INTELLANAV STABLEPOINT™
Ablation Catheter

Boston Scientific
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NEwTON AF

Clinical Evaluation of the STABLEPOINT™ Catheter and Force Sensing System for Paroxysmal Atrial Fibrillation

NEwTON AF Study (NCT04580914) presented at AHA 2023

Objective

The purpose of the NEwTON AF Clinical Study was to demonstrate that the INTELLANAV STABLEPOINT™ Catheter and Force Sensing System with DIRECTSENSE™ Technology is safe and effective for the treatment of drug refractory, recurrent symptomatic paroxysmal atrial fibrillation.

Methods

- Prospective, single-arm, multi-center, global study conducted at 46 sites: North America (27), Europe (12), Asia-Pacific (7).
- 299 atrial fibrillation (AF) patients were treated for de novo pulmonary vein isolation (PVI) with the investigational INTELLANAV STABLEPOINT™ catheter and guided by RHYTHMIA™ HDx.

Procedural characteristics and safety

- **Procedural Characteristics:**
  - Mean procedure time was 166 min, mean LA dwell time was 136 min, mean fluoroscopy team was 15 min, total radiofrequency (RF) duration was 11.5 ± 6 seconds, and mean contact force was 13.5 ± 7g.
  - High-power short-duration (45-50W) was used exclusively in 210 cases (148 min procedure time), and conventional (<45W) power was used in 82 cases (208 min procedure time).
- **Safety:** There were no steam pops or recorded cases of esophageal fistulas.

Results

- **Local Impedance (LI):**
  - Starting LI was 155.1 Ω with an absolute LI drop of 21.2 Ω and a 13.6% LI drop.
  - LI drops of ≥20 Ω trended toward better 6m outcomes (84.2% vs 73.3%, p=0.04).
  - At 12m, LI drop was predictive of freedom from recurrence (HR 0.6, p=0.003), CF alone was not.
- **Outcomes:**
  - Acute procedural success, defined as isolation of all PVs with STABLEPOINT, was achieved in 294 (98.3%) of patients.
  - The freedom from predefined adverse events was 96.0%; events included pericarditis (6), access complications (2), pulmonary edema (2), pulmonary embolism (1), cerebrovascular accident (1), tamponade (1).
  - At 12 months, freedom from documented recurrence of AF was 73.9%, while freedom from AFL and AT was 90.2% and 97.6%, respectively.

Results

83% First pass isolation rate

96% Freedom from adverse events

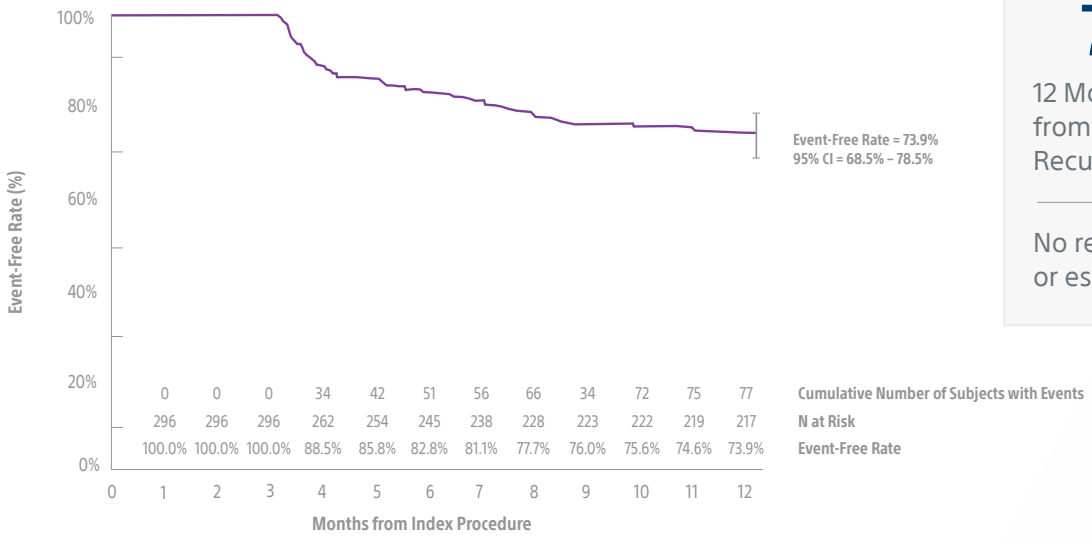
0 Steam pops or esophageal fistula

74% Freedom from documented recurrence of AF

72% Cases performed with HPSD

21Ω/14% Mean LI drop and %LI drop

AF Recurrence



74%

12 Month Freedom from Documented Recurrence of AF

No reported steam pops or esophageal fistulas

Conclusions

The NEwTON AF Study met all safety and effectiveness endpoints. The 30-day and 12-month primary safety as well as the acute, 6-month and 12-month primary effectiveness endpoints met the specified performance criteria for the use of the catheter in this patient population. This data will be used to support submissions for FDA approval of this STABLEPOINT Ablation Catheter.

For more information,
visit our Clinical evidence webpage and educare.bostonscientific.com

Scan for more information

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INTELLANAV STABLEPOINT™ Ablation Catheter

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential 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 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 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 < 8.5F • in the coronary vasculature

WARNINGS • If the visibility of the EP catheters are 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 radiofrequency 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 with 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 Instruction 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. • Note: The change in local impedance during RF delivery should not be used independent of established clinical indicators of RF tissue response (e.g., electrograms, generator impedance, pace capture). Select ablation settings and limits (e.g., temperature limit, irrigation flow rate, power level, RF duration) in accordance with the Operational Instructions below. Increases in contact force, ablation duration or power in pursuit of a specific change in local impedance are not recommended. • The INTELLANAV STABLEPOINT Catheter is not intended to be used with an RF Controller output setting exceeding 50 watts or 290 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 exiting 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, and 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 ablation 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: 290 Vpk. • Warnings for patients with implantable pacemakers (PPMs) and Implantable Cardioverter Defibrillators (ICDs): • PPMs, ICDs, and leads can be adversely affected by ablation energy. It is important to refer to the device manufacturer's instructions 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 the pacemaker or defibrillator per the manufacturer guidelines during ablation. The device 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 • Program the ICD Tachy therapy to "Off" to prevent inappropriate shock and/or possible damage to the device from the ablation procedure. Remember to turn Tach Therapy to "On" once ablation is complete. • 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 dislodgment. • Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function. • Do not ablate from within the coronary artery as the resulting myocardial injury can be fatal. Adequate visualization techniques, such as fluoroscopy 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 over-torqued 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 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 Irrigation 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 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. • 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 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. • Use both fluoroscopy or other visualization technique such as echocardiography, and electrograms to verify catheter location during navigation and RF. Incorrect catheter localization may lead to incorrect clinical conclusion or patient injury. • Local impedance is affected by many factors including 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 a generator 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 ardioversion. 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 Transspetal 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 and 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. • Note: Refer to the Instructions for Use on compatible RHYTHMIA Mapping System for instructions on how to perform warm-up. • 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. • Note: Refer to the Instructions for Use on compatible RHYTHMIA Mapping System for instructions on how to zero the catheter. • 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. • Note: Refer to the Instructions for Use on compatible RHYTHMIA Mapping System for a list of sheaths that are compatible with the sheath detect software feature. • To ensure proper function of the local impedance reading, ensure the tip electrode and all three ring electrodes are outside of a sheath. • Note: Refer to the error messages and notifications section of the compatible RHYTHMIA Mapping System instructions for use for system-releated messages and indications related to DIRECTSENSE. • 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. • Note: Refer to the error messages and notifications section of the compatible RHYTHMIA Mapping System instructions for use for system-related messages and indications related to force range and inaccurate force reading. • 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 INTELLAGEN 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 which 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. Do not increase power before checking for obvious defects or misapplication. • 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 one and one-half (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. • 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. • Adequate filtering must be used to allow continuous monitoring of the surface Electrocardiogram (ECG) during RF power applications.

POTENTIAL 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 • Electric shock • Hypertension • Hypotension • Infection/inflammation (including pericarditis and pleuritis)/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 • Fluid volume overload • Respiratory distress/insufficiency/failure/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 • Thrombosis • Injury due to embolism/thromboembolism/air embolism/foreign body embolism • Cerebrovascular Accident (CVA)/stroke • Transient Ischemic Attack (TIA) • Myocardial infarction • Neurological impairments 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 ablation catheter(s) and/or the interventional 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. 97183419 (Rev B.3)

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