IntellaNav™ ST
Ablation Catheter

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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

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

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 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 embryonic 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 power.
output or 060 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 if any equipment used in connection with the BSC catheters be type CE, be defibrillation proof, meet EN 60601-1 electrical safety requirements, and comply with all local regulatory requirements for the specified intended use.

• Maximum IntelliNav™ 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 IntelliNav 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 caused by entrapment of the catheter within a prosthetic heart valve (mechanical or tissue), as this may result in damage internal wires. Manual pre-bending of the distal tip of the catheter to perform 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 IntelliNav 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 should 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-power 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)

• Atrialventricular 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 cardiac ultrastructures

• Electric shock

• Embolism, venous, arterial (i.e., aic, cerebrovascular accident, myocardial infarction, pulmonary embolism)

• Fistula (arterial, venous, or atrio-esophageal)

• Gastritis

• Hematoma or ecchymosis

• Hemoptysis

• Hemorrhage

• Hemorrhax

• Hypertension

• Hypothermia

• Infarction

• Myocardial infarction

• Nerve palsy or weakness

• Pain

• Perforation

• Pericardial or pleural effusion

• Pericarditis or pleuritis

• Pheonix or intercostal nerve damage

• Pleurisy

• Pneumothorax

• Pseudoaneumus

• 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

• Vassospasm

• Vasovagal reaction

• Vessel occlusion

• Visual blunting

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-excitation, 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 documented AVNRT. Lesions were made anteriorly or 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 and increase in the AH interval and the interval and an increase in the VA block cycle length by at least 50% over baseline. Ablation 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™ Temperature Ablation Catheter and SteeroCath-ATM 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 642 patients were enrolled in the study. Six patients were excluded from the analysis of efficacy, either because their arrhythmias could not be induced or they were 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 a non-protocol catheter in the 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, 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 antiarrhythmia 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. Clinical Data Reported in the Medical Literature

<table>
<thead>
<tr>
<th>Arhythmia</th>
<th>N</th>
<th>Acute Success</th>
<th>Chronic Success</th>
<th>Complications</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Flutter</td>
<td>1427</td>
<td>72-100%</td>
<td>85-100%</td>
<td>6-0%</td>
<td>Linear lesions across islets</td>
</tr>
<tr>
<td>Ventricular Tachycardia</td>
<td>1463</td>
<td>66-85%</td>
<td>88%</td>
<td>2-6%</td>
<td>Right and left ventricles</td>
</tr>
<tr>
<td>Atrial Tachycardia</td>
<td>494</td>
<td>91-95%</td>
<td>85%</td>
<td>3%</td>
<td>Right and left atria</td>
</tr>
</tbody>
</table>

Table 3. Technical Specifications

<table>
<thead>
<tr>
<th>Arhythmia</th>
<th>N</th>
<th>Acute Success</th>
<th>Chronic Success</th>
<th>Complications</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Flutter</td>
<td>1427</td>
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<tr>
<td>Atrial Tachycardia</td>
<td>494</td>
<td>91-95%</td>
<td>85%</td>
<td>3%</td>
<td>Right and left atria</td>
</tr>
</tbody>
</table>

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 1988 North American Society for Pacing and Electrophysiology (NASPE) Prospective Catheter Ablation Registry®. 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).
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 DFUs/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 Cables. 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

TROUBLESHOOTING

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Corrective Action Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lack of temperature rise</td>
<td>Inadequate contact between electrode and tissue</td>
<td>1. Discontinue RF delivery. 2. Adjust Catheter position to improve contact and stability. 3. Re-initiate RF delivery.</td>
</tr>
<tr>
<td>• Low temperature</td>
<td>Electrode not stable on endocardium</td>
<td>1. Discontinue RF delivery. 2. Adjust Catheter position to improve contact and stability. 3. Re-initiate RF delivery.</td>
</tr>
<tr>
<td>• Fluctuating temperature</td>
<td>Fluctuating power</td>
<td>1. Discontinue RF delivery. 2. Adjust Catheter position to improve contact and stability. 3. Re-initiate RF delivery.</td>
</tr>
<tr>
<td>• Sudden drop in temperature</td>
<td>Loss of contact or shift in electrode position</td>
<td>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.</td>
</tr>
</tbody>
</table>

REFERENCES


8. Tsai CF, et al. Is 8-mm more effective than 4-mm tip electrode catheter for ablation of typical atrial flutter. Circulation 1999; 100:768-771.


17. Black (K). AE. 05.0
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.

Maestro Radiofrequency (RF) Cardiac Ablation Controller

Maestro Cardiac Ablation Pod

IntellaNav™ ST Ablation Catheter

Rhythmia Connection Box

IntellaNav™ Ablation Catheter Cable

Dispersive Pad

To Rhythmia Mapping System

Figure 2. System Connections