



Sterilization Instructions - Extremity Sets

Cleaning

SUMMA Hand | Hand locking | Foot | Wrist | Ankle/Ankle Distal Tibia/Diaphysis | Humerus | Clavicle System's accessories (surgical instruments) can be reused after cleaning and sterilizing.

They must be cleaned before reuse. Following instructions are recommended for cleaning;

A. Pre-cleaning

- (1) Disassemble the device where possible.
- (2) Remove gross soil using paper wipes and solution of cleaning agent.
- (3) Immerse the device in solution of cleaning agent for the time recommended by the detergent's manufacturer.
- (4) Use suitable brushes (never metal brushes or steel wool) to clean the device thoroughly.
- (5) Rinse in running water until all traces of cleaning solution are removed.
- (6) Visually inspect for any remaining soil and repeat the steps above if necessary.

B. Cleaning

- (1) Immerse the device completely in solution of cleaning agent and activate the ultrasonic bath at the concentration and temperature specified in the detergent manufacturer's instructions.
- (2) Follow the same as the clauses (4) – (6) of instructions for pre-cleaning.

Sterilization

SUMMA Hand | Hand locking | Foot | Wrist | Ankle/Ankle Distal Tibia/Diaphysis | Humerus | Clavicle System must be sterilized before use. Following instructions are recommended;

- (1) Place the devices in the appropriate block (kit or tray) using forceps and/or powder-free gloves to avoid contamination and any other negative effect on the surface of device.
- (2) Wrap the block with a surgical drape.
- (3) Sterilize in the autoclave validated and maintained in accordance with ISO 17665 and ANSI AAMI ST79. Following parameters are validated in accordance with ISO 17665-1 and recommended for sterilization:

Cycle	Temperature	Exposure	Load	Drying Time
Gravity	132°C	15 minutes	Wrapped*	30 minutes
Pre-vacuum	132°C	4 minutes	Wrapped*	30 minutes

* In the case of load characteristics, we recommend usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation.

- (4) **Caution:** plates and screws are disposable (single use only). Do not reuse. Summa Orthopaedics bears no responsibility for any plate or screw that is reused and problems or issues arising from that use.