

Processing Acumed Non-Sterile Implants

Cautions

- Any implant contaminated with blood, tissue and/or bodily fluids/matter should be processed according to hospital protocol.
- Do not use an implant if the surface has been damaged.
- In accordance with AORN and AAMI guidelines, Acumed does not recommend or support flash sterilization of implants.
- Refer to appropriate product Instructions for Use (IFU) for sterility requirements

Limits on reprocessing

- Implants should be inspected for damage such as corrosion, scratches, residues, and corrosion.
- Damaged implants should be discarded.

Manual Processing

Equipment: Soft bristled brush, neutral enzymatic cleaner or neutral detergent with a pH \leq 8.5.

1. Prepare a solution using warm tap water and detergent or cleaner. Follow the enzymatic cleaner or detergent manufacturer's recommendations for use paying close attention to the correct exposure time, temperature, water quality, and concentration.
2. Carefully wash the implant manually. Do not use steel wool or abrasive cleaners on implants.
3. Rinse implant thoroughly with DI or purified water. Use DI or purified water for final rinse.
4. Dry the implant using a clean soft, lint-free cloth to avoid scratching the surface.

Ultrasonic Processing

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

1. Prepare a solution using warm tap water and detergent or cleaner. Follow the enzymatic cleaner or detergent manufacturer's recommendations for use paying close attention to the correct exposure time, temperature, water quality, and concentration.
2. Clean implants ultrasonically for a minimum of 15 minutes.
3. Rinse implant thoroughly with DI or purified water. Use DI or purified water for final rinse.
4. Dry the implant using a clean soft, lint-free cloth to avoid scratching the surface.

Mechanical Processing

Equipment: Washer/disinfector, neutral enzymatic cleaner or neutral detergent with a pH \leq 8.5.

Cycle	Minimum Time (minutes)	Minimum Temperature/Water	Type of Detergent
Pre-wash	2	Cold tap Water	N/A
Enzyme Wash	2	Warm tap water	Neutral enzymatic pH \leq 8.5
Wash II	5	Warm tap water ($>40^{\circ}\text{C}$)	Detergent with pH \leq 8.5
Rinse	2	Warm DI or purified water ($>40^{\circ}\text{C}$)	N/A
Dry	40	90°C	N/A

Additional Information

Users should wear appropriate personal protective equipment (PPE) when processing implants.

All users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines and standards and hospital policies.