Performance Verification: Material characteristics, electrical profiles and mechanical designs are identified and compared with predicate original manufacturer devices. Torsion, deflection, joint seal integrity and tensile strength testing establish the mechanical functionality and reliability of reprocessed electrophysiology (EP) catheters.

Decontamination and Cleaning: Accepted EP catheters undergo comprehensive cleaning that incorporates prolonged soaking, cleaning and rinsing in pH-neutral enzymatic cleansers and sanitizers that are compatible with all device materials. Residual levels of organic materials, such as protein, hemoglobin and total organic carbon are quantified and compared with acceptable standards. Stryker’s standards are based on AAMI TIR30, a series of processes, materials, test methods and acceptance criteria for cleaning medical devices.

Visual Inspection: All reprocessed EP catheters are thoroughly inspected under magnification to evaluate each device component for cleanliness and surface defects. All non-conforming EP catheters are rejected.

Electrical Profile: The electrical road map for reprocessed EP catheters includes measurement and/or calculation of continuity to verify functionality as well as isolation (cross talk), to detect any breakdown of electrical insulation. Short circuits are detected by measuring the resistance between each pair of electrodes.

Product Summary:
- Fixed, steerable and mapping catheters
- Broad range of sizes and electrode configurations
- Every major original manufacturer

The 20-pole Lasso® 2515 NAV eco Catheter.
PRODUCT INFORMATION

**Mechanical Integrity:** All reprocessed EP catheters are tested and verified for mechanical functionality. Curves are measured against standard templates to ensure the direction, shape and plane of the curve meet Stryker’s established criteria. Tip protectors are placed on fixed curve catheters to ensure that the radius of the curvature remains unchanged.

**Pyrogen Free:** Confirmation of EP catheter cleanliness is accomplished by daily lot testing of bacterial endotoxins to an established acceptance criteria of less than 20 endotoxin units per device.

**Device Tracking:** Every reprocessed EP catheter is identified by a unique serial number to ensure strict life cycle control of every device.

**Packaging & Labeling:** All reprocessed diagnostic EP catheters are packaged individually either in coiled or straight mylar/Tyvek® pouches prior to sterilization. Appropriate curve protectors are placed on the fixed curve catheter tips. Catheters are packed coiled on restraint boards or in thermoformed trays for stability and protection. The outer package sizes are designed to closely match the original manufacturer package sizes. Catheters are labeled by item number for easy and accurate identification.

**Sterilization:** Ethylene oxide sterilization is validated as per ANSI/AAMI/ISO 11135 to a sterility assurance level of $10^{-6}$. Ethylene oxide residuals do not exceed maximum allowable limits of ANSI/AAMI/ISO 10993-7.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Average Annual Usage*</th>
<th>Average (OM)** Acquisition Cost***</th>
<th>Savings Estimate</th>
<th>Savings Percentage*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bard Steerable</td>
<td>300</td>
<td>$400</td>
<td>$76,500</td>
<td>64%</td>
</tr>
<tr>
<td>Bard Fixed</td>
<td>150</td>
<td>$120</td>
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<tr>
<td>Biosense Webster</td>
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<tr>
<td>St. Jude Medical Steerable</td>
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<td>$750</td>
<td>$74,700</td>
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</tr>
</tbody>
</table>

- Assumes 150 Atrial Fibrillation cases performed in one year
- OM – Original Manufacturer
- Source: ECRI Institute; Actual savings estimate will depend on OM pricing extended to hospital

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