

Straumann Guarantee® Questionnaire

straumanngroup.ca/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 _____
Prov _____ Postal Code _____

Check if same as Sold To

Ship to Account #: _____
Address 1 _____
Address 2 _____
Address 3 _____
City _____
Prov _____ Postal 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 any relevant radiographs.

Article REF Number	Lot/Serial/Project #	Placement Date	Event/Removal Date	Site FDI
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 Canada Ltd.
ATTN: Regulatory Affairs
1109 Clay Avenue, Unit 8
Burlington, ON L7L 0A1

Questions?
Phone: 800/363 4024
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 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. PUREloc® and Novaloc® abutments*	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).***	–	–

* 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 Canada Ltd.
ATTN: Regulatory Affairs
1109 Clay Avenue, Unit 8
Burlington, ON L7L 0A1

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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Straumann Canada Ltd.
ATTN: Regulatory Affairs
1109 Clay Avenue, Unit 8
Burlington, ON L7L 0A1



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