

NON-INVASIVE MEDICAL DEVICES

DUT COMPRESSION SLEEVES • PNEUMATIC TOURNIQUET CUFFS
PULSE OXIMETER SENSORS



stryker[®]

Sustainability Solutions

REPROCESSED NON-INVASIVE DEVICES

STRYKER'S PORTFOLIO OF REPROCESSED SINGLE-USE DEVICES

Non-invasive devices reprocessed by Stryker include: DVT compression sleeves, pulse oximeter sensors and pneumatic tourniquet cuffs. Original manufacturers of Stryker's reprocessed non-invasive devices include: Kendall, Huntleigh, Compression Therapy Concepts, Hill-Rom, Masimo®, Zimmer and Stryker. Restep® DVT compression sleeves are both manufactured and reprocessed by Stryker.

Stryker understands that safety always comes first in using medical devices and has a long-standing history of providing high-quality reprocessed non-invasive devices to healthcare providers.

Over the years, the United States Food and Drug Administration (FDA) has increased regulation surrounding reprocessed devices. After extensive analysis, both the FDA and the Government Accountability Office (GAO) have concluded reprocessed single-use devices that meet the FDA's regulatory requirements are safe and substantially equivalent to counterpart devices produced by original manufacturers. Since Stryker's reprocessing programs help organizations reduce costs and environmental impact, these programs represent an advancement in responsible healthcare.

© DVT Compression Sleeves



© Pulse Oximeter Sensors



© Pneumatic Tourniquet Cuffs



THE SCIENCE OF REPROCESSING



IDENTITY CONTROL

Identifying devices with permanent cycle marks ensures stringent control of reprocessing cycles.



VISUAL INSPECTION

Devices are inspected for debris, contamination, and for overall device integrity.



DISASSEMBLY

Pulse oximeter sensor adhesive is removed and replaced. Other non-invasive devices do not require disassembly.

PERFORMANCE TESTING

Measurements for reprocessed devices are compared to original manufacturer devices. Stryker evaluates the reliability of all devices under actual and simulated use conditions. Data has conclusively demonstrated that no significant difference can be ascertained between Stryker devices and original devices.

Following validated protocols, every device is subjected to a unique reprocessing method. Process controls are in place to ensure that every device is reprocessed according to strict protocols. Quality control personnel are always on site to verify records, and every reprocessed device is inspected multiple times throughout the production cycle.

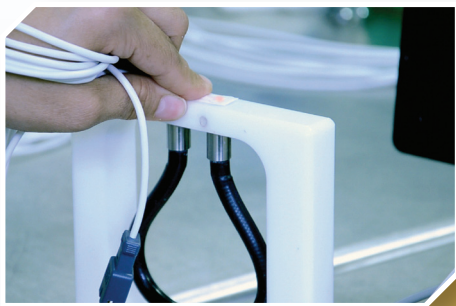
At any stage of reprocessing, staff members are authorized to remove any non-conforming devices or device components. If appropriate to the device, the process concludes with function tests. Devices are then packaged in original manufacturer case quantities and sterilized, if applicable.

All devices are sterilized with ethylene oxide gas to a sterility assurance level of 10^{-6} , per ANSI/AAMI/ISO 11135, and quarantined until biological indicators pass evaluation by Quality Assurance teams. Ethylene oxide residuals never exceed maximum allowable limits of ANSI/AAMI/ISO 10993-7.

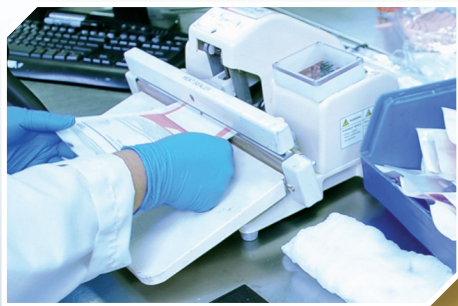
Stryker’s robust cleaning systems employ a rigorous validation paradigm that far exceeds a worst-case scenario in terms of soil and dwell times, which mimic storage and shipping conditions.



COMPREHENSIVE CLEANING
Devices are subjected to tailored, validated cleaning processes that render the components safe.



PERFORMANCE TESTING
100% of devices are function tested and inspected to ensure they meet performance standards.



PACKAGING AND STERILIZATION
Devices meet all industry standards for packaging and sterilization.

Device Type	Annual Savings Estimate*	Waste Diversion Estimate
DVT Compression Sleeves	\$27,950	5,358 lbs.
Pneumatic Tourniquet Cuffs	\$28,883	1,425 lbs.
Pulse Oximeter Sensors	\$99,000	1,100 lbs.
Total Savings	\$155,883	7,883 lbs.

*Savings estimates are based on best-demonstrated practices at a hospital with an average of 250 beds. A hospital’s true savings potential is not realized immediately; rather, savings may increase over time as reprocessing is continuously embraced by staff as a standard best practice.

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THE SCIENCE OF REPROCESSING

CLEAN, SAFE & FUNCTIONAL

With more than two decades of reprocessing experience, Stryker delivers clean, safe and functional non-invasive devices. Stryker's design control process incorporates internal and independent third-party validation of all cleaning systems.

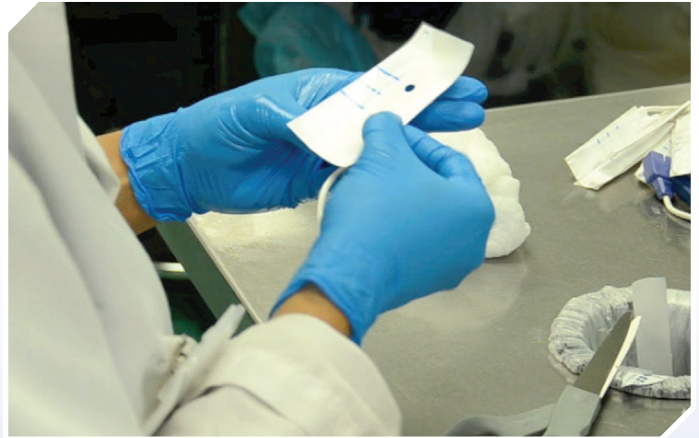
Stryker's robust cleaning systems employ a rigorous validation paradigm that exceeds a worst-case scenario in terms of soil and dwell times, which mimic storage and shipping conditions.

Every inoculated device is subjected to Stryker's decontamination, cleaning, and inspection procedures. Clean devices are sent to a special laboratory for extraction and testing. The lab tests for organic soil such as protein and total organic carbon. Extraction and testing is performed according to strict industry standards. Organic soil residual levels are quantified and must meet acceptable standards as indicated by AAMI TIR 30.



Visual inspection of DVT compression sleeves

Several tests including sterility, bacteriostasis/fungistasis and comparative resistance are performed to ensure the sterility of the reprocessed devices. Stryker validates the sterilization process to a sterility assurance level of 10^{-6} and utilizes specially designed procedures to ensure sterility meets FDA-recognized standards. Procedures are designed to assure the validity of the sterilization process according to standards recognized by the FDA for performing sterilization



Adhesive tape is removed and replaced during reprocessing of pulse oximeter sensors

validations. Stryker's validations are based on ANSI/AAMI/ISO 11135, which establishes requirements for sterilization of medical devices.

Bench testing is conducted to verify that device characteristics are not compromised following the maximum number of proposed cleared reprocessing cycles. Test samples must meet all acceptance criteria, demonstrating the reprocessed device remains safe and effective for clinical use.

VALIDATION TESTING

Stryker's validation procedures include:

- Performance Testing
- Stress Testing
- Adhesion Testing (pulse oximeter sensors)
- Biocompatibility Testing

COLLECTION

PROTOCOL

DVT compression sleeves and pneumatic tourniquet cuffs are collected in hamper-stands or x-stands with recyclable bags, which are collected regularly by local service representatives.

Devices are logged in and tallied, and then entered into the production stream for reprocessing. Finished devices are available immediately to customers for purchase through Stryker's Rapid Return system.



Stryker offers a variety of collection containers tailored to collection sites and customer volumes. Stryker collection containers and associated materials are approved by infection control professionals to be placed in a variety of areas such as patient rooms, soiled utility areas and central sterile processing departments. Stryker offers a variety of pulse oximeter sensor containers, including four-gallon and two-gallon, which may be mounted on walls or placed on counter tops.

ON-DEMAND



Stryker also offers On-Demand ordering, allowing for a simplified method for integrating product into customers' supply chains.

On-Demand provides Stryker the ability to electronically process orders via GHX Healthcare Exchange for customers that utilize electronic data interchange (EDI) transactions. This innovation will allow purchasing staff to eliminate paper invoices and fully utilize their materials management information system as intended for replenishing inventory.

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