Instruction for cleaning, disinfection and sterilization of non-sterile and reusable devices

1. Description

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

This instruction is valid and intended for:

a) single use non-sterile medical devices and
b) reusable instruments which shall be sterilized before use to ensure proper preparation for sterilization.

The medical devices produced and sold by ROOTT 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 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. If will be changed parameters or selected different cycles other than described in this instruction, the customer shall validate it on his behalf.

The following legal regulations and guidelines are applied:

- EU Regulation 2017 / 745 on medical devices
- ISO 17664
- ISO 15883
- ISO 11607
- EN 13060
- EN 285
- ISO 17665
- ISO 15223-1.

General principles

All dental superstructures and associated surgical instruments manufactured by ROOTT AG are supplied in non-sterile conditions and must be sterilized prior to use.

Range products for which cleaning, disinfection and sterilization procedure under this instruction is applied:

- Reusable surgical instruments;
- Tools for the implantation procedure;
- Instruments for handpieces;
- Surgical cassettes;
- Single use medical devices;
- Related superstructures.

2. Warnings

Prior to using the surgical cassette, please remove the packaging film from the cassette.

Be aware that surgical cassettes as well as dental superstructures and other surgical instruments must be sterilized before use.

Make sure not to drop / scratch surgical cassettes and avoid shocks to protect the cassette and its contents.

Always check the absence of sharp edges that could appear during the life cycle of the surgical cassette 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 ROOTT AG that must be cleaned, disinfected and sterilized prior to use are not intended to be resterilized.

Instruction for cleaning, disinfection and sterilization of non-sterile and reusable devices

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. All parts of the devices should be checked for visible soil and /or corrosion.

Do not exceed the number of uses provided in the instructions for use for the particular product.

Not properly cleaned, disinfected and sterilized reusable instruments, especially not discarded damaged instruments, may increase risk of biofilm formation. To avoid this ensure that the complete cleaning, disinfection and sterilization instructions were followed under this instruction for use.

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

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

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

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

3. Cautions/ Precautions

ROOTT AG defines the maximum number of uses appropriate for Implant drills. For more information check Instruction for use for Implant Drills. The useful life of the reusable instruments 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.

4. Requirements

For process:

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

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.

Recommended Alkaline Cleaning and Disinfecting Solutions:

- Washer-Disinfector:
  - For cleaning and disinfection, use Neodisher MediClean forte solution.
  - To rinse and neutralize alkaline residues, use the Neodisher Z solution.
- Ultrasonic Bath:
  - For cleaning and disinfection, use Stammpur DR 8 solution.

Please Note! Only the cleaning and disinfecting solutions listed above have been validated for use in washer-disinfectors and ultrasonic baths. The use of any other cleaning or disinfecting solutions has not been validated, and their safety and effectiveness are not guaranteed. Any use of non-validated solutions falls outside the manufacturer's responsibility.

Not recommended to use cleaning solutions containing cleaning agents as following:

- For stainless steel products: chlorine, oxalic acid, hydrogen peroxide. Using these substances for stainless steel products may provoke pitting and contact corrosion.
- For titanium products: chlorine, oxidizing acids (e.g. nitric acid, sulfuric acid, oxalic acid), hydrogen peroxide.
- For plastics products: oxidizing acids.

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 agent),
- 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 barriers 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)).

5. 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.

Pre-cleaning

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 is:

Stage	Water	Detergent	Temperature	Dwell time
Prewash	10 l	-	unheated	-

Main wash	10.5 l	Neodisher MediClean forte (62ml)	55°C	10 min
Rinse	9.0 l	Neodisher Z (13 ml)	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.

Before placing the products, the detergent 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.

The products are placed not directly in the ultrasonic tube, but in beaker glasses which are fitted into the tray.

The cleaning procedure should be set per manufacturer's instruction of the ultrasonic bath.

Specification of the washing process is:

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

*Rinsing means 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.

Do not exceed the number of uses provided in the instructions for use of the particular product.

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 must 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 dry 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.

Additional information for cleaning, disinfection and sterilization of instrument sets:

Surgical cassettes must be cleaned, disinfected and sterilized before the use and between each uses.

Before the treatment of steam sterilization of surgical cassette, ensure that all original packaging is removed including protective films.

Surgical cassette and whole its content must be cleaned, disinfected and sterilized regardless of whether all products were used during the operation.

At the point of use and before the pre-cleaning procedure take instruments from the surgical cassette with forceps and wear gloves. Do not place contaminated products into the cassette with unused ones. Transfer used instruments to the pre-treatment within 2 hours, pre-treat, pre-clean, clean and disinfect according to this instruction.

Take out unused instruments from the cassette, disassemble cassette into the separate parts: body and lid. Follow the instructions for pre-cleaning procedure, ensure that chemicals are compatible with cassettes material. All visible dirt should be removed by brushing with a soft brush under running water. Clean and rinse thoroughly all lumens in cassette. Follow “Pre-cleaning” and “Mechanical cleaning and disinfection in Washer-Disinfector” procedures.

Separate cassette and instruments, place the disassembled cassette in an ultrasonic bath, follow instructions of procedure according to the clause “Manual cleaning and disinfection in Ultrasonic Bath”.

After the surgical cassette is washed and completely dried, check the cassette for its functionality - the lid should smoothly close, lasered information should not be worn out, no visible changes in color or material itself.

If cleaned, disinfected and inspected instruments are completely dried, load them into the cassette in intended places (see titles on the top of cassette).

Close the cassette and ensure that the lid is closed correctly, check the stability of instruments. The instruments are inserted correctly, no one is falling out when the cassette is turned upside down. Pack into the package suitable for steam sterilization. Follow the procedure “Packaging”.

During the loading into the sterilizer of the packed surgical cassettes into packages suitable for steam sterilization bags, ensure that cassette do not touch the walls of sterilizer, sterilizer is not overloaded, always keep lid of cassette upwards, do not place cassette on side or down on top of the lid.

Run and monitor the cycle of steam sterilizer, follow the sterilization procedure “Sterilization”.

After drying, check the packages from visible moisture. If moisture / water are visible on the surface or condensate in the cassettes cavities, repackage and re-sterilize using a longer drying time. Always ensure that the cassette is completely dried.

Ensure the storage conditions are fulfilled according to the procedure “Storage”.

6. Please note

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

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

7. Validity

Upon publication of these instructions for use, all previous versions are superseded.

8. Disposal

Safety discards potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, recycling or disposal of packaging materials shall follow local country and government legislation on packaging and packaging waste, where applicable.

According to the Warranty and return policy, disposed ROOTT AG medical devices under specified conditions which are failed, fractured or damaged, after removal, together with the accompanying documents, can be returned to ROOTT AG under a feedback procedure. Potentially biologically contaminated product for ROOTT AG determined as a returned product that was in use.

Used devices under *Warranty and return policy,* returned to a ROOTT AG should have been cleaned and decontaminated by the user before shipment and labeled as such. Decontamination of used devices should be performed by *Instruction for Product Return*.

9. Manufacturer and Authorized Representative information

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10. Symbols explanation

Available in *Instruction for explanation of symbols on ROOTT product labelling.*

CE 2797

Change history:

Ver	Date	Change description	Responsible

Instruction for cleaning, disinfection and sterilization of non-sterile and reusable devices

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
10	2021-05-25	Title “instrument tray” changed into the “surgical cassette”. Added and clarified product groups for which this instruction is applied. Added additional information about cleaning, disinfection and sterilization instructions for instrument sets; Added cleaning agents which are not recommended for stainless steel, titanium products and for plastics products as well as. Added to symbols: MD, UDI, Caution, Steam sterilization (132°C), Do not re-use, Do not resterilize, Date of manufacture, Authorized representative in the European Community / European Union, Importer, Health care centre or doctor and Date.	V. Shulezhko D. Karpavicius
11	2022-06-01	Added disposal information, changed format Added information to check instructions for use to particular products regarding times of uses. Added SRN number for manufacturer	V. Shulezhko D. Karpavicius
12	2022-12-05	Manufacturer address changed from “Seestrasse 58 8806 Bäch Switzerland” to “Bahnhofstrasse 16 6037 Root Switzerland”.	V. Shulezhko D. Karpavicius
13	2025-01-27	To section 4. Requirements for disinfectants have been added information regarding validated solutions for washer - disinfector and ultrasonic bath; To section 5. Procedure added information of detergents to be used for man wash and rinse steps. Instruction have been reviewed and updated with the following information: - Section 4: Information regarding validated solutions for washer-disinfectors and ultrasonic bath has been added to the disinfectant requirements. - Section 5: Details about the detergents to be used during the cleaning and rinse steps have been added to the procedure. - The information regarding the parameter Level 9 as the program number for the main wash in the ultrasonic bath has been removed.	V. Shulezhko D. Karpavicius
	Revision 2025-03-21	Updated format of address for EU REP according the certificate and EUDAMED	V. Shulezhko
14	2026-01-21	Updated authorized representative symbol from EC rep to EU rep	V. Shulezhko
15	2026-05-12	Legal manufacturer name of TRATE AG have been renamed to ROOTT AG EU rep name of TRATE UAB have been renamed to Root UAB	V. Shulezhko