

Reprocessing Overview
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Reprocessing By the Numbers

1. *FDA Clearance*

30140235

Provision is an FDA registered, FDA compliant, medical device manufacturer. Our FDA registration # is 3014023545.

Under the auspices of the FDA's regulations, which are consistent with our FDA 510(k) product clearances, we take a used Single Use Surgical Device, such as an Ablation Wand, Arthroscopic Shaver, Carpal Tunnel Release Blade, Saw Blade, Drill Bit, Bur, Coblator, etc., and return it to a condition that is substantially equivalent to that of a new device. Our quality standards and FDA compliance processes are built around a set of validation protocols that include comprehensive decontamination and cleaning protocols, refurbishing, recalibration, tip-to-tip microscopic inspection, functionality testing on each and every device, packaging, labeling, sterilization, electrical safety, and biocompatibility. We are not a "mom and pop" operation. We are a technologically advanced medical device reprocessing company who is standing ready to earn your trust and confidence.

2. *Device Preparation / Sterilization Cleaning & Decontamination*

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All Provision devices are disinfected and cleaned using a 77-step process wherein we use steam in combination with separate ultrasonic baths of enzymatic cleaners, degreasers, and disinfectants to clean each device.

At each washing station, all devices are also handwashed with the aid of commercially adapted microscopes to confirm the removal of all bioburden. After rinsing the devices free of all cleaning solutions, all devices are then placed into specially designed cabinet dryers which maximize the drying process at controlled temperatures for specific periods of time. Following this process, devices are then placed in temperature-controlled vacuum ovens which facilitate the evaporation of any remaining fluids.

Refurbishing, Performance Testing, Visual Inspection

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Once identified, each device is completely refurbished and/or recalibrated using a proven 12-step process that complies with manufacturing protocols established for each class of device.

This process uses a state-of-the-art proprietary system that allows for precise, automated, and replicable quality of each device. Upon completion of these refurbishing steps, each device is then inspected using a 10-step process where every device is inspected under microscope from the proximal tip at one end to the distal tip at the other end and is then tested to ensure form, fit and functionality.

2nd Wash & Final Inspection

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All devices which have passed our primary inspection and functionality testing are then washed a second time using a 34-step process to remove any residue created during the refurbishing process and are inspected again using a 6-step process to ensure that the product meets our quality standards.

Sterilization

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Once devices have passed a final inspection, they are then packaged and labeled using a 14-step process and are sterilized using Ethylene Oxide. Provision protocols include the utilization of a standard “overkill method” of sterilization which exposes all devices to Ethylene Oxide for twice the time needed to meet 10^{-6} Sterility Assurance Level. These are the exact same sterilization protocols used by the majority of all other surgical device manufactures. Finally, all sterilization records are maintained electronically and are available upon request.

Independent Lab Verification

Once the sterilization cycle has been completed, our product is then properly aerated and biological indicators are sent to and reviewed by a 3rd party independent lab. If all sterility parameters have been met, we are notified and subsequently release the order for shipment.

Visible Evidence of Sterilization

To build comfort in the use of Provision’s reprocessed devices, we also incorporate two steps to ensure the sterility of each shipment of devices. First, prior to Sterilization, we affix a label on the shipping carton that reads “Caution: Non-Sterile.” After EtO Sterilization, we affix a label on the shipping carton that reads “Product is Sterile.” Secondly, contained within each shipping carton, we place an EtO sterilization indicator strip on the top of the devices packaged within the shipping carton. Each strip is 8” long by ¾” wide. Prior to sterilization, this indicator strip will appear blue in color. After EtO sterilization, the blue strip will turn brown.

Labeling on Shipping Cartons & Sterilization Indicator Strips



Sterility Assurance Protocols Step 2

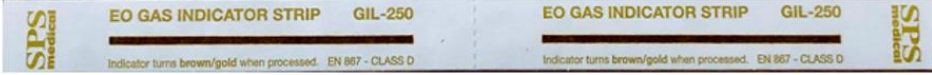
Contained within each shipping carton, we now place an EtO sterilization indicator strip on the top of the devices packaged within the shipping carton. Each strip is 8" long by ¾" wide. Prior to sterilization, this indicator strip will appear blue in color. After EtO sterilization, the blue strip will turn brown.

Prior to EtO Sterilization – Indicator Strip is blue.



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After EtO Sterilization – Indicator Strip is brown.



3. Medical Device Standards

The Association for the Advancement of Medical Instrumentation, (AAMI), is an organization founded to advance the development, and safe and effective use of medical technology. AAMI was created by the medical device industry as both a vehicle to help clients introduce innovative medical devices into common medical practice and to set safety standards in both their design and usage. In order to ensure the highest level of safety, Provision supports and implements AAMI standards in our workplace such as:

- **Operational Standards of Performance - Disinfection and Cleaning**

Our quality standards and FDA compliance processes relating to the Disinfection and Cleaning of devices are built around a set of validation protocols that include:

- AAMI TIR 12:1994, Designing, Testing, and Labeling Reprocessed Medical Devices
- USP 24-NF 19 Total Organic Carbon
- AAMI TIR30: 2003, A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices

- **Operational Standards of Performance - Electrical Safety:**

- AAMI HF18:2001, Electrosurgical devices
- IEC 60601-1-1, Medical Electrical Equipment—General Requirements for Safety

- **Operational Standards of Performance - Biocompatibility:**

- ISO 10993 Biological Evaluation of Medical Devices
- ISO 11607-1 Packaging for Terminally Sterilized Medical Devices
- ASTM F1980-2002 Standard Guide for Accelerated Aging of Sterile Medical Device Packages
- ASTM F1585-00 Standard Guide for Integrity Testing of Porous Barrier Medical Packages
- ASTM F1929-98 Standard Test Method for Detecting Seal Leaks in Medical Packaging (Dye)
- ASTM F2096-02 Standard Test Method for Detecting Leaks in Medical Packaging (Bubble Test)

- ASTM F88-00 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4169-01 Standard Practice for Performance Testing of Shipping Container Systems

4. *Quality Management Systems*

Quality Management Systems, QMS, is a collection of business processes focused on achieving quality policy and quality objectives to meet customer requirements. QMS serves as the foundation of the Provision organizational structure, policies, procedures, and processes.

5. *Current Good Manufacturing Practices*

cGMP regulations are enforced by the FDA and provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures identity & quality by requiring that manufacturers adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting, and investigating product quality deviations, and maintaining reliable testing laboratories. Provision embraces such business practices so that our medical devices will meet consistent quality standards.

Utilizing the guidelines set forth by the FDA and employing Medical Device Standards, QMS processes and cGMP practices, Provision provides a safe environment for all employees and delivers consistency in the quality of our devices.

6. *Auditing the process*

Provision employs a staff of Quality Assurance and Regulatory Affairs personnel who provide oversight of all processes within the production of a Provision reprocessed device. Such processes are subject to validation standards which include specific protocols governing cleaning and decontamination, electrical safety, and biocompatibility as well as packaging, labeling, and sterilization protocols. All reprocessing is performed in our state-of-the-art reprocessing center in Bend, OR where validated controls guide every step of our operation. Processes are validated and cannot be changed unless such changes are re-validated and cleared by QA/RA.

At Provision, we also contract with an independent industry expert to audit and verify our processes. In addition, we are subject to regular FDA inspections wherein we are regulated for our quality control, decontamination & sterilization protocols, design & system control, validation & verification processes.

7. *Access to Information / Documentation*

Provision has built a highly sophisticated, fully automated, external customer portal which marries both internal and external customer communications. This state-of-the-art system, called SMART, provides real-time information to access customer metrics, trend and track orders, access industry information and serves as a library for all Provision IFUs.