

<b>TRATE</b>	<b>Technical Documentation</b>	Instruction	<b>No. INS-RUD.02</b>
	<b>Subject:</b> Instruction for use reusable devices from Dental Implant System ROOTT		
<b>Developed by:</b>	Director of Quality V. Shulezhko	<b>Approved by:</b>	Member S. Shulezhka 2019-02-18

**Instruction for use  
Dental Implant System ROOTT  
Reusable devices**

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.

Regarding the previously mentioned products, the following legal regulations and guidelines are applied:

- 93/42/EEC Medical device directive,
- Federal Health 2001:44:1115-1126: Hygienic requirements for medical device preparation (Recommendations of the Commission on the compliance with the requirements of hygiene in hospitals at the Robert Koch Institute and the Federal Ministry of medicines and medical devices),
- ISO 17664,
- DIN EN ISO/ANSI AAMI ISO 11607,
- DIN EN 13060 and/or DIN EN 285,
- DIN EN ISO 17665.

**Reusability**

Frequent processing has minor effects on the instruments. The end of the product life is normally determined by wear and damage during use (cutting instruments are an exception; see below). Therefore, instruments can be reused with appropriate care, provided they are undamaged and not contaminated. Do not use instruments beyond the effective product life cycle nor use damaged and/or contaminated instruments.

**Cutting instruments**

If appropriately cared for, and provided they are undamaged and not contaminated, the cutting instruments can be reused up to a maximum of 10 times (1 time use = placement of 1 implant); any further use extending beyond this number or the use of damaged and/or contaminated instruments is not allowed. Maintain a checklist for these instruments recording the number of uses.

All surgical residues that stick to and dry on the instruments (incrustations) lead to corrosion. Exposing instruments to moisture for large amounts of time also leads to damage! Possible initial and further damages and their causes:

<b>Cause:</b>	<b>Damage occurring</b>
Blood, pus, secretion, tissue residues, bone residues	Corrosion, rusting
Saline solution, iodine tinctures, unsuitable water, unsuitable and/or incorrectly used cleaning agents and disinfectants	Pitting, discoloration
Steel wool, steel brushes	Contact corrosion, destruction of the material surface, removal of oxide layer p increased susceptibility to corrosion
Contact between instruments of different metallic materials	Contact corrosion

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Overloading the instruments	Cutting surfaces become blunt, are damaged p increased susceptibility to corrosion
Mutual contact of the instruments	Damage of the instruments, especially of cutting surfaces p increased susceptibility to corrosion
Impurities in the sterilizer, e.g. due to already corroded instruments, or improper maintenance of the sterilizer	Initial rust: contaminating intact instruments with rust
Insufficient drying of the instruments	Corrosion, rust

**7 measures that help to avoid greater problems:**

1. Use each instrument only for its intended purpose.
2. Never let surgical residues (blood, secretion, tissue residues) dry on an instrument; clean immediately after surgery.
3. Thoroughly clean off incrustations with soft brushes only. Disassemble instruments, clean cavities especially well.
4. Never disinfect, clean (also ultrasound) or sterilize instruments made of different materials together.
5. Use only cleaning agents and disinfectants intended for the material and follow the instructions for use of the manufacturers.
6. Rinse disinfectants and cleaning agents very thoroughly with water.
7. Never leave or store instruments moist or wet.

**Principles**

If possible, a mechanical method (disinfector) should be used for cleaning and disinfection. A manual method should be used only if a mechanical method is not available, because of its clearly lower effectiveness and reproducibility. This also applies when using an ultrasonic bath.

Perform pretreatment both in manual and in mechanical cleaning!

It is important to use protective clothing while cleaning contaminated instruments. Always wear protective glasses, face mask, gloves, etc. for your own safety during all activities.

**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),

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- 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 disinfectant 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 disinfectant 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 disinfectant.
4. Start the programme.
5. Remove the products from the disinfectant 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 they 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 - disinfectant 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.

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**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.*

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## Inspection

Check all instruments after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipping and contamination and sort out damaged instruments. Critical areas such as handle structures, joints or blind holes, in particular, must be inspected carefully.

You can use a magnifying glass and direct lighting for better visibility. Instruments with illegible markings/labeling must also be replaced. Instruments which are still contaminated must be cleaned and disinfected anew. Damaged, corroded or worn instruments should not come into contact with intact instruments to avoid contact corrosion.

## Maintenance

Reassemble the disassembled instruments.

## Packaging

If applicable: Sort the cleaned and disinfected instruments into the associated sterilization cassette.

Pack the instruments or the sterilization cassettes singly or doubly in disposable sterilization packaging corresponding to the following requirements:

- Suitable for steam sterilization (temperature resistance up to at least 137 °C, sufficient steam permeability).
- Sufficient protection of the instruments or sterilization packaging against mechanical damage.
- DIN EN ISO/ANSI AAMI ISO 11607.

An indicator strip with the date of the sterilization and the expiration date should be affixed to every sterilization packaging. This will help to indicate if and when the material was sterilized.

## 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).










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

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tear of the instrument. In this context, known restrictions as to the frequency of instrument use need to be observed.

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

### Signs explanation

	Consult instructions for use
	Catalogue number
	Batch code
	Use by
	Non-sterile
	Do not use if package is damaged
	Keep away from sunlight
	Keep away from water
	Manufacturer

## CE 2797

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

### Notes!

- For the purpose of legibility, TRATE does not use <sup>TM</sup> or © in the text. This does not affect TRATE's rights with regard to registered trademarks
- Some products may not be available in all markets. Please contact your local TRATE representative to review the product range available.

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