

This instruction applies to all Dental Implant System ROOTT products, produced by TRATE AG. Dental Implant System ROOTT is a system of endosseous dental implants with corresponding abutments, gingiva formers, covering and fixing screws, other prosthetic parts and associated surgical instruments (hereinafter - products).

This document describes the general procedures for handling and shipment of complaint-related products which were in use and in direct contact with human body fluids and tissues.

For general product return / exchange follow the procedure described within the Warranty and Return Policy.

General requirements for returned products

Used products should have been decontaminated and/or sterilised by the user **before shipment** and labelled as such. The container and/or label should indicate that decontamination has been performed.



Returned products shall be sent sterile and disinfected, in double pouches (containers) and into the outer shipping container with a label that product was in use and sterilised prior to be returned.

Non-decontaminated and non-sterilized devices are not accepted, unless otherwise specifically instructed.

Generic recommendations for cleaning and decontamination of product prior to be returned

The retrieved implant shall be thoroughly rinsed under running water, but not scrubbed, to remove all biological contaminants. Disposable swabs, brushes, and wipes may be used to remove visible debris from implants, in conjunction with an appropriate chemical agent. Proper protective precautions should be followed.

All solutions to be used in the cleaning of retrieved implants shall be prepared at the time of cleaning and shall not be stored for future use. Depending on local sewage company requirements chemical cleaning agents might need to be neutralised before discarding into the sanitary sewer.

Device	Cleaning method*	Decontamination method**
Metallic products	Intense water rinse, 70% to 80% aqueous ethanol or isopropanol with subsequent ultrasonic treatment or proteolytic enzyme or sodium hypochlorite solution (50 mg/l to 60 mg/l) or 3% hydrogen peroxide	Steam autoclave, at least 121°C at a gauge pressure of 1 atm for a minimum of 15 minutes. Sterility indicator on the pouch should show that it has been put through a sterilisation cycle. Dry for 10 minutes in the chamber.

* percentage are volume fractions,

**for products which cannot be sterilised, please follow only the disinfection instructions and insert the applicable product(s) into a sterilisation pouch. For disinfecting, a soaking time of 2 h to 3 h is sufficient. However a 24 h contact time may be used to provide an extra margin safety.

Requirements for packaging

All retrieved implants which are intended for shipment shall be packed in a manner which minimises the potential for breakage, surface damage, contamination of environment during the transit. All products should be handled and packaged in accordance with the infection control requirements under all national and legal requirements relevant Health and Safety legislation, directive on waste.

Product shall be packed using the following three layers of packaging:

- primary container
- secondary container
- outer shipping container

Each implant shall be packed separately in its own primary container and securely closed. Each primary container shall be placed to the secondary container and securely closed. The secondary container shall be placed in an outer shipping container using shock-resistant packing materials.

Requirements for labelling

Immediately after containing the implants, all containers shall be labelled to ensure their precise identification at some later date. The labels used shall be of a non-removable type. The label shall contain at least the following information:

a) name, address and telephone number of sender;



b) biological risks symbol

c) the word "Decontaminated"

All packing slips and labels shall be affixed to the outer shipping container so that the receiver is not required to open the outer shipping container in order to identify its contents or the intended receiver.

These requirements are in addition to, and do not replace, any other packaging or other requirements for the transportation of biological materials prescribed by governmental bodies.

Documentation to be supplied with the returned products

The following documentation shall be supplied with the returned products:

- treatment history
- results of pre-implantation and pre-explantation checks
- X-rays before and after
- label information for the future identification
- details of cleaning and decontamination of returned products
- copy of payment receipt for the performed implantation

The above documents shall be placed inside the outer shipping container so that the receiving facility is not required to open a secondary container.

Information for sending:

Company:	TRATE AG
Address	Bahnhofstrasse 16, 6037 Root, Switzerland
Email:	ch@trate.com
Phone:	+41 41 450 01 01
Contact Person:	To the QA Department


Validity

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

Please note

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Change history:

Ver	Date	Change description	Approval	Signature
01	2020-10-19	Printing date	V. Shulezhko	
02	2022-11-02	Manufacturer address changed from "Seestrasse 58 8806 Bäch Switzerland" to "Bahnhofstrasse 16 6037 Root Switzerland".	V. Shulezhko	