

Phibo® prosthetic components and instruments are not supplied sterile. Do not use products if packaging has been damaged or opened.

Prosthetic components and instruments for use in the mouth must be cleaned, disinfected and sterilised prior to use. Reusable instruments and components must also be cleaned, disinfected and sterilised after use.

Immediately after implantation:

Disassemble instruments comprising several parts into their components according to the instructions for use (e.g. wrench). Damaged or dull instruments should be set aside (sharp instruments should be replaced after a maximum of 10 uses) and disinfected and cleaned separately.

Manual cleaning and preparation of units

Brush and rinse under running water to remove loose particles in all zones and crevices of instruments for between 20 and 30 seconds until all residue is removed.

Disinfection of units

Immerse the instruments in an adequate disinfectant bath, strictly following the manufacturer's instructions regarding dose/concentration, immersion time and temperature. *Instrunet Instrumental PRD* (universal disinfectant for instruments), a disinfectant with CE marking especially indicated for dental health material is recommended.

Unit disinfection process

Disinfection may be manual or automatic. The instruments should not be in contact with one another.

1. Prepare the disinfectant solution using tap water and following the manufacturer's instructions for use to achieve a final concentration of 5% *Instrunet Instrumental PRD*.
2. Mix the solution by stirring gently and then pour it into the ultrasonic bath tray.
3. Immerse the clean and thoroughly rinsed instruments in the bath for 30 minutes at 60°C with a power setting of 50 W (40 KHz), making sure that they are fully submerged and in contact with the disinfectant.
4. Rinse the material with sterile water for 30 seconds and dry thoroughly under aseptic conditions (with gauze, paper, filtered air, etc.). Do not use hydrogen peroxide, oxidising acids (nitric acid, sulphuric acid, oxalic acid, etc.) or any product with a high chlorine content.

Sterilisation of units

Metal products should be sterilised in a steam autoclave, using a sterilising cycle at 134°C, for at least 6 minutes. Do not remove the sterilised product until after completion of the drying cycle. We recommend using a sterilisation control, recording the date and expiry date, in addition to performing periodic controls of the sterilisation process using biological indicators.

IMPORTANT: Do not sterilise plastic products in the autoclave. Do not use dry heat sterilisers, as they may damage metal and plastic products.

This document was reviewed and approved on 2013/02/20
PROSPLDEEN_rev001