

Sterilization Instructions

Cleaning & Disinfection

- Automated cleaning and disinfection in washer-disinfection using a validated procedure according to ISO 15883-1 in a washer-disinfector (W/D). The cleaning must be performed using mild alkaline cleaning agents approved for surgical instruments. Load products so that cannulations and holes can drain. The trays must not be overloaded to guarantee optimal rinsing. The following cleaning process has been validated with the cleaning agent Neodisher MediClean Forte® (Dr. Weigert).

Method	Time	Temperature	Medium
Pre-rinsing	1 min	No temperature control	Water
Cleaning	5 min	55°C	1% detergent
Neutralization	2 min	No temperature control	Water
Rinsing	1 min	No temperature control	Water
Thermal disinfection	5 min	90°C	RO or DI water
Drying	25 min	100°C	

RO=Reversed Osmose Water; DI=Demi Water

Caution: Do not use any type of alcohol for cleaning the product before sterilization. Only neutral or mild alkaline cleaning and disinfection agents are permitted (pH < 11).

Sterilization

- Before starting sterilization of the product, the product must be packaged according to ISO 11607-1:2019 packaging for terminally sterilized medical device.
- The sterilization process must be carried out using a validated procedure: steam sterilization according to ISO 17665-1:2016 in a steam sterilizer according to EN 285. The following sterilization process has been validated for products which conform to '3DMM Design Guidelines for surgical guides':

Method	Moist heat sterilization according to EN ISO 17665-1
Cycle	Fractionated pre-vacuum dynamic air removal
Temperature	134°C
Exposure Time	3 minutes
Cool Time	30 minutes (minimum, in chamber)
Drying Time	60 minutes (minimum, at room temperature)