

Processed by



## Instructions for Use Reusable Ablation Catheter Cables

**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **STERILE**

### Explanation of Icons



Sterilized by Ethylene Oxide Gas



Date of Processing



Use by Date

**REF**

Ascent Product Code



See Instructions For Use

## Reusable Ablation Catheter Cables

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### **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.

### **Indications for Use**

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

### **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.
- 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.
- Test lead-to-lead leakage and end-to-end resistance before use. Recommended maximum leakage current from any connected device to the patient must not exceed 1.0 microamps at 250 volts and resistance should not exceed 10 ohms.

### **Precautions**

- Do not immerse cable connectors in liquids.
- Do not expose cables to strong 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.

### **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.
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 Ascent Healthcare 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. Return the device and packaging to Ascent Healthcare 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.

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9. 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.
10. To disconnect, grasp the connectors on both cable and catheter side and pull. Do not pull directly on the cable or the catheter.
11. After use, devices to be cleaned using Ascent's cleaning method should be placed in the appropriate collection container system and staged for pickup.

### Compatibility

- Use the appropriate ablation catheter cable for the ablation catheter being utilized.

### Storage and Handling

- Store at 10° C to 50° C.
- Do not expose to relative humidity above 95%.

### Cleaning and Disinfection

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

### Warranty

Ascent Healthcare Solutions (**ASCENT**) will process medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of processed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of processed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any processed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant processed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. The OEM information listed on the label is provided as device ID prior to reprocessing 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.