

# Instructions for Use Reprocessed Achieve Catheter Connecting Cable

# Reprocessed Device for Single Use

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

#### **DEVICE DESCRIPTION**

The reprocessed Achieve Catheter Connecting Cable, Model 2ACHC, provides conduction from the proximal end of the mapping catheter to standard shielded ECG pins that connect into standard EP recording and pacing equipment.

#### INDICATIONS FOR USE

The reprocessed cable is designed for use only with the Achieve family of mapping catheters. It is intended to provide connection of the catheter to a standard ECG interface box.

#### **CONTRAINDICATIONS FOR USE**

• There are no known contraindications to this cable.

#### **WARNINGS and PRECAUTIONS**

- Do not immerse the cable connectors in fluids.
- Do not expose cable to organic solvents.
- Inspect the sterile packaging and cable for damage or defects (i.e. cuts, kinks, nicks, crushed, cracking or elongated sections) prior to use.
- Check to verify the cable is within the expiration date. Do not use if the product date has expired.

## **ADVERSE REACTIONS**

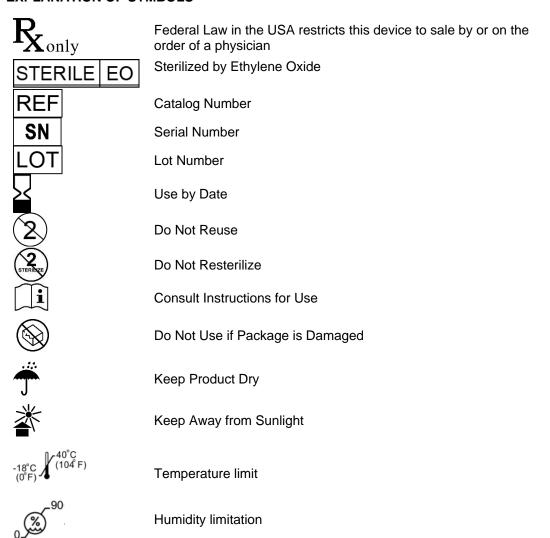
None.

## **DIRECTIONS**

- The package label is detachable and may be affixed to the medical record of the patient.
- Before beginning the procedure, verify compatibility of all devices and accessories.
- Inspect the cable and packaging before opening. The contents of the package are sterile unless
  the package is opened or damaged. If the cable is kinked or damaged or if the packaging is
  compromised, do not use the cable. Do not attempt to repair any damage. Return the cable and
  packaging to Innovative Health.
- Connect the shielded tip jacks from the cable to the ECG interface box.
   Note: When connecting to the EP recording system, electrodes 9 and 10 will not be used for models within the Achieve family that have 8 electrodes.
- Connect the cable single connector to the mapping catheter electrical connector.

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## **EXPLANATION OF SYMBOLS**



As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

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

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

Achieve is a registered trademark of Medtronic, Inc.

Please refer to www.innovative-health.com for product warranty.