Instructions for Use
Reprocessed Umbilical 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 umbilical cable is an insulated, multi-conductor cable that is 200 cm (6.6 ft) in length with multi-pin connectors at each end.

INDICATIONS FOR USE
The reprocessed cable provides an electrical connection between the IntellaMap Orion Mapping Catheter and the Signal Station of the Rhythmia Mapping System. The reprocessed Umbilical Cable is intended to be used with an Orion Mapping Catheter during electrophysiology procedures, electroanatomical mapping, intracardiac stimulation (pacing) and/or recording of electrical potentials.

CONTRAINDICATIONS FOR USE
There are no known contraindications against the use of this reprocessed umbilical cable.

WARNINGS
None known.

PRECAUTIONS
- Be sure to read and understand all warnings, precautions, and instructions before using the reprocessed umbilical cable.
- Do not immerse the cable connectors in fluids and keep the connectors dry.
- Do not expose cable to organic solvents.
- To minimize the risk of damage, do not sharply bend or kink the umbilical cable. Do not use excessive force when connecting or disconnecting the umbilical cable connections.
- 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.
- Only use the reprocessed umbilical cable in environments typical of an electrophysiology lab.

ADVERSE REACTIONS
- There are no known contraindications against the use of this reprocessed umbilical cable.
- It is important to carefully review the Indications for Use and Adverse Events section in the associated compatible catheter Directions for Use and/or equipment prior to use.

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

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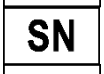
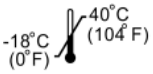
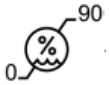
unless the package is opened or damaged. If the cable is kinked or damaged or if the packaging is compromised, do not use the cable. Do not attempt to repair any damage. Return the cable and packaging to Innovative Health.

- Read all product information and instructions prior to using the reprocessed umbilical cable.
- To connect a reprocessed umbilical cable connector, rotate the latch ring towards the arrow symbol while inserting the connector to the socket. Release the latch ring and test the connection by gently pulling on the connector.
- Prior to using the reprocessed umbilical cable, ensure that all cable connectors are securely attached. Loose connections may affect system operation.
- To disconnect, rotate the latch ring towards the arrow symbol and pull gently.
- For information regarding using the reprocessed umbilical cable with electrophysiology mapping or recording systems, refer to the manual that accompanies that system to ensure the umbilical cable is appropriate for that system.
- 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
	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
	Temperature limit
	Humidity limitation

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.

IntellaMap Orion is a registered trademark of Boston Scientific Corporation.

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