



READ CAREFULLY BEFORE USE

en PREPARATION and REPROCESSING INSTRUCTIONS according to ISO 17664

Scope

These instructions are designed according to ISO 17664 and applicable to all SHOFU reusable rotary dental instruments for intraoral use. All SHOFU reusable abrasives and polishers should be cleaned and sterilized according to these instructions before first use and each subsequent reuse.

Note: For users in the European Union, separate instructions according to EN ISO 17764 is available in www.shofu.de.

Warnings

- Chlorine disinfectant and peracetic acid must not be used to avoid corrosion of the instruments.
- Do not expose the instruments to non-approved chemical solutions (i.e. solutions not listed in these instructions).

Limitations on reprocessing

Instruments do not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to routine use, cleaning, disinfection and/or sterilization processes. The product life is determined by wear and damage caused during use. Any damaged or defective instruments must not be used (i.g. instruments with corrosion, surface flaws, deformation, dirt and exposed shank, etc.).

Instructions

1. Initial treatment after use

Perform the following steps within one (1) hour of the patient procedure to prevent contamination from drying on the instruments:

- Detach single-use components from the reusable components and discard the single-use components.
- Prepare an enzymatic bath using 8 mL of Advanced Sterilization Products Enzo[®]/Cidezyme[®] Enzymatic Detergent per 1 L of tap water.
- Immerse instruments for a minimum of three (3) minutes.

2. Cleaning

Method A Mechanical cleaning and disinfection (recommended)

A-1. Preparation

- The following will be required for cleaning and disinfection of the instruments:
 - Soft-bristled toothbrush
 - Critical water (water that is extensively treated, usually by a multistep treatment process that could include a carbon bed, softening, DI and RO or distillation)
 - Non-linting wipes or cloths for drying
 - neodisher[®] MediClean forte
 - Suitable bur block
 - ISO 15883 compliant washer disinfectant

A-2. Manual pre-cleaning

- Using a soft-bristled toothbrush, brush the instrument in enzymatic bath for a minimum of 30 seconds and until no visible contamination is present.
- Remove instruments from enzymatic bath.
- Rinse the instrument under running tap water, for a minimum of 10 seconds.

A-3. Mechanical cleaning and disinfection

- Place the instruments into a bur block. Leave the block lid open and place the block on the shelf of an ISO 15883 compliant washer disinfectant.

- Perform automated cleaning and disinfection using the following parameters:

Phase	Minimum time	Temperature	Type of detergent/water
Pre-Wash	2 minutes	Cold	Tap water
Draining			
Wash	5 minutes	Heated (55 °C/131 °F)	Tap water and 0.5 % (5 mL/L) neodisher® MediClean forte
Draining			
Rinse 1	3 minutes	Cold	Critical water
Draining			
Rinse 2	2 minutes	Cold	Critical water
Draining			
Thermal Rinse	5 minutes	Heated (≥ 90 °C/194 °F)	Critical water
Dry	15 minutes	Heated	

Notes: Cleaning and disinfection validation has been performed using Miele Professional G7836 CD washer disinfector with vario-TD program. Parameters may vary depending on the washer disinfectors.

- If needed, thoroughly dry all surfaces of the instruments using non-linting wipes or cloths, changing wipes/cloths when necessary to ensure that the instruments are completely dry.

A-4. Inspection

- Visually inspect each instrument for the absence or presence of remaining contamination in a well-lit area. If contamination is present, repeat the mechanical cleaning and disinfection until all visible contamination is removed.

Note: Discard the instruments if any damage or defects (e.g. corrosion, surface flaws and/or deformations), which would prevent proper operation, are found.

Method B] Manual cleaning

B-1. Preparation

- The following will be required for manual cleaning of the instruments:
 - Advanced Sterilization Products EnzoI®/Cidezyme® Enzymatic Detergent
 - Soft-bristled toothbrush
 - Critical water (water that is extensively treated, usually by a multistep treatment process that could include a carbon bed, softening, DI and RO or distillation)
 - Non-linting wipes or cloths for drying
 - Sonicator
 - Glass beaker

B-2. Manual cleaning

- Remove instruments from enzymatic bath.
- Using a soft-bristled toothbrush, brush the instruments for a minimum of 30 seconds and until no visible contamination is present.
- Rinse the instruments under running tap water, for a minimum of 10 seconds.
- Prepare enzymatic detergent solution using Advanced Sterilization Products EnzoI® or Cidezyme® Enzymatic Detergent according to the detergent manufacturer's instructions using 8 to 16 mL per liter of tap water.
- Pour the enzymatic detergent solution in a glass beaker and place the beaker in a sonicator. Degas the sonicator.
- Immerse the instruments in the solution of the beaker and sonicate the instruments for 15 to 20 minutes at a temperature range of 35 °C/95 °F to 45 °C/113 °F and a frequency of 44±6 kHz.
- Rinse the instruments in a critical water bath for a minimum of 30 seconds.

- Thoroughly dry all surfaces of the instruments using non-linting wipes or cloths, changing wipes/ cloths when necessary to ensure that the instruments are completely dry.

B-3. Inspection

- Visually inspect each instrument for the absence or presence of remaining contamination in a well-lit area. If contamination is present, repeat the manual cleaning until all visible contamination is removed.

Note: Discard the instruments if any damage or defects (e.g. corrosion, surface flaws and/or deformations), which would prevent proper operation, are found.

3. Storage after cleaning

Instruments should be protected from contamination until sterilization. Disinfected and dried instruments should be handled and stored in a manner that protects them from recontamination.

4. Sterilization

4-1. Preparation

The following will be required for sterilization:

- EN13060 compliant autoclave or AAMI ST8 compliant autoclave
- Suitable bur block
- FDA approved and/or ISO 11607-1 compliant pouches for steam sterilization, as applicable

4-2. Packaging

- Handle instruments as follows:
 - Place a single instrument in a sterilization pouch in accordance with local procedures (e.g. AAMI ST79).
 - Place multiple instruments in a bur block and then place the bur block in a sterilization pouch in accordance with local procedures (e.g. AAMI ST79).

4-3. Sterilization

Sterilize the instruments using the appropriate parameters listed below:

Procedure	Dynamic-air-removal Steam Sterilization Cycle
Exposure time	≥4 minutes
Temperature	132 °C/270 °F
Minimum drying time	20 minutes

5. Storage after sterilization

- Keep instruments in sterilization packaging in a dry and clean environment.
- Sterility cannot be guaranteed if packaging becomes open, damaged, or wet.
- Check the packaging and the instruments before using them (packaging integrity, no excessive humidity and validity period).

Customer service

- The cleaning, disinfection and sterilization information is provided in accordance with ISO 17664, AAMI TIR12, and AAMI TIR30.
- These instructions have been validated by SHOFU INC. as being capable of preparing the rotary dental instruments for reuse. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommended process in these instructions should be properly evaluated for effectiveness with potential adverse consequences.

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