Recommendations for reconditioning

for: Carbide Burs
Steel burs stainless
Stainless Surgical Burs and Cutters
Stainless Root Canal instruments

In the case of the recommendations for reconditioning below, the manufacturer of the instruments has ensured that these are safe and **suitable** for use on the product. The user is responsible for ensuring that the reconditioning actually carried out with the equipment used, the materials and the personnel in the reconditioning facility achieves the desired aims and that the instruments are marked as required and that documentation is completed. Normally, this requires the validation and routine monitoring of the procedure. Equally, each deviation from the instructions provided should be carefully checked for effectiveness and potential adverse consequences by the person in charge of reprocessing.

As the products are destined to be used for surgical, paradontological or endodontic procedures such as root canal debridement, they may penetrate the skin or the mucosa and come into contact with blood, internal tissues or organs (including wounds). Therefore, we recommend that they be assigned to risk group Critical B if used for their intended purpose.

Please also take note of the statutory regulations valid in your country as well as the hygiene rules followed by the doctor's practice or the hospital. This applies in particular to the different rules regarding effective prion deactivation (not relevant for USA).. The recommendation of the commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch-Institut (RKI) and the Federal Institute for drugs and medical devices (BfArM) for reconditioning must be considered.

All products need to be cleaned, disinfected and sterilised prior to use; this applies in particular to the first-time use of products i.e. after their delivery because all products are supplied non-sterile (cleaning and disinfecting after the removal of transport packaging; sterilisation after removing wrapping).

As you are responsible for the sterility of the products during use, please ensure that, as a rule, only sufficiently validated device and product-specific procedures are used for the cleaning/ disinfecting and sterilisation process, that the used devices (disinfector/ WD (Washer-Disinifector), sterilizer) are maintained and checked at regular intervals and that the validated parameters are adhered to during each cycle.

Please ensure that, after use, you separate the soiled products and do not return them to the bur sterilization tray to avoid further contamination. After cleaning/ disinfecting the soiled products, arrange them in the sterilization tray and sterilise the fully loaded sterilization tray.

The thorough cleaning and disinfecting is indispensable in order to achieve effective sterilisation.

Limitations of reconditioning:

If the instruments are not identified as single use, all instruments can be used again. The end of serviceability is only determined by wear and tear or damage to the instruments. The dental surgeon is responsible for rejecting damaged and worn instruments at an early stage. Carry out visual inspection for intactness and cleanliness, repeat the cleaning process if any contamination remains.

General rules for the reprocessing:

Reconditioning can be carried out by an automated procedure (WD (Washer-Disinifector)) or manually. According to recommendations of the Robert-Koch-Institut (RKI) treatment is preferably effected by machines. The manual procedure should only be used alternatively, if an automated procedure is unavailable. A standardised procedure is specified for manual reconditioning. Pre-treatment needs to be carried out in both cases. Apply hygiene-effective measures in line with the RKI guidelines at your workplace and carry out all work using powder and latex-free gloves.

When choosing the cleaning and disinfecting agents ensure that they do not contain the following components:

- organic, mineral and oxidising acids (minimum admitted pH value 5,5)

- strong lyes (maximum admitted pH value 11, neutral/enzymatic, weak alkaline or alkaline cleaner recommended)
- organic solvents (e.g. alcohol, ether, ketone, benzine)
- oxidizing agents (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

When choosing an appropriate cleaning system you need to ensure:

- that it is generally suitable for the cleaning of products made of metal and plastic,
- that, in addition, – if no thermic disinfection is used - a disinfectant is used
- that only a disinfectant is used whose efficacy has been certified (e.g. VAH/DGHM FDA/EPA clearance or CE marking)
- that the disinfection is compatible with the used cleaning agents
- that the concentrations, temperature and soaking time as well as post-rinsing recommended by the manufacturer of the cleaning and the disinfectant agents are adhered to at all times.
- that the cleaning agent, where used, is suitable for ultrasound cleaning (no production of foam)
- that only freshly made solutions are used and water that is either sterile or low in germs (max. 10 germs/ml) and endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) and only use filtered (oil-free, low-germ and low particle) pressurised air for drying.

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.

Precondition for the use of combined cleaning/disinfecting agents is a very low degree of contamination (no visible soiling) in result of an effective carried out pre-cleaning of the instruments, otherwise combined cleaning/disinfecting agents should not be used.

Never clean any instruments and sterilization trays by use of metal brushes or steel wool and do not expose any instruments and sterilization trays to temperatures higher than 138 °C (280 °F).

All the Products, bur blocks and sterilisation trays should never be exposed to temperatures exceeding 138 °C (280 °F).

When choosing a disinfector (WD (Washer-Disinifector)) you will have to ensure:

- that the effectiveness of the disinfector has been certified (e.g. it has been licensed by the DGHM or the FDA/EPA clearance or has CE marking according to DIN EN ISO 15883)
- that the used programme is suitable for the products and has a sufficient number of rinsing cycles
- that, if at all possible, a programme is used that has been certified for thermic disinfection (A_0-value ≥3000 or – with regard to older devices – at least 5 minutes at 90 °C (194 °F)) (chemical disinfection runs the risk of disinfectant residues remaining on the instrument)
- that only sterile water or water with low levels of germs (max. 10 germs/ml) and endotoxins (max. 0.25 endotoxin units/ml) is used for the post-purge cycle (e.g. purified water/highly purified water)
- that the air used for drying is filtered (oil-free, low contamination with microorganisms and particles)

If a WD is built in accordance with DIN EN ISO 15883 and regularly tested and maintained during its service life, it meets the above mentioned requirements with regard to water and air quality.

We only recommend the use of the steam sterilization procedures with a fractional vacuum process and a sufficient product drying.

By choosing the sterilisation procedure, please note that:

- Steam sterilizer are according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- Maximum sterilisation temperature 134 °C (273 °F; plus tolerance according to EN ISO 17665)
- sterilisation time (exposure time at the sterilization temperature)

As a rule, the flash sterilisation procedure is not admissible. Furthermore, do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation or plasma sterilisation. In order to avoid stains and corrosion, the steam must be substance-free (see limit values included in DIN EN 13060). When sterilising several devices, the maximum load of the sterilising apparatus must not be exceeded (observe the manufacturer's instructions).

Storage/Pretreatment:

Abrasive impurities need to be removed from the products directly after use (within 1 h maximum) with nylon brushes intended for the purpose (never using metal brushes or steel wool). Remove contaminated instruments of the sterilization tray and rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F). Soak the disassembled instruments for the given soaking time in the pre-cleaning solution (aldehyde-free (otherwise fixation of blood impurities). Pay attention that there is no contact between the instruments. They should be sufficiently covered. Assist cleaning by careful brushing at beginning of soaking and subsequent ultrasonic treatment (after brushing, for the minimum soaking time, but not less than 5 min). The method of use, reaction time and suitability of disinfectants for certain types of instruments are covered by the manufacturer's instructions, and it is essential that these are observed.

Remove the instruments of the cleaning solution and post-rinse them at least three times (not less than 1 min) under running water. Check the instruments on visible remnants. In case of still remaining remnants (e.g. bone or dentin particles) repeat the pretreatment otherwise discard the instrument.

Please note that the disinfectants used during pre-treatment only ensure personal protection and can be no substitute for the disinfection procedure to be used later - after completion of the cleaning process.

Reconditioning:

Reconditioning can be carried out by mechanically or manually. According to recommendations of the Robert-Koch-Institut (RKI) treatment is preferably effected by machines. A standardised procedure is specified for manual reconditioning.

Mechanical cleaning and disinfection:

The instruments should be rinsed under running water immediately before mechanical cleaning.

Place the instruments in suitable stands (for example Miele E 491) into a standard cleaning and disinfection machine (WD (Washer-Disinifector)) with the following programme sequence:

Vario TD programme:	4 minutes pre-washing with drinking water
	5 minutes washing at 55°C with an alkaline cleaning agent
	3 minutes rinsing with tap water
	2 minutes intermediate rinsing with tap water
	thermal disinfection, at least 5 minutes at 90°C

Remove and dry instruments when programme is completed (preferably in accordance with the RKI recommendation using compressed air).

Carry out visual inspection for intactness and cleanliness, repeat the cleaning process if any contamination remains.

The evidence of the basic suitability of the products for an efficient cleaning by means of machines was provided in an automatic cleaning/disinfection machine Miele G 7735 CD, using an alkaline cleaning agent (0.5% Neodisher FA, Dr. Weigert, Hamburg).

We point out that the performance review of an automatic cleaning/disinfection unit in accordance with ISO 15883-1 section 6.1.3.4.4 includes the proof of absence of process residues.

Manual cleaning and disinfection:

Rinse the instruments under running water.

Heavily contaminated instruments should be cleaned first manually, by soaking the instruments in cold water (at least 5 minutes) and removing visible contamination with a soft nylon brush.

Place the instruments in mesh baskets into an ultrasound bath with cleaning and disinfection liquid.

The manufacturer's instructions (instruction manual) for the cleaning and disinfection agents have to be observed by all means in order to ensure safe handling. Data about limit values for chemical residues can be found in the safety data sheets of the cleaning/disinfection agents that must be put at disposal by the manufacturer of these agents.

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At the end of the stipulated reaction time, rinse the instruments thoroughly with running water (preferably distilled water, minimum volume 200ml) and dry immediately (preferably in accordance with the RKI recommendation using compressed air).

Carry out visual inspection for intactness and cleanliness, repeat the cleaning process if any contamination remains. Since manual cleaning does not involve any automatic procedures, visual inspection is extremely important. The use of a magnifying device is recommended.

The evidence of the basic suitability of the products for an efficient manual cleaning was provided in the ultrasonic bath, using the cleaning agents and disinfectants (0.5%, Neodisher Medizym, Dr. Weigert, Hamburg) with the parameters 5 min at 45°C in the ultrasonic bath.

Checking:

After all products have been cleaned and/or cleaned/disinfected, check them for corrosion, damaged surfaces/bare patches, broken/chipped-off edges, deformations (e.g. bent rather than round) and impurities and eliminate damaged products. Products that are still contaminated need to be cleaned and disinfected once more.

Packaging:

Arrange the cleaned and disinfected products in the block/sterilisation tray. Wrap the products and/or the bur blocks/sterilisation trays using disposable sterilisation packaging (disposable or double packaging) that meet the following requirements (material/process):

- DIN EN ISO/ANSI AAMI ISO 11607
- Suitable for steam sterilisation (thermal stability up to 138 °C (280 °F) sufficient steam permeability)
- Sufficient protection of the products and/or sterilisation packaging against mechanical damage

By individual packaging: the packaging must be sufficiently large to ensure that the sealing is tension-free.

Sterilisation:

Suitable packaging should be selected for the instruments and the sterilisation procedure, and the instructions of the manufacturer of the sterilizer should be observed.

We recommend the steam sterilisation with the following parameters:

- Fractioned pre-vacuum (3 times)
- Sterilization temperature 134ºC
- Holding temperature: 5 minutes (full cycle)[2]
- Drying time: 10 minutes[3]

[2] or 18 min (prion deactivation, not relevant for USA)

[3] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

The evidence of the basic suitability of the products for an efficient steam sterilisation was provided using a steam sterilisator Selectomat HP 666-1HR.

Storage

Prior to the first use of the device, the product should be stored in its original packaging at room temperature in dust- and humidity-free conditions. Subsequently, the products should be stored in appropriate hygienically maintained containers (protected from dust, humidity and recontamination).

After sterilisation, the products need to be stored in sterilisation wrapping in a dry and dust-free place. Please note the shelf-life resulting from the validation of the sterilisation wrapping.

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