ROOTT
open implant system

ROOTT
Warranty Statement

Sure I can!

ROOTT Warranty Statement

1 Guarantee beneficiary and scope

This guarantee (the "ROOTT Guarantee" as defined below) from the TRATE AG, Bach, Switzerland applies to the products listed below and in favor of the attending physician/dentist only (the "User"). Third parties, particularly patients or intermediate suppliers, may not derive any rights from this ROOTT Guarantee. The ROOTT Guarantee covers the replacement of products of the ROOTT Dental Implant System as defined in Section 2. The ROOTT Guarantee only covers the replacement of ROOTT Products and not any associated costs, including but not limited to any associated treatments.

2 Products covered by ROOTT Guarantee

	Implant	Abutment attached to an implant
10 years	———	Replacement with equivalent metal abutment *
25 years	Replacement with equivalent implant and equivalent abutment, if necessary	———

*including screw-retained bars and bridges; excluding consumable products and retentive products

3 Guarantee conditions

TRATE AG hereby guarantees that, if any ROOTT Product is defective as a result of a failure of the material strength and stability of the ROOTT Product during the guarantee periods set out in Section 2, TRATE will replace the ROOTT Product with the same or substantially equivalent product as set forth in Section 2. The guarantee periods above commence at the time of treatment with a ROOTT Product by the User. Provided however that the following guarantee conditions are individually and collectively met and documented:

3.1 ROOTT Products have been used exclusively and not in combination with any other manufacturer's products;

3.2 Return of the ROOTT Products in sterilized condition, disinfected if appropriate or as indicated in the instructions for use;

3.3 Compliance with and application of ROOTT instructions (in the instructions for use, among others) valid at the time of treatment as well as recognized dental procedures, during and after the treatment;

3.4 Good oral hygiene of the patient as monitored by the User;

3.5 No guarantee case resulting from an accident, a trauma or any other damage caused by the patient or a third party;

3.6 Filing of a completed and signed guarantee form not later than three months after a guarantee case arises.

4 Limits and limitations

This ROOTT Guarantee is the only guarantee provided by TRATE AG and shall apply in addition to the warranty rights conferred under the sales agreement. The User remains free to claim rights against his supplier. TRATE AG HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED AND TRATE AG HEREBY EXCLUDES ANY LIABILITY FOR LOST EARNINGS AND DIRECT OR INDIRECT DAMAGES AS WELL AS COLLATERAL AND CONSEQUENTIAL DAMAGES, DIRECTLY OR INDIRECTLY RELATED TO ROOTT PRODUCTS, SERVICES OR INFORMATION.

5 Guarantee territory

This ROOTT Guarantee applies worldwide to ROOTT Products sold by a TRATE AG Partners, affiliated company or an official distributor of TRATE AG.

6 Modification or termination

TRATE AG may modify or terminate this ROOTT Guarantee at any time in whole or in part. Changes to or the termination of the ROOTT Guarantee will not affect the guarantee given under this ROOTT Guarantee for ROOTT Products installed prior to the date of the change or termination.

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Manufacturer

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CE

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

Guarantee Questionnaire

1 Customer information

Clinician's name

Address

Customer account number

Telephone

Country

Reported by

2 Product information (Please list all involved ROOTT products)

Article number

LOT number

Placement date (D/M/Y)

Removal date (D/M/Y)

Regio

3 General patient information (Complete this section only if returning implants)

Patient ID Age Female ☐ Male ☐

Medical records

- ☐ Diabetes Mellitus
- ☐ Radiation Tx-head/neck area
- ☐ Illness requiring steroids
- ☐ Chemotherapy around time of implant placement
- ☐ Psychological disorder
- ☐ Xerostomia
- ☐ lymphatic disorder
- ☐ Drug or alcohol abuse
- ☐ Uncontrolled endocrine illness
- ☐ Compromised immuno resistance
- ☐ Blood coagulation disorder

Allergies: _____

Other local or systemic diseases which may be significant: _____

Does the patient smoke? ☐ Yes ☐ No

☐ No significant findings

4 Surgical information (Complete this section only if returning implants)

☐ Manual placement ☐ Handpiece adapter

If implant was placed and removed the same day, was another implant successfully placed in the site during surgery? ☐ Yes ☐ No

If you experienced difficulty with inserting device/pre-mounted transfer part this occurred upon:

- ☐ Implant insertion into bone
- ☐ Removal of device from implant
- ☐ Removal of implant from vial
- Other: _____

At the time of surgery, were any of the following present:

- ☐ Periodontal disease
- ☐ Diseased mucous membrane
- ☐ local infection/subacute chronic osteitis
- ☐ Complication in site preparation

Bone quality	☐ Type I	☐ Type II	☐ Type III	☐ Type IV
Was the site tapped?	☐ Yes	☐ No	☐ N/A	
Holding key used	☐ Yes	☐ No	☐ N/A	
Was primary stability achieved?	☐ Yes	☐ No		
Did implant achieve osseointegration?	☐ Yes	☐ No		
Was the implant surface completely covered with bone?	☐ Yes	☐ No		

Was augmentation performed at the time of surgery?

☐ No ☐ Sinus ☐ Ridge Materialused: _____

Was GTR membrane used?

☐ No ☐ Yes ☐ Resorbable ☐ Non-resorbable Material used: _____

5 Event Information (Complete this section only if returning implants)

Hygiene around implant ☐ Excellent ☐ Good ☐ Fair ☐ Poor

Were any of the following involved in the event?

☐ Trauma/Accident ☐ Implant fracture ☐ Tongue (pressure) ☐ Inadequate bone quality/quantity
☐ Biomechanical overload ☐ Overheating of bone ☐ Bruxism ☐ Previous bone augmentation
☐ Immediate extraction site ☐ Peri-implantitis ☐ Boneresorption ☐ Nerveencroachment
☐ Adjacent to endodontic tooth ☐ Infection ☐ Sinusperforation Other: _____

At the time of implant failure there was (check all that apply):

☐ Pain ☐ Bleeding ☐ Swelling ☐ Numbness
☐ Mobility ☐ Fistula ☐ Asymptomatic ☐ Inflammation
☐ Hypersensitivity ☐ Increased sensitivity ☐ Abscess Other: _____

Was the prosthesis fitted? ☐ No ☐ Yes If yes, please complete section 6.

Please comment on why you think the implant failed/was removed:

_____

_____

6 Prosthesis Information (Complete this section only if returning abutments and restorations)

Project no.: _____ ☐ Model ☐ Insertion ☐ In use

Type of restoration ☐ Crown ☐ Bridge ☐ RPD (upper) ☐ RPD (lower)
☐ Full (upper) ☐ Full (lower) Other: _____

Date abutment was installed ☐☐ ☐☐ ☐☐☐☐ Date of abutment removal (D/M/Y) ☐☐ ☐☐ ☐☐☐☐

Torque control device used? ☐ Yes, torque applied ☐☐ Ncm ☐ No ☐ Unknown

Date of temporary restoration installation ☐☐ ☐☐ ☐☐☐☐ Date of final restoration installation ☐☐ ☐☐ ☐☐☐☐

Was the recall appointment schedule followed ☐ Yes ☐ No

Description of event:

_____

_____

7 Instruments (Complete this section only if returning instruments)

Approximate number of uses: (Cutting instruments only) ☐ Initial use ☐ 2-5 ☐ 6-10 ☐ 10-15 ☐ More than 15

Type of cleaning method used ☐ Manual ☐ Ultrasonic ☐ Thermodisinfection Other: _____

Type of sterilization method used ☐ Autoclave ☐ Dry heat ☐ Chemiclave

Short description of incident:

_____

_____

Please return questionnaire, autoclaved product and include X-rays (as appropriate).
Use a padded pouch to return items – failure to do so could result in items lost during shipment and void guarantee program.
Autoclave all products and label them as sterile.

Based on the ROOTT Guarantee Terms and Conditions, please consider replacing the above listed products.

Doctor's Signature: _____ Date: _____

For internal use only

☐ CSN ☐ PSO ☐ ASR ☐ RPC ☐ Info incomplete ☐ Std/No