Instructions for Cleaning and Sterilization

Integra™ EndoRelease™ Endoscopic Cubital Tunnel Release System

Instruction for Reprocessing:

The cannula, obturator, obturator handle, and spatula are provided non-sterile and must be sterilized prior to surgery. The following instructions should be used for cleaning and decontaminating non-sterile product. All products should be cleaned, decontaminated and sterilized before use. Always immediately clean and decontaminate all devices that have been soiled.

Manual Cleaning Procedure:

1. Prepare a neutral pH enzymatic detergent, Enzol®, as per the manufacturer's recommendation at 1 oz. per gallon using lukewarm tap water.
2. Fully immerse each device in the prepared detergent and allow them to soak for a minimum of two minutes.
3. After soaking the devices, scrub them using a soft bristle brush and circular strokes to remove any visible soil. Pay particular attention to all the areas where the soil could be imbedded (i.e. grooves, crevices, lumens, blind holes). Use a syringe to flush lumens and a pipe cleaner to clean lumens and holes. Perform cleaning under the water surface to limit aerosolization of the cleaning fluid and soil, as well as for worker and environmental safety.
4. Rinse devices in lukewarm deionized water for a minimum of one minute to remove any detergent residuals.
5. Prepare a neutral pH enzymatic detergent, Enzol®, in a sonicator as per the manufacturer's recommendation at 1 oz. per gallon using lukewarm tap water. Fully immerse the devices in the detergent and sonicate for 10 minutes.
6. After sonication, rinse the devices with lukewarm reverse osmosis/ deionized water for one minute.
7. Dry the devices using a clean cloth.

Automated Cleaning Procedure:

1. Prepare an enzymatic detergent (Klenzyme®) using lukewarm tap water as per the manufacturer's recommendation.
2. Fully immerse the devices and allow to soak for a minimum of two minutes.
3. Following the soak time, flush any lumens of the device using a syringe.
4. Rinse the devices under lukewarm running tap water for a minimum of one minute.
5. Place the devices into an automated washer (Steris 444 or equivalent). The washer cycle parameters are:

Phase	Recirculation Time (Min.)	Water Temperature	Detergent
Pre-Wash 1	02:00	Cold Tap Water	NA
Enzyme Wash	01:00	Hot Tap Water	Klenzyme®, 1 oz/gal
Wash 1	02:00	60°C	Renu-Klenz™ 1/2oz/gallon
Rinse 1	05:00	Hot Tap Water	NA

6. Dry the devices with a clean cloth and visually examine to determine if all adherent visible soil has been removed.

Thermal Disinfection Cycle for Automated Cleaning Procedure:

Thermal disinfection rinse/cycle should be used at 82.2 °C for 1 minute.

Packaging and Sterility

Each blade is provided packaged sterile. Blades are designed as single-use, disposable products and should not be re-sterilized. Resterilization and subsequent reuse will dull the blades and may result in cross contamination or impaired function of the product. Sharpness of the blades is not guaranteed with repeated use. Any blade, once used, should be discarded according to hospital policy. Prior to use, inspect the integrity of package for damage that may compromise sterility of the device. If damaged, sterility may be compromised and the product should not be used.

Sterilization Parameters:

Method:	Steam	Steam
Cycle:	Gravity	Vacuum
Temperature:	270°F (132°C)	270°F (132°C)
Exposure Time:	30 Minutes	4 Minutes
Drying Time (Min):	20 Minutes	20 Minutes

These sterilization parameters assume that all instruments have been properly cleaned and decontaminated prior to sterilization. The parameters are validated to sterilize specific configurations as noted in the tray markings. If other products are added to the tray or to the sterilizer, the recommended parameters may not be valid and new cycle parameters may need to be validated by the user. The autoclave must be properly installed, maintained and calibrated.

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