

# Straumann Guarantee<sup>®</sup> Questionnaire

straumanngroup.us/eshop

File Number (if known)

## CUSTOMER INFORMATION

### Customer Details

Facility Name \_\_\_\_\_  
Clinician Name \_\_\_\_\_  
Contact Phone \_\_\_\_\_  
Contact E-Mail \_\_\_\_\_

Sold to Account #: \_\_\_\_\_  
Address 1 \_\_\_\_\_  
Address 2 \_\_\_\_\_  
Address 3 \_\_\_\_\_  
City \_\_\_\_\_  
State \_\_\_\_\_ Zip Code \_\_\_\_\_

*Check if same as Sold To*

Ship to Account #: \_\_\_\_\_  
Address 1 \_\_\_\_\_  
Address 2 \_\_\_\_\_  
Address 3 \_\_\_\_\_  
City \_\_\_\_\_  
State \_\_\_\_\_ Zip Code \_\_\_\_\_

## PATIENT INFORMATION

### Patient Detail (for privacy DO NOT use patient's name)

Patient ID \_\_\_\_\_  
Patient Age \_\_\_\_\_  
Gender: Female Male  
Other \_\_\_\_\_  
Smoker? No Yes

### History

Psychological disorder      Blood coagulation disorder      Illness requiring steroids  
Lymphatic disorder      Untreated endocrine illness      Coincident chemotherapy  
Drug or alcohol abuse      Diabetes Mellitus      Xerostomia  
Compromised immunity      Radiation Tx (head/neck area)      No significant findings  
Relevant allergies: \_\_\_\_\_ Relevant diseases: \_\_\_\_\_

## PRODUCT INFORMATION \*Please list all involved Straumann products

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

Article REF Number	Lot/Serial/Project #	Placement Date	Event/Removal Date	Site ADA
1 _____	_____	_____	_____	_____
2 _____	_____	_____	_____	_____
3 _____	_____	_____	_____	_____

Exchange with same Article#(s)? Yes No; specify Article (REF) No(s): 1 2 3  
Was the product used in a patient?: Yes No

## DESCRIPTION OF EVENT

## SURGERY INFORMATION - IMPLANT RELATED (required for implants)

Placement Method: Manually Handpiece adapter

If implant was placed and removed on same day, was another implant successfully placed at site during surgery?

Yes No – Why not? \_\_\_\_\_

If you experienced difficulty inserting an implant with a pre-mounted transfer piece when did this occur (check one)?

Implant removal from vial      Implant insertion into bone      Removal of device from implant

At the time of surgery, were any of the following conditions present (check all that apply)?

Periodontal disease      Local infection      Diseased mucous membrane      Complication in site prep

Bone quality (type):	I	II	III	IV
Was site tapped?	Yes	No		
Bone-level profile drill used?	Yes	No		
Tissue-level profile drill used?	Yes	No		
Was holding key used?	Yes	No		
Was primary stability achieved?	Yes	No		
Was osseointegration achieved?	Yes	No		
Was implant covered with bone?	Yes	No		
Was the implant immediately loaded?	Yes	No		

Was augmentation performed during surgery? Yes No  
Type of augmentation Sinus Ridge  
Material Used? \_\_\_\_\_  
Was a membrane used?  
Yes No Resorbable Non-Resorbable  
Material Used? \_\_\_\_\_

**EVENT INFORMATION** (required for Implant and Biomaterial products)

Assessment of hygiene around implant:    Excellent    Good    Fair    Poor

Why do you believe the event occurred:

Were any of the following conditions involved in the event (check all that apply)?

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

At the time of the event or implant failure/removal, was there (check all that apply)?

- |          |                       |                  |
|----------|-----------------------|------------------|
| Pain     | Increased Sensitivity | Numbness         |
| Mobility | Abscess               | Inflammation     |
| Bleeding | Swelling              | Hypersensitivity |
| Fistula  | Asymptomatic          | Other: _____     |

Was the prosthesis fitted?    Yes    No    For multiple unit restorations (i.e., bridges and dentures), how many implants supported the restoration: \_\_\_\_\_

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

Bone loss; Extent (mm): \_\_\_\_\_    Dehiscence    Fenestration    Peri-implantitis    Other: \_\_\_\_\_

**PROSTHESIS INFORMATION** (required for Abutment, Straumann CARES® Digital Solutions restoration, Roxolid and PURE Ceramic fracture)

Type of prosthesis?    Crown    Bridge    Inlay/Onlay    Veneer    Full (upper)    Full (lower)    Other: \_\_\_\_\_

Date abutment was installed \_\_\_\_\_    Date temporary restoration installed \_\_\_\_\_

Date abutment was removed \_\_\_\_\_    Date final restoration installed \_\_\_\_\_

Torque Control Device used    Unknown    No    Yes --- Torque Applied (Ncm): \_\_\_\_\_

Was the recall appointment schedule followed?    Yes    No

**INSTRUMENT INFORMATION** (required for Surgical Instruments)

Be sure to *thoroughly clean* instruments and *reassess* prior to returning; most instances of poor instrument performance are due to retained contamination.

Approximate number of uses (cutting tools)?    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    Other: \_\_\_\_\_

Reason for return?    Rust    Other: \_\_\_\_\_

Straumann Use Only	
Product Returned?	
Product Lost?	
Product Sterile?	

**SUBMISSION INFORMATION**

Products must be returned within 90 days of the date of the event in *protective packaging* (padded mailer) using a method that allows for shipment *tracking*:

- The complete product must be returned for investigation (i.e., package for a labeling issue)
- For products contaminated with bodily fluids, metal or ceramic items must be *autoclaved and marked sterile* by either an autoclave indicator or hand written; plastic items must be *cold sterilized*.
- Only one replacement implant per day per tooth site qualifies for replacement under the Straumann Guarantee.
- Relevant radiographs (these will not be returned unless specifically requested, please send copies).

Send shipment to: Straumann USA, LLC  
ATTN: Regulatory Affairs  
60 Minuteman Road  
Andover, MA 01810

Questions?  
Phone: 800/448 8168  
Fax: 978/747 0023  
E-Mail: reg\_complaint@straumann.com

Upon receipt, Straumann will review your feedback, assess the returned product and determine whether the product meets the conditions for replacement under the Straumann Guarantee. When all necessary information and product is received, replacement product can be provided in a timely manner.

Straumann Internal Use Only	
CSN - back office activity	
Regulatory Product Complaint	
PSO    Information incomplete	
ASR    Standard / No Report	
Straumann RA Signature	Date

**SIGNATURE** (required - may be electronic)





By signing below I am acknowledging that I understand the terms and conditions of the Straumann Guarantee® and that the information being provided is truthful and accurate.

Clinician Name (print): \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**1. Guarantee beneficiary and scope**

This guarantee (the “Straumann Guarantee” as defined below) from Straumann USA LLC., Andover, MA (“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 chair time, lab fees and any other associated treatment.

**2. Straumann Products covered by the Straumann Guarantee**

	Implant	Abutment attached to an implant	Tooth - and implant-supported restoration*
 5 Year Limited Warranty	–	Replacement with equivalent ceramic abutment including ceramic screw-retained bars and bridges. PUREloc® and Novaloc® abutments*	Replacement with equivalent ceramic restoration**
 10 Year Limited Warranty	–	Replacement with equivalent metal screw-retained bars and bridges*	Replacement with equivalent metal restoration and resin nano ceramic restoration**
 Lifetime Limited Warranty	Replacement with equivalent implant and equivalent abutment, if finalized.	Replacement with equivalent metal abutment	–
 Lifetime+ Limited Warranty	Replacement with equivalent implant and equivalent abutment, if finalized. Additionally, for Straumann® PURE Ceramic Implant System & Roxolid® Implants a treatment compensation in the amount of \$1,500. if implant fractures (reported after October 1, 2018).***	–	–

\* Excluding consumable products and retentive products such as ball anchors and LOCATOR®. (LOCATOR® is a trademark of Zest Anchor LLC)  
 \*\* Including Straumann® CARES® copings, full contour crowns and bridges. EXCLUDING all other products offered by Straumann, particularly Straumann® CARES®, inlays, onlays, veneers, partial crowns and Straumann® CARES® Guided Surgery products.  
 \*\*\* Excludes small diameter implants placed in the molar region. Abutment, abutment lot/serial number or CARES project number must be provided to confirm only Straumann original products have been used. Not applicable for Straumann Mini Implants under the Straumann Lifetime Guarantee.

**3. Straumann 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;
- 3.2 Return of the Straumann Products in sterilized condition (or disinfected if delivered as such);
- 3.3 Compliance with and application of 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 questionnaire not later than 90 days after a guarantee case arises;
- 3.7 For customized Straumann Products the User shall provide Straumann with the design data.
- 3.8 Special requirements for the “Lifetime Plus Guarantee: The complaint case must be submitted and approved for product replacement first. **The Lifetime Plus Guarantee claim must be submitted online (via eShop) with restoration details within 6 months after fracture.**

**4. Limits and limitations**

This Straumann Guarantee is the only guarantee provided by Straumann and shall apply in addition to the warranty rights conferred under the sales agreement. The User remains free to claim rights against his supplier. 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.

**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 for Straumann Products installed prior to the date of the change or termination.

**CONTACTS**

Should you have any questions please contact:  
 Your local Territory Manager or Straumann  
 Regulatory Affairs.

Straumann USA, LLC  
**ATTN:Regulatory Affairs**  
 60 Minuteman Road  
 Andover, MA 01810

E-Mail: [reg\\_complaint@straumann.com](mailto:reg_complaint@straumann.com)  
 Phone: 800/448 8168  
 Fax: 978/747 0023

**RETAIN FOR YOUR RECORDS**

File Number:	Patient ID:	Article Number:	Lot Number:	Event Date:

Straumann USA, LLC  
**ATTN:Regulatory Affairs**  
60 Minuteman Road  
Andover, MA 01810



Package Address - Clip and Tape to Package

### Did you remember to...

- Verify the terms and conditions
- Complete the Straumann Guarantee Questionnaire as completely as possible
- Include your Straumann Account Number(s) on the Questionnaire
- Sterilize the product and mark it as STERILE
- Attach the Product to the Questionnaire or write the Patient ID on the container
- Have the Clinician sign and date Page 2
- Send Product and Questionnaire in protective packaging via a traceable method
- Keep Page 3 for your records