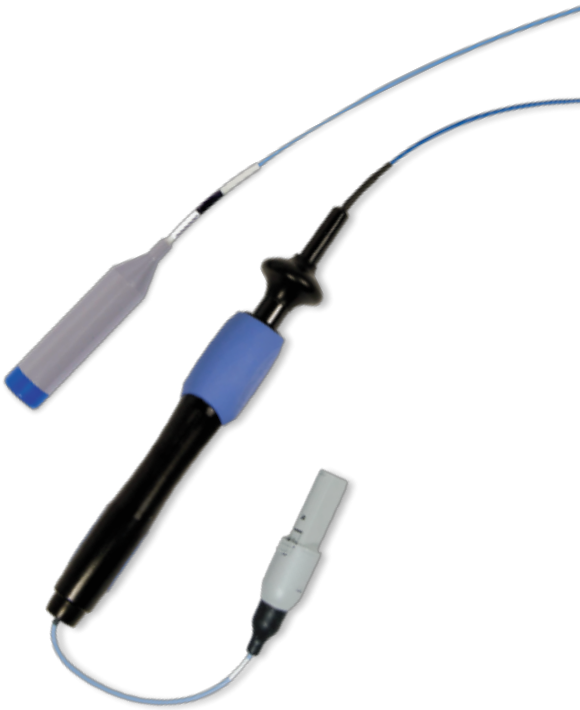
Reprocessing **overview**

Electrophysiology catheters

- **Product availability:** Reprocessed EP catheters are packaged in case quantities equivalent to original equipment manufacturer (OEM) packaging and released for sale.
- **Decontamination and cleaning:** Reprocessed EP catheters are initially inspected for visible damage. Devices found with visible damage or gross contamination are rejected immediately. Every EP catheter then undergoes a multi-step cleaning process that involves:
  - Lot testing of bacterial endotoxins to an established acceptance criteria of less than 20 endotoxin units per device
  - Prolonged soaking, cleaning and rinsing in pH-neutral enzymatic cleansers and sanitizers that are compatible with all device materials
- **Device tracking:** Every EP catheter is marked for reprocessing cycles to ensure the device is never reprocessed beyond its maximum number of cleared cycles. Upon receipt, all quantities of approved devices are scanned into a device tracking system and recorded.
- **Auditing the process:** Routine quality control audits are completed to ensure process integrity. Reports are provided to senior management for operating line performance and control. Additionally, finished product performance attributes, including cleaning endpoints, are routinely subjected to random sampling and inspection.
- **Documentation:** Production support staff is required to sign off after performing each reprocessing step. Detailed documentation ensures traceability of critical steps performed. Records are maintained in accordance with FDA and ISO requirements.
- **Performance testing:** Every EP catheter is functionally tested using proprietary equipment to make sure that it meets intended use. This includes measuring curves against standard templates to ensure the direction, shape and plane of the curve meets Stryker's established criteria. Tip protectors are placed on fixed curve catheters to ensure that the radius of the curvature remains unchanged. All testing ensures devices meet pre-determined performance specifications.
- **Visual inspection:** Every EP catheter is inspected throughout various steps of the production process to ensure non-conforming products are rejected. Devices are inspected for debris, contamination and overall device integrity.
- **Packaging:** EP catheters are packaged individually in Tyvek pouches. The packaging is sealed and labeled as sterile.
- **Ethylene oxide exposure:** Ethylene oxide (EO) exposure is validated utilizing ANSI/AAMI/ISO 11135 for the sterilization process. The sterilization process is validated to consistently and reliably achieve a Sterility Assurance Level (SAL) of 10^{-6}. EO residuals do not exceed maximum allowable limits of ANSI/AAMI/ISO 10993-7.

Product summary

- EP Catheters are reprocessed by us and originally manufactured by companies such as Biosense Webster, Abbott/St. Jude, Boston Scientific, Baylis Medical Company, and Medtronic.



Sustainability Solutions **1 888 888 3433** **sustainability.stryker.com**

MKT10247 Rev. A 1932 | 1810 West Drake Drive, Tempe, AZ 85283 USA | 888 888 3433 | Copyright © 2019 Stryker