



Instructions for Use

Reprocessed Radia™ Steerable Diagnostic Electrophysiology 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 Radia Steerable Diagnostic Electrophysiology (EP) Catheter is a radiopaque, flexible, insulated catheter with a polymer shaft and a 2mm distal tip. The catheter handle has a rotary mechanism which, when rotated from the neutral position, results in curvature of the distal tip.

INDICATIONS FOR USE

The Reprocessed Radia Steerable Diagnostic EP Catheter is intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

CONTRAINDICATIONS FOR USE

- The catheter should not be used in conditions where manipulation of the catheter would be unsafe (e.g. intracardiac mural thrombus).
- The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

WARNINGS

- This device should be used only by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing.
- The risks of using electrophysiology catheters include those risks related to heart catheterization, such as thromboembolism, perforation, tamponade, and infection. The induction of an unintended arrhythmia is a known complication.
- Do not use excessive force to advance or withdraw the catheter when resistance is encountered.
- Catheter advancement should be done under fluoroscopic guidance.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

- Do not attempt to use the reprocessed EP catheter prior to completely reading and understanding the *Directions for use*.
- Inspect the packaging and catheter for damage or defects prior to use.
- Use only sterile saline or water to wipe the catheter.
- Avoid submerging the catheter handle in any solution.
- The catheter is equipped with a cable connector; use with the appropriate cable.
- Excessive bending, torqueing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.

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ADVERSE REACTIONS

None listed.

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 to Innovative Health. **Do not attempt to resterilize.**
- Remove the catheter from its package using appropriate sterile technique and place it in a sterile work area.
- Inspect the electrodes and catheter for integrity, continuity of leads and overall condition. Do not use the catheter if damage is observed. Return any damaged catheter to Innovative Health.
- Connect the catheter to the appropriate cable.
- Insert the catheter by using a standard percutaneous catheter introducer.
- The catheter should be passed from a peripheral vessel to the desired intracardiac position under fluoroscopic guidance.
- The catheter tip can be deflected by rotating the thumbwheel mechanism on the handle from the neutral position. When the thumbwheel is in the neutral position, the tip is approximately straight.
- The catheter tip is in a neutral position when the white indicator dot is visible through the handle window and the arrow aligns with indicator dot.
- Upon completion, return the catheter to the neutral position prior to removal from the patient.

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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



Keep Product Dry



Keep Away from Sunlight



Do Not Use if Package is Damaged



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.

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