Instructions for Use
Reprocessed Torqr Diagnostic Electrophysiology (EP) Catheter

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 Torqr Diagnostic EP Catheter is a flexible, radiopaque catheter constructed of extruded polyurethane over stainless steel braid and platinum electrodes. The catheter is of high torque construction to aid in precise catheter placement.

INDICATIONS FOR USE
The Reprocessed Torqr Catheter is intended for use in diagnostic electrophysiologic procedures. The catheter is designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.

CONTRAINDICATIONS
There are no known contraindications for this catheter.

WARNINGS
- This device should be used only by or under the supervision of physicians well trained in electrophysiology, including the placement and use of intracardiac electrode catheters.
- Do not use catheter for intracardiac ablation or for DC ablation. United states law does not permit the use of this catheter for these types of ablation.
- Use electrical recording stimulation equipment that is “front end isolated” or use an isolated patient cable. Current leakage from any connected electrical equipment must not exceed 10μA for intracardiac electrodes.
- To be used with only Medtronic cables.
- Tactile feedback of reprocessed device may vary during use.

PRECAUTIONS
- Do not attempt to use the reprocessed electrophysiology catheter prior to completely reading and understanding the *directions for use.*
- Do not alter this device.
- Inspect the packaging and catheter for damage or defects prior to use.
- Do not excessively bend or kink the catheter. Excessive bending or kinking may damage internal electrode wires and/or distal tip shaping capabilities.
- Do not allow moisture onto the connectors on the catheter or cables. If the connectors get wet, the system may not function correctly.
- Do not wipe the catheter with organic solvents, such as alcohol, to maintain optimal patient safety and catheter electrode integrity.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).

ADVERSE REACTIONS

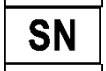
- Potential risk and complications - perforation of the vasculature is an inherent risk of any catheter placement. Additional potential complications are those attending any intracardiac catheterization procedure including but not limited to, cardiac tamponade, thromboembolic episodes, hematoma, pneumothorax, local or systemic infection, and death.

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the catheter is damaged or if the package is compromised, do not use the catheter. Return the catheter and packaging to Innovative Health. Do not attempt to resterilize.
- Remove the catheter from the package and place it in a sterile work area using aseptic technique.
- Inspect the catheter carefully for electrode integrity and overall condition. Do not use the catheter if the electrodes or tip is loose, misshapen, or otherwise visibly damaged.
- Anticoagulation is to be used at all times during the procedure.
- Perform vascular access utilizing a sterile technique. The catheter may be inserted from femoral, brachial, subclavian, or jugular access sites.
- Connect the catheter to the catheter cable.
    a. Match connector colors for proper cable to catheter connection
    b. Connect the cable and align the double arrows on the cable's plastic connector with the external button on the catheter handle connector.
    c. Press the connectors together. Do not force the connection.

  Note: to disconnect the catheter cable from the catheter, pull back on the grip ring to release the lock before removing the connector.
- Connect the lead pins of the Catheter Connecting Cable to the appropriate electronic recording and/or stimulation equipment. Refer to the Catheter Connecting Cable Technical Manual for further information
- Advance the catheter into the desired area of the heart using fluoroscopic and ECG guidance.

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 and Radioactive Sources
	Non-pyrogenic

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.