

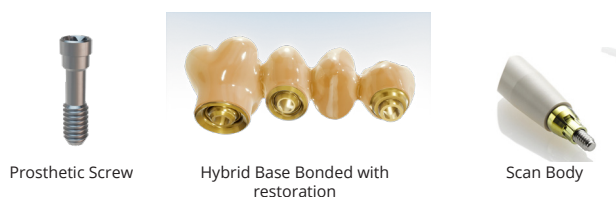
Sterilization and Cleaning Guideline

1. Initial treatment at the point of use

- To prevent any contamination from drying it is recommended that cleaning- and sterilization takes place not later than 2 hours after use.
- Keep devices moist after use to prevent soil from drying on them.
- Contaminated devices should be transported to the area for cleaning in a clean and closed box/container that avoids spreading of the contamination.

2. Preparation for cleaning

Where applicable, disassemble devices until each device consists of one part.



3. Cleaning

- Prepare a solution of a mild alkaline detergent Neodisher MediClean Forte 0.5%, temperature 15-20 °C.
- Completely submerge the devices in the cleaning solution for five (5) minutes. Whilst submerged, brush the devices with attention to the critical and hard-to-reach areas with a soft-bristled brush for a minimum of 30 seconds and flush hollow devices using a syringe with 0.5 mL of cleaning solution.
- Rinse one (1) minute under cold running tap water (15-20°C)
- Place the devices into the washing racks without overloading them. Then place the racks on the wash supports of the washer-disinfector. Avoid any contact between the devices, which may cause damage during washing
- Using a valid washer disinfector (according to ISO 15883 requirements) and an alkaline enzymatic detergent such as Neodisher MediClean Forte, use the minimal cycle parameters set points mentioned in the following table.

Cycle	Minimum Time	Minimum Temperature	Type of Detergent/Water
Pre-Cleaning	2 minutes	Cold (< 45°C)	Tap water
Wash	10 minutes	Heated (50-60°C)	Neodisher MediClean Forte (0.2-1%)
Rinse	2 minutes	Cold (< 45°C)	Critical water ¹
Thermal Rinse	5 minutes	Heated (90°C)	Critical water ¹

¹ As per AAMI TIR34, water extensively treated usually by a multistep treatment process that may include a carbon bed, softening, DI, and RO or distillation, to ensure that the microorganisms and the inorganic and organic material are removed from the water

- At the end of the program remove the devices.

Automated disinfection

For Europe, the thermal disinfection corresponds to the Thermal Rinse phase of five (5) minutes at a minimum of 90°C, listed in Table 2

4. Drying

If not completely dry, dry devices with single use, non-linting wipe or a towel or by air gun with compressed air.

5. Maintenance, Inspection and Testing

Any device showing visible damage or wear must be exchanged. End of life of device is normally determined by wear and damage due to use. End of life of devices is exceeded if visual inspection shows unacceptable deterioration like wear, corrosion, discoloration, pitting crackles etc.

6. Packaging

- Devices should be sterilized disassembled according to their Instructions For Use
- Place the devices in the double sterilization packaging (pouches made of paper or plastic film, conforming to ISO 13060, DIN EN 258 and ANSI/AAMI ST79
- For USA use FDA-cleared pouches
- Physical-chemical indicators may be used on or in the packaging system
- For USA use FDA-approved wraps

7. Sterilization

- Use a steam sterilizer conforming to EN 13060, DIN 285, and /or ST79
- Use the sterilization parameters provided in the table below, which have been validated

Note: For US: Steam Sterilization Cycle 132°C (270°F)/4min.



Procedure	Dynamic-air-removal-sterilization Cycle	
Exposure time	4 min	3 min.
Temperature	132°C (270°F)	134°C (273°F)