



EN Instructions for Use

READ CAREFULLY BEFORE USE

PREPARATION and REPROCESSING

SCOPE

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

WARNINGS

1. Chlorine disinfectant must not be used to avoid corrosion of the instruments.
2. Avoid any temperature over 135 °C/275 °F.

LIMITATIONS ON PROCESSING

The end of life is determined by wear and damage in use. Do not use damaged or defective instruments i.e. corrosion, surface flaw, deformation, dirt and exposure of shank etc.

INSTRUCTIONS

●Initial treatment at the point of use

For reuse, proceed to cleaning process within one hour after finish using intraorally. Dried contaminants are hard to remove, making cleaning more difficult.

●Cleaning: Automated

Place the instruments in a bur block (e.g. Bur Block) and set it into the washer disinfector. Then, run the cleaning program.

Table. Parameters for cleaning

Process chemicals	Alkaline cleaner, DR. WEIGERT neodisher® FA 0.5%
Water quality	Tap water that conforms to the criteria of each country.
Water quality for final rinse	Fully demineralized water
Cycle parameters	<ul style="list-style-type: none">- 4 min pre-washing with cold water- Draining- 5 min washing with neodisher® FA 0.5 %- Draining- 3 min neutralizing with warm water (> 40 °C/104 °F)- Draining- 2 min intermediate rinsing with warm water (> 40 °C/104 °F)- Draining
Electrical conductivity of the rinsing water after final rinse	< 79 µS/cm※

- The washer disinfector manufacturer's instructions for use must be observed. Do not exceed the washer disinfector's maximum load capacity.
- Observe the process chemicals manufacturer's instructions for use with reference to concentration, temperature and contact time.

※Concentration of residual process chemical is less than 87 ppm.

●Disinfection: Automated

Place the instruments in a bur block (e.g. Bur Block) and set it into the washer disinfector※. Then, run the thermal disinfection program following the washer disinfector manufacturer's instructions for use. Store in hot water at 90°C or higher for at least 5 minutes (A_0 value > 3000).

※Washer disinfector should comply with ISO 15883.

●Drying

Dry the device using a non-shedding wipe.

- The device must be dried completely before autoclave. Residual water could cause pitting corrosion or insufficient sterilization.

●Inspection

Visually inspect to confirm thorough removal of debris. Repeat the cycle if needed. Do not use if any damage or defect, i.e. corrosion, surface flaw, deformation and dirt etc, which would prevent proper operation, is found.

●Packaging

Place the instruments in pouches validated for sterilization (ex. VP Stericlin).

●Sterilization

Use the following cycle for autoclaving complying with EN 13060 or EN 285.

Cycle type	Holding time (minutes)	Temperature	Dry Time (minutes)
Pre-vacuum (3 times)	3	134 °C/273 °F	10

- Sterilizer manufacturer's instructions must be observed. Their maximum load should not be exceeded.

●Storage


The instruments should be stored in the sterilization pouch until required.

VALIDATION CONDITIONS

Automatic cleaning	Sterilization (complying with EN ISO 17665)
Washer disinfectant: Miele G 7735 CD Program: Vario TD (cleaning step) Detergent: DR. WEIGERT neodisher® FA 0.5% Rinsing: 2 min with warm water (> 40 °C/104 °F)	Autoclave: MMM 6-6-6 Selectomat HP Sterilization pouch: VP Stericlin Pre-vacuum: 3 times Holding time half cycle: 1.5 min Sterilization temperature: 134 °C/273 °F Drying time: 10 min

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