

Reprocessed by



Instructions for Use Reprocessed Electrophysiology Catheter Cables


Reprocessed Device for Single Use

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 Reprocessing

 Use by Date

REF Ascent Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Electrophysiology Catheter Cables

Electrophysiology Catheter Cable Description

Electrophysiology catheter cables are designed as electrode cables with a multi-pin connector on the distal end and the appropriate number of tails on the proximal end. The cables either interface an EP catheter with the appropriate external stimulation or recording equipment or, serve as an extension cable between an EP catheter and equipment out of immediate reach.

Indications for Use

Reprocessed electrophysiology catheter cables are indicated for use with the appropriate electrode catheter during electrophysiology studies.

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.
- Do not connect the electrophysiology catheter cable to devices or power sources other than the appropriate electrode catheter(s) and equipment. Connecting the electrophysiology 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 electrophysiology 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. Recommended maximum leakage current from any connected device to the patient must not exceed 10 microamps.

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 electrophysiology catheter cable model with electrophysiology catheter model in use.
- Improper handling may result in patient or operator injury.

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. Do not attempt to resterilize.
5. Remove the device from the package and place it in a sterile work area using aseptic technique.
6. 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.
7. To attach the electrophysiology catheter cable to the electrode 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.
8. Hold the catheter connector in place and push the extension cable connector firmly into the catheter connector.
9. Attach the electrophysiology catheter cable to the ECG monitoring or stimulation terminal.
10. Observe polarity of proximally located connector pins of the patient cable when connecting to the electrical equipment. Isolate any unused connector pins to reduce development of accidental current pathways to the heart.
11. If the electrode catheter needs to be repositioned, the electrophysiology catheter cable may be disconnected as the electrode catheter is moved to the new location under fluoroscopic guidance and reconnected. Verify proper catheter placement after relocation.

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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. Follow a suitable electrophysiology study protocol.

Compatibility

- Use the appropriate reprocessed electrophysiology catheter cable for the electrode catheter being utilized.
- The connector on the proximal end is designed to universally fit electrophysiology recording equipment.

Storage and Handling

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

Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess 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 reprocessed 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 reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed 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 reprocessed (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.