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INTELLANAV STABLEPOINT™
Ablation Catheter
Clinical Compendium

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2022 CLINICAL PUBLICATIONS

Optimal Local Impedance Parameters for Successful Pulmonary Vein Isolation in Patients with Atrial Fibrillation
Fukaya H, Mori H, Oikawa J, et al.

Journal of Cardiovascular Electrophysiology (November 2022), available at:
https://onlinelibrary.wiley.com/doi/10.1111/jce.15748

- STABLEPOINT™ local impedance (LI) parameters for successful pulmonary vein isolation (PVI) were evaluated for 102 patients (5257 ablations).
- LI drops were higher for successful vs unsuccessful ablations.
- The optimal LI drop was 20.0 Ω and the LI % cutoff value was 11.6%.

Requirement of Larger Local Impedance Reduction for Successful Lesion Formation at Carinal Area during Pulmonary Vein Isolation
Ikenouchi T, Takigawa M, Goya M, et al.

Journal of Interventional Cardiac Electrophysiology (July 2022), available at:
https://doi.org/10.1007/s10840-022-01282-1

- Evaluated the local impedance (LI) drop and % LI drop for predication in acute lesion durability during PVI with STABLEPOINT.
- 23 patients underwent PVI with the operators blinded to LI.
- Generator impedance drop, LI drop and % LI drop were associated with successful lesions.
- The carina was significantly associated with gaps.
- LI drop and % LI drop were equally predictive of acute lesion durability.
- Optimal LI drops were ≥ 24Ω with ≥15% LI drop at the carina, ≥ 21Ω with ≥14% at non-carinal sites significantly predicted acute successful lesions with a negative predictive value of 93-99%.

Prospective Evaluation of Local Impedance Drop to Guide Left Atrial Posterior Wall Ablation with High Power
Solimene F, Schillaci V, Stabile G, et al.
*Ablation of persistent AF patients is outside the use of labeled indication of the STABLEPOINT Catheter

Journal of Interventional Cardiac Electrophysiology (July 2022), available at:
https://doi.org/10.1007/s10840-022-01317-7

- Evaluated the safety and efficacy of posterior wall isolation (PWI) using high power (50 W) ablation.
- 30 persistent AF patients received PWI with STABLEPOINT.
- First-pass floor line block was achieved in 26 (87%) and first-pass roof line block in 17 (57%).
- After touch-up ablations, PWI was achieved in 28 patients (93%) with endocardial ablation only.
- Local impedance (LI) drop was the most important predictor of acute conduction block.
- The optimal LI drops were 19 Ω roof line and 18 Ω for the floor line.
- Catheter orientation angle, CR and baseline LI were not significant predictors of acute block.

2022 CLINICAL PUBLICATIONS

When Local Impedance Meets Contact Force: Preliminary Experience from the CHARISMA Registry
Solimene F, De Sanctis V, Maggio R, et al.

Journal of Interventional Cardiac Electrophysiology (March 2022), available at:
https://doi.org/10.1007/s10840-022-01163-7

- Investigated the impact of contact force (CF) on local impedance (LI) during pulmonary vein isolation (PVI).
- 45 de novo PVI patients were treated with STABLEPOINT with a total number of 2895 point-by-point ablations.
- The total procedure time was 118 ± 34 min with a total fluoroscopy time of 13 ± 8 min.
- For each 10 g of CF, LI drop increased from 22.4 ± 7Ω to 24.0 ± 8Ω at 2 to 25 g CF intervals with little change beyond 25g.
- CF significantly affected LI drop with higher contact (> 25 g) appearing to have less impact on LI drop.

The Correlation Between Local Impedance Drop and Catheter Contact in Clinical Pulmonary Vein Isolation Use
Yasumoto K, Egami Y, Kawanami S, et al.

PACE (August 2022) available at: https://doi.org/10.1111/pace.14500

- Studied the correlation between LI drop and catheter contact parameters.
- Contact angle showed good correlation with LI drop and multivariate analysis showed that CA was an independent predictor for LI drop among the parameters tested.
- The LI drop in the blocked segments (27.3 ± 9.8 Ω) was significantly higher than in the segments with conduction gaps (19.6 ± 6.4 Ω).

Local Impedance Measurements during Contact Force-Guided Cavotricuspid Isthmus Ablation for Predicting an Effective Radiofrequency Ablation
Sasaki T, Nakamura K, Minami K.

Journal of Arrhythmia (April 2022), available at: https://doi.org/10.1002/joa3.12680

- The relationship between contact force (CF) and local impedance (LI) were evaluated for cavotricuspid isthmus (CTI) ablation.
- A total of 50 patients and 602 lesions were analyzed.
- Starting LI, absolute and % LI drops were greater in effective vs ineffective ablation sites.
- Initial and mean CF did not differ at effective and ineffective ablation sites.
- Results of this study found that LI drops of 21Ω and 10.8% drop change may be appropriate ablation targets for CTI ablation.

2021 CLINICAL PUBLICATION

The Role of Local Impedance Drop in the Acute Lesion Efficacy during Pulmonary Vein Isolation Performed with a New Contact Force Sensing Catheter—A Pilot Study
Szegedi N, Sallo Z, Perge P, et al.

PLOS ONE (September 2021), available at: https://doi.org/10.1371/journal.pone.0257050

- Pilot study that evaluated the local impedance (LI) cut-off value that predicts successful pulmonary vein isolation (PVI) lesion formation.
- There was a total of 645 RF applications, 561 were successful and 84 were unsuccessful.
- Successful applications were shorter and had a larger LI drop.
- There was no difference in successful and unsuccessful lesions for mean CF, FTI, or CF range.
- The optimal LI drop was 21.8 Ω on the anterior wall and 18.3 Ω on the posterior wall.

2022 PRECLINICAL PUBLICATION

Improved Ablation Efficiency in PVI Guided by Contact Force and Local Impedance: Chronic Canine Model
Gutbrod S, Shuros A, Koya V, et al.

Frontiers in Physiology (January 2022), available at:
https://www.frontiersin.org/articles/10.3389/fphys.2021.808541/full

- Assessed the effects of local impedance (LI) on ablation workflow when combined with contact force (CF).
- The LI during RF ranged from 23.0 – 34.0 Ω at both 30W and 50W workflows.
- There was an inverse relationship between LI prior to RF delivery and the RF duration required for an effective lesion.
- After 5 g of force, there was no correlation between force and LI drop.
- The 50W power strategy was the most efficient. LI + CF allows for customization of the ablation strategy based on local tissue variation rather than a uniform approach that could potentially lead to overtreatment.

2020 PRECLINICAL PUBLICATION

Combined Local Impedance and Contact Force for Radiofrequency Ablation Assessment
Garrott K, Laughner J, Gutbrod S, et al.

Heart Rhythm (August 2020), available at: *https://doi.org/10.1016/j.hrthm.2020.03.016*

- Evaluated the utility of local impedance (LI) with contact force (CF) in assessing RF ablation efficacy in vivo.
- In vivo, STABLEPOINT LI was different between when the catheter was in contact with blood pool vs myocardium.
- LI drop correlated with lesion depth both in vitro and in vivo informing sufficient lesion creation (LI > 20Ω) and excessive heating with LI drops > 65Ω.
- Total RF time was significantly reduced when using LI guidance compared to 30 second workflow.

2022 IN-VITRO PUBLICATIONS

Time Dependency in the Radiofrequency Lesion Formation for a Local Impedance Guided Catheter in an Ex Vivo Experimental Model
Kawano D, Mori H, Tsutsui K, et al.

Journal of Arrhythmia (December 2022), available at:
https://onlinelibrary.wiley.com/doi/10.1002/joa3.12789

- In an ex vivo experimental model, the relationships between local impedance (LI), RF delivery time and lesion formation were tested.
- The correlation between LI drop and ablation time was non-linear.
- The time to a 90% decay in the LI drop differed depending on the power setting, with the 50W setting being shorter than the 40W setting.
- Deeper and winder lesion were predominately created within the time to 90% decay of the LI drop.

Comparison of Two Catheters Measuring Local Impedance: Local Impedance Variation vs Lesion Characteristics and Steam Pops
Amemiya M, Takigawa M, Goya M, et al.

Journal of Interventional Cardiac Electrophysiology (April 2022), available at:
https://doi.org/10.1007/s10840-022-01214-z

- Investigated the difference in local impedance (LI) on the MIFI OI and STABLEPOINT catheters in-vitro.
- The absolute LI drop was significantly larger for the STABLEPOINT catheter but the % LI drops were similar.
- The lesions produced by the STABLEPOINT catheter were generally larger.
- In both catheters, %LI drop was superior to LI drop in correlation to lesion size and in predicting steam pops and normalizing the difference between catheters.

2021 EDITORIAL

Local Impedance for the Optimization of Radiofrequency Lesion Delivery: A Review of Bench and Clinical Data
Chu G, Peter Calvert P, Futyma P, et al.

Journal of Cardiovascular Electrophysiology (December 2021), available at:
https://onlinelibrary.wiley.com/doi/10.1111/jce.15335

- RF catheter ablation has been evolving for over three decades.
- The role of impedance in determining lesion creation is an important piece of this process.
- Local impedance (LI) is a novel tool which has the potential to understand substrate and tailor ablation in a way not possible with other ablation metrics and tools.

INTELLANAV STABLEPOINT™ Ablation Catheter

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE The INTELLANAV STABLEPOINT 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 typical 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 STABLEPOINT Catheter is contraindicated for use: • in patients with active systemic infection; • in patients with a mechanical prosthetic heart valve through which the catheter must pass; • in patients with conditions where insertion into or manipulation in the cardiac chambers is unsafe as these conditions (e.g., presence of intracardiac thrombus or myxoma, history of recent cardiac surgery with atriotomy, etc.) may increase the risk of systemic embolism or cardiac perforation; • in patients who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation; • in patients who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach; • in patients who are hemodynamically unstable; • in patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe, such as but not limited to, a recent previous cardiac surgery (e.g., ventriculotomy or atriotomy, Coronary Artery Bypass Graft [CABG], PTCA/PCI/coronary stent procedure/unstable angina) and/or in patients with congenital heart disease where the underlying abnormality increases the risk of the ablation (e.g. severe rotational anomalies of the heart or great vessels); • via transseptal approach in patients with an intra-atrial baffle or a foramen ovale patch; • via retrograde transaortic approach in patients with a prosthetic aortic valve. Do not use this device: • with a long sheath or a short introducer < 8.5 F. • in the coronary vasculature.

WARNINGS • If the visibility of the EP catheters is compromised for any reason, the user should stop and not resume ablation therapy until catheter visibility is established in order to prevent patient injuries such as perforation, heart block and injury to adjacent structures. • Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology and in the techniques of open-irrigated RF powered catheter mapping and ablation, and in the specific approach to be used, in a fully-equipped electrophysiology lab. • Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures. There is an increased risk of thromboemboli if appropriate anticoagulation levels are not maintained while the transseptal sheath and/or catheter is in the left side of the heart. Administer anticoagulation therapy during and post-procedure according to the institution's standards to minimize bleeding and thrombotic complications. • Carefully read all equipment and ancillary device instructions required for the procedure prior to use. Observe all contraindications, warnings, and precautions noted in these directions. Failure to do so may result in patient complications. • Before using, inspect the INTELLANAV STABLEPOINT Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that, if used, may cause patient and/or user injury. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed. • Using the INTELLANAV STABLEPOINT Catheter at lower than the prescribed flow rates specified in the Operational Instructions may increase the potential for thrombus, coagulum, and char that may result in embolism. • Electromagnetic Interference (EMI) from any source during normal operation may adversely affect the visualization and tracking of the catheter during the procedure, which can cause patient injuries such as perforation, heart block and injury to adjacent structures. • Carefully follow the power and the correlating flow rate procedures as specified in the Operational Instructions. Performing ablation with high power, insufficient flow rate, excessive contact force and/or excessive RF duration without moving the tip of the ablation catheter may lead to perforation, arrhythmias, damage to adjacent structures, and/or embolism. • Avoid increasing power or duration of RF application beyond your standard of care to target a specific change in local impedance. Doing so may result in damage to adjacent structures, perforation caused by steam pop, arrhythmias, and/or embolism. • The INTELLANAV STABLEPOINT Catheter is not intended to be used with an RF Controller output setting exceeding 50 Watts or 133 Vpk. The safety and performance of the INTELLANAV STABLEPOINT Catheter at powers exceeding 50 Watts has not been evaluated in a clinical trial. Exceeding recommended power settings or using flow rates lower than recommended settings may increase the risk of patient injury. • Patients who have had a prior atrial flutter ablation procedure may be at greater risk for perforation and/or pericardial effusion with the use of this catheter system. • Patients undergoing septal accessory pathway, Atrioventricular (AV) node reentry tachycardia, and/or atrial flutter ablation are at risk for complete AV block which requires the implantation of a temporary and/or permanent pacemaker. • During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces to minimize the potential for electrical shock. • Ensure that the cable/catheter connection remains dry throughout the procedure in order to prevent electric shock or other patient injuries as well as to prevent loss of device function. • Electrodes and stimulating devices can provide paths of high frequency current. The risk of burns can be reduced but not eliminated by placing the electrodes as far away as possible from the ablation site and the Dispersive Pad. Protective impedances may reduce the risk of burns and permit continuous monitoring of the Electrocardiogram (ECG) during energy delivery. • Before use, ensure irrigation ports are patent and jetting by infusing heparinized normal saline through the catheter tubing. Patency of irrigation ports is important to maintain cooling function and minimize risks of coagulum, fibrin, thrombus and char that may result in embolism as well as perforation caused by steam pop. • Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the dilator or catheter. • Do not continue using the catheter if the irrigation ports are occluded or the catheter is not functioning properly. • Due to the design of the INTELLANAV STABLEPOINT Catheter tip, the velocity of fluid exiting the irrigation ports may change based on rate and pressure of flushing. As long as there is fluid jetting out of each port, regardless of the velocity, the catheter is functioning as designed and may be used. However, if any irrigation port has no flow (or extremely low flow compared to adjacent ports) despite attempts to flush the irrigation port, do not insert the catheter in the patient as there may be potential risk of embolism. • Electrical recording or stimulation equipment must be isolated. Current leakage from any electrical equipment that is connected to the patient must not exceed 10 microamps for intracardiac electrodes. • Care must be taken to ensure that any equipment used in connection with the BSC catheters be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use to reduce the potential risk of inadvertent electrical shock. • Do not insert or withdraw the INTELLANAV STABLEPOINT Catheter without straightening the catheter tip (returning the steering lever to neutral position) in order to prevent entanglement/ entrapment within the valve and/or other device that may result in myocardial trauma and/or may require additional medical/surgical intervention. • 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. • Maximum Catheter Rated Voltage: 133 Vpk. • Warnings for patients with implantable pacemakers and Implantable Cardioverter/Defibrillators (ICDs): • Pacemakers, implantable cardioverter/defibrillators, and leads can be adversely affected by radiofrequency energy. It is important to refer to the device manufacturer's instruction for use prior to performing ablation procedures. • 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. • Temporarily reprogram pacemaker per the manufacturer guidelines during RF ablation to a non-tracking 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. • Deactivate ICDs as they could discharge and injure the patient or be damaged by the ablation procedure. • Have temporary external sources of pacing and defibrillation available. • Perform a complete analysis of the implanted device function after ablation. • Fluoroscopic or appropriate imaging guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgement. • Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function. • Remember to reactivate the pulse generator after turning off the RF ablation equipment. • Do not ablate from within the coronary artery as the resulting myocardial injury can be fatal. Adequate visualization techniques, such as fluorosocopy or intracardiac echocardiography are necessary during the transaortic approach to avoid placement of the ablation catheter in the coronary vasculature. • During RF ablation, care must be taken not to deliver RF energy on or near the coronary artery even on the right side of the heart, as the resulting myocardial injury can be fatal. • Ablation in contact with any other electrodes alters the function of the catheter and can lead to thrombus, coagulum, or char formation that may result in embolism. • At no time should a INTELLANAV STABLEPOINT Catheter be advanced or withdrawn when resistance is felt, without determining the cause. Valve damage, vascular and/or cardiac perforation is a risk with any intracardiac catheter. • 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 tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage. • Do not use the INTELLANAV STABLEPOINT ablation system in the proximity of Magnetic Resonance Imaging (MRI) equipment because the MRI equipment may adversely impact the function of an RF Controller and the ablation system may adversely impact the image quality. This can also lead to loss of visibility during ablation which can cause patient injuries such as perforation, heart block and injury to adjacent structures. • Do not use the INTELLANAV STABLEPOINT ablation system and its accessories in an in an oxygen rich environment or near flammable anesthetics. • Catheter ablation procedures present the potential for significant radiation exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the radiation beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Due to radiation exposure during catheter ablation, the safety and effectiveness of this device has not yet been established in pregnant and/or nursing women and pediatric patients. • There are no data to support the safety and effectiveness of this device in the pediatric population. • In the event of a suspected failure of the integrity of fluid flow through the catheter or the tubing set or if there is a rapid temperature rise of > 15 °C noted on the RF Controller, the procedure should be stopped, and the catheter withdrawn to reduce the risk of steam pop that could result in adverse events including perforation, embolism or injury to adjacent structures. Both the 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 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. • Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism. • Excessive curves or kinking of the catheter may damage internal wires and components, including the cooling lumen. This damage may affect steering performance or force accuracy and may cause patient injury. • Excessive manipulation of the distal tip and spring region may cause permanent damage to the contact force elements resulting in inaccurate force readings. • Manual bending and/or twisting of the distal curve can damage the steering mechanism and cooling lumens and may cause catheter failure and patient injury. • Do not scrub the tip electrode as this may result in irrigation port(s) occlusion and may lead to catheter failure and patient injury. • Use both fluoroscopy, or other visualization technique such as echocardiography, and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade. • Do not use excessive force to advance or withdraw the catheter. The firmness of the tip dictates that care shall be taken to prevent perforation of the heart during catheter manipulation. If the force-sensing feature is active, evaluate applied force to avoid applying excessive loads. • Local impedance is affected by many factors including tissue conductivity, contact force, catheter orientation (focal/drag) power, duration, irrigation flow, tissue changes, and electrode char/thrombus/steam pop. • During RF, due to tissue heating, local impedance may not represent catheter proximity or stability nor relative position of the catheter tip-to-tissue, as it is when RF is OFF. • Do not deliver RF energy with the catheter outside the target site. RF Controllers can deliver significant electrical energy and may cause patient injury. • In the event of RF Controller cut-off (impedance or temperature), the catheter must be withdrawn and the tip electrode cleaned of coagulum before RF energy is reapplied. Ensure that all of the irrigation holes are patent prior to reuse to reduce the risk of embolism and/or perforation. • Verify effective contact between the patient and the Dispersive Pad whenever the patient is repositioned as patient movement may disrupt Dispersive Pad contact resulting in patient injury and/or extended procedure times. • Always verify that the tubing set, catheter and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing and catheter can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system. • Patients undergoing left sided ablation procedures should be closely monitored during and post procedure for clinical manifestations of infarction, pulmonary vein injury, nerve damage, embolism and/or atrial esophageal fistula. • Patients undergoing a long irrigated ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely due to the increased risk for bleeding/ hemorrhage and/or embolism. • Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution. • The INTELLANAV STABLEPOINT 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. • Inspect irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism. • If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the 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. • Do not deliver RF energy when the tip electrode is withdrawn or partially withdrawn into a sheath, to minimize the risk of char or coagulum formation. • Guiding catheters and/or long introducer sheaths present the potential for thromboembolic events. Pre-flush and maintain lumen patency with heparinized intravenous infusion. • Do not wipe this catheter with organic solvents such as alcohol or immerse the handle cable connector in fluids. This may result in electrical or mechanical catheter failures. It may also result in an allergic reaction from the patient. • Irrigation flow during RF ablation may distort distal tip electrogram recordings due to the signal conductivity of the external cooling solution. Careful monitoring of additional intracardiac electrograms during RF application is recommended to reduce the possibility of inadvertent injury to adjacent structures if appropriate. Higher power coupled with higher flow rates may exacerbate the distortion of the EGM signal recordings. • Pre-procedural anticoagulation therapy is at the discretion of the physician. However, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy, pre-, during and post-ablation to reduce the incidence of major complications. Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures. • The safety and/or efficacy of epicardial use of the INTELLANAV STABLEPOINT Catheter has not been evaluated in a clinical trial. • The Transseptal Puncture (TSP) presents a potential risk for perforation/ tamponade; echocardiography and/or fluoroscopic images should be used to guide the transseptal puncture and a real-time arterial blood pressure monitor should be applied. TSP may induce an air embolus; use proper aspiration and flushing techniques to minimize air embolus. • Care should be used during multiple sheath/catheter exchanges through the transseptal puncture to avoid causing a residual atrial septal defect that would require repair. • To avoid patient injury, manipulate the sheath carefully when performing the transseptal puncture especially if the patient has any of the following conditions: • Enlarged aortic root • Marked right atrial enlargement • Small left atrium • Marked skeletal deformity or distortion of the thoracic configuration (e.g., scoliosis) • Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

PRECAUTIONS • The INTELLANAV STABLEPOINT Catheter is designed for use with a compatible RF Controller, Irrigation Pump and Irrigation Tubing Set that meets the catheter flow rate requirements, a compatible Mapping System, and compatible Connection Box. • The contact force reading is for information only and is not intended to replace standard handling precautions. • The local impedance reading is for information only and is not intended to replace standard handling precautions. • The catheter must be warmed up prior to use. If the catheter has not reached a steady state condition prior to use, there is a potential for measurement drift to occur, which could result in an inaccurate force reading. • Ensure catheter tip is not in contact with myocardial wall or other device when zeroing the contact force reading. Failure to do so could result in inaccurate force reading. • Always zero the contact force reading following insertion into the patient or moving the catheter from one heart chamber to another. • To ensure proper function of the contact force reading, ensure the tip electrode and distal ring electrode are outside of a sheath. • To ensure proper function of the local impedance reading, ensure the tip electrode and all three ring electrodes are outside of a sheath. • When applying high force during mapping and RF application, the user should monitor the contact force visualization on the RHYTHMIA Mapping System screen to ensure the force does not exceed the operating range. • 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. • Electromagnetic Interference (EMI) produced by the INTELLANAV STABLEPOINT Catheter when used in conjunction with the RF Controller during normal operation may adversely affect the performance of other equipment. • Do not use the temperature sensor to monitor tissue temperature. The temperature sensor located within the electrode will not reflect either electrode-tissue interface or tissue temperature due to the cooling effects of the saline irrigation of the electrode. • Use only sterile saline and gauze pad to clean the tip. • Verify the RF Controller is in the control mode which will deliver the amount of power specified by the power setting unless the measured temperature exceeds the temperature setting. Temperature controlled RF delivery may be affected by the cooling effects of the saline irrigation of the electrode. For example, the MAESTRO 4000 RF Cardiac Ablation Controller has these settings in the power control mode. • Equipment/accessories carrying high frequency alternating current may cause direct coupled interference and therefore, may disrupt the operation of the RF Controller. It may be necessary to take risk control measures, such as re-orienting, relocating, or shielding the interfering equipment/accessories. • Use only Dispersive Pads that meet or exceed IEC 60601-2-2 requirements and follow the Dispersive Pad manufacturer's instructions for use. The use of Dispersive Pads which meet ANSI/AAMI requirements (HF18) is recommended. • Apparent low power output, high impedance reading or failure of the equipment to function correctly at normal settings may indicate faulty application of the Dispersive Pad or failure of an electrical lead. • The INTELLANAV STABLEPOINT Catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. Do not rotate the handle and catheter shaft more than 1½ full rotations (540°). If the desired catheter tip position is not achieved, adjust the catheter's curve to disengage the catheter tip from the heart wall before resuming rotation of the handle and catheter shaft. • Electrophysiology catheters and systems are intended for use only in radiation shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines. • The risk of igniting flammable gases or other materials is inherent in electrosurgery. Precautions must be taken to restrict flammable materials from the electrosurgical suite. • Adequate filtering must be used to allow continuous monitoring of the surface Electrocardiogram (ECG) during RF power applications. • Do not use the INTELLANAV STABLEPOINT ablation system and its accessories closer than 30 cm (12 inches) to any Wireless Power Transfer (WPT) and 5G cellular devices, otherwise electromagnetic interference from those devices could result in degradation of the performance of this equipment.

ADVERSE EVENTS Potential adverse events associated with use of the INTELLANAV STABLEPOINT Catheter include, but are not limited to: • Pain or discomfort, for example: • Angina • Chest pain • Non-cardiovascular pain • Cardiac arrest • Death • Hypertension • Hypotension • Infection/inflammation/exposure to biohazardous material • Edema/heart failure/pleural effusion • Procedural related side effects, for example: • Allergic reaction (including anaphylaxis) • Genitourinary complication • Side effects related to medication or anesthesia • Radiation injury/tissue burn • Renal failure/insufficiency • Vasovagal response • Respiratory distress/insufficiency/dyspnea • Arrhythmia (new or exacerbated) • Conduction pathway injury (heart block, nodal injury, etc.) • Nerve injury, for example: • Phrenic nerve injury • Vagal nerve injury • Gastrointestinal disorders • Vessel trauma, including: • Perforation • Dissection • Coronary artery injury • Vasospasm • Occlusion • Hemothorax • Cardiac trauma, for example: • Cardiac perforation/cardiac tamponade/pericardial effusion • Valvular damage • Stiff left atrial syndrome • Injury related to tissue damage and/or adjacent structures, for example: • Esophageal injury • Pulmonary injury • Catheter entrapment • Physical trauma • Fistula, for example: • Atrio-esophageal fistula • Bronchopericardial fistula • PV stenosis and its symptoms, for example: • Cough • Shortness of breath • Fatigue • Hemoptysis • Surgical and access complications, for example: • Hematoma/seroma • AV fistula • Bleeding • Pseudoaneurysm • Pneumothorax • Residual atrial septal defect • Injury due to embolism/thromboembolism/air embolism/foreign body embolism • Cerebrovascular Accident (CVA)/stroke • Transient Ischemia Attack (TIA) • Myocardial infarction • Neurological impairment and its symptoms, for example: • Cognitive changes, visual disturbances, headache, motor impairment, sensory impairment, and speech impairment • Pulmonary embolism • Asymptomatic cerebral embolism. The potential adverse events may be related to the diagnostic mapping catheter(s) and/or the interventional ablation device(s) and/or the procedure. The severity and/or the frequency of these potential adverse events may vary and may result in prolonged procedure time and/or additional medical and/or surgical intervention, implantation of a permanent device such as a pacemaker, and in rare cases, may result in death. Refer to the RF Controller, Irrigation Pump, and other ancillary device instructions for additional potential adverse events related to their use with the INTELLANAV STABLEPOINT Catheter. 97183419 (Rev. A)

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