Instructions for the reprocessing (Cleaning, disinfecting and sterilizing) of medical devices produced by TRATE AG

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Change Index

Revision	Date	Description of changes
Rev. 1	26.02.2013	Printing date
Rev. 2	17.06.2013	Corrections for validation the reprocessing
Rev. 3	01.10.2013	Adding information on detergents and cleaning and sterilization instruments after the validation of the reprocessing of medical device (acc. to validation protocol Nr. 11540_20130617 from 23.09.2013)

The medical devices produced and sold by TRATE AG are re-usable unless their label contains explicit information to the contrary. However, as a rule, it is the sole responsibility of the doctor/expert using the devices to decide whether, depending on the respective case and the potential wear and tear of the products, he can re-use the products and how frequently he uses them. In case of doubt, it is always advisable to discard the products early and to replace them. The manufacturer TRATE AG cannot guarantee the faultless function and performance of the products combined with a maximum degree of safety if the products are overused.

NOTE! This instruction valid for instruments only! Never resterilize dental implants!!!

These reprocessing instructions apply in principle to all medical devices making up the product range supplied by TRATE AG. Any particular features and/or exclusions that only concern individual items or groups of items are referred to separately. As to the general application and safety instructions concerning the use of the products, we would advise you to consult the application and safety instructions for the medical products of TRATE AG, which are available separately (see also at www.trate.ch).

General rules

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

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, sterilizer) are maintained and checked at regular intervals and
- that the validated parameters are adhered to during each cycle

Please ensure that, during use, you separate the soiled products and do not return them to the bur block/instrument tray to avoid further contamination of the loaded bur block/instrument tray. After cleaning/disinfecting the soiled products, arrange them in the bur block/instrument tray and sterilise the fully loaded bur block/instrument tray.
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. You will find further instructions for the reprocessing of medical products and information on suitable products to carry out the reprocessing on the internet at www.dghm.de or at www.rki.de.
As the products are destined to be used for surgical, paradontological procedures, 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.
Attention: For some products, additional aspects need to be considered (see chapter on 'Special instructions')!

Cleaning and disinfecting

Basic rules:
Ideally, a mechanical procedure (disinfector) should be used for the cleaning and disinfecting process. Due to their clearly reduced effectiveness and reproducibility, manual procedures – even if they include the use of an ultrasound bath – should only be used if an automated procedure is unavailable. 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.

Pre-treatment:

- Abrasive impurities need to be removed from the products directly after use (within two hours maximum)

- To do so, use running water or a disinfectant solution; the disinfectant must not contain aldehydes (which could fix blood residues to the instrument surface), its effectiveness should be established (e.g. it should be certified by the VAH (German Association for Applied Hygiene), the DGHM (German Society for Hygiene and Microbiology) or the FDA or have CE marking)
- It should be suitable for the disinfection of the products and compatible with the products (see chapter on 'Material resistance'). For the manual removal of impurities, only use nylon brushes intended for the purpose (also see the chapter on 'Special Instructions') or clean soft and lint-free cloths that you only use for this purpose.
- Do not use metal brushes or steel wool.
- As to products with lumen (cavities): rinse all cavities three times by using a disposable syringe (minimum volume 5-10 ml) and a cannula. 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.

Mechanical cleaning/disinfection (disinfector/RDG (cleaning and disinfection device):
When choosing a disinfector 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 or has CE marking according to DIN EN ISO 15883)
- that, if at all possible, a programme is used that has been certified for thermic disinfection (A0-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 the used programme is suitable for the products and has a sufficient number of rinsing cycles
- 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 and that the disinfector is regularly maintained and checked.

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, – When no thermic disinfector is used , the disinfection detergent should be certified by the VAH (German Association for Applied Hygiene), the DGHM (German Society for Hygiene and Microbiology) or the FDA or have CE marking)
- the detergent should be compatible with the products.

It is essential that the concentrations recommended by the manufacturer of the cleaning and the disinfectant agent (if required) are adhered to at all times.
Procedure:

1. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components.
2. When using products with lumen: ensure that all lumens are rinsed effectively as part of the pre-treatment process.
3. Place the disassembled products in the disinfector.
4. Start the programme.
5. Remove the products from the disinfector after the programme has finished.
6. Check and wrap the products straight after removal if possible (see chapters on 'Checking', 'Maintenance' and 'Packaging') if necessary, after thet have been dried off completely in a clean place.

Proof of the general suitability for effective mechanical cleaning and disinfecting has been provided by an independent certified test laboratory using the washer - disinfector G 7892 CD (thermic disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher mediclean forte, Dosiersystem DOS 1 (Dr. Weigert GmbH & Co. KG, Hamburg). As part of the testing the laboratory used the above described procedure

Manual cleaning and disinfection:
When choosing an appropriate cleaning and disinfecting agent you need to ensure

- that they are generally suitable for the cleaning and/or disinfection of products made of metal and plastic
- that the cleaning agent, where used, is suitable for ultrasound cleaning (no production of foam)
- the disinfection detergent should be certified by the VAH (German Association for Applied Hygiene), the DGHM (German Society for Hygiene and Microbiology) or the FDA or have CE marking) and that it is compatible with the used cleaning agent
- that the used chemicals are compatible with the products (see chapter on 'Material resistance')
- Only use freshly made solutions 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 air for drying or a lint free cloth before packaging

Ideally, combined cleaning/disinfecting agents should not be used. Combined cleaning/disinfecting agents can only be used in cases where there is a very low degree of contamination (no visible soiling).
It is essential that the concentrations and contact times recommended by the manufacturer of the cleaning and the disinfectant agents are adhered to at all times.

Procedure:
Cleaning
Pre-treatment for the ultrasonic treatment:

1. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components.
2. Place instrument into a suitable disinfectant with active cleaning properties so that all surfaces, inner cavities, lumens and openings come into contact with the solution. Follow the disinfectant manufacturer's instructions.
3. Remove the device from the disinfectant solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to reach areas.

Ultrasonic treatment:

1. Before placing instruments into the ultrasonic unit, turn on the ultrasonic machine and let it run for 30 minutes to de-gas the solution. Use the suitable disinfectant with active cleaning properties and follow the disinfectant manufacturer's instructions. This process removes any gas or air bubbles in the solution. As with all types of cleaning, multi-component instruments should be disassembled. Make sure instruments have plenty of room. Don't overload your ultrasonic cleaner. Don't mix dissimilar metals (such as titanium and stainless steel) in the same cycle to prevent cross-plating.
2. Set the control panel per manufacturers' instructions and start the cleaning process
3. Upon completion of the cycle, rinse instruments after ultrasonic cleaning with water to remove ultrasonic cleaning solution. Take the products out of the cleaning bath and rinse at least three times thoroughly with water. Final rinsing to be done with distilled or deionized water. With regard to products with lumen: rinse all instrument lumens five times at the beginning and or at the end of the contact time using a disposal syringe (minimum volume 5-10ml) and a cannula.
4. Dry with soft and lint free cloth before packaging. Dry lumens and conduits with compressed air.

5. Check the products (see chapters on 'Checking' and 'Maintenance').

Disinfection:

1. Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components.
2. Immediately after use, immerse all instruments in a cleaning or disinfecting agent or in combined cleaning and disinfecting agent to serve as own security and to prevent the contaminants from drying. Always adhere to the manufacturer's instructions regarding concentration and reaction time of the cleaning or disinfecting agent or combined cleaning and disinfecting agent. With regard to products with lumen: rinse all instrument lumens five times at the beginning and or at the end of the contact time using a disposal syringe (minimum volume 5-10 ml) and a cannula.
3. Afterwards, take the products out of the disinfecting bath and rinse them thoroughly with water at least three times. With regard to products with lumen: rinse all instrument lumens five times at the beginning and or at the end of the contact time using a disposal syringe (minimum volume 5-10 ml) and a cannula.
4. Dry the products by blowing them dry using filtered pressurised air or with a lint free cloth before packaging.
5. Wrap the products, if possible, straight after removal (see chapter on 'Packaging', if necessary, after they have been dried off completely in a clean place).

Proof of the general suitability for effective manual cleaning and disinfecting has been provided by an independent certified test laboratory using the ultrasonic bath Powersonic P 2600 D ultrasonic system (Martin Walter Ultraschalltechnik AG, Straubenhardt) and cleaning agent Neodisher Z, Dosiersystem DOS 3 (Dr. Weigert GmbH & Co. KG, Hamburg) and the disinfectant Stammopur DR 8 (Dr. Weigert GmbH & Co. KG, Hamburg). As part of the testing, the laboratory used the above described procedure.

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 (limited numbers for re-use see chapter on 'Re-use'). Products that are still contaminated need to be cleaned and disinfected once more.

Maintenance

Re-assemble disassembled products (see specific instructions). Instrument oils must not be used.

Packaging

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

- DIN EN ISO/ANSI AAMI ISO 11607
- Suitable for steam sterilisation (thermal stability up to 137 °C (279 °F) sufficient steam permeability)
- Sufficient protection of the products and/or sterilisation packaging against mechanical damage
- Regular maintenance according to the manufacturer's specifications (sterilisation container)
- Individual packaging: the packaging must be sufficiently large to ensure that the sealing is tension-free.

Sterilisation

We only recommend the use of the sterilisation procedures listed below!

Steam sterilisation

- Use of a fractional vacuum process or a gravitation process* (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060 and/or DIN EN 285
- Validated according to DIN EN ISO 17665 (up to now: DIN EN 554/ANSI AAMI ISO 11134) (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ)))
- Maximum sterilisation temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665 (up to now: DIN EN 554/ANSI AAMI ISO 11134))
- Sterilisation time (exposure time at the sterilisation temperature) at least 20 min at 121 °C (250 °F) and/or at least 5** min. at 132 °C (270 °F)/134 °C (273°F)

* Use of the less effective gravitation procedure is only admissible if the fractional vacuum process is unavailable.
**or 18 min (prion deactivation).

Proof of the general suitability of the products for effective steam sterilisation has been provided by an independent certified test laboratory using the Autoclave Euro - Selectomat (MMM Münchener Medizin Mechanik GmbH, Planegg / München) as well as the fractional process and the gravitation process. During the testing, the laboratory took into account the typical hospital and practice conditions as well as the procedure described above.

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

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.

Material resistance

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

- organic, mineral and oxidising acids (minimum admissible pH value 5.5)
- strong alkaline solutions (maximum admissible pH value 8.5, neutral/enzymatic cleaning agent recommended)
- organic solutions (e.g. alcohols, ether, ketones, benzines)
- oxidants (e.g. hydrogen peroxides) - halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

Never clean products, bur blocks and sterilisation trays using metal brushes or steel wool. Products, bur blocks and sterilisation trays should never be exposed to temperatures exceeding 137 °C (279 °F)!

Re-use

When it comes to products that are re-used, the end of their useful life tends to depend on their wear and tear as well as the use-related damage. Therefore, it is necessary to check the instrument after or prior to each re-use (see section on 'Checking'). Independently of this, it is the sole responsibility of the physician using the instrument to decide upon re-

use based on the respective case as well as the potential wear and tear of the instrument. In this context, known restrictions as to the frequency of instrument use need to be observed.

If you fail to observe them, we do not accept any liability!

Special instructions

Drill extension:

- Disassemble instrument completely prior to cleaning and disinfecting
- Reassemble instrument prior to wrapping and sterilisation

Instrument trays:

- Cleaning and disinfecting only without products being loaded (products must not be cleaned and disinfected whilst they are in the bur block/ instrument tray)
- Remove attachments prior to cleaning and disinfecting and clean and disinfect in disassembled state

Universal Torque Ratchet:

- Disassemble instrument completely prior to cleaning and disinfecting
- Move joint several times to and fro during pre-cleaning and manual cleaning and disinfecting
- Reassemble instrument prior to wrapping and sterilisation.

The above instructions have been validated by the manufacturer of the medical devices who found them to be SUITABLE for preparing a medical device for re-use. It is up to the person in charge of the reprocessing to ensure that, based on the use of the correct equipment, material and personnel in the reprocessing facility; the actual reconditioning process produces the desired results. 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.

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This medical product is CE marked in accordance with Directive 93/42/EEC on medical devices

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