Customer Complaint Form

Conditions for dealing with complaints:

All Biotech Dental products must be handled in accordance with the surgical protocols recommended by Biotech Dental and in compliance with the indications and contraindications mentioned in the instruction leaflet.

Cases will only be considered if the practitioner meets **the following conditions**:

- The product **MUST** be returned **cleaned, sterilised, and packaged in a sterile bag**;
- Copies of **pre- and post-operative X-rays** must be sent as well as the X-ray highlighting the incident, if this relates to the implant or prosthetic component
- **The questionnaire below must be completed and returned within ≤ 30 days of the failure.**

This questionnaire will enable us to analyse the case, with the aim of improving our products. Please answer all these questions and send everything to the address below:

BIOTECH DENTAL
Service Qualité
305 Allées de Craponne
13300 SALON DE PROVENCE
reclamation@biotech-dental.com
Tel.: +33 (0)4 90 44 60 60
Fax: +33 (0)4 90 44 60 61

Customer Complaint Form

Area reserved for Biotech Dental	
Registration date:	**Case number: .....**

INFORMATION ABOUT THE CUSTOMER

Name of healthcare establishment:

Customer no.:

Name of clinician:
Distributor name (export):
Address:
Country:

Telephone
Email:

Sales Manager

Date of request: __ / __ / ____

Treatment of products before dispatch

Product cleaned	☐ Yes	☐ No
Product decontaminated	☐ Yes	☐ No
Product sterilised	☐ Yes	☐ No

INFORMATION ABOUT THE PRODUCT

Type of product:

☐ Anomaly involving instrument/ancillary device ☐ Incident involving prosthesis/CAD-CAM component

Product reference(s)	Batch number Or Traceability label	Quantity
___	___	___
___	___	___
___	___	___

Date of purchase: __ / __ / ____

Used in the mouth: ☐ Yes ☐ No

Date of incident: __ / __ / ____ Date fitted: __ / __ / ____

Dental site Date removed: __ / __ / ____

Number of uses: ☐ None ☐ < 10 ☐ 10 ≤ 20 ☐ > 20

Use of ancillary device ☐ Manual ☐ Motorised (brand……)

If motorised: Rotation speed ..... Tightening torque..... N.cm

GENERAL INFORMATION

Patient

Patient ID: Patient's age: Patient's sex: ☐ Female ☐ Male

Medical imaging ☐ Yes ☐ No

Medical history: ☐ Nothing to report

☐ Diabetes mellitus	☐ Xerostomia
☐ Vitamin D deficiency	☐ Periodontal disease
☐ Blood disorders	☐ Poor oral hygiene
☐ Taking medication	☐ Cardiovascular disease

Date used: 27/02/2025

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☐ Radiotherapy and chemotherapy in the head and neck region
☐ Previous dental surgery at the site
☐ Tobacco, alcohol, drugs
☐ Allergies: _____
☐ Disorder treated with steroids (uncontrolled endocrine disorder or other)
☐ Bone or lymphatic metabolism disorders (osteoporosis/fibro-osseous disorders)
☐ Other local or systemic disorders that may have an influence: _____

Incident:

Nature of the incident:

☐ Breakage/fracture
☐ Rust/oxidation
☐ Blocking
☐ Staining/corrosion
☐ Other (please specify)

When did the incident occur:

☐ On receiving the product
☐ On opening the packaging
☐ On being used in the mouth
☐ When taking an impression
☐ When the post was inserted
☐ When the prosthesis was inserted
☐ After the operation
☐ During cleaning, sterilisation

Type of treatment

☐ Single
☐ Multiple
☐ One-session surgery
☐ Two-session surgery
☐ Full
☐ Temporary restoration

What is the impact of the incident on the patient:

☐ Rescheduling of an appointment before surgery
☐ Suspension of surgery in progress
☐ Injury
☐ Other (please specify)

Cases of fracture, breakage, blocking, deformation, and matting

Do you think one or more of the following factors is linked to this incident?

☐ Trauma/accident
☐ Changes to the ancillary device due to grinding
☐ Limitation of mouth opening
☐ Changes to the prosthetic component due to grinding
☐ Poor irrigation/overheating of the bone
☐ Overloading of equipment
☐ Problems with occlusion
☐ Parafunctional habits/bruxism
☐ Bone quality, *underline the relevant type* (a/ type I b/ type II c/ type III d/type IV)
☐ Position of adjacent and opposite teeth, *underline the relevant tooth* (a/ natural tooth; b/ single, multiple prosthesis(es); c/ no tooth)
☐ Other (please specify) ……

Prosthesis present? ☐ Yes ☐ No

Type of prosthesis used?

☐ Crown
☐ Bridge
☐ Partial removable prosthesis
☐ Full removable prosthesis
☐ Other (please specify)

Type of assembly?

☐ Cemented
☐ Screwed in
☐ Stabilised by attachment
☐ Telescopic
☐ Other (please specify)

Material used for the prosthesis?

☐ Metal
☐ Resin
☐ Ceramics
☐ Zirconia
☐ Other (please specify)

Implant used:

Reference Batch number

Date used: 27/02/2025

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Staining, wear, and corrosion

What cleaning method is used?

☐ Manual only ☐ Ultrasound ☐ Thermal disinfection ☐ Other (please specify)

What product was used for cleaning?

☐ Chlorhexidine 2% ☐ Saline solution ☐ Alcohol 70%
☐ Hydrogen peroxide (H2O2) ☐ Aldehyde: product name ☐ Other (please specify)

What equipment was used for cleaning?

☐ Nylon brushes ☐ Multi-purpose sponge ☐ Wire brush ☐ Steel wool
☐ Other (please specify)

Do you work with irrigation? ☐ Yes ☐ No

Soak time: _____in minutes

Did you perform drying after cleaning? ☐ Yes ☐ No

If so ☐ In air ☐ Specific equipment: _____

What decontamination and sterilisation method is used?

☐ Autoclave ☐ Chemiclave ☐ Dry heat ☐ Tray with ultrasound
☐ Thermal disinfector ☐ Manual method ☐ Other (please specify)
If autoclave: programme used_____ and duration_____

Equipment load rules observed (no overloading) ☐ No ☐ Yes
Equipment inspected and maintained in accordance with the manufacturer's instructions ☐ No ☐ Yes

Case involving packaging

Description of incident

☐ Inversion ☐ Foreign body ☐ Empty packaging
☐ Opened packaging ☐ Illegible information ☐ Other……

Other questions

More detailed explanation of the incident:

……
……
……
……
……
……

The returned product must be **autoclaved, packaged,** and **marked** as **sterile**.
Use suitable protection when sending items (bubble wrap etc.). **Any damage to or loss of the product will invalidate the warranty.**

Signature of clinician: **Date:**

Date used: 27/02/2025