

Useful Information About Our Repackaging Program

Thank you for considering AnewMed's repackaging/recertification program for single-use medical devices. We repackage select* Class 1 and 2 unused expired and open-but-unused single-use devices. (*See page 3 & 4 of this document for device types we do and do not accept.) Our production facility is located in Tucker, Georgia just east of Atlanta and we have been in operation since 2012.

Sterilization Overview

Products that meet our criteria and are approved safe to re-sterilize, are repackaged and relabeled in our CME (controlled manufacturing environment). Device loads are then transported to a contract facility for ethylene oxide gas sterilization.

Because our loads can consist of highly variable product types, the sterilization cycle we employ is modeled after the convenience kit industry. Convenience kits, because of their high density present an excellent worst-case model, and our fully validated cycle utilizes a double over-kill method with a 5-hour gas exposure, enabling us to achieve the desired SAL (Sterility Assurance Level) of 10^{-6} .

We recognize when it comes to patient safety there can be no compromise, and our protocols for packaging, sterilization-monitoring, and device-tracking were developed with this in mind.

Repackaging vs. Reprocessing

To be clear, AnewMed is NOT a reprocessor. Reprocessors such as Stryker Sustainability, SterilMed and Medline Renewal work with soiled devices— disinfecting, cleaning, remanufacturing, testing—in the process creating products unique from those of the original manufacturer. Per FDA, they are effectively new products, of which the reprocessor is considered the new manufacturer.

By contrast, AnewMed handles only unused expired and open-but-unused devices. We partner with hospitals and ASC's—many of whom already utilize reprocessing services—that simply want an additional way to create value and help keep devices out of landfills.

We maintain a fluctuating stock of repackaged devices at an approximate 20% discount from our med surplus competitors. Additionally, we offer a liquidation option for your expired devices: simply send in devices that meet our criteria outlined on pages 3 & 4 and we will repackage what is marketable, splitting the sales with you. Current commission rate is 25%. (Monthly check and statement provided).

Beyond that, we will repackage-to-order (“recertify”) your expired devices at 50% of what you pay for OEM new.

Thanks again for your interest. Provided on the next pages is some additional information regarding our company and business. If you have additional questions, please don't hesitate to contact us.

Sincerely,

The AnewMed Team

email: info@anewmed.com

call: 770-263-9633

www.anewmed.com

AnewMed's FDA Registration Number: 3009711423
Owner/Operator Number: 10041338

Our FDA registration:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=143537>

Code of Federal Regulations 21CFR807.20 -- Procedures for Device Establishments

[21CFR807.20 - See \(a\)\(3\)](#)

Our sterilization validation summary (sensitive information omitted):

<http://www.anewmed.com/ANMValidationSummary130131.pdf>

Devices We Repackage & Sell

- **EP Cath Lab:**
Balloon Inflation Devices; Cardiac Biopsy Forceps; Angiographic, Guide and Cardiac Imaging Catheters; EP Catheters and Cables; Femoral Compression Devices, Introducers & more
 - *by AngioDynamics, Boston Scientific, Biosense Webster, Cook, Cordis, Medtronic, Merit Medical, Radi, St. Jude Medical, Terumo & more...*
- **GI Lab:**
Biopsy Forceps; Biliary Stents; Cytology Brushes; Cautery Pencils; Guidewire; Multipolar Electrocautery Probes (MPEC); Snares & more
 - *by Abbott, Bard, Boston Scientific, Bovie, ConMed, Cook, GyruS, Medtronic, Navilyst, Olympus, St. Jude Medical, Terumo, US Endoscopy & others*
- **Multi-Department:**
B/P Cuffs; Compression Sleeves For Thigh, Foot & Calf/Knee; Pulse Oximeter Probes; Tubing; Wound Drain/Debridement/Irrigation & more
 - *by Bard, Covidien, Huntleigh, Masimo, Stryker, Zimmer & many more...*
- **OR-Cardiology:**
Aortic Punches; Insufflation Needles; Vein Harvesters; Vessel Sealers; Etc.
 - *by Covidien, Ethicon, Maquet, Medtronic, Quest Medical, Salient Surgical, Terumo & more...*
- **OR-ENT:**
ENT Bits, Burs, Blades & Shavers; Ear Vent Tubes; ENT Balloon Inflation Devices, Sinus Catheters
 - *by Acclarent, Intellus & Medtronic Xomed/ENT*
- **OR-General/Gyn:**
Babcocks; Miscellaneous Catheters; Cautery Pencils; Cranial Perforators; Cutting Forceps; Dilator Sets; Dissectors; Resection Electrodes; Forceps; Harmonic Scalpels; IAB Catheter Kits; Laparoscopic Scissors; Linear Cutters; Multi-Clip Applicators; Open Linear Staplers; Reloads; Retractors; Skin Staplers; Suture Closure Devices; Trocars & Trocar Accessories; Feeding Tube Kits; Vein Strippers; Vessel Sealers; Etc.
 - *by Applied Medical, Atrium, Bard, Boston Scientific, Codman, Cook, Covidien, Edwards Lifesciences, Ethicon, Gore, GyruS, Integra, Kimberly-Clark, Maquet, Microline, Medtronic & more...*
- **OR-Ophthalmic:**
Eye Blades; Vitrectomy Kits with Probe; Light Pipes; Ophthalmic Accessories; Phaco Tips
 - *by Alcon, Bausch & Lomb, BD, Synergetics, Welch Allyn & others*
- **OR-Orthopedic:**
Arthroscopic Shavers; Burrs - Carbide, Diamond, Stainless Steel, Tapered Router & Specialty; Drill Bits; External Fixation - Assembly Kits, Clamps, Connecting Rods, Distraction Rods, Dynamization Clips, Nuts/Bolts, Pins, Rings & Screws; Ortho Knives; Cutters; Rasps; Reamers; RF Arthroscopy Probes; RF Electrodes; Saw Blades; Tourniquet Cuffs; Trocar/Cannulas, Orthopedic; Tubing, Arthroscopic; Wire Pass Drills; Etc.
 - *by Arthrex, ArthroCare, Biomet, Braun, Covidien, ConMed, Depuy, Medtronic, Olympus, Smith & Nephew, Stryker, Synthes, Zimmer & many more...*
- **OR-Urology:**
Stone Retrieval Baskets & Ureteral Stents & much more!
 - *by Bard, Boston Scientific, Cook & others*



Call 1.770.ANEWMED (263.9633) for more info!

Devices Not Repackaged by AnewMed

The following devices do not meet current product approval criteria and cannot be repackaged.

- Devices expired 5 years or more.
- Used or soiled devices.
- Reprocessed devices.
 - Brands include:
 - Medline Renewal / Medassis
 - SterilMed
 - Stryker Sustainability / Ascent
- Loose devices (No package/original label).*
 - *Open-but-unused devices accepted if original label accompanies them.
- Devices less than \$25.
- Class III devices.
- Devices containing batteries.
- Devices containing latex.
- Devices containing pharmaceuticals or other liquids. Kits with these included.
- Bone Cement.
- Devices in foil packages.
- Devices containing absorbable materials. Absorbable sutures and fasteners included.
 - Often labeled with “Collagen” (“Bovine”- or “Porcine” collagen), “BAO”, “Bio-absorbable”, “Composite” or “Bio-composite”.**