

TRATE

Instruction No. 16.22.000.04 Warranty and Return Policy

This warranty and return policy applies to all products, produced by TRATE AG. This policy only covers the replacement of products, but not any associated costs and expenses, including but not limited to any associated treatments.

Warranty conditions

TRATE AG hereby guarantees that, if any product is defective as a result of a failure of the material strength and stability of the product during the guarantee period, TRATE will replace the product with the same or substantially equivalent product.

Provided however that the following guarantee conditions are individually and collectively met and documented:

- Warranty duration - lifetime, in case, when will be proven that ROOTT system components were used in accordance with the requirements of the instruction for use and under indications, conditions and contraindications which described by the manufacturer in the instructions for use.
- Products have been used exclusively and not in combination with any other manufacturer's products
- Warranty case appeared because products were implanted to the patient with absolute / relative contraindications
- No guarantee case resulting from an accident, a trauma or any other damage caused by the patient or a third party
- Providing a request for guaranty not later than three months after a case arises.
- Implants with an expired sterilization date can be exchanged if the customer sends a notification 7 months prior to the expiration date with clear determination of the LOT number and quantity. Notification can be sent to your regional TRATE Manager or via form on the TRATE web page: <https://trate.com/warranty-and-return-policy/>
- Implants where the content of the package was compromised (implants out of the green holder) can be exchanged if the customer sends a notification immediately after product delivery with clear determination of the LOT number and quantity. Notification can be sent to your regional TRATE Manager or via form on the TRATE web page: <https://trate.com/warranty-and-return-policy/>

Eligibility

To receive warranty benefits, the treating clinician or distributor must:

- a) Notify TRATE AG. Notification is accomplished by submission of a properly completed Warranty and Return Form with return of properly cleaned and decontaminated device packed such to prevent damage throughout transportation. Clear procedure for cleaning, decontamination, packaging and labeling for such devices available in Instruction for Product return.
- b) Be current in all financial account activities with TRATE AG
- c) Be sure that all devices covered by this Warranty Policy installed in accordance with TRATE prescribed procedures, including the IFU, and in accordance with accepted medical / dental practices.

Important! Warranty and Return Form available on the webpage www.trate.com as Annex to the Warranty and Return Policy or you may contact your Customer Service representative. All warranty claim submissions must include the LOT number of all devices. Failure to provide this information or any other required information, or failure to return original devices, may result void of the warranty policy.

Limits and limitations

This warranty policy is the only warranty provided by TRATE AG. TRATE AG hereby disclaims any other warranties, express or implied hereby TRATE excludes any liability for lost earnings and direct or indirect damages as well as collateral and consequential damages, directly and indirectly related to products, services and information.

Guarantee territory

This guarantee applies worldwide to the products manufactured by TRATE AG.



**Instruction No. 16.22.000.04
Warranty and Return Policy**

Modification or termination

TRATE may modify or terminate this warranty policy at any time in whole or in part. Changes to or termination of the warranty policy will not affect the warranty given for the products implanted prior to the date of the change or termination.

Product exchange

Not used products can be exchanged (same or greater value) within twelve (12) months of invoice date but must have a minimum six (6) months shelf life.

All items must be in their original packaging, undamaged, unmarked and unopened.

In any case the Warranty and Return Form shall be filled and sent together with the products.

If the product was in use, follow the procedure for cleaning, decontamination, packaging and labeling for such devices available in Instruction for Product return.

Reporting procedure

Distributors / Healthcare professionals / Patients that have received information about suspected incidents related to a TRATE products, shall immediately forward this information to the manufacturer via submission of application in "Contact us" on the webpage www.trate.com or call Customer Service at + 41 79 848 19 18.

TRATE

Instruction No. 16.22.000.04 Warranty and Return Policy

Annex 1

Warranty and Return Form

Reason for return and replacement

- Dropped during surgery Loss of sterility (opened, but not used)
- Placed and removed immediately during surgery Loss of sterility (package damaged, but not used)
- Implant Failure Product exchange (original package, not used)
- Other. Please explain _____

Product information

Catalog REF No.	
LOT No.	
Quantity	
Expiration date	

Clinical Information, if applicable

Please fill, if product was in use

Name and address of dental office			
Surgeon name			
Patient name or ID			
Patient gender		Patient age	
History of substance abuse	<input type="checkbox"/> Smoking, <input type="checkbox"/> Alcoholism, <input type="checkbox"/> Diabetes, <input type="checkbox"/> Chronic periodontitis, <input type="checkbox"/> Poor oral hygiene, <input type="checkbox"/> Significant bone loss, <input type="checkbox"/> Other:		
Diagnosis at implantation			
Date of implantation		Date of removal	
Antibiotics and drugs used		Duration of use	
Post-operative treatment		Duration of use	

TRATE

Instruction No. 16.22.000.04 Warranty and Return Policy

Complications	<input type="checkbox"/> Edema, <input type="checkbox"/> Haematomas, <input type="checkbox"/> Bleeding, <input type="checkbox"/> Infection, <input type="checkbox"/> Significant pain <input type="checkbox"/> Flap dehiscence, <input type="checkbox"/> Sensory disorders, <input type="checkbox"/> Other:
Reason for removal	<input type="checkbox"/> Failure, <input type="checkbox"/> Pain, <input type="checkbox"/> Infection, <input type="checkbox"/> Allergy

Please provide information on the methods used for cleaning and decontamination of returned products:	
--	--



TRATE AG must receive product return within 30 days since this form submission.



It's recommended that you will return the product and this form with a traceable shipping method (UPS, FedEx, DPD, DHL) to the address below:

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



If you have any questions, please call Customer Service at + 41 79 848 19 18

Change history

Rev.	Date	Change description	Established / Checked / Released
01	2015-05-31	Printing date	VS / VS / SS
02	2017-02-04	Changed number of documents from 16.18.000 to 16.22.000, added handling procedure for failed implants, to the name of instruction was added broken and damaged definitions.	VS / VS / SS
03	2020-10-23	Changed name of the document from Warranty statement to Warranty and return policy, added reporting procedure instead of feedback procedure, added warranty and return form	VS / SJ / SS
04	2022-12-05	Manufacturer address changed from "Seestrasse 58 8806 Bäch Switzerland" to "Bahnhofstrasse 16 6037 Root Switzerland".	VS / SJ / SS

Approvals



**Instruction No. 16.22.000.04
Warranty and Return Policy**

Developer	Reviewer	Approval
Vladlena Shulezhko	Skaidre Janusaitiene	Siarhei Shulezhka
2022-12-05	2022-12-05	2022-12-05