ORTHOPEDIC/ARTHROSCOPIC SURGERY DEVICES

ARTHROSCOPIC WANDS • ARTHROSCOPIC SHAVERS
BITS, BLADES AND BURS
Stryker's portfolio of single-use devices for orthopedic surgery includes arthroscopic wands originally manufactured by Mitek, Arthrocare and Stryker. Stryker reprocesses arthroscopic shavers and burs originally manufactured by Smith & Nephew, Mitek, Arthrocare, Dyonics, Smith & Nephew, and Stryker. Stryker also reprocesses surgical accessories such as bits, blades, and burs originally manufactured by Acumed, Biomet, DePuy, Hall Surgical, Linvatec, Mectra Labs, Microaire, Smith & Nephew, Stryker, Synthes, and Zimmer. Included are surgical drill bits, saw blades, burs, chisels, rasps, taps, and reamers used in orthopedic, pediatric, and cardiac surgeries. Surgical accessories vary in length, width, surface area, cutting edge, and flutes (burs) and are indicated for use in patients requiring surgery involving bone and bony structures.

**ARTHROSCOPIC WAND REPROCESSING**

Arthroscopic wands and electrodes, sometimes referred to as soft tissue ablaters, are radio frequency surgical tools designed for removal and dissection of tissue in arthroscopic surgeries. Reprocessed arthroscopic wands are Class II devices under Code of Federal Regulations (21 CFR 878.4400) and require pre-market submission prior to sale under the United States Food and Drug Administration (FDA) regulation.

Arthroscopic wands are initially inspected under video magnification for cracked or broken electrode tips, handles, cords, and connector pins. If necessary, original heat-shrink coating is removed to ensure thorough cleaning of all surfaces. Wands are cleaned with multiple ultra-sonication heat baths using tailored cleaning agents in custom racks that allow for flushing and decontamination of internal cannulas and suction tubing where applicable. Every wand is function tested to verify continuous electrical arc formation while energized by its compatible electrosurgical unit generator. Flow testing verifies suction tubing is capable of maintaining free-movement fluid flow and demonstrates no signs of leakage or obstruction. Magnified visual inspection verifies non-conforming devices are rejected. Inspection includes identification of loose, missing or damaged electrodes and suction plates, shaft heat shrink integrity, foreign debris, damaged or missing pins in electrical connector and overall device integrity. Every device is marked in compliance with Medical Device User Fee Stabilization Act (MDUFSA) requirements, packaged, and sterilized.

Devices are packaged in thermoformed trays, sealed, and packaged in chipboard boxes in original manufacturer case quantities.
**ARTHROSCOPIC SHAVER REPROCESSING**

Arthroscopic shavers and burs can be used to abrade, cut and excise tissue and bone, remove loose fragments and shave away debris in arthroscopic surgeries. The arthroscopic shavers and bur components reprocessed by Stryker include a bur or blade that rotates within an outer housing and are used in conjunction with the appropriate hand piece and generator. Reprocessed arthroscopic shavers and burs are indicated for use in arthroscopic surgical procedures of the joints where the cutting and removal of soft and hard tissue of bone and joints is needed in patients requiring orthopedic surgery. Utilization of the shavers and burs requires use of an appropriate irrigant. Reprocessed arthroscopic shavers are Class II devices under 21 CFR 888.1100 and require pre-market submission prior to sale under FDA regulation.

Arthroscopic shavers and burs are initially inspected for visible damage. Shavers and burs are decontaminated and cleaned through a multi-step process that involves disassembly of removable components, where applicable, to expose mated surfaces or difficult-to-reach areas for effective cleaning such as seals, radio frequency identification parts and washers.

**Cleaning steps include:** use of enzyme cleansers, multiple ultra-sonication baths with tailored cleaning agents and manual brushing while undergoing magnified visual inspection. All devices and components are visually inspected under lighted magnification at multiple stages during the process for the presence of non-conforming damage, debris, cosmetic defects, rust, pitting, dryness, cracks and overall device integrity. Every device is function tested at multiple stages during reprocessing.

**Tests include:** pull testing to identify damaged hubs, drop testing to verify smooth insertion and mating of inner and outer shafts, spin testing to confirm free rotation and proper mating, and radio frequency chip recognition by original manufacturer consoles. Every device is marked in compliance with MDUFSA requirements. Devices are packaged in thermoformed trays, sealed, and packaged in chipboard boxes in original manufacturer case quantities.
BITS, BLADES & BURS REPROCESSING

Stryker reprocessed surgical accessories are Class I, exempt devices under various sections of the (21 CFR), which requires FDA listing and registration. Stryker is required to perform testing and validation necessary for FDA routine inspection as well as ensuring equivalency, safety and effectiveness through established design and quality controls.

Surgical accessories are logged in upon receipt and inspected for visible damage. The validated cleaning process includes use of enzymatic detergents to remove organic contaminants, manual brushing while undergoing magnified inspection, multiple heat baths including use of ultra-sonication and pressure washing used to reach targeted crevices. Finished devices are packaged in Tyvek® peel pouches with distal ends covered by tip protectors (where applicable), and sealed within another pouch for double protection during shipping and handling. Patella reamers and precision blades have unique packaging inserts. Pouched devices are packaged in a variety of configurations and box quantities, depending upon amounts ordered.

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.

THE SCIENCE OF REPROCESSING

IDENTITY CONTROL
Devices are marked with identifiers for identity control and cycle marking.

COMPREHENSIVE CLEANING
Devices are subjected to tailored, validated cleaning processes.

PERFORMANCE TESTING
Arthrosopic shavers and wands are tested in saline to verify activation and proper functionality.
THE SCIENCE OF SHARPENING

Every device with a cutting edge is sharpened using advanced sharpening technology with minimal material removal by redefining and restoring edges to manufacturer specifications. Computer numerical controlled (CNC) sharpening is used to restore cutting edges, which provides accuracy within tolerances of one half of one thousandth of an inch. The CNC sharpening method is repeatable for consistent and uniform production results.

To determine device dimensions programmed into CNC machines, thousands of original devices are measured to determine original manufacturer specifications. Devices may undergo precision honing, which includes: coning to facilitate small bore access, flexible diamond disking to follow the original contours of the device, and leather lapping to de-bur, duplicate and refine cutting edges.

Finally, every device is measured post-sharpening with an optical comparator. The optical comparator magnifies the sharpened device to enable comparison against a template of acceptable measurements. Any device not within tight tolerances is rejected.

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Annual Savings Estimate</th>
<th>Waste Diversion Estimate</th>
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</thead>
<tbody>
<tr>
<td>Arthroscopic Wands</td>
<td>$35,448</td>
<td>114 lbs.</td>
</tr>
<tr>
<td>Arthroscopic Shavers</td>
<td>$25,109</td>
<td>74 lbs.</td>
</tr>
<tr>
<td>Bits/Blades/Burs</td>
<td>$18,744</td>
<td>30 lbs.</td>
</tr>
<tr>
<td><strong>Total Savings</strong></td>
<td><strong>$79,301</strong></td>
<td><strong>218 lbs.</strong></td>
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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.
Stryker'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.

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.