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RECOMMENDED HYGIENE PROCEDURES

Manufacturer's information on the reprocessing of medical products semi critical B and critical B according to the KRINKO guideline "Requirements on the hygiene for reprocessing of medical products" and the DIN EN ISO 17664.

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Products: The present manufacturer's information applies to all instruments supplied by acurata GmbH & Co. KG that are used for surgical, periodontal or endodontic treatments. These are rotating tungsten carbide, diamond and polishing instruments as well as oscillating instruments made of stainless steel or nickel-titanium. The product range includes exclusively instruments delivered in non-sterile condition. These have to be prepared prior to first use (begin with step 1) and prior to any further use (begin with step 2).

Limited number of reprocessing cycles: The end of a product's service life is determined by damage and wear caused by use. Frequent reprocessing does not affect the performance of these instruments. Disposable products (marked ⊗ on the label) shall not be reused or reprocessed.

Basic note: Observe the legal provisions concerning the reprocessing of medical products valid in your country (e.g. in Germany www.rki.de). The manufacturer assures that the reprocessing methods detailed below are appropriate for the reprocessing of the mentioned groups of instruments for their reutilization in regard of their intended use. The operator is responsible that the applied methods of reprocessing, based on his risk assessment with the used equipment, material, process parameters and staff achieve the required results for the intended use. To guarantee this, routine controls of the validated mechanical and/or manual reprocessing methods are necessary. Any deviation from the validated method below detailed must be checked and released by the operator to ensure effectiveness and to avoid possible adverse consequences. **The hygiene procedure recommendation is available on our website in its current version: https://www.acurata.de/en-US/products/hygiene-recommendations**

1

Preparation incl. storage and transportation

For first use preparation begin with step 2. Place instruments immediately or at the latest one hour after use on a patient, in a cleaning/disinfection tank filled with a suitable detergent/disinfectant (non-fixing/ aldehyde-free, e.g. BIB forte eco). Set up the drill bath acc. to manufacturer's instructions; for BIB forte eco mix concentrate with water - first the water, then add concentrate. Cover the tank. Pay attention to the application time (e.g. BIB forte eco 0,5% 60 min.). The transport of the instruments to the place of preparation should be made in a contamination protected cleaning/disinfection tank.

2

Cleaning and disinfection

According to the directive of the Robert Koch Institute (RKI) and Commission for Hospital Hygiene and Infection Prevention (KRINKO) it is preferential that the preparation of semi-critical B products is carried out mechanically; critical B products shall in any case be prepared mechanically. For products with long, tight lumina or cavities the cleaning has to be performed mechanical. For root canal instruments silicone stoppers have to be removed prior to reprocessing.

Mechanical cleaning – validated method

Equipment: Cleaning brush, mechanical washer/disinfector acc. to EN ISO 15883 (RDG) (e.g. Miele with Vario TD program), detergent (e.g. 0,5% cleaner Neodisher mediclean), acurata bur stand made of stainless steel.

Method: Remove instruments from instrument stand / cleaning-disinfection-tank immediately before mechanical reprocessing and brush off all visible contamination in a cold water bath. Place the instruments into the opened bur stand. Start mechanical cleaning according to the instructions of the manufacturer of the machinery and of the detergent. The following process is validated: Program Vario TD: 2 min. precleaning, 5 min cleaning at 55 °C with detergent, 3 min. neutralizing, 2 min. intermediate rinsing, final rinsing with appropriate (VE-) water 5 min. at >90 °C.

Thermal disinfection in a validated washer/disinfector

Perform the mechanical cleaning (see above, e.g. Miele washer/disinfector with Vario TD program)
incl. thermal disinfection with the instruments fixed in a bur holder. The manufacturer's instructions for the device must be observed. For validated washer/ disinfectors the disinfection is demonstrably assured. acurata products are thermostabile up to 134 °C.

Manual cleaning and disinfection – standardized method

Equipment: Cleaning brush (e.g. synthetic brush, sterilizable), ultrasonic bath, detergant & disinfectant with approved efficiency for dental instruments (e.g. BIB forte eco, Alpro Medical), bur stand for rotating oscillating instruments (e.g. acurata bur stand made of stainless steel); the manufacturers' instructions must be observed.

Method: Remove instruments from bur stand / cleaning-disinfection tank immediately before manual cleaning. Brush off all visible contamination in a cold water bath. Rinse the instrument and the bur stand under running water. Put the instrument into a suitable strainer element and place it into the ultrasonic unit filled with detergent & disinfectant. Perform cleaning and disinfection according to the instructions of the manufacturers of the ultrasonic bath and the detergent and disinfectant; e.g. BIB forte eco 3% - 10 min. at 55 °C tested to EN 14476. After the application time rinse the instrument thoroughly with appropriate water (e.g. VE-water). Dry the instruments preferably with medical compressed-air. According to KRINKO the manual reprocessing is finalized by a thermal disinfection in a steam sterilizer. Follow manufacturer specifications.

Visual examination with a suitable enlarger to ensure that the instrument is clean and undamanged (an enlargement of 8x -10x is recommended). If after reprocessing still residues of contamination are visible, repeat the cleaning and disinfecting process until no visible contamination is left. Instruments showing defects are to be discarded immediately (e.g. missing diamond coating, blunt and chipped blades, deformations, corroded surfaces or non-removable residual contamination).

3

Final reprocessing steps – sterile packaging and sterilization – Medical products critical B – validated method with moist heat:

Equipment: Steam sterilizer Co. MMM Selectomat HP, acurata bur stand made of stainless steel, transparent sterilization bag (Steriking o. VP Stericlin), sealed seam device Co. Hawo

Packaging: Prior to sterilization place the instruments in the bur holder and pack them altogether doubly in sterilization bags and weld them with a sealed seam device. The instruments must be protected. For the packing an appropriate standardized method has to be applied.

Sterilization: An effective steam sterilization of the packaged instruments is proven successfully in the pre-vacuum steam sterilization method with the following minimal parameters: 3 pre-vacuum phases, 132 °C sterilization temperature, holding time 3 min. (full cycle), drying time 10min. Follow the instructions of the device manufacturer. Note: The products are not suitable for a sterilization in a hot-air sterilizer or chemiclave.

4

Transport and storage During transport and storage, the reprocessed products must be protected from recontamination. Further the packed sterile goods must be protected also from dust and moisture.