Reprocessing **overview**

Electrocardiogram (ECG) leads and cables

Product availability: Reprocessed ECG leads and cables are packaged in case quantities equivalent to original equipment manufacturer (OEM) packaging and distributed for sale.

Decontamination and cleaning: Reprocessed ECG leads and cables are initially inspected for visible damage. Devices found with exposed or damaged circuitry are rejected immediately. Every ECG lead then undergoes pre-processing through a multi-step process that involves:

- Visual inspection and removal of any debris on the connectors
- An automated cleaning process using medical grade cleaners and disinfectants
- Visual inspection and manual removal of residual contamination

Device tracking: All ECG leads and cables are labeled with a distinct bar code to ensure devices are never reprocessed beyond the 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 end points, 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: All ECG leads and cables are functionally tested for continuity to ensure substantial equivalence to the OEM's device. Functional testing development and validation has been performed according to ANSI/AAMI EC53 and IEC 60601-1 standards.

Visual inspection: All ECG leads and cables 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.

Packaging: ECG leads and cables are packaged individually in polyethylene bags. The packaging is heat-sealed and labeled as non-sterile.

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.

Product summary

- Our reprocessed ECG leads and cables include 3, 5 and 6-lead models originally manufactured by Covidien, Philips and AMC&E.
- All reprocessed ECG leads and cables are visually inspected and performance tested to ensure functionality.

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