Boston Scientific

Advancing science for life™

NAVEGUE
COM CONFIANÇA

Portfólio de Cateteres - aÇnïtiÃos

NAV-Enabled

INTELLAMAP ORION™
MAPPING CATHETER

INTELLANAV MIFI™ OI
ABLATION CATHETER

INTELLANAV™ OI
ABLATION CATHETER

INTELLANAV MIFI™ XP
ABLATION CATHETER

INTELLANAV™ XP
ABLATION CATHETER

INTELLANAV™ ST
ABLATION CATHETER

Sistema de Mapeamento RHYTHMIA HDx

O portfólio dos cateteres nav-enabled da Boston Scientific possui uma tecnologia de navegação magnética garantindo precisão e eficiência.

Todos estes modelos são otimizados para serem utilizados em conjunto com o mapeamento de alta definição, RHYTHMIA HDx™, proporcionando clareza para todos os tipos de complexidades.

Precisão maior que
1mm Durante a navega-ão
UTILIZANDO O SISTEMA DE MAPEAMENTO RHYTHMIA™

8x *ELETRODOS* **MENORES**

Maximiza o contato e minimiza sinais de far field. Maior clareza dos sinais coletados.

0.4 mm² *ELETRODOS PLANOS*

Sinais mais agudos, Melhor qualidade dos sinais para uma localização precisa dos circuitos arritmogênicos.

64 *ELETRODOS* **PLANOS**

Maior coleta de pontos de EGM de forma rápida e eficiente.

Efetividade para as arritmias mais complexas

INTELLAMAP ORION™
MAPPING CATHETER

INTELLAMAP ORION™ MAPPING CATHETER

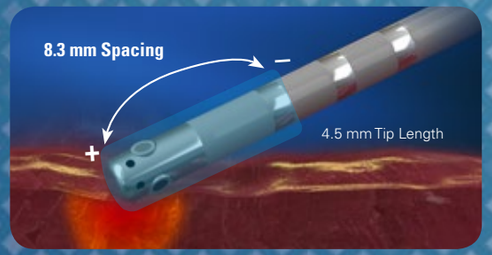
1 mm **Diâmetro** de *Eletrodo*

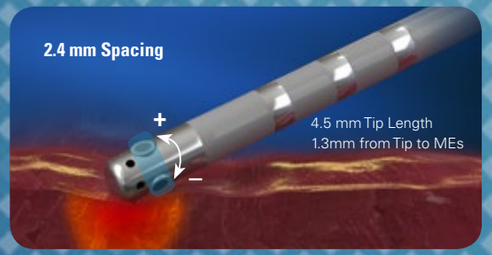
Tecnologia com Mini-eletrodos e resfriamento total da ponta distal.

Os Mini-Eletrodos em conjunto com o Resfriamento total da ponta, oferecem um alto desempenho durante o resfriamento do cateter terap°utico.

INTELLANAV MIFI™ OPEN-IRRIGATED
ABLATION CATHETER

LOCALIZAÇÃO PRECISA





Bipolos Convencionais

- Maior detecção de Far-Fields
- Maior antena de detecção em relação ao local de ablação.
- Limitação de estimular e ablacionar simultaneamente.

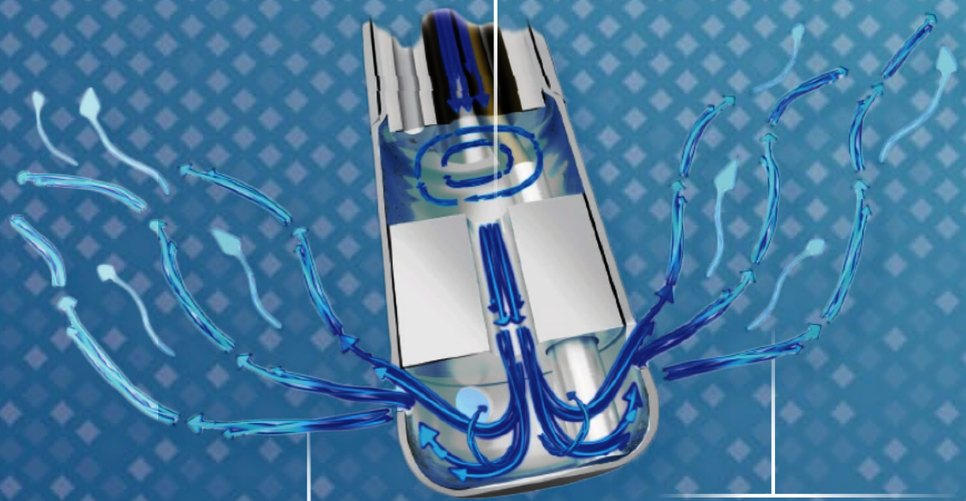
Mini - Eletrodos

- Maior precisão da área de ablação.
- Permite mapear de forma mais precisa os locais alvos de ablação.
- Possibilidade de pace durante a ablação sem distorção dos sinais

Dupla câmara de resfriamento interno e design de saída de fluxo que reduz a formação de coágulos e trombos.

TOTAL TIP COOLING™

RESFRIAMENTO INTERNO



EXCELENTE CAPACIDADE DE RESFRIAMENTO

Resfriamento consistente durante a entrega de energia por RF mais eficiente que os cateteres irrigados convencionais.

Resfriamento ativo durante a saída de fluxo garantindo o resfriamento total da ponta.

Performance de resfriamento
Confiabilidade de Navegação

INTELLANAV™ OPEN-IRRIGATED
ABLATION CATHETER

1 mm *Diâmetro de Eletrodo*

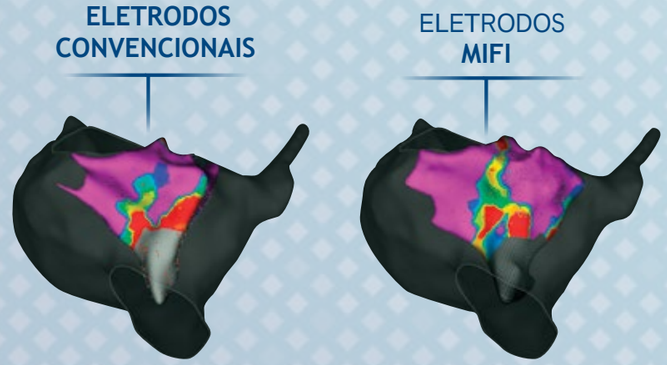
Localização precisa com a maior resolução de sinal de cateteres terapêuticos existente no mercado.

Eficiência em uma ponta de 8mm

Os Mini-Eletrodos auxiliam na efetividade do tratamento

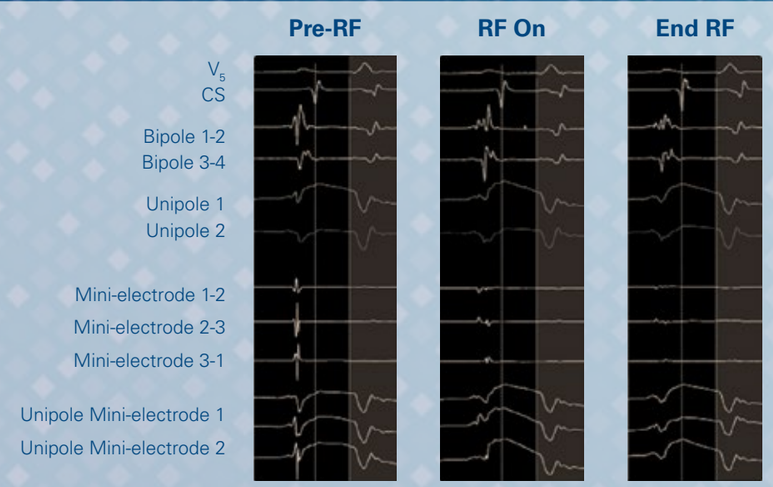
INTELLANAV MIFI™ XP
ABLATION CATHETER

ANÁLISE EFETIVA DO TECIDO



Images courtesy of Kevin Makati, MD. from St. Joseph's Hospital in Tampa, FL.

MAIOR CONTROLE DURANTE A ABLAÇÃO



Os Mini-Eletrodos demonstram uma redução significante da amplitude e uma clareza nos sinais durante a ablação em comparação aos eletrogramas bipolares.

Case images courtesy of W. Jackman, MD. University of Oklahoma Health Sciences Center.

96%

SUCESSO CRÔNICO
REALIZADO EM ESTUDOS.

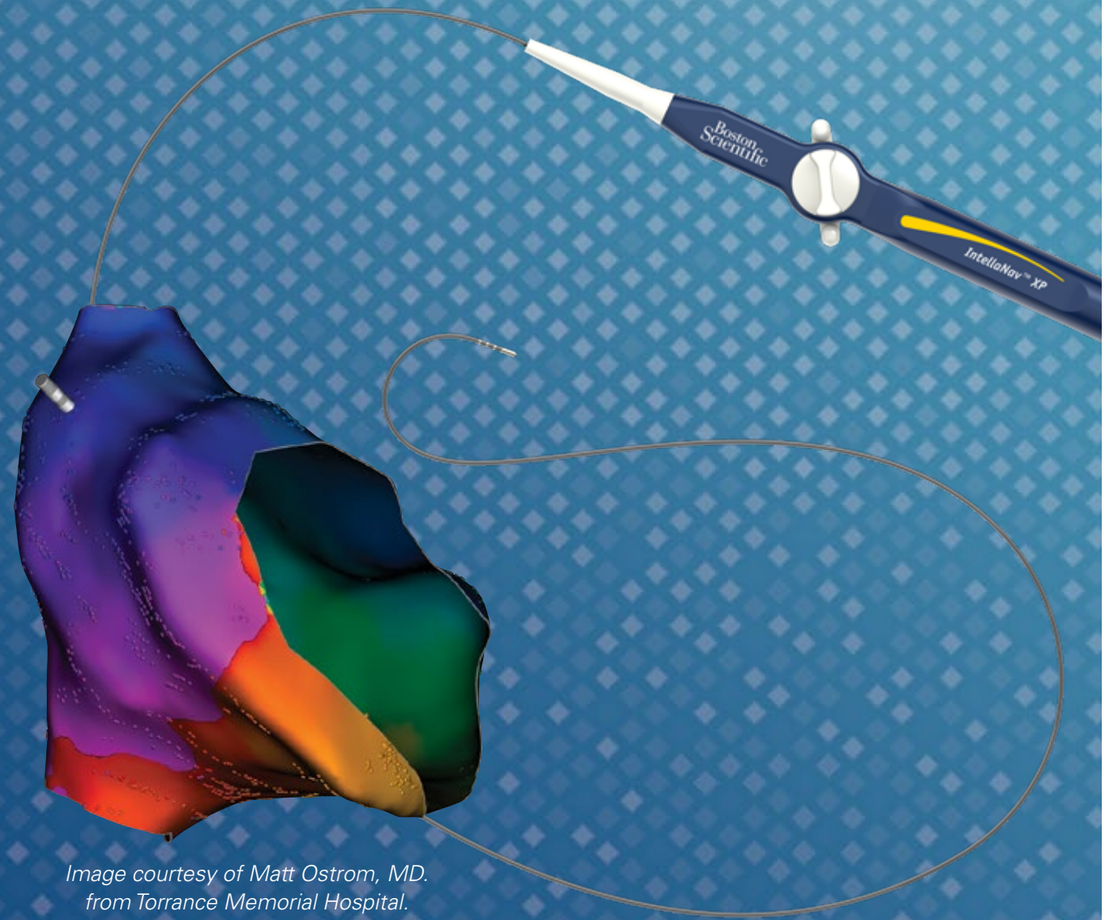


Image courtesy of Matt Ostrom, MD. from Torrance Memorial Hospital.

Excelentes resultados em conjunto com o mapeamento de alta definição.

INTELLANAV™ XP
ABLATION CATHETER

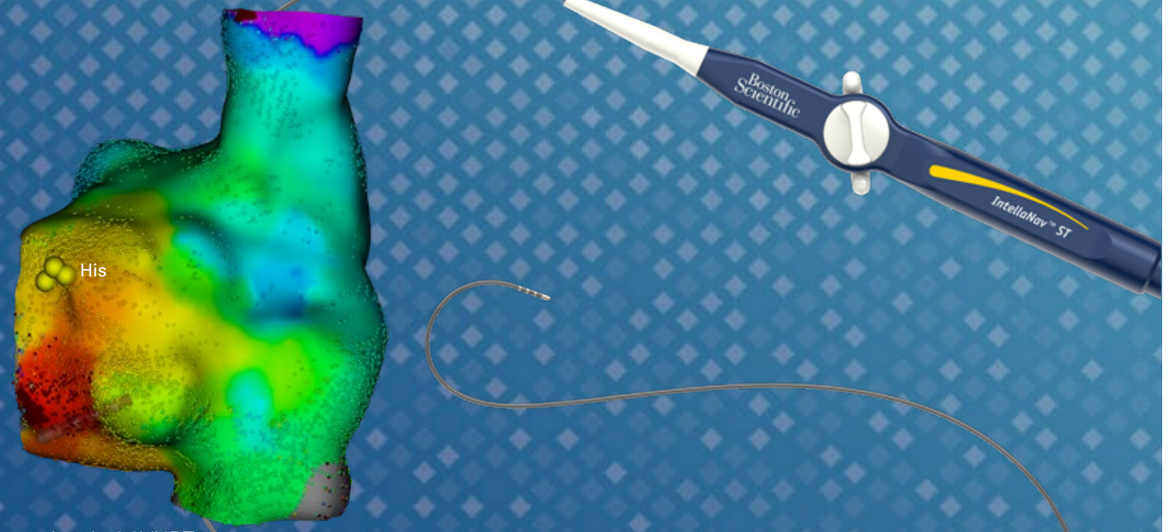
INTELLANAV™ XP ABLATION CATHETER

Ponta 4 mm

A precisão de uma ponta sólida 4mm + a precisão de um controle magnético de navegação.

INTELLANAV™ ST
ABLATION CATHETER

Ablaç»es precisas em procedimentos de TPSV, Maior controle cr²tico da localização do sistema de condução normal.



Atypical AVNRT
Image courtesy of Hazim Al-Ameri, MD. from William Beaumont Royal Oak.

1. Data on file.
2. Calculation utilizes labeled size of electrodes on one commercially available electrophysiology mapping catheter.
3. Lo LW, Lin YJ, Chang HY, et al. A novel map and ablate technology to identify the arrhythmogenic atrial substrate. Poster session presented at Heart Rhythm Society; 2012 May; Boston, MA. IA02-8 (Right atrial canine model utilizing EnSite™ NavX™, n=9)
4. Data on file. Technote 3: Irrigated RF Tip Electrode Cooling Dynamics: Impact of Optimized Internal Cooling (EP-361206-AB).
5. SSE Clinical data on file, Boston Scientific.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

INTELLAMAP ORION™ High-Resolution Mapping Catheter
INDICATIONS FOR USE: The IntellaMap Orion High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart. **CONTRAINDICATIONS:** The IntellaMap Orion Catheter should not be used in: Patients who are not candidates for transvascular catheter procedures. Patients with a hypercoagulable state or who cannot tolerate heparin anticoagulation therapy. Patients with prosthetic or stenotic valves, in the chamber where the prosthetic or stenotic valve reside. Patients with active systemic infection. Pediatric patients. Pregnant and/or nursing patients. Patients with any other condition where catheter manipulation may not be safe. The IntellaMap Orion Catheter should not be used for radio frequency (RF) ablation. The IntellaMap Orion Catheter should not be used inside an MRI machine. **WARNINGS:** Keep the connector dry; wet connector pins may affect performance. Do not allow the handle or cabling to be immersed in fluid. Do not use the catheter to deliver ablation therapy. Do not expose the catheter to alcohol or other cleaning solvents. Do not operate the catheter against resistance. If resistance is felt during advancement, retraction, articulation, deployment or un-deployment, stop and evaluate device location under fluoroscopy. Do not advance or retract the catheter through a sheath when deployed or articulated. In order to reduce the risk of clot formation: Maintain an activated clotting time (ACT) of greater than 300 sec. at all times during use of the catheter, and continuously flush the electrode array with saline via the irrigation port at the proximal end. Do not use the catheter with equipment (such as stimulators or recording systems) that is not isolated. **PRECAUTIONS:** To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue. Always undeploy the catheter prior to removal from the patient. Use visualization (such as fluoroscopy) to verify undeployment. Always move the articulation control lever to its neutral position to straighten the catheter prior to removal from the patient. Only use guiding sheaths with curves that allow passage of the catheter without using excessive force. When used with a steerable guiding introducer sheath: Ensure under fluoroscopy that the guiding introducer sheath distal end is straight or, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath. Do not articulate the sheath while the catheter array is inside the articulating section. Do not deploy or articulate the catheter while the distal end is inside a sheath. Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the IntellaMap Orion Catheter. To prevent entanglement, use care when using the catheter in the proximity of other catheters. When pacing, verify desired waveform is observed. Prior to insertion into vasculature, ensure removal of all air from the catheter lumen; use a pressured saline bag to flush saline through the catheter shaft and electrode array. **POTENTIAL ADVERSE EVENTS:** Serious adverse events have been reported in the literature in relation to cardiac catheterization including: stroke, cardiac tamponade, perforation, myocardial infarction, pulmonary embolism, and death. Complications reported included also (in alphabetical order): air embolism, arrhythmia, AV fistula, hematomas, hemothorax, pneumothorax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding, and vasovagal reactions. 91078319 (Rev AA)

INTELLANAV MIFI™ OPEN-IRRIGATED Ablation Catheter
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:** Note: The IntellaNav MiFi OI Catheter is not designed to be compatible with the Maestro 3000® RF Cardiac Ablation System. 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. 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 pre-pubescent children. In the presence of anticoagulation, there may be an increased risk of bleeding from all causes. 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 preoperative pacing, sensing, and therapy parameters after the ablation procedure. Temporarily reprogram the pacemaker per the manufacturer guidelines during RF ablation to a nontracking 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. Fluoroscopic guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgment. 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 tendinae. 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. 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. **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. Patients undergoing a long irrigated ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely. **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). 92164033 (Rev. B)

INTELLANAV™ OPEN-IRRIGATED Ablation Catheter
INDICATIONS FOR USE: The IntellaNav™ OI Catheter, when used with a compatible Radiofrequency (RF) 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 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. Note: The IntellaNav OI Catheter is not designed to be compatible with the Maestro 3000® RF Cardiac Ablation System. 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. Careful consideration must 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. 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.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. Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism. 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. In the event of a suspected failure of the integrity of fluid flow through the IntellaNav OI Catheter or if there is a rapid temperature rise of greater than 15 degrees C noted on the RF Controller, the procedure should be stopped, and the IntellaNav OI Catheter withdrawn to reduce the risk of steam pop that could result in perforation. Both the IntellaNav OI Catheter and the Irrigation Tubing Set should be replaced. 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. Do not scrub the tip electrode as this may result in irrigation port(s) occlusion and may lead to IntellaNav OI Catheter failure and/or patient injury. In the event of RF Controller cut-off (impedance or temperature), the IntellaNav 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. 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. 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 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. **PRECAUTIONS:** The IntellaNav OI Catheter is not intended to be used with a RF generator output setting exceeding 50 W or 200 Volts peak. The IntellaNav™ OI Catheter is highly torqueable. Avoid overtorquing. Over-rotating the handle and catheter shaft may cause damage to the distal tip or catheter assembly. The IntellaNav 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 OI Catheter. **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). 91164701 (Rev. C)

INTELLANAV™ XP Ablation Catheter and INTELLNAV MIFI™ XP Ablation Catheter
INDICATIONS FOR USE: The Boston Scientific Corporation IntellaNav XP and MiFi XP Catheters are indicated for use with the BSC high power Cardiac Ablation Controllers (Maestro 3000 Controller and Maestro 4000 Controller) and Accessories for the treatment of sustained or recurrent type I atrial flutter in patients age 18 or older. The BSC high power Cardiac Ablation Controllers and Accessories are indicated for use in conjunction with standard and high power catheters for cardiac ablation procedures. **CONTRAINDICATIONS:** Do not use this device: in patients with active systemic infection; via the transseptal approach in patients with left atrial thrombus or myxoma; via the retrograde approach in patients with aortic valve replacement. **WARNINGS:** Peri-procedural anti-coagulation therapy is at the discretion of the physician, however, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy, pre, during and post-ablation to reduce the incidence of major complications. Because the long-term effects of exposure to ionizing radiation are unknown, careful consideration should therefore be given to pregnant women and pre-pubescent children. 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. 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 atrial flutter 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 periprocedural stroke risk. Do not pass the IntellaNav XP or MiFi XP 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:** Do not place the distal end of the catheter near magnets. Do not attempt to operate the Controller before thoroughly reading the appropriate BSC high power Cardiac Ablation Controller & Accessories Operator's Manuals. The IntellaNav XP and MiFi XP Catheters are 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 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. Unlike with conventional catheters, a sudden rise in system impedance is not an indication of coagulum formation. Therefore, to minimize coagulum, it is recommended that the catheter periodically be removed and the distal tip cleaned after each line of block. Adequate signal filtering must be used to allow continuous monitoring of the surface electrocardiograms (ECGs) and intracardiac electrograms (EGMs) during RF power applications. When using the IntellaNav XP or MiFi XP Catheter, it is required that two Dispersive Pads satisfying the requirements of IEC 60601-1/IEC 60601-1-2 be used as the ablation return electrodes or skin burns may result. Use of only one Dispersive Pad will not allow the operator to fully access the higher power capabilities of the Controller. Placement of the Dispersive Pads 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 Pads or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. Electromagnetic interference (EMI) produced by the Cardiac Ablation Controller during the delivery of RF power may adversely affect the performance of other equipment. **POTENTIAL ADVERSE EVENTS:** Potential adverse events (in alphabetical order), that may be associated with cardiac catheterization and ablation include, but are not limited to: allergic reaction (including anaphylaxis), angina, arrhythmias, arterial or pulmonary embolism, arterial-venous fistula, atrioventricular node damage (transient/permanent), back pain and/or groin pain, cardiac perforation, cardiac respiratory arrest, catheter entrapment, cerebral vascular accident, chest pain/discomfort, complete heart block (transient/permanent), complications of sedative agents (e.g. aspiration pneumonia), death, effusion (pericardial/pleural), hematoma/bruising, hemoptysis, hemorrhage, hemothorax, hypotension, infection, myocardial infarction, nerve palsy or weakness, pericarditis, phrenic nerve damage/diaphragmatic paralysis, pleurisy, pneumothorax, pseudoaneurysm, pulmonary edema, radiation exposure, sinoatrial node damage, skin burn (defibrillator/cardioverter/radiation), tamponade, transient ischemic attack (TIA), valvular damage, vasovagal reactions, visual blurring. 91136894 (Rev AA)

INTELLANAV™ ST Ablation Catheter

INDICATIONS FOR USE: The Boston Scientific Corporation IntellaNav™ ST Catheter, when used with a compatible radiofrequency controller, is indicated for creating endocardial lesions during cardiac ablation procedures to treat arrhythmia 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 18 years 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. Maximum IntellaNav™ ST Catheter Rated Voltage: 178 Vrms (251 Vpk). 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. 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. 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. Do not increase power before checking for obvious defects or misapplication. Electromagnetic interference (EMI) produced by the RF Controller during the delivery of RF power may adversely affect the performance of other equipment. **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 and Visual blurring. 92222790 (Rev. A)

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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