



Processing Recommendations Medical Devices Carbide instruments and diamond instruments

General information

Instruments are delivered not sterile unless labelled otherwise and must therefore be processed appropriately prior to use.

Handling of devices supplied as sterile (i.e. with sterile label)

Instruments in sterile packaging that have been damaged in transit need to be returned to Frank Dental. Instruments in sterile packaging must not be used directly if the packaging has been inadvertently opened; they should first be processed by sterilisation.

The shelf life based on the results of the sterilisation packaging validation must be respected.

Disposable products, marked with the symbol (⊗) may only be processed once before first use and may not be reused.

According to KRINKO BfArm (which is the Commission for Hospital Hygiene and Infection Prevention of the German Federal Institute for Drugs and Medical Devices) a classification in the Critical A risk group is recommended; country-specific requirements must be observed.

The frequency of repeat deployment of the device is at the user's discretion and should be based on the respective application. Damaged and worn instruments should be promptly discarded.

Only use cleaning and disinfection equipment that is compliant with EN ISO 15883 and an autoclave with a fractionated vacuum cycle that is compliant with DIN EN 13060/DIN EN 285/ANSI AAMI ST79 and validated as per DIN EN ISO 17665.

Only use suitable and approved cleaning agents and disinfectants according to the manufacturer's instructions.

Storage/Pretreatment

Remove visible residues with a soft nylon brush under running cold water for at least 1 minute to avoid their build-up.

Then place the instruments in a drill bath (preferably with an ultrasonic insert) with a non-protein-fixing and non-aldehyde-containing disinfecting and cleaning solution for the specified time.

Remove instruments from the bath and rinse thoroughly under running water. Check the instruments for any visible residues. If any residues still persist (particularly bone or dentine particles) either repeat the pre-cleaning process or dispose of the instrument.

Machine cleaning and disinfection:

Instruments should be rinsed under running water for at least 1 minute immediately before machine cleaning.

Use a suitable instrument stand to load instruments into the cleaning and disinfection machine to avoid damaging the devices.

Run the following programme:

- 2 min pre-cleaning with cold tap water (10°C - 25°C)
- Drain
- 5-minute cleaning at 55°C with tap water and an alkaline cleaner
- Drain
- 3 min additional rinse with cold deionised water (10°C - 25°C)
- Drain
- 2 min additional rinse with cold deionised water (10°C - 25°C)
- Drain
- Thermal disinfection: at least 5 minutes at 90°C

When finished, remove instruments and dry (preferably with compressed air, as recommended by the Robert Koch Institute).

The basic compatibility of devices for effective machine cleaning was demonstrated in a Miele G 7836 CD washer/disinfector using an alkaline detergent (0.5%, Neodisher MediZym Dr. Weigert, Hamburg).

Visual inspection:

Visually inspect for cleanliness and integrity; we recommend using a 10x magnifying glass. Repeat the cleaning process to remove any remaining traces of contamination. Please dispose of the instruments if contamination is still visible after repeated cleaning and disinfection. Damaged and worn instruments should be discarded.

Packaging:

Use suitable steam sterilisation packaging (temperature resistant up to at least 138 °C (280 °F) and good steam permeability) with dimensions which ensure that the seal is not under tension, and that complies with DIN EN ISO/ANSI AAMI ISO 11607-1.

Sterilisation:

Autoclave using the following parameters:

- Fractionated prevacuum (3x)
- Sterilisation temperature: 134°C
- Holding temperature: 5 min (full cycle)
- Drying time: 10 min*

*The actual drying time required is directly dependent on the parameters for which the user bears sole responsibility (e.g. load configuration and density, condition of the autoclave) and must therefore be determined by the user. Nevertheless, drying times of 20 minutes should not be exceeded.

The basic supportive proof to determine that the devices can be effectively steam-sterilised was established using a Selectomat HP 666-1HR autoclave.

Storage:

Prior to initial use, devices should be stored in their original packaging at room temperature, and in an environment protected from dust and moisture.

Instruments should be stored and transported in hygienically maintained trays, racks, or other suitable containers. Stored items must be protected from dust, moisture, and recontamination.