# Instructions for Reprocessing

for all devices supplied non-sterile, such as drills, tools and prosthetic components

## 1. Instructions for Use and Safety

Unsterile devices have to be cleaned, disinfected and sterilized before use. This applies to drills and tools for both initial and subsequent use. The preparation of drills and tools is limited to a maximum of 10 cycles. The prosthetic components are designed for single use and are therefore cleaned, disinfected, and sterilized only once prior to use. The user is responsible for the sterility of the device groups mentioned above. It has to be guaranteed that a validated procedure and validated parameters are used during cleaning, disinfection and sterilization and that the equipment used for this is checked and serviced in regular intervals. Thorough cleaning is an essential precondition for a successful disinfection and sterilization.
Mechanical cleaning, disinfection and sterilization must be carried out for all device groups.
In addition, please observe the legal regulations applicable in your country for the reprocessing of medical devices as well as the hygiene regulations applicable in the dental practice or dental clinic. This applies in particular to the various guidelines for the inactivation of prions. This requires the use of detergents that have proven to be effective in inactivating prions and longer holding times during sterilization.

## 2. Place of Use

Dental practices and clinics.

## 3. Reprocessing Instructions

*Step 1 Pre-treatment and transport*
Equipment:
Detergent/disinfectant [pH value ≤ 10], instrument disinfection tray and drill disinfection container

The following points have to be observed:

- Free of aldehydes (aldehydes have a blood and protein fixating effect)
- Approved agents with demonstrated efficiency (e. g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE mark)
- The disinfection during the pre-treatment only serves to protect the staff. This does not replace the disinfection after the cleaning step.
- When placed in the instrument disinfection tray, all instruments have to be completely covered by the solution.

After use, the devices should be placed in a disinfection tray filled with a cleaning/disinfecting solution or disinfecting solution (observe the instructions provided by the manufacturer with regard to the concentration and the temperature of the solution as well as the minimum and maximum residence time). Reprocessing must take place shortly after use (≤ 2 hours). The instruments should be transported in the disinfection tray to the site where reprocessing is to take place.

*Step 2 Preparation for cleaning*
Equipment: Nylon brush, running water, interdental brush 1.1 - 5.0 mm for hollow spaces.
Remove the devices from the cleaning/disinfection tank just before before starting the cleaning process. Remove any visible contamination and the residues of the detergent/disinfectant or


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disinfectant with a nylon brush (do not use a brush with metal bristles) under running water (less than 45 °C to prevent protein fixation). Rinse for 1 minute. Make sure that all hollow spaces have been cleaned thoroughly with the help of an interdental brush.

*Step 3 Mechanical cleaning and disinfection*
Washer/disinfector in compliance with ISO 15883, detergent (e. g. Neodisher MediClean forte; co. Dr. Weigert)

The following points have to be observed:
- the cleaning agent's basic suitability for metal instruments
- use of approved agents with demonstrated efficiency (e. g. VAH/DGHM or FDA/EPA authorization/clearance/registration or CE mark)
- washer/disinfector is checked according to EN ISO 15883 and the efficiency of the device has to be categorically recognized (e.g. CE mark according to EN ISO 15883 or DGHM or FDA approval/release/registration)
- washer/disinfector has to be serviced/maintained on a regular basis
- washer/disinfector is tested in accordance with EN ISO 15883 and with generally recognized efficiency ($A_0$ value ≥ 3000 or at least 5 minutes at 90 °C)
- In view of the hazard posed by possible residues of the disinfectant on the instruments, chemical disinfection is not authorized
- the effective removal of detergent residues, e. g. by a program with a sufficient number of rinsing steps (at least three rinsing steps after cleaning or neutralization, if used) or by conductivity-based rinsing control
- the placement of the products in a sieve in the washer/ disinfector
- the manufacturer's instructions for the concentration and quantity of detergent
- allow the products to cool down and remove them from the washer/ disinfector when the cycle is complete

*Step 4 Drying*
Equipment: Compressed medical air (oil-free and with a low-germ)
Dry the devices with compressed air. Make sure all hard-to-reach areas are dried properly.

*Step 5 Packaging*
Equipment: single or double sterilization packaging (paper/foil)
The following points have to be observed:
- Sterilization packaging in compliance with EN/ISO/ANSI AAMI ISO 11607 (in the USA: FDA approval)
- The packaging has to be suitable for steam sterilization.
- Disposable sterilization packaging must not be under tension.
- The cleaned, disinfected and dried devices have to be packed in disposable sterilization packages.

*Step 6 Sterilization*
Equipment: Autoclave
The following points have to be observed:
- fractionated pre-vacuum with at least 3x evacuation
- the use of quick sterilization programs is not authorized
- device in compliance with EN 13060/EN 285 or ANSI AAMI ST79 (in the USA: FDA approval)


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- validated according to EN ISO 17665 (valid IQ/OQ (start-up) and product-specific performance qualification (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance as per EN ISO 17665)
- the autoclave has to be serviced and maintained in regular intervals
- the use of other sterilization methods (dry heat, gamma radiation, formaldehyde as well as ethylene-oxide sterilization and plasma sterilization) is not authorized

| Country | Fractionated pre-vacuum Process | Holding time, temperature |
|---|---|---|
| USA | yes | at least 4 minutes at 132 °C (270 °F)<br>drying time: 20 minutes |
| Germany | yes | at least 5 minutes at 134 °C (273 °F) |
| Other countries | yes | at least 3 minutes at 132 °C (270 °F)/134 °C (273 °F) |

## 4. Storage

Once all processing steps have been completed and the intactness and cleanliness of the devices have been ensured, they can be released and stored. The storage location should be clean and protected from dust, moisture, light, temperature and recontamination. Do not store together with cleaning agents and other chemicals.

## 5. Maintenance

Damaged products and products where the tension spring does not engage when the instrument is clamped must be sorted out.

## 6. Control and functional test

Before using the products, visually check for damage (e.g. bending, wear) and function, e.g. the tension spring of the drill extension must engage when the instrument is clamped.

## 7. Procedure in case of serious adverse events

All serious adverse events occurred in connection with the device have to be reported to the manufacturer and the competent national authority.

## 8. Safety and liability

Please also note the general recommendations for use and safety in the current instructions for use. The use of third-party components may impair the function of the BoneTrust® implant system and excludes any warranty or replacement service by Medical Instinct® Deutschland GmbH. This applies in particular to non-recommended, different application procedures. The processing and use of Medical Instinct® Deutschland GmbH products is beyond our control and is the sole responsibility of the user. Any liability for damage caused by this is excluded.

Conduct a patient history (anamnesis) including imaging diagnostics prior to each procedure and inform the patient of all risks, side effects, and potential incompatibilities.
For intraoral use, ensure that the products are secured against aspiration or accidental dropping.
Prior to application, check that the device is suitable for use in accordance with its intended use.
Check the color coding and labeling to avoid confusion between product variants.
Re-use or re-sterilization of the single-use devices is not permitted. Re-using or re-sterilization of single-use devices increases the risk of infection and risk-free functional safety cannot be


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guaranteed. Inspect the products and their inner packaging for damage before use. Do not use damaged products or products with damaged packaging. Sterility cannot be guaranteed for damaged or previously opened packaging.