Product complaint form
Implant systems

For internal use only
Notification no.

1 Customer information

Customer number*

Customer name*

Telephone*

Email address*

Alternate phone number

Contact name

2 Nature of product complaint

This complaint form does not cover individualized NobelProcera products. If your complaint is about one of these products please contact customer care.

Date of occurrence

2.1 Occurence of event

- ☐ Before clinical procedure (i.e. any procedures where there was no patient involved)
- ☐ During clinical procedure (i.e. during placement of implant/prosthetics)
- ☐ After clinical procedure (i.e. after placement of implant/prosthetics)

2.2 Product type*

2.3 Product complaint type*

☐ Implant

- ☐ Broken/fractured component
- ☐ Components couldn't be separated
- ☐ Deformation
- ☐ Dropped from the implant driver
- ☐ External trauma (e.g. car accident)
- ☐ Failure to osseointegrate
- ☐ Fracture of bone (e.g. buccal plate) during implant insertion
- ☐ Implant fracture at/after delivery of prosthetic restoration
- ☐ Implant fracture at implant placement
- ☐ Labeling
- ☐ Loss of osseointegration
- ☐ Packaging
- ☐ Primary stability couldn't be achieved
- ☐ Surface defect (product)
- ☐ Other (please specify)

☐ Abutment/Screw

- ☐ Abutment screw loosening
- ☐ Broken/fractured component
- ☐ Components couldn't be separated
- ☐ Deformation
- ☐ External trauma (e.g. car accident)
- ☐ Labeling
- ☐ Packaging
- ☐ Surface defect (product)
- ☐ Other (please specify)

☐ Instrument/Tool

- ☐ Broken/fractured component
- ☐ Components couldn't be separated
- ☐ Deformation
- ☐ External trauma (e.g. car accident)
- ☐ Labeling
- ☐ Packaging
- ☐ Surface defect (product)
- ☐ Other (please specify)

2.4 Was the product used on a patient when the event occurred?*

Please only select "yes" if the patient was in touch with the component

Implant		Abutment/Screw		Instrument/Tool	
☐ Yes	☐ No	☐ Yes	☐ No	☐ Yes	☐ No
Continue on section A (page 2)	**Continue on section E** (page 6)	**Continue on section B** (page 3)	**Continue on section E** (page 6)	**Continue on section C** (page 4)	**Continue on section C** (page 4, chapter 8 Instrument/Tooling information) **and after that to section E**

* Mandatory fields are marked with an asterisk

Section A: Implants

3 Clinical procedure information

3.1 Surgery dates*

Date of product placement

☐ Date not known
☐ Product was never placed

Second surgery date

☐ Date not known
☐ There was no second surgery

Implant loading date

☐ Date not known
☐ Implant was not loaded

Product removal date

☐ Date not known
☐ Product was not removed

3.2 Was the implant removed due to*

☐ Pain
☐ Numbness
☐ Pain & numbness
☐ Product was not removed
☐ None of the above

Did the pain and/or numbness disappear after the implant removal?* ☐ Yes ☐ No

3.3 Were any of the following conditions involved in the event?*
(Check all that apply)

☐ Overheating of bone
☐ Infection
☐ Granulated tissue around implant
☐ Significant bone loss around implant
☐ Nerve injury symptoms (loss of feeling)
☐ Peri-implantitis
☐ Implant placement in previously/simultaneously grafted site
☐ Sinus perforation
☐ Biomechanical overload
☐ None of the above

3.4 Bone quality*

☐ Type I Majority of residual bone made of cortical bone (hard bone)
☐ Type II Presence of thick cortical bone surrounding spongy bone (medium/hard bone)
☐ Type III Thin layer of cortical bone surrounding medium density spongy bone (medium/soft bone)
☐ Type IV Thin layer of cortical bone surrounding low density spongy bone (soft bone)

4 Prosthesis information (only fill out this section if the implant was loaded)

4.1 Types of prosthesis*

☐ Abutment and cemented crown/bridge
☐ Implant bridge/bar
☐ Screw-retained crown
☐ Other (please specify)

4.2 Type of implant prosthesis*

☐ Original Nobel Biocare/NobelProcera abutment/implant bridge bar

Article no.*

☐ Article number not known

Batch no.*

☐ Batch number not known

File number

Product description

☐ Non-original implant restoration
☐ Product details not known

4.3 Please add information about the instrument or tooling used during the procedure

▼ Please confirm that all required fields are answered and continue to section D (page 5).

* Mandatory fields are marked with an asterisk

Section B: Abutments/Screws

5 Clinical procedure information

5.1 Surgery dates*

Date of product placement

☐ Date not known
☐ Product was never placed

Date of product removal

☐ Date not known
☐ Product was never removed

5.2 Were any of the following conditions involved in the event?*
(Check all that apply)

☐ Overheating of bone
☐ Infection
☐ Granulated tissue around implant
☐ Significant bone loss around implant
☐ Nerve injury symptoms (loss of feeling)
☐ Peri-implantitis
☐ Implant placement in previously/ simultaneously grafted site
☐ Sinus perforation
☐ Biomechanical overload
☐ None of the above

6 Implant information (only fill out this section if the product is an abutment)

6.1 Type of implant*

☐ Original Nobel Biocare implant

Article no.*

☐ Article number not known

Lot batch no.

☐ Batch number not known

Product description*

☐ Product details are not known
☐ Non-Nobel Biocare implant

6.2 Please add information about the instrument or tooling used during the procedure

▼ Please confirm that all required fields are answered and continue to section D (page 5).

* Mandatory fields are marked with an asterisk

Section C: Instruments

7 Clinical procedure information

7.1 Were any of the following conditions involved in the event?*
(Check all that apply)

- ☐ Overheating of bone
- ☐ Infection
- ☐ Granulated tissue around implant
- ☐ Significant bone loss around implant
- ☐ Nerve injury symptoms (loss of feeling)
- ☐ Peri-implantitis
- ☐ Implant placement in previously/ simultaneously grafted site
- ☐ Sinus perforation
- ☐ Biomechanical overload
- ☐ None of the above

8 Instrument/Tooling information

8.1 How many times were the implant site preparation tools used prior to this procedure?

☐ Initial use ☐ 2–5 ☐ 6–10 ☐ 10–15 ☐ More than 15

8.2 Which cleaning method was used?*

☐ Manual ☐ Ultrasonic ☐ Thermo-disinfection ☐ Other (please specify)

8.3 Which sterilization method was used?*

☐ Autoclave ☐ Dry heat ☐ Chemical ☐ Other (please specify)

▼ Please confirm that all required fields are answered and continue to section D (page 5).

Section D: Patient information

9 Patient information

Patient code*

Patient age (at time of event)

Sex
☐ Male ☐ Female

9.1 Patient profile
(Check everything that applies)
☐ Bruxer ☐ Diabetic ☐ Smoker ☐ None of the above ☐ Other (please specify)

9.2 Please describe the hygiene around the implant*
☐ Excellent ☐ Good ☐ Fair ☐ Poor

9.3 Patient injury*
☐ No ☐ Yes (if yes, please fill in the below two questions)

Type of injury
☐ Permanent impairment of the body function or structure (please specify)
☐ Medical/surgical intervention to preclude permanent impairment (please specify)
☐ Other (please specify)

Current patient status
☐ Recovered from injury
☐ Recovered from injury with permanent impairment
☐ Under treatment
☐ Unknown
☐ Other (please specify)

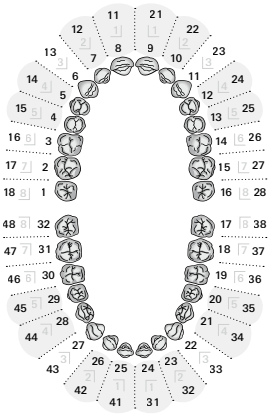
▼ Please confirm that all required fields are answered and continue to section E (page 6).

Section E: Product information and replacement

10 Product information

Article no.*

Tooth position



☐ Article number unknown

Lot/batch no.*

☐ Lot/batch not available

Product description*

10.1 Is your product available for return?* ☐ Yes ☐ No (if no, please explain)

10.2 Product decontamination* ☐ Please confirm that you will decontaminate all materials before shipping to Nobel Biocare.

10.3 Comment

11 Product replacement

Article no.	Product description

11.1 Shipping address

Street, house no.*

Post/zip code*

City*

State

Country*

Terms and conditions* ☐ I confirm that data provided in this product complaint form is correct. I understand that no patient data (including, but not limited to, patient's name) shall be shared or otherwise sent to Nobel Biocare through this form without the patient's written express consent. I understand that data will be processed in compliance with Nobel Biocare Privacy Policy, accessible at nobelbiocare.com/international/en/footer/privacy-policy.html

Signature

Date

* Mandatory fields are marked with an asterisk

How to report a product complaint
For implants, abutments, clinical screws, instruments and tools

At Nobel Biocare we take all product complaints very seriously. Our ultimate goal is to identify the root cause of product failures, implement countermeasures and integrate our learnings into new product developments. In order to do this and to comply with regulatory reporting requirements, we ask you to complete our product complaint form. See below.

To submit a product complaint, please perform the following steps:

1. Fill in the product complaint form	
2. Decontaminate the product(s)	For returns, all products received from a patient must be decontaminated. Please follow the applicable instructions below: – Disinfection: Use agent intended for manual disinfection, e.g. orto-phtalaldehyde solution (rinse carefully and do not clean mechanically). – Sterilization: **For USA:** Steam sterilization 270 °F (132 °C) for four minutes when using pre-vacuum method and 15 minutes when using the gravity method. Dry for 20 to 30 minutes when using pre-vacuum method and 15 to 30 minutes when using the gravity method. **For outside USA:** Temperature 132 °C (270 °F), max. 137 °C (279 °F) for three minutes (up to 20 minutes). Dry for 10 minutes in chamber. Important: A sterilization pouch must be used and the indicator on the pouch should show that it has been put through a sterilization cycle. For products which cannot be sterilised, please follow only the disinfection instructions and insert the applicable product(s) into a sterilisation pouch.
3. If available, prepare copies of supporting documents	e.g. X-rays/photos along with Patient ID number
4. Pack and ship the product(s) with the product complaint form and copies of supporting documents and ship it to your local customer service or returns department	**Sterilization pouch** Please write the following information on the pouch: – Product description (e.g. NobelReplace xxxx) – Date the issue occurred – Patient code **Outer shipping container, with registered mail** – Name and address of Customer Service or Returns department Nobel Biocare – Use a box or a padded envelope as shipping container – Label the shipping container as “Decontaminated”

Upon receipt, we will review your complaint and provide a replacement product according to our Warranty Program terms.

Nobel Biocare is not responsible for lost shipments. Please use a shipment method that allows for shipment tracking.

Address to ship the defective product:

Please refer to page 8 to select the address relevant to the country of residence.

Address to ship the defective product

Australia
Nobel Biocare – Customer Service
Level 4, 7 Eden Park Road, Macquarie Park, NSW 2113
Australia

order.australia@nobelbiocare.com
1800 804 597

Austria
Nobel Biocare Österreich GmbH
c/o Mailboxes etc.
Modecenterstraße 22/B3/101
1030 Wien
Österreich

info.austria@nobelbiocare.com
01 892 89 90

Belgium
Nobel Biocare Belgium NV
Zone Maalbeek - Roekhout 17
1702 Groot-Bijgaarden

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+32 (0)2 467 41 70

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1-800-939-9394

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