

## **Are the reprocessed products FDA approved?**

Yes, all our products are reprocessed under FDA regulations and have received FDA 510(k) clearances. The FDA has provided the industry with specific regulatory guidelines to reprocess the products. The process has been approved for over 15 years. Reprocessing is utilized by the top 20 "Best Hospitals," listed in USA News and World Report and is endorsed by major organizations such as the AHA, AORN, and AMA.

## **Are the products sterilized?**

Yes, the products are remanufactured, repackaged, and sterilized in high quality vacuum packaged pouches labeled per FDA regulations. Reprocessed product arrive with one-year shelf life.

## **What is the cleaning process like?**

Device cleaning is comprised of a 7-step process defined by the FDA, which includes an inspection of every device. By inspecting each product, we will be able to guarantee the product is functioning to FDA standards, and that it has passed all steps in the process including cleaning, disinfection, refurbishing and sterilization.

## **Do the original manufactures allow it?**

Once the device is purchased by a health facility, the FDA allows remanufacturing of single use devices by reprocessing under strict FDA regulation. The FDA has specifically published step-by-step extensive guidelines and regulatory policies that companies can follow to obtain a new 510(k) clearance to reprocess single-use devices (SUD) of the original manufacturer.

## **What do we do with the contaminated products after surgery?**

Used medical devices should be cleaned following the protocols provided by Green OR and your facility. Medical devices should be wiped down carefully, flushed, disassembled (as necessary) and allowed to dry prior to placing in Green OR's collection bins. You will be able to ship back bins when they are full, or according your facility's schedule. More detailed instructions will be provided in a full in-service training guide for you and your team.

## **How do I know what to collect and not collect?**

Simple...when in doubt, include it. We can process over 2,100 product items, from blades, bits and burs, to wands, rasps, reamers, trocars, compression, and much more. Some items that should generally NOT be collected include sharps, needles, and paper products.

## **What happens if I put something in the bins that is not able to be reprocessed?**

We will sort through all the devices we receive from the collection bins of contaminated products, keep what we can reprocess and only charge for what gets reprocessed. We have a very high reclamation rate. If a product cannot be reprocessed, we will dispose of those products free of charge. We have over 2,100 SKUs that can be processed which accounts for about 85% of disposables.

## What other facilities/hospitals are reprocessing?

The top 20 hospitals as reported in US NEWS & WORLD REPORT are reprocessing.

## What is the warranty?

- **Reprocessed in Compliance with FDA:** Reprocessed SUDs have been cleaned, refurbished, tested, inspected, packaged & sterilized, (non-invasive are prepared according to High Level Disinfection protocols) in material compliance with FDA regulations.
- **100% Device Inspection for Quality Assurance:** Reprocessed SUDs will be substantially equivalent to the corresponding new SUD in the area of form, fit and function for their intended use and original purpose and will perform the functions for which they were originally designed in material compliance with FDA regulations.
- **100% Sterile:** Sterility of all unopened or undamaged packaging on reprocessed SUDs is one year from the date stamp on the packaging.
- **100% Return Policy:** In the event that a reprocessed SUD does not perform properly, the Customer can return the reprocessed SUD at Green OR Expense. We will evaluate the device for form, fit and function and provide a formal written Complaint Response within ten (10) days of receipt and determine what credit is due the Customer.

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