

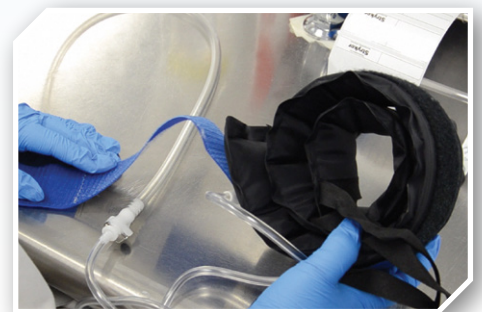
PNEUMATIC TOURNIQUET CUFFS



Product Summary:

- Includes models originally manufactured by Stryker and Zimmer

- ◎ **Product Availability:** Stryker reprocessed pneumatic tourniquet cuffs are distributed to customers in case quantities of ten units per corrugated cardboard box and are distributed for sale.
- ◎ **Decontamination and Cleaning:** Reprocessed tourniquet cuffs are decontaminated and cleaned through a multi-step process that involves pre-treatment of visible soil using cleaning agents, tailored to all soil types.
- ◎ **Device Tracking:** Every tourniquet cuff is labeled with a distinct, permanent marking to ensure the device is never reprocessed beyond its maximum number of cleared cycles. Tourniquet cuffs that have reached their maximum validated cycles are rejected.
- ◎ **Quality Control:** Routine quality control audits and daily monitoring ensure process integrity. Additionally, finished product performance attributes including cleaning end points are routinely subjected to random sampling and testing.



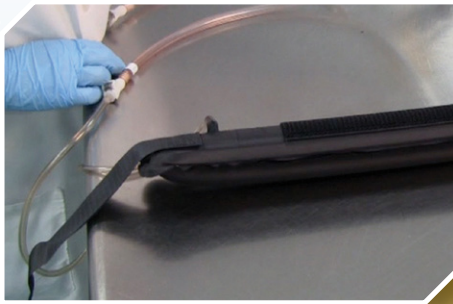
Inflation testing of tourniquet cuff

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PRODUCT INFORMATION

Device Type	Annual Savings Estimate*	Waste Diversion Estimate
Pneumatic Tourniquet Cuffs	\$28,883	1,425 lbs.



PERFORMANCE TESTING



VISUAL INSPECTION



PACKAGING

- Documentation:** Production support staff are required to sign off after performing each reprocessing step. Detailed documentation assures trace-ability of critical steps performed. Records are maintained in accordance with FDA and ISO requirements.
- Performance Testing:** Tourniquet cuffs are inspected to ensure tubing is not kinked, which could potentially restrict pressurized air flow. All devices are inflation tested using a proprietary fixture that has an accuracy of detecting leaks as small as ± 0.025 liters per minute. Devices are pressurized and rejected if any leakage is detected. Clinical pressure regulated control units compensate and correct any detected leaks or decay up to four liters per minute, depending upon device size.
- Visual Inspection:** Every tourniquet cuff is inspected throughout various steps of the production process to ensure non-conforming products are rejected. Devices are inspected for debris, contamination, and for overall device integrity.
- Packaging:** Reprocessed tourniquet cuffs are packaged individually in Tyvek® peel pouches with or without a stockinette limb protection sleeve to mirror the original manufacturer device. Pouches allow for sufficient ethylene oxide exchange during sterilization. Every reprocessed tourniquet cuff is labeled "STERILE, EO."
- 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.

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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.

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