BIOTECH DENTAL

Warranty Protocol for Dental Implants

All Biotech Dental implants must be handled and fitted 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 implant **MUST** be returned, together with all the elements involved (prosthetic phases etc.), **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 implant failure;
- **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

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The use of components that are not part of the Biotech Dental system will result in the rejection of all claims against Biotech Dental in terms of warranty or product replacement.

Case number: .....

Registration date: .....

INFORMATION ABOUT THE CUSTOMER

Name of healthcare establishment: Customer no.:

Name of clinician:

Distributor name (export):

Address: Telephone

Country: Sales Manager

Email:

INFORMATION ABOUT THE IMPLANT

Reference	Batch number	Date fitted (DD/MM/YYYY)	Date removed (DD/MM/YYYY)	Date of incident___
_____	_____	__/__/____	__/__/____	Implant site __

GENERAL INFORMATION ABOUT THE PATIENT

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

Is the patient a smoker? ☐ Yes ☐ No

If so, how many cigarettes/day: ☐ Fewer than 10 ☐ More than 10

Oral hygiene ☐ Excellent ☐ Good ☐ Average ☐ Poor

Bone quality ☐ Type I ☐ Type II ☐ Type III ☐ Type IV

Condition of the implantation site concerned:

☐ Dental agenesis ☐ Old tooth loss Date: __/__/____ ☐ Recent tooth loss Date: __/__/____ ☐ Immediate implantation (tooth present)

Covid and vaccination

Has the patient had Covid-19? ☐ Yes ☐ No

Have they been vaccinated against Covid-19? ☐ Yes ☐ No

If so, what type of vaccine was administered? _

Number of doses _____

Date used: 27/02/2025

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Medical history: ☐ Nothing to report

☐ Diabetes mellitus
☐ Vitamin D deficiency
☐ Radiotherapy and chemotherapy in the head and neck region
☐ Drug or alcohol abuse
☐ 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: _____
☐ Xerostomia
☐ Previous peri-implantitis
☐ Previous dental surgery at the site
☐ Allergies: _____

DESCRIPTION OF THE INCIDENT

☐ Implant fracture
☐ Mobility
☐ Choice of implant/medical device
☐ Peri-implant infection
☐ Other _____(Please specify)

In the case of implant failure, do you think one or more of the following factors is linked to the loss of the implant?

☐ Difficulties associated with surgery (sinus perforation, nerve compression, bone overheating, immediate implantation, inadequate bone quantity)
☐ Periodontal disease (local/generalised)
☐ Proximity to a lesion
☐ Immunosuppressed patient
☐ Coagulation disorder
☐ Proximity to a tooth or root within 1.5 mm
☐ Trauma/accident
☐ Problems with occlusion
☐ Excess biomechanical load
☐ Parafunctional habits (bruxism or other)
☐ Unsatisfactory result
☐ Other (please specify): _____

If Other, please specify (required):

Did the patient suffer any adverse effects?

☐ Nothing to report
☐ Pain
☐ Haematoma
☐ Permanent temporary local nerve damage
☐ Tissue necrosis following heating of the bone
☐ Sensitivity
☐ Loosening
☐ Inflammation
☐ Gingival hyperplasia
☐ Speech problems
☐ Infection
☐ Breakage or loss of a component
☐ Aesthetic problems
☐ Oedema
☐ Bone loss
☐ Temporary local nerve damage
☐ Lesion involving adjacent teeth
☐ Peri-implant issues over time, potentially leading to revision or removal of the implant
☐ Allergic reaction to the various materials contained in BIOTECH DENTAL implants

SURGICAL INFORMATION

To help us assess the warranty protocol, please return all the components used during implantation (implant, screws, prosthetic phase, instrument(s) involved in the failure)

Did you use guided surgery?

☐ Yes
☐ No

If so, which type:

☐ AtlaSurgery 1
☐ AtlaSurgery 2
☐ Pilot surgery
☐ Free-hand surgery

Comments

Date used: 27/02/2025

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Approximate number of drill bit uses: ☐ 1 to 10 ☐ 10 to 20 ☐ More than 20

Was a reamer used at the preparation stage? ☐ Yes ☐ No

Was primary stability achieved? ☐ Yes ☐ No **Implant torque**: _____N.cm

Surgery time: ☐ One-session surgery ☐ Two-session surgery ☐ Cosmetic procedure/Immediate care

Fitting of the implant: ☐ Manual ☐ Ratchet ☐ Contra-angle

Was a graft performed at the implant site?
☐ No
☐ Yes
If so:
☐ Before the intervention ☐ During the intervention
Date of graft:
(DD/MM/YYYY) __/__/____
Does the graft involve
☐ Bone ☐ Soft tissue

If soft tissue:
Was a membrane used? ☐ No ☐ Yes
Type of membrane: ☐ Resorbable ☐ Non-resorbable Material used:
If bone graft:

Type of bone augmentation performed: ☐ Sinus lift ☐ Ridge augmentation ☐ Other (please specify)

Was a bone substitute used: ☐ No ☐ Yes
Type of bone substitute: ☐ Allogenic ☐ Xenogenic ☐ Synthetic Material used:
Was a membrane used? ☐ No ☐ Yes
Type of membrane: ☐ Resorbable ☐ Non-resorbable Material used:

INFORMATION ABOUT THE PROSTHESIS

Was the prosthesis inserted? ☐ Yes ☐ No

If this is the case, please complete the paragraph below regarding information on the prosthesis

Types of prosthesis:
☐ Crown ☐ Bridge ☐ Partial removable prosthesis ☐ Full removable prosthesis

Type of assembly used:
☐ Cemented prosthesis ☐ Screw-retained prosthesis ☐ Removable prosthesis on an attachment ☐ Telescopic prosthesis

Type of post:
☐ Post from BD catalogue: BD post reference: _____ Batch number: _____
☐ Made-to-measure post: Manufacturer Biotech Dental Digital Other manufacturer: _____
☐ Other (please specify):

Screw or post screwed in with: ☐ Ratchet ☐ Contra-angle ☐ Manually
Screwing torque _____N.cm
Date of impression (DD/MM/YYYY): __/__/____
Date temporary prosthesis fitted (DD/MM/YYYY): __/__/____
Date final prosthesis fitted (DD/MM/YYYY): __/__/____

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Other questions:

What is the impact of the incident on the patient:

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

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:**