NobelProcera®
Individualized products.
How to report a product complaint.

The importance of required information

To ensure a safe and effective product, customer feedback is a central part of Nobel Biocare's Post Market Surveillance continuous improvement process. It is important to obtain all necessary information about the product event details to be able to perform a proper investigation.

The information is required for product development and for statistical analysis to ensure product safety. Additionally, it is needed for regulatory requirements as Nobel Biocare is a Medical Device manufacturer.

The complete version of Nobel Biocare warranty program - Terms and conditions is available for downloading at http://www.nobelbiocare.com/en/warranty/default.aspx

How to submit a product complaint

When reporting a product complaint and requesting a replacement product, the entire complaint questionnaire must be completed. The product must be returned to perform an adequate and relevant investigation.

– If applicable, disinfect and autoclave the complaint products and label them according to instructions below.
– Non-sterilized devices may be considered biological hazards.
– If applicable, include x-rays/photos and other documentation.
– Send the sterilized product(s) and original product investigation questionnaire to your local Customer Service representative as soon as possible.

Do not hesitate to contact your Nobel Biocare USA representative if you have any concerns. For returns please send to: Nobel Biocare USA, LLC Attn: Returns Department,22715 Savi Ranch Parkway, Yorba Linda, CA 92887

Complaint product sterilization instructions

– All complaint products retrieved from patient must be sterilized
– Disinfection: 70 % to 80 % aqueous ethanol (rinse carefully and do not mechanically clean)
– Sterilization: at 132–135 °C / 270–275 °F (max 137 °C / 279 °F) for a minimum of 3 minutes in sealed pouches indicating exposure.

To ensure product identification and traceability the following information must be provided;

Primary package:

1.Product description (e.g. Reference: XXXXX)
2.Name or initials of retriever
3.Date and clinical contact details
4.Unique patient ID

Customer to fill in: Information requested in points 1 to 4

Secondary package

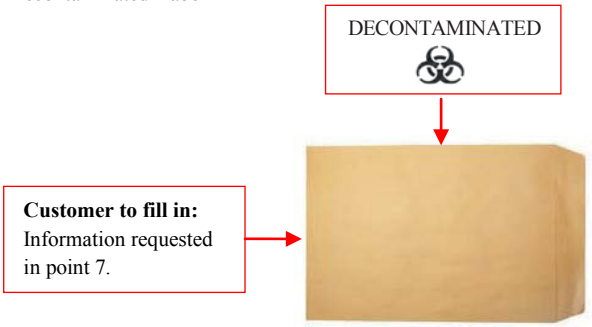
5.Name or initials of retriever and clinical contact details
6.A "Decontaminated" label

Customer to fill in: Information requested in points 5 and 6.

Customer Service to fill in: Questionnaire ID no

Outer shipping package

7.Name, address and telephone number (Sender)
8.A "Decontaminated" label



Customer to fill in: Information requested in point 7.

Product investigation questionnaire – NobelProcera individualized product

Nobel Biocare Customer info

Account no: _____

Customer Name: _____

Address: _____

Post/Zip code: _____

Country: _____

Telephone: _____

Patient info

Only applicable for clinical or after clinical events

Patient identification (only one patient/investigation questionnaire)

ID: _____

Age: _____

○ Female ○ Male

Patient injury?

Risk for a permanent impairment of a body function or structure, or necessitates medical/surgical intervention to preclude permanent impairment of a body function or structure.

Yes ○ No ○

If Yes, please explain: _____

Patient profile

☐ Bruxism/Oral parafunctions

☐ Occlusion problems

☐ Trauma

☐ Other: _____

Any observations by patient e.g. special conditions when the event occured?

Yes ○ No ○

If Yes, please explain: _____

Product info

Quality Notification Filled out by CS

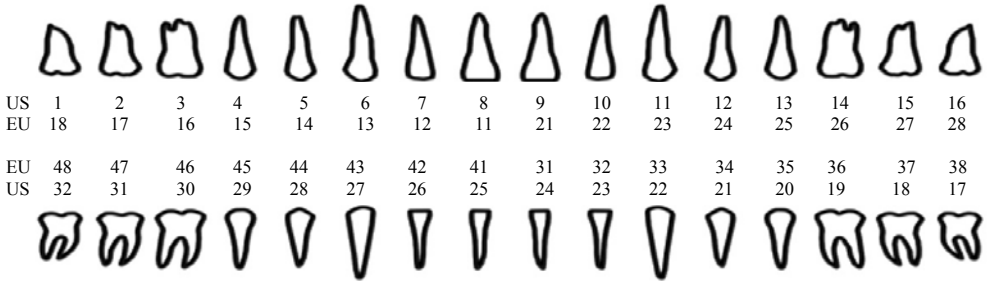
Information of returned products and the corresponding remake order

EU ○ US ○

Order type	Article no	Product description	Order no.	File name	Tooth position
Original					
Remake**					
Original					
Remake**					
Original					
Remake**					

CS = Customer Service Nobel Biocare

** Fill out if applicable



Dates

Restoration	Month	Day	Year
Date of restoration placement			
Date of lab event/clinical event			

Issue description

1. Location/activity (only one option)

- ◯ Lab – Initial inspection
- ◯ Lab – During/after product finalization
- ◯ Clinic – Initial inspection
- ◯ Clinic – During try in/clinical procedure
- ◯ After – Clinical procedure

2. Issue type with description

Fit

- ◯ Tight fit
- ◯ Loose fit
- ◯ Bad fit/Rocking
- ◯ Loosening
- ◯ Poor margin fit

Toward

- ◯ implant replica
- ◯ scanned die
- ◯ adapter
- ◯ implant
- ◯ preparation
- ◯ screw
- ◯ attachment/riders and implant bar

Color/Shade

- ◯ Too dark
- ◯ Too light
- ◯ Spots

Damage/Fracture/Surface

- ◯ Core material/framework of product
- ◯ Veneering material
- ◯ Veneering and core material/framework
- ◯ Chipped/jaggered margin
- ◯ Screw
- ◯ Adapter
- ◯ Attachment/riders
- ◯ Poor surface quality

Design

- ◯ Product not according to design/specifications
- ◯ Rotation
- ◯ Wrong platform on product

Transit/Shipment

- ◯ Wrong shipment
- ◯ Damaged shipment
- ◯ No product/component in shipment
- ◯ Wrong screw
- ◯ Wrong adapter
- ◯ Wrong platform on product
- ◯ Product delivered twice

Any other product involved in the complaint?

Yes ◯ No ◯

Description of product: _____

Additional documentation and comments

Product sterilization

Confirmation of sterilized complaint product(s)

◯ Yes

Note: Products MUST be autoclaved in pouches indicating exposure.

Signature

Signature confirming the stated conditions in this questionnaire

Name: _____

Date: _____