Boston Scientific

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IntellaNav MiFi™ Open-Irrigated

Ablation Catheter

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℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Carefully read all ancillary device instructions prior to use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications.

DEVICE DESCRIPTION

The IntellaNav MiFi Open-Irrigated (OI) Ablation Catheter (henceforth referred to as the IntellaNav MiFi OI Catheter) is a 7.5F (2.5 mm) quadripolar open-irrigated ablation catheter designed to deliver Radiofrequency (RF) energy to the 4.5 mm catheter tip electrode for cardiac ablation. The IntellaNav MiFi OI Catheter incorporates a position sensor for magnetic tracking and navigation of the catheter on a Rhythmia Mapping System.

The IntellaNav MiFi OI Catheter is designed to be used with a commercially available RF Controller, an Irrigation Pump and Irrigation Tubing Set that meets the catheter flow rate requirements, a commercially available Connection Box, and a commercially available Mapping System.

The IntellaNav MiFi OI Catheter incorporates an open-irrigated cooling mechanism through a tip that is partitioned into two chambers. The proximal chamber circulates normal saline (0.9 %) within the tip to cool the proximal end of the tip electrode and mitigate overheating while the distal chamber allows the fluid to flow through six irrigation holes into the patient's vasculature, thereby cooling the tip/tissue interface. A luer connection at the proximal end of the handle connects the catheter to the Irrigation Tubing Set, allowing the Irrigation Pump to generate the flow of saline to the catheter.

The electrode segment is comprised of a tip electrode, three ring electrodes, and includes three diagnostic mini electrodes embedded in the tip. The tip electrode has an embedded temperature sensor and delivers RF energy for cardiac ablation. The ring electrodes record Electrogram (EGM) signals for mapping and deliver stimulus for pacing. The three diagnostic mini electrodes are designed to provide additional high resolution, localized electrogram information. The IntellaNav MiFi OI Catheter interfaces with standard RF Generators and recording equipment through the Connection Box. The handle includes the electrical connector for the cable connection to the Connection Box and one luer fitting used to connect the catheter to the Irrigation Tubing Set.

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The IntellaNav MiFi™ OI Catheter is shown in Figure 1.

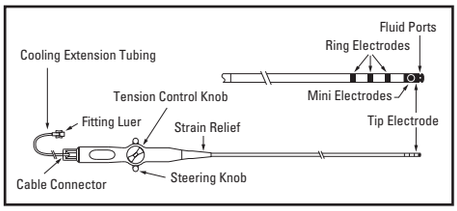

Figure 1. IntellaNav MiFi OI Catheter

User Information

The IntellaNav MiFi OI Catheter is to be used only by physicians fully trained in cardiac electrophysiology procedures. Assistance to prepare and run the system may only be provided by appropriately trained personnel.

Contents

One (1) Sterile IntellaNav MiFi OI 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

- 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.
- Carefully read all ancillary device instructions prior to use. Observe all contraindications, warnings, and precautions noted in these directions. Failure to do so may result in patient complications.

Note: The IntellaNav MiFi OI Catheter is not designed to be compatible with the Maestro 3000™ RF Cardiac Ablation System.

- Before using, inspect the IntellaNav MiFi OI Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that may cause patient and/or user injury if the catheter is used. Do not use defective or damaged devices. Replace damaged device(s) if necessary.
- No modification of this equipment is allowed.
- Contents are supplied STERILE using an EO process and should be used by the "Use By" date on the device package. Do not use the device if past the "Use By" date. Do not use if sterile barrier is damaged as use of non-sterile devices may result in patient injury. If damage is found, call your BSC representative.
- 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.
- Catheter ablation procedures present the potential for significant x-ray 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 x-ray 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. Careful consideration must therefore be given for this use of the device in pregnant women. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in prepubescent children.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Start the initial RF application at low power and carefully follow the power titration and the correlating flow rate procedures as specified in the instructions for use. A drop in impedance may be an indicator of lesion creation. Too rapid an increase in power during ablation, increasing power with a decrease in impedance, ablating at high power (> 30 W) or insufficient flow rate may lead to perforation caused by steam pop, arrhythmias, damage to adjacent structures, and/or 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 prepubescent children.
- Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism.
- During energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces to minimize the potential for electrical shock.
- 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 during energy delivery.
- Before use, ensure irrigation ports are patent by infusing heparinized normal saline through the catheter tubing. Patency of irrigation ports is important to maintain cooling function and minimize risks of coagulum and char that may result in embolism as well as perforation caused by steam pop.
- Do not continue using the IntellaNav MiFi OI Catheter if the irrigation ports are occluded or the catheter is not functioning properly.
- Due to the design of the IntellaNav MiFi OI 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.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
- 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.
- Maximum Catheter Rated Voltage: 150 Vrms (212 Vpk).
- 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 pre-operative pacing, sensing, and therapy parameters after the ablation procedure.
  - Temporarily reprogram the 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.
  - 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.
  - Perform a complete analysis of the implanted device function after ablation.
  - Fluoroscopic 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.
  - Remember to reactivate the pulse generator after turning off the RF ablation equipment.
- 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 an IntellaNav MiFi OI 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.
- 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.

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- Excessive curves or kinking of the IntellaNav MiFi™ OI Catheter may damage internal wires and components, including the cooling lumen. This damage may affect steering performance and may cause patient injury.
- Manual bending and/or twisting of the distal curve can damage the steering mechanism and cooling lumens and may cause IntellaNav MiFi OI Catheter failure and patient injury.
- Do not scrub the tip electrode as this may result in irrigation port(s) occlusion and may lead to IntellaNav MiFi OI Catheter failure and/or patient injury.
- Use both fluoroscopy and electrograms to monitor the advancement of the IntellaNav MiFi OI Catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade.
- Do not deliver RF energy with the IntellaNav MiFi OI Catheter outside the target site. The RF Controller can deliver significant electrical energy and may cause patient injury.
- In the event of RF Controller cut-off (impedance or temperature), the IntellaNav MiFi OI 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.
- 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.
- Always verify that the Irrigation Tubing Set, IntellaNav MiFi OI Catheter and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing and IntellaNav MiFi OI Catheter can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system.
- 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.
- 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 the IntellaNav MiFi OI 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.
- Use only sterile saline and gauze pad to clean the tip.
- 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.

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.
- The IntellaNav MiFi OI 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.
- 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.
- Electromagnetic Interference (EMI) produced by the IntellaNav MiFi OI Catheter when used in conjunction with the RF Controller during normal operation may adversely affect the performance of other equipment.
- The IntellaNav MiFi OI Catheter is not intended to be used with a RF generator output setting exceeding 50 W or 212 Volts peak.
- 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.
- Do not use the IntellaNav MiFi OI Catheter in the proximity of Magnetic Resonance Imaging (MRI) equipment because the MRI equipment may adversely impact the function of the RF Controller which may adversely impact the MRI equipment's image quality.
- Use only Dispersive Pads which meet or exceed IEC 60601-1/ 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 MiFi OI 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.
- Do not insert or withdraw the catheter without straightening the catheter tip (returning the steering lever to neutral position).
- Electrophysiology catheters and systems are intended for use only in radiation shielded rooms due to electromagnetic compatibility requirements and other hospital safety guidelines.
- Ensure that the cable /catheter connection remains dry throughout the procedure.
- The IntellaNav MiFi OI Catheter contains Bis (2-ethyhexyl) phthalate (DEHP). BSC has assessed the residual patient risk associated with phthalates in this device to be minimal; however, BSC has not assessed the residual patient risk associated with phthalates which may be contained in non-BSC ancillary devices required for use in conjunction with the IntellaNav MiFi OI Catheter.
- 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.
- Patients undergoing a long irrigated ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely.
- Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the dilator or catheter.
- After use, handle and dispose of product and packaging in accordance with hospital biohazard procedure, administrative and/or local government policy.

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)

CLINICAL STUDY

BLOCK-CTI

Boston Scientific conducted a clinical study (BLOCk-CTI) to establish a reasonable assurance of safety and effectiveness of radiofrequency cardiac ablation using the Blazer™ OI Catheter in the treatment of type I Atrial Flutter (AFL). The clinical study was conducted using a surrogate system consisting of the Stockert™ 70 Radiofrequency Generator and the CoolFlow™ Irrigation Pump and Tubing Set. However, on the basis of the engineering testing and animal studies, the results of the BLOCk-CTI study may be extrapolated to the use of Blazer OI Catheter with the Maestro RF Generator and MetriQ™ Pump. These data from the clinical study are summarized below.

Objective

A multi-center clinical study was conducted using the Blazer Open-Irrigated Catheter. The purpose of the clinical study was to demonstrate that the Blazer Open-Irrigated Investigational Catheter is non-inferior to that of the Control Catheters when used to ablate the Cavo-tricuspid Isthmus (CTI) for the treatment of sustained or recurrent type 1 atrial flutter.

Study Design

BLOCk-CTI (Blazer Open-Irrigated Radiofrequency Catheter for the Treatment of Type 1 Atrial Flutter) was a prospective, randomized, controlled, single-blinded, multi-center U.S. investigation. A Roll-in cohort was introduced into the study for investigators to use the Blazer Open-Irrigated Catheter and a Control Catheter but these subjects were not part of the

endpoint analyses. In this study, the Control devices were open-irrigated radiofrequency ablation catheters that received FDA market-approval for the treatment of type 1 atrial flutter and the Investigational device was the Blazer™ Open-Irrigated Catheter.

Patients were treated between January 17, 2011 and January 15, 2014. The database for this PMA reflected data collected through January 15, 2014 and included 302 patients. There were 24 investigational sites. All adverse events and deaths reported in this study were reviewed and adjudicated by a Clinical Events Committee (CEC). The CEC was comprised of independent physicians, and its decisions were based upon independent physician review of data.

Study Endpoints

Primary Safety Endpoint

The Primary Safety Endpoint was the Procedure-related Complication-free rate at 7 days post-procedure. Procedure-related complications were defined as adverse events that are related to the ablation procedure or catheter and result in death, life threatening complication, or a persistent or significant disability/incapacity or required intervention to prevent impairment of a body function or damage to a body structure. The difference in Procedure-related Complication-free rates between the randomized groups was calculated and compared against a 10 % non-inferiority margin.

Primary Effectiveness Endpoint

The Primary Effectiveness Endpoint was Acute Success. Acute Success was defined as demonstration of bi-directional cavo-tricuspid isthmus block 30 minutes following the last RF application in the CTI with the sole use of the randomized Investigational or selected Control Catheter only. Acute Success was evaluated for each randomized group and the difference between the two groups was compared against a 10 % non-inferiority margin.

Secondary Effectiveness Endpoints

The Secondary Effectiveness Endpoint for the study was Chronic Success, evaluated separately for All Treated subjects (all subjects that had an ablation procedure) and Acute Success subjects (defined by the Primary Effectiveness Endpoints). Chronic Success was defined as freedom from recurrence of type I atrial flutter at 3 months post-procedure. Subjects who were prescribed Anti-arrhythmic Drugs (AADs) for the treatment of type I AFL during the follow-up period were considered chronic failures. Chronic Success was evaluated in two secondary endpoints: Chronic Success in Acute Successes and Chronic Success in All Treated Subjects. The difference in Chronic Success rates between the randomized groups was compared against a 10 % non-inferiority margin.

Tertiary Objectives

The following was evaluated for differences between the Investigational and Control groups as tertiary objectives:

- Total procedure time (first catheter inserted to last catheter removed)
  - Procedure time for patients without concomitant arrhythmias ablated
  - Procedure time for patients with concomitant arrhythmias ablated
- Fluoroscopy time
  - Fluoroscopy time for patients without concomitant arrhythmias ablated
  - Fluoroscopy time for patients with concomitant arrhythmias ablated
- Total number of RF applications per patient
- Cumulative RF time per patient
- Frequency and severity of arrhythmia-related symptoms at 3 months post-procedure as compared to baseline

Patient Accountability

All subjects who signed the Informed Consent form were considered enrolled in the study and counted towards the enrollment ceiling. Subjects were classified as either part of the Roll-in cohort or the Randomized cohort.

Roll-in — To facilitate the investigator's familiarity with the Blazer OI Catheter and the EGMs, the study included a cohort of subjects considered to be "Roll-in" subjects. Investigational sites without previous experience with the Blazer OI Catheter or the Control Catheter were required to utilize one Roll-in subject for each treatment arm. Roll-in requirements could be waived for Investigational sites that had previous experience.

Randomized — Once the Roll-in requirements were met at an investigational site, the subsequent enrolled subjects were part of the Randomized cohort, and were randomized 1:1 to receive treatment with either the Control Catheter or the Investigational Catheter.

Enrolled subjects were further classified into the subject statuses described below.

Intent — A subject who had been enrolled but then withdrawn from the study and did not undergo the protocol-required ablation procedure.

Attempt — A subject who had been enrolled and had anesthesia or sedation administered in preparation for the ablation procedure but did not receive ablation therapy with the treatment or Control Catheter Per-Protocol.

Treatment subject — A subject who had an ablation procedure and received ablation therapy with the Investigational or Control Catheter.

Each Primary Endpoint was analyzed based on Modified Intention-to-Treat (mITT), Per-Protocol (PP), and As Treated (AT) Populations. The Modified Intention-to-Treat analysis included all Randomized Treatment subjects in their randomized group, regardless of compliance to the assigned treatment. The Per-Protocol analysis included subjects who were treated with the randomized catheter, had complete endpoint data, and had no major protocol violations.

The As Treated analysis was done for each Primary Endpoint to account for one subject where the subject was randomized to the Investigational Catheter but mistakenly treated with the Control Catheter. The As Treated analysis included subjects in the group for which they received treatment, regardless of randomization.

Table 1 shows the disposition of subjects in the BLOCk-CTI study. There were five subjects enrolled and classified as part of the Randomized cohort, but who withdrew prior to being randomized. Subjects that were randomized and underwent an ablation procedure were referred to as Randomized Treatment subjects, and these were the subjects eligible for endpoint analyses. Among the Randomized cohort, there were 30 Randomized subjects classified as Intents (20 subjects) or Attempts (10 subjects). Since these subjects did not have an ablation procedure, they were not eligible for any endpoint analyses.

Subjects classified as Roll-ins, Not Randomized, Randomized Intents and Randomized Attempts were not included in endpoint analyses. Table 1 also summarizes the accountability of the Randomized Treatment subjects for inclusion in each endpoint analysis for each analysis type.

Table 1: Subject Disposition and Accountability for Endpoint Analysis

	Control	Investigational	Total
Enrolled Subjects			302
Roll-in Cohort	17	30	47
Not Randomized	N/A	N/A	5
Randomized Cohort	125	125	250
Intents	10	10	20
Subject did not meet eligibility criteria	4	4	8
Subject refused testing/follow-up	1	1	2
Subject withdrawn by physician	2	3	5
Insurance issues	2	1	3
Lab equipment issues	1	1	2
Attempts	4	6	10
Subject did not meet eligibility criteria	3	3	6
Lab equipment issues	1	2	3
Subject anatomical issues	0	1	1
Treatment Subjects (Eligible for Endpoint Analysis)	111	109	220
3-month follow-up visit completed	106	104	210
3-month follow-up visit not completed	5	5	10
Death	0	1	1
Withdrawals	1	3	4
Additional missed 3-month follow-ups	4	1	5
Endpoint Accountability for Randomized Treatment Subjects (N = 220)			
Primary Safety: 7-Day Procedure-Related Complications			
Modified Intention-to-Treat	111	109	220
Per-Protocol	111	107	218
Excluded due to randomization error*	0	1	1
Excluded due to withdrawal within 7 days	0	1	1
As Treated*	112	108	220
Primary Effectiveness: Acute Success			
Modified Intention-to-Treat	111	109	220
Per-Protocol	111	108	219
Excluded due to randomization error*	0	1	1
As Treated*	112	108	220
Secondary Effectiveness: Chronic Success in All Treated Subjects			
Modified Intention-to-Treat	111	109	220
Secondary Effectiveness: Chronic Success in Acute Success Subjects			
Modified Intention-to-Treat (Acute Success Subjects Only)	99	95	194

*One subject randomized to Investigational group was treated with the Control Catheter only.

There were four Randomized Treatment subjects that withdrew from the study. A summary of withdrawal reasons for these subjects is included in Table 2.

Table 2: Randomized Subjects Withdrawal Summary

Reason	Control	Investigational
Subject refused testing/follow-up	0	2
Subject "lost to follow-up"	1	1
Total	1	3

Study Population Demographics and Baseline Parameters

The average age of the subjects was 66 ± 10 years for the Control group and 65 ± 11 years for the Investigational group.

For both treatment groups, the majority of subjects were male. The Control group enrolled 96 male subjects (76.8 %) and the Investigational group enrolled 102 male subjects (81.6 %). There were 29 females enrolled in the Control group, (23.2 %) and 23 female subjects enrolled in the Investigational group, (18.4 %). The demographics of the study population are typical for an atrial flutter ablation study performed in the US.

Overall, there were no imbalances in baseline characteristics between the two treatment groups as shown in Table 3.

Table 3: Baseline Characteristics (Randomized Cohort N = 250)

Characteristic	Measurement or Category	Control (N = 125)	Investigational (N = 125)	P-Value
Age (years)	N	125	125	0.66
	Mean ± SD	66 ± 10	65 ± 11	
	Range	35–85	25–91	
Gender [N (%)]	Female	29 (23.2)	23 (18.4)	0.35
	Male	96 (76.8)	102 (81.6)	
Cardiac and cardiovascular disease history	Hypertrophic cardiomyopathy [N (%)]	1 (0.8)	2 (1.6)	0.56
	Ischemic cardiomyopathy [N (%)]	12 (9.6)	9 (7.2)	0.49
	Non-ischemic cardiomyopathy [N (%)]	2 (1.6)	3 (2.4)	0.65
	Congestive Heart Failure (CHF) [N (%)]	22 (17.6)	17 (13.6)	0.38
	Coronary artery disease [N (%)]	44 (35.2)	44 (35.2)	1.00
	Hypertension [N (%)]	88 (70.4)	81 (64.8)	0.34
	Prior myocardial infarction [N (%)]	20 (16.0)	23 (18.4)	0.62
	Valvular disease [N (%)]	22 (17.6)	27 (21.6)	0.43
Cardiac intervention/surgery history	Angiography/ angioplasty [N (%)]	13 (10.4)	12 (9.6)	0.83
	Stent [N (%)]	20 (16.0)	10 (8.0)	0.05
	CABG [N (%)]	25 (20.0)	24 (19.2)	0.87
	Device implant (CRT) [N (%)]	1 (0.8)	0 (0)	0.32
	Device implant (ICD) [N (%)]	8 (6.4)	5 (4.0)	0.39
	Pacemaker implant [N (%)]	3 (2.4)	10 (8.0)	0.05
	Heart valve repair/ replacement [N (%)]	5 (4.0)	12 (9.6)	0.08
Significant non-cardiovascular disease history	Type II diabetes [N (%)]	35 (28.0)	30 (24.0)	0.47
	Hyperlipidemia [N (%)]	75 (60.0)	77 (61.6)	0.80
Conduction disorder	1st degree AV block [N (%)]	13 (10.4)	17 (13.6)	0.44
	2nd degree AV block (Mobitz I) [N (%)]	2 (1.6)	9 (7.2)	0.03
	2nd degree AV block (Mobitz II) [N (%)]	2 (1.6)	0 (0)	0.16
History of non-type I AFL atrial arrhythmias	Atrial fibrillation [N (%)]	57 (45.6)	72 (57.6)	0.08
	Atypical atrial flutter [N (%)]	2 (1.6)	2 (1.6)	1.00
	Sick sinus syndrome [N (%)]	9 (7.2)	7 (5.6)	0.61

Results

Procedural Data

The goal of the ablation procedure was to produce bi-directional conduction block between the tricuspid annulus and inferior vena cava at the CTI. Subjects with type I atrial flutter were randomized to be treated with either the Investigational device or the Control device in the ablation procedure.

Three subjects were ablated for a concomitant arrhythmia, two subjects for atrial tachycardia and one subject for atrial fibrillation and atypical flutter, during the index procedure for type I atrial flutter.

Control Catheters Used

Investigators used a total of 112 Control Catheters as the initial catheter in the ablation procedure for 111 randomized Control subjects and one (1) randomized to the Investigation group. The ThermoCool™ Open-Irrigated Catheter (Biosense Webster) was the most frequently used catheter in the Control group (66/112), followed by the ThermoCool OI Nav Catheters (32/112) and the St. Jude Medical Cool Path™, Therapy Cool Path™, and Safire BLU™ Duo Ablation Catheters (14/112).

Ablation Parameters

The ablation parameters to achieve bi-directional block are shown in Table 4 for the Control and Investigational Catheters.

Table 4: Ablation Parameters*

Procedure Parameter	Measurement	Control N = 111	Investigational N = 109
RF applications with randomized catheter	N	1262	1313
	Mean ± SD	14 ± 12	15 ± 10
	Range	1–71	1–67
Ablation duration (seconds)	N	1260	1313
	Mean ± SD	96 ± 91	91 ± 78
	Range	0–999	0–742
Starting power	N	1260	1306
	Mean ± SD	20 ± 2	19 ± 2
	Range	0–35	0–30
Max Power (W)	N	1259	1308
	Mean ± SD	36 ± 7	37 ± 9
	Range	0–50	0–50
Average power (W)	N	1255	1301
	Mean ± SD	31 ± 7	32 ± 8
	Range	0–48	0–49
Max temperature (°C)	N	1259	1300
	Mean ± SD	38 ± 5	33 ± 3
	Range	23–63	0–72
Average temperature (°C)	N	1255	1301
	Mean ± SD	34 ± 4	29 ± 2
	Range	23–51	21–46
Max impedance (Ω)	N	1254	1299
	Mean ± SD	141 ± 51	155 ± 46
	Range	62–999	0–940
Average impedance (Ω)	N	1255	1300
	Mean ± SD	119 ± 30	132 ± 34
	Range	35–380	33–230

*Only includes data from randomized catheters.

Fluids Received During the Procedure

Procedural fluids administered via the open-irrigated catheters and non-catheter sources were recorded as shown in Table 5. The Investigational Catheter used more fluid than the Control Catheter. Patients randomized to the Control group received an ablation using any open-irrigated RF ablation catheter with FDA market approval for the treatment of type I AFL, when used in conjunction with the catheter's corresponding market-approved generator and pump. Fluid infusion rates for the Control Catheter pump(s) were programmed per the manufacturer's instructions for use and some had lower flow rates than the Investigational Catheter. The choice of the Control Catheter used during the procedure was left up to the discretion of the Investigator.

Table 5: Fluid and Flow Rates Recorded During the Ablation Procedure

Fluid infusion	Measurement	Control	Investigational
Primary flow rate for RF applications <= 30 W	N	110	109
	Mean ± SD	18 ± 7	20 ± 6
	Range	8–30	15–30
Primary flow rate for RF applications > 30 W	N	110	107
	Mean ± SD	25 ± 7	30 ± 1
	Range	13–30	15–30
Total fluid infused through ablation catheter (mL)	N	108	108
	Mean ± SD	611 ± 433	699 ± 386
	Range	20–2346	50–1881
Total fluid infused through non-catheter sources (mL)	N	109	109
	Mean ± SD	449 ± 337	544 ± 416
	Range	0–1900	0–2000
Total fluid output from the patient (mL)	N	110	109
	Mean ± SD	113 ± 304	133 ± 393
	Range	0–1300	0–2200

Primary Safety Endpoint

The objective of the Primary Safety Endpoint was to demonstrate that the proportion of subjects free from Procedure-related complications in the Investigational group is non-inferior to that in the Control group. The safety of the Blazer™ OI Catheter was evaluated by the Procedure-related Complication-free rate at 7 days post-procedure. The Primary Safety Endpoint was determined after all adverse events that occurred within seven (7) days of the procedure were adjudicated by an independent Clinical Event Committee.

The Primary Safety Endpoint analysis includes all Randomized Treatment subjects (111 Control and 109 Investigational). Based on the Modified Intention-to-Treat analysis, the 7-day Procedure-related Complication-free rate was 98.2 % in the Control group and 93.6 % in the Investigational group. The difference in the 7-day Procedure-related Complication-free rate between the Control and the Investigational groups was 4.6 %. The upper 95 % confidence bound of 9.78 % was less than the non-inferiority margin of 10 %, demonstrating non-inferiority between the two groups. The results of the Primary Safety Endpoint are shown in Table 6. The Primary Safety Endpoint results were consistent across three analysis cohorts (e.g., mITT, PP and AT) and supported the safety of the Blazer OI Catheter for the treatment of type I atrial flutter.

Table 6: Primary Safety Endpoint Results (Randomized Treatment Subjects N = 220)

Analysis Cohort	Study Group	Subjects Event-Free	Treatment Subjects	Procedure-Related Complication-Free Rate	Difference (One-Sided Upper 95 % Bound)	Endpoint Result
Modified Intention-to-Treat	Control	109	111	98.2 %	4.6 % (9.78 %)	Pass
	Investigational	102	109	93.6 %		
Per-Protocol	Control	109	111	98.2 %	4.7 % (9.98 %)	Pass
	Investigational	100	107	93.5 %		
As Treated	Control	110	112	98.2 %	4.7 % (9.89 %)	Pass
	Investigational	101	108	93.5 %		

Of the 220 Randomized Treatment subjects, 9 subjects (7 Investigational and 2 Control) had Procedure-related complications that are detailed in Table 7.

Table 7: Primary Safety Endpoint Events by Group (Randomized Treatment Subjects N = 220)

Primary Safety Events	Investigational Group N = 109	Control Group N = 111
Cerebrovascular Accident (CVA) resulting in death	1 (0.9 %)	0
Congestive heart failure	0	1 (0.9 %)
Hypotension	2 (1.8 %)	0
Vasovagal reaction	1 (0.9 %)	0
Junctional rhythm requiring pacemaker implantation	1 (0.9 %)	0
Pseudoaneurysm with hematoma	0	1 (0.9 %)
Pseudoaneurysm	1 (0.9 %)	0
Urinary tract infection	1 (0.9 %)	0
Total	**7* (6.4 %)**	**2 (1.8 %)**

*None of the primary safety events in the Investigational group was adjudicated by the Clinical Events Committee as related to the Blazer OI Catheter.

There were no device-related complications reported in the Randomized Treatment subjects. There was one death reported during the course of the clinical study that was adjudicated by the Clinical Events Committee as Procedure-related event. The subject was a 64-year-old male with a medical history of Coronary Artery Disease (CAD), hypertension, and Myocardial Infarction (MI) with coronary artery bypass graft surgery. The subject also had a history of Chronic Obstructive Pulmonary Disease (COPD), hyperlipidemia and asthma. There was no prior history of embolic phenomena and the subject was Class 1 for the New York Heart Association Functional Classification. The subject was on ASA (325 mg.QD) for 21 days pre-procedure and Accupril for persistent type I atrial flutter. No anticoagulation therapy was administered prior to, during or after the ablation procedure. No Transesophageal Echocardiogram (TEE) was performed to exclude left atrial thrombus prior to the ablation procedure. The subject underwent CTI ablation using the Investigational Catheter and Acute Success was achieved without immediate complications. On day three post-procedure, the subject presented to the Emergency Department with left sided weakness, facial droop, aphasia and dysarthria. Head CT was negative for acute intracranial hemorrhage. The diagnosis of ischemic stroke (right MCA distribution) was made. Shortly after thrombolysis therapy with IV tPA administrated within two hours of symptom onset, the subject deteriorated. Repeat head CT showed massive parenchymal hemorrhagic transformation of the infarct with massive effect and midline shift. The subject passed away on day four post-procedure. The cause of the death was massive cerebral hemorrhage status post tPA for embolic stroke. The ischemic stroke could be attributed to inadequate peri-procedure anticoagulation and lack of pre-procedure TEE for exclusion of left atrial thrombus. Not performing a TEE prior to the ablation procedure in this subject with persistent AFL who was not anticoagulated pre-procedure was also a study protocol violation.

Primary Effectiveness Endpoint Acute Success

The objective of the Primary Effectiveness Endpoint was to demonstrate that the proportion of subjects with Acute Success in the Investigational group was non-inferior to that in the Control group. Acute Success was defined as demonstration of bi-directional CTI block 30 minutes following the last RF application in the CTI, with the sole use of the randomized Investigational or selected Control Catheter.

The Primary Effectiveness Endpoint analysis includes all 220 Randomized Treatment subjects (111 Control and 109 Investigational). Based on the Modified Intention-to-Treat analysis, the Acute Success rate was 89.2 % in the Control group and 87.2 % in the Investigational group, respectively, as shown in Table 8. The difference in the Acute Success rates between the Control and the Investigational groups was 2.0 %. The upper 95 % confidence bound of 9.4 % was less than the non-inferiority margin of 10 %, demonstrating non-inferiority between the two groups. The results of the Per-Protocol and As Treated analyses were consistent with the mITT analysis and supported the effectiveness of the Blazer Open-Irrigated Ablation Catheter for the treatment of type I atrial flutter.

Table 8: Primary Effectiveness Endpoint Results: Acute Success (Randomized Treatment Subjects N = 220)

Analysis Cohort	Study Group	Successful Procedures	Total Procedures	% Success	Difference (One-Sided Upper 95 % Bound)	Endpoint Result
Modified Intention-to-Treat	Control	99	111	89.2 %	2.03 % (9.37 %)	Pass
	Investigational	95	109	87.2 %		
Per-Protocol	Control	99	111	89.2 %	2.15 % (9.53 %)	Pass
	Investigational	94	108	87.0 %		
As Treated	Control	100	112	89.3 %	2.25 % (9.61 %)	Pass
	Investigational	94	108	87.0 %		

Secondary Effectiveness-Chronic Success

The objective of each of the Secondary Effectiveness Endpoints was to demonstrate that the proportion of subjects with Chronic Success in the Investigational group was non-inferior to that in the Control group. Chronic Success was evaluated for All Treated subjects and randomized subjects who had Acute Success separately.

Subjects that were followed through 3 months or had an ECG documented recurrence of type I atrial flutter with less than 3 months of follow-up were considered to have complete data.

Subjects that withdrew or died with no arrhythmia recurrence or did not follow the protocol with regards to follow-up requirements were considered to have incomplete data. These subjects with incomplete data were reviewed to determine if there was sufficient data to determine Chronic Success. Subjects with insufficient data to determine Chronic Success were included in the analysis, but could not be considered as Chronic Successes, and therefore counted against the endpoint.

Among the 220 Randomized Treatment subjects, 19 (ten Control and nine Investigational) had incomplete data due to death (n = 1, one Investigational), request to be withdrawn (n = 4, one Control and three Investigational), or missing follow-up ECG/visit (n = 14, nine Control and five Investigational).

Six subjects in the Investigational group (five Acute Successes and one acute failure) had ECG documented type I AFL recurrence during the 3-month follow-up period and thus were classified as chronic failures; no subjects from the Control group were classified chronic failures due to ECG documented type I AFL recurrence or on AADs for type I AFL during follow-up.

Chronic Success in Acute Successes

The analysis of this Secondary Endpoint was performed in the Modified Intention-to-Treat cohort and included only Randomized Treatment subjects who had Acute Success (99 Control and 95 Investigational). The Chronic Success rate was 89.9 % in the Control group and 85.3 % in the Investigational group, respectively. The difference in the Chronic Success rates between the Control and the Investigational groups was 4.64 %. The upper 95 % confidence bound of 12.64 % was greater than the non-inferiority margin of 10 %, resulting in failure to demonstrate non-inferiority between the two groups. The results of this secondary endpoint analysis are shown in Table 9.

Table 9: Chronic Success in Acute Successes (Randomized Treatment Subjects with Acute Success N = 194)

Analysis Cohort	Study Group	Chronic Success	Total Acute Subjects	% Success	Difference (One-Sided Upper 95 % Bound)	Endpoint Result
Modified Intention-to-Treat	Control	89	99	89.9 %	4.64 % (12.64 %)	Fail
	Investigational	81	95	85.3 %		

Chronic Success in All Treated Subjects

The analysis of this secondary endpoint was performed in the Modified Intention-to-Treat cohort and included all 220 Randomized Treatment subjects (111 Control and 109 Investigational). In this analysis, all acute failures were classified as chronic failures.

The Chronic Success rate was 80.2 % in the Control group and 74.3 % in the Investigational group, respectively. The difference in the Chronic Success rates between the Control and the Investigational groups was 5.87 %. The upper 95 % confidence bound of 15.08 % was greater than the non-inferiority margin of 10 %, resulting in failure to demonstrate non-inferiority between the two groups. The results of this secondary endpoint are shown in Table 10.

Table 10: Chronic Success in All Treated Subjects (Randomized Treatment Subjects N = 220)

Analysis Cohort	Study Group	Chronic Success	Total Treatment Subjects	% Success	Difference (One-Sided Upper 95 % Bound)	Endpoint Result
Modified Intention-to-Treat	Control	89	111	80.2 %	5.87 % (15.08 %)	Fail
	Investigational	81	109	74.3 %		

Although the clinical study failed to statistically demonstrate non-inferiority in chronic success, the difference in the Chronic Success rates between the Investigational and Control groups was small (about 5 %) and is not considered clinically meaningful. The vast majority of the Acute Successes in the Investigational group had no type I atrial flutter recurrence during follow-up, supporting the effectiveness of the Blazer™ Open-Irrigated Ablation Catheter for the treatment of type I atrial flutter.

Data Summary on Tertiary Objectives

The tertiary objectives included procedure time, fluoroscopy time, number of RF applications, RF time, and changes in frequency and severity of arrhythmia-related symptoms. These data are summarized in Table 11.

Table 11: Tertiary Objectives Summary (Randomized Treatment Subjects N = 220)

Tertiary Objective	Measurement	Control (N = 111)	Investigational (N = 109)
Total procedure time for subjects without concomitant arrhythmias ablated (minutes)	N	108	109
	Mean ± SD	94 ± 41	98 ± 34
	Minimum–Maximum	44–250	33–190
	Median	83	93
Total procedure time for subjects with concomitant arrhythmias ablated (minutes)	N	3	0
	Mean ± SD	153 ± 86	N/A
	Minimum–Maximum	84–249	N/A
	Median	127	N/A
Fluoroscopy time for subjects without concomitant arrhythmias ablated (minutes)	N	108	109
	Mean ± SD	14 ± 15	17 ± 10
	Minimum–Maximum	0–83	2–46
	Median	10	15
Fluoroscopy time for subjects with concomitant arrhythmias ablated (minutes)	N	3	0
	Mean ± SD	53 ± 65	N/A
	Minimum–Maximum	11–127	N/A
	Median	20	N/A
Total number of RF applications per patient	N	111	108
	RF applications per patient	12.4	13.6
Cumulative RF time per patient (seconds)	N	110	108
	Mean ± SD	1170 ± 976	1199 ± 842
	Minimum–Maximum	180–4739	159–4452
	Median	856	992
Change in frequency of arrhythmia-related symptoms (3 months-baseline)	N	106	104
	Mean ± SD	-6.9 ± 7.4	-7.8 ± 7.4
	Minimum, Maximum	-25, 15	-35, 11
	Median	-5	-6
Change in severity of arrhythmia-related symptoms (3 months-baseline)	N	106	104
	Mean ± SD	-5.3 ± 6.8	-5.9 ± 6.2
	Minimum, Maximum	-28, 11	-26, 7
	Median	-4	-4.5

Study Conclusion

The clinical study met its predefined success criterion by meeting both primary safety and effectiveness endpoints. There were no device related complications in the Investigational group. The vast majority of the subjects in whom Acute Success was obtained using the Blazer Open-Irrigated Ablation Catheter were free of type I atrial flutter recurrence during 3-month follow-up. The study results support a reasonable assurance of safety and effectiveness of this Blazer OI Catheter when used in accordance with the Indications for Use.

ZERO AF

Boston Scientific conducted a clinical study (ZERO AF) to establish a reasonable assurance of safety and effectiveness of radiofrequency cardiac ablation using the Blazer OI Catheter in the treatment of paroxysmal atrial fibrillation (PAF). The clinical study was conducted using a surrogate system consisting of the Stockert™ 70 Radiofrequency Generator and the CoolFlow™ Irrigation Pump and Tubing Set. However, on the basis of the engineering testing and animal studies, the results of the ZERO AF study may be extrapolated to the use of Blazer OI Catheter with the Maestro RF Generator and MetriQ™ Pump. These data from the clinical study are summarized below.

Objective

A multi-center clinical study was conducted using the Blazer OI Catheter. The purpose of the clinical study was to demonstrate that the Blazer Open-Irrigated Investigational Catheter is non-inferior to that of the Control catheters when used for the treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation in patients age 18 or older.

Study Design

The ZERO AF study was a prospective, 1:1 randomized, single-blinded, multi-center, controlled global investigation conducted at 39 Investigational sites (26 sites in US, 13 sites in OUS (Outside the United States)). Subjects randomized to the Investigational arm received ablation therapy with the Investigational Blazer Open-Irrigated Ablation Catheter along with the St. Jude Medical EnSite™ NavX, EnSite Velocity Cardiac, or Boston Scientific Rhythmia Mapping System. The Control devices used in the study are the Biosense Webster ThermoCool™ SF NAV, NaviStar ThermoCool™ and EZ Steer ThermoCool™ NAV Ablation Catheters, hereafter referred to collectively as ThermoCool Catheters, and the CARTO™ Imaging System (Biosense Webster, Inc.). A commercially available radiofrequency generator (Stockert 70/EP-Shuttle), CoolFlow Irrigation Pump and the CoolFlow Tubing Kit were used in the study.

Subjects were enrolled between November 1, 2012 and August 26, 2015. The last Twelve-Month follow-up took place on October 13, 2016 and the study is considered complete. The database for this PMA reflected data collected through 12 months follow-up and included 398 patients.

All adverse events and deaths reported in this study were reviewed and adjudicated by a Clinical Events Committee (CEC). The CEC was comprised of independent physicians, and its decisions were based upon independent physician review of data.

Subject in-and Exclusion Criteria

The study's inclusion and exclusion criteria are summarized below.

Subjects were included in the study if they met all the inclusion criteria listed below:

- History of recurrent symptomatic PAF* with ≥ 2 episodes reported within the 365 days prior to enrollment
- At least 1 episode of PAF documented by Holter monitor, rhythm strip, Trans-telephonic Monitor (TTM), or 12-lead ECG in the 365 days prior to enrollment
- Refractory or intolerant to at least one Beta Blocker, Calcium Channel Blocker, Class I OR Class III Anti-arrhythmic Drug (AAD)
- Age 18 or above, or of legal age to give informed consent specific to state and national law
- Competent and willing to provide written informed consent to participate in the study and agree to comply with follow-up visits and evaluation

*Definition of PAF is AF episodes that last ≥ 30 seconds in duration and terminate within seven days. Clinical symptoms associated with PAF may include, but are not limited to, palpitations, syncope, light-headedness, chest pain/tightness, shortness of breath, and extreme fatigue.

Subjects were ineligible to participate if they met one of the exclusion criteria listed below:

- Have any of the following heart conditions within 90 days prior to enrollment:
  - New York Heart Association (NYHA) Class III or IV
  - Left Ventricular Ejection Fraction (LVEF) < 35 %
  - Left Atrial (LA) diameter > 5.5 cm
  - Unstable angina or ongoing myocardial ischemia
  - Transmural myocardial infarction
- Congenital structural heart disease that increases the risk of ablation or precludes catheter placement
- Undergone any left atrial catheter or surgical ablation
- Have had a coronary intervention, cardiac surgery, or other cardiac ablation within 90 days prior to enrollment
- Had > 1 Atrial Fibrillation (AF) episode lasting greater than seven days, with no episodes having lasted greater than 30 days, within the past year
- Subjects regularly prescribed amiodarone therapy during the 120 days prior to enrollment
- Contraindication to anticoagulation therapy
- Creatinine > 2.5 mg/dL or creatinine clearance < 30 mL/min within 90 days prior to enrollment
- Prosthetic mitral or tricuspid heart valves
- Confirmed cardiac thrombus within 30 days prior to enrollment
- Implanted pacemaker, ICD, or CRT leads within 180 days prior to enrollment
- History of CVA, TIA or PE within 180 days prior to enrollment
- Left atrial appendage closure device
- Any other significant uncontrolled or unstable medical condition (e.g., sepsis, acute metabolic illness, end stage COPD)
- Enrolled in any concurrent clinical trial without documented pre-approval from BSC
- Women who are pregnant or plan to become pregnant within the course of their participation in the investigation
- Life expectancy ≤ 2 years (730 days) per physician opinion

Follow-up Schedule

All patients were scheduled to return for follow-up examinations at pre-discharge, one month, two months, three months, six months and 12 months post-procedure. Adverse events and complications were recorded at all visits. Table 12 lists the protocol-required baseline, procedural, and follow-up assessments.

Table 12: Data Collection Schedule

Procedure/Assessment	Enrollment	Index Procedure (<60 d PE)	Blanking Period			Repeat Procedure	Effectiveness Evaluation Period			
			Pre-Discharge (5–72 h Post-IP)	1-Mo (±7 d) FU	2-Mo (±7 d) Phone Check	Repeat (≤90 d Post-IP)	Additional FU	3-Mo (±14 d) FU	6-Mo (±14 d) FU	12-Mo (±21 d) FU
Informed Consent Process	X	--	--	--	--	--	--	--	--	--
Eligibility Criteria	X	--	--	--	--	--	--	--	--	--
Subject Demographics	X	--	--	--	--	--	--	--	--	--
Medical History	X	--	--	--	--	--	--	--	--	--
Physical Assessment	X	--	X	X	--	--	--	--	--	X
Quality of Life (SF36v2.0)	X	--	--	--	--	--	--	--	X	X
NIH Stroke Scale	X	--	X	--	--	X (2)	--	--	--	X
PV Sub-Study Cardiac CT/MRI	X[i]	--	--	--	--	--	--	X[i]		--
Non-Sub-Study PV Visualization		X		X[vi]	X[vi]	X	X[vi]	X[vi]	X[vi]	X[vi]
Neurology Consultation	--	--	X[iv]			X[iv]				X[iv]
Brain MRI Scan[v]	--	--	X[v]	--	--	X[v]	--	--	--	X[v]
TTE	X[ii]	--	--	--	--	--	--	--	--	--
TEE	X[ii]	X[iii]	--	--	--	--	--	--	--	--
Procedural Data	--	X	--	--	--	X	--	--	--	--
12-Lead ECG	--	--	X	X	--	--	X	X	X	X
Holter Monitor (24 h)	--	--	--	--	--	--	--	--	X	X
Event Monitor (TTM)	--	--	X	X	X	--	X	X	X	X
Medications	X	X	X	X	X	X	X	X	X	X
Adverse Events	--	X	X	X	X	X	X	X	X	X
Protocol Deviations	X	X	X	X	X	X	X	X	X	X

X = Required; -- = Not required
Abbreviations: d = Day(s), h = Hour(s), PE = Post-enrollment, IP = Index Procedure, NIH = National Institutes of Health, ECG = Electrocardiogram, TTM = Trans-telephonic Monitor, Mo = Month, TTE = Trans-thoracic Echocardiogram, TEE = Transesophageal Echocardiogram, CT = Computed Tomography, MRI = Magnetic Resonance Imaging, SF = Short Form, FU = Follow-up, PV = Pulmonary Vein
i = Only required if part of PV imaging sub-study
ii = Either TTE or TEE only required if data not available within 6 months prior to enrollment
iii = Only required if anticoagulation requirements are not met, if subject's CHADS2 score is ≥ 1,or subject's left atrium is enlarged (≥ 4.5 cm)
iv = Neurology consult is only required if NIH scale worsens from the previous assessment
v = Brain MRI scan preferred, CT accepted if MRI not available. Only required if neurology consultation determines possibility of new stroke.
vi = Cardiac CT/MRI scan will be required for all subjects if PV stenosis is suspected at any time throughout the follow-up period

Study Endpoints

Primary Safety Endpoint

The safety of the Blazer™ Open-Irrigated Ablation Catheter was evaluated by demonstrating that the Investigational group Primary Safety Endpoint event rate is non-inferior to that of the Control group. Primary Safety Endpoint events were defined as any of the following:

- Procedure-related Serious Adverse Events (SAEs) at seven days post-index procedure or hospital discharge, whichever is later
- Significant pulmonary vein stenosis (≥ 70 % reduction in diameter from baseline) occurred within 12 months of the index procedure
- Atrio-esophageal fistulas that occurred within 12 months of the index procedure

All adverse events were adjudicated by an independent committee of physicians as to their severity and relationship to the Investigational and Control Catheters and/or procedure.

Primary Effectiveness Endpoint

The effectiveness of the Blazer Open-Irrigated Ablation Catheter was evaluated by demonstrating that the proportion of subjects free from failure in the Investigational group is non-inferior to those in the Control group at 12 months after the index ablation procedure. Failure was defined as a Randomized subject being an acute procedure failure, having more than one repeat procedure during the Blanking Period, having a repeat procedure outside the Blanking Period, or having any of the following between 91 days and 12 months post-procedure:

- A documented symptomatic AF, AT, or AFL (≥ 30 seconds in duration or from a 10-second 12-lead ECG)
- Prescribed a higher dose of a previously failed AAD*
- Prescribed a new AAD*

*AADs for this endpoint consisted of all Class I/III medications and Class II/IV medications taken explicitly for control of arrhythmia recurrence.

Secondary Effectiveness Endpoint

The Secondary Effectiveness Endpoint of acute procedural success was evaluated by demonstrating that the Investigational group acute procedural success rate is non-inferior to that of the Control group. Acute procedural success was defined as a subject that successfully had all clinically relevant PVs electrically isolated, by demonstration of entrance block at a minimum and no evidence of exit conduction with the Investigational or Control Catheter only.

Each endpoint was analyzed and evaluated for success based on Modified Intention-to-Treat and Per-Protocol (PP) subject cohorts. The mITT analysis included all Randomized Treatment subjects in their Randomized group, regardless of compliance to the assigned treatment. The Per-Protocol analysis included subjects who were treated with the Randomized catheter, had complete endpoint data, and had no major protocol violations.

Accountability of PMA Cohort

All subjects who signed the Informed Consent Form were considered enrolled in the study and counted towards the enrollment ceiling. Subjects were classified as either part of the Roll-in cohort or the Randomized cohort:

Roll-in Subject — To help facilitate Investigators' familiarity with the new Investigational system, the first two subjects enrolled by the first two Investigators assigned could be classified as "Roll-in" subjects and would not undergo randomization.

Randomized Subject — After the Roll-in subject criteria or case review was satisfied for the treating physician, their subjects were randomized 1:1 to either the Investigational or Control arm of the study. Randomization was stratified by Investigational site. Study subjects were not informed of their randomization assignment. Subjects could be informed of their randomization assignment at the end of the Twelve-Month follow-up visit upon request. Subjects were further classified as Intent, Attempt, and Treatment as described below.

Intent — Refers to a subject who was enrolled but withdrew from the study and did not undergo the protocol-required ablation procedure.

Attempt — Refers to a subject who was enrolled and had anesthesia or sedation administered in preparation for the ablation procedure but did not receive ablation therapy with the Investigational or Control Catheter Per-Protocol.

Treatment — Refers to all enrolled subjects who received ablation therapy with the Investigational or Control Catheter.

Table 13 shows the subject disposition for all Roll-in and Randomized subjects. Data from Roll-in subjects are not included in endpoint analyses.

Table 13: Subject Disposition and Accountability for Endpoint Analysis

	Control	Investigational	Total
Enrolled subjects			398
Roll-in Cohort	3	56	59
Randomized Cohort	172	167	339
Intents	5	8	13
Adverse event	0	1	1
Did not meet eligibility criteria	2	2	4
Investigator discretion	1	1	2
Lost to follow-up	0	1	1
No longer meets protocol criteria	1	2	3
No product available	1	0	1
Withdrew from study participation	0	1	1
Attempts	3	2	5
Treatment Subjects (Eligible for Endpoint Analysis)	164	157	321
12-month follow-up visit completed	145	139	284
12-month follow-up visit not completed	19	18	37
Death	1	1	2
Withdrawals	16	16	32
Missed 12-month follow-up	2	1	3
Endpoint Accountability for Randomized Treatment Subjects (N = 321)			
Primary Safety Endpoint and Secondary Effectiveness Endpoint			
Modified Intention-to-Treat	164	157	321
Per-Protocol	160	157	317
Excluded due to randomization error*	4	0	4
Primary Effectiveness Endpoint			
Modified Intention-to-Treat	164	157	321
Complete Data	152	146	298
Imputed Data	12	11	23
Per-Protocol	148	146	294
Excluded due to randomization error*	4	0	4
Excluded due to incomplete follow-up endpoint event (includes death, withdrawal, and missed visit with no TTM in window)	12	11	23

*Four subjects randomized to the Control group were treated with the Investigational Catheter.

There were 42 Treatment subjects (35 Randomized and 7 Roll-in) that withdrew from the study. A summary of withdrawal reasons for these subjects is included in Table 14.

Table 14: Treatment Subjects Withdrawal Summary

Reason for Withdrawal	Control N (%)	Investigational N (%)
Adverse event	1 (5.6)	1 (4.2)
Investigator discretion	1 (5.6)	2 (8.3)
Lost to follow-up	5 (27.8)	2 (8.3)
No longer meets protocol criteria	3 (16.7)	0 (0)
Study device change/revision	2 (11.1)	5 (20.8)
Withdrew from study participation	4 (22.2)	12 (50)
Other	2 (11.1)	2 (8.3)
Total	**18**	**24**

Study Population Demographics and Baseline Parameters

The tables in this section include data from all Randomized subjects (N = 339).

The average age of the subjects is 59 ± 10 years for the Control group and 60 ± 11 years for the Investigational group. For both Treatment groups, the majority of subjects were male; the Control group had 107 male subjects (62 %) and the Investigational group had 105 male subjects (63 %). The male gender predominance is consistent with previous clinical studies for RF ablation of PAF. The majority of subjects for both Treatment groups were evaluated as non-heart failure; the Control group with 92 subjects (53.5 %) and the Investigational group with 76 subjects (45.5 %).

Overall, there were no significant imbalances in baseline characteristics between the two Treatment groups. Table 15 presents the demographics and physical assessment data for all Randomized patients.

Table 15: Baseline Characteristics

Characteristic	Measurement	Control (N = 172)	Investigational (N = 167)	P-Value
Age at index procedure (years)	N	172	167	
	Mean ± SD	59 ± 10	60 ± 11	0.32
	Range	31–82	22–84	
Gender [N (%)]	Female	65 (38)	62 (37)	0.9
	Male	107 (62)	105 (63)	
Height (cm)	N	169	165	
	Mean ± SD	174 ± 9	173 ± 9	0.5
	Range	150–200	150–193	
Weight (kg)	N	169	165	
	Mean ± SD	90 ± 22	89 ± 19	0.55
	Range	53–218	46–167	
Resting heart rate (bpm)	N	169	164	
	Mean ± SD	67 ± 15	71 ± 19	0.08
	Range	39–130	43–156	
Resting systolic BP (mmHg)	N	169	164	
	Mean ± SD	130 ± 20	131 ± 16	0.7
	Range	90–191	96–171	
Resting diastolic BP (mmHg)	N	169	164	
	Mean ± SD	76 ± 11	77 ± 11	0.38
	Range	48–110	50–116	
Creatinine (mg/dL)	N	166	161	
	Mean ± SD	0.9 ± 0.2	0.9 ± 0.2	0.42
	Range	0.4–1.5	0.5–2.5	
NYHA class	I	64 (37.2)	67 (40.1)	0.3
	II	13 (7.6)	17 (10.2)	
	Non HF	92 (53.5)	76 (45.5)	
	Not Assessed	3 (1.7)	7 (4.2)	
Left atrial diameter (cm)	N	165	162	
	Mean ± SD	3.97 ± 0.65	3.96 ± 0.65	0.86
	Range	2.30–5.50	2.30–5.50	
LVEF (%)	N	164	161	
	Mean ± SD	60.4 ± 7.4	60.2 ± 7.2	0.76
	Range	38.0–86.0	35.0–84.0	

Pre-existing conditions and arrhythmia/conduction disorder history of Randomized subjects are summarized in Table 16 and Table 17.

Table 16: Pre-existing Conditions Recorded at Baseline

Characteristic	Category	Control (N = 172)	Investigational (N = 167)	P-Value
Cardiac/cardiovascular disease history	Dilated cardiomyopathy [N (%)]	0 (0)	3 (1.8)	0.08
	Hypertrophic cardiomyopathy [N (%)]	4 (2.3)	2 (1.2)	0.43
	Ischemic cardiomyopathy [N (%)]	3 (1.7)	5 (3.0)	0.45
	Non-ischemic cardiomyopathy [N (%)]	1 (0.6)	6 (3.6)	0.05
	Cerebral vascular disease [N (%)]	3 (1.7)	2 (1.2)	0.68
	Congestive Heart Failure (CHF) [N (%)]	5 (2.9)	8 (4.8)	0.37
	Coronary artery disease [N (%)]	21 (12.2)	18 (10.8)	0.68
	Hypertension [N (%)]	84 (48.8)	98 (58.7)	0.07
	Myocardial infarction [N (%)]	1 (0.6)	6 (3.6)	0.05
	Peripheral vascular disease [N (%)]	2 (1.2)	4 (2.4)	0.39
	Pulmonary hypertension [N (%)]	1 (0.6)	2 (1.2)	0.54
	Aortic valvular disease [N (%)]	1 (0.6)	5 (3.0)	0.09
	Mitral valvular disease [N (%)]	7 (4.1)	7 (4.2)	0.96
	Pulmonic valvular disease [N (%)]	1 (0.6)	3 (1.8)	0.3
	Tricuspid valvular disease [N (%)]	3 (1.7)	5 (3.0)	0.45
	Other cardiac disease history* [N (%)]	9 (5.2)	5 (3.0)	0.3
Cardiac intervention/ surgery history	Aneurysmectomy [N (%)]	0 (0)	2 (1.2)	0.15
	Angiography/ angioplasty [N (%)]	5 (2.9)	8 (4.8)	0.37
	Stent [N (%)]	8 (4.7)	10 (6.0)	0.58
	CABG [N (%)]	3 (1.7)	5 (3.0)	0.45
	Device implant (CRT) [N (%)]	0 (0)	2 (1.2)	0.15
	Device implant (ICD) [N (%)]	1 (0.6)	3 (1.8)	0.3
	Pacemaker implant [N (%)]	3 (1.7)	8 (4.8)	0.11
	Heart valve repair/ replacement [N (%)]	0 (0)	2 (1.2)	0.15
	Other cardiac intervention/ surgery** [N (%)]	5 (2.9)	6 (3.6)	0.72
Significant non-cardiovascular disease history	COPD [N (%)]	10 (5.8)	5 (3.0)	0.21
	Type I diabetes [N (%)]	4 (2.3)	1 (0.6)	0.19
	Type II diabetes [N (%)]	18 (10.5)	18 (10.8)	0.93
	Hepatic disease [N (%)]	1 (0.6)	1 (0.6)	0.98
	Neurologic disease [N (%)]	4 (2.3)	5 (3.0)	0.7
	Renal disease [N (%)]	6 (3.5)	4 (2.4)	0.55
	GI bleed or other coagulopathies [N (%)]	2 (1.2)	4 (2.4)	0.39
	Hyperlipidemia [N (%)]	69 (40.1)	64 (38.3)	0.74
	Sleep apnea [N (%)]	27 (15.7)	23 (13.8)	0.62
	Other non-cardiovascular disease*** [N (%)]	44 (25.6)	47 (28.1)	0.59

*Other Cardiac Disease History: Aortic Atheroma, Diastolic Dysfunction, ST Abnormality, Left Ventricular Hypertrophy, Scleroderma, Syncope, Atypical chest pain, Diastolic Dysfunction, Idiopathic Pulmonary Embolism, Aortic Stenosis, Pericarditis

**Other Cardiac Intervention/Surgery History: Cardiac Ablation, Loop recorder implantation, Cardioversion, Left brachial embolectomy

***Other Non-Cardiovascular Disease History: Allergy, Anemia, Anxiety, Cancer, Dermatological issues, Dyslipidemia, Gastrointestinal, Gynaecological Diseases, Hypercholesterolemia, Hyperglycemia, Hyperuricemia, Hypomagnesium, Hypotension, Hypothyroidism, Medication intolerances, Musculoskeletal Diseases, Neurological Diseases, Obesity, Ophthalmological Diseases, Pulmonary Diseases, Rheumatological Diseases, Sleeping Disorders

Table 17: Arrhythmia/Conduction Disorder History

Characteristic	Category	Control (N = 172)	Investigational (N = 167)	P-Value
Arrhythmia and conduction disorder history	1st degree AV block [N (%)]	23 (13.4)	24 (14.4)	0.79
	2nd degree AV block (Mobitz 2) [N (%)]	1 (0.6)	0 (0)	0.32
	3rd degree AV block [N (%)]	0 (0)	2 (1.2)	0.15
	Intraventricular conduction delay [N (%)]	12 (7.0)	16 (9.6)	0.38
	Left bundle branch block [N (%)]	2 (1.2)	1 (0.6)	0.58
	Right bundle branch block [N (%)]	3 (1.7)	12 (7.2)	0.01
	Other conduction disorder* [N (%)]	25 (14.5)	27 (16.2)	0.68
	Atrial flutter [N (%)]	45 (26.2)	42 (25.1)	0.83

*Other Conduction Disorder History: Atrial Tachycardia, Atrioventricular Nodal Reentry Tachycardia (AVNRT), Cardiac Arrest, Junctional Tachycardia, Low Voltage QRS, Mild ST/T changes, Non-sustained Ventricular Tachycardia, Premature Atrial Contractions, Premature Ventricular Contractions, Sick Sinus Syndrome, Sinus Bradycardia, Sinus Tachycardia, Supraventricular Ectopic Beat, Supraventricular Tachycardia, Syncope, Tachy-Brady Syndrome, Variable AV Block, Ventricular Fibrillation, Ventricular Tachycardia, Wolff Parkinson White Syndrome

Procedural Data

The tables in this section include data from all Randomized Treatment subjects (N = 321).

The goal of the ablation procedure was electrical isolation of all clinically relevant pulmonary veins. Use of multiple catheter curves of a single catheter type was allowed in both arms; however, use of only one catheter type was allowed. Once the Control Catheter type was selected by the Investigator and Investigators could not switch to another Control Catheter type. If multiple catheter curves of a single catheter type were required or if a catheter was changed from a uni-directional curve to a bi-directional curve, these were considered same types of catheters and would not affect the outcome determination of acute success.

The largest proportion of the Control cases were completed with the ThermoCool™ SF NAV (42 %) with the rest of the cases closely split between the EZ Steer ThermoCool™ NAV (27.4 %) and the NaviStar ThermoCool™ (28 %). Four Control subjects were incorrectly treated with the Blazer™ Open-Irrigated Ablation Catheter. For the Investigational group, all index procedures were initiated with the Blazer Open-Irrigated Ablation Catheter. The summary of Control devices used for study procedures is included in Table 18.

Table 18: Catheters Used in the Procedure

Catheter	Control N (%)	Investigational N (%)
Blazer Open-Irrigated	4 (2.4)*	157 (100)
EZ Steer ThermoCool NAV	46 (28)	0 (0.0)
NaviStar ThermoCool	45 (27.4)	0 (0.0)
ThermoCool SF NAV	69 (42.1)	0 (0.0)

*Four subjects were randomized to Control but treated with a Blazer Open-Irrigated Ablation Catheter.

Table 19 includes the procedural data for Randomized Treatment subjects treated with only the Randomized catheter.

Table 19: Ablation Parameters — ONLY Randomized Treatment Catheters Used for Control and Investigational

Procedure Parameter	Measurement	Control	Investigational
RF applications in the PVs	N	153	129
	Mean ± SD	38 ± 25	38 ± 30
Total RF applications for procedure	N	153	129
	Mean ± SD	42 ± 27	41 ± 32
RF time in PVs (minutes)	N	152	129
	Mean ± SD	41 ± 22	37 ± 25
Total RF time for procedure (minutes)	N	152	129
	Mean ± SD	45 ± 25	41 ± 26
Starting power (W)	N	152	129
	Mean ± SD	19 ± 4	19 ± 3
Max power (W)	N	151	128
	Mean ± SD	37 ± 6	36 ± 6
Average power (W)	N	148	125
	Mean ± SD	30 ± 5	30 ± 5
Max temperature (°C)	N	148	125
	Mean ± SD	38 ± 5	36 ± 4
Average temperature (°C)	N	148	125
	Mean ± SD	32 ± 3	31 ± 3
Max impedance (Ω)	N	148	125
	Mean ± SD	178 ± 55	195 ± 45
Average impedance (Ω)	N	148	125
	Mean ± SD	125 ± 21	152 ± 30

Fluids Received During the Procedure

Procedural fluid volumes administered via the open-irrigated catheters were recorded as shown in Table 20. The choice of the Control Catheter used during the procedure was left up to the discretion of the Investigator. Fluid infusion rates were programmed per the manufacturer's instructions for use. As the ThermoCool SF has lower prescribed flow rates than the Investigational Catheter, use of the ThermoCool SF in the study could account for the Investigational Catheter having a higher mean (1.34 ± 0.71 L versus 1.18 ± 0.64 L) total fluid infusion.

Table 20: Fluid Volumes Infused During Ablation Procedure

Fluid Infusion	Measurement	Control	Investigational
Fluid infused from catheter sources (L)	N	162	155
	Mean ± SD	1.18 ± 0.64	1.34 ± 0.71
	Range	0.20–4.00	0.10–3.50

Procedure and Fluoroscopy Duration

Procedure duration for the ZERO AF Study was defined as the time from first catheter inserted to last catheter removed in order to reduce variability in data reported due to procedure preparations and pre-ablation activities. As shown in Table 21, the mean procedure duration and mean fluoroscopy duration was similar for the Control and Investigational groups.

Table 21: Procedure Duration and Fluoroscopy Duration

Procedure Parameter	Measurement	Control	Investigational
Procedure duration (minutes)	N	164	156
	Mean ± SD	162 ± 66	168 ± 63
	Range	62–469	73–401
Fluoroscopy duration (minutes)	N	163	156
	Mean ± SD	25 ± 17	28 ± 18
	Range	0–90	3–85

Ablation Locations for All Randomized Treatment Subjects

Table 22 shows a summary of the number of PVs ablated and the acute success of the Pulmonary Vein Isolation (PVI). For the Investigational group, 141 subjects had four or more PVs ablated with 140 of those cases resulting in all PVs isolated.

Eleven subjects in the Investigational group had three PVs ablated resulting in all PVs isolated.

For 147 subjects in the Control group, four or more PVs were ablated resulting in all PVs isolated. Fifteen subjects in the Control group had three PVs ablated, with all cases achieving acute success for PVI.

Table 22: Pulmonary Vein Isolation

	Control		Investigational	
PV Locations Ablated	Ablated	Acute PVI Success	Ablated	Acute PVI Success
4+ PV Locations	147	147	141	140
3 PV Locations	15	15	11	11
2 PV Locations	2	1	4	4
1 PV Location	0	0	1	0

The majority of the Randomized subjects in the study underwent only ablation of the PVs (N = 197) with 98 such cases in the Control group and 99 cases in the Investigational group. For the next two largest categories of procedure, 57 subjects (30 Control, 27 Investigational) underwent pulmonary vein isolation and ablation of the cavo-tricuspid isthmus and 46 subjects (25 Control, 21 Investigational) underwent PV ablation and additional non-PV Foci in the right or left atria. Table 23 shows the full breakdown for all Randomized subjects by assigned group.

Table 23: Ablation Locations for All Randomized Subjects

Ablation Locations	Control N (%)	Investigational N (%)
PV Only	98 (59.8)	99 (63.1)
PV + CTI	30 (18.3)	27 (17.2)
PV + RA/LA	24 (14.6)	20 (12.7)
PV + Additional Induced	0 (0.0)	4 (2.5)
PV + CTI + RA/LA	11 (6.7)	6 (3.8)
PV + RA/LA + Additional Induced	1 (0.6)	1 (0.6)

Safety and Effectiveness Results

The tables in this section include data from all Randomized Treatment subjects (N = 321).

Primary Safety Endpoint

The objective of the Primary Safety Endpoint was to demonstrate that the proportion of subjects free from Primary Safety events in the Investigational group is non-inferior to that in the Control group. The Primary Safety Endpoint analysis includes all Randomized Treatment subjects (164 Control and 157 Investigational). Based on the Modified Intention-to-Treat analysis, the Primary Safety event-free rate was 90.24 % in the Control group and 89.17 % in the Investigational group. The difference in the rates between the Control and the Investigational groups was 1.07 %. The upper 95 % confidence bound of 6.93 % was less than the non-inferiority margin of 9 %, demonstrating non-inferiority between the two groups.

The results of the Primary Safety Endpoint are shown in Table 24. The Primary Safety Endpoint results were consistent between the two analysis cohorts (mITT and PP) and support the safety of the Blazer Open-Irrigated Ablation Catheter for the treatment of PAF.

Table 24: Primary Safety Endpoint Results

Endpoint	Analysis	Study Group	Successful Procedures	Total Procedures	% Success	Difference (One-Sided Upper 95 % Bound)	Endpoint Result
Primary Safety Endpoint Non-Inferiority Margin: 9 %	mITT	Control	148	164	90.24 %	1.07 % (6.93 %)	Pass
		Investigational	140	157	89.17 %		
	PP	Control	145	160	90.63 %	1.45 % (7.35 %)	Pass
		Investigational	140	157	89.17 %		

Of the 321 Randomized Treatment subjects, 33 subjects (16 Control and 17 Investigational) had Safety Endpoint events as detailed in Table 25.

Table 25: Primary Safety Endpoint Events by Group

Adverse Event	Control Events (Subjects)	Investigational Events (Subjects)
AV fistula	1 (1)	0 (0)
Arrhythmia (severe bradycardia)	0 (0)	1 (1)
Arterial/venous thromboembolic events	0 (0)	1 (1)
Atypical atrial flutter	1 (1)	0 (0)
Cardiac arrest	0 (0)	1 (1)
Cardiac tamponade/perforation	3 (3)	4 (4)
Dizziness	0 (0)	1 (1)
Dyspnea	1 (1)	0 (0)
Fluid volume overload (i.e., diuresis, electrolyte imbalance) (ablation procedure)	0 (0)	1 (1)
Gastrointestinal	1 (1)	2 (2)
Genitourinary	0 (0)	1 (1)
Head, Eyes, Ears, Nose, Throat (HEENT)	2 (2)	0 (0)
Heart failure/pulmonary edema	0 (0)	2 (2)
Hematoma (ablation procedure)	0 (0)	1 (1)
Hypotension	0 (0)	1 (1)
Multiple symptoms	0 (0)	1 (1)
Myocardial infarction	0 (0)	1 (1)
Pulmonary	4 (4)	3 (3)
Pulmonary vein stenosis—significant (> 70 %)	2 (2)	1 (1)
Rectus sheath hematoma	0 (0)	1 (1)
Sanguineous drainage	1 (1)	0 (0)
Total	**16 (16)**	**23 (17)**

Two Randomized Treatment subjects (one Control subject and one Investigational subject) died during the course of the clinical study. Both deaths were adjudicated by the Clinical Events Committee as not procedure-related.

Adverse Effects That Occurred in the Clinical Study

Adverse effects are defined in Table 26 and reported in Table 27.

Table 26: Definitions of Adverse Effects

Term	Definition
Complication	A clinical complication is a clinical event that required an invasive intervention, injury, or death (e.g., surgical evacuation of a hematoma, lead dislodgment requiring lead repositioning, generator replacement, loss or abandonment of therapy).
Observation	A clinical observation is a clinical event that did not result in invasive intervention, injury, or death, and is not an unanticipated adverse event. Corrective actions were simple adjustments such as reprogramming of the pulse generator or antibiotic treatment of a pocket infection.

Table 27: Ablation Related Adverse Effects

	Control N = 167				Investigational N = 159			
	Complications		Observations		Complications		Observations	
Adverse Event	N Events	N Patients (%)	N Events	N Patients (%)	N Events	N Patients (%)	N Events	N Patients (%)
Ablation Related Events	**13**	**13 (7.8)**	**30**	**21 (12.6)**	**20**	**14 (8.8)**	**48**	**36 (22.6)**
AV fistula	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)
Allergic reaction (ablation procedure)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	1	1 (0.6)
Anesthesia/sedation related complication (ablation procedure)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	3	1 (0.6)
Arrhythmia (ablation procedure)	1	1 (0.6)	1	1 (0.6)	3	3 (1.9)	1	1 (0.6)
Atrial tachycardia	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)
Atypical atrial flutter	1	1 (0.6)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)
Back discomfort	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Breathing difficulties	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)
Cardiac arrest	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)
Cardiac tamponade/ perforation	3	3 (1.8)	0	0 (0.0)	4	4 (2.5)	0	0 (0.0)
Chest pain	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	3	3 (1.9)
Dyspnea on exertion	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)
Edema (ablation procedure)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2	2 (1.3)
Fever	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	1	1 (0.6)
Fluid volume overload (i.e., diuresis, electrolyte imbalance) (ablation procedure)	0	0 (0.0)	0	0 (0.0)	2	2 (1.3)	0	0 (0.0)
Gastroparesis (ablation procedure)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)
Genitourinary	0	0 (0.0)	3	3 (1.8)	2	2 (1.3)	4	3 (1.9)
Groin pain	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)
Heart failure	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)
Hematoma (ablation procedure)	0	0 (0.0)	5	5 (3.0)	1	1 (0.6)	8	7 (4.4)
Hemorrhage (ablation procedure)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	2	2 (1.3)
Hypotension (ablation procedure)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)
Long QT	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)
Multiple symptoms	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)
Non-toxic LLE cellulitis	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)
Pain neuromuscular/non-cardiovascular (ablation procedure)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2	2 (1.3)
Pericardial effusion (ablation procedure)*	1	1 (0.6)	3	3 (1.8)	0	0 (0.0)	5@	5 (3.1)
Pericarditis (ablation procedure)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)
Peripheral neuropathy	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)
Pleuritis (ablation procedure)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)
Pulmonary	2	2 (1.2)	3	3 (1.8)	2	2 (1.3)	1	1 (0.6)
Pulmonary vein stenosis—mild or moderate (< 70 %)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	4	4 (2.5)
Pulmonary vein stenosis—significant (> 70 %)	2	2 (1.2)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)
Rectus sheath hematoma	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)
Sanguineous drainage	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)
Sore throat	0	0 (0.0)	3	3 (1.8)	0	0 (0.0)	0	0 (0.0)
Swollen groin	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	2	2 (1.3)
Tachycardia (ablation procedure)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)
Typical atrial flutter	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	1	1 (0.6)
Vagal denervation symptoms	0	0 (0.0)	1	1 (0.6)	0	0 (0.0)	0	0 (0.0)
Visual blurring/ disturbances (ablation procedure)	0	0 (0.0)	0	0 (0.0)	0	0 (0.0)	1	1 (0.6)

*Non-significant pericardial effusion, no hemodynamic compromise, no action taken

@One subject experienced a perforation/tamponade both reported as an initial primary adverse event and also reported as a pericardial effusion without any intervention 19 days post procedure.

Primary Effectiveness Endpoint

Chronic success was defined as freedom from recurrence of atrial arrhythmias at 12 months post-procedure. Recurrences included being an acute procedure failure, having more than one repeat procedure within 90 days, prescribed a new AAD or higher dose of a previously failed AAD after 90 days, or a documented symptomatic AF, AT, or AFL episode after 90 days. The objective of the Primary Effectiveness Endpoint was to demonstrate that the proportion of subjects with chronic success in the Investigational group was non-inferior to that in the Control group.

The Modified Intention-to-Treat analysis of the Primary Effectiveness Endpoint included all 321 Randomized Treatment subjects (164 Control and 157 Investigational). Subjects that withdrew or died with no primary effectiveness event or met pre-defined criteria for incomplete follow-up data were classified as having incomplete data. Multiple imputation methods were used to determine primary effectiveness endpoint outcomes for these subjects in the mITT analysis. Among the 321 Randomized Treatment subjects, outcomes were imputed for 23 subjects (12 Control and 11 Investigational).

Based on the mITT analysis, the chronic success rate was 65.85 % in the Control group and 64.97 % in the Investigational group. The difference in the chronic success rates between the Control group and the Investigational group was 0.89 %. The upper 95 % confidence bound of 9.54 % was less than the non-inferiority margin of 15 %, demonstrating non-inferiority between the two groups.

The results of the Primary Effectiveness Endpoint are shown in Table 28. The results of the Per-Protocol analyses were consistent with the mITT analysis and support the effectiveness of the Blazer™ OI Catheter for the treatment of PAF.

Table 28: Primary Effectiveness Endpoint Results

Endpoint	Analysis	Study Group	Successful Procedures	Total Procedures	% Success	Difference (One-Sided Upper 95 % Bound)	Endpoint Result
Chronic Success Non-Inferiority Margin: 15 %	mITT	Control	108	164	65.85 %	0.89 % (9.54 %)	Pass
		Investigational	102	157	64.97 %		
	PP	Control	95	148	64.19 %	-0.19 % (8.92 %)	Pass
		Investigational	94	146	64.38 %		

Secondary Effectiveness Endpoint

An acute success was defined as subject that successfully had all clinically relevant PVs electrically isolated, by demonstration of entrance block at a minimum and no evidence of exit conduction with the Investigational or Control Catheter only. The objective of the Secondary Effectiveness Endpoint was to demonstrate that the proportion of subjects with acute success in the Investigational group was non-inferior to that in the Control group.

The Modified Intention-to-Treat analysis of the Secondary Effectiveness Endpoint included all 321 Randomized Treatment subjects (164 Control and 157 Investigational). Based on the Modified Intention-to-Treat analysis, the acute success rate was 89.39 % in the Control group and 98.73 % in the Investigational group. The difference in the acute success rates between the Control group and the Investigational group was 0.66 %. The upper 95 % confidence bound of 4.75 % was less than the non-inferiority margin of 10 %, demonstrating non-inferiority between the two groups.

The results of the Secondary Effectiveness Endpoint are shown in Table 29. The results of the Per-Protocol were consistent with the mITT analysis and support the effectiveness of the Blazer Open-Irrigated Ablation Catheter for the treatment of PAF.

Table 29: Secondary Effectiveness Endpoint Results

Endpoint	Analysis	Study Group	Successful Procedures	Total Procedures	% Success	Difference (One-Sided Upper 95 % Bound)	Endpoint Result
Acute Procedural Success Non-Inferiority Margin: 10 %	mITT	Control	163	164	99.39 %	0.66 % (4.75 %)	Pass
		Investigational	155	157	98.73 %		
	PP	Control	159	160	99.38 %	0.65 % (4.78 %)	Pass
		Investigational	155	157	98.73 %		

Study Conclusion

All Primary and Secondary Endpoints for the ZERO AF study were met. The study results indicate that the overall safety and effectiveness profile of the Blazer Open-Irrigated Catheters is similar to that of the Control catheters for the treatment of drug refractory, symptomatic paroxysmal atrial fibrillation. Taken together, the study results support a reasonable assurance of safety and effectiveness of the Blazer OI Catheter when used in accordance with the Indications for Use.

HOW SUPPLIED

The IntellaNav MiFi™ OI Catheter is supplied sterile using an Ethylene Oxide (EO) process. Peel-off labels for device and accessories can be used for device traceability. In addition to the IntellaNav MiFi OI Catheter, please refer to the Materials Required section below for a detailed list of other materials typically required in an Electrophysiology (EP) procedure.

- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.
- Do not use the device if past the "Use By" date.

Handling and Storage

Operating Environment

- Ambient Temperature: 10 °C to 40 °C
- Relative Humidity: 30 % to 75 %
- Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

- Temperature: -29 °C to 60 °C
- Relative Humidity: Uncontrolled
- Atmospheric Pressure: Uncontrolled

Storage Environment

- Temperature: 15 °C to 30 °C
- Relative Humidity: Uncontrolled
- Atmospheric Pressure: Uncontrolled

MATERIALS REQUIRED

Intracardiac electrophysiology and cardiac ablation procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

In addition to the IntellaNav MiFi OI Catheter, the following materials, devices, and equipment will be required:

- Compatible Connection Box
- Compatible RF Controller and accessories
- Irrigation Pump and accessories
- IntellaNav™ Ablation Catheter Cable
- Irrigation Tubing Set

Accessories:

- Commercially available disposable Dispersive Pads that meet or exceed IEC 60601-1/ IEC 60601-2-2 requirements
- Sterile, normal (0.9 %), heparinized (1 u heparin/mL) saline (commercially available)
- 8F (2.67 mm) or greater Venous Introducer Sheath (8.5F sheath is recommended)

Optional Additional Equipment:

- Compatible Mapping System and accessories

SETUP AND OPERATIONAL INSTRUCTIONS

Caution: Before use, inspect the packaging for any violation of the sterile barrier and inspect the IntellaNav MiFi OI Catheter for any defects. Do not use potentially contaminated or defective equipment.

Please refer to the operator's manuals and Directions for Use (DFUs)/Instructions for Use (IFUs) for the Irrigation Pump, RF Controller, Mapping System, Connection Box, and the Irrigation Tubing Set for instructions on connecting and operating these systems in conjunction with the IntellaNav MiFi OI Catheter. Use the appropriate accessory cables to connect the IntellaNav MiFi OI Catheter to accessory equipment.

1. Attach the Dispersive Pad to the patient and RF Controller.
2. Attach the Location Reference Patch Kit to the patient per the DFU.
3. Connect the patient to an ECG recording system to facilitate arrhythmia monitoring per the standard operating procedure of the electrophysiology lab or manufacturer's operator's manual.

Note: This should be done prior to introducing any intracardiac catheters.

4. Open the IntellaNav MiFi OI Catheter and IntellaNav Cable packages and the Irrigation Tubing Set package. Carefully transfer the package contents into the sterile field, maintaining sterile technique.
5. Obtain vascular access via a vein (e.g., a femoral vein) under aseptic conditions. Then place an introducer sheath into the vein using a standard percutaneous technique.
6. Connect the Connection Box to the RF Controller (and the Mapping System if desired) according to the operator's manuals, DFUs, and/or IFUs.
7. Connect the RF Controller to a recording system (and the Mapping system if desired) with the appropriate interface cables according to the operator's manuals, DFUs, and/or IFUs.
8. Connect the IntellaNav MiFi OI Catheter to the Connection Box using the IntellaNav Ablation Catheter Cable. The end of the IntellaNav Cable with the red band should be inserted into the Connection Box. Ensure that the cable/catheter connection remains dry throughout the procedure. For connection information, refer to the DFU/IFU for additional connection instructions.
9. Turn ON the power to the RF Controller.
10. The RF Controller's default temperature limit is 50 °C, but can be set lower at physician discretion.
11. Turn on the Irrigation Pump.
12. Make sure that the Irrigation Pump has the following flow rates: 2 mL/min (Standby), 17 mL/ min (Low Ablation Flow—30 W or less), 30 mL/min (High Ablation Flow—above 30 W). Refer to the Irrigation Pump operator's manual for instructions on how to adjust the pump settings if required.
13. Refer to either the Irrigation Tubing Set or Irrigation Pump DFU for instructions to connect the Irrigation Tubing Set to irrigation fluid and install into the Irrigation Pump.
14. Connect the IntellaNav MiFi OI Catheter to the Irrigation Tubing Set via the luer fitting at the proximal end of the catheter handle. Care must be taken to ensure all luer fittings are secure to prevent leaking.
15. Purge the IntellaNav MiFi OI Catheter and Irrigation Tubing Set. Fluid should exit all six (6) irrigation ports during the flushing process. Assure that no air remains within the Irrigation Tubing Set or lumen and all irrigation ports are patent.

16. Set the pre-RF delay and post-RF delay on the Irrigation Pump (default is 2 seconds). Reference the Irrigation Pump operator's manual for instructions on how to change the pre-RF delay and post-RF delay (default is 2 seconds).
17. Check the catheter steering by articulating the steering knob prior to inserting the catheter in the sheath.
18. Before placing the IntellaNav MiFi™ OI Catheter in the sheath, begin continuous irrigation at a flow rate of 2 mL/min, i.e., standby flow. Check for any leaks at the tip of the IntellaNav MiFi OI Catheter (other than normal saline flowing out of the distal ports), at the IntellaNav MiFi OI Catheter handle, and at the luer connections and tubing joints.
19. Under fluoroscopic guidance, insert the IntellaNav MiFi OI Catheter into the sheath and advance through the vasculature into the heart.

Note: The degree of tip deflection of the IntellaNav MiFi OI Catheter is controlled by the Steering Knob on the IntellaNav MiFi OI Catheter handle (See Figure 1). If the Steering Knob is turned in a clockwise direction from its neutral position, the tip will curve proportionately in one direction depending upon the curve option selected. Turning the Steering Knob in the counter-clockwise direction will cause the tip to deflect in the opposite direction. To prevent overstressing the tip, the Steering Knob movement is limited by the handle design. The tension adjust knob may be used when the desired catheter placement is achieved.

20. Determine the area of interest for ablation.
21. Set the initial power level to 15 W to 20 W.

Note: Confirm the increased irrigation flow rate prior to onset of RF energy by observation of a decrease in tip electrode temperature of at least a 2 °C. If it is necessary to ablate with power levels of 31 W to 50 W, increase the irrigation flow rate to 30 mL/min before onset of RF delivery then return the flow rate to 2 mL/min post-RF energy delivery.

Warning: Using the IntellaNav MiFi OI Catheter at lower than prescribed flow rates may increase the potential for thrombus, coagulum, and char that may result in embolism.

22. Start the procedure at 15 W to 20 W. Power may be increased by 5 W to 10 W increments as needed to create a transmural lesion. A greater than 80 % reduction in unipolar electrogram amplitude or emergence of double potentials of equal and low amplitude may be indicators of a transmural lesion.

Note: Too rapid an increase in power during ablation, ablating at high power (> 30 W) or insufficient flow rate may lead to perforation caused by steam pop, arrhythmias, damage to adjacent structures, and/or embolism.

23. Do not ablate for greater than 60 seconds in duration without moving the tip of the IntellaNav MiFi OI Catheter.
24. RF energy may be reapplied to the same or alternate sites using the same catheter.

End of Procedure

1. Prior to removing the IntellaNav MiFi OI Catheter, completely straighten the distal end of the catheter.
2. Withdraw the IntellaNav MiFi OI Catheter when the procedure is finished.
3. Turn off the RF Controller and Irrigation Pump.
4. Dispose of the catheter(s) per hospital's biohazard procedures.
5. Carefully monitor patient while in recovery to ensure hemostasis is achieved and any complications are immediately treated.

TROUBLESHOOTING

Problems	Possible Cause	Corrective Action Procedure
Temperature not displayed	Poor catheter/cable connections	1. Verify that the Cable is plugged into the Connection Box, and the IntellaNav MiFi OI Catheter. 2. Verify that the Connection Box is connected to the RF Controller. 3. Replace cable and/or catheter. 4. If the RF Controller still does not display temperature, there may be a malfunction in the temperature sensing system. 5. Consult the operator's manual and correct this malfunction prior to reapplying RF energy.
• Impedance cutoff • Temperature cutoff	Char/coagulum on tip electrode	1. Discontinue RF delivery. 2. Straighten the distal end and withdraw the IntellaNav MiFi OI Catheter. 3. Inspect tip electrode for any char/coagulum. 4. If present, gently wipe the tip section with a sterile gauze dampened with sterile saline (do not scrub or twist the tip electrode as damage to the tip electrode bond may occur and loosen the tip electrode). 5. Prior to reinsertion, ensure the irrigation ports are patent. If irrigation port occlusion occurs: a. Ensure IntellaNav MiFi OI Catheter is removed from the patient. b. Fill a 1 mL or 2 mL syringe with sterile saline and attach to the stop-cock sidearm of the IntellaNav MiFi OI Catheter. c. Carefully inject the saline from the syringe into the IntellaNav MiFi OI Catheter. Fluid should exit all six (6) irrigation ports during the flushing process. d. Repeat steps b and c, if necessary. e. If the irrigation ports are cleared, the IntellaNav MiFi OI Catheter can be reintroduced into the patient. **WARNING**: Do not continue using the IntellaNav MiFi OI Catheter if the irrigation ports are occluded or the catheter is not functioning properly.
Suspected failure of fluid flow integrity	• Leak in catheter and/or Irrigation Tubing Set • Irrigation Pump out of calibration	1. Discontinue RF delivery. 2. Straightening the distal end and withdraw catheter. 3. Replace IntellaNav MiFi OI Catheter and Irrigation tubing set, prime outside of the patient. 4. Replace IntellaNav MiFi OI Catheter and/or Irrigation tubing set if parameters do not appear normal or if there is any abnormality of the integrity of fluid flow. 5. Refer to the Irrigation Pump operator's manual to verify fluid flow is accurate. 6. Contact BSC representative to replace Irrigation pump.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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