are incorporated herein by reference in its entirety. The organosilane coupling agents here include, but not limited to, various commercially available amino-or amine-containing silanes, such as 3-aminopropyl trimethoxysilane, 3-aminopropyl triethoxysilane, 4-aminobutyl triethoxysilane, N-phenylaminomethyl triethoxysilane, 4-amino-3,3-dimethylbutyl trimethoxysilane, N-(2-aminoethyl)-3-aminopropyl trimethoxysilane, etc. That is, the pre-made rubber members (e.g., discrete rubber members **320-322** or **420-425**) are briefly dipped or immersed into an effective coating solution comprising one or more active organosilane coupling agent(s) and let the coating fully dry or cured under ambient or elevated temperatures (at optimal humidity of 50 to 60%) via the so-called hydrolysis-condensation cure mechanism as known in silicone chemistry. The resultant coating for the rubber members (e.g., discrete rubber members **320-322** or **420-425**) would not only exhibit adherences to the silicone rubber substrates, but also have the activated silicone surfaces rich in active amino or amine groups, which exhibit inherent molecular affinity to polyamides or nylons, thermoplastic polyurethanes, and the like, for thermal fusion bonding by these thermoplastic polymer materials.

[0116] The portion **750**A, **750**B, and/or **750**C of the distal shaft section **250**, where electrode(s) is to be mounted (in FIG. **7**), may have a very thin outer thermoplastic polymer skin, as part of the outer thermoplastic layer **230** that may have “reflowed” from the other portion **280** of the distal shaft section **250** where electrode(s) are not present. When present and bonded to the exterior surface of the rubber members, such a skin-like outer thermoplastic layer **230** would not noticeably affect radial compression of the rubber members **220** and impose any noticeable physical resistance to the hyperelastic bounce of the rubber members **220**, either. That is, under the radial compressive pressures exerted by a swaged ring electrode, this will allow the rubber members with the high hyperelastic deformability to be able to actively take the very high radial compressive deformations while without the occurrence of material yielding, and then attain a steady push-back forces against the swaged electrodes for reliable securement and sealing of the swaged electrodes, because of the unique stress relaxation characteristics and very low compression sets (at about 14%) of silicone rubber.

[0117] As compared to the shaft design shown in FIG. **3**, the shaft design shown in FIG. **4** with two protruding portions (e.g., **401**, **402**) at two sides may likely provide relatively high push-back pressures and forces against the swaged electrodes, because the side protrusions have been twisted by swaging and would tend to energetically bounce back.

EXAMPLE #2

[0118] For the shaft design shown in FIGS. **2**(*a*)-**2**(*g*), the inner thermoplastic layer **210** and the outer thermoplastic layer **230** are premade of thermoplastic polymers having a relatively high material hardness (e.g., Shore 72D; Pebax 7233SA01) and a relatively low material hardness (e.g., Shore D35; Pebax 3522 SA01) by means of melt extrusion, respectively. A single tubular rubber member is premade of a reactive silicone rubber compound (e.g., Momentive Tufel III 92656) by means of a reactive liquid extrusion process and optionally a post-forming thermal cure process, as detailed in Example #1.

[0119] To manufacture the portion **250**A of the distal shaft section **250** (in FIGS. **2**(*a*)-**2**(*g*)), the inner thermoplastic layer **210**, cut in a length equal to that of the entire distal shaft section **250**, is introduced to snugly fit onto a shaft-forming mandrel. Optionally, the layer **210** is partially covered by the metallic braided layer **213** extending from the premade, integral PDA (see FIG. **7**). Then, the tubular rubber member **220** cut in a length somewhat less than that of the distal shaft section **250** is centered about the distal shaft section **250**, and then directly disposed over the inner thermoplastic layer **210** or the metallic braided layer **213**. Further, the outer thermoplastic layer **230**, cut in a length equal to that of the distal shaft section **250**, is disposed over the tubular rubber member **220**. By heating, the resultant nonbonded shaft assembly for the distal shaft section **250** at a high temperature of about 200° C. to 240° C. for 10 to 20 minutes, the inner and outer thermoplastic layers **210** and **230** will melt to reflow and fully lock the tubular rubber member in position between the bonded layers **210** and **230**, thereby forming the integral distal shaft section **250** of the catheter **100**.

[0120] In some embodiments, a singular tubular rubber member **220** may include one or more longitudinally disposed slots or holes die-cut through the wall of the tubular rubber member **220** to assure melt flow into any unoccupied spaces that may exist between the inner thermoplastic layer

210 and the tubular rubber member **220**. The tubular rubber member **220** is not melt-processable or re-shapable, thus the slots or holes enhance the intimate thermal-fusion bonding of the inner and outer thermoplastic layers (i.e., **210** and **230**) across and with the tubular rubber member **220**.

[0121] Similar to the above example #1, to impart the intimate layer-to-layer adherence via thermal fuse bonding or melt reflow, exterior surfaces of the inner thermoplastic layer **210** and the tubular rubber member **220** may be siliconized and chemically activated, respectively, by using the same or similar coating solution comprising one or more amino/amine-containing organosilane coupling agents at a concentration of about 2 to 5% prior to the above shaft assembling process. To enhance the layer-to-layer adherence between the tubular rubber member **220** and the inner thermoplastic layer **210** (e.g., made of Pebax 7233 SA01) layer or the outer layer **230** (e.g., made of Pebax 3533), a thin film layer of an instant CA adhesive (e.g., Loctite 4011) may be applied in between.

EXAMPLE #3

[0122] In some embodiments, to simplify and facilitate relevant manufacturing processes of the distal shaft section **250**, the rubber members/layer as shown in FIGS. **2**(*a*)-**2**(*g*)-**4** can be pre-formed over the pre-formed inner thermoplastic layer **210** as a liner, thereby forming the so-called integral liner-gasket entity. The inner thermoplastic layer **210** (or the liner) is made of a relatively rigid thermoplastic polymer material, whose solid-state thermal transition temperature of material (e.g., melting temperature for semi-crystalline thermoplastic polymer or glass transition temperature for amorphous thermoplastic polymer) is considerably higher than the applicable cure temperature (e.g., 110° C. to 170° C.) for typical silicone rubber compounds. For instance, the inner thermoplastic layer **210** is melt-extruded of nylon 6 (e.g., Zytel 7301 NC010), whose characteristic melting temperature is about 221° C. The pre-formed inner thermoplastic layer **210** is continuously fed through an extrusion die as the liner, onto which the rubber members/layer are shaped in the desired geometric profiles, followed by an in situ curing to result in an intimately bonded liner-gasket entity, via a reactive liquid/paste extrusion process with use of a self-adhesion silicone rubber compound, e.g., Silastic RBL-9694-30P. To optimally enhance crosslink density and minimize the permanent compression set for the in situ cured silicone rubber material, a post-forming curing can be optionally conducted at elevated temperature of up to 170° C. for about two hours, while without any thermo-physical compromise on the solid-state structural integrity of the so-formed integral liner-gasket entity. In addition, to improve the melt adhesion of the outer thermoplastic layer **230** (which may be pre-extruded of a relatively soft polymer material (e.g., Pebax 3533 SA01) with the integral liner-gasket entity, similar chemical treatment on the integral liner-gasket entity comprising the silicone rubber member/layer, as detailed above, can be carried out because the cured silicone rubber material within the integral liner-gasket entity may no longer exhibit any adhesion properties with other thermoplastic materials (e.g., an outer thermoplastic layer **230**, tip-fitting shaft section **253**, moisture-barrier shaft section **254**, etc.).

[0123] Then, the resultant shaft assembly (i.e., the distal shaft section **250**) comprising an integral liner-gasket (or an integral inner thermoplastic layer-tubular rubber member) entity, along with other functional shaft sections (e.g., tip-fitting shaft section **253**, moisture-barrier shaft section **254**, etc.), is fully enclosed by a high-temperature heat shrink tube (e.g., PTFE heat shrink tube), and heated to high temperature of about 270° C. by means of induction heating. As such, the inner and outer thermoplastic layers **210** and **230**, along with other functional shaft sections (e.g., **253** and **254**), will melt and redistribute to result in the intimate adherences between different polymer materials upon cooling.

[0124] FIG. **13** is a schematic and block diagram view of a system **10** that can be used for ablation (e.g., RF ablation or pulsed field ablation) to destroy abnormal cardiac tissue within the heart anatomy. In particular, system **10** may be used for electroporation-induced primary necrosis therapy, which refers to the effects of delivering electrical current in such manner as to directly cause an irreversible loss of plasma membrane (cell wall) integrity leading to its breakdown and cell necrosis. This mechanism of cell death may be viewed as an “outside-in” process, meaning that the disruption of the outside wall of the cell causes detrimental effects to the inside of the cell. Typically, for classical plasma membrane electroporation, electric current is delivered as a pulsed electric field (i.e., pulsed field ablation (PFA)) in the form of short-duration pulses (e.g., 0.1 to 20 ms duration) between closely spaced electrodes capable of delivering an electric field strength of about 0.1 to 1.0 kV/cm.

[0125] The system **10** includes a catheter (e.g., **100**) having an elongate shaft (e.g., **120** including a distal shaft section **250** with one or more rubber members) coupled to a handle assembly **110**. A connector **130** may be coupled at a proximal end of the handle **110** to provide mechanical and electrical connection(s) for cable **56** extending from an ablation generator **26**. The connector **130** may comprise conventional components known in the art and as shown is disposed at the proximal end of the catheter **100**. The catheter **100** may also include other conventional components not illustrated herein such as a temperature sensor, additional electrodes, and corresponding conductors or leads disposable via the elongate shaft **120**.

[0126] In some embodiments, the catheter **100** includes a diagnostic and/or therapeutic shaft assembly (i.e., FSA **270**) attached to the distal end portion **201**A of the deflectable shaft section **200**. The diagnostic and/or therapeutic shaft assembly comprising an electrode shaft section can have any suitable configuration for performing a diagnostic and/or therapeutic medical procedure. For example, in some embodiments, the diagnostic and/or therapeutic shaft assembly (i.e., FSA **270**) includes an electrode shaft section **250** with the electrodes **112** configured to accomplish a diagnostic and/or therapeutic medical procedure (e.g., the electrode shaft section **250**). For example, the diagnostic and/or therapeutic shaft assembly comprising the electrode shaft section (e.g., **250**) can include electrodes **112** that are electrically coupled to the generator **26** via suitable electrical wire or other suitable electrical conductors extending through the elongate shaft **120**.

[0127] The electrodes **112** may be used for a variety of diagnostic and therapeutic purposes including, for example and without limitation, cardiac mapping and/or ablation (e.g., IRE ablation). For example, and in some embodiments, the distal shaft portion **250** with the electrodes **112** may be configured as a bipolar electrode assembly for use in bipolar-based electroporation therapy. Specifically, electrodes **112** are individually electrically coupled to the generator **26** (e.g., via suitable electrical wire or other suitable electrical conductors extending through catheter shaft **200**) and are configured to be selectively energized (e.g., by the generator **26** and/or computer system **32**) with opposite polarities to generate a potential and corresponding electric field therebetween, for PFA therapy. That is, one of electrodes **112** is configured to function as a cathode, and the other is configured to function as an anode. Electrodes **112** may be any suitable electroporation electrodes. In the exemplary embodiment, electrodes **112** are ring electrodes. Electrodes **112** may have any other shape or configuration. It is realized that the shape, size, and/or configuration of electrodes **112** may impact various parameters of the applied electroporation therapy. For example, increasing the surface area of one or both electrodes **112** may reduce the applied voltage needed to cause the same level of tissue destruction. Further, the electrodes **112** on the distal shaft section **250** may be configured as a bipolar electrode assembly. In some embodiments, electrode assembly **100** may configured as a monopolar electrode assembly and use a patch electrode (e.g., return electrode **18**) as a return or indifferent electrode.

[0128] In some embodiments, the catheter **100** may be configured as an introducer that includes a lumen configured to accommodate insertion and advancement of a diagnostic and/or therapeutic catheter to a target site within a patient's vasculature. The diagnostic and/or therapeutic catheter can be configured for use in any suitable medical procedure such as, for example, cardiac mapping and/or ablation (e.g., PFA).

[0129] The handle **110** is configured to be held by a clinician and operable to articulate the deflectable section **200** of the catheter shaft **120**. The handle **110** includes a pull wire actuation mechanism that is drivingly coupled with the deflectable shaft section **200** via two pull wires (also referred as deflection wires) affixed onto a pull ring **261** disposed at the distal end of the deflectable shaft section **200**. The pull wire actuation mechanism includes an input element that is articulable by the clinician to articulate the pull wires to selectively curve the deflectable shaft section **200**. The handle **110** can be further configured to vary the shape, size, and/or orientation of another portion of the catheter **100** other than the deflectable shaft section, such as the electrode shaft section **250**. The handle **110** can have any suitable configuration, such as configurations that are conventional in the art.

[0130] A plurality of return electrodes designated **18**, **20**, and **21**, which are diagrammatic of the body connections that may be used by the various sub-systems included in the overall system **10**, such as an electroporation generator **26**, an electrophysiology (EP) monitor such as an ECG monitor **28**, a localization and navigation system **30** for visualization, mapping and navigation of internal body structures. In the illustrated embodiment, return electrodes **18**, **20**, and **21** are patch electrodes. It should be understood that the illustration of a single patch electrode is diagrammatic only (for clarity) and that such sub-systems to which these patch electrodes are connected may, and typically will, include more than one patch (body surface) electrode. The system **1400** may further include a main computer system **32** (including an electronic control unit **50** and data storage-memory **52**), which may be integrated with system **30** provided for visualization, mapping and navigation of internal body structures in certain embodiments. The computer system **32** may further include conventional interface components, such as various user input/output mechanisms **34***a* and a display **34***b*, among other components.

[0131] The generator **26** may be configured to energize the electrode element(s) in accordance with a RF ablation or an electroporation energization strategy, which may be predetermined or may be user-selectable. For electroporation, a variable impedance **27** allows the impedance of the system to be varied to limit arcing from the catheter electrode of catheter (e.g., **100**). Moreover, variable impedance **27** may be used to change one or more characteristics, such as amplitude, duration, pulse shape, and the like, of an output of the generator **26**. Although illustrated as a separate component, variable impedance **27** may be incorporated in the catheter **100** or generator **26**. In some embodiments, each variable impedance **27** may be connected to a different catheter electrode or group of catheter electrodes to allow the impedance through each catheter electrode or group of catheter electrodes to be separately varied. Additional details of an example electroporation systems are discussed in a PCT publication no. WO2018102376A1, the entire disclosure which is incorporated herein by reference.

EXAMPLE EMBODIMENTS

[0132] In one or more embodiments of the present disclosure, a catheter shaft assembly includes an elongate tubular inner layer, a first rubber member, an elongate outer layer, and one or more ring electrodes. The first rubber member is disposed on an exterior surface of the elongate tubular inner layer. The elongate outer layer covers an exterior surface of the first rubber member or the elongate tubular inner layer. The one or more ring electrodes are attached to and encircle the elongate outer layer or the first rubber member. Each of the ring electrodes induces a radial hyperelastic deformation of the first rubber member that inhibits loss of an interference fit between the ring electrode and the elongate outer layer or the first rubber member. Optionally, the elongate tubular inner layer can have the same length as the elongate outer layer. Optionally, the first rubber member can be elongated and can have a length equal to or shorter than the elongate tubular inner layer or the elongate outer layer. Optionally, the first rubber member can be disposed between the elongate tubular inner layer and the elongate outer layer. Optionally, the catheter shaft assembly further includes a second rubber member. Optionally, each of the first rubber member and the second rubber member can have a length equal to or longer than a ring electrode of the one or more ring electrodes. Optionally, the first rubber member can be longitudinally spaced apart from the second rubber member along the elongate tubular inner layer. Optionally, the catheter shaft assembly can further include a third rubber member having a length equal to or longer than a ring electrode of the one or more ring electrodes. Optionally, the first, second, and third rubber members can be longitudinally spaced apart from each other at equal distances or varying distances. Optionally, the first rubber member encircles and extends along a first length of the elongate tubular inner layer. Optionally, the catheter shaft assembly can further include a second rubber member and a third rubber member, wherein the first rubber member, the second rubber member, and the third rubber member are circumferentially distributed and spaced apart along the elongate tubular inner layer, and wherein each of the one or more ring electrodes induces a radial hyperelastic deformation on each of the first rubber member, the second rubber member, and the third rubber member that inhibits loss of the interference fit between each of the ring electrodes and the elongate outer layer, the first rubber member, the second rubber member, or the third rubber member. Optionally, the catheter shaft assembly can further include a fourth rubber member, a fifth rubber member, and a sixth rubber member, wherein the first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, and the sixth rubber member are circumferentially distributed and spaced apart along the first length of the elongate tubular inner layer, and wherein each of the one or more ring electrodes induces a radial hyperelastic deformation of each of the first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, and the sixth rubber member that inhibits loss of the interference fit between the one or more ring electrodes and the elongate outer layer, the first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, or the sixth rubber member. Optionally, at least one of the first rubber member and the second rubber member can include a protruding portion shaped to enhance coupling with the elongate outer layer. Optionally, the first rubber member can be a tubular rubber member that includes at least one longitudinally oriented through slot or holes for facilitating melt flow-induced space filling and thermal fusion bonding of the elongate tubular inner layer, the elongate outer layer, and the first rubber member. Optionally, the first rubber member can include a protruding portion shaped to enhance coupling with the elongate outer layer or the elongate tubular inner layer. Optionally, the catheter shaft assembly can further include a first electrode wire electrically connected to a first ring electrode of the one or more ring electrodes, wherein the first rubber member includes a first electrode wire hole through which the first electrode wire extends. Optionally, the first rubber member can include a potting hole configured to accommodate injection of a potting adhesive through the potting hole into a lumen defined by the elongate tubular inner layer. Optionally, the catheter shaft assembly can further include a metallic braided layer that is longitudinally disposed over the exterior surface of the elongate tubular inner layer and under an interior surface of the first rubber member. Optionally, the elongate tubular inner layer can include a thermoplastic or thermoplastic elastomer material. Optionally, the thermoplastic or thermoplastic elastomer material can have a durometer of greater than Shore D40. Optionally, the thermoplastic or thermoplastic elastomer material can have a durometer in a range of Shore D60 to D85.

[0133] Optionally, the elongate outer layer can include a thermoplastic or thermoplastic elastomer material. Optionally, the thermoplastic or thermoplastic elastomer material can be the same as that of the elongate tubular inner layer. Optionally, the thermoplastic or thermoplastic elastomer material can be different from that of an elongate tubular inner layer and can have a durometer of less than Shore D60. Optionally, the first rubber member can have a durometer equal to or less than Shore A65. Optionally, the first rubber member can include silicone rubber. Optionally, the first rubber member can be chemically treated to impart chemical compatibility with at least one of the elongate tubular inner layer or the elongate outer layer.

[0134] In one or more embodiments of the present disclosure, a method of manufacturing a catheter shaft assembly includes forming a tubular inner thermoplastic layer, forming a first shaft assembly by placing a first rubber member or in situ forming the first rubber member on an exterior surface of the tubular inner thermoplastic layer, forming a second shaft assembly by placing an outer thermoplastic layer over the first shaft assembly, forming a bonded catheter shaft by thermal-fusion bonding between the tubular inner thermoplastic layer and the outer thermoplastic layer within the second shaft assembly, and attaching a first ring electrode to the bonded catheter shaft so that the first ring electrode induces a radial hyperelastic deformation of the first rubber member that inhibits loss of an interference fit between the first ring electrode and the bonded catheter shaft. Optionally, the first rubber member can encircle and extend along a first length of the bonded catheter shaft. Optionally, forming the first shaft assembly can include placing a plurality of discrete rubber members on the exterior surface of the tubular inner thermoplastic layer so that the discrete rubber members are circumferentially distributed and spaced apart along a first length of the tubular inner thermoplastic layer, wherein the plurality of discrete rubber members includes the first rubber member. Optionally, one or more of the discrete rubber members can include a protruding portion shaped to enhance coupling of the discrete rubber member with the outer thermoplastic layer. Optionally, forming the first shaft assembly can include applying an adhesive to the exterior surface of the tubular inner thermoplastic layer, wherein the adhesive, when cured, is thermoplastic in nature. Optionally, the adhesive can include a cyanoacrylate adhesive including at least one of: a cyanoacrylate monomer or oligomer. Optionally, the thermal-fusion bonding can include melting and reflowing the tubular inner thermoplastic layer and the outer thermoplastic layer of the second shaft assembly under radial compressive pressure. Optionally, forming the bonded catheter shaft further can include placing a heat-shrinkable tube over the outer thermoplastic layer prior to heating the second shaft assembly. Optionally, the first rubber member can have a durometer equal to or less than Shore A65. Optionally, the first rubber member can be made of a silicone rubber compound. Optionally, attaching the first ring electrode to the bonded catheter shaft can include swagging the first ring electrode onto the bonded catheter shaft using a swaging die. Optionally, the method can further include treating the first rubber member with one or more silane coupling agent to impart chemical compatibility with at least one of the tubular inner thermoplastic layer or the outer thermoplastic layer.

[0135] It is to be understood that terms such as “distal,” “proximal,” “top,” “bottom,” “front,” “side,” “length,” “inner,” and the like that can be used herein merely describe points of reference and do not necessarily limit embodiments of the present disclosure to any particular orientation or configuration. As used herein, “proximal” refers to a direction toward the end of the catheter near the clinician and “distal” refers to a direction away from the clinician and (generally) inside the body of a patient. Furthermore, terms such as “first,” “second,” “third,” etc., merely identify one of a number of portions, components, steps, operations, functions, and/or points of reference as disclosed herein, and likewise do not necessarily limit embodiments of the present disclosure to any particular configuration or orientation.

[0136] The terms “longitudinal,” “axial” or “axially” are generally longitudinal as used herein to describe the relative position related to a catheter, a catheter handle, or other components of the system herein. For example, “longitudinal” or “axial” indicates an axis passing along a center of a catheter from a proximal end to a distal end, or along a center of the catheter handle from a proximal end to a distal end. The term “radial” generally refers to a direction perpendicular to the “axial” direction.

[0137] Disjunctive language such as the phrase “at least one of X, Y, or Z,” unless specifically stated otherwise, is intended to be understood within the context as used in general to present that an item, term, etc., may be either X, Y, or Z, or any combination thereof (e.g., X, Y, and/or Z). Thus, such disjunctive language is not generally intended to, and should not, imply that certain embodiments require at least one of X, at least one of Y, or at least one of Z to each be present.

[0138] While certain embodiments have been described, these embodiments have been presented by way of example only and are not intended to limit the scope of the present disclosures. Indeed, the novel methods, apparatuses and systems described herein can be embodied in a variety of other forms; furthermore, various omissions, substitutions and changes in the form of the methods, apparatuses and systems described herein can be made without departing from the spirit of the present disclosures. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of the present disclosures.

Claims

1. A catheter shaft assembly comprising: an elongate tubular inner layer; a first rubber member disposed on an exterior surface of the elongate tubular inner layer; an elongate outer layer that covers an exterior surface of the first rubber member or the elongate tubular inner layer; and one or more ring electrodes attached to and encircling the elongate outer layer or the first rubber member, wherein each of the ring electrodes induces a radial hyperelastic deformation of the first rubber member that inhibits loss of an interference fit between the ring electrode and the elongate outer layer or the first rubber member.
2. The catheter shaft assembly of claim 1, wherein the elongate tubular inner layer has the same length as the elongate outer layer.
3. The catheter shaft assembly of claim 1, wherein the first rubber member is elongated, and has a length equal to or shorter than the elongate tubular inner layer or the elongate outer layer; and wherein the first rubber member is disposed between the elongate tubular inner layer and the elongate outer layer.
4. The catheter shaft assembly of claim 1, further comprising a second rubber member; wherein each of the first rubber member and the second rubber member has a length equal to or longer than a ring electrode of the one or more ring electrodes; and wherein the first rubber member is longitudinally spaced apart from the second rubber member along the elongate tubular inner layer.
5. The catheter shaft assembly of claim 4, further comprising a third rubber member having a length equal to or longer than a ring electrode of the one or more ring electrodes, wherein the first, second, and third rubber members are longitudinally spaced apart from each other at equal distances or varying distances
6. (canceled)
7. The catheter shaft assembly of claim 1, wherein the first rubber member encircles and extends along a first length of the elongate tubular inner layer, further comprising a second rubber member and a third rubber member, wherein the first rubber member, the second rubber member, and the third rubber member are circumferentially distributed and spaced apart along the elongate tubular inner layer; and wherein each of the one or more ring electrodes induces a radial hyperelastic deformation on each of the first rubber member, the second rubber member, and the third rubber member that inhibits loss of the interference fit between each of the ring electrodes and the elongate outer layer, the first rubber member, the second rubber member, or the third rubber member.
8. The catheter shaft assembly of claim 7, further comprising a fourth rubber member, a fifth rubber member, and a sixth rubber member, wherein: the first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, and the sixth rubber member are circumferentially distributed and spaced apart along the first length of the elongate tubular inner layer; and each of the one or more ring electrodes induces a radial hyperelastic deformation of each of the first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, and the sixth rubber member that inhibits loss of the interference fit between the one or more ring electrodes and the elongate outer layer, the first rubber member, the second rubber member, the third rubber member, the fourth rubber member, the fifth rubber member, or the sixth rubber member.
9. The catheter shaft assembly of claim 7, wherein at least one of the first rubber member and the second rubber member comprises a protruding portion shaped to enhance coupling with the elongate outer layer.
10. The catheter shaft assembly of claim 1, wherein the first rubber member is a tubular rubber

member comprising at least one longitudinally-oriented through slot or holes for facilitating melt flow-induced space filling and thermal fusion bonding of the elongate tubular inner layer, the elongate outer layer, and the first rubber member.

11. The catheter shaft assembly of claim 1, wherein the first rubber member comprises a protruding portion shaped to enhance coupling with the elongate outer layer or the elongate tubular inner layer.

12. The catheter shaft assembly of claim 1, further comprising a first electrode wire electrically connected to a first ring electrode of the one or more ring electrodes, wherein the first rubber member comprises a first electrode wire hole through which the first electrode wire extends.

13. The catheter shaft assembly of claim 1, wherein the first rubber member comprises a potting hole configured to accommodate injection of a potting adhesive through the potting hole into a lumen defined by the elongate tubular inner layer.

14. The catheter shaft assembly of claim 1, further comprising a metallic braided layer that is longitudinally disposed over the exterior surface of the elongate tubular inner layer and under an interior surface of the first rubber member.

15. The catheter shaft assembly of claim 1, wherein the elongate tubular inner layer comprises a thermoplastic or thermoplastic elastomer material, wherein the thermoplastic or thermoplastic elastomer material has a durometer in a range of Shore D60 to D85.

16.-**17**. (canceled)

18. The catheter shaft assembly of claim 1, wherein the elongate outer layer comprises a thermoplastic or thermoplastic elastomer material.

19. The catheter shaft assembly of claim 18, wherein the thermoplastic or thermoplastic elastomer material is the same as that of the elongate tubular inner layer.

20. The catheter shaft assembly of claim 18, wherein the thermoplastic or thermoplastic elastomer material is different from that of an elongate tubular inner layer and has a durometer of less than Shore D60.

21. The catheter shaft assembly of claim 1, wherein the first rubber member has a durometer equal to or less than Shore A65.

22. The catheter shaft assembly of claim 1, wherein the first rubber member comprises silicone rubber.

23. The catheter shaft assembly of claim 1, wherein the first rubber member is chemically treated to impart chemical compatibility with at least one of the elongate tubular inner layer or the elongate outer layer.

24.-**35**. (canceled)
