Instructions for Use
Reprocessed FARASTAR Catheter Connection 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 FARASTAR Catheter Connection Cable (henceforth referred to as the reprocessed FARASTAR Connection Cable) has multi-pin quick-disconnect plugs that connect the FARASTAR Pulsed Field Ablation (PFA) Generator to a FARAPULSE Catheter.

INDICATIONS FOR USE
The reprocessed FARASTAR Connection Cable is intended to be used with a FARAPULSE Catheter during an Electrophysiology procedure for cardiac tissue ablation.

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

CLINICAL BENEFIT STATEMENT
When operated by the intended user the clinical benefit (as determined by the Original Manufacturer) of the FARAPULSE PFA System is the elimination of atrial fibrillation by selectively creating durable conduction block at targeted myocardial tissue with low likelihood of damage to adjacent structures. Pulsed field ablation does not rely on thermal effects and thereby incurs low risk of thermal damage such as pulmonary vein stenosis, phrenic nerve injury, or esophageal injury. In addition, pulsed field ablation therapy is less invasive than open-chest surgical interventions.

CONTRAINDICATIONS FOR USE
It is important to carefully review the Contraindications section of the associated compatible FARAPULSE Catheter Instructions for Use prior to use.

WARNINGS
- Carefully read all instructions prior to use including the Instructions for Use for the associated compatible FARAPULSE Catheter. Observe all indications, contraindications, warnings and precautions noted in these instructions. 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. No repair or modification of this equipment is allowed as this may result in electrical shock or inducement of arrhythmias. Do not use if sterile barrier is damaged or unintentionally opened before use, as use of non-sterile devices may result in patient injury.

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

PRECAUTIONS

- The reprocessed FARASTAR Connection Cable is a component of the FARAPULSE PFA System and is intended for those physicians who are specialists trained in cardiac ablation procedures to treat cardiac arrhythmias in a fully-equipped electrophysiology laboratory. Assistance to connect the cable and operate the FARASTAR Generator may only be provided by fully trained electrophysiology laboratory staff.
- It is important to carefully review the Precautions section in the associated compatible FARAPULSE Catheter Instructions for Use prior to use.
- Use only with the FARASTAR generator. Consult the FARASTAR Generator User Manual for more information.
- 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 damaged equipment.
- 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.

ADVERSE REACTIONS

- It is important to carefully review the Adverse Events section in the associated compatible FARAPULSE Catheter Instructions for Use prior to use and FARASTAR PFA Generator User Manual 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 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.
- Prior to use, consult the compatible FARAPULSE PFA Generator and Catheter IFUs.
    1. Introduce the cable aseptically into the sterile field.
    2. In the sterile field, connect either end of the cable to a compatible FARAPULSE Catheter.
    3. In the non-sterile field, connect the cable to the FARASTAR PFA Generator.
    4. Prior to using the cable, ensure that all cable connectors are securely attached.

  Note: To disconnect, rotate the latch ring toward the arrow symbol and pull gently.
- Upon use, please return the device per Innovative Health's instructions.

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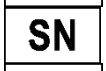
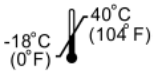
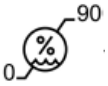
IFU-ECC-0003 Rev. 1 2025-02-27

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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