Processed by

stryker®

Sustainability Solutions

Instructions for Use
Reusable Ablation Catheter Cables

- **STERILE**

Explanation of Symbols

℞Only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Processing
	Use by Date
REF	Catalogue Number
	See Instructions For Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight
	Do not resterilize

Stryker Sustainability Solutions, Inc. © 2014, 2022
1810 W. Drake Dr.
Tempe, AZ (USA) 85283
sustainability.stryker.com
888.888.3433

Ablation Catheter Cable Description
Ablation catheter cables are designed as electrode cables with a multi-pin connector on the distal end which connects to an ablation catheter and a multi-pin connector on the proximal end which connects to the appropriate equipment. The cables either interface an ablation catheter with the appropriate external radiofrequency generator or, serve as an extension cable between an ablation catheter and equipment out of immediate reach. The reusable sensor enabled ablation connection cables are used for sensor enabled catheter positioning and navigation applications.

Indications for Use
Reusable ablation catheter cables are indicated for use with the appropriate ablation catheter during cardiac ablation procedures.

Reusable sensor enabled ablation connection cables are intended for use with a compatible radiofrequency generator and sensor enabled catheter positioning and navigation applications.

Contraindications for Use
None.

Warnings
- The use of this device requires a thorough understanding of the techniques and principles of angiography, electrophysiology and transvenous intracardiac electrophysiology studies and temporary pacing and cardiac ablation.
- Prior to use, refer to the applicable catheter and equipment instructions for use. Observe all indications, contraindications, warnings and precautions described in these directions. Failure to do so may result in patient complications.
- Do not connect the ablation catheter cable to devices or power sources other than the appropriate ablation catheter(s) and equipment. Connecting the ablation catheter cable to an inappropriate electrical connection such as a wall socket may result in serious injury to patient and operator or damage to equipment.
- Employ proper electromechanical device guidelines and hospital standards in cases where conventional line powered equipment is used near the patient. Extraneous electrical currents may reach the ablation equipment, catheter and heart and could result in lethal arrhythmias.
- To prevent injury to patient or operator, use extreme caution if employing components with unprotected male pin connectors during device set-up.
- Verify that all amplifiers, pacing equipment and ECG equipment is isolated or patient injury or death may occur.
- Ensure the reusable sensor enabled connection cable is at room temperature before use to ensure accurate temperature measurement.
- Connected equipment must be patient isolated and current leakage must not exceed 10 microamps.
- Do not use if packaging is damaged. Do not use if labeling is incomplete or illegible.
- The cable should be visually inspected for any damage prior to use. If damage is present, discard the cable. Do not attempt to repair any damages.

Precautions
- Do not immerse cable connectors in liquids. Ensure the cable remains dry throughout the procedure.
- Do not expose cables to strong or organic solvents.
- Use of additional electrical equipment could cause noise induction into the cable.
- Follow standard grounding precautions for electrosurgical instruments.
- Prior to use, verify compatibility of ablation catheter cable model with ablation catheter model in use.
- Improper handling may result in patient or operator injury.
- Do not alter this device.
- Observe polarity.
- Store this device in a cool, dark, dry area.
- Refer to the appropriate radiofrequency (RF) generator manual for operating instructions for the RF generator.
- If the cable becomes electrically discontinuous or a break occurs in the cable wire, arcing may occur in the patient-return or active circuit and may burn the patient or create a fire.
- Personnel handling the connector cable should wear gloves.
- The connector cable has been evaluated at a maximum voltage of 240 volts.

Adverse Reactions
None.

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify compatibility of all devices and accessories. Consult the instructions for use of applicable compatible devices and accessories to ensure proper use.
3. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the device if the sterility has been compromised. If the package is damaged or if it was opened and the device not used, return the device and package to Stryker Sustainability Solutions.
4. Remove the device from the package and place it in a sterile work area using aseptic technique.
5. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Do not attempt to repair any damage. Return the device and packaging to Stryker Sustainability Solutions if it is not in acceptable condition for the procedure.
6. To attach the ablation catheter cable to the ablation catheter, push the cable connector into the catheter connector. In models with arrow(s) on the cable connector, line up arrow(s) and line prior to pushing in.
7. Hold the catheter connector in place and push the extension cable connector firmly into the catheter connector.
8. Attach the ablation catheter cable to the appropriate radiofrequency generator or appropriate equipment.
9. For Biosense Webster® Carto® Reusable Ablation Cables and SMARTABLATE® Reusable Ablation Cables one end of the cable states “To System” and must be connected to the System, the other end (“catheter end”) states the catalog number and must be connected to the catheter.
10. For Boston Scientific® IntellaNav™ Reusable Ablation Cables:
    - In the non-sterile field, connect the cable to the red port marked “ABL CATH” on the Rhythmia™ mapping system’s connection box.
    - In the sterile field, connect the black cable plug into the handle of the IntellaNav™ Catheter.
    - Refer to the associated compatible IntellaNav™ catheter instructions for use for cable configuration of the catheter with the Rhythmia™ Mapping System to verify cable connectivity.
11. For Reusable Sensor Enabled Ablation Connection Cables:
    - Use the connection with the green strain relief for the reusable sensor enabled ablation connection cable to connect to the Flexability™ Ablation Catheter, Sensor Enabled™.
    - When connecting the reusable sensor enabled ablation connection cable to an RF generator, refer to the RF generator instructions for use for details and diagrams on how to connect the cable to the RF generator. Use the connection with the yellow strain relief to connect to the RF generator.
    - Use the connection with the white strain relief for the reusable sensor enabled ablation connection cable to connect to the navigation and positioning systems. For the MediGuide™ System, connect the white strain relief to the MediGuide™ Cath Connect, Sensor Enabled™. For the EnSite Precision™ System, connect the white strain relief to the EnSite Precision™ Link, Sensor Enabled™.
12. To disconnect, grasp the connectors on both cable and catheter side and pull. Do not pull directly on the cable or the catheter.
13. For EnSite X Sensor Enabled diagnostic and non-Sensor Enabled diagnostic cables:
    - Use the connection with the black strain relief to connect to the catheter. For the magnetic extension cable, use the white receptacle to connect to the matching cable connector.
    - Use the connection with the green (10-pole) strain relief to connect to the matching amplifier input on the EnSite™ X System. For the magnetic extension cable, use the white plug to connect to the matching amplifier input on the EnSite™ X System.
    - Ensure that the connection is secure between the cable and connecting equipment.
    - To disconnect the Sensor Enabled™ diagnostic and non-Sensor Enabled™ diagnostic cables, twist the grey connector nut from the amplifier. To disconnect the catheter side, push the plug into the receptable and pull it out, or depress the tab to disengage the locking mechanism and disconnect the cable. To disconnect the magnetic extension cable from the amplifier, push the plug into the receptacle and pull it out, and to disconnect from the cable side, push the plug into the receptacle and pull it out.
14. If the ablation catheter needs to be repositioned, the ablation catheter cable may be disconnected as the catheter is moved to the new location under fluoroscopic guidance and reconnected. Verify proper catheter placement after relocation.

Compatibility

- Use the appropriate ablation catheter cable for the ablation catheter being utilized. Refer to the catheter and equipment instructions for use for additional information on compatibility.

Storage and Handling

- Store at 10° C to 50° C.
- Do not expose to relative humidity above 95%.
- Do not expose Biosense Webster® Carto® Reusable Ablation Cables to relative humidity above 85%.

Cleaning and Disinfection

1. Product must be thoroughly cleaned using a validated method after each use.
2. Devices to be cleaned using Stryker's cleaning method should be placed in the appropriate collection container system and staged for pickup.

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The OEM information listed on the label is provided as device ID prior to processing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

ACC Rev L 09/2022 RM702081