



(51) International Patent Classification:
A61B 18/14 (2006.01)

(21) International Application Number:
PCT/US2016/063250

(22) International Filing Date:
22 November 2016 (22.11.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/262,098 2 December 2015 (02.12.2015) US

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(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM,

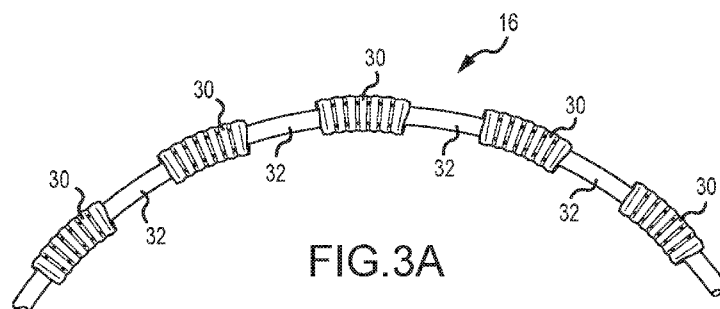
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: RADIOFREQUENCY ABLATION DEVICE



(57) Abstract: An ablation catheter includes a distal region, which may be disposed into or capable of being shaped into at least a partial loop, and a plurality of individually electrically addressable flexible ablation electrodes disposed within the distal region and separated by a plurality of electrically insulating gaps. The plurality of individually electrically addressable flexible ablation electrodes can include a plurality of pleated ablation electrodes. In embodiments, the pleated ablation electrodes are irrigated, for example via irrigation ports within the troughs of their pleats. The individually electrically addressable flexible ablation electrodes can also include a plurality of commonly electrically addressable rigid electrode segments separated by a plurality of flexible inter-electrode gaps. The plurality of individually electrically addressable flexible ablation electrodes cover at least 50%, and, in embodiments, at least 80%, of an overall length of the distal region.

RADIOFREQUENCY ABLATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of United States provisional application no. 62/262,098, filed 2 December 2015, which is hereby incorporated by reference as though fully set forth herein.

BACKGROUND

[0002] The instant disclosure relates generally to tissue ablation. In particular, the instant disclosure relates to a medical device for use in creating a circumferential lesion about a blood vessel, such as in pulmonary vein (PV) isolation procedures.

[0003] In the normal heart, contraction and relaxation of the heart muscle (myocardium) takes place in an organized fashion as electro-chemical signals pass sequentially through the myocardium from the sinoatrial (SA) node, which comprises a bundle of unique cells disposed in the wall of the right atrium, to the atrioventricular (AV) node and then a long a well-defined route, which includes the His-Purkinje system, into the left and right ventricles. Sometimes, however, abnormal rhythms occur in the heart, which are referred to generally as arrhythmias.

[0004] Certain arrhythmias, referred to as atrial arrhythmias, occur in the atria. Three of the most common atrial arrhythmias are ectopic atrial tachycardia, atrial fibrillation (AF), and atrial flutter. AF can result in significant patient discomfort and even death because of a number of associated problems, including: irregular heart rate, which causes patient discomfort and anxiety; loss of synchronous atrioventricular contractions, which compromises cardiac hemodynamics, resulting in varying levels of congestive heart failure; and stasis of blood flow, which increases the likelihood of thromboembolism, a leading cause of stroke.

[0005] One common medical procedure for the treatment of certain types of cardiac arrhythmia, specifically including AF, is catheter ablation. In many ablation procedures, energy, such as radiofrequency (RF) energy or high intensity focused ultrasound (HIFU) energy, is delivered to cardiac tissue in order to heat the tissue and create a permanent scar or lesion that is electrically inactive.

[0006] It is known that, in some instances, stray electrical signals find a pathway down the pulmonary veins and into the left atrium of the heart. In these instances, it may be advantageous to produce a circumferential lesion at or near the ostium of one or more of the pulmonary veins. Desirably, such a circumferential lesion would electrically isolate the pulmonary vein from the left atrium, completely blocking stray signals from traveling down the pulmonary vein and into the left atrium. Thus, such procedures are known as PV isolation procedures.

[0007] Various extant devices are known to perform PV isolation procedures. For example, several ablation catheters for use in PV isolation procedures incorporate a number of rigid, generally cylindrical electrodes at their distal end. Such devices, however, pose various challenges, such as achieving uniform and consistent contact pressure between the electrodes and the adjacent tissue along the full length of the electrode-tissue interface, and/or requiring the device to be repositioned within the ostium in order to complete a circumferential lesion.

BRIEF SUMMARY

[0008] Disclosed herein is an ablation device, including: a catheter body including a distal region; and a plurality of individually electrically addressable flexible ablation electrodes disposed within the distal region and separated by a plurality of electrically insulating gaps. In embodiments of the disclosure, the distal region of the catheter body can be predisposed into at least a partial loop. The ablation device can further include a balloon positioned on the catheter body such that, when the balloon is expanded, it exerts a radially outwardly directed force on the at least a partial loop, for example to urge the flexible ablation electrodes into contact with adjacent tissue. A length of the distal region can also be adjustable.

[0009] According to aspects of the disclosure, the plurality of individually electrically addressable flexible ablation electrodes include a plurality of pleated ablation electrodes. It is also contemplated that a plurality of irrigation ports can be provided through the plurality of pleated ablation electrodes into an interior of the distal region of the catheter body. For example, the plurality of irrigation ports can be positioned within a plurality of troughs of the plurality of pleated ablation electrodes.

[0010] According to other aspects of the disclosure, at least one individually electrically addressable flexible ablation electrode can include a plurality of commonly electrically addressable rigid electrode segments separated by a plurality of flexible inter-electrode gaps.

[0011] In certain embodiments disclosed herein, the plurality of individually electrically addressable flexible ablation electrodes cover at least 50% of an overall length of the distal region of the catheter body. In other embodiments disclosed herein, the plurality of individually electrically addressable flexible ablation electrodes cover at least 80% of the overall length of the distal region of the catheter body.

[0012] Optionally, at least some electrically insulating gaps of the plurality of electrically insulating gaps can be rigid. For example, at least some electrically insulating gaps of the plurality of electrically insulating gaps can include a ceramic material.

[0013] Also disclosed herein is an ablation device including: a catheter body including a distal region predisposed into at least a partial loop; and a plurality of pleated ablation electrodes disposed within the distal region, wherein the plurality of pleated ablation electrodes cover at least 50% of an overall length of the distal region of the catheter body, and wherein the plurality of pleated ablation electrodes are individually electrically addressable and electrically isolated from each other by a plurality of interelectrode gaps.

[0014] In embodiments, the distal region of the catheter body includes a continuous length of a flexible polymeric material, and the plurality of pleated ablation electrodes are positioned on an outer surface of the continuous length of the flexible polymeric material. In other embodiments, the plurality of interelectrode gaps includes a plurality of flexible polymeric segments that interconnect the plurality of pleated ablation electrodes. In still other embodiments, the plurality of interelectrode gaps includes a plurality of rigid segments that interconnect the plurality of pleated ablation electrodes.

[0015] It is also contemplated that a length of the distal region of the catheter body can be adjusted by adjusting a spacing between adjacent pleats of the plurality of pleated ablation electrodes, for example by using hydraulic or pneumatic pressure to extend the length of the distal region of the catheter body during or after device placement. Alternatively, the flexible electrodes themselves may be non-extendable or minimally extendable, but the catheter body

running through and/or interconnecting the flexible electrodes may be extendable, such as by using hydraulic or pneumatic pressure and/or via the use of a push/pull extension wire.

[0016] In a further aspect of the disclosure, an ablation device includes: a catheter body including a distal region predisposed into at least a partial loop; and a plurality of flexible ablation electrodes disposed within the distal region, wherein each flexible ablation electrode of the plurality of ablation electrodes includes a plurality of rigid electrode segments interconnected by a plurality of flexible segments, and wherein the plurality of flexible ablation electrodes are individually electrically addressable and electrically isolated from each other. Optionally, a balloon can be positioned on the catheter body such that, when the balloon is expanded, it urges the plurality of flexible ablation electrodes into contact with an adjacent tissue.

[0017] The instant disclosure also provides a method of forming a contiguous circumferential lesion, including the steps of: positioning an ablation device within a blood vessel, the ablation device including: a catheter body including a distal region; and a plurality of individually electrically addressable flexible ablation electrodes disposed within the distal region and separated by a plurality of electrically insulating gaps; bringing the individually electrically addressable flexible ablation electrodes into contact with a wall of the blood vessel; and activating the individually electrically addressable flexible ablation electrodes to deliver ablating energy to the wall of the blood vessel; and repositioning the ablation device within the blood vessel two or fewer times, thereby forming the contiguous circumferential lesion with fewer than three total placements of the ablation device within the blood vessel.

[0018] The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Figure 1 illustrates an exemplary ablation catheter according to embodiments of the instant disclosure.

[0020] Figure 2A is a close up of the distal region of the exemplary ablation catheter shown in Figure 1.

[0021] Figure 2B is an end view of Figure 2A.

[0022] Figure 3A depicts a portion of the distal region of the exemplary ablation catheter shown in Figure 1 including a plurality of flexible ablation electrodes thereon.

[0023] Figure 3B is a close up view of a flexible ablation electrode according to aspects of the instant disclosure.

[0024] Figure 3C is a transverse cross-section of a flexible ablation electrode taken along line 3C-3C in Figure 3B.

[0025] Figure 4 depicts another embodiment of the distal region of an ablation catheter incorporating flexible ablation electrodes according to the teachings herein.

[0026] Figure 5 depicts a necklace of electrode segments.

[0027] Figure 6 illustrates the use of a balloon to bring a necklace of electrode segments, such as shown in Figure 5, into contact with the ostium of a blood vessel.

DETAILED DESCRIPTION

[0028] The present disclosure provides medical devices, such as catheters, suitable for use in creating an ablation lesion about the circumference of a blood vessel. For purposes of illustration, several exemplary embodiments will be described herein in detail in connection with a system that utilizes radiofrequency (RF) energy for ablation in the context of a PV isolation procedure. It should be understood, however, that the teachings herein can be utilized in other contexts, particularly those where lesions are to be made and/or electrical sensing/mapping is to be performed along an extended path on target tissue. Indeed, the teachings herein can be applied to good advantage in the creation of extended circumferential- or helical-path lesions and/or circumferential- or helical-path electrical sensing/mapping, such as performed in or at anatomical lumens (*e.g.*, PVs, renal arteries). For example, the teachings herein can be applied to catheters for use in electrophysiology studies, such as the Inquiry™ Optima™ diagnostic catheter of St. Jude Medical, Inc., as well as in spinal and/or renal denervation procedures.

[0029] The devices disclosed herein provide a high percentage of electrode-tissue coverage along a lesion path, such that each placement of the device covers more of the intended lesion path. As such, fewer total device placements are necessary to form a contiguous circumferential lesion. As used herein, a “contiguous circumferential lesion” is a lesion about the circumference of a vessel, either with two disconnected ends (as is the case with a helical lesion), or with two

connected ends (as is the case with a typical OS-entry lesion), and without gaps along the desired lesion path.

[0030] Referring now to the figures, Figure 1 depicts an exemplary ablation catheter 10 according to a first aspect of the present disclosure. Catheter 10 generally includes an elongate catheter body 12, which, in some embodiments, is tubular (*e.g.*, it defines at least one lumen therethrough). Catheter body 12 includes a proximal region 14, a distal region 16, and a neck region 18 between proximal region 14 and distal region 16. The relative lengths of proximal region 14, distal region 16, and neck region 18 as depicted in Figure 1 are merely illustrative and may vary without departing from the spirit and scope of the instant disclosure. Of course, the overall length of catheter body 12 should be long enough to reach the intended destination within the patient's body (*e.g.*, the ostium of a pulmonary vein), typically between about 110cm and about 120cm long.

[0031] Catheter body 12 will typically be made of a biocompatible polymeric material, such as polytetrafluoroethylene (PTFE) tubing (*e.g.*, TEFLON® brand tubing). Of course, other polymeric materials, such as fluorinated ethylene-propylene copolymer (FEP), perfluoroalkoxyethylene (PFA), poly(vinylidene fluoride), poly(ethylene-co-tetrafluoroethylene), and other fluoropolymers, may be utilized. Additional suitable materials for catheter body 12 include, without limitation, polyamide-based thermoplastic elastomers (namely poly(ether-block-amide), such as PEBAX®), polyester-based thermoplastic elastomers (*e.g.*, HYTREL®), thermoplastic polyurethanes (*e.g.*, PELLETHANE®, ESTANE®), ionic thermoplastic elastomers, functionalized thermoplastic olefins, and any combinations thereof. In general, suitable materials for catheter body 12 may also be selected from various thermoplastics, including, without limitation, polyamides, polyurethanes, polyesters, functionalized polyolefins, polycarbonate, polysulfones, polyimides, polyketones, liquid crystal polymers and any combination thereof. It is also contemplated that the durometer of catheter body 12 may vary along its length. In general, the basic construction of catheter body 12 will be familiar to those of ordinary skill in the art, and thus will not be discussed in further detail herein.

[0032] As shown in Figures 1, 2A, and 2B, distal region 16 of catheter body 12 can assume at least a partial loop shape. In embodiments, distal region 16 is predisposed into a partial loop shape. In other embodiments, controls can be provided on handle 22 to actuate distal region 16

to assume and/or alter the loop shape of distal region 16. This loop shape allows distal region 16 to conform to the shape of adjacent tissue, for example, of a pulmonary vein ostium inner diameter or tapered entrance region. The partial loop may take a number of configurations (*e.g.*, single loop, multiple loops in the form of a helix, etc.), depending on the intended or desired use of catheter 10, consistent with the present teachings. Therefore, it should be understood that the loop configurations depicted in Figures 1, 2A, and 2B are merely illustrative.

[0033] Figures 2A and 2B also illustrate that distal region 16 includes a plurality of flexible ablation electrodes 20. In embodiments, flexible ablation electrodes 20 are disposed on the exterior surface of catheter body 12 (that is, they form rings around catheter body 12). In other embodiments, catheter body 12 does not pass through flexible ablation electrodes 20; rather, flexible ablation electrodes 20 are interconnected by shorter segments of catheter body 12.

[0034] Of course, in addition to serving therapeutic purposes (*e.g.*, cardiac ablation), electrodes 20 can also serve sensing purposes (*e.g.*, cardiac mapping and/or diagnosis) or other purposes (*e.g.*, pacing). Various configurations of electrodes 20 will be discussed in further detail below.

[0035] As discussed in greater detail below, in embodiments of the disclosure, electrodes 20 are individually electrically addressable. That is, each electrode 20 can be activated and/or deactivated independent of every other electrode 20. Alternatively, at least some of electrodes 20 can be commonly electrically addressable (*e.g.*, multiple electrodes 20 can share a common dedicated electrical channel to an RF ablation generator, such that they activate and deactivate simultaneously).

[0036] Referring again to Figure 1, a handle 22 is coupled to proximal region 14 of catheter body 12. Handle 22 can include suitable actuators (*e.g.*, knob 24), for example to control the deflection of catheter body 12, for example as described in United States patent no. 8,369,923, which is hereby incorporated by reference as though fully set forth herein, and/or the radius of curvature of distal region 16. Various handles and their associated actuators for use in connection with electrophysiology catheters are known, and thus handle 22 will not be described in further detail herein.

[0037] It is contemplated that the radius of curvature of the loop of distal region 16 may be adjustable, for example to conform to the varying sizes of pulmonary vein ostia of patients of

different ages. This additional control may be provided, for example, via the use of an activation wire that is adapted to alter the radius of curvature of the loop of distal region 16. One suitable material for the activation wire is stainless steel, though other materials can be employed without departing from the spirit and scope of the instant disclosure.

[0038] In some embodiments, one end (*e.g.*, the distal end) of the activation wire may be coupled to the tip of catheter body 12 (*e.g.*, coupled to a distal-most tip electrode of electrodes 20), while the other end (*e.g.*, the proximal end) of the activation wire may be coupled to an actuator (*e.g.*, knob 24) on handle 22. Thus, for example, turning knob 24 can place the activation wire in tension, thereby altering the radius of curvature of the loop of distal region 16.

[0039] Another exemplary mechanism for varying the radius of curvature of the loop of distal region 16 is described in United States patent no. 7,606,609, which is hereby incorporated by reference as though fully set forth herein.

[0040] A shaping wire can also extend through neck region 18 and at least partially through distal region 16 in order to help predispose or bias distal region 16 into the loop shape depicted throughout the Figures. The shaping wire can be made from a shape memory material such as nitinol. As discussed above, knob 24 can also facilitate alterations in the radius of curvature of distal region 16.

[0041] Having now described various aspects of the construction of catheter 10 in general, several embodiments of distal region 16, and, in particular, of electrodes 20, will be described with reference to Figures 3A-6.

[0042] Figure 3A depicts a first embodiment of distal region 16 including a plurality of pleated or corrugated ablation electrodes 30, each of which is individually flexible (for the sake of illustration, only a segment of distal region 16, including five pleated flexible ablation electrodes 30, is shown in Figure 3A). Figure 3B is a close-up view of one pleated ablation electrode 30.

[0043] As shown in Figure 3A, pleated electrodes 30 are separated by a plurality of gaps 32, which can be of the same flexible material as catheter body 12 more generally (*e.g.*, a polymeric material). Flexible gaps 32, however, are shorter than flexible pleated electrodes 30, such that much of the curvature of distal region 16 is achieved through the flexibility of electrodes 30. Thus, according to aspects of the disclosure, pleated electrodes 30 cover at least about 50% of

the overall length of distal region 16. In other aspects of the disclosure, pleated electrodes 30 cover at least about 65% of the overall length of distal region 16. In still other aspects of the disclosure, pleated electrodes cover at least about 80% of the overall length of distal region 16.

[0044] Advantageously, using electrodes 30 that are longer than gaps 32 therebetween both allows catheter 10 to sit more intimately against tissue to be ablated. This minimizes the need to fill gaps in an isolation lesion by employing additional offset placements of ablation catheter 10 upon the tissue. Additionally, the use of gap-filling bipolar lesioning between neighboring electrodes 30 (so-called “band-aid” lesioning) can be minimized (*e.g.*, at lower bipolar power) or eliminated entirely.

[0045] Pleated or corrugated electrodes 30 can be formed by electroforming, hydroforming, roll-forming or any other suitable manufacturing technique to create a bellows of generally cylindrical or tubular shape, and desirably lacking any sharp corners in the undulations (*see* Figures 3B and 3C). In order to transfer RF energy to adjacent tissue, at least the outer surface 34 of pleated electrodes 30 (*see* Figure 3C) will be metallic, for example plated or sputtered platinum or gold. The remainder 36 of the wall of pleated electrodes 30 can be nickel, copper, titanium, stainless steel, or another suitable material to lend flexing strength to pleated electrodes 30.

[0046] For example, electrodes 30 can be formed by overplating an aluminum mandrel at high deposition rates with nickel, copper, and/or gold, to a thickness of between about 0.001 inches and about 0.005 inches to form layer 36. A gold electrode, forming layer 34, can then be formed with a thickness on the order of hundreds to thousands of angstroms. The aluminum mandrel can then be dissolved, such as according to known electroforming practice.

[0047] Overall, pleated electrodes 30 are hollow corrugated shells defining a central bore or lumen 38, which can be used, for example, to route signal and/or power cables to and/or from pleated electrodes 30 and/or to flow an irrigant to and through pleated electrodes 30.

[0048] As described above, in embodiments of the disclosure, catheter body 12 passes through lumens 38 of pleated electrodes 30. In other embodiments shorter segments of catheter body 12 are bonded to the end regions of pleated electrodes 30, rather than passing continuously through lumens 38 of pleated electrodes 30.

[0049] Figure 3B depicts pleats that are generally parallel when electrode 30 is relaxed (that is, unbent). It is also contemplated, however, that the pleats can be helically wound about a central axis, such as in the manner of the threads on a screw. It is also contemplated that the overall diameter of pleated electrode 30 can vary, for example being larger towards the middle of Figure 3B than towards the left and right ends of Figure 3B (that is, olive-shaped); this can help counteract any radially-measured potential diameter reduction when pleated electrode 30 bends. It can also facilitate more intimate tissue contact.

[0050] According to aspects of this disclosure, the spacing or pitch between pleats or corrugations is at least about twice the thickness of the wall of pleated electrode 20 (*i.e.*, the combined thickness of outer surface 34 and remainder 36). In other aspects, the pitch of the pleats is at least about four times the thickness of the wall of pleated electrode 20. In still other aspects, the pitch of the pleats is at least about six times the thickness of the wall of pleated electrode 20.

[0051] In embodiments, pleated electrodes 30 are irrigated electrodes and include a plurality of irrigation ports 40 through the wall of pleated electrode 30 and into central lumen 38. Irrigation ports 40 allow an irrigant (*e.g.*, saline) to be exhausted *in vivo* from central lumen 38, for example for tissue and/or electrode cooling purposes.

[0052] As shown in Figure 3B, it is desirable for irrigation ports 40 to be positioned within the troughs of the pleats or corrugations, as this configuration helps prevent occlusion of irrigation ports 40 when pleated electrode 30 is brought firmly into contact with tissue to be ablated. Of course, irrigation ports 40 could also be positioned anywhere else on pleated electrode 30 without departing from the scope of this disclosure. Irrigation ports 40 can, for example, be lasered, mechanically-drilled, or electro-discharge machined.

[0053] It is also contemplated that gaps 32 separating pleated electrodes 30, or portions thereof, can instead be rigid (electrodes 30 remain flexible). For example, gaps 32 as depicted in Figure 3A cover about one-third of the total length of distal region 16. In one embodiment, therefore, electrodes 30 could each be about 6 mm long, and each gap 32 could be about 3 mm long. Each rigid gap 32 could be made of a ceramic material (*e.g.*, zirconia-toughened alumina, silicon nitride) having a diameter slightly smaller than electrodes 30 (as shown), and a wall thickness, for example, of between about 0.010 inches to about 0.005 inches.

[0054] Figure 4 depicts an embodiment where ceramic segments 39 (shown in phantom) fill gaps 32 and bridge between adjacent electrodes 30, with electrodes 30 nearly continuous across gaps 32 because (1) gaps 32 are surface-metalized, with a narrow kerf 41 to electrically isolate adjacent electrodes 30 from each other; and/or (2) adjacent electrodes 30 have optionally rigid end regions that partially overlay gaps 32 without abutting.

[0055] Figure 5 depicts a further embodiment of distal region 16 of catheter 10 according to the teachings herein. As shown in Figure 5, each flexible ablation electrode 20 includes a plurality of shorter, rigid electrode segments 52 separated by flexible interelectrode gaps 54. This structure is referred to herein as a “necklace” of electrically ganged electrode segments 52. The electrode segments 52 that electrically make up any given flexible ablation electrode 20 (*e.g.*, a subset of the overall plurality of electrode segments 52) can be configured to activate simultaneously (*e.g.*, they can each share a common dedicated electrical channel to an RF generator, and therefore can be commonly electrically addressable), but independent of the electrode segments 52 that make up any other flexible ablation electrode 20 (*e.g.*, the electrode segments 52 of other flexible ablation electrodes 20 can occupy different electrical channels to the RF generator). Alternatively, each electrode segment 52 can be individually electrically addressable (that is, each electrode segment 52 can be activated and/or deactivated independently of every other electrode segment 52). Advantageously, by electrically ganging several short rigid electrode segments 52 together to make longer flexible ablation electrodes 20, one can significantly increase bending flexibility without significantly increasing the number of electrical channels required for ablation catheter 10.

[0056] For example, in the device shown in Figure 5, each rigid electrode segment 52 can have a length of about 4 mm, and the length of the intervening interelectrode gaps can be about 1 mm. If each flexible ablation electrode 20 in turn includes three rigid electrode segments 52, then each flexible ablation electrode 20 has an overall length of about 15 mm long.

[0057] In additional aspects of the disclosure, the pleats or corrugations allow electrode segments 30 of Figure 1 to expand and/or contract along their length, which in turn allows distal region 16 to change length. For example, by expanding or stretching electrode segments 30 along their length when catheter 10 is positioned, for example, within a PV ostium or antrum, distal region 16 of catheter 10 can be made to conform more closely thereto with higher contact

pressure (*e.g.*, in the manner of a compliant balloon). A push/pull guidewire can be employed to help ensure that the increase in length results in better radial conformance between distal region 16 and the adjacent tissue, and does not instead lead to axial tissue-slippage of distal region 16 along the PV ostium. It is also contemplated that rigid electrode segments (*e.g.*, segments 52, as shown in Figure 5) can slide along the length of distal region 16 in order to change its length. This can be implemented, for example, by having axially extendable segments 32 or an extendable continuous lumen running through all electrodes 20.

[0058] In other embodiments, a pressurized liquid (*e.g.*, saline) or gas (*e.g.*, CO₂) can be used to hydraulically or pneumatically, respectively, distend or contract extendable distal region 16 as described above. Further, where pleated or corrugated electrodes are employed, the pleats or corrugations themselves can allow distal region 16 to expand and/or contract along its length. Such pressurization can be independent of irrigant flow.

[0059] Yet a further embodiment according to the instant disclosure is shown in Figure 6. More particularly, Figure 6 depicts an inflatable balloon, bladder, or membrane 60 that expands in a manner that forces the necklace of electrode segments 52 radially outwards, and thus into better conformal contact with adjacent tissue (*e.g.*, the PV ostium 62). Balloon 60 can be bonded or attached to the ablation electrodes 20 or mounted elsewhere on catheter body 12 and slid into place proximate electrodes 20. Balloon 60 can be inflated either before or after being placed within the looped distal region 16.

[0060] In use, catheter 10 is introduced into a patient's body proximate an area of interest, such as a pulmonary vein ostium. Of course, catheter 10 may be introduced surgically (*e.g.*, via an incision in the patient's chest) or non-surgically (*e.g.*, navigated through the patient's vasculature to a desired site, with or without the assistance of a sheath, guidewire, or the like). Flexible ablation electrodes 20 can be brought into intimate contact with the tissue to be ablated, for example the interior antrum wall of the PV ostium, such as by inflating balloon 60, and RF energy can be delivered into the tissue via flexible ablation electrodes 20. Balloon 60 may also provide cooling, such as by flow of saline therethrough. In one embodiment of the disclosure, for example, electrodes 20 could have no internal irrigant cooling, instead being cooled by a fluid flowing through an adjacent balloon 60.

[0061] As discussed above, the use of flexible electrodes 20 facilitates the creation of a contiguous circumferential lesion (which, as described above, includes helical lesions) with a minimized need to reposition catheter 10 and/or to use bipolar lesions to close gaps of unablated tissue between monopolar lesions. The use of flexible electrodes 20 also facilitates more uniform contact force between the electrode and the tissue along its length, which minimizes the risk of charring. The inventors have demonstrated 80% coverage by flexible electrodes with only 20% intraelectrode spaces. The inventors have further established that, if bipolar ablation voltage is employed to fill gaps, it can be at a lower bipolar voltage that minimizes undesirable tissue damage.

[0062] Although several embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this invention.

[0063] For example, embodiments disclosed herein can be irrigated, and can include, for example, one or more bimaterial valves (*see* United States patent no. 8,641,707, which is hereby incorporated by reference as though fully set forth herein) to deliver the irrigant to or through one or more electrodes.

[0064] All directional references (*e.g.*, upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (*e.g.*, attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other.

[0065] It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure may be made without departing from the spirit of the invention as defined in the appended claims.

CLAIMS

What is claimed is:

1. An ablation device, comprising:
a catheter body including a distal region; and
a plurality of individually electrically addressable flexible ablation electrodes disposed within the distal region and separated by a plurality of electrically insulating gaps.
2. The ablation device according to claim 1, wherein the distal region of the catheter body is predisposed into at least a partial loop.
3. The ablation device according to claim 2, further comprising a balloon positioned on the catheter body such that, when the balloon is expanded, it exerts a radially outwardly directed force on the at least a partial loop.
4. The ablation device according to claim 1, wherein the plurality of individually electrically addressable flexible ablation electrodes comprises a plurality of pleated ablation electrodes.
5. The ablation device according to claim 4, further comprising a plurality of irrigation ports through the plurality of pleated ablation electrodes into an interior of the distal region of the catheter body.
6. The ablation device according to claim 5, wherein the plurality of irrigation ports are positioned within a plurality of troughs of the plurality of pleated ablation electrodes.
7. The ablation device according to claim 1, wherein the plurality of individually electrically addressable flexible ablation electrodes cover at least 50% of an overall length of the distal region of the catheter body.
8. The ablation device according to claim 7, wherein the plurality of individually electrically addressable flexible ablation electrodes cover at least 80% of the overall length of the distal region of the catheter body.

9. The ablation device according to claim 1, wherein at least some electrically insulating gaps of the plurality of electrically insulating gaps are rigid.
10. The ablation device according to claim 1, wherein at least some electrically insulating gaps of the plurality of electrically insulating gaps comprise a ceramic material.
11. The ablation device according to claim 1, wherein at least one individually electrically addressable flexible ablation electrode comprises a plurality of commonly electrically addressable rigid electrode segments separated by a plurality of flexible inter-electrode gaps.
12. The ablation device according to claim 1, wherein a length of the distal region is adjustable.
13. An ablation device, comprising:
 - a catheter body comprising a distal region predisposed into at least a partial loop; and
 - a plurality of pleated ablation electrodes disposed within the distal region, wherein the plurality of pleated ablation electrodes cover at least 50% of an overall length of the distal region of the catheter body, and wherein the plurality of pleated ablation electrodes are individually electrically addressable and electrically isolated from each other by a plurality of interelectrode gaps.
14. The ablation device according to claim 13, wherein the distal region of the catheter body comprises a continuous length of a flexible polymeric material, and wherein the plurality of pleated ablation electrodes are positioned on an outer surface of the continuous length of the flexible polymeric material.
15. The ablation device according to claim 13, wherein the plurality of interelectrode gaps comprises a plurality of flexible polymeric segments, and wherein the plurality of flexible polymeric segments interconnect the plurality of pleated ablation electrodes.
16. The ablation device according to claim 13, wherein the plurality of interelectrode gaps comprises a plurality of rigid segments, and wherein the plurality of rigid segments interconnect the plurality of pleated ablation electrodes.

17. The ablation device according to claim 13, wherein a length of the distal region of the catheter body can be adjusted by adjusting a spacing between adjacent pleats of the plurality of pleated ablation electrodes.

18. An ablation device, comprising:

a catheter body comprising a distal region predisposed into at least a partial loop; and

a plurality of flexible ablation electrodes disposed within the distal region, wherein each flexible ablation electrode of the plurality of ablation electrodes comprises a plurality of rigid electrode segments interconnected by a plurality of flexible segments, and

wherein the plurality of flexible ablation electrodes are individually electrically addressable and electrically isolated from each other.

19. The ablation device according to claim 18, further comprising a balloon positioned on the catheter body such that, when the balloon is expanded, it urges the plurality of flexible ablation electrodes into contact with an adjacent tissue.

20. A method of forming a contiguous circumferential lesion, comprising:

positioning an ablation device within a blood vessel, the ablation device comprising:

a catheter body including a distal region; and

a plurality of individually electrically addressable flexible ablation electrodes disposed within the distal region and separated by a plurality of electrically insulating gaps;

bringing the individually electrically addressable flexible ablation electrodes into contact with a wall of the blood vessel; and

activating the individually electrically addressable flexible ablation electrodes to deliver ablating energy to the wall of the blood vessel; and

repositioning the ablation device within the blood vessel two or fewer times,

thereby forming the contiguous circumferential lesion with fewer than three total placements of the ablation device within the blood vessel.

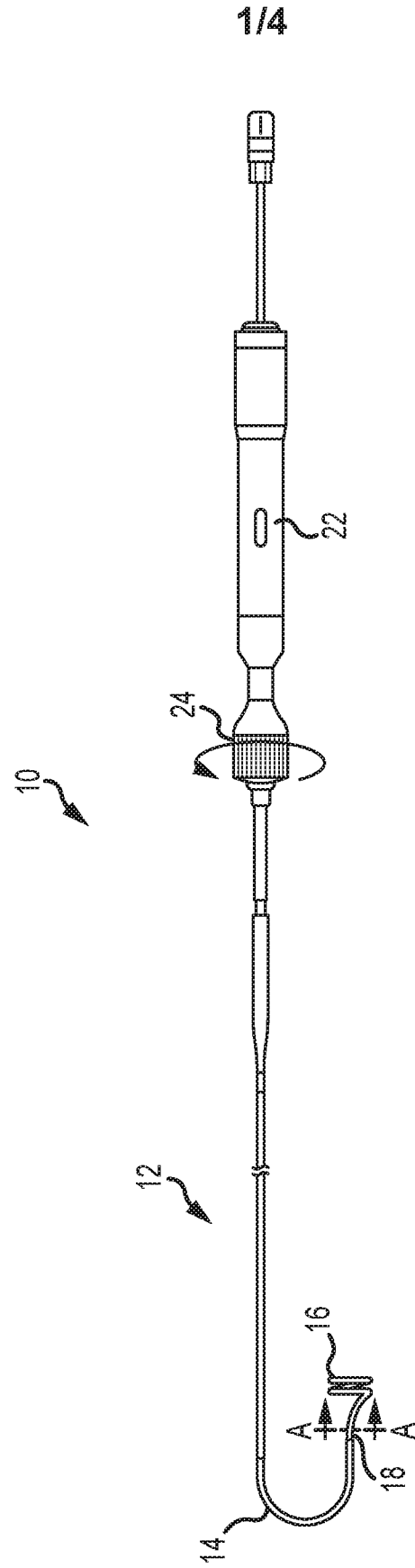


FIG.1

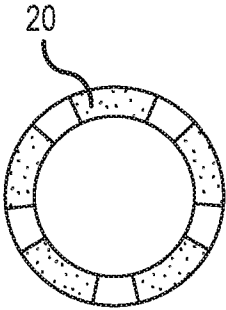


FIG. 2B

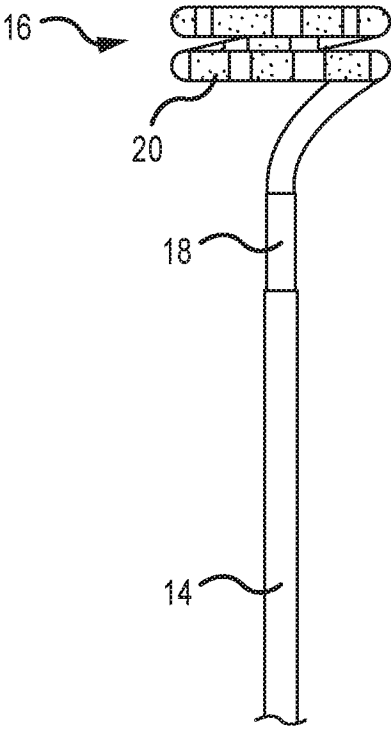
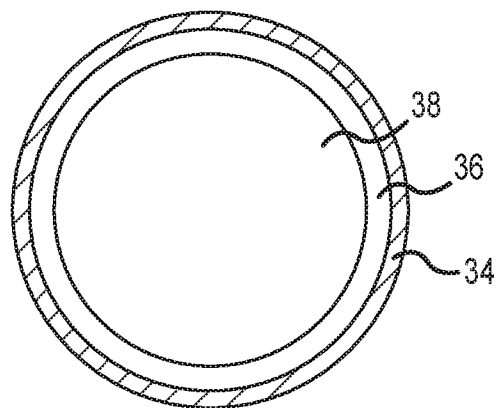
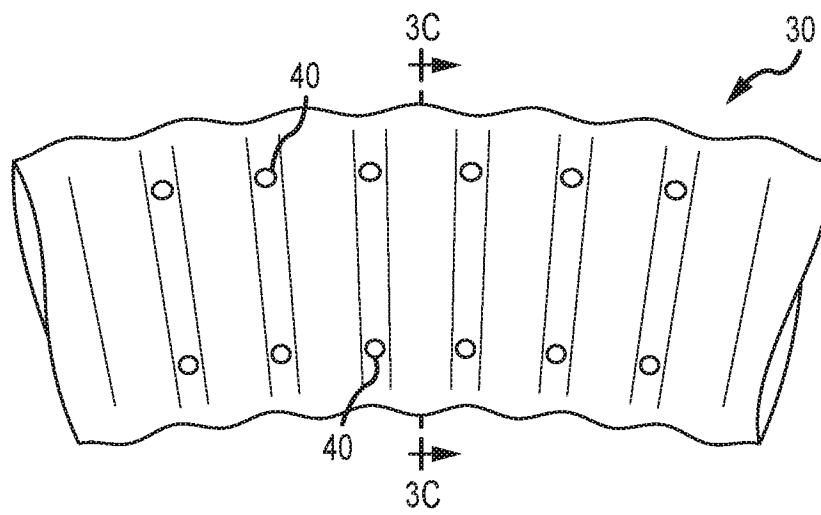
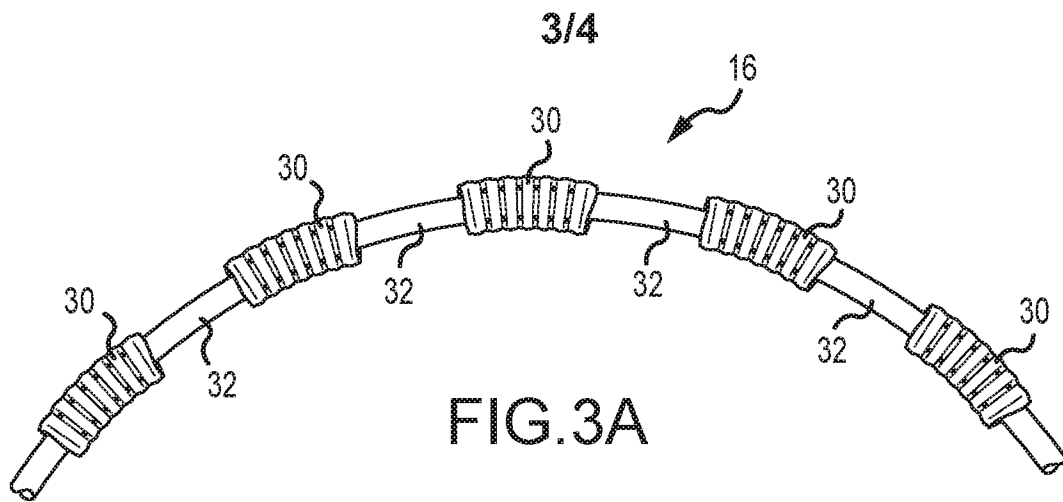


FIG. 2A



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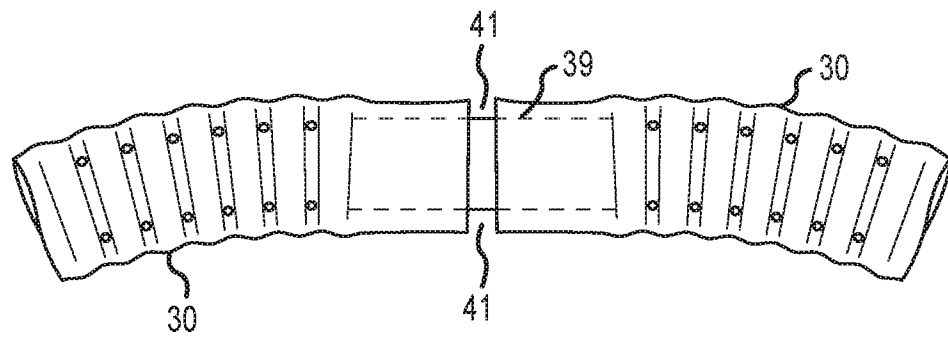


FIG. 4

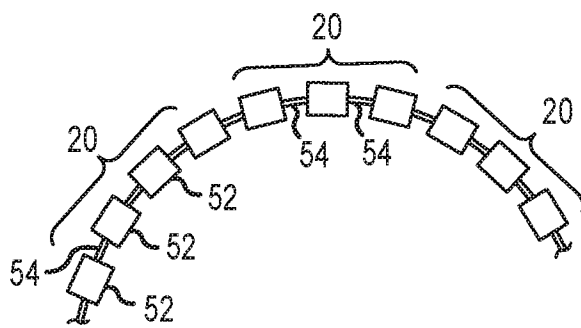


FIG. 5

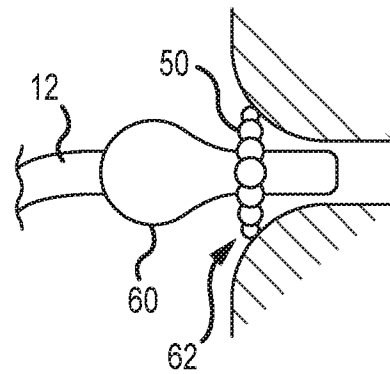


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2016/063250

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B18/14

ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/286684 A1 (HATA CARY [US] ET AL) 11 November 2010 (2010-11-11) abstract; figures 1-15 paragraphs [0005] - [0055] -----	1,2,4,5, 7,9-11
X	US 2004/082948 A1 (STEWART MARK T [US] ET AL) 29 April 2004 (2004-04-29) abstract; figures 1-19 paragraphs [0013] - [0179] -----	1,2,7-12
X	US 2011/112524 A1 (STERN ROGER ALAN [US] ET AL) 12 May 2011 (2011-05-12)	1,2,4, 7-14,17
Y	abstract; figures 1-5 paragraphs [0029] - [0189] ----- -/-	15,16, 18,19



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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

"&" document member of the same patent family

Date of the actual completion of the international search

14 March 2017

Date of mailing of the international search report

06/04/2017

Name and mailing address of the ISA/

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Authorized officer

Lins, Stephanie

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2016/063250

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/313417 A1 (DE LA RAMA ALAN [US] ET AL) 22 December 2011 (2011-12-22) abstract; figures 1-13 paragraphs [0004] - [0074] -----	1,2,4-12
X	US 6 142 994 A (SWANSON DAVID K [US] ET AL) 7 November 2000 (2000-11-07)	1,2,4, 7-12
Y	abstract; figures 1-100 columns 25-39 -----	15,16,18
X	US 2002/022870 A1 (TRUCKAI CSABA [US] ET AL) 21 February 2002 (2002-02-21)	1-9,12
Y	the whole document -----	19

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Information on patent family members

International application No

PCT/US2016/063250

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/063250

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.