

Straumann Guarantee® Questionnaire

straumanngroup.ca/eshop

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* (see page 3 for additional info)

- 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**.
- 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**.
- 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 _____
Prov _____ Postal Code _____

Check if same as Sold To

Sold to Account #: _____
Address 1 _____
Address 2 _____
Address 3 _____
City _____
Prov _____ Postal 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/Project #	Placement Date*	Event/Removal Date*	Site (FDI)	Order Type
1 _____	_____	_____	_____	_____	Consignment Standard
2 _____	_____	_____	_____	_____	Consignment Standard
3 _____	_____	_____	_____	_____	Consignment Standard

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

Exchange with same Article#(s)? Yes No; specify Article (REF) No(s): 1 2 3

Was the product used in a patient?: Yes No

SURGERY INFORMATION - IMPLANT RELATED (required for implants)

Placement Method: Manually Handpiece adapter Torque Applied (Ncm) _____

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

Difficulty related to: Patient condition Product related

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

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

Was augmentation performed during surgery? No Sinus Ridge Other
Was GTR membrane used? No Resorbable Non-Resorbable Brand used? _____
Was bone substitute used? No AlloGraft XenoGraft BoneCeramic Other: _____
Was a regeneration/growth protein used? No Emdogain® Gem21® Arestin® Other: _____

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

Empty box for event description.

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 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 (Ncm): _____

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 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? Yes, On _____ 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

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 Canada Ltd. ATTN: Regulatory Affairs 3375 North Service Rd., Units B12-14 Burlington, ON L7N 3G2
Questions? Phone: 800/363 4024 Fax: 978/747 0023 E-Mail: reg_complaint@straumann.com

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

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.

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 Canada Ltd., Burlington, ON (“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	–
 Lifetime+ Guarantee	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).****	–	–

* Valid as of 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 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.

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 Canada Ltd.
ATTN: Regulatory Affairs
 3375 North Service Rd., Units B12-14
 Burlington, ON L7N 3G2

E-Mail: reg_complaint@straumann.com
 Phone: 800/363 4024
 Fax: 978/747 0023

RETAIN FOR YOUR RECORDS

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

Straumann Canada Ltd.
ATTN: Regulatory Affairs
3375 North Service Rd., Units B12-14
Burlington, ON L7N 3G2



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