FARAPULSE

FARAWAVE™

Pulsed Field Ablation Catheter

REF M004PFCE41M401; M004PFCE41M402

BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, FARAWAVE, en, 51622663-01A_pretrans

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FARAWAVE™
Pulsed Field Ablation Catheter

℞ ONLY

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

REUSE 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 (BSC) 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.

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

DEVICE DESCRIPTION

The FARAWAVE Pulsed Field Ablation (PFA) Catheter (henceforth referred to as the FARAWAVE Catheter) is a component of the FARAPULSE™ PFA System.

The FARAWAVE Catheter is an over-the-wire, multi-electrode catheter designed to deliver PFA energy to the distal section for cardiac ablation. The FARAWAVE Catheter distal section consists of five splines with four electrodes located on each spline, twenty electrodes total.

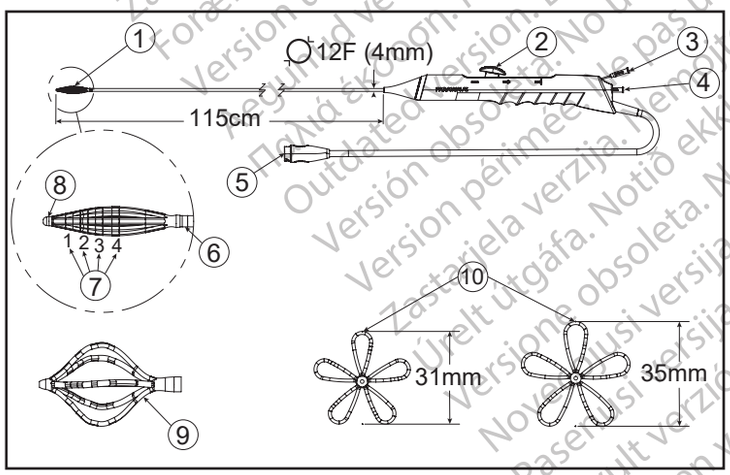

Figure 1. FARAWAVE Catheter

(1) Distal splines (2) Deployment mechanism (3) Flush port (4) Guidewire hub (5) Cable connector (6) Radiopaque marker (7) Four electrodes on five splines (8) Radiopaque tip (9) Partial ("basket") deployment (10) Full ("flower") deployment

The FARAWAVE Catheter handle features a deployment mechanism that enables the ability to deploy the distal section into multiple configurations, where the partially deployed configuration is a "basket" shape and the fully deployed configuration is a "flower" shape. The symbols on the FARAWAVE Catheter handle indicate each configuration:

Table 1. FARAWAVE Catheter Configurations

Symbol	Configuration
	Undeployed
	Partially deployed ("basket")
	Fully deployed ("flower")

The FARAWAVE Catheter is a 12F catheter and is compatible with the FARADRIVE™ Steerable Sheath (henceforth referred to as the FARADRIVE Sheath). The FARAWAVE Catheter is available in two sizes, 31 mm and 35 mm, representative of the fully deployed diameter.

For ablation, the FARAWAVE Catheter is designed to be used with the FARASTAR™ Catheter Connection Cable and FARASTAR Generator.

Contents

One (1) sterile FARAWAVE Catheter

Materials

Contains Cobalt; CAS No 7440-48-4; EC No. 231-158-0. Defined as a 1B according to the European Commission in a concentration above 0.1% weight by weight.

Note: This device is made with a metal alloy which contains cobalt. Current scientific evidence supports that metal alloys containing cobalt used in medical devices do not cause an increased risk of cancer or adverse reproductive effects.

Non-pyrogenic

This device meets pyrogen limit specifications for all patient-contacting parts.

INTENDED USE

The FARAPULSE Pulsed Field Ablation (PFA) System is intended for the isolation of the pulmonary veins in the treatment of paroxysmal atrial fibrillation by rendering targeted cardiac tissue electrically non-conductive to prevent cardiac arrhythmia initiation or maintenance. The FARAWAVE Catheter is part of the FARAPULSE PFA System.

Intended User

Use of the FARAWAVE Catheter is intended for those physicians who are specialists trained in cardiac ablation procedures to treat cardiac arrhythmias in a fully-equipped electrophysiology laboratory. Device specific physician in-service training is made available by the manufacturer.

Indications for Use

The FARAWAVE Catheter is indicated for the isolation of pulmonary veins in the treatment of paroxysmal atrial fibrillation.

Intended Patient Population

The FARAPULSE PFA System is intended for use in adult (18 ≤ age ≤ 75 years) cardiac arrhythmia patients, excluding pregnant or nursing patients.

Clinical Benefit Statement

When operated by the intended user, the clinical benefits of using the FARAPULSE PFA System is the elimination of atrial fibrillation by selectively creating durable conduction block at targeted myocardial tissue with low likelihood of damage to adjacent structures. Pulsed field ablation does not rely on thermal effects and thereby incurs low risk of thermal damage such as pulmonary vein stenosis, phrenic nerve injury, or esophageal injury. In addition, pulsed field ablation therapy is less invasive than open-chest surgical interventions.

Summary of Safety and Clinical Performance

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (EUDAMED) website: (https://ec.europa.eu/tools/eudamed)

CONTRAINDICATIONS

The FARAWAVE Catheter is contraindicated for use:

- in patients with active systemic infection;
- in patients with a mechanical prosthetic heart valve through which the catheter must pass;
- in patients with conditions where insertion into or manipulation in the cardiac chambers is unsafe as these conditions (e.g., presence of intracardiac thrombus or myxoma, history of recent cardiac surgery with atriotomy, etc.) may increase the risk of systemic embolism or cardiac perforation;
- in patients with a bleeding disorder, or who are unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation;
- in patients who have vena cava embolic protection filter devices and/or known femoral thrombus who require catheter insertion from the femoral approach;
- in patients with a contraindication to an invasive electrophysiology procedure where insertion or manipulation of a catheter in the cardiac chambers is deemed unsafe, such as but not limited to, a recent previous cardiac surgery (e.g., ventriculotomy or atriotomy, Coronary Artery Bypass Graft [CABG], PTCA/PCI/coronary stent procedure/unstable angina) and/or in patients with congenital heart disease where the underlying abnormality increases the risk of the ablation (e.g. severe rotational anomalies of the heart or great vessels);
- via transseptal approach in patients with an intra-atrial baffle or a foramen ovale patch.

WARNINGS

- If the visibility of the EP catheters is compromised for any reason, the user should stop and not resume ablation therapy until catheter visibility is established in order to prevent patient injuries such as perforation, heart block and injury to adjacent structures.
- Cardiac mapping and ablation procedures should be performed only by physicians thoroughly trained in invasive cardiology, in the techniques of mapping and ablation, and

in the specific approach to be used, in a fully-equipped electrophysiology lab.

- Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures. There is an increased risk of thromboemboli if appropriate anticoagulation levels are not maintained while the transseptal sheath and/or catheter is in the left side of the heart. Administer anticoagulation therapy during and post procedure according to the institution's standards to minimize bleeding and thrombotic complications.
- Carefully read all equipment and ancillary device instructions required for the procedure prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications.
- Do not use the device if past the "Use By" date on the device package. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury.
- Before using, inspect the FARAWAVE Catheter for any defects or physical damage, including electrical insulation on the cables and the catheter shaft that, if used, may cause patient and/or user injury. Do not use defective or damaged devices. Replace damaged equipment if necessary. No modification of this equipment is allowed.
- Electromagnetic Interference (EMI) from any source during normal operation may adversely affect the visualization and tracking of the catheter during the procedure, which can cause patient injuries such as perforation, heart block and injury to adjacent structures.
- Use of the FARAWAVE Catheter with generators other than the FARASTAR Generator can lead to unexpected energy delivery resulting in either insufficient ablation treatment or over-delivery of energy leading to possible patient hazardous events such as thrombus formation, tissue damage, etc.
- Patients undergoing ablation are at risk for complete AV block which requires the implantation of a temporary and/or permanent pacemaker.
- When the catheter is in the patient, neither the patient nor the catheter connector should not be allowed to come in contact with grounded metal surfaces to minimize the potential for electrical shock.
- Ensure that the cable/catheter connection remains dry throughout the procedure in order to prevent electric shock or other patient injuries as well as to prevent loss of device function.
- Fibrin may accumulate in or on the sheath/catheter assembly during the procedure. Aspirate when removing the catheter.
- In the presence of anticoagulation, there may be an increased risk of bleeding from all causes.
- Electrical recording or stimulation equipment must be isolated. Current leakage from any electrical equipment that is connected to the patient must not exceed 10 microamps for intracardiac electrodes.
- Care must be taken to ensure that any equipment used in connection with the FARAWAVE Catheter be type CF, be defibrillation proof, meet IEC 60601-1 electrical safety requirements, and comply with all local regulatory requirements for specified intended use to reduce the potential risk of inadvertent electrical shock.
- Do not touch the patient when ablation energy is being delivered to prevent the risk of electric shock.
- Stimulation of cardiac tissues caused by pacing stimulus and/or ablation 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):
  - Pacemakers, implantable cardioverter/defibrillators, and leads can be adversely affected by ablation energy. It is important to refer to the device manufacturer's instruction for use prior to performing ablation procedures.
  - Do not apply ablation energy directly to a lead or to tissue immediately in contact with a lead because it could potentially damage the lead or lead function.
  - Temporarily reprogram the pacemaker per the manufacturer guidelines during ablation to a non-tracking pacing mode if pacing is likely to be required during the ablation. The pacemaker could be damaged by the ablation procedure. Interrogate the device fully after the ablation per the manufacturer guidelines and reprogram to preoperative sensing and pacing parameters.
  - Deactivate ICDs as they could discharge and injure the patient or be damaged by the ablation procedure.
  - Have temporary external sources of pacing and defibrillation available.
  - Perform a complete analysis of the implanted device function after ablation.
  - Fluoroscopic or appropriate imaging guidance and care must be taken during catheter advancement, manipulation, and withdrawal to avoid lead dislodgement.
  - Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function.
  - Remember to reactivate the pulse generator after turning off the ablation equipment.
- Ablation in contact with any other electrodes alters the function of the catheter and can lead to embolism.
- At no time should a FARAWAVE Catheter be advanced, withdrawn, rotated, deployed or undeployed when resistance is felt, without determining the cause. Valve damage, vascular and/or cardiac perforation is a risk with any intracardiac catheter.
- Catheter entrapment within the heart or blood vessels is a possible complication of cardiac ablation procedures. The potential for catheter entrapment may be increased when the catheter is over torqued and/or positioned in the chordae tendineae. The occurrence of this complication may necessitate surgical intervention and/or repair of injured tissue and/or valve damage.
- Do not use the FARAWAVE Catheter in the proximity of Magnetic Resonance Imaging (MRI) equipment because the MRI equipment may adversely impact the function of a PFA Generator and the ablation system may adversely impact the image quality. This can also lead to loss of visibility during ablation which can cause patient injuries such as perforation, heart block and injury to adjacent structures.
- Catheter ablation procedures present the potential for significant radiation exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the radiation beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. Careful consideration must therefore be given for this use of the device in pregnant women and/ or prepubescent children.
- There are no data to support the safety and effectiveness of this device in the pediatric population.
- Prior to the procedure, always identify the patient's risk of volume overload. Monitor the patient's fluid balance throughout the procedure and after the procedure to avoid fluid volume overload. Some patients may have factors that reduce their ability to handle the volume overload, making them susceptible to developing pulmonary edema or heart failure during or after the procedure. Patients with congestive heart failure or renal insufficiency, and the elderly are particularly susceptible.
- Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism.
- Excessive curves or kinking of the catheter may damage internal wires and components, including the flush lumen. This damage may affect mechanical and electrical performance leading to patient injury.
- Do not attempt to bend, kink, or shape the patient-contact portions or flush lumen of the FARAWAVE Catheter. Doing so could cause electrical or mechanical catheter failure resulting in patient injury. Kinking of the flush lumen may compromise flow through the device leading to potential thrombus formation and embolism.
- Use both fluoroscopy, or other visualization techniques such as echocardiography, and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade.
- The FARAWAVE Catheter tip and guidewire move forward during device undeployment. Device deployment and undeployment should be visualized using fluoroscopy. Failure to do so may result in catheter damage and/or patient injury.
- Do not deliver ablation energy with the catheter outside the target site. Ablation Generators can deliver significant electrical energy and may cause patient injury such as arrhythmia and heart block.
- Always verify that the tubing set, catheter, sheath and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing, catheter or sheath can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system.
- Patients undergoing left-sided ablation procedures should be closely monitored during and post procedure for clinical manifestations of infarction, pulmonary vein injury, nerve damage, and/or embolism.
- Patients undergoing an ablation procedure have the potential for greater anticoagulation and therefore Activated Coagulation Time (ACT) should be monitored closely due to the increased risk for bleeding/ hemorrhage and/or embolism.
- Patients with hemodynamic instability or cardiogenic shock are at increased risk for life-threatening adverse events and ablation must be done with extreme caution.
- The FARAWAVE Catheter is not intended to be used for internal cardioversion. Doing so may result in perforation, arrhythmias, embolism, thrombus and/or patient death.
- Inspect irrigation saline for air bubbles and remove any air bubbles prior to its use in the procedure. Air bubbles in the irrigation saline may cause embolism.
- If there is uncertainty regarding the patient's anticoagulation status or rhythm prior to the procedure, there should be a low threshold to perform a Transesophageal Echocardiogram (TEE) prior to the procedure to confirm absence of mural thrombus and/ or thrombus in the left atrial appendage.

- Guiding catheters and/or long introducer sheaths present the potential for thromboembolic events. Pre-flush and maintain lumen patency with heparinized intravenous infusion.
- Do not wipe this catheter with organic solvents such as alcohol or immerse the handle and/or cable connector in fluids. This may result in electrical or mechanical catheter failures. It may also result in an allergic reaction from the patient.
- Pre-procedural anticoagulation therapy is at the discretion of the physician. However, patients with a history of thromboembolic events may require therapeutic anticoagulation therapy, pre-, during and post-ablation to reduce the incidence of major complications. Peri-procedural anticoagulation therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures.
- The safety and/or efficacy of epicardial use of the FARAWAVE Catheter has not been evaluated in a clinical trial.
- Care should be used during multiple sheath/catheter exchanges through the transseptal puncture to avoid causing a residual atrial septal defect that would require repair.
- Do not leave the FARAWAVE Catheter in the patient for more than four (4) hours. Failure to remove the device before four hours after first insertion could result in formation of thrombus with attendant stroke risks.
- Use of the FARAWAVE Catheter with delivery devices other than the FARADRIVE Sheath can result in poor access to endocardial locations, inefficient ablation delivery and inadequate procedural outcomes.
- Cardiac ablation has the potential of causing unintended myocardial injury. Clinical indications of myocardial ischemia should be closely monitored during the procedure (e.g., ECG changes).
- The FARAWAVE Catheter has not been studied clinically in the mitral isthmus or cavotricuspid isthmus areas. Ablations in areas adjacent to coronary arteries may lead to coronary artery spasm and/or injury, and the resulting myocardial injury can be fatal.
- Ensure that the guidewire is properly inserted into the catheter for adequate support during use. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire fully inserted, at or past the FARAWAVE Catheter tip. Failure to do so may result in catheter damage and/or patient injury.
- When positioning on cardiac structures, the guidewire should be retracted to prevent cardiac perforation or tissue damage.
- The risk of igniting flammable gases or other materials is potential outcome of ablation procedures. Precautions must be taken to restrict flammable materials from the electrosurgical suite.
- Take care when manipulating the guidewire to prevent cardiac or vessel trauma.
- 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.
- Minimize catheter exchanges and always advance and withdraw components through the valve slowly to minimize the vacuum created during withdrawal and to reduce the risk of air embolism. Follow advancement or withdrawal of catheters with appropriate aspiration and flushing according to institutional standards or consensus statements.
- Instruct users with co-implanted devices to refer to ancillary device labeling as well as the manufacturer of the ancillary device for recommended compatibility and settings.
- Use caution when advancing, retracting or otherwise manipulating system components to avoid damaging tissue or vessels or interfering with previously implanted medical devices.
- Ensure that the guidewire is not contacting ablation electrodes prior to starting ablation to prevent inappropriate energy delivery.
- Always un-deploy the catheter and withdraw the catheter into the sheath before removing the catheter from the Left Atrium (LA). Deploying the catheter in the septal puncture site or crossing the septum while the catheter is unsheathed or deployed may cause serious atrial septal defects or other cardiac and vessel trauma. Use visualization (such as fluoroscopy) to verify undeployment.
- Avoid deploying the catheter in constrained parts of the anatomy to prevent cardiac trauma or damage to the device.
- Prior to starting ablation verify that the catheter has been positioned and deployed correctly to prevent inappropriate application of ablation energy.
- Do not deploy the catheter while the distal end is inside the sheath as it could lead to catheter damage which may result in patient harm.
- PV potentials recorded from the electrodes on the FARAWAVE Catheter will likely show a significant reduction in amplitude after the first application of PFA. This should not be used as an indication that no further ablation is necessary. The nominal dose of PFA should be delivered in accordance to the parameters listed in the Operational Instructions section, regardless of absence of PV signal.
- Potential biohazard after use. Handle and dispose of in accordance with applicable regulations.

PRECAUTIONS

- Do not attempt to use with devices, including guidewires, larger than the delivery lumen diameter specified on the package label.
- Care must be taken to ensure all luer fittings are secure to prevent leaking.
- It is essential that a cardiac defibrillator with paddles connected is readily available in the procedure room for use if Ventricular Fibrillation is noted subsequent to ablation.
- There are no data to support the safety and effectiveness of this device in patients older than 75 years.
- Device deployment friction is increased when attempting to deploy the device when the catheter shaft is bent. FARAWAVE Catheter deployment should always occur with the catheter shaft as straight as possible.
- Do not apply excessive force to the deployment mechanism when deploying the catheter as doing so may damage the catheter.
- Avoid allowing the distal end of the catheter to be put into an acute bend, particularly when advancing the catheter beyond the sheath or deploying the catheter. A catheter exchange may be necessary if the catheter deploys improperly.

ADVERSE EVENTS

Potential adverse events associated with use of the FARAWAVE Catheter includes, but are not limited to:

- Pain or discomfort, for example:
  - Angina
  - Chest pain
  - Non-cardiovascular pain
- Cardiac arrest
- Death
- Electric shock
- Hypotension
- Infection/inflammation/exposure to biohazardous material
- Edema/heart failure/pleural effusion
- Hemolysis
- Renal failure/insufficiency
- Procedural related side effects, for example:
  - Allergic reaction (including anaphylaxis)
  - Genitourinary complication
  - Side effects related to medication or anesthesia
  - Radiation injury/tissue burn
  - Vasovagal response
  - Fluid volume overload
- Respiratory distress/insufficiency/dyspnea
- Arrhythmia (new or exacerbated)
  - Conduction pathway injury (heart block, nodal injury, etc.)
- Nerve injury, for example:
  - Phrenic nerve injury
  - Vagal nerve injury
- Gastrointestinal disorders
- Vessel trauma, including:
  - Perforation
  - Dissection
  - Coronary artery injury
  - Vasospasm
  - Occlusion
  - Hemothorax
- Cardiac trauma, for example:
  - Cardiac perforation/cardiac tamponade/pericardial effusion
  - Valvular damage
  - Stiff left atrial syndrome
- Injury related to tissue damage and/or adjacent structures, for example:
  - Esophageal injury
  - Pulmonary injury
  - Catheter entrapment
  - Physical trauma
- Fistula, for example:
  - Atrio-esophageal fistula
  - Bronchopericardial fistula

- PV stenosis and its symptoms, for example:
  - Cough
  - Shortness of breath, fatigue
  - Hemoptysis
- Surgical and access complications, for example:
  - Hematoma/seroma
  - AV fistula
  - Bleeding
  - Pseudoaneurysm
  - Pneumothorax
  - Residual atrial septal defect
- Thrombus/thrombosis
- Muscle spasm
- Injury due to embolism/thromboembolism/air embolism/foreign body embolism
  - Cerebrovascular Accident (CVA)/stroke
  - Transient Ischemia Attack (TIA)
  - Myocardial infarction
  - Neurological impairment and its symptoms, for example:
    - Cognitive changes, visual disturbances, headache, motor impairment, sensory impairment, and speech impairment
  - Pulmonary embolism
  - Asymptomatic cerebral embolism

The potential adverse events may be related to the ablation catheter(s) and/or the interventional procedure. The severity and/or the frequency of these potential adverse events may vary and may result in prolonged procedure time and/or additional medical and/or surgical intervention, implantation of a permanent device such as a pacemaker, and in rare cases, may result in death.

HOW SUPPLIED

Device Details

One (1) FARAWAVE Catheter is supplied sterile using an Ethylene Oxide (EO) process.

WARNING: Do not use the device if past the "Use By" date on the device package. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury.

Handling and Storage

Store in a cool, dry, dark place, with temperature excursions between -29 °C and 60 °C degrees permitted. Do not use if the FARAWAVE Catheter is exposed to environmental conditions beyond this range.

OPERATIONAL INSTRUCTIONS

Compatible Related Devices

Intracardiac electrophysiology and cardiac ablation procedures should be performed in a fully equipped clinical electrophysiology lab. In addition to the FARAWAVE Catheter, the following devices and materials are intended to be used:

- FARADRIVE Sheath
- FARASTAR Generator
- FARASTAR Recording System Module
- FARASTAR Catheter Connection Cable or FARASTAR Catheter Connection Cable (Gen 2)
- Standard commercially available guidewires up to 0.035"

Preparation

WARNING: Before use, inspect the packaging for any violation of the sterile barrier and inspect the FARAWAVE Catheter for any defects. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire. Do not use potentially contaminated or defective equipment.

WARNING: Ensure that the guidewire is properly inserted into the catheter for adequate support during use. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire fully inserted, at or past the FARAWAVE Catheter tip. Failure to do so may result in catheter damage and/or patient injury.

Please refer to the operator's manuals and Instructions for Use for the FARASTAR Generator, FARASTAR Catheter Connection Cable and the FARADRIVE Sheath for instructions on connecting and operating these systems in conjunction with the FARAWAVE Catheter. Use appropriate accessory cables to connect the catheter to the appropriate accessory equipment.

1. Connect the patient to an ECG recording system to facilitate arrhythmia monitoring per the standard operating procedure of the electrophysiology lab or manufacturer's operator's manual.

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

2. Open the FARAWAVE Catheter package. Carefully transfer the package contents into the sterile field, maintaining aseptic technique.
3. Connect the FARAWAVE Catheter to the FARASTAR Generator using a FARASTAR Catheter Connection Cable, maintaining aseptic technique. Ensure that the cable/catheter connection remains dry throughout the procedure. For connection information, refer to the FARASTAR Catheter Connection Cable IFU for additional connection instructions.
4. Turn on the FARASTAR Generator.
5. Obtain femoral vein access under aseptic conditions. Then place an introducer sheath into the vein using a standard percutaneous technique.
6. Obtain left atrial, transseptal access using standard techniques and commercially available equipment. (Refer to the FARADRIVE Sheath IFU for guidance on transseptal access and placement of the FARADRIVE Sheath.)
7. Flush the guidewire lumen and flush port lumen with sterile saline. Connect the flush port to a continuous flush line with pressurized heparinized saline and purge the catheter and tubing of all air bubbles. Ensure all luer fittings are secure.

   WARNING: Always verify that the tubing set, catheter, sheath and all connections have been properly cleared of air prior to inserting the catheter into the vasculature. Air entrapped in the tubing, catheter or sheath can cause potential injury or cardiac arrest. The operator is responsible for removing all air from the system.

8. Insert a standard commercially available 0.035" guidewire through the FARAWAVE Catheter until the tip of the wire is aligned with the tip of the catheter.

   Caution: Device deployment friction is increased when attempting to deploy the device when the catheter shaft is bent. FARAWAVE Catheter deployment should always occur with the catheter shaft as straight as possible.

Procedure

Standard procedures for electrophysiology studies will be followed.

WARNING: Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures. There is an increased risk of thromboemboli if appropriate anticoagulation levels are not maintained while the transseptal sheath and/or catheter is in the left side of the heart. Administer anticoagulation therapy during and post procedure according to the institution's standards to minimize bleeding and thrombotic complications.

1. Before placing the FARAWAVE Catheter in the sheath, begin continuous irrigation.

   WARNING: Always maintain a constant heparinized normal saline infusion to prevent coagulation within the lumen of the catheter that may result in embolism.

2. Compress the splines of the FARAWAVE Catheter for insertion and allow flush to fill the compressed spline array prior to inserting the sheath.

   WARNING: Use both fluoroscopy, or other visualization technique such as echocardiography, and electrograms to monitor the advancement of the catheter to the area of the endocardium under investigation to avoid conduction pathway injury, cardiac perforation or tamponade.

3. Advance the FARAWAVE Catheter and the guidewire together into the FARADRIVE Sheath taking care to avoid introducing air into the sheath.
4. Once the distal end of the FARAWAVE Catheter has been fully inserted through the valve, slowly aspirate and flush the FARADRIVE Sheath. Refer to the FARADRIVE Sheath IFU for additional instructions on minimizing air ingress.
5. Under standard imaging guidance (e.g. fluoroscopy or echocardiography), track the guidewire to the target pulmonary vein.
6. Advance the FARAWAVE Catheter over the guidewire into the left atrium. Ensure the tip of the catheter is not bent as it advances beyond the sheath. Ensure the proximal marker band on the catheter is within or beyond the marker band at the tip of the sheath.

   CAUTION: Avoid allowing the distal end of the catheter to be put into an acute bend, particularly when advancing the catheter beyond the sheath or deploying the catheter. A catheter exchange may be necessary if the catheter deploys improperly.

7. Check that the distal portion of the FARAWAVE Catheter is free to move. Under standard imaging guidance, carefully deploy the distal splines by pressing down the button and sliding it proximally until the splines deploy into the desired shape. Deployment locks when the button is released.

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WARNING: Do not deploy the catheter while the distal end is inside the sheath as it could lead to catheter damage which may result in patient harm.

WARNING: Ensure that the guidewire is properly inserted into the catheter for adequate support during use. Do not attempt to deploy or un-deploy the FARAWAVE Catheter without a guidewire fully inserted, at or past the FARAWAVE Catheter tip. Failure to do so may result in catheter damage and/or patient injury.

8. Position the FARAWAVE Catheter at the ostium of the targeted pulmonary vein. Use both standard imaging techniques and intracardiac electrograms to aid in uniform positioning of the catheter splines and electrodes while obtaining good tissue apposition. Ensure a stable position is achieved before delivering PFA.
9. If applicable, apply sedative bolus per site protocol.
10. Follow the recommended ablation parameters in the table below. (Refer to the FARASTAR Generator IFU for detailed instructions.)

Note: The following table details nominal dose parameters for PV isolation with PFA.

Parameter	Nominal Value (Per PV)
Voltage Amplitude	1.8 kV or 2.0 kV
Total PFA Applications	8
PFA Applications in Full Deployment	4
PFA Applications in Partial Deployment	4

Note: Some anatomies may restrict the ability to achieve the partial or full deployment state. In these cases, ablations may be performed in the achievable full or partial deployment state. Incomplete or interrupted deliveries should be repeated.

11. Deliver ablation from the FARASTAR Generator at the selected output setting.
12. When ablation is complete, verify that the position of the FARAWAVE Catheter has not changed.
13. Deliver an additional application in the same location. Total number of applications at this site is now two (2).
14. Rotate the FARAWAVE Catheter and reposition at the PV ostium using standard imaging techniques and intracardiac electrograms to aid in uniform positioning of the splines and electrodes while obtaining good tissue apposition. The splines should engage the vein in a different position than the previous two ablations. Ensure a stable position is achieved before delivering PFA.
15. Deliver an additional set of two (2) applications. Total number of applications at this site is now four (4).
16. Retract the FARAWAVE Catheter over the guidewire. Change the deployment shape and re-advance to the target ablation site. The splines should engage the vein in a different position than the previous two positions. Ensure a stable position is achieved before delivering PFA.
17. Deliver an additional set of two (2) applications. Total number of applications at this site is now six (6).
18. Rotate the FARAWAVE Catheter and reposition at the PV ostium using standard imaging techniques and intracardiac electrograms to aid in uniform positioning of the splines and electrodes while obtaining good tissue apposition. The splines should engage the vein in a different position than the previous two ablations. Ensure a stable position is achieved before delivering PFA.
19. Deliver an additional set of two (2) applications. Total number of applications at this site is now eight (8).
20. If needed, perform additional ablations.

Note: After energy delivery, the FARASTAR Generator automatically routes the FARAWAVE Catheter electrodes to the EGM Connector. Signals formed from these electrodes can be viewed on the Recording/Mapping System.

Caution: PV potentials recorded from the electrodes on the FARAWAVE Catheter will likely show a significant reduction in amplitude after the first application of PFA. This should not be used as an indication that no further ablation is necessary. The nominal dose of PFA should be delivered in accordance to the parameters listed in the table above, regardless of absence of PV signal.

End of Procedure

1. Carefully un-deploy the FARAWAVE Catheter and retract the catheter over the guidewire until it is completely inside the FARADRIVE Sheath.

WARNING: The FARAWAVE Catheter tip and guidewire move forward during device undeployment. Device deployment and undeployment should be visualized using fluoroscopy. Failure to do so may result in catheter damage and/or patient injury.

2. Retract the guidewire into the FARADRIVE Sheath.
3. Carefully withdraw the FARAWAVE Catheter, along with the guidewire, from the body through the FARADRIVE Sheath using caution to avoid introducing air into the sheath upon removal.
4. Carefully withdraw the FARADRIVE Sheath from the left atrium in accordance with its IFU.
5. Turn off the FARASTAR Generator.

Disposal

To minimize risk of infection or microbial hazards after use, dispose of device and packaging as follows:

After use, the catheter may contain biohazardous substances. The catheter and packaging should be treated and disposed of as biohazardous waste in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

Post-Procedure

Carefully monitor patient while in recovery to ensure hemostasis is achieved and any complications are immediately treated.

Complaint Reporting

In the event that a serious incident occurred in relation to the device, including all patient deaths for procedures where the FARAPULSE product was used, the event should be reported to Boston Scientific and the competent authority of the Member State in which the user and/or patient is established.

Boston Scientific's local contact information may be found at: www.bostonscientific.com

Return any catheter related to a complaint, patient harm, injury, or death to Boston Scientific using a BSC Returned Product Kit.

- Returning products for analysis and providing product performance observations helps drive higher reliability on an ongoing basis.
- Be sure to follow the instructions with regard to packaging and shipping any biohazard devices taking care not to expose the handle or connector to fluid that may compromise the catheter and limit analysis.

PATIENT COUNSELING INFORMATION

The physician should consider the following points while counseling patients on the use of the FARAWAVE Catheter in association with the electrophysiological cardiac interventional procedure:

- Discuss the risks and benefits including review of potential adverse events listed in this document.
- Discuss post procedure instructions, including any lifestyle changes, medications, when to call the Healthcare Provider (HCP) and any post procedure follow-up that might be needed.

WARRANTY

For device warranty information, visit www.bostonscientific.com/warranty.

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary.

Additional symbols are defined at the end of this document.

BSC (MB IFU Template 8.5 x 11 Global, 92310050M), IFU, FARAWAVE, en, 51622663-01A_pretrans

Contents

GW Maximum Guidewire OD

CH REP
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