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LOCAL IMPEDANCE DROP DURING PULMONARY VEIN ISOLATION PREDICTS LATE RECONNECTION IN PATIENTS WITH PAROXYSMAL ATRIAL FIBRILLATION: RESULTS OF THE LOCALIZE CLINICAL TRIAL

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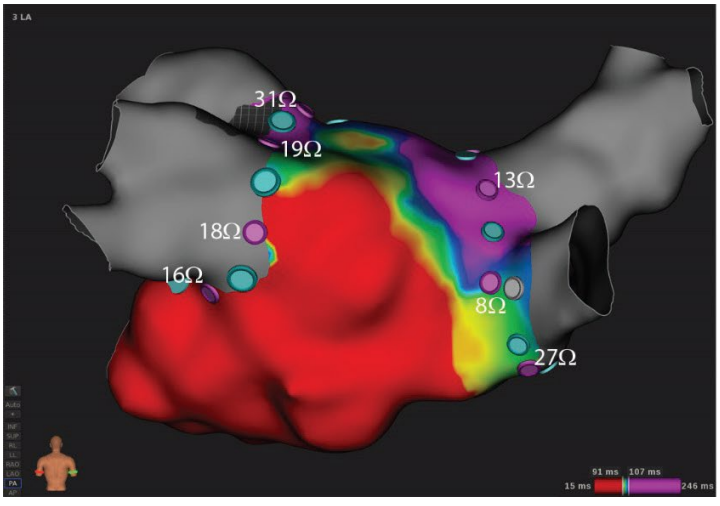
Background: Radiofrequency lesion efficacy is routinely monitored with generator impedance drop. Evaluation of a local impedance (LI) metric (DIRECTSENSE™, Boston Scientific) found LI drop to be highly predictive of effective lesion formation.

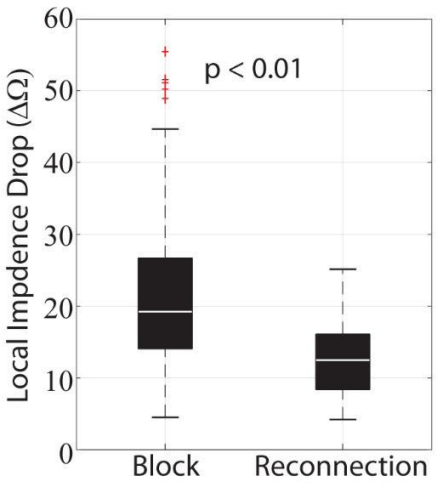
Objective: To evaluate whether LI drop during PVI is associated with late PV reconnection (PVr) in patients with paroxysmal AF.

Methods: The multicenter LOCALIZE trial consists of an index PVI procedure and a mandated 3-month follow-up mapping procedure. LA maps were created and ipsilateral PVs were divided into 8 segments. Point-by-point PVI, blinded to LI, was performed and residual gaps were ablated after a 20 min waiting period. At follow-up, late PVr sites were identified on electroanatomical maps. Median LI drop within each segment of the index procedure was calculated offline (Fig. Left).

Results: Forty-one de novo PVI and follow-up procedures were analyzed. At follow-up, blocked segments had significantly larger LI drops (19.2 [14.1-26.7] Ω) than segments with late PVr (12.5 [8.4-16.1] Ω, p<0.01, Fig. Right). In view of wall thickness differences, the association between LI drop and block was further evaluated for anterior/roof and posterior/inferior segments with inter-lesion distance ≤6mm. Anterior block segments had significantly larger LI drops (20.7 [15.9-28.1] Ω) than posterior block segments (16.0 [11.4-24.2] Ω, p<0.01). Optimal LI cutoff values were 17Ω in anterior segments and 14Ω posteriorly (positive predictive value for block: 98.8% and 98.4%, respectively).

Conclusion: With inter-lesion spacing of ≤6mm, reaching a LI drop of ≥17Ω anteriorly and ≥14Ω posteriorly was predictive of durable segment block in de novo PVI.





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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)

INTELLAMAP ORION™ Mapping Catheter 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)

INTELLANAV MIFI™ OPEN-IRRIGATED Ablation Catheter 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)

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.

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Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

The term DIRECTSENSE™ Technology is being used to encompass both the DIRECTSENSE™ Technology and DIRECTSENSE™ RF Technology software packages.

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