

Implant Handling

This document provides recommendations for cleaning and sterilizing non-sterile ZEUS implants.

Processing Non-Sterile Implants

This document provides recommendations for cleaning and sterilizing non-sterile ZEUS implants only. Explanted ZEUS implants must never be reprocessed and should be handled according to hospital protocol upon removal. It must be noted that most implants provided sterile but rendered un-sterile (package opened but unused) can be processed via these recommendations. To determine which sterile implants can be resterilized, refer to the package insert included with the sterile implant. Any implants that has not been used, but has become soiled, should be handled according to hospital protocol. ZEUS does not recommend the processing of soiled implants. These recommendations are to be followed unless otherwise noted on specific product insets.

Cautions

- ✚ Any Implant that has not been used, but has become soiled should be handled according to hospital protocol. ZEUS does not recommend the reprocessing of soiled implants.
- ✚ ZEUS implants should not be lubricated
- ✚ Do not use a ZEUS implant if the surface has been damaged
- ✚ Do not use steelwool or abrasive cleaners on ZEUS implants
- ✚ ZEUS implants should not be processed or transported with any type of soiled or contaminated materials
- ✚ In accordance with the CDC, AORN and AAMI guidelines, ZEUS does not recommend or support the flash sterilization of implants
- ✚ ZEUS implants are critical devices and must be terminally sterilized prior to use
- ✚ The sterilization parameters are only valid for devices that are adequately cleaned
- ✚ The following parameters are only valid for properly installed, maintained, compliant reprocessing equipment

Limits on reprocessing

- ✚ Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on ZEUS implants
- ✚ ZEUS implants should be inspected for corrosion, damage such as scratches and notches, debris, discoloration of residue
- ✚ Damaged implants should be discarded

Processing Instructions

Point of Use Care

- ✚ Implants should remain covered until needed to avoid becoming soiled or contaminated. Only those to be implanted should be handled
- ✚ Minimal handling of implants is necessary to prevent damage to the surface

Containment and Transportation

- ✚ Implants should not come in contact with soiled devices and/or equipment
- ✚ To avoid contamination, implants should be transported from soiled devices

Preparation for Processing

Any implant contaminated with blood, tissue and/or bodily fluids/matter should be processed according to hospital protocol, ZEUS does not recommend the reprocessing of soiled implants.

Processing – Manual Method

Equipment: Soft-bristled brush, lint-free cloth, neutral enzymatic cleaner detergent with a pH \leq 8.5.

- ✚ Prepare a fresh solution using warm deionized (DI) or purified (PURW) water and detergent or cleaner. Follow the enzymatic cleaner or detergent manufacturers
- ✚ Instructions for use for the correct exposure time, temperature, water quality (i.e. pH, hardness) and concentration. Note: a fresh solution is newly-made, clean solution
- ✚ Carefully wash implant manually
- ✚ Rinse implant thoroughly with deionized (DI) or Purified (PURW) water. Use DI or PURW for final rinse
- ✚ Dry implant using a clean soft, lint-free cloth to avoid scratching the surface

Processing-Ultrasonic Method

Equipment: Ultrasonic cleaner, neutral enzymatic cleaner or natural detergent with a pH \leq 8.5. Note: Ultrasonic cleaning may cause further damage to implants that have prior surface damage.

Prepare a fresh detergent solution using a neutral pH enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for the correct dilution, temperature, water quality (i.e. pH hardness) and exposure time. Note: a fresh solution is a newly-made, clean solution.

Clean ZEUS Implant ultrasonically for a minimum 15 minutes.

Rinse implant thoroughly with deionized (DI) or Purified (PURW) water. USE DI or PURW for final rinse.

Dry implant using a clean soft, lint-free cloth to avoid scratching the surface.

Processing – Mechanical Method

Equipment: Water/disinfectant, neutral enzymatic cleaner and/or natural detergent with a pH \leq 8.5. Use the following cycle parameters:

Cycle	Minimum Time(minutes)	Minimum Temperature/Water	Type of Detergent
Pre-wash	2	Cold tap Water	N/A
Wash I	2	Cool to warm tap water	Neutral enzymatic pH <8.5
Wash II	5	Warm tap water (>40*c)	Detergent with pH<8.5
Rinse	2	Warm DI or PURW (.40*C)	N/A
Dry	40	90*c	N/A

Thermal Disinfection

For automated cleaning, thermal disinfect at 93°C for minimum of 5 minutes.

Inspection

- ✚ ZEUS implants should be inspected after processing, prior to Sterilization.
- ✚ Any Implant with corrosion, discoloration, scratches, flaws, residue or debris should be discarded.

Sterilization

- The following are the recommendations for the sterilization of ZEUS implants:

Cycle	Minimum Time(minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time
Pre-vacuum	4	132°C(270°F)	20 minutes

*When applying dry times to ZEUS cases and their accessories, dry times outside the standard healthcare pre-vacuum parameters may be required. This is especially important for polymer-based (plastic) case/trays used in conjunct on with heavy duty nonwoven sterilization wraps. The current recommended dry times for ZEUS cases can range from a standard 20 minutes to an extended time of 20 minutes. The dry times most often influenced by the presence of polymer based (plastic) materials; therefore, changes such as reduced weight, elimination of silicone mats and/or change in sterile barrier system (i.e. heavy grade to light grade wrap or a sterilization container) can reduce the necessary dry time. Dry times may be highly variable due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, stem quality, implant material, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

- The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load should be followed. The autoclave must be properly installed, maintained, and calibrated. Only legally marketed, FDA cleared sterilization wrap/pouches should be used by the end-user for packaging terminally sterilized devices

- For product sterile, refer to devices specification insert for limitations for regarding re-sterilization.

Processing – Mechanical Method

- Sterile product that has exceeded the labeled expiration date and intact original packaging, may be sterilized using the above sterilization parameters unless product is coated, i.e. HA, Plasma, etc. or re-sterilization is not permitted. Refer to device specific insert for limitations regarding re-sterilization
- The cleaning and sterilization information is provided in accordance with ANSI/AAMI ST81, ISO 17664, AAMITIR 12 and AAMI ST77
- The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile ZEUS medical implant. It remains the responsibility to the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the processing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendation provided should be properly evaluated for effectiveness and potential adverse consequences
- All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards
- Users should do an appropriate personal protective equipment (PPE) while processing implants

Manufactured Contact

For further information, contact ZEUS Customer Service Department.