Straumann Guarantee® 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 _____

MANDATORY

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

PRODUCT INFORMATION *Please list all involved Straumann products

Was the product used in a patient?: ☐ Yes ☐ No ***(Placement date is mandatory ONLY if used in a patient and removed)***

	Article REF Number	Lot/Serial/Project #	Placement Date	Event/Removal Date	ADA Site *(tooth number)*
1					
2					
3					

If implant was placed and removed on the same day, was another implant successfully placed in the same site during surgery?
(***MANDATORY if placed and removed the same day***) ☐ Yes ☐ No

DESCRIPTION OF EVENT/ WHY DO YOU BELIEVE THE EVENT OCCURRED:

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

Placement Method: ☐ Manually ☐ Handpiece adapter

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? _____

straumanngroup

EVENT INFORMATION (required for Implant and Biomaterial products)

Assessment of hygiene around implant: ☐ Excellent ☐ Good ☐ Fair ☐ Poor

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

☐ Trauma/Accident
☐ Overheating of bone
☐ Peri-implantitis
☐ Sinus perforation
☐ Infection
☐ Implant fracture [*Article and lot numbers of the prosthesis and relevant radiographs must be provided and the Prosthesis Information section must be completed*]
☐ Bruxism
☐ Nerve encroachment
☐ Tongue pressure
☐ Immediate extraction site
☐ Inadequate bone quality/quantity
☐ Previous bone augmentation
☐ Biomechanical overload
☐ Adjacent to endodontic tooth
☐ Bone resorption

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

☐ Pain
☐ Mobility
☐ Bleeding
☐ Fistula
☐ Increased Sensitivity
☐ Abscess
☐ Swelling
☐ Asymptomatic
☐ Numbness
☐ Inflammation
☐ Hypersensitivity
☐ 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).
- Reimbursement with equivalent replacement product will be processed.

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 Day/Mo./Year

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: _____

STRAUMANN GUARANTEE® (valid as of October 1, 2018)

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. PUREIoc® 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**.
3.9 Reimbursement with equivalent replacement product will be processed.

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
Phone: 800/448 8168
Fax: 978/747 0023

RETAIN FOR YOUR RECORDS

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

USLIT.479 9/22 V3

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