SureTek Medical

Surgical Resource Technology

Summary of Reprocessing Services and Process Validations

SureTek Reprocessing Services are summarized below:

1. Used instruments are cleaned to remove visible contamination and stored at the user facility in a reusable recycling bin or nylon bag supplied by SureTek.

2. Depending upon customer preference, the recycling containers are placed within the operating room, central processing or materials management areas.

3. Containers are shipped by FedEx ground to SureTek's Greenville, SC facility when they are at least ¾ full, generally 1-2 times per month.

4. Upon receipt at SureTek, devices undergo a full-cycle decontamination with hydrogen peroxide, enzymatic and disinfectant detergents, and inventoried by Manufacturer, Model and quantities received.

5. Within 3 days of receipt, an Order Receipt Notification with expected shipping date is sent by email/FAX to the sales representative and customer for issuance of a purchase order (if required).

6. Each surgical instrument is refurbished according to SureTek SOP, including sharpening, polishing, repair of instrument handles, replacement of electrical insulation and instrument lubrication.

7. Each instrument undergoes electromechanical functionality testing and microscope inspection by a qualified biomedical engineer or surgical technician.

8. Unacceptable devices are rejected and not returned to customer.

9. The handles of acceptable devices are labeled with SureTek logo (ST) followed by a dot to indicate each number of reprocessing cycles.

10. Devices are packaged in paper-plastic, heat-sealable medical grade pouches with embedded chemical indicators that change from pink-to-yellow during exposure to ethylene oxide sterilant gas.

11. Pouches are labeled with manufacturer, model, device description and reprocessor information with a sterility expiration date of one year.

12. Products are sterilized by ethylene oxide and then aerated to remove sterilant residues.

13. Sterilization process is monitored with temperature/humidity recorders and 10^6 populations of biological spore indicators (*B atrophaeus*) incubated for 48 hours post-sterilization.

14. Following an acceptable quality assurance review of all process records and biological indicators, the instruments (less rejects) are returned to the customer via FedEx ground.

15. Collection containers are decontaminated and returned to customer with the order.

16. Total process turnaround time is 5-7 business days + transit times for shipping to and from our facility.

17. Customer is invoiced only for those devices that can be returned for an additional use.

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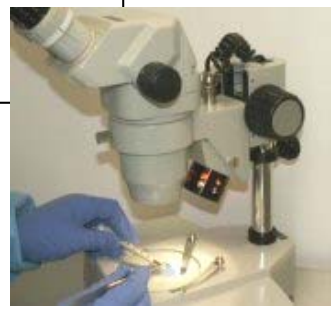
SureTek Recycling Flowchart

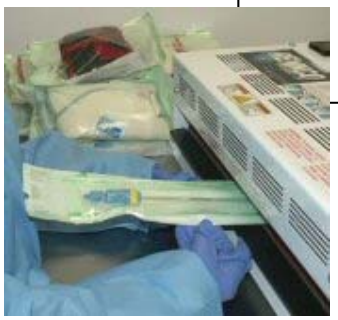
Surgical Center
uses surgical instrument on a single patient, cleans to remove all visible contamination and ships to SureTek for reprocessing.

SureTek Decontamination
utilizes ultrasonic, pressurized steam and manual cleaning with disinfectants, dual-enzymatics and hydrogen peroxide followed by DI water rinse and drying.

SureTek Refurbishing
sharpens, polishes and cleans each instrument under microscope, and marks the device handle with SureTek logo and number of reprocessing cycles.



SureTek Quality Assurance
performs 100% electromechanical testing, microscope inspection and label verification. Unacceptable devices are rejected and not returned to customer.



SureTek Packaging
utilizes polyethylene-paper pouches with EO chemical indicator. Outer pouch is labeled with manufacturer, model, device and reprocessor information.

SureTek Sterilization
is by ethylene oxide chamber method. Each cycle monitored with 10^6 spore indicators. Devices are returned to customer following acceptable QA review of process records.

SureTek Medical 25-B Maple Creek Circle Greenville, SC 29607 864.299.9743 www.suretekmedical.com

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Summary of Reprocessing Services and Process Validations

Summary of Process Validation Protocols

Product Decontamination: All surgical instruments undergo decontamination using devices undergo a full-cycle decontamination with hydrogen peroxide, enzymatic and disinfectant detergents with manual cleaning, high pressure steam and heated ultrasonics. This cleaning process is validated in accordance with ASTM E2314 *Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Instruments Using a Microbiological Method* to be effective at removing all visible contamination and providing a 99.9% reduction in pre-sterilization bioburden.

Product Packaging: SureTek utilizes WIPAK SteriKing peel pouches for ethylene oxide sterilization. The manufacturer certifies each lot of pouches to the standard 11607 *Packaging for Terminally Sterilized Medical Devices*. Each pouch is embedded with a chemical indicator that changes from pink to yellow following exposure to EO gas. Surgical instruments are double-pouched; tourniquet cuffs and foot/leg compression sleeves are single-pouched. SureTek has validated its packaging configurations to maintain product sterility for one year following sterilization. This validation was performed in accordance with ASTM tests designed to simulate worst case handling, distribution and storage conditions:

- ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier Material*
- ASTM F2096 *Standard Test Method for Leak Testing Using Bubble Emission Techniques*
- ASTM 1929 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- ASTM D4169 *Standard Practice for Performance Testing of Shipping Containers and Systems*
- ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Medical Device Packages*

Product Labeling: The outer pouch is labeled with all information on the reprocessor, Lot #, original manufacturer, device model, description and dimensions, sterilization method, and customer name. Each device is labeled for one year shelf life from the date of sterilization. Used instruments are labeled as "Reprocessed by SureTek Medical", while Open/Unused devices are labeled as "Repackaged for Sterilization by SureTek Medical".

Sterilization: All products undergo preconditioning to controlled temperature and humidity conditions followed by ethylene oxide (EO) sterilization using a 3M SteriVac system. This process is validated to achieve a sterility assurance level of 10^{-6} using a half-cycle, "overkill" method as specified in ISO 11135 *Medical devices - Validation and routine control of ethylene oxide sterilization.* This method requires that the process achieve product sterility following an EO exposure cycle that is one-half that used during routine production cycles. Product sterility testing is conducted by independent test laboratories. Each sterilization cycle is monitored with temperature/humidity recorders and 10^6 populations of biological spore indicators (*B atrophaeus*) incubated for 48 hours post-sterilization.

FDA Review: In accordance with federal regulations, SureTek validation testing for its decontamination, packaging and sterilization services has undergone extensive review by FDA Office of Device Evaluation and has been determined to be "substantially equivalent" to that of medical device manufacturers. Our FDA clearance letter can be found at the following link on the FDA website: www.accessdata.fda.gov/cdrh_docs/pdf5/K052692.pdf.