The Science of Reprocessing

Clean, Safe & Functional

With more than two decades of reprocessing experience, Stryker delivers safe, functional and sterile surgical 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 far 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. Extraction and testing is performed according to strict industry standards. Efficiency of extraction, blood soil and positive control filters are included in the summary report. Residual levels are quantified and must meet acceptable standards as indicated by AAMI TR 30. 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-regulated standards. Procedures are designed to assure the viability of the sterilization process according to standards recognized by the FDA for performing sterilization validations. Stryker’s validations are based on ANSI/AAMI/ISO 11135, which establishes requirements for sterilization of medical devices.

Validation Testing

A significant component of Stryker’s validation procedures required for FDA 510(k) clearance is the performance of numerous validation tests such as:
• Dielectric strength testing
• Cut-testing
• Grasping force testing
• Sealing pressure testing
• Seal integrity

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.

Reprocessed Surgical Devices

Laparoscopic Instruments • Suture Passers
Trocars • Ultrasonic Scalpels

Sustainability Solutions

Strayer's reprocessing program, called Advantage, is designed to maximize collections of surgical devices and minimize extra effort required by clinical staff. The proprietary Advantage collection system container is placed according to facility operations and is designed to minimize room turnover times. Surgical devices are placed in Advantage containers and returned to Stryker’s facility. 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.

Final inspection under magnification of laparoscopic scissors after sharpening

Strayer delivers clean, safe, functional and sterile surgical devices.
STRYKER’S PORTFOLIO OF REPROCESSED SINGLE-USE DEVICES

Laparoscopic devices reprocessed by Stryker include: trocars, suture passers, laparoscopic instruments and ultrasonic scalpels originally manufactured by Ethicon Endo-Surgery, Covidien, Applied Medical, and others. Open surgical devices include ultrasonic scalpels originally manufactured by Ethicon Endo-Surgery, and LigaSure™, originally manufactured by Covidien.

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

THE SCIENCE OF REPROCESSING

IDENTITY CONTROL

Identifying devices with unique barcodes ensures control of reprocessing cycles.

DISASSEMBLY

Devices are disassembled to basic components where applicable to facilitate cleaning and inspection.

COMPREHENSIVE CLEANING

Devices are subjected to validated cleaning processes that render the components safe.

REASSEMBLY

Using only components that pass stringent tolerances, finished devices are reassembled where applicable.

PERFORMANCE TESTING

Performance testing for surgical devices is divided into two categories: structural and mechanical. Structural tests assess the overall structural soundness of devices, ensuring that devices will be delivered to the point of use in working condition. Structural tests assess the functional capabilities of devices as they relate to use, ensuring that devices function as intended when delivered.

Electrical testing of the LigaSure™ Hand Activated Sealer/Divider

IDENTITY CONTROL

PERFORMANCE TESTING

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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.

Electrical testing of the LigaSure™ Hand Activated Sealer/Divider

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THE SCIENCE OF REPROCESSING

IDENTITY CONTROL
Identifying devices with unique barcodes ensures control of reprocessing cycles.

DISASSEMBLY
Devices are disassembled to base components (where applicable) to facilitate cleaning and inspection.

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

REAASSEMBLY
Using only components that pass stringent tolerances, finished devices are reassembled (where applicable).

PERFORMANCE TESTING
100% of all devices are function tested and/or inspected to ensure performance.

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

IDENTITY CONTROL
Identifying devices with unique barcodes ensures control of reprocessing cycles.

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Devices are disassembled to base components (where applicable) to facilitate cleaning and inspection.

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Performance testing for surgical devices is divided into two categories: structural and mechanical. Structural tests assess the overall structural soundness of devices, ensuring that devices will be delivered to the point of use in working condition. Mechanical tests assess the functional capabilities of devices as they relate to use, ensuring that devices function as intended when delivered.

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<table>
<thead>
<tr>
<th>Device Type</th>
<th>Annual Savings Estimate</th>
<th>Waste Diversion Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic Devices</td>
<td>$46,899</td>
<td>2,144 lbs.</td>
</tr>
<tr>
<td>Ligasure Sealer/Dividers</td>
<td>$65,880</td>
<td>118 lbs.</td>
</tr>
<tr>
<td>Suture Passers</td>
<td>$12,764</td>
<td>31 lbs.</td>
</tr>
<tr>
<td>Trocars</td>
<td>$62,172</td>
<td>992 lbs.</td>
</tr>
<tr>
<td>Ultrasonic Scalpels</td>
<td>$101,096</td>
<td>536 lbs.</td>
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<tr>
<td><strong>Total Savings</strong></td>
<td><strong>$288,811</strong></td>
<td><strong>3,821 lbs.</strong></td>
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</tbody>
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*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.

The third-party trademarks used herein are trademarks of their respective owners.
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Electrical testing of the LigaSure™ Hand Activated Sealer/Divider

Device Type | Annual Savings Estimate* | Waste Diversion Estimate
---|---|---
Laparoscopic Devices | $46,899 | 2,144 lbs.
LigaSure Sealer/Dividers | $65,880 | 31 lbs.
Suture Passers | $12,764 | 3lbs.
Trocars | $62,172 | 992 lbs.
Ultrasonic Scalpel | $101,096 | 536 lbs.
Total Savings | $288,811 | 3,821 lbs.

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**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 QR 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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**VALIDATION TESTING**

A significant component of Stryker’s validation procedures required for FDA 510(k) clearance is the performance of numerous validator tests such as:

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