Neodent® Limited Warranty Questionnaire

neodent.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
☐ 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 Neodent products

	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

Drill sequence	*Indicate size*
Initial	
Alvin	
Pilot	
Countersink	
Facility drill	
Other	

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, 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? _____

NEODENT®
A Straumann Group Brand

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
☐ 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: _____

Why do you believe the event occurred:

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 and CARES® Digital Solutions restoration

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:_____

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

SUBMISSION INFORMATION

Products must be returned within 30 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 Neodent Limited Warranty.
- 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

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

Upon receipt, Neodent will review your feedback, assess the returned product and determine whether the product meets the conditions for replacement under the Neodent Limited Warranty. 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 Neodent Limited Warranty. I declare that the items described above were properly sterilized, and that the information being provided is truthful and accurate.

Clinician Name (print): _____ Signature: _____ Date: _____

NEODENT® LIMITED WARRANTY (VALID AS OF OCTOBER 1, 2020)

1. Scope of Limited Warranty

1.1 Straumann warrants to dentists, users of its products, the replacement of implants, surgical instruments and prosthetic components used on patients that present defects or adverse events, according to the warranty periods referred to in item 2, provided they have acquired original Neodent products, respecting the operating instructions provided by Neodent and subject to the conditions and limitations of warranties described below. This limited warranty covers only the exchange of Neodent products; other costs associated with the treatment are not covered, including materials and the treatment itself.

1.2 This limited warranty requires:

a) The legitimate acquisition of original products from Straumann by the dentist without the combination of products with other brands;
b) The patient's careful selection with clinical indication for treatment with dental implant and the proper use of this therapy;
c) That the patient does not have any contraindication described in the instructions for use before, during or after the implant installation;
d) The use of the product was carried out in strict accordance with the guidelines and recommendations in the instructions of use for each product;
e) Compliance with care before and after surgery, as well as proper and regular oral hygiene of the patient;
f) Documented follow-up visits;
g) That the prosthesis installed on the implant (or to be substituted) allows the correct occlusion between arches.
h) That the warranty claim form is submitted fully completed to Straumann.

1.3 The limited warranty is exclusive to the professional dentist, explicitly excluding any right to third parties, patients or intermediate suppliers.

1.4 In case the conditions described in this limited warranty are in disagreement with local legislation the provisions of this limited warranty will prevail.

2. Limited Warranty Periods

2.1 Neodent offers the following warranty periods for its products:

	Implants	Components on implants
Ten (10) years of Limited Warranty		Stock Titanium Abutments does not cover customizable and temporary abutments. Replacement by an equal or equivalent metal component
Lifetime Limited Warranty	Replacement by an equal or equivalent implant and an equivalent pillar, when necessary.	

2.2 Intermediate components, customizable and/or which have undergone customization, as well as provisional prosthetic components are excluded from this limited warranty, as well as other provisional items.

3. Limited warranty conditions

3.1 In order to apply the conditions described herein, both the patient and the professional need to take the best possible care before, during and after use of the products manufactured by Neodent.
3.2 Straumann recommends that the dentist observe the indications and contraindications of each patient, following the recommendations contained in the product instructions for use. ent, covering all implants and products placed from this date.
3.3 Straumann asks the professional dentist to ensure that there was proper oral hygiene by the patient and that consultations were regularly observed and documented.
3.4 Straumann shall only examine the product after receiving the limited warranty form.
3.5 The replacement of the product takes place only after the receipt of the form and within the term of 30 (thirty) days described above.

4. Exclusions from this limited warranty

This limited warranty does not apply to:

4.1 Neodent product that has not been used in accordance with the manufacturer's instructions for use;
4.2 Neodent product that has suffered any kind of contamination caused by a professional or by third parties;
4.3 Neodent product that has been modified or combined with third party products not manufactured by Neodent;
4.4 Existence of contraindications mentioned in the instructions for use;
4.5 Incorrect handling of the product by the professional dentist;
4.6 Customized and/or temporary prosthetic components;
4.7 Failure or defect in the product caused by accident, trauma or any cause at the responsibility of the patient, professional or third parties;
4.8 Products that undergo modifications performed by the dentist and / or third parties.

5. Limited warranty limitations and loss of limited warranty

5.1 The limited warranty set forth herein is the only limited warranty granted by Straumann.
5.2 Straumann assumes no responsibility over the professional dentist for loss of business, revenues, or lost profits, and recognizes that the only link between them is mercantile, resulting from the purchase and sale of products manufactured by Neodent.
5.3 It is the professional's responsibility to use the products according to the instructions for use. The use of prosthetic abutments and/or instruments from other manufacturers does not ensure the perfect function of the system and voids any product warranty.
5.4 By acquiring the Neodent implants and participating in the limited warranty program, the professional dentist accepts the terms and conditions set forth herein.

6. How to undertake Products Exchange under this limited warranty

6.1 For technical report request, the products purchased from an authorized distributor should be sent exclusively to the care of this authorized distributor/subsidiary:

Sending Products

6.2 Sending the properly sanitized and sterilized product in wet steam (autoclave) is mandatory, in accordance with the Declaration of Sterilization.

The properly sanitized and sterilized product should be sent accompanied by the following documents:

6.3 Statement Sterilization accompanying the Limited Warranty Form, completed by the client, including the required information such as: product batch number, number of the Invoice, sterilization cycle number, date and responsible for sterilization;
6.4 Copy of the purchase invoice of the product;
6.5 Form filled out completely, stating all the required data;
6.6 Periapical or panoramic radiographs.

Note: For countries that the legislation does not allow patient information, this data does not apply.

6.7 Products that are not cleaned and sterilized will not be accepted for replacement and application of this limited warranty, and will be:

- Discarded when received;
- The dentist assumes all responsibility for the costs of a possible hiring of subcontractors for the sterilization of products shipped without complying the above items.

6.8 The preparation of the technical report by Straumann shall be made within forty-five (45) business days of receipt by the legal manufacturer, provided that all the conditions described herein are met.
6.9 Straumann assures there the confidentiality of patient's clinical information.

7. Modifications and Termination of Limited Warranty

Straumann reserves the right to change the warranty periods at any time, in whole or in part. The modification of this Limited Warranty Policy will not affect products placed prior to amendments thereto.

8. Term

The terms contained in this Limited Warranty Policy shall come into effect from the date mentioned in the heading of this document, covering all implants and products placed from this date.

CONTACTS

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

Straumann Canada Limited
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:

Straumann Canada Limited
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 Neodent® limited warranty questionnaire as completely as possible
- Include your Neodent 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 and 4 for your records