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Caution

Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

Cleaning and handling of surgical instruments

Surgical instruments are provided non-sterile, and must be cleaned and sterilized before use. After use, these instruments must be properly cleaned, disinfected, sterilized and stored. The following information outlines the proper steps for reprocessing surgical instruments.

- Prepare detergent according to the manufacturers recommendations.
- Prepare enzymatic cleaner according to the manufacturers recommendations.
- Manual cleaning can be performed using, gloves, brushes, absorbent disposable cloth.
- If ultrasonic equipment is used it should be monitored routinely to ensure the equipment is working properly.

Limitations and restrictions of reprocessing: Surgical instruments are designed for their durability and ability for reuse. Reusable instruments are typically manufactured from stainless steel, which permits a long life when handled and maintained properly. Damage may occur to the instruments during use.

Warning

Cleaning/Disinfection

Use caution when handling sharp instruments to avoid injury. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.

Clean instruments as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with cold water or an appropriate detergent or enzymatic solution to delay drying. Clean all instruments whether or not they were used or inadvertently contacted with blood or saline solution.

The cleaning process must be conducted so that all parts of the surgical instrument are exposed as permitted by instrument design. The cleaning process should include an individual properly gowned with appropriate glove and personal protective equipment. This may require disassembly of instruments with multiple or removable parts. Instruments with mating surfaces, serrations, lumens, blind holes, etc. must be carefully cleaned to remove all visible debris from the items. Additional assembly/disassembly instructions may be found in the product specific surgical technique.

Clean instruments to remove gross contamination and disinfect instruments to reduce the number of viable microorganisms. Rinse in cold water to remove gross contamination.

- Bathe the instruments in enzymatic detergent solution prepared according to the manufacturer directions at least 5 minutes.
- Scrub component thoroughly with a soft brush and/or pipe cleaner, repeatedly flush any narrow

lumens with enzymatic detergent solution using a syringe.

- Rinse with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any narrow lumens.
- Bathe the instruments in a detergent solution prepared according to the manufacturer directions for a minimum of 5 minutes.
- Scrub thoroughly with a soft brush and/or pipe cleaner, repeatedly flush narrow lumens with detergent solution using a syringe.
- Thoroughly rinse/flush with purified deionized/reverse osmosis water.
- Sonicate for a minimum of 10 minutes in an enzymatic detergent solution prepared according to the manufacturer directions.
- Rinse thoroughly with cold purified deionized or reverse osmosis water.
- Dry the instruments with a clean, disposable, absorbent cloth.
- Visually inspect all visible surfaces, internal and external for cleanliness.
- If necessary re-clean/disinfect the instrument until it is visibly clean.

Automated Cleaning/Disinfection

- An automatic cleaning process may involve a washer-sterilizer, a washer- sanitizer/disinfector, ultrasonic cleaner or other related type machines that clean and decontaminate items. There are many different types of automatic washer systems, each with their own unique instructions that must be followed.
- Ultrasonic cleaners can be used with hot water per manufacturer's recommended temperature (usually 90-140° F or 32-60° C) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for the ultrasonic cleaners. Be aware that loading patterns, instrument cassettes, water temperature and other external factors may change the effectiveness of the equipment.

Sterilization

Surgical instruments manufactured of stainless steel may be steam sterilized. All items to be sterilized must be thoroughly cleaned, disinfected, and packaged appropriately for the type of sterilization. The package must permit contact of the sterilant with the item, while also serving as a barrier to microorganisms, during any storage period. An FDA-cleared wrap must be used when steam sterilizing reusable surgical instruments. Users should wear non-linting gloves when handling reusable instruments, to minimize bioburden and particulate. Inspect the product packaging for tears, holes, moisture or other defects. If these concerns are present segregate these items and reprocess them.

The following steam sterilization cycle has been validated for the surgical instrument set:

Prevacuum 270° F (132° C), Exposure Temperature 270° F (132° C), Exposure Time 4 minutes, Dry Time 30 minutes.

All instruments returned to the manufacturer must be cleaned and decontaminated before shipping. The four main types of packaging for steam sterilization consist of textiles, non- wovens, pouch packaging and rigid container systems. These packaging types offer various levels of protection from contamination, which must be consistent with the final intent of the item. A rigid container system (tray) should be wrapped to prevent contamination from entering through the holes.