Instructions for Use
Reprocessed AFFERA Catheter Extension 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 AFFERA catheter extension cable (AFR-00006) is designed to connect a compatible catheter to the HexaMap catheter interface unit (CIU) and Affera ablation system.

INDICATIONS FOR USE
Refer to the instructions for use accompanying the compatible electrophysiology catheter for the specific indications for use.

It is important to carefully review the Indications for Use section in the associated compatible electrophysiology catheter Instructions for Use prior to use.

CONTRAINDICATIONS FOR USE
There are no known contraindications for the use of this cable. It is important to carefully review the Contraindications section of the associated compatible electrophysiology catheter Instructions for Use prior to use.

WARNINGS AND PRECAUTIONS
- Carefully check the condition of all packaging upon receipt of the cable. The cable is provided sterile. Sterility may be compromised if packaging is damaged. (e.g. cut, torn, punctured, or ripped).
- Carefully inspect the cable prior to use. Inspect for physical damage, including electrical insulation, cuts, kinks, nicks, crushed, elongated sections, or bent pins. Do not use cables that appear damaged.
- Ensure that the cable/catheter connection remains dry throughout the procedure.
- To minimize the risk of damage, do not sharply bend or kink the cable. Do not use excessive force when connecting or disconnecting the cable connections.
- Carefully read all instructions prior to use including the Instructions for Use for the Affera ablation system, Affera mapping system, and compatible catheter before use. Observe all contraindications, warnings, and precautions noted in the directions. Failure to do so may result in patient complications.
- Before using, inspect the cable for any defects or physical damage, including electrical insulation on the cable that may cause patient and/or user injury if the device is used. Replace damaged equipment. Do not use defective or damaged devices. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury.
- Position connecting cables to avoid contact with the patient and other electrical leads.
- The reprocessed catheter extension cable is packaged and sterilized for single patient use only. Do not reuse or resterilize the device.
- The pouch contents are sterile unless the package has been damaged or opened.

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- The catheter extension cable must be used by the Use-by date printed on the package label. Do not use the cable after the Use-by date.
- The catheter extension cable is intended for use only with compatible Medtronic devices and equipment.
- Cardiac mapping and ablation procedures are to be performed only by physicians trained in electrophysiology procedures in a fully equipped electrophysiology laboratory.
- Do not submerge the cable connectors in any liquid. If the cable connector is wet, do not use the cable.
- Do not expose the device to organic solvents such as alcohol.

ADVERSE REACTIONS

- It is important to carefully review the Adverse Events section in the associated compatible electrophysiology catheter Instructions for Use prior to use for potential complications and adverse events associated with cardiac mapping and ablation procedures.

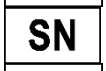
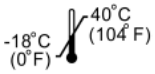
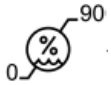
DIRECTIONS

- 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 to Innovative Health.
- On the catheter extension cable, the circular 52-pole connector is intended for connection to compatible Affera equipment.
- To connect, align the key and press the connector into the receptacle.
- To remove, rotate the outer ring counterclockwise to release the locking mechanism and pull the connector from the receptacle.
- The oblong edge card connector is intended for connection to the compatible catheter. Properly orient the connector and press into the catheter handle until the locking mechanism clicks into place.
- To remove, press the thumb activated release button and pull the connector from the catheter handle.
- Upon use, please return the device per Innovative Health's instructions.

DEVICE COMPATIBILITY

- Use only with the Sphere-9 catheter (not supplied) and verify compatibility with other required 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
	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
	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.

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

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IFU-ECC-0004 Rev.1 2026-08-17