Reprocessing **overview**

stryker

Reprocessed MyoSure Tissue Removal Suite

Decontamination and cleaning: Our reprocessed hysteroscopic tissue removal devices are initially inspected for visible damage. Devices found with visible damage or gross contamination are rejected immediately. Every device then undergoes a multi-step cleaning process that involves shaft disassembly, handle disassembly, shroud milling, shaft pre-treatment and inner/outer shaft cleaning.

1. The OEM shroud is removed and discarded. The handpiece is separated to prepare all internal components for cleaning.
2. The cutting shaft, outer shaft and drive cable are all separately cleaned in batches.
3. Synergies have been identified within our cleaning lines to optimize the use of water and unnecessary chemicals. This will reduce water use by 164 gallons each time a batch of devices goes through the cleaning process.

Replacement components: The MyoSure LITE cutting shaft is sharpened and the MyoSure, MyoSure REACH, MyoSure XL and MyoSure XL for Fluent undergo complete blade replacements that are equally robust, wear resistant and will provide equal cutting performance.

- Polyvinyl chloride (PVC) is a chemical or concern for our healthcare partners. To align with their harmful chemical reduction goals, we have sourced PVC-free tubing to replace the original suction tubing.
- On most models, the shroud is replaced with a bio-based plastic that is manufactured using sustainably sourced trees. Not only does this allow for reduced reliance on petroleum-based plastic, but for every two trees that are removed for the bio-plastic, three are planted, thus safeguarding this renewable resource for future generations.

Performance testing: Every tissue removal device is functionally tested using electrical testing, suction testing, blade inspection to ensure cutting performance, foot pedal activation, hand piece button operation for XL models and recognition by OEM control unit.

Visual inspection: All tissue removal devices are inspected throughout various steps of the production process to ensure non-conforming products are rejected. Devices are inspected for debris, contamination and for overall device integrity. Before assembly, an automated vision system is utilized to ensure components are in the proper location.

Device tracking: Each tissue removal device is labeled with a barcode on the handle and 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.

Packaging: Hysteroscopic tissue removal devices are packaged individually in our unique packaging design, consisting of the thermoformed trey, Tyvek lid and corrugated shipping box. Compared to OEM packaging, we have reduced the packaging weight by 34%, which will result in 53,000 lbs. of material reduction over five years. The packaging is also able to be recycled within typical hospital streams. Finally, our MyoSure devices are packaged in case quantities equivalent to the original equipment manufacturer and distributed for sale.

Ethylene oxide exposure: Ethylene oxide (EO) exposure is validated utilizing ANSI/AAMI/ISO 11135 as a guideline for this bioburden reduction process. EO decontamination validation demonstrates the process and equipment are capable of consistently and reliably achieving a minimum six spore log reduction (SLR). EO residuals do not exceed maximum allowable limits of ANSI/AAMI/ISO 10993-7.

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 end points, are routinely subjected to random sampling and inspection.

Documentation: Production support staff are 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.

Product summary

- Our reprocessed tissue removal devices include the following models: MyoSure, MyoSure LITE, MyoSure REACH, MyoSure XL and MyoSure XL for Fluent) originally manufactured by Hologic.
- Our devices are redesigned for sustainability to reduce packaging, polyvinyl chloride (PVC) along with water and chemical waste.

Sustainability Solutions 1 888 888 3433 sustainability.stryker.com

MKT10344 REV A 2204 | Stryker, 1810 West Drake Drive, Tempe, AZ 85283 USA | 888 888 3433 | Copyright © 2022 Stryker