HYGIENE RECOMMENDATIONS

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Manufacturer information on cleaning, disinfection, and sterilization for medical devices according to DIN EN ISO 17664-1.
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Products: This manufacturer information applies to all instruments supplied by acurata GmbH & Co. KGaA for dental applications used in invasive and surgically invasive procedures.
These are powered tungsten carbide and polishing instruments intended for reprocessing, as well as single-use polishers.
The product range consists exclusively of non-sterile instruments. These must be reprocessed before first use (beginning with step 2) and after each subsequent use (beginning with step 1).

⚠ For certain high-risk products with long, narrow lumina, hard-to-reach cavities, or internal cooling channels, a specific cleaning procedure according to the instructions in the packaging insert must be followed, if applicable.

⚠ The disinfectant solution, bur bath, and cleaning agents used by the reprocessor must be explicitly suitable for rubber polishers, plastics, and silicones.

General note: Observe all applicable national regulations regarding the cleaning and reprocessing of medical devices. In Germany, the recommendations of the Robert Koch Institute (RKI) and the Commission for Hospital Hygiene and Infection Prevention (KRINKO) must be observed. The manufacturer ensures that the validated procedures specified below for cleaning and sterilization of the instrument groups mentioned are suitable for their intended reuse. The operator of the medical device is responsible for ensuring that the actual reprocessing procedure—based on their own risk assessment, available equipment, materials, process chemistry, process parameters, and trained personnel—achieves the required results. Routine checks of validated reprocessing procedures are required. Any deviation from the validated procedure (e.g., use of different detergents) must be carefully tested by the reprocessor for effectiveness, and potential adverse effects must be assessed.

Limitation of reprocessing: The end of the product's service life is determined by wear and damage resulting from use. Single-use products must not be reused or reprocessed (indicated on the label).

If the brushes are reprocessed after use, the cleanliness of the products cannot be guaranteed. The number of reprocessing cycles has been defined as follows:

⚠
- Tungsten carbide instruments: up to 15x
- Polishers: up to 10x
- Polishing discs: single-use product, reprocessing not possible
- Polishing brushes: single-use product, reprocessing not possible

1 Preparation / Environment, including Storage and Transport

Reprocessing should take place under controlled and hygienic environmental conditions. All national workplace hygiene regulations must be observed. For first-time use, start with step 2.
Immediately after use (within 60 minutes at the latest), place instruments into a bur bath (e.g., burr sterilizer/disinfector) filled with a suitable non-fixing / aldehyde-free cleaning and disinfecting agent (e.g., BIB forte eco). Prepare the bur bath according to the manufacturer's instructions (e.g., 0.5 % solution, maximum immersion time 60 minutes). Always add water first, then concentrate. Cover the container and observe the exposure time. Transport the instruments to the reprocessing area safely within the closed container to prevent contamination.

2 Cleaning / Disinfection / Drying

All non-sterile instruments must be cleaned mechanically before use using a validated procedure.

Mechanical Cleaning – Validated Process

Validated Equipment

Bur bath – sterilizable opal-glass container with perforated lid and sieve insert

Cleaning brush – sterilizable plastic brush with nylon bristles

Washer-disinfector (WD) – DIN EN ISO 15883-1 (e.g., Miele Professional G 7836 CD)

Detergent – Dr. Weigert Neodisher mediclean (0.5 % solution)

Instrument rack – sterilizable stainless steel with silicone inserts (e.g., acurata 030.H30)

Loading trolley – for WD, multi-level

Magnifying device – minimum 8× magnification

Tap water – minimum drinking water quality

DI water – deionized (fully demineralized) water

Sequence of the Validated Process:

Remove instruments from the bur bath immediately before machine cleaning, brush under running cold tap water until all visible soil is removed. Load new and reprocessed instruments into the open rack. Place the open rack in the washer-disinfector. Avoid overloading and shadowing.
Run the WD cleaning cycle ("Vario TD" program, Miele) according to EN ISO 15883-1.

Validated Cycle Parameters:

- Pre-rinse with tap water 2 min (20 °C ± 5 °C)
- Drain
- Main wash 5 min at 55 °C ± 5 °C with detergent
- Drain
- Neutralization 3 min with DI water at 20 °C ± 5 °C
- Intermediate rinse 2 min with DI water at 20 °C ± 5 °C
- Thermal disinfection 5 min at 90 °C ± 5 °C hold time
- Drying 10 min at 90 °C ± 5 °C

3 Inspection / Verification

Visually inspect all instruments for cleanliness and integrity using a magnification device (≥ 8×). If residual contamination remains visible, repeat the entire cleaning cycle until no contamination is observed.
Instruments showing any of the following defects must not be reused and must be disposed of immediately:

- Corroded surfaces or visible residues that cannot be removed
- Damaged, bent, or deformed shafts or working parts
- Tungsten carbide instruments with blunt or broken cutting edges
- Polishers with discoloration or deformation (including excessive wear)

4 Packaging / Sterilization

If sterilization is required, use a Type B moist-heat process with suitable sterile barrier systems.

Steam sterilization – Validated process

Validated Equipment

Steam sterilizer – DIN EN 285 (e.g., MMM Selectomat PL 669-1H L)

Instrument rack – sterilizable stainless steel with silicone inserts (e.g., acurata 030.H30)

Sterilization pouches – transparent, DIN EN ISO 11607-1 (e.g., Wipak SteriKing)

Sealing device – Hawo GM03

Process:

Load instruments into the rack, double-pack them in sterilization pouches, and seal using the sealing device. Alternatively, single packaging without the rack is permitted if the instruments are protected. Use a standardized sealing method and inspect all seals for integrity before sterilization.

Place the packaged instruments in the steam sterilizer, observing the manufacturer's loading patterns and parameters. The loading parameters and loading patterns specified by the device manufacturer must be observed. Successful steam sterilization of the packaged instruments has been validated in the pre-vacuum steam sterilization process using the following minimum parameters:

- 3 pre-vacuum phases
- 132 °C sterilization temperature
- 3 min hold time (full cycle)
- 10 min drying time

After completion, remove the items, allow to cool, and re-check seal integrity. Instruments are thermostable up to 134 °C. (KRINKO / BfArM recommend sterilization at 134 °C for a minimum of 5 minutes.)

⚠ **The products are not suitable for sterilization in chemical autoclaves or hot-air disinfectors.**

5 Transport / Storage

Transport and store reprocessed instruments protected against recontamination, either in sterile packaging or suitable cassettes.
Ensure adequate protection against dust and moisture during storage at all times.

6 Disposal

Dispose of instruments in a way that prevents contamination of third parties. Observe national regulations and legislation. Due to the materials used, disposal is generally possible via domestic waste.
The latest version of these hygiene recommendations is always available on our website: www.acurata.de/ifu
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