Instructions for Use
Reprocessed Dynamic Tip™, Dynamic XT™ and EP XT™ 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 Dynamic Tip, Dynamic XT and EP XT Steerable Diagnostic Electrophysiology (EP) Catheters are radiopaque, flexible, insulated catheters with a polymer shaft. The catheters have a plunger mechanism, which, when moved forward or back, results in curvature of the distal tip.

INDICATIONS FOR USE
The Reprocessed Dynamic Tip, Dynamic XT, and EP XT Steerable Diagnostic EP Catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

CONTRAINDICATIONS FOR USE
- 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
- The device(s) should be used by physicians thoroughly trained in the techniques of intracardiac electrophysiology studies and temporary pacing.
- The risk of using electrophysiology catheters include those risk 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.
- The safety and effectiveness of this device as an ablation catheter have not been established. Therefore, such use is considered investigational.
- Use only sterile saline or water to wipe this catheter.
- Avoid submerging the catheter handle in any solution.
- The catheter is equipped with a cable connector; use with the appropriate cable.
- Excessive bending, torquing, or kinking of the electrode catheter may cause damage to the catheter, including damage to the internal wires.

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

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 for reprocessing. **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 carefully for integrity, continuity of leads and overall condition. Do not use the catheter if damage is observed. Return the catheter to Innovative Health.
- Insert the catheter by using a standard percutaneous catheter introducer.
- The electrode catheter should be passed from a peripheral vessel to the desired intracardiac position under fluoroscopic guidance.
- **For Dynamic Tip and Dynamic XT:** The catheter tip can be deflected by advancing or retracting the plunger mechanism on the handle. When the plunger mechanism is in the fully retracted position, the tip is approximately straight.
- **For EP XT:** The catheter tip is in a straight position when the white indicator dot is visible through the handle window. Rotate the white handle between the thumb and forefinger in a clockwise motion until the desired curve is attained. To straighten the tip, rotate in a counterclockwise motion until the white indicator dot reappears.
- All catheter adjustments should be done under fluoroscopic guidance.
- Upon completion of the procedure, return the catheter to the neutral position prior to removal from the patient.

Explanation of Symbols

Rx only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
REF	Catalog Number
SN	Serial Number
LOT	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
	Upper Limit of Temperature
	Type CF Applied Part
	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 gas (EO). 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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