



For the sterilization of Biotech Dental surgical kits, the following general guidelines should be followed:

1. Cleaning:

- Verify that all components of the surgical kit are fully disassembled prior to cleaning
- Follow the specific cleaning recommendations provided by Biotech Dental (reference: Page 2 & Page 3).

2. Rinsing and Drying:

- After cleaning, rinse the components thoroughly with demineralized water.
- Use residue-free compressed air to dry the instruments completely.

3. Sterilization:

- Reassemble all dismantled components prior to sterilization.
- Place all components in sterilization pouches and ensure they are properly sealed, using either self-adhesive or heat-sealed pouches
- Use a Class B vacuum autoclave according to EN13060 standards for sterilization.
- For specific autoclave settings, you can use one of the following programs:
 - o 134 °C (273.2 °F) for a minimum of 3 minutes.
 - o 121 °C (249.8 °F) for a minimum of 15 minutes.

4. Post-Sterilization:

- Ensure that the sterilized components are stored in a sterile environment until use.

These steps ensure that the surgical kits are properly sterilized and safe for use in dental procedures. Always refer to the specific instructions provided by Biotech Dental for any additional details or updates.

RECOMMENDATIONS

Decontamination, cleaning, and sterilization of non-sterile, reusable devices and their associated kits

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).

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

Warning

Before use

Decontamination (pre-disinfection) and cleaning are mandatory prior to any sterilization process. All devices intended for sterilization, including those not used, must be thoroughly cleaned

Involved Personnel and Facilities

All cleaning, sterilization, and pre-disinfection procedures must be carried out exclusively by trained personnel wearing appropriate protective equipment, within facilities suited for these operations, and in strict compliance with applicable regulations and standards

Decontamination and cleaning products

To prevent damage to components, only decontamination (pre-disinfection) and cleaning agents compatible with all treated materials may be used. The selected product shall also possess proven antimicrobial efficacy to reduce the risk of infection. (bactericide EN 1040, fungicide EN 1275, virucide HIV-1, HBV, Herpes Virus).

- Alkaline and corrosive agents must not be used on medical devices manufactured from stainless steel and aluminum: bleach, aqueous hypochlorite and sodium chloride solutions
- The use of physiological saline must not be used due to its corrosive effects on stainless steel.

Quality of water

Water used to decontaminate (pre-disinfection), clean, rinse and sterilize 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 performed as soon as possible after each intervention. It is essential to prevent dust or debris from drying on the equipment (< 2 hours).

After dismantling, immerse the devices and instruments in a compatible decontamination solution that does not bind proteins (neutral pH with no aldehyde), while following the manufacturer's instructions for concentration and soaking time.

The use of a low-frequency ultrasonic bath is recommended, ensuring that cutting instruments do not come into contact with one another. To prevent solution saturation, the decontaminant must be replaced after each use.

□ Cleaning

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

□ Packaging

Immediately after cleaning, thoroughly rinse all devices with demineralized or reverse osmosis water. Instruments must then be carefully dried prior to sterilization, with manual drying preferred, followed by medical-grade compressed air to ensure a complete finish

□ Rinse & Dry

Regardless of the cleaning method used, instruments must be packaged immediately to minimize the risk of contamination. When sterilizing on metal mesh trays, a double paper wrap is required. If packaging is delayed by more than 2 hours, the cleaning process must be repeated.

□ Sterilization

Arrange all devices so that their surfaces are fully exposed to steam. Instruments must be thoroughly cleaned prior to sterilization. Steam sterilization is the recommended method for these devices

Country	Cycle	Sterilization 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 18minutes	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 sterilization (equipment, materials and operator). Under no circumstances can BIOTECH DENTAL be held responsible for poor sterilization of the loaned equipment. The tracking sheet for loan material and deposit should be filled (Ref. F01_PAV02).

