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Surgical Tray Sterilization Instructions



NON-STERILE



Surgical instruments are packaged non-sterile. Surgical instruments should be cleaned and sterilized prior to each use.

Cleaning & Disinfection

Prevent body fluids, hard and soft tissues from drying on the instruments by cleaning as soon as possible after use. Automated cleaning may not be effective. Thorough manual cleaning process is recommended. When applicable, disassemble trays and instruments prior to cleaning.



Cautions:

Universal precautions for the handling of contaminated or biohazardous materials should be observed.

DO NOT USE cleaning agents containing hydrogen peroxide, chlorine or chloride. The active agents are corrosive to stainless steel.

Preliminary Manual Cleaning

A preliminary manual cleaning is needed for heavily soiled instruments, instruments that have accumulated organic debris or come in contact with saline. Use a soft brush (no metal bristles) so as to completely remove residue.

1. Wipe instruments using a soft, disposable non-shedding wipe.
2. Soak in lukewarm enzymatic solution for 20 minutes.
3. Rinse instruments thoroughly using running water from the faucet or distilled water.

Routine Cleaning

4. Wash the instruments using a broad spectrum cleaning solution. Rinse in water and dry thoroughly.
5. Prepare a neutral pH enzyme cleaning detergent solution per manufacturer's instructions and place in a sonication unit.
6. Completely submerge instrument in cleaning solution and sonicate for 10 minutes, preferably at 45-50kHz.
7. Rinse instrument in purified (de-ionized or distilled) water thoroughly for at least 3 minutes.
8. Repeat above two steps with freshly prepared cleansing solution.
9. Dry the instrument with a clean, disposable, absorbent non-shedding wipe.

Packaging for Sterilization

10. Enclose the product to be sterilized in a standard polyethylene/Tyvek (or equivalent) sterilization pouch. Sets of instruments may be loaded into dedicated instrument trays or general purpose trays for sterilization.

Sterilization

11. Steam sterilize using a gravity cycle for 20 minutes at a minimum temperature of 132°C (270°F). To avoid deformation, surgical tray should not touch walls of steam sterilizer. When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load requirements are followed. Drying times will vary according to load size.

Note: Cleaning and sterilization instructions validated by Implant Direct Sybron Manufacturing, LLC. to obtain:

Cleaning: An average 99.9980% reduction in viable counts of bioburden. ENZOL Enzymatic Detergent and Renu-Klenz neutral pH detergent were used to validate this process per the manufacturer's dilution instructions.

Sterilization: 10⁶ SAL



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For translation visit www.implantdirect.com/surgical_translate.htm



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