



ADVICES

Decontamination, cleaning and sterilisation of non sterilised and reusable devices, and their kit

Information

These recommendations are for professionals using BIOTECH DENTAL kits. Based on the DGS/R13/2011/449 instruction on 1st December 2011. Biotech Dental's products from the kit should not be used on highly infectious tissues, nor during invasive procedures with a risk of NCTAs (Non Conventional Transmissible Agents).

Kit should be destroyed in case of suspicious patient or affected by TSE (Transmissible Spongiform Encephalopathy).

Warning

✓ **Before use**

Decontamination (Pre-disinfection) and Cleaning operations are mandatory before any sterilisation. Clean all devices to be sterilised, even the unused tools.

✓ **Staff involved and premises**

Any cleaning and sterilisation decontamination (pre-disinfection) protocol, can only be undertaken by a trained and protected staff member. In premises adapted to the performed operations, and by respecting regulations and standards.

✓ **Decontamination and cleaning products**

To avoid damaging components, it is mandatory to only use decontamination (pre-disinfection) and cleaning products, which are compatible with all treated materials. The chosen product must be able to block infectious risks thanks to its antimicrobial activity (bactericide EN 1040, fungicide EN 1275, virucide HIV-1, HBV, Herpes Virus).

- Forbid alkaline and corrosive products on medical devices made of stainless steel and aluminium: bleach, aqueous hypochlorite and sodium chloride solutions
- The use of physiological saline is forbidden because of corrosive effect on stainless steel.

✓ **Quality of water**

Water used to decontaminate (pre-disinfection), clean, rinse and sterilise must be consistent with regulations and standards.

User can refer to the FD S 98-135 §9-4 norm.

Protocol

✓ **Decontamination (pre-disinfection)**





Decontamination should be done as close as possible, after each intervention. Avoid dust drying on equipment at any cost (< 2 hours).

Once the devices and tools are dismantled, immerse them in a compatible decontaminant solution that does not bind proteins (neutral pH with no aldehyde), while respecting the manufacturer advices (concentration, soaking time). Soaking in a low-frequency ultrasound bath is recommended (however, insure all cutting tools do not knock together). To avoid saturation, the decontaminant solution must be renew after each use.

✓ **Cleaning**

Cleaning can be performed manually in a decontaminant bath, with a brush (eg. soft nylon brush).

✓ **Rinse – Dry**

Immediatly after cleaning, you must rinse with abundant demineralised water or osmosis. Products will then be meticulously dried, before sterilisation process. Manual drying will be favoured (medical quality compressed air for the finish).

✓ **Packaging**

Whatever cleaning method has been used, material should be immediately packed to avoid an infection. If sterilisation is on metal mesh trays, use a double paper wrapping. In case of a late packaging (> 2 hours), cleaning should be reconsidered.

✓ **Sterilisation**

Place all devices so their surfaces are in direct contact with steam.

Devices must be cleaned before being sterilised. Steam sterilisation is recommended for the following autoclave cycles:

Country	Cycle	Sterilisation parameters	Drying duration
Europe	Dynamic air removal (pre-vacuum)	134°C for 3 minutes	20 min
France	Dynamic air removal (pre-vacuum)	134°C for 18 minutes	20 min
USA	Dynamic air removal (pre-vacuum)	132°C (270°F) for 4 minutes	20 min

Dry heat is prohibited.

✓ **Return**

After being used and in case of a loan, the device should be returned to BIOTECH DENTAL, it should be cleaned and decontaminated. It is the healthcare facility or practitioner's responsibility to ensure cleaning and sterilisation (equipment, materials and operator). Under no circumstances can BIOTECH DENTAL be held responsible for poor sterilisation of the loaned equipment. The tracking sheet for loan material and deposit should be filled (Ref. F01_PAV02).

