Instructions for Use
Reprocessed (Reusable) Catheter Interface/Connector Cables

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 catheter interface cables are designed as electrode cables with a multi-pin connector on the distal end which connects to a catheter (diagnostic or ablation) and a multi-pin connector on the proximal end which connects to the appropriate equipment. The cables either interface a catheter with the appropriate external stimulation or recording equipment or, serve as an extension cable between a catheter and equipment out of immediate reach.

For a list of compatible generators, please refer to the applicable Original Manufacturer's Compatibility Matrix.

INDICATIONS FOR USE

The cable provides a means to interface an electrophysiology catheter to the appropriate equipment.

The EnSite X catheter cables are intended to be used with the EnSite X EP System to connect catheters to the EnSite X EP System amplifier.

The cable may be re-used subject to the cleaning and sterilization services provided by Innovative Health.

CONTRAINDICATIONS FOR USE

- There are no known contraindications to this cable.

WARNINGS

- Patient or operator injury can result from improper handling or storage of the cable.
- Do not bend the cable excessively. Excessive bending or kinking of the cable may damage the integrity of the cable and may lead to patient injury. Care must be taken when handling the cable.
- If a break occurs in the cable wire or the cable becomes otherwise electrically discontinuous, arcing may occur in the patient-return or active circuit and may burn the patient or create a fire.
- Failure to isolate unused connector pins may result in accidental current pathways to the heart.
- Do not twist the cable or use excessive force while inserting or disconnecting. Twisting the cable or use of excessive force may result in damage to the pin connectors. Misconnection of the pins to the sockets could lead to malfunction of the catheter.
- Never disconnect the cable from the catheter/equipment by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable.
- No modification of the device or equipment is allowed. Do not use defective equipment.
- Connected equipment current leakage (for Sensor Enabled Ablation Connection Cable) must not exceed 10 microamps.
- The Electrophysiology Cable (DEX-10) should be used with the EPstar Fixed Electrophysiology Catheters only.

PRECAUTIONS

- Do not immerse the cable connectors in fluids. Exposure to fluids may result in shorting of electrical signals.
- Personnel handling the cable should wear gloves.
- Standard grounding procedures should be followed if electrosurgical instruments are used.
- If used in the presence of electrical equipment, noise may be induced into signals conducted by the cable.
- For reuse of the cable, return to Innovative Health for additional processing.
- Do not expose cable to organic solvents.
- Ensure that the cable/catheter connection remains dry throughout the procedure.
- Inspect the packaging and cable for damage or defects (i.e. cuts, kinks, nicks, bulges, loose strain reliefs or connectors, cracks crushed or elongated sections and electrical insulation) prior to use.
- Use patient isolated equipment.
- Cables should be used by or under the supervision of physicians thoroughly trained in techniques of intracardiac electrophysiology.
- Adequate filtering must be used to allow continuous monitoring of the electrocardiogram (ECG) signals during the procedure.
- The Sensor Enabled Ablation Connection Cable should only be used by or under the supervision of physicians trained in ablation procedures using compatible navigation and visualization technology systems.
- The Sensor Enabled Ablation Connection Cable has been evaluated at a maximum voltage of 240 volts.
- For Medtronic RF Catheter Cables:
    - The RF Catheter Cable should be used only by or under the supervision of physicians well trained in electrophysiology, including the placement and use of intracardiac electrode catheters, and experienced in performing radiofrequency catheter ablation procedures.
    - Do not deliver direct current (DC) energy through the RF catheter cable. The cable is not designed to deliver DC energy, and no testing has been performed to demonstrate the device performance during DC energy delivery.
    - Do not coil cable during use. Coiling could reduce RF generator effectiveness.
    - Do not use RF power generators which have maximum output voltages that exceed 173 Vrms.
- For the IntellaNav StablePoint Catheter Cables:
    - The cable facilitates transmission of signals and provides a passage of RF energy to the catheter.

ADVERSE REACTIONS

- For the EnSite X Catheter Connector Cables:
    - Potential Adverse Events include electrical shock and infection.
- For the IntellaNav Stablepoint Catheter Cables:
    - Refer to the Indications for Use and Adverse Events Sections in the associated compatible Catheter IFU, System User Manual, and Connection Box IFU.

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.
- **Note:** When connecting to a radio-frequency generator, refer to the appropriate Original Manufacturer's generator instructions for details and system compatibility.
- 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 damaged or the packaging is compromised, do not use the cable. Do not attempt to repair any damage. Return the cable and packaging to Innovative Health.
- Do not attempt to resterilize.

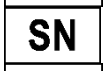
Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

- Ensure alignment of pins via rotation as required, prior to connection.
- Ensure each cable end is securely connected to the proper equipment. The “system” end of the cable states “To System” and must be connected to the System. The “catheter” end of the cable states the catalog number and must be connected to the catheter.
- For Boston Scientific SureLink cables, an audible click indicates that the two connectors are locked together.
- For Sensor Enabled cables, use the connection with the white strain relief to connect to appropriate navigation and positioning systems.
- For Boston Scientific IntellaTip MiFi Open-Irrigated cables, the yellow cable plugs into the port marked "Catheter Cable" on the Filter Module and the red cable plugs into the Controller. Connect the white cable plug into the proximal end of the applicable catheter.
- For Boston Scientific IntellaTip MiFi XP cables, the yellow cable plugs into the port marked "Catheter Cable" on the Filter Module and the red cable plugs into the center port marked “STD/XP” on the Ablation Pod. Connect the black cable plug into the proximal end of the applicable catheter.
- For information on how to connect a specific cable, refer to the applicable catheter and equipment instructions for use.
- For Sensor Enabled Ablation Connection Cable;
    a. Verify the connector cable is at room temperature prior to use to ensure accurate temperature measurement.
    b. Use the connection with the green strain relief to connect to the FlexAbility Ablation Catheter, Sensor Enabled.
    c. When connecting 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.
    d. Use the connection with the white strain relief to connect to the navigation and positioning systems.
        - For the MediGuide System, connect the white strain relief to the MediGuide CathConnect, Sensor Enabled.
        - For the EnSite Precision System, connect the white strain relief to the EnSite Precision Link, Sensor Enabled.
- For Medtronic RF Catheter Cables:
    a. Insert the Lemo connector on the 05106S RF catheter cable into the ablation catheter connection on the ATAKR Family RF ablation generator, or the Lemo receptacle on the extension cable.
    b. Attach the Redel plug to the RF catheter cable.
    c. To disconnect the cable, pull back on the locking ring to release the cable, then detach the cable from each connector.
- For EnSite X Catheter Connector Cables
    a. For Sensor Enabled diagnostic and non-Sensor Enabled diagnostic cables, use the connection with the black strain relief to connect to the catheter. For the bifurcated cables, use the red connector for pole 1-10 and the black connector for poles 11-20. For the magnetic extension cable, use the white receptacle to connect to the matching cable connector.
    b. For Sensor Enabled diagnostic and non-Sensor Enabled diagnostic cables, use the connection with the green (10-pole) or blue (20-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.
    c. Ensure that the connection is secure between the cable and connecting equipment.
    d. 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.

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257
www.innovative-health.com
877.400.3740 (t)

- Ensure that the connection is secure between the cable and connecting equipment.
- Upon use, please return the device per Innovative Health's instructions.

EXPLANATION OF SYMBOLS

	Federal Law in the USA restricts this device to sale by or on the order of a physician
	Sterilized by Ethylene Oxide Gas
	Catalog Number
	Serial Number
	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight
	Manufacturer

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.

The third-party trademarks used herein are for device identification and are trademarks of their respective owners.

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