

Neodent® Limited Warranty Questionnaire

File Number (if known)

Submit your product issue online via neodent.us/eshop

To qualify for reimbursement, please submit a completed/signed guarantee questionnaire along with the failed product in sterile condition (i.e., autoclaved), within 90 days of the removal/event date.

CUSTOMER INFORMATION

Customer Details

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

Sold to Account #: _____
 Address 1 _____
 Address 2 _____
 Address 3 _____
 City _____
 State _____ Postal Code _____

Check if same as Sold To

Ship to Account #: _____
 Address 1 _____
 Address 2 _____
 Address 3 _____
 City _____
 State _____ Postal Code _____

MANDATORY (Failure to complete the mandatory sections could potentially result in warranty disqualification)

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 Neodent products

- 1
- 2
- 3

Article REF Number	Lot/Serial/Project #	Placement Date	Event/Removal Date	ADA Site (tooth number)
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

If the implant was placed and removed on the same day (i.e. placement and removal date are the same), was another implant successfully placed in the same site during surgery?

Yes No – Why not? _____

REASON FOR COMPLAINT

Drill sequence	Indicate size	Drill sequence	Indicate size
Initial		Zygomatic Drills	
Alvin		Tapered Drills	
Pilot		Pilot	
Countersink		Other	
Facility drill			

Was the sequence of drills used correct? Yes No Not reported

SURGERY INFORMATION - IMPLANT RELATED (required for implants)

Was the product used in a patient?: Yes No

Placement Method: Manually Handpiece adapter Digital Navigation Torque applied _____ Ncm

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? _____

EVENT INFORMATION (required for Implant and Biomaterial products)

Assessment of hygiene around implant: Excellent Good Fair Poor

Was the recall appointment schedule followed? Yes No

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

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): _____

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 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 Neodent Limited Warranty.
- Relevant radiographs (these will not be returned unless specifically requested, please send copies).

Send shipment to: Straumann USA, LLC

ATTN: Regulatory Affairs

60 Minuteman Road
Andover, MA 01810

Questions?

Phone: 800/448 8168 - Option 6

E-Mail: reg_complaint@straumann.com

Neodent Internal Use Only

Non-RPC

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, 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 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:

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 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