Instruction for
cleaning, disinfection and sterilization
of non sterile and reusable medical devices
Dental Implant System ROOTT

Dental Implant System ROOTT is a system of endosseous dental implants with corresponding abutments, gingiva formers, covering and fixing screws, other prosthetic parts and surgical instruments.

The medical devices produced and sold by TRATE AG are just for professional use.

This instruction is valid and intended for single use non-sterile medical devices which shall be sterilized before use to ensure proper preparation for sterilization and for reusable instruments proper preparation for re-sterilization.

The medical devices produced and sold by TRATE AG are reusable unless their label contains explicit information to the contrary. However, as a rule, it is the sole responsibility of the doctor using the devices to decide whether, depending on the respective case and the potential wear and tear of the products, he can reuse 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.

The manufacturer assumes no responsibility for the use of other sterilization methods than those prescribed in this instruction for TRATE AG medical devices. If will be changed parameters or selected different cycles other than described in this instruction, the customer shall validate it on his behalf.

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

- 93/42/EEC Medical device directive, ISO 17664, ISO 15883, ISO 11607, EN 13060 and/or EN 285, ISO 17665, ISO 15223-1.

General principles:

TRATE AG single use non-sterile medical devices (to be sterilized before use) and reusable instruments are supplied in non-sterile conditions. These can only be used in sterile conditions.

TRATE AG single use non-sterile medical devices (to be sterilized before use) and reusable instruments here are suitable for steam sterilisation.

Warnings:

Prior using of TRS-S Instrument tray, please remove the packaging film from the tray.

Be aware that TRS-S Instrument tray must be sterilized before use (follow the process described below in this instruction).

Make sure not to drop/ scratch/ sterilization trays and avoid shocks to protect the tray and its contents.

Always check the absence of sharp edges that could appear during the life cycle of sterilization tray to minimize the risk of skin break-in of health professionals.

The flash sterilization procedure is not admissible. Furthermore, do not use hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

When sterilizing several devices, the maximum load of the sterilizing apparatus must not be exceeded (observe the manufacturer's instructions).

The use of non-sterilized, improperly sterilized or damaged medical devices can cause infections.

Single use medical devices produced by TRATE AG that must be cleaned, disinfected and sterilized prior to use are not intended to be resterilized.

All reusable instruments are to be cleaned, disinfected and sterilized prior to each application, this required in particular for the first-time use after delivery of the unsterile instruments (cleaning and disinfection after removal of transport packaging, sterilisation after removing wrapping) an effective cleaning and disinfection is an indispensable requirement for an effective sterilization of reusable instruments.

Frequent processing has minor effects on the instruments. The end of the product life is normally determined by wear and damage during use (reusable instruments are an exception; see below). Therefore, instruments can be reused with appropriate care, provided they are undamaged and not contaminated. Before preparing for sterilization, all medical devices should be inspected under good light conditions is sufficient. All parts of the devices should be checked for visible soil and /or corrosion.

In order to avoid stains and corrosion, the steam must be substance-free.

Do not use instruments beyond the effective product life cycle not use damaged and/or contaminated instruments.

Perform thacking of the reference number marked on the label / kit and on the device itself. Do not use the product if a difference is identified. The REF number on the device and on the kit must be the same.

Products must be disassembled prior reprocessing. The information of assembling and disassembling of the products is provided in the *Assemble and disassemble of the products*.

Cautions/ Precautions

TRATE AG does not define the maximum number of uses appropriate for reusable instruments. The useful life of these devices depends on a number of factors including the methods and duration of each use and the handling between uses.

Products should not be used if are visible these defects (see: *Examples of inspection of the defects*):

- Corrosion, rusting;
- Pitting, discoloration;
- Cutting surfaces become blunt, are damaged, increased susceptibility to corrosion;
- Destruction of the material surface, removal of oxide layer increased susceptibility to corrosion;
- Damage of the instruments, especially of cutting surfaces increased susceptibility to corrosion.

Causes of defects:

- Unsuitable and/or incorrectly used cleaning agents and disinfectants, saline solution, iodine tinctures, unsuitable water;
- Cleaning with steel wool, steel brushes;
- Contact between instruments of different metallic materials;
- Overloading the instruments;
- Mutual contact of the instruments;
- Impurities in the sterilizer, e.g. due to already corroded instruments, or improper maintenance of the sterilizer;
- Insufficient drying of the instruments.

Product life time will be preserved and extended if:

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

Requirements:

For process:

Only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection and sterilisation.

Cleaning procedure shall be used which is valid within the cleaning.

Used devices (disinfector, sterilizer) are regularly maintained, are checked at regular intervals and the validated parameters are adhered to during each cycle.

For disinfectants:

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 (e.g. VAH/DGHM 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.

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 disinfectant agents are adhered to at all times.

For equipment:

When choosing a Washer-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 ISO 15883),
- a programme is used that has been certified for thermal disinfection (A0-value > 3000 or – with regard to older devices – at least 5 minutes at 90 °C) (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 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, e.g. VAH/DGHM or the FDA or have CE marking) and that it is compatible with the used cleaning ageng),
- the detergent should be compatible with the products.
- It is essential that the concentrations recommended by the manufacturer of the cleaning and disinfectant agent (if required) are adhered to at all times.

For packaging materials

Packaging materials must be suitable for steam sterilization (e.g. autoclave bags) and sterile barrier should be performed according to the instructions specified in ISO 11607.

For Steam sterilizer

When choosing steam sterilizer you will have to ensure:

- Steam sterilizer has CE marking according to EN 13060 and/or EN 285.
- Validated according to ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ)).

Procedure:

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).

The devices are immersed into a cleaning and disinfecting agent or in a combined cleaning/disinfecting agent.

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. It should be suitable for the disinfection of the products and compatible with the products.

As to products with lumen (cavities): rinse all cavities three/five times at the beginning and/or at the end of the contact time using a disposable syringe (minimum volume 5-10 ml).

For the manual removal of impurities, only use nylon brushes intended for the purpose or clean soft and lint-free cloths that you only use for this purpose.

Do not use metal brushes or steel wool.

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.

Check the instruments on visible impurities. In case of still remaining impurities (e.g. bone or dentin particles) repeat.

The devices are then cleaned manually in the ultrasonic bath or mechanically in the washer-disinfector.

Precleaning

- The products are placed into the same detergent/disinfectant that is used in the main cleaning and brushed by the use of nylon brushes in order to assure the cleaning of difficult surfaces like inner cavates, lumens and openings.
- This procedure is repeated three times. The lumen (cavities) should be rinsed three times by using a disposable syringe) minimum volume 5 ml) and a cannula.
- Finally products are rinsed with tap water in order to remove the detached soil and the wash solution.

Mechanical cleaning and disinfection in Washer-Disinfector

- Place the disassembled products in the washer-disinfector.
- Specification of the washing process:

Stage	Water	Detergent	Temperature	Dwell time
Prewash	10 l	-	unheated	-
Main wash	10.5 l	62ml (DOS 1)	55°C	10 min
Rinse	9.0 l	13 ml (DOS 3)	unheated	-
Rinse	9.0 l ROW*	-	unheated	-
Thermic disinfection	9.5 l ROW	-	90-93°C	5 min
Dry	-	-	99°C	35 min

* ROW- reverse osmosis water

- Start the programme. A disinfector should be used with a certified programme (A0-value > 3000 or – with regard to older devices – at least 5 minutes at 90 °C).
- Remove the products from the disinfector after the programme has finished.
- Check and wrap the products straight after removal if possible if necessary, after that have been dried off completely in a clean place.

Manual cleaning and disinfection in Ultrasonic Bath

- Before the ultrasonic treatment is started products should be disassembled and placed into a suitable disinfectant solution with active cleaning properties. All surfaces and cavities, lumens and openings have to be in contact with the solution. After treatment products should be rinsed with tap water for a minimum of 3 min and then cleaned in the ultrasonic bath.
- *Dissimilar metals should not be mixed in the same cleaning cycle.*
- The ultrasonic bath should be filled with detergent and should be degassed for 30 min. Only fresh made solutions and water that is either sterile or low in germs and endotoxin should be used.
- The disinfectant with active cleaning properties should be used according to the disinfectant manufacturer's instructions.
- Products placed in the ultrasonic bath.
- The cleaning procedure should be set per manufacturer's instruction of the ultrasonic bath.
- Specification of the washing process:

Stage	Instrument	Detergent	Concentration	Parameters
Main wash	Ultrasonic bath	Stampour DR 8	2%	30 min, 40°C; Level 9
Rinsing*	Manual	Running water ROW)	-	Rinse thoroughly*
Dry	Pressurized air	-	-	Optical Dry

* Rinsing: the products are removed from the beaker and rinsed at least three times thoroughly with running water (ROW quality). Cavities, lumens and openings are rinsed five times using a disposable syringe (minimum volume 5 ml) and a cannula.

- Upon completion of the cleaning cycle products should be rinsed with water at least three times. Final rinsing should be done with distilled or deionised water. Products with lumen should be rinsed three times at the beginning and / or at the end of the contact time using a disposable syringe (minimum volume 5-10 ml) and a cannula.
- Products should be dried with soft and lint-free cloth, lumens additionally with compressed air.
- After degassing the ultrasonic bath products are placed in it in a way that the products have plenty of room.
- Remove the products from the disinfector after the programme has finished.
- Check and wrap the products straight after removal if possible if necessary, after that have been dried off completely in a clean place.

Inspection

- Check all devices during pretreatment and after precleaning, (mechanical or manual) cleaning and disinfection processes for corrosion, damaged surfaces, chipping and contamination and sort out damaged instruments:
    - Is the device visibly clean,
    - Is there any rust or corrosion,
    - Are the cutting edges dull or worn out,
    - Are the fittings deformed,
    - Are any parts broken,
    - Have any parts fallen apart.
- Damaged, corroded or worn devices should not come into contact with intact instruments to avoid contact corrosion.

Packaging

- For sterilization cleaned, disinfected and inspected products are placed where appropriate in burr block/sterilization tray or to autoclave bags. The burr block / sterilization tray is wrapped in an autoclave bag.
- Instruments and sterilization packs must be protected against mechanical damage.
- 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 product was sterilized.

Sterilization

- The products can be sterilized in the autoclave at 132 °C in one standard sterilization cycle with a dwell time of 3 minutes to achieve a SAL of 10^{-6}.

Storage

Prior to the first use of the device, products should be stored in its original packaging at room temperature in dust free and humidity free conditions and not exposed to direct sunlight.

Subsequently, the products should be stored in appropriate hygienically maintained containers (protected from dust, humidity and recontamination).

After sterilization, the products need to be stored in sterilization wrapping in a dry and dust free place and not exposed to direct sunlight. Follow the expiration date marked in the sterilization label.

Please note

For the purpose of legibility, TRATE does not use ™ or ® in the text. This does not affect TRATE's rights with regards to registered trademarks.

Some products may not be available in all markets. Please contact your local TRATE representative to review the product range available.

Signs explanation

Symbols according ISO 15223-1

	Consult instructions for use
	Catalogue number
	Batch code
	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

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Change history:

Ver	Date	Change description	Responsible
1	2013-02-26	Printing date	V. Shulezhko D. Karpavicius
2	2013-06-17	Reprocessing parameters added	V. Shulezhko D. Karpavicius
3	2013-10-01	Added information on detergents and cleaning precaution and warnings	V. Shulezhko D. Karpavicius
4	2017-04-24	Symbol “Manufacturer” placed near by manufacturer address	V. Shulezhko D. Karpavicius
5	2019-02-18	NB number was changed from 0086 to 2797	V. Shulezhko D. Karpavicius
6	2019-04-19	Was added Information about residual risks, side effects warnings	V. Shulezhko D. Karpavicius
7	2020-01-31	Added warnings for TRS instrument tray as outputs of annual risk assessment	V. Shulezhko S. Janusaitiene

8	2020-06-25	Added information to the related documents: *Assemble and disassemble of the products* and *Examples of inspection of the defects*	V. Shulezhko D. Karpavicius
9	2020-08-31	Added information to warnings to avoid dropping of trays and a need to check the absence of sharp edges that could appear during the life cycle of sterilization tray to minimize the risk of skin break-in of health professionals	V. Shulezhko D. Karpavicius