BIOTECH DENTAL

Guarantee Protocol for Dental Implants

All Biotech Dental implants must be handled and implanted following the surgical protocols recommended by Biotech Dental and in compliance with the indications and contraindications mentioned in the instructions for use.

The attached guarantee protocol only applies to Biotech Dental implants and those that have been implanted in compliance with the information listed above. The file will only be studied if the practitioner meets the following conditions:

- Implant returned, as well as all suspected items (Prosthesis parts, etc.) **that have been cleaned, sterilised and packaged in sterile packaging**;

- Send copies of the pre- and postoperative X-rays, as well as the X-ray showing the implant failure;

- **Return of the questionnaire below, completed <u>within one month following the failure</u>**.

This questionnaire will make it possible for us to analyse the case, with the objective being to improve our products. We ask that you please reply to all of these questions and send everything to the address below:

BIOTECH DENTAL
Quality Department
305 Allées de Craponne
13300 SALON DE PROVENCE
qualite@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 lead to the rejection of all claims made to Biotech Dental under the guarantee or for the replacement of the product.

INFORMATION CONCERNING THE CLIENT

Clinician's name: Client's No.:

Distributor's name (Export):
Practitioner's name (Export):

Address: Telephone:

Country: Reported by:
Email:

INFORMATION CONCERNING THE IMPLANT

Reference _____ Batch No. _____ Implant date (DD/MM/YYYY) __/__/____ Removal date (DD/MM/YYYY) __/__/____ Implant site __

DESCRIPTION OF THE INCIDENT

☐ Fracture of the implant ☐ Loss of sensitivity ☐ Fistula
☐ Peri-implant infection ☐ Oedema ☐ Others: _____
☐ Pain ☐ Bleeding
☐ Mobility

Was the prosthesis inserted? ☐ Yes ☐ No

Is this is the case, please complete the paragraph related to the information concerning the prosthesis.

In your opinion, is one of the criteria related to the loss of the implant?

☐ Trauma/Accident
☐ Inadequate quantity/quality of gum
☐ Proximity of a tooth that had undergone orthodontic treatment
☐ Perforated sinus
☐ Surgical problems
☐ Immunosuppressed patient
☐ Compressed nerve
☐ Inadequate bone quantity/quality
☐ Biomechanical overload
☐ Infection
☐ Immediate extraction/implantation
☐ Coagulation problems
☐ Bone overheating
☐ Other : _____

GENERAL PATIENT INFORMATION

Patient ID: Age: ☐ Female ☐ Male

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

Clinical exam of the implant site:

☐ Dental agenesis ☐ Post-extraction Date: __/__/____ ☐ Past edentulism Date: __/__/____ ☐ Recent edentulism Date: __/__/____

Medical history: ☐ Nothing of note

☐ Diabetes
☐ Radiation in the head/neck
☐ Disease treated with steroids
☐ Osteoporosis
☐ Chemotherapy in the period around the placement of the implant
☐ Abusive consumption of drugs or alcohol
☐ Uncontrolled endocrine disease
☐ Xerostomia
☐ Lymphatic disorders
☐ Fibro-osseous diseases
☐ Allergies: _____
☐ Bone metabolism disorder
☐ Other local or systemic diseases that could have an influence: _____

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Pre/peri-operative situation:

☐Periodontal disease ☐Bruxism ☐Parafunctional habits

☐Local infection ☐Complication during preparation of the site ☐Occlusion problems

Is the patient a smoker? ☐Yes ☐No

If yes, how many cigarettes/day: ☐less than 10 ☐more than 10

Hygiene around the implant ☐Excellent ☐Good ☐Average ☐Poor

SURGICAL INFORMATION

In order for the guarantee protocol to be reviewed, please return all of the components used during implant (Implant, screw, prosthesis phase, instrument(s), suspected reason for the failure)

Approximate number of uses of drills: ☐1 to 10 ☐10 to 20 ☐+20

Was the zone threaded/drilled? ☐Yes ☐No

Implant placement: ☐ Manual ☐Ratchet ☐Contra-angle

Implant torque: _____No. Cm

Was primary stability achieved? ☐Yes ☐No

Surgery time: 1 surgery time ☐ 2 surgery times ☐ Cosmetic procedure/Immediate care ☐

Was a bone graft realized on the site before implantation?

☐No ☐Yes : Date of the bone graft : (DD/MM/YYYY)

Was an increase in bone volume carried out during the intervention?

☐No ☐Sinus ☐Crest ☐Material used:

Was an RTG membrane used?

☐No ☐Yes ☐Absorbable ☐Non-absorbable ☐Material used:

Was a soft tissue transplant carried out on the site before implantation?

☐No ☐Yes : Date of the bone graft : (DD/MM/YYYY)

INFORMATION ON THE PROSTHESIS (Complete this section when the prosthesis is inserted)

Type of prosthesis

☐Crown ☐Bridge ☐Partial prosthesis ☐Complete prosthesis

☐Telescopic prosthesis ☐Sealed prosthesis ☐Screw-retained prosthesis

Biotech Reference: _____ Batch number: _____

Implant of the screw or foundation ☐Ratchet ☐Contra-angle ☐Manual implant Torque _____No. Cm

Provisional prosthesis implant date (DD/MM/YYYY): __/__/____

Final prosthesis implant date (DD/MM/YYYY): __/__/____

Comments:

The returned product must imperatively be **autoclaved, shrink-wrapped** and **marked** as **sterile.**
Use adequate protection during shipment (bubble wrap, etc.). **Any damage or loss of the product will lead to the end of the guarantee protocol.**

Practitioner signature: **Date:**