Instructions for Use
Reprocessed (Reusable) Catheter Interface 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 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.
- 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.
- Misconnection of the pins to the sockets could lead to malfunction of the catheter.
- No modification of the device or equipment is allowed.
- Connected equipment current leakage (for Sensor Enabled Ablation Connection Cable) must not exceed 10 microamps.

PRECAUTIONS

- Do not immerse the cable connectors in fluids.
- 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, crushed or elongated sections and electrical insulation) prior to use.
- Use patient isolated equipment.

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- 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.

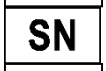
ADVERSE REACTIONS

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.
- **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.
- 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.
- Ensure that the connection is secure between the cable and connecting equipment.

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

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.