NEODENT® EXCELLENCE AND INNOVATION

Neodent Guarantee Questionnaire

Tracking Number

Neodent welcomes feedback about our products in order to allow us to learn as much as possible about how our products perform under actual use, as well as to assist us in complying with our regulatory reporting responsibilities. We ask that you complete this form with as much detail as possible and, if appropriate to the event, that you provide the explanted product(s) in sterile condition and any relevant radiographs (not returned unless requested).

An incomplete form will lead to the return of the product, and the transportation costs will be the responsibility of the customer. A new form must be submitted for each product used by a dental professional.

Guarantee Conditions

The following conditions must be met for replacement under the Neodent Guarantee:

- Products must be returned within ***90 days*** of the date of the event or device removal.
- Metal or ceramic items must be ***autoclaved*** and ***marked sterile*** by either an autoclave indicator or hand written.
- Plastic items must be ***cold sterilized*** and have the word ***sterile*** hand written on the package.
- 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 Neodent Guarantee.
- ***Service duration*** (placement date to removal date) must be ***within Guarantee Term limits***.

Customer Information

Correspondence Address:
Clinician Name: _____
Address: _____
Address: _____
City: _____ State: _____
Country: _____ Phone: _____
E-mail: _____

Shipping Address: ☐ Check if same as Correspondence Address
Clinician Name: _____
Address: _____
Address: _____
City: _____ State: _____
Country: _____ Phone: _____
E-mail: _____

Product Information

*replacements cannot be provided without this information.

Product #1:
Article (REF) Number: _____
Lot/Serial Number: _____
Placement Date*: _____
Event/Removal Date*: _____
Site (ADA): _____
Replace with same device(s)?
If no, specify article (REF) No(s): _____

Product #2:
Article (REF) Number: _____
Lot/Serial Number: _____
Placement Date*: _____
Event/Removal Date*: _____
Site (ADA): _____
Replace with same device(s)?
If no, specify article (REF) No(s): _____

Patient Information (only required for implants)

Patient Detail
Patient ID: _____
(for privacy compliance DO NOT use patient's name)
Date of Birth: _____
Gender: ☐ Male ☐ Female
Smoker: ☐ Yes ☐ No
Relevant Allergies (list): _____
_____

Medical History

☐ No significant findings	☐ Drug or Alcohol Abuse
☐ Psychological Disorder	☐ Compromised Immunity
☐ Blood Coagulation Disorder	☐ Lymphatic Disorder
☐ Untreated Endocrine Illness	☐ Diabetes Mellitus
☐ Radiation Tx (head/neck)	☐ Illness Requiring Steroids
☐ Coincident Chemotherapy	☐ Xerostomia

Surgery Information - Implant Related (only required for implants)

If implant was placed and removed on same day, was another implant successfully placed at site during surgery?
Please explain: _____
If you experienced difficulty inserting an implant with a pre-mounted transfer piece (i.e. dropped) when did this occur?
(check one) ☐ N/A ☐ Implant removed 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): ☐ Local infection
☐ Periodontal disease ☐ Complication in site prep ☐ Subacute chronic osteitis ☐ Diseased mucous membrane

Implant Factors:
Was primary stability achieved? ☐ Yes ☐ No ☐ N/A
Was osseointegration achieved? ☐ Yes ☐ No ☐ N/A
Was implant covered with bone? ☐ Yes ☐ No ☐ N/A
Bone quality (type): ☐ I ☐ II ☐ III ☐ IV

Surgery Information *Continued* - Implant Related (only required for implants)

Implant Factors *Continued*:
Was a bone graft placed? ☐ Yes ☐ No If yes, what material was used? _____
Was an immediate loading procedure used? ☐ Yes ☐ No
If yes, what is the prosthetic component used? _____

Event Information (only required for implants)

Why do you believe the event occurred? _____
_____
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	☐ Implant fracture	☐ Poor bone quality/quantity
☐ Overheating of bone	☐ Bruxism	☐ Previous bone augmentation
☐ Peri-implantitis	☐ Nerve encroachment	☐ Adjacent to endotontic 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	☐ Fistula	☐ Swelling
☐ Mobility	☐ Hypersensitivity	☐ Asymptomatic
☐ Bleeding	☐ Abscess	☐ Numbness
☐ Inflammation	☐ Dehiscence	☐ Other: _____

Was the prosthesis fitted? ☐ Yes ☐ No
For multiple 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

When did failure occur? ☐ On model ☐ At insertion ☐ In use ☐ Other: _____
Type of restoration? ☐ Crown ☐ Bridge ☐ RPD (upper) ☐ RPD (lower) ☐ Full (upper) ☐ Full (lower)
☐ Other: _____
Torque control device used: ☐ Unknown ☐ No ☐ Yes - Torque applied (N-cm) _____
Date abutment was installed: _____ Date of abutment removal: _____
Date temporary restoration installed: _____ Date final restoration installed: _____
Description of event: _____
_____

Instrument Information (only 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: _____

Submission information

Return the following in protective packaging 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 & 2 of this completed Neodent Guarantee Questionnaire
- Relevant radiographs are required for all implant and abutment guarantee submissions (these will not be returned unless specifically requested, please only send copies)

Send shipments to: Neodent USA, Inc. / ATTN: Regulatory Affairs
60 Minuteman Road
Andover, MA 01810

Questions? Call: 855/412-8883
Fax: 855/412-8884
E-Mail: info@neodentusa.com

Tracking No.

Upon receipt, Neodent will review your feedback, assess the returned product and determine whether the product meets the defined conditions for replacement. When all necessary information is received, a replacement will be provided.

By signing below, I am acknowledging that I understand the terms and conditions of the Neodent guarantee and that the information being provided is truthful and accurate.

Clinician Signature: Date: