STRAUMANN® GUARANTEE

Dental Implant System

STRAUMANN® GUARANTEE

1. GUARANTEE BENEFICIARY AND SCOPE

This guarantee (the "Straumann Guarantee" as defined below) from the Institut Straumann AG, Basel, Switzerland ("Straumann") 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 Straumann Guarantee. The Straumann Guarantee covers the replacement of products of the Straumann® Dental Implant System SDIS and certain limited Straumann® CARES® products (the "Straumann Products") as defined in Section 2. The Straumann Guarantee only covers the replacement of Straumann Products and not any associated costs, including but not limited to any associated treatments.

For Straumann® Roxolid® Implants and the Straumann® PURE Ceramic Implant System, the extended „Lifetime Plus Guarantee" applies. It covers the replacement of the Straumann® Roxolid®/PURE Ceramic Implant System product and an additional treatment compensation in the amount of in case of an implant fracture with a Straumann® Roxolid® Implant/PURE Ceramic Implant System.

2. STRAUMANN PRODUCTS COVERED BY THE STRAUMANN GUARANTEE

	Implant	Abutment attached to an implant	Tooth- and implant-supported restoration*
5 YEARS	–	Replacement with equivalent ceramic abutment including ceramic screw-retained bars and bridges*	Replacement with equivalent ceramic restoration**
10 YEARS	–	Novaloc® Abutments, replaced with equivalent Novaloc® Abutment*** Replacement with equivalent metal screw-retained bars and bridges*	Replacement with equivalent metal restoration**
LIFETIME	Replacement with equivalent implant and equivalent abutment, if finalized.	Replacement with equivalent metal abutment	–
LIFETIME PLUS	Replacement with equivalent implant and equivalent abutment, if necessary. Additionally, for Straumann® PURE Ceramic Implant System & Roxolid® Implants**** it covers a treatment compensation in the amount of if implant fractures.	–	–

* Excluding consumable products and retentive products such as ball anchors.
** Including Straumann® CARES® crowns and bridges. EXCLUDING all other products offered by Straumann, particularly Straumann® CARES® inlays, onlays, veneers, partial crowns and Straumann® CARES® Guided Surgery products.
*** Excluding any matrices and inserts as they are subject to natural wear and tear.
**** Not applicable for Straumann® Mini Implants. Straumann® Mini Implants underly the Straumann® Lifetime Guarantee.

3. GUARANTEE CONDITIONS

Straumann hereby guarantees that, if any Straumann Product is defective as a result of a failure of the material strength and stability of the Straumann Product during the guarantee periods set out in Section 2, Straumann will replace the Straumann 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 Straumann Product by the User. Provided however that the following guarantee conditions are individually and collectively met and documented:

3.1 Straumann Products have been used exclusively and not in combination with any other manufacturer's products (except for the combinations that Straumann recommends);
3.2 Submission of a completed and signed guarantee form not later than 90 days after a guarantee case arises;
3.3 Return of the Straumann Products in sterilized condition, disinfected if appropriate or as indicated in the instructions for use;
3.4 Compliance with and application of Straumann's 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;
3.5 Good oral hygiene of the patient as monitored by the User;
3.6 No guarantee case resulting from an accident, a trauma or any other damage caused by the patient or a third party;
3.7 For customized Straumann Products the User shall provide Straumann with the design data;
3.8 The Straumann Lifetime Plus Guarantee applies to Straumann Roxolid Implants and Straumann PURE implants exclusively, which have been used in combination with Straumann products and not in combination with any other manufacturer's products or product of the Straumann Group. Additional requirements for the Lifetime Plus Guarantee applying to Straumann PURE Ceramic Implant System and Roxolid implants:
The complaint case must be submitted and approved for product replacement first.
The Lifetime Plus Guarantee claim must be submitted online (URL) with restoration details within 6 months after fracture.

4. LIMITS AND LIMITATIONS

This Straumann Guarantee is the only guarantee provided by Straumann.
STRAUMANN HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED AND STRAUMANN HEREBY EXCLUDES ANY LIABILITY FOR LOST EARNINGS AND DIRECT OR INDIRECT DAMAGES AS WELL AS COLLATERAL AND CONSEQUENTIAL DAMAGES, DIRECTLY OR INDIRECTLY RELATED TO STRAUMANN PRODUCTS, SERVICES OR INFORMATION.

5. GUARANTEE TERRITORY

This Straumann Guarantee applies worldwide to Straumann Products sold by a Straumann affiliated company or an official distributor of Straumann.
The Straumann® PURE Ceramic Implant System and Roxolid® Lifetime Plus Guarantee is only applicable if the User practices in the following countries: Switzerland, Germany, United Kingdom, Netherlands, France, Sweden, Norway, Portugal, Spain, Austria, Belgium, Finland, Italy, Denmark, Hungary, Czech Republic, United Stated of America, Canada, Australia, New Zealand, South Africa, Ireland, Luxembourg.

6. MODIFICATION OR TERMINATION

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

GUARANTEE QUESTIONNAIRE

1. CUSTOMER INFORMATION

Clinician's Name

Address

Customer Account #

Telephone

Country

Reported by

2. PRODUCT INFORMATION (Please list all involved Straumann Products)

Lifetime Plus claims must be accompanied by the restoration and restoration details (include here).

Article Number	LOT Number	Placement Date (D/M/Y)	Removal/Event Date (D/M/Y)	Regio

3.GENERAL PATIENT INFORMATION (Only required with implant complaints)

Patient ID No* Age ☐ Female ☐ Male

*For data privacy reasons DO NOT insert patient's name

Medical Record:

☐ 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 (Only required with implant complaints)

☐ 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 implant from vial
☐ Removal of device from implant
Other: _____

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

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

Bone quality	☐ Type I	☐ Type II	☐ Type III	☐ Type IV
Was the site tapped?	☐ Yes	☐ No	☐ N/A	
Bone Level Profile Drill used?	☐ Yes	☐ No	☐ N/A	
Tisue Level Profile Drill used?	☐ 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

Material used: _____

Was GTR membrane used?

☐ No ☐ Yes ☐ Resorbable ☐ Non-resorbable

Material used: _____

GUARANTEE QUESTIONNAIRE

5. EVENT INFORMATION (Only required with implant complaints)

Hygiene around implant ☐ Excellent ☐ Good ☐ Fair ☐ Poor

Were any of the following involved in the event?

☐ Trauma/Accident
☐ Biomechanical overload
☐ Immediate extraction site
☐ Adjacent to endodontic tooth
☐ Tongue (pressure)
☐ Implant fracture
☐ Overheating of bone
☐ Peri-implantitis
☐ Infection
☐ Bruxism
☐ Inadequate bone quality/quantity
☐ Previous bone augmentation
☐ Nerve encroachment
☐ Sinus perforation
☐ Bone resorption

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.

If the implant is not being removed, is there evidence of the following (check all that apply)?

Extent (mm): Bone Loss _____ Dehiscence _____ Peri-implantitis _____ Fenestration _____ Other _____

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

_____

_____

6. PROSTHESIS INFORMATION (Only required for abutment and restoration complaints)

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

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

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

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

Torque Control Device used? ☐ Yes ☐ No ☐ Unknown Was the recall appointment schedule followed ☐ Yes ☐ No

Torque applied ☐☐ Ncm

Description of event:

_____

_____

7. INSTRUMENTS (Only required for instrument complaints)

Approximate number of uses: ☐ initial use ☐ 2–5 ☐ 6–10 ☐ 10–15 ☐ more than 15
(Cutting instruments only)

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 package 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 Straumann Guarantee Terms and Conditions, please consider replacing the above listed products.

Please note that your data will be transferred to Institut Straumann AG, Basel, Switzerland but may also be transferred for further investigations to the countries where the respective manufacturer of the product is domiciled. This may include countries outside the European Union for which there is no European Commission decision that they ensure an adequate level of protection for personal data.

Doctor's Signature: _____ Date: _____

For internal use only

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

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