Straumann Guarantee® Questionnaire

File Number (if known) _____

Please complete this form with as much detail as possible; ***missing information will delay processing***.
If appropriate, provide the explanted product(s) in sterile condition and any relevant radiographs (not returned unless requested).
Attach sterilized product to this form or write the patient identifier and File Number (if known) on product package.

GUARANTEE CONDITIONS

- Products must be returned within ***90 days*** of the date of the event or device removal and ***Service duration*** must be ***within Guarantee Term limits***.
- Metal or ceramic items must be ***autoclaved*** and ***marked sterile*** by either an autoclave indicator or hand written; plastic items must be ***cold sterilized***.
- Products must be shipped in ***protective packaging*** using a method that allows for shipment ***tracking***.
- Only ***one replacement implant per day per tooth site*** qualifies for replacement under the Straumann Guarantee.

CUSTOMER INFORMATION

Customer Details
Facility Name _____
Clinician Name _____
Contact Phone _____
Contact E-Mail _____

Sold to Account #: _____
Address 1 _____
Address 2 _____
Address 3 _____
City _____
State/Prov _____ Zip Code _____

☐ *Check if same as Sold To*
Ship to Account #: _____
Address 1 _____
Address 2 _____
Address 3 _____
City _____
State/Prov _____ Zip Code _____

PATIENT INFORMATION (required for implants)

Patient Detail *(for privacy **DO NOT** use patient's name)*
Patient ID _____
Date of Birth _____
Gender: ◯ Female ◯ Male
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 * Replacements cannot be provided without this information

Article (REF) Number*	Lot/Serial Number	Placement Date*	Event/Removal Date*	Site (ADA)

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

Roxolid implant fracture claims *must* be accompanied by either the restoration or restoration details - include here.

☐ **Check if you previously notified Straumann Regulatory about this event.** ☐ **Check if the product is from Consigned Inventory**

Replace with same device(s)? ◯ Yes ◯ No; specify Article (REF) No(s): _____

For Customized Abutments, was product created via: ◯ Own Scan/CAD ◯ Scan Service ◯ Scan & Shape Service Project No.: _____

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)?
◯ N/A ◯ Implant removal from vial ◯ Implant insertion into bone ◯ Transfer piece removal ◯ Other: _____

At the time of surgery, were any of the following conditions present (check all that apply)?
☐ Periodontal disease ☐ Local infection ☐ Subacute chronic osteitis ☐ Diseased mucous membrane ☐ Complication in site prep

Other Factors:
Was site tapped? ◯ Yes ◯ No
Was holding key used? ◯ Yes ◯ No
Bone quality (type): ◯ I ◯ II ◯ III ◯ IV
Bone-level profile drill used? ◯ Yes ◯ No
Tissue-level profile drill used? ◯ Yes ◯ No
Was primary stability achieved? ◯ N/A ◯ No ◯ Yes
Was osseointegration achieved? ◯ N/A ◯ No ◯ Yes
Was implant covered with bone? ◯ N/A ◯ No ◯ Yes

SURGERY INFORMATION - OTHER DEVICES (required for Implant and Regenerative products)

Was augmentation performed during surgery? ◯ No ◯ Sinus ◯ Ridge ◯ Other Material used? _____
Was GTR membrane used? ◯ No ◯ Resorbable ◯ Non-Resorbable Material used? _____
Was a Straumann Biomaterial product used? ☐ No ☐ Emdogain ☐ AlloGraft ☐ XenoGraft ☐ BoneCeramic Other: _____

straumann®
simply doing more℠

EVENT INFORMATION (required for Implant and Biomaterial products)

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

Why do you believe the event occured:

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

☐ Trauma/Accident	☐ Implant fracture	☐ Poor bone quality/quantity
☐ Overheating of bone	☐ Bruxism	☐ Previous bone augmentation
☐ Peri-implantitis	☐ Nerve encroachment	☐ Adjacent to endodontic tooth
☐ Sinus perforation	☐ Tongue pressure	☐ Biomechanical overload
☐ 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? ○ No ○ Yes **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 and Roxolid fracture)

Type of prosthesis? ○ Crown ○ Bridge ○ RPD (upper) ○ RPD (lower) ○ 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 (N-cm): _____

SCDS Project No.: _____

Was the recall appointment schedule followed? ○ Yes ○ No **Description of event:** _____

Information about fit: ○ Too wide ○ Too narrow ○ Rocking ○ Short prepline ○ Marginal gap ○ Other: _____

Where issue occurred: ○ Model ○ Mouth ○ Both ○ Other: _____

What was scanned?: ○ Abutment ○ Plaster ○ Wax-up ○ Acrylic ○ Intra-oral/Jaw ○ Metal **Was scan spray used?** ○ Yes ○ No

When did fracture occur? ○ Cementation ○ As delivered ○ After final ○ During prep ○ After provisional ○ During try-in

Parts swallowed/inhaled? ○ N/A ○ Swallowed ○ Inhaled **Where did fracture occur?** ○ Framework ○ Veneer ○ Both

Problem with framework: ☐ Spotted Shading ☐ Finishing (surface) ☐ Wall thickness too thin ☐ Incorrect shading **Framework processed?** ○ Yes ○ No

Problem with veneering: ☐ Bubbles ☐ Cracks ☐ Unusual oxide layer ☐ Other

When problem occurred: ○ Oxidization fire ○ Opaque fire ○ 1st dentin fire ○ 2nd dentin fire ○ Lustre fire ○ Other

Were these products used? ☐ Binder ☐ Pre-opaque ☐ Opaque paste ☐ Opaque powder ☐ None of these

Ceramic material used? _____ **Firing oven cleaned/calibrated regularly?** ○ No ○ Yes; latest:

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: _____

NOTICE
Evaluation of ratchet/torque devices occurs in Europe. Replace or return decisions take longer than for other devices.

SUBMISSION INFORMATION

Return the following in ***protective packaging*** (padded mailer) using a method that allows for shipment ***tracking***:

- Explanted product(s) in ***sterile*** condition (devices not sterilized do not qualify for replacement)
- Printed copy of Pages 1 and 2 of completed Straumann Guarantee Questionnaire (even if e-mailed)
- Relevant radiographs (these will not be returned unless specifically requested, please send copies).

Send shipment to: Straumann North America
ATTN: Regulatory Affairs
60 Minuteman Road
Andover, MA 01810

Questions?
Phone: 800/448 8168 Option 4
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: _____

STRAUMANN GUARANTEE (valid as of October 1, 2016)

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 Guarantee	–	Replacement with equivalent ceramic abutment including ceramic screw-retained bars and bridges**	Replacement with equivalent ceramic restoration***
10 Year Guarantee	–	Replacement with equivalent metal screw-retained bars and bridges**	Replacement with equivalent metal restoration and resin nano ceramic restoration***
Lifetime Guarantee	Replacement with equivalent implant and equivalent abutment, if finalized.	Replacement with equivalent metal abutment	–
Roxolid® Lifetime+ Guarantee	Replacement with equivalent implant and equivalent abutment, if finalized. Additionally, for Straumann® Roxolid® Implants a treatment compensation in the amount of $1,500. if implant fractures (reported after July 31, 2016).****	–	–

* Valid as of October 1, 2016

** 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 3.3 mm 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.

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 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;
3.4 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 "Roxolid Lifetime Plus Guarantee: The complaint case must be submitted and approved for product replacement first. The Roxolid 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 Straumann Territory Manager or
Straumann Regulatory Affairs.

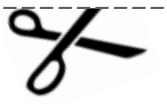
Straumann North America
ATTN: Regulatory Affairs
60 Minuteman Road
Andover, MA 01810

E-Mail: reg_complaint@straumann.com
Phone: 800/448 8168 (Option 4)
Fax: 978/747 0023

RETAIN FOR YOUR RECORDS

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

Straumann North America
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