Utility of Local Impedance to Guide High-Power Short-Duration Radiofrequency Catheter Ablation for Atrial Fibrillation

Ziad F. Issa, MD, MMM

Pulmonary vein (PV) electrical isolation has become the leading interventional treatment in patients with atrial fibrillation (AF). Currently, one of the prevailing approaches to the electrical isolation of PVs is point-by-point radiofrequency (RF) ablation, which involves creating contiguous, transmural lesions encircling the PV antrum. However, long-term efficacy remains unsatisfactory, which is related, at least in part, to PV reconnection caused by nondurable RF lesion formation during the initial ablation. An important reason for inadequate ablation is the limited ability to assess creation of RF lesions in real-time and the lack of reliable metrics to guide titration of energy power and duration.

Several intraprocedural parameters have been utilized to guide RF energy delivery and to assess adequacy of the ablation lesion created, including electrode temperature, impedance, and electrophysiological (EP) effects of ablation. Recently, a novel ablation catheter (IntellaNav MIFI Open-Irrigated [OI], Boston Scientific) enabled measuring local impedance (LI) at the distal electrode of the catheter (Figure 1). Here we present a case where LI was used to monitor and guide RF application during high-power short-duration (HPSD) ablation of AF.[1]

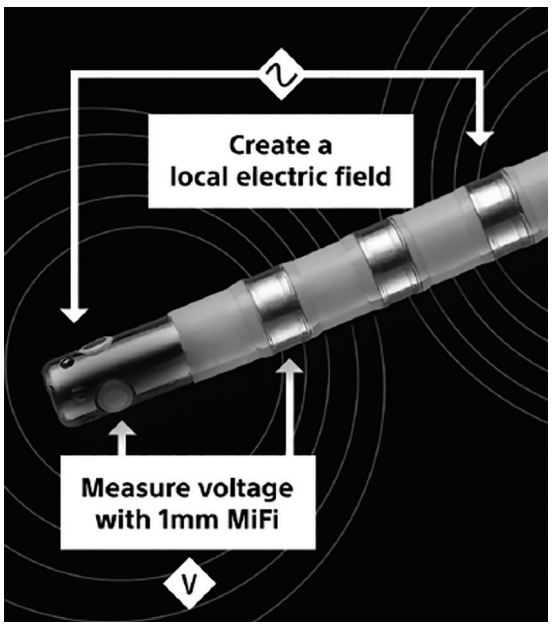

Figure 1. Local impedance field (~) is created by driving non-stimulatory current from the tip of the catheter to the proximal ring electrode, while voltage (V) is measured from the tip to distal ring electrode.

Case Description

A 72-year-old female with history of dilated cardiomyopathy, hypertension, and symptomatic paroxysmal AF refractory to amiodarone therapy presented for catheter ablation of AF. The procedure was performed under general anesthesia. A temperature probe was inserted to monitor esophageal temperature during ablation. Two steerable long sheaths were advanced into the left atrium (LA) using two transseptal punctures. Electroanatomical mapping was performed using the Orion mini-basket catheter (Boston Scientific) and Rhythmia Mapping System (Boston Scientific) during atrial pacing to create a 3D shell of the LA and PVs. Additionally, PV electrograms were recorded baseline by the Orion catheter positioned sequentially at the ostium of each PV.

Circumferential ablation around the antrum of each PV was performed using a point-by-point technique using a 4-mm-tip open-irrigation ablation catheter (IntellaNav MIFI OI). RF energy was applied at each site at a power output of 50 W, a maximum temperature of 43˚C, and an irrigation rate of 30 ml/min.

During RF ablation, the Orion catheter was positioned away from the targeted PV during PV isolation to reduce interference with manipulation of the ablation catheter. Adequacy of each RF application was solely guided by LI measured from the ablation catheter. Automatic annotation of RF ablation applications was based on the following use-defined parameters: (1) catheter stability (≤2 mm); (2) LI drops (ΔLI) by ≥5 Ω (regardless of baseline LI) within the first 5 seconds of starting RF energy delivery; and (3) RF application duration of ≥5 seconds. Each tagged RF application was continued for a total duration of 6-10 seconds for the LA posterior wall and 10-15 seconds for other LA regions. RF lesions meeting automated annotation criteria were marked with a 4-mm-diameter point tag (Videos 1-2 available at eplabdigest.com).

If the LI failed to drop quickly (i.e., <5-Ω decrease

Here we present a case where local impedance was used to monitor and guide radiofrequency application during high-power short-duration ablation of atrial fibrillation.

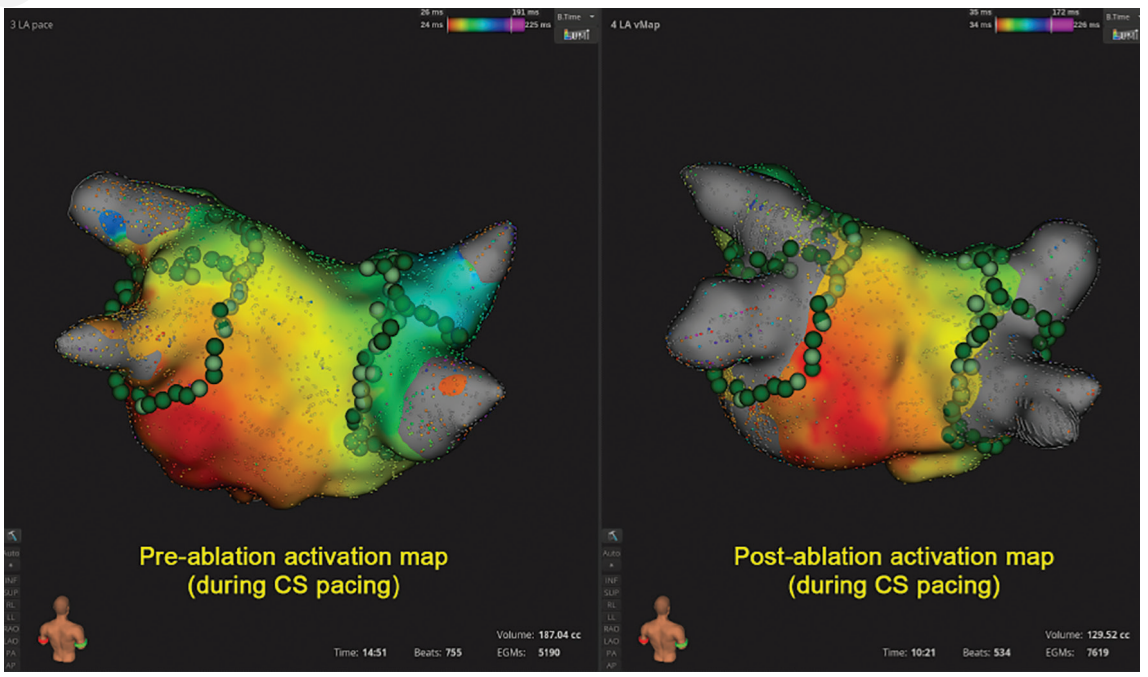

Figure 2. Electroanatomical (Rhythmia) activation map during pacing from the distal coronary sinus (CS) before (left) and after (right) pulmonary vein (PV) isolation. Complete electrical isolation of all 4 PVs was achieved after first-pass ablation guided by local impedance. ***(Image courtesy of Boston Scientific.)***

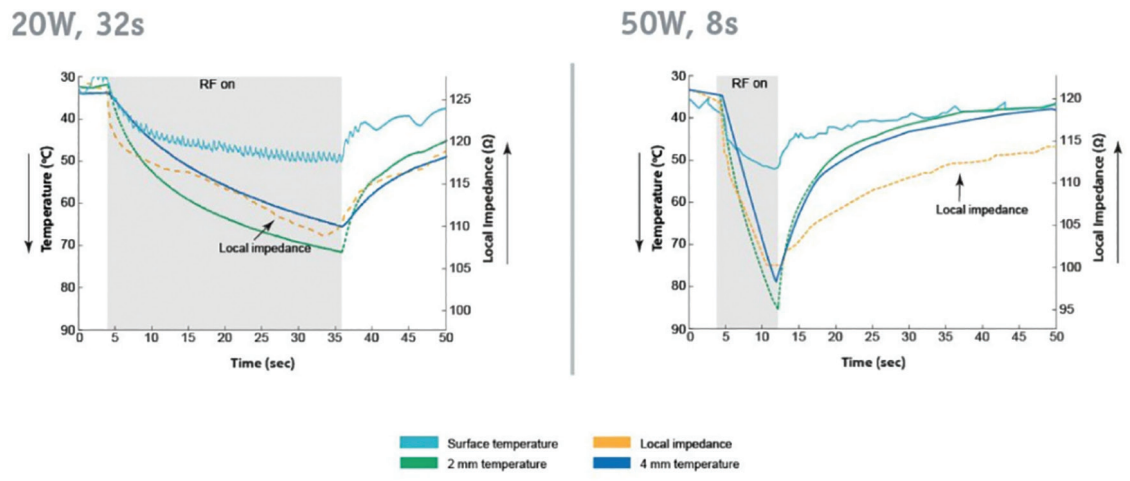

Figure 3. Correlation of temperature profiles at varying depths with the local impedance (LI) measured in bench study during radiofrequency (RF) ablation. Note the strong correlation of LI with intramural temperature during conventional and high-power short-duration ablation. Also note the large discrepancy between tissue surface temperature and intramural temperature. ***(Image courtesy of Boston Scientific.)***

within the first 5 seconds of energy delivery), RF application was interrupted and the ablation catheter was adjusted to achieve better tissue contact and stability, and RF was reapplied. Additionally, RF delivery was stopped (even if the target RF application duration had not been reached) if the catheter moved, if esophageal temperature rose to >40°C, or if LI decreased by >20% of baseline LI (Video 3). First-pass PV ablation was considered complete once each PV antrum had been completely encircled with contiguous ablation lesions with a maximum inter-tag distance of 4-5 mm.

After first-pass circumferential ablation of all PVs, activation mapping using the Orion catheter was performed during atrial pacing. Complete PV isolation was observed, as indicated by the absence of PV potentials recorded from the Orion mapping catheter placed sequentially at each PV ostium (Figure 2, Video 4). Ongoing PV isolation was confirmed a minimum of 20 min after isolation of each PV, with intravenous catecholamines administered to unmask sites of dormant conduction.

Discussion

RF lesion creation is thermally mediated. For ablation to be effective, RF power must be increased to achieve tissue temperatures substantially higher than 50°C. At the same time, for ablation to be safe, the highest tissue temperature must be maintained at less than 100°C to prevent steam pops and coagulum formation. Therefore, directly measuring temperature at multiple points within the myocardium is the optimal method to monitor lesion formation and guide the titration of power output and duration of RF application. However, technologies to directly measure tissue temperature during RF ablation are currently not available for clinical use.

Electrode temperature has been used to monitor RF application. However, catheter tip temperature is not a reliable measure of tissue temperature, as it is also influenced by convective cooling, electrode-tissue contact, and type and location of the temperature sensor. Active cooling of the ablation electrode by saline irrigation further exaggerates the discrepancy between monitored electrode temperature and tissue temperature, so that temperature feedback cannot be used to guide RF ablation. Furthermore, in addition to cooling the ablation electrode, saline irrigation cools tissue surface but not subendocardial tissue; hence, maximal tissue heating occurs several millimeters from the electrode-tissue interface. As a result, endocardial surface temperature is significantly lower than intramural temperature and correlates poorly with RF lesion size. As such, electrode temperature will inevitably underestimate intramural tissue temperature, the main determinant of lesion formation and the layer where steam pops form.

Adequacy of RF energy delivery is often monitored indirectly by real-time analysis of EP function of the tissue being ablated, such as local signal attenuation, loss of local tissue capture, conduction block, and arrhythmia termination. However, EP changes alone are not sufficient at ensuring a durable RF lesion, since the loss of EP function typically occurs well before cell necrosis and, hence, does not discriminate between reversible and irreversible cell injury.

In the absence of real-time assessment of lesion development, several input-based metrics and lesion indexing algorithms (such as force-time integral, ablation index, and lesion size index) were developed to assist physicians in monitoring RF lesion formation. These indices use combinations of contact force, RF power, and duration, and while these metrics are important ingredients for an effective ablation lesion, they are not reflective of lesion formation, and they do not completely express the amount of RF energy transferred between the electrode and the atrial tissue. Further, these indices prescribe a certain "RF dose" as the "effective dose" without accounting for variable tissue characteristics or the role of resistive load and the extent of electrode-tissue coverage. Studies have demonstrated that applied energy power, current, and duration are poor indicators of the extent of lesion formation, and the actual tissue temperature remains the only predictor of the actual lesion size.

The magnitude of the current delivered by the RF generator used in ablation is largely determined by the impedance between the tip of the ablation catheter and the dispersive electrode ("system impedance" or "generator impedance" [GI]). As tissue temperature rises during RF energy application, ions within the tissue being heated become more mobile, resulting in a decrease in impedance to current flow. Hence, a drop in GI resulting from RF ablation can serve as a real-time marker of tissue heating and is considered a surrogate of lesion formation. In fact, RF lesion diameter and depth have been shown to correlate well with impedance drop. However, several factors limit the utility of GI as a monitoring tool. GI represents a global impedance value measured in all structures in series between the catheter tip and the indifferent body-surface electrode. As such, GI can be influenced by the electrical properties of not only the myocardium but also lungs and other structures in the mediastinum and thoracic wall. The large contribution of these variables dwarfs the relatively low magnitude of GI change from ablation itself, thereby limiting both its sensitivity to small drops in impedance localized at the catheter tip and its clinical utility for real-time monitoring of tissue heating and lesion formation, especially during HPSD ablation in the LA.

Evidence from experimental and clinical studies suggests that a local impedance drop of 10-20 Ω correlates with maximal tissue temperatures and lesion depths in the range of what would be needed to produce a durable lesion at the desired depth (1-3 mm) for transmural lesions in the left atrium.

Recently, a novel ablation catheter (IntellaNav MIFI OI) allowed for measuring LI at the distal electrode of the catheter. This catheter incorporates 3 equally spaced minielectrodes in the catheter tip. A local electric field is created by altering

the nonstimulatory current (5.0 µA at 14.5 kHz) between each tip of the 3 minielectrodes and the proximal ring of the ablation catheter. Voltage is measured between the miniature electrodes and the distal ring, and impedance is calculated by dividing the voltage by the stimulatory current (Figure 1). The minielectrodes within the tip electrode measure potential field distortions caused by nearby cardiac structures or contact with high-resistivity myocardium.[1]

Several studies demonstrated that LI measurement provides valuable information on catheter-tissue coupling, tissue characteristics, and lesion formation during RF catheter ablation. LI was able to discriminate between healthy myocardium and blood pool. Importantly, LI drop was found to indicate volumetric tissue heating with high fidelity to intramural temperature (Figure 3). Both the absolute and percentage LI drops during energy delivery were significantly greater at successful RF lesions than unsuccessful lesions. In fact, experimental studies have demonstrated a greater correlation of LI drop with lesion size than measured tissue surface temperature or force–time integral. Furthermore, excessive LI drop during RF ablation often portended excessive tissue heating and steam pops.

Evidence from experimental and clinical studies suggests that a LI drop of 10-20 Ω correlates with maximal tissue temperatures and lesion depths in the range of what would be needed to produce a durable lesion at the desired depth (1-3 mm) for transmural lesions in the LA, whereas large LI drops (>30-35 Ω) often indicated excessive tissue heating (intramural temperature nearing 100°C) and potentially portended steam pops/char formation. In patients undergoing PV isolation, LI-guided ablation allowed tailoring of RF energy delivery within the LA, optimizing efficacy without increasing the risk of complications. However, large, randomized trials are still required to validate these findings.[2-4]

LI differs from GI. Unlike GI, LI measurement is based on the near electric field generated at the catheter tip; therefore, changes in LI are more specific to changes in the myocardium directly under the catheter tip and are more immune to global variables. Additionally, the change in LI during ongoing ablation is significantly more prominent than that in GI, providing a fourfold greater working range that permits more precise titration of energy delivery, especially during high-power RF application when tissue heating occurs rapidly (Videos 1-3). LI also differs from electrode temperature; LI drop dynamically follows the rate of intramural temperature rise, whereas electrode temperature correlates with tissue surface temperature (Figure 3).

Unlike input-based indices, which are composed of operator-controlled parameters, impedance drop is a direct measure of actual tissue heating. Additionally, whereas contact force indicates the extent of mechanical coupling between the ablation electrode and tissue, LI indicates electrical coupling, that is, the electrical resistive properties of tissues in contact with the ablation electrode as well as the extent of electrode surface coverage. Healthy myocardium displays a larger resistivity compared with blood pool and scar tissue. This is of significant importance, given that the ratio of RF current dissipating into the blood pool and current heating the tissue is determined by the ratios of electric impedances between RF electrode, blood pool, and cardiac tissue and by the percent electrode surface area covered by myocardium and blood. Greater degrees of electrode coverage by myocardial tissue allow larger proportions of the RF current to be delivered to the tissue (regardless of the contact force) and, hence, more efficient resistive heating.

Importantly, the utility of LI to guide HPSD has not been fully evaluated. We found that LI monitoring was particularly suited for HPSD ablation strategies for PV isolation. The immediate and large magnitude of drop in LI during effective RF energy delivery allowed rapid assessment of tissue heating and titration of RF energy delivery to create safe and effective ablation lesions. We found the LI algorithm, detailed in the case presented here, to be very effective in guiding titration of RF energy delivery to achieve enduring first-pass PV isolation in >80% of the PVs (unpublished data). This was achieved without concomitant monitoring of PV electrical activity during energy delivery and, hence, can facilitate PV isolation procedures using a single transseptal access, whereby electroanatomical mapping is initially performed using the Orion catheter, followed by circumferential PV ablation, and then activation mapping of the PVs. Also, it is important to note that not infrequently, excessive drops in the LI were observed within the first few seconds of HPSD ablation, which prompted cessation of RF applications that would have otherwise been continued (Video 3). Those RF applications were found to be effective despite their abbreviated duration, which suggests that LI monitoring can be of value in reducing the total RF ablation time without limiting efficacy. However, large, randomized studies are needed to assess the long-term durability of RF lesions and clinical outcome of this approach.

Local impedance (LI) measurement provides useful insights into catheter-tissue coupling, tissue characteristics, and thermal lesion formation during radiofrequency (RF) ablation. LI drop can serve as a real-time surrogate of tissue heating to guide energy titration of RF application.

Summary

Striking the optimal balance between efficacy and safety of irrigated RF ablation during PV isolation remains challenging. LI measurement provides useful insights into catheter-tissue coupling, tissue characteristics, and thermal lesion formation during RF ablation. LI drop can serve as a real-time surrogate of tissue heating to guide energy titration of RF application. ■

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Videos 1-4 are available at www.eplabdigest.com.

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INTELLAMAP ORION™ Mapping Catheter
INTENDED USE/INDICATIONS FOR USE: The IntellaMap Orion High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.
CONTRAINDICATIONS: The IntellaMap Orion Catheter should not be used in: Patients who are not candidates for transvascular catheter procedures. Patients with a hypercoagulable state or who cannot tolerate heparin anticoagulation therapy. Patients with prosthetic or stenotic valves, in the chamber where the prosthetic or stenotic valve reside. Patients with active systemic infection. Pediatric patients. Pregnant and/or nursing patients. Patients with any other condition where catheter manipulation may not be safe. The IntellaMap Orion Catheter should not be used for radio frequency (RF) ablation. The IntellaMap Orion Catheter should not be used inside an MRI machine.
WARNINGS: Keep the connector dry; wet connector pins may affect performance. Do not allow the handle or cabling to be immersed in fluid. Do not use the catheter to deliver ablation therapy. Do not expose the catheter to alcohol or other cleaning solvents. Do not operate the catheter against resistance. If resistance is felt during advancement, retraction, articulation, deployment or un deployment, stop and evaluate device location under fluoroscopy. Do not advance or retract the catheter through a sheath when deployed or articulated. In order to reduce the risk of clot formation: Maintain an activated clotting time (ACT) of greater than 300 seconds at all times during use of the catheter, and Continuously flush the electrode array with saline via the irrigation port at the proximal end. Do not use the catheter with equipment (such as stimulators or recording systems) that is not isolated.
PRECAUTIONS: To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue. Always undeploy the catheter prior to removal from the patient. Use visualization (such as fluoroscopy) to verify undeployment. Always move the articulation control lever to its neutral position to straighten the catheter prior to removal from the patient. Only use guiding sheaths with curves that allow passage of the catheter without using excessive force. When used with a steerable guiding introducer sheath: Ensure under fluoroscopy that the guiding introducer sheath distal end is straight or, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath. Do not articulate the sheath while the catheter array is inside the articulating section. Do not deploy or articulate the catheter while the distal end is inside a sheath. Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the IntellaMap Orion Catheter. To prevent entanglement, use care when using the catheter in the proximity of other catheters. When pacing, verify desired waveform is observed. Prior to insertion into vasculature, ensure removal of all air from the catheter lumen; use a pressured saline bag to flush saline through the catheter shaft and electrode array.
POTENTIAL ADVERSE EVENTS: Serious adverse events have been reported in the literature in relation to cardiac catheterization including: stroke, cardiac tamponade, perforation, myocardial infarction, pulmonary embolism, and death. Complications reported included also (in alphabetical order): air embolism, arrhythmia, AV fistula, hematomas, hemothorax, pneumothorax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding, and vasovagal reactions. 91078319 (Rev. A)
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTELLANAV MIFI™ OPEN-IRRIGATED Ablation Catheter
INTENDED USE/INDICATIONS FOR USE: The IntellaNav MiFi™ OI Catheter, when used with a compatible Radiofrequency Controller and Irrigation Pump, is indicated for: cardiac electrophysiological mapping. delivering diagnostic pacing stimuli. RF ablation of sustained or recurrent type 1 Atrial Flutter in patients age 18 years or older. Treatment of drug refractory, recurrent, symptomatic, Paroxysmal Atrial Fibrillation (PAF) in patients age 18 years or older, when used with a compatible mapping system.
CONTRAINDICATIONS: The IntellaNav MiFi OI Catheter is contraindicated for use in patients: with active systemic infection; with a mechanical prosthetic heart valve through which the catheter must pass; unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation; who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach; who are hemodynamically unstable; who have myxoma or an intracardiac thrombus; who have had a ventriculotomy or atriotomy within the preceding eight weeks; Who have had a Patent Foramen Ovale (PFO) occlusion device.
WARNINGS: Note: The IntellaNav MiFi OI Catheter is not designed to be compatible with the Maestro 3000® RF Cardiac Ablation System. Using the IntellaNav MiFi OI Catheter at lower than prescribed flow rate may increase the potential for thrombus, coagulum, and char that may result in embolism. Collateral tissue damage is a possibility when using the catheter at the upper power setting (50 W) or durations longer than 60 seconds or with a decrease in impedance without moving the catheter tip. Power should be increased to >30 W only if lower energies do not achieve the intended result. Patients undergoing an atrial flutter ablation are at risk for complete Atrioventricular (AV) block which requires the implantation of a temporary and or permanent pacemaker. There are no data to support the safety and effectiveness of this device in the pediatric population. Because the long term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children. In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. Stimulation of cardiac tissues caused by pacing stimulus and/or RF energy may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns. Warnings for patients with implantable pacemakers and implantable cardioverter/defibrillators (ICDs): Temporarily adjust tachytherapy settings of an ICD per the manufacturer guidelines during RF ablation as the device could reset or deliver inappropriate defibrillation therapy resulting in patient injury. The ICD could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reactivate the ICD's preoperative pacing, sensing, and therapy parameters after the ablation procedure. Temporarily reprogram the pacemaker per the manufacturer guidelines during RF ablation to a nontracking pacing mode if pacing is likely to be required during the ablation. The pacemaker could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reprogram to preoperative sensing and pacing parameters. Have temporary external sources of pacing and defibrillation available. Do not apply RF energy directly to a lead or to tissue immediately in contact with a lead because it could potentially damage the lead or lead function. Fluoroscopic guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgment. Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is overtorqued and/or positioned in the chordae tendinae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage. In the event of a suspected failure of the integrity of fluid flow through the IntellaNav MiFi OI Catheter or if there is a rapid temperature rise of greater than 15 °C noted on the RF Controller, the procedure should be stopped, and the IntellaNav MiFi OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the IntellaNav MiFi OI Catheter and the Irrigation Tubing Set should be replaced. The replacement catheter and tubing set must be primed outside the body prior to insertion to reduce the risk of air embolism. Prior to the procedure, always identify the patient's risk of volume overload. Monitor the patient's fluid balance throughout the procedure and after the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible. Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution. This IntellaNav MiFi OI Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death. The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown. If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the atrial flutter procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of mural thrombus and/or thrombus in the left atrial appendage.
PRECAUTIONS: Do not place the distal end of the catheter near magnets. Magnetization of the catheter may result in degradation of magnetic tracking precision. Such degradation may be manifested by an unstable or complete loss of rendering of the position and/or orientation of the catheter by a magnetic tracking system. If this occurs, the catheter should be replaced. Patients undergoing a long irrigated ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely.
POTENTIAL ADVERSE EVENTS: Potential adverse events which may be associated with catheterization and ablation include: Allergic reaction (including anaphylaxis), Angina, Arrhythmias (new or exacerbation of existing arrhythmias), Cardiac perforation, Cardiac/respiratory arrest, Catheter entrapment, Cerebrovascular accident (CVA), Chest discomfort, Conduction pathway injury, Complete heart block (transient/permanent), Complications of sedative agents/anesthesia, Congestive heart failure, Death, Edema, Effusion (pericardial/pleural), Embolism (venous/arterial) (e.g., air embolism, cerebrovascular accident, Myocardial Infarction (MI), pulmonary embolism), Esophageal injury, Exacerbation of existing conditions, Fistula (arterial-venous/atrio-esophageal), Fluid volume overload, Gastroparesis/Gastrointestinal (GI) events, Hematoma, Hemorrhage, Hemothorax, Hypertension, Hypotension, Inadvertent injury to adjacent structures, Infection, Lead dislodgement,Myocardial infarction, Nerve injury (phrenic/vagus), Pericarditis, Pleuritis, Pneumothorax, Pseudoaneurysm, Pulmonary/pedal edema, Pulmonary vein stenosis, Radiation exposure, Renal insufficiency/failure, Residual Atrial Septal Defects (ASD), Skin burns (radiation/defibrillator/ cardioverter), Tamponade, Transient ischemic attack (TIA), Thrombosis, Valvular damage, Vasospasm, Vasovagal reactions, Vessel trauma (perforation/dissection/rupture). 92164033 (Rev. C)
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RHYTHMIA HDx™ Mapping System
INTENDED USE: The RHYTHMIA HDx™ Mapping System (the system) is a 3D mapping and navigation system used in EP procedures. The SiS and related accessories provide data connection pathways for external input/output devices (e.g. catheters and recording systems) and serve as the data conduit to the system workstation and software.
INDICATIONS FOR USE: The RHYTHMIA HDx Mapping System and accessories are indicated for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of intracardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be recorded and displayed on the system's display screen.
CONTRAINDICATIONS: There are no known contraindications.
WARNINGS: Diagnosis and treatment of cardiac arrhythmias using the system in conjunction with radio frequency (RF) ablation and other medical devices may pose a risk of adverse events. Adverse events (e.g. cardiac perforation, new arrhythmias, exacerbation of existing arrhythmias) may require additional intervention. Do not use the system to route life-sustaining pacing signals. Only diagnostic stimulation signals (e.g. induction) may be routed through the system. All devices that are connected to system hardware must independently meet IEC 60601-1 requirements as well as any other relevant safety standards. The combined hardware configuration must also meet IEC 60601-1 safety standards. The use of system hardware with accessories and devices that do not comply with relevant standards may reduce the safety of the system, cause equipment damage or system malfunction, or harm to the patient or user. System hardware must be connected solely to a functional, properly-tested supply main with protective ground (earth). Do not use extension cords or adapters for ungrounded outlets. The use of a faulty or ungrounded supply main increases the risk of electrical shock and system malfunction. Do not connect more than one ablation catheter simultaneously to the Ablation System when used with Rhythmia HDx Mapping System. The system generates electrical impedance fields as part of its normal operation. Do not use other systems that also generate electrical impedance fields in the same procedure, as this may interfere with the system's normal operation and reduce the quality of catheter localization, and signals. Do not operate the localization generator within 200 mm of an implanted CIED (cardiac implantable electronic device.) Doing so may affect CIED pacing, temporarily suspend tachycardia therapy delivery, or lead to patient discomfort.
CAUTIONS: Use care when attaching the body surface electrodes to lead connectors. To minimize the risk of electric shock, make sure that electrodes and lead connectors do not contact one another or contact ground. Properly prepare the skin prior to attaching the electrodes to prevent receiving low quality signals from body surface electrodes. Do not use excessive gel as this may lead to signal crossover between electrodes. To minimize signal interference, route the surface ECG cables across the torso instead of alongside it. To ensure correct clinical decisions, use fluoroscopy, ultrasound, pace mapping or other visualization techniques to verify mapping results and catheter position. Always compare the anatomical map to the patient's expected anatomy. Incorrect catheter localization may lead to incorrect clinical conclusion or patient injury. The localization generator may interfere with implanted cardiac implantable electronic devices (CIEDs). When mapping a patient with such a device, consider interrogating the device pre – and post-procedure. This will identify any changes in programmed parameters which could then be corrected before transferring the patient from the procedure room. Consult the CIED manufacturer instructions for additional information. If it becomes necessary to interrogate or program an implanted CIED while using the system, temporarily turn off the localization generator by using the on-screen button located on the annotating and editing maps toolbar.
POTENTIAL ADVERSE EVENTS: Any potential clinical complications are in large part expected to be related to the accessory diagnostic and/or ablation catheters that are used with the system, rather than the system itself. In order to identify potential adverse events, the user is instructed to read pertinent directions for use documents associated with the catheters and ablation generators that will be employed during a mapping session. As with other mapping systems, the RHYTHMIA HDx™ Mapping System can be incidentally associated with minor or major clinical complications intrinsic to intracardiac procedures. Potential adverse events associated with the use of the system include, but are not limited to, the following: Arrhythmias Due to the programmed electrical stimulation performed during EP diagnostic procedures and catheter manipulations, patients undergoing EP procedures are at potential risk of arrhythmia. The patient may experience discomfort from the rapid pacing and/or the initiation of an arrhythmia. While the system has no active role in RF ablation, a risk does exist that the effectiveness of an RF ablation procedure could be suboptimal and cause the targeted arrhythmia to reoccur. Misinterpretation of data Poor catheter localization may lead to clinical data misinterpretation and the potential of resultant patient injury. To ensure correct clinical decisions, the physician must use fluoroscopy, ultrasound, pace mapping or other visualization techniques to verify 3-D mapping results and catheter position. Electrical Hazards With any electrical system there is a potential risk of electrical shock to the user, patient, and service representative. 92106607 (Rev. E)
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