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IntellaNav™ ST

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 instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.

DEVICE DESCRIPTION

The IntellaNav™ ST Ablation Catheter (henceforth referred to as the IntellaNav ST Catheter) is a quadripolar ring electrode cardiac ablation catheter. It is designed to allow for therapeutic ablation, intracardiac diagnostic recordings, and pacing capabilities. The IntellaNav ST Catheter does not include the ability to resolve mechanical contact forces.

The electrode segment of the IntellaNav ST Catheter (ST=Small Tip) is comprised of a distal tip electrode and three ring electrodes. The IntellaNav ST Catheter delivers radiofrequency (RF) energy for cardiac ablation through the distal tip electrode which is 4 mm in length and has a 7F (2.33 mm) diameter; the distal tip electrode has an embedded temperature sensor and incorporates a position sensor for magnetic tracking and navigation of the catheter on the Rhythmia Mapping System. The three ring electrodes record the electrogram (EGM) signals for mapping and deliver stimulus for pacing (fig 1).

The IntellaNav ST Catheter has an electrical connector located in the handle which allows the catheter to be connected to the Rhythmia Connection Box using the IntellaNav Ablation Catheter Cable. The Rhythmia Connection Box allows the catheter to interface with standard recording equipment, the Rhythmia Mapping System, and the Maestro Radiofrequency (RF) Cardiac Ablation Controller, (henceforth referred to as the RF Controller) via the Maestro Cardiac Ablation Pod (henceforth referred to as the pod).

RF power is delivered between the catheter's distal tip electrode and a commercially available external dispersive pad. A dispersive pad was tested with the BSC Cardiac Ablation system to meet safety requirements per IEC 60601-1 and IEC 60601-1-2.

User Information

The IntellaNav ST Catheter is to be used by physicians thoroughly trained in invasive cardiology and in the techniques of RF powered catheter mapping and ablation, in the specific approach to be used, and in a fully-equipped electrophysiology lab.

Contents

One (1) sterile IntellaNav ST Catheter

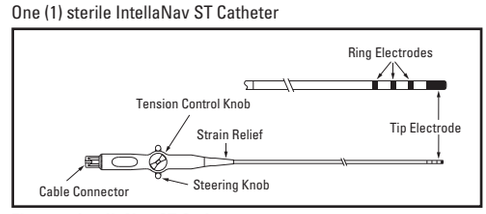

Figure 1. IntellaNav ST Catheter

A summary of the technical specifications for the IntellaNav ST Catheter is provided in Table 1, Technical Specifications.

Table 1. Technical Specifications

Description	Specification
Sterilization EO sterilization Single Use Only	STERILE
Distal torque attributes	High Torque
Handle Design	Similar to the IntellaNav XP Catheter Handle
IntellaNav ST Catheter Usable shaft length	110 cm
IntellaNav ST Catheter Shaft Diameter	7F (2.33 mm)
Distal Tip Electrode Dimensions Diameter x Length	7F (2.33 mm) x 4 mm
Distal Tip Electrode	Compatible with 8F sheath
Curve Configuration Symmetric Only	Standard Large, K2
Electrode Spacing Distal tip to first ring Ring to ring	 2.5 mm 2.5 mm
Electrode Configuration	Quadripolar (4 electrodes)
Ring Electrode Length	1.27 mm
Electrical Connectors	Quick Connect
Maximum Wattage	50 Watts

INTENDED USE / INDICATIONS FOR USE

The IntellaNav ST Catheter, when used with a compatible radiofrequency controller, is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia.

CONTRAINDICATIONS

The IntellaNav ST Catheter is intended to treat patients age 18 or older that have cardiac arrhythmias.

The use of the device is contraindicated in patients:

- with active systemic infection.
- who have had a ventriculotomy or atriotomy within the preceding eight weeks.
- via the transeptal approach in patients with left atrial thrombus of myxoma, or interatrial baffle or patch.
- via the retrograde transaortic approach in patients with aortic valve replacement.
- who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach.

WARNINGS

Before operating the device, read these warnings carefully:

- Peri-procedural anticoagulation therapy is at the discretion of the physician; however, patients with a history of thromboembolic events may require the therapeutic anticoagulation therapy, pre-, during, and post ablation to reduce the incidence of major complications.
- Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should be given to pregnant patients.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to:
  a. Retain temporary external sources of pacing available during ablation
  b. Reprogram the pacing system temporarily to minimum

output or 000 mode to minimize risk of inappropriate pacing.

c. Exercise extreme caution during ablation when in close proximity to atrial or ventricular permanent pacing leads.

d. Perform complete pacing system analysis on all patients after ablation. Implanted cardioverter / defibrillators should be deactivated during delivery of RF power.

- 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 positioned in the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissues.
- Care must be taken to ensure that any equipment used in connection with the BSC catheters be type CF, be defibrillation proof, meet EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.
- Maximum IntellaNav™ ST Catheter Rated Voltage: 178 Vrms (251 Vpk).
- No modification of this equipment is allowed.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
- If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the procedure, there should be a low threshold to perform a transesophageal echocardiogram (TEE) prior to the procedure to confirm absence of thrombus in the left atrial appendage based on an individual patient-centered medical assessment of peri-procedural stroke risk.
- Do not pass the IntellaNav ST Catheter through any prosthetic heart valve (mechanical or tissue), as this may cause entrapment of the catheter and/or damage to the prosthetic heart valve, resulting in valvular insufficiency and/or premature failure of the prosthetic valve.
- Do not deliver RF energy when the tip electrode is withdrawn or partially withdrawn into a sheath, to minimize the risk of char or coagulum formation.
- There are no data to support the safety and effectiveness of this device in the pediatric population.
- 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.

PRECAUTIONS

Observe these precautions, before using the device:

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 ST Catheters are intended for use with the BSC RF Controllers and accessories only.

- Avoid over-torquing the catheter. 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 times the full rotation (540 degrees). 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.
- Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be done under fluoroscopic guidance.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Excessive bending or kinking of the catheter shaft may damage internal wires. Manual pre-bending of the distal curve can damage the steering mechanism and may cause patient injury.
- Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in the techniques of RF powered catheter mapping and ablation in a fully-equipped electrophysiology laboratory.
- The catheter impedance LED display of the RF Controller should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted, power delivery should be discontinued. The catheter should be removed and the distal tip of the catheter cleaned to eliminate any coagulum.
- Adequate signal filtering must be used to allow continuous monitoring of the surface electrocardiograms (ECGs) during RF power applications.
- When using the IntellaNav ST Catheter, it is required that a dispersive pad satisfy the requirements of IEC 60601-1/ IEC 60601-1-2 be used as the ablation return electrodes or skin burns may result.
- Placement of the dispersive pad on the thigh could be associated with higher impedance, which could result in automatic RF power shut-off.
- During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.
- Apparent low power output or failure of the equipment to function correctly at normal settings may indicate faulty application of the dispersive pad or failure of an electrical lead.
- Do not increase power before checking for obvious defects or misapplication.
- Regularly inspect and test re-usable cables and accessories.
- Electromagnetic interference (EMI) produced by the RF Controller during the delivery of RF power may adversely affect the performance of other equipment.
- Equipment/accessories carrying a current at 150-300 kHz alternating current near the catheter cable may cause direct coupled interference and therefore may disrupt the operation of non-BSC RF generators. It may be necessary to take mitigation measures, such as re-orienting, relocating, or shielding the interfering equipment/accessories.

ADVERSE EVENTS

The following potential adverse events (in alphabetical order) may be associated with cardiac catheterization and cardiac ablation procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery. These include but are not limited to:

- Allergic reaction (including anaphylaxis)
- Angina
- Arrhythmias (new or exacerbation of existing arrhythmias)
- Atrioventricular node damage (transient or permanent)
- Cardiac or respiratory arrest
- Catheter entrapment or entanglement
- Chest pain or discomfort
- Complete heart block (transient or permanent)
- Complications of sedative agents (e.g. aspiration pneumonia)
- Death
- Damage to vessel intima or cardia ultrastructures
- Electric shock
- Embolism, venous, arterial (i.e., air, cerebrovascular accident, myocardial infarction, pulmonary embolism)
- Fistula (arterial, venous, or atrio-esophageal)
- Gastroparesis
- Hematoma or ecchymosis
- Hemoptysis
- Hemorrhage
- Hemothorax
- Hypertension
- Hypotension
- Infection
- Myocardial infarction
- Nerve palsy or weakness
- Pain
- Perforation
- Pericardial or pleural effusion
- Pericarditis or pleuritis
- Phrenic or intercostal nerve damage
- Pleurisy
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Radiation exposure
- Sinus or AV node injury
- Skin burn (defibrillator, cardioverter or radiation)
- Stenosis–pulmonary vein
- Stroke or cerebral vascular event
- Tamponade
- Thrombosis
- Transient ischemic attack (TIA)
- Valvular damage
- Vasospasm
- Vasovagal reaction
- Vessel occlusion
- Visual blurring

ELECTROPHYSIOLOGY ENDPOINTS

Target sites are selected based on both the location of the ablation catheters on fluoroscopy and on the characteristics of the intracardiac electrogram recorded from the distal poles of the ablation catheter. The effectiveness of each radiofrequency power application is assessed by recording the surface ECG and intracardiac signals, and by incremental pacing and extra stimulation. These maneuvers provide objective evidence of whether conduction has been blocked in the targeted pathway and whether SVT remains inducible. Specific endpoints for each type of ablation are as follows:

Accessory Pathway

Successful ablation is defined as the complete elimination of conduction over the accessory pathway. This is evident as an abrupt increase in the AV and V-A interval recorded at the target site. This is accompanied by a change in the retrograde activation sequence. In patients with manifest pre-excitations, successful ablation is associated with disappearance of the delta wave from the surface ECG. Patients with successful AV ablation no longer have inducible SVT mediated by the pathway.

AVNRT

There are two techniques for AV nodal modification in patients with typical AVNRT. Lesions made anteriorly, near the apex of the triangle of Koch, selectively affect fast AV nodal pathway functions. Endpoints for fast pathway ablations include and increase in the AH interval and the interval and an increase in the VA block cycle length by at least 50% over baseline.

Lesions made posteriorly, near the ostium of the coronary sinus interfere with slow AV nodal pathway function. Endpoints for slow pathway ablation include the occurrence of junctional ectopy during delivery of RF power as well as changes in AV nodal function. After successful slow pathway ablation, there is often elimination of dual AV nodal physiology. However, in some patients there is attenuation without complete elimination of slow pathway function. These patients have discontinuous AV nodal function curves and sometimes have single AV nodal entrant echo beats after ablation. An endpoint which is sought in all patients after AV nodal modification is the elimination of inducible, sustained AVNRT.

AV Junction Ablation

The occurrence of persistent complete AV block after RF power applications is the endpoint for AV junctional ablation. Complete AV block is readily diagnosed by observation of the surface ECG and/or intracardiac electrograms.

CLINICAL STUDIES

In clinical studies of the SteeroCath-T™ Temperature Ablation Catheter and SteeroCath-A™ Catheter in over 450 patients, the following ablation procedures were performed:

- Accessory Pathway Ablation. Candidates were patients with Wolff-Parkinson-White (WPW) Syndrome or concealed accessory pathways. Successful ablation of accessory pathways was curative.
- AV Nodal Modification. Candidates were patients with AV nodal reentrant tachycardias (AVNRT). Successful AV nodal modifications obviated the need for a pacemaker and were curative.
- AV Junction Ablation. Candidates were patients with atrial fibrillation or flutter. Successful ablation of the AV junction produced third degree atrioventricular (AV) block and necessitated insertion of a permanent ventricular pacemaker.

A total of 462 patients were enrolled in the study. Six patients were excluded from the analysis of efficacy, either because their arrhythmias could not be induced and they were not treated with the device (4 patients), or they did not meet the study inclusion criteria (2 patients).

An intent-to-treat analysis for evaluating effectiveness was based on the 456 patients who met the inclusion criteria. The outcome of the initial procedure was used in the calculation of success, and the use of non-protocol catheters during that initial procedure constituted a failure. Successful ablations were performed in 207 of 257 (81%) of patients with accessory pathways, 116 of 126 (92%) of patients with AVNRT, and 52 of 56

(93%) of patients with a rapid ventricular response to an atrial arrhythmia, for an overall success rate in patients with a single ablation indication of 85% (375/439). For the remaining 17 patients who had two indications for ablation, complete success was obtained in 9 patients (53%), and partial success, that is defined as one successfully ablated target, was observed in 3 patients (18%).

The outcomes from procedures in all 462 enrolled patients were included in the safety analysis, which included 42 repeat ablations after an initial failure or recurrence, and 9 additional ablation procedures in patients who were later identified as having a second ablation indication. A total of 57 complications were reported during these 513 procedures for a complication rate of 11%. Seventeen of the 57 complications were attributed to the ablation catheter.

Five deaths were reported among the patients during follow-up. Pulmonary embolism, secondary to femoral vein thrombosis and endocarditis at the ablation site, contributed to deaths that occurred within two month of the ablation procedure in 2 of the 458 patients (0.44%) .

The following were also noted:

- Clinical data indicated an overall recurrence rate of approximately 10% for patients undergoing successful ablation with the BSC Cardiac Ablation System. Most recurrences were noted in AV Modification procedures and recurrences were rarely noted following AV junction ablation.
- No data were collected to support that the thermistor ablation catheter is more safe and effective than the standard ablation catheter. Although a significant reduction in the incidence of impedance rise was observed during the study when the thermistor catheter was used because the operator could decrease power when measured temperature increased, no benefit to the patient was demonstrated.
- Typical anticoagulation protocols during left-sided procedures in the clinical study included:
  1. initial intravenous heparin injection of 3,000-10,000 units,
  2. maintenance of appropriate heparinization by heparin drop or repeat bolus if necessary, followed by
  3. post-procedural administration of one aspirin per day for a period of one to three months unless contraindicated.
- The average fluoroscopy time was 39.9 +29.9 minutes and ranged from a minimum of 5 minutes to a maximum of 157 minutes.

Table 2 summarizes power delivery and temperature data from the study for the three different types of ablation procedures performed in the clinical trials:

Table 2. Summary of Power Delivery for Accessory Pathway, AV Modification and AV Junction Ablation Procedures

	Number of RF Applications >10 Seconds		Applied Power (Watts)		Duration (Seconds)	
AV Junction:	Range:	1-14	Range:	14-50	Range:	11-120
Ablation	Median:	3	Median:	31.5	Median:	41.9
Total (N=52)						
AV Modification	Range:	1-44	Range:	5-50	Range:	11-120
Total (N=115)	Median:	5	Median:	29.3	Median:	32.3
Accessory Pathway:	Range:	1-34	Range:	3-50	Range:	11-111
Total (N=207)	Median:	3	Mean:	33.2	Median:	29.3

Although no specific protocol was designed to evaluate the use of thermometry, there were no differences observed in safety and effectiveness of the device with or without the thermistor. The following observations were noted:

- Insufficient tissue heating was occasionally associated with either a lack of, or nonpermanent interruption of conduction at the target site. Conversely, high temperatures increased the likelihood of an impedance rise due to coagulum formation on the electrode tip.
- During successful ablations, temperature rose steadily before leveling off at a constant temperature plateau. Operators tended to reduce RF power levels when the measured temperature showed no sign of leveling off as it approached a desired target temperature level. When RF power was not reduced in the presence of an excessively rapid temperature rise, the temperature would typically exceed the targeted temperature.
- When temperature did not increase upon the delivery of RF power, or when the temperature was rather low and irregular, operators typically suspected the catheter tip-to-endocardium contact was unstable. Similarly, sudden temperature drops observed during ablation were interpreted as indicating loss of tissue contact, or a shifted tip position. When these temperature patterns were observed, ablation was stopped, and the catheter was repositioned to improve tip-tissue stability and ensure the intended site was being accessed. RF power delivery was then resumed after repositioning, to avoid ineffective power delivery and/or ablation of unintended regions.

Clinical Data Reported in the Medical Literature

RF ablation catheters for the treatment of cardiac arrhythmias which incorporate temperature sensing capability (Blazer® II Temperature Ablation Catheter) are a mature technology. The biophysics of RF lesion creation which using conventional RF technology is also well characterized and predictable as reported in the medical literature [13-15].

Safety And Effectiveness

There is extensive medical literature reporting the safe and effective use of conventional RF ablation catheters for treating a variety of arrhythmias in addition to those performed in the clinical trials. Table 3 shows data pooled from the medical literature (using various catheters) on three arrhythmias to specifically illustrate different ablation techniques. Literature data for these arrhythmias were chosen to demonstrate the safety and effectiveness of using conventional RF catheters to create either focal or linear lesions in any of the four chambers of the heart. Existing data for the treatment of these three arrhythmias are discussed in more detail below.

Table 3. Technical Specifications

Arrhythmia	N	Acute Success	Chronic Success	Complications	Comments
Atrial Flutter [1,6-8,10,11,16]	1437	72-100%	85-100%	0-6%	Linear lesions across isthmus
Ventricular Tachycardia [10,11,16]	1463	66-85%	86%	2-8%	Right and left ventricles
Atrial Tachycardia [4,16]	494	91%	85%	3%	Right and left atria

Atrial Flutter

Atrial flutter is usually a well defined macro-reentrant circuit with the critical zone defined as the isthmus between the tricuspid valve and the inferior vena cava. Radiofrequency ablation of atrial flutter in this location with the creation of a linear lesion across the tricuspid isthmus has proven to be successful in the majority of patients treated. This technique using RF ablation is becoming a first line therapy for atrial flutter with highly predictable results. In the 1998 North American Society for Pacing and Electrophysiology (NASPE) Prospective Catheter Ablation Registry[16]. 477 patients were treated with RF ablation for atrial flutter. The major complication rate was less than 3% and included bleeding/hematoma (3 patients), cardiac tamponade (1 patient), hemopneumothorax (1 patient), new tricuspid regurgitation (1 patient), hypoxia (1 patient), and hypotension (1 patient).

Ventricular Tachycardia

Patients being treated with RF ablation for ventricular tachycardia (VT) usually have either ischemic VT or "normal heart" VT. Patients with ischemic VT often have multiple comorbidities and have undergone various other treatment modalities, including multiple antiarrhythmic medications. Radiofrequency ablation of VT requires placement of the catheter in either the right or the left ventricle depending on the underlying substrate. Acute and chronic success rates are variable because patients often have multiple VT morphologies, especially in ischemic heart disease patients where the underlying disease substrate is progressive. Radiofrequency ablation procedures for "normal heart" VT are often curative, whereas procedures for ischemic VT are often palliative (i.e., reduces the number of implantable cardioverter defibrillator discharges for ventricular tachycardia episodes). In the 1998 NASPE Prospective Catheter Ablation Registry[16], 299 patients were treated with RF ablation for VT. The major complication rate was 3.8% and included cardiac tamponade (2 patients), respiratory failure (1 patient), sepsis (1 patient), worsening congestive heart failure (2 patients), and pericarditis (1 patient).

Atrial Tachycardia

A third atrial arrhythmia commonly treated with RF ablation is atrial tachycardia (AT). Radiofrequency ablation of AT usually involves creating a local lesion in either the right or left atrium. Electrophysiologic mechanisms of AT include automaticity, triggered automaticity, and reentry. Success rates vary because of the heterogenicity of this arrhythmia. In the 1998 NASPE Prospective Catheter Ablation Registry[16], there were 216 patients that had atrial tachycardia ablations and the major complication rate was 3%. The reported complications were cardiac tamponade (2 patients), transient AV block (1 patient), aspiration pneumonia (1 patient), and right atrial to aortic fistulae (1 patient).

American College of Cardiology/American Heart Association Guidelines

Under the American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for Clinical Electrophysiological and Catheter Ablation Procedures[12], RF ablation is given a Class I indication for the treatment of many tachyarrhythmias.

HOW SUPPLIED

The IntellaNav™ ST Catheter is supplied sterile using an ethylene oxide (EO) process.

Do not use if the package is opened or damaged.

Do not use if labeling is incomplete or illegible.

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

Additional Equipment Required For Safe Use

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. Ancillary materials required to perform cardiac ablation are as follows:

- One (1) IntellaNav Ablation Catheter Cable
- One (1) Rhythmia Connection Box for the IntellaNav Catheter and RF Controller
- One (1) RF Controller with pod
- One (1) 8F (2.67 mm) minimum hemostatic percutaneous catheter introducer or a long introducer sheath
- One (1) dispersive pad meeting IEC 60601-1/60601-1-2 requirements for electrosurgical electrodes

Refer to corresponding manufacturer's user manuals for specific material information.

SETUP AND OPERATION INSPECTION

Prior to Use

Inspection Prior to Use

Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised, or if the contents are damaged, contact your Boston Scientific representative. Check the "Use By" date on the device package. Do not use the device if past the "Use By" date.

Prior to use of the BSC Cardiac Ablation System, the individual components including the IntellaNav™ ST Catheter, the RF Controller, pod, Foot switch, and Rhythmia Connection Box should be carefully examined for damage or defects as should all equipment used in the procedure.

Do not use defective equipment.

Setting up the System

Refer to the RF Controller and accessories operator's manuals, Directions for Use (DFU), or Instructions for Use (IFU) for detailed instructions for connecting the system and setting ablation parameters.

Please refer to the Operator's manuals and Directions for Use (DFUs)/Instructions for Use (IFU) for the Rhythmia Mapping System, RF Controller, and Rhythmia Connection Box for instructions on connecting and operating these systems in conjunction with the IntellaNav ST Catheter. Use the appropriate accessory cables to connect the IntellaNav ST Catheter to accessory equipment.

Attaching the Dispersive Pad

Read the manufacturer's manual before installing the dispersive pad.

1. Place a dispersive pad on the patient on a well-vascularized, convex skin surface that is in close proximity to the ablation site (left upper quadrant of the back is suggested unless the patient's scapula is especially prominent or patient is extremely thin). Other possible locations are the upper arm or left flank area.
2. Avoid scar tissue, bony prominences, adipose tissue or distal areas from the heart (thigh), or any areas where fluid may pool. Shave, clean and dry the application site as needed. Check for wrinkles or folds when applying the pad as these decrease conductivity.
3. Install the dispersive pad connector into the dispersive pad receptacles located on the front panels of the pod.

Figure 2 illustrates the cable configuration for the IntellaNav ST Catheter, Rhythmia Connection Box, RF Controller, and pod.

DIRECTIONS FOR USE

Prior to insertion of the IntellaNav ST Catheter, prepare the entry site according to standard aseptic practices. Size the hemostatic introducer sheath, according to the tip electrode diameter for the cardiac ablation catheter in use.

1. Attach the dispersive pad to the patient and RF Controller per the manufacturer's operator's manual(s).
2. Attach the Rhythmia 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.
4. Open the IntellaNav ST Catheter and IntellaNav Cable packages. 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 Rhythmia Connection Box to the pod (and Rhythmia Mapping System if desired). Refer to Figure 2 and the RF Controller, Rhythmia Connection Box, and Rhythmia Mapping System DFU/IFUs.
7. Connect the RF Controller to a recording system (and the Rhythmia Mapping System if desired) with the appropriate interface cables according to the operators' manuals, DFUs, and/or IFUs.
8. Connect the IntellaNav ST Catheter to the Rhythmia Connection Box using the IntellaNav Ablation Catheter Cable. The end of the IntellaNav Cable with the red band should be inserted into the Rhythmia Connection Box. Refer to Figure 2. Ensure that the cable to catheter connection remains dry throughout the procedure. For connection information, refer to the Rhythmia Connection Box DFU.
9. Turn ON the power to the RF Controller.
10. Ensure the RF Controller recognizes the IntellaNav ST as a standard power catheter and defaults to Temperature Control mode.
11. Check the catheter steering by articulating the steering knob prior to inserting the catheter in the sheath.
12. Under fluoroscopic guidance, insert the IntellaNav ST Catheter into the sheath and advance through the vasculature into the heart.
13. When the ablation site has been accessed and the tip of the catheter is in contact against the endocardial surface, intracardiac electrogram signals may be obtained. Bipolar electrogram signals can be recorded between the distal tip electrode and any ring electrode, or between any two ring electrodes even during RF ablation.
14. Once the arrhythmogenic site has been located, the same catheter can be used therapeutically in the "Ablate" mode to deliver discrete bursts of radiofrequency (RF) power. Radiofrequency power is delivered to the tissue via the distal tip (ablation) electrode which results in thermal necrosis (ablation) of the arrhythmogenic tissue. To begin RF power delivery, press the RF POWER CONTROL Button on the RF Controller's front panel once or hold the Foot switch down. The POWER Display shows the RF power delivered to the IntellaNav ST Catheter (in watts).

Note: If the physician knows that the tip is in a confined space or in a region of unusually low flow such as under a valve leaflet, a lower initial power set point (10-20 watts) should be used. Otherwise, start the ablation at an intermediate RF power level of 20-25 watts, which will facilitate subsequent upward or downward adjustments.

15. During RF delivery, monitor key parameters and adjust therapy delivery accordingly.

END OF PROCEDURE

1. Before removing the catheter, straighten the distal end of the catheter completely.
2. Withdraw the IntellaNav ST Catheter from the vessel.
3. Remove the introducer or long introducer sheath and then follow standard practice for management of the insertion site.

TROUBLESHOOTING

Problem	Possible Cause	Corrective Action Procedure
• Lack of temperature rise	Inadequate contact between electrode and tissue	1. Discontinue RF delivery. 2. Adjust Catheter position to improve contact and stability. 3. Re-initiate RF delivery.
• Low temperature • Fluctuating temperature • Fluctuating power	Electrode not stable on endocardium	1. Discontinue RF delivery. 2. Adjust Catheter position to improve contact and stability. 3. Re-initiate RF delivery.
• Sudden drop in temperature • Sudden rise in power	Loss of contact or shift in electrode position	1. Discontinue RF delivery immediately to prevent ablation of non-targeted tissue. 2. Tip position should be assessed using fluoroscopic and electrogram information. 3. Re-initiate RF delivery.

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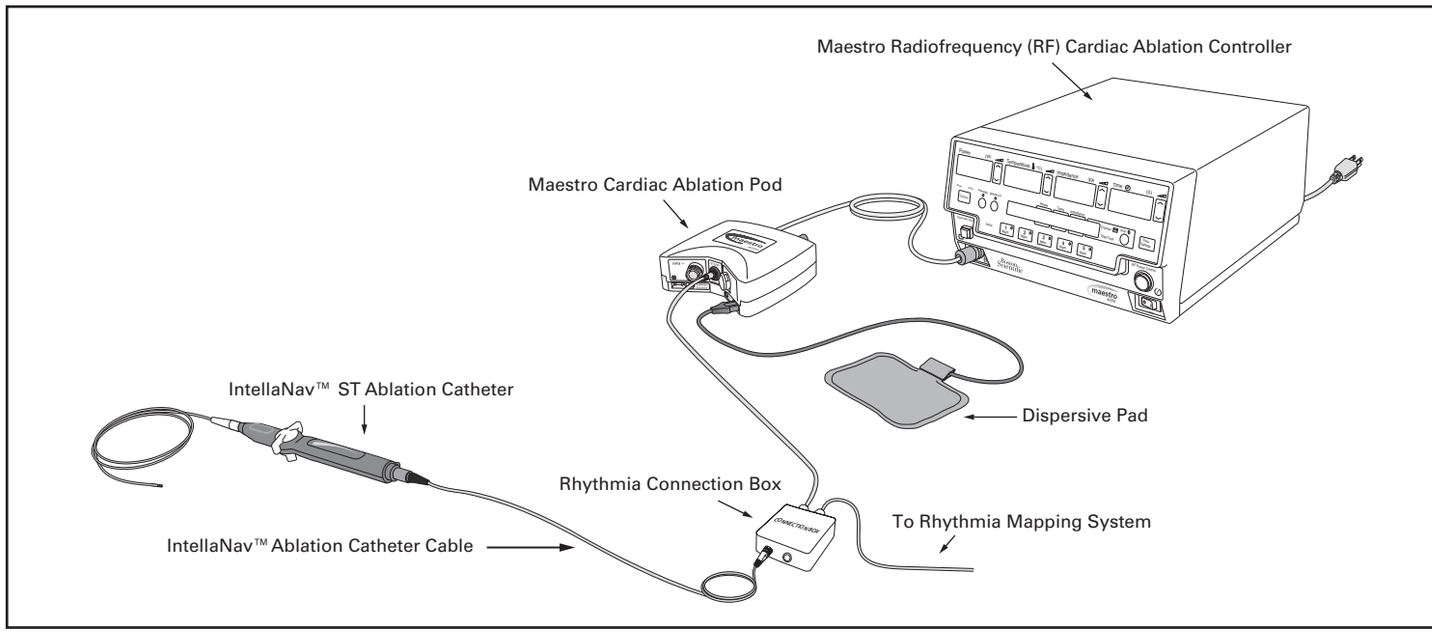

Figure 2. System Connections

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