



READ CAREFULLY BEFORE USE

en PREPARATION and REPROCESSING INSTRUCTIONS according to EN ISO 17664 for users in the European Union

Scope

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

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 and disinfection

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 instruments in enzymatic bath for a minimum of 30 seconds and until no visible contamination is present.
- Remove the instruments from enzymatic bath.
- Rinse the instruments 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)	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 Disinfection	5 minutes	Heated (≥ 90 °C)	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 and disinfection

B-1. Manual cleaning

B-1-1. Preparation

- The following will be required for manual cleaning of the instruments:
 - Advanced Sterilization Products Enzo[®]/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-1-2. 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 Enzo[®] 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 to 45 °C 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-1-3. 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.

B-2. Manual disinfection

B-2-1. Preparation

- The following will be required for manual disinfection of the instruments:
 - Trays or basins for immersion of instruments during disinfection and rinsing
 - At least limited virucidal instrument disinfectant on VAH List (e.g. CIDEX® OPA High level disinfection solution with a concentration of 0.55% of of ortho-phthalaldehyde)
 - 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) for final rinsing.
 - Sterile, non-linting wipes or cloths for drying

B-2-2. Manual disinfection

- Prepare the disinfectant solution according to the manufacturer's instructions.
- Completely immerse the instruments in the disinfectant solution.
- Remove the instruments from the disinfectant solution.
- Rinse the instruments thoroughly with critical water.
- Thoroughly dry all surfaces of the instruments using sterile, non-linting wipes or cloths, changing wipes/cloths when necessary to ensure that the instruments are completely dry.

Notes: Perform manual disinfection following the disinfectant manufacturer's instruction.

3. Storage after disinfection

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:

- EN 13060 compliant autoclave
- Suitable bur block
- ISO 11607-1 compliant pouches for steam sterilization, as applicable

4-2. Packaging

Handle instrument(s) 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 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	≥ 3 minutes
Temperature	134 °C
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 use (packaging integrity, no excessive humidity and validity period).

Customer service

- The cleaning, disinfection and sterilization information is provided in accordance with EN 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 to achieve 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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