



Cleaning and Sterilization Instructions - Extremity Sets

Cleaning

SUMMA Hand / Foot / Wrist / Ankle / Ankle Fibula Hook Plate / Ankle Distal Tibia / Diaphysis / Humerus / Clavicle / Cannulated Screw I Elbow / Small Fragment 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) Using suitable brushes (never metal brushes or steel wool), 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.
- (3) Use a disposable dust-free absorbent (lint-free and drying material) to immediately wipe off the moisture from the instruments.

NOTE: It is recommended to use 0 to 25 us/cm of critical water for the final rinse. (e.g. pre filter, A/C filter, RO filter, 0.22um filter or equivalent used).

Sterilization

SUMMA Hand / Foot / Wrist / Ankle / Ankle Fibula Hook Plate / Ankle Distal Tibia / Diaphysis / Humerus / Clavicle / Cannulated Screw I Elbow / Small Fragment System must be sterilized before use. Following instructions are recommended:

- (1) Place the devices in the appropriate tray using forceps and/or powder-free gloves to avoid contamination and any other negative effect on the surface of device.
- (2) Wrap the tray using FDA cleared sterilization wrap (ex. KimGuard KC500).
- (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	Drying Time
Gravity	132°C	15 minutes	30 minutes
Pre-vacuum	132°C	4 minutes	30 minutes

- (4) **Caution — plates and screws are single use only. DO NOT REUSE — SUMMA is not responsible for any issues arising from the REUSE of single use items.**