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Rx only

The below symbols conform with ISO 15223-1:2016 Medical device labels, labelling and information to be supplied
Part 1: General Requirements

Symbol	Title/Meaning	ISO 7000 Ref. No.
	Manufacturer	3082
FR	Date of manufacture	2497
	Use-by date	2607
REF	Catalog number	2493
LOT	Batch code	2492
	Do not re-use	1051
	Keep away from sunlight	0624
	Do not use if package is damaged	2606
	Do not resterilize	2608
	Keep dry	0626
NON STERILE	Non sterile	2609
	Consult instructions for use : Follow the link to the eIFU: https://ifu.biotech-dental.com	1641
	Caution, consult accompanying documents	0434A
STERILE R	Sterilized using irradiation	2502
	Double sterile barrier system	3704
MD	Medical device	
UDI	Unique Device Identifier	
CE	CE marking of conformity	
CE 0459	Medical device complying with European Directive 93/42/EEC	
Rx Only	Prescription device. Caution: U.S. federal law restricts this device to sale by or on the order of an authorised dentist.	
MR	MR Conditionnal	

These products must be handled by TRAINED, QUALIFIED individuals who HAVE READ these instructions.

1. INTENDED USE/INDICATIONS FOR USE

Kontact™ Dental Implant System is indicated for use in partially or fully edentulous patients to support maxillary or mandibular single unit, multiple-unit, or overdenture dental restorations. Kontact™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and the occlusal loading is appropriate. Kontact™ Dental Implant System 3 mm diameter implants and prosthetics components are indicated for use in surgical and restorative applications in the maxillary lateral incisor or mandibular incisor regions.
All digitally designed Kontact™ Dental Implant System CAD/CAM abutments are intended to be sent to a Biotech Dental validated milling center for manufacture.

2. DEVICE DESCRIPTION

BIOTECH DENTAL KONTACT™ dental implant system consists of:
- Kontact™ dental implants in Ti-6Al-4V ELI surgical grade titanium alloy which complies with ASTM F136/ISO 5832-3, Kontact™ S and Kontact™ S+ dental implants in surgical grade 4 titanium which complies with ASTM F67/ISO 5832-2.
- titanium alloy abutments which comply with the applicable standards,
- additional prosthetic titanium, titanium alloy, other metals or polymer components which comply with the applicable standards,
- ancillary medical grade stainless steel, titanium and titanium alloy instrumentation,

For the identification purpose, the majority of the instruments bear a visible reference and manufacturing batch number. The sterile products are identified on the packaging. If the word 'sterile' is not specifically stated, the products are supplied non-sterile and must be sterilised before use by the staff concerned. The dental implant system is radiopaque.

3. GENERAL CONDITIONS OF USE

The dental implant system must only be used by experienced surgeons:
- trained in implantology and techniques for the use of BIOTECH DENTAL medical devices,
- in the observance of the indications. contraindications and precautions which are to be indicated to the patient during the postoperative phase and which are mentioned in these instructions as well as in surgical and prosthetic protocols available on request,
- on premises compatible with the aseptic conditions required by these instructions,

Under no circumstances may the dental implant system be used with devices from another manufacturer During the period from implantation to load-bearing, BIOTECH DENTAL undertakes to replace any implant or prosthetic component, provided that the above-mentioned conditions have been observed. The practitioner will be responsible for complications resulting from any use which fails to comply with recommendations or asepsis. These complications may under no circumstances be attributed to BIOTECH DENTAL and will lead to the rejection of any claims against BIOTECH DENTAL involving warranty or product replacement.

4. CONTRAINDICATIONS

Kontact™ Dental Implant System must not be used in patients who present local and/or general contraindications to oral surgery. These contraindications must be carefully assessed when the decision is made by the surgeon. Among other things, the contraindications constitute:
- factors which interfere with the healing process and bone and tissue regeneration such as metabolic bone disease, connective tissue disorders, type 2 diabetes, steroid therapy, bone infections, alcohol and tobacco abuse, anticoagulant therapy,
- diseases or immunosuppressive therapies such as chemotherapy and radiotherapy,
- bone volume and bone quality which are insufficient for accepting implants in sufficient number and size and supporting functional loads,
- bruxism, parafunctional habits, occlusion and/or temporomandibular joint disorders,
- insufficient gum quality and/or quantity,
- oral infections and inflammation such as paradontitis and gingivitis,
- allergy to one of the components (see §2),
- poor oral hygiene.

5. PRECAUTIONS FOR USE

- In order to avoid swallowing or inhalation of small components, it is recommended that they be secured as much as possible.
- BIOTECH DENTAL must be informed of any incident or problem concerning an implant or instrument.
- Implant treatment is not recommended for pregnant or nursing women.
- WARNING : Small diameter implants and angled abutments are not recommended for the posterior region.

Preoperative precautions:
- The user must ensure that the material is in good condition and working properly before use. Under no circumstances must the material be used if damage to the surface or shape is visible.
- a patient evaluation is necessary for determining any factor which is likely to expose the patient to a risk resulting from insertion of the implant or which may affect the healing of the bone/soft tissue.

Certain criteria must be taken into consideration with regard to the indication for surgery and the choice of implant:
- the occlusal surface of the implant must ideally be smaller than the prosthetic tooth to ensure the flaring of the soft tissue and the emergence profile of the prosthesis,
- a minimum space of 1.5 mm between the implant and the adjacent root, 3 mm between 2 implants, and a minimum bone thickness of 1 mm around the vestibular and lingual surfaces of the implant,
- in the event of suspected hypersensitivity or proven hypersensitivity to foreign bodies, it is recommended that Ti-6Al-4V ELI titanium tolerance has been checked prior to implantation of the material.
- Radiographic and/or CT scan evaluation and a clinical treatment plan are essential for the purposes of ensuring complete safety.
- Selection of abutment gingival height should consider implant placement relative to bone crest and gingival depth. For implants placed sub crestal, it is recommended to select a gingival height at least 0.5 mm greater than the placement depth of the implant. For example, an implant placed 2 mm sub-crestal should be restored with a prosthetic device which has a 2.5 mm or larger gingival height component.

Peroperative precautions:
- Primary stability of the implant is essential,
- The choice of the type of implant and its size will be a matter for the surgeon; this will depend on the particular patient and the patient's pathology. The size and the nature of the osseous structures will determine the surgeon's choice. The surgeon will also have to consider the stresses exerted on the implant after the procedure,
- Implants must not be deformed. At the risk of causing abnormal fatigue of the implant, the manipulations will have to be progressive. An

excessive effort exerted on the implant might induce stresses exerted which could cause a fracture or deformation of the implant responsible for secondary effects. Tightening speed : 15 rpm. Maximum recommended tightening torque: 80 N.cm.
- It is up to the practitioner to determine the settings of the equipment depending on the particular clinical case, and to check that the equipment is working properly prior to every procedure. It is recommended that the drilling sequences be conducted at a slow speed and with profuse and constant external irrigation. The recommended rotational speed is from 700 to 1,200 rpm in the case of drilling, not exceeding 1,500 rpm, and 200 to 400 rpm for boring,
Since the drill are very sharp, caution should be exercised when gripping them in order to avoid being cut. In addition, due to their helical-fluted designs, their use can result in a drag phenomenon which is detrimental to drilling precision. In order to correct this possibility, it is recommended to use stops provided for this purpose,
- Cutting tools (countersinks, drills, taps and reamers) must not be used more than 20 times in order to prevent problems and any heating of the bone. A specific tracking sheet for the drills is available on request.
Post-operative precautions:
After insertion of the implant, osseointegration is achieved within 4 months (mandible) and 6 months (maxillary) respectively. The surgeon must establish post-operative follow-up and will be responsible for informing the patient concerning:
- actions to avoid following the insertion of an implant and the precautions to be taken in the course of normal daily activity. The patient must understand that prior to complete osseous consolidation, a metallic material is not as strong as healthy osseous structures, and that metallic materials will break if subjected to intense or abnormal stresses,
- the efficacy of the implant depends on their behaviour and his oral hygiene,
- potential risks and adverse effects associated with the insertion of a dental implant,
- the possibility of failure of osseointegrated implant,
- the need to report any sensitivity appearing in the operated area, per- or post-operatively,
- potential interaction with other procedures and therapeutic or diagnostic devices. Temporary abutments and temporary PEEK sleeves can remain in the patient for up to a maximum of 180 days.
The recommended tightening torque for abutments is 20 N.cm.

6. POSSIBLE ADVERSE EFFECTS

The implantation techniques are accompanied by contraindications and risks of use. They can also be related to use of the device as well as the surgical intervention and may include (a non-exhaustive list):
- pain, sensitivity, speech disorders, oedema and haematomas,
- loosening, rupture or loss of a component,
- transient or permanent local nerve injury,
- inflammation, infection, lesion of adjacent teeth,
- tissue necrosis following heating of the bone,
- gingival hyperplasia,
- aesthetic problems,
- an allergic reaction to various materials composing BIOTECH DENTAL implants.
- risk of peri-implant bone loss over time which may lead to revision or removal of the implant.

7. STERILITY AND TRACEABILITY

Sterile delivered Device: dental implants delivered with a cover screw in the implant packaging, are sterile (sterilisation by gamma radiation). The integrity of the packaging must be checked before use to ensure that the sterility of the contents has not been altered. Under proper storage, the packaging maintains sterility until the expiry date. Do not use if the packaging has been damaged. Dental implants supplied in double-barrier sterile packaging must be used once the blister strip has been opened. Usage cannot be deferred. Labels on the different levels of packaging as well as free labels will make it possible to ensure perfect traceability based on the reference number and the lot number of the implant. Sterile single-use devices should not be reused and re-sterilised under any circumstances. In case of re-sterilization of a non-re-sterilizable medical device, the prevention of iatrogenic transmission of pathogens by these devices is no longer guaranteed and materiovigilance incident may occur.
Non sterile delivered devices: ancillary instrumentation and prosthetic parts are supplied degreased but not sterile. It will be the responsibility of the concerned staff to proceed with decontamination, cleaning and sterilisation before and after every procedure (for reusable products) in accordance with current recommendations, unless otherwise stated on the labelling.

8. CLEANING AND STERILISATION OF NON-STERILE DEVICES

Warnings

Before use : Decontamination (Pre-disinfection) and cleaning are imperative before any sterilisation process takes place. Clean all devices to be sterilised, even instruments that have not been used. Applicable staff and facility : Any decontamination (pre-disinfection) and cleaning and sterilisation protocols can only be carried out by properly trained and protected staff at facilities that are suitable for the operations being carried out and in compliance with the regulations and standards in force.
Cleaning and decontamination products : In order to prevent deterioration or damage to the components, it is imperative that only decontamination (pre-disinfection) and cleaning products are used which are compatible with the different combinations of materials being treated. The selected product should provide protection against infectious risks through to its antimicrobial activity (bactericide EN 1040, fungicide EN 1275, virucide HIV-1, HBV and Herpes Virus).
Alkaline and corrosive products are prohibited for stainless steel and aluminium medical devices: bleach, aqueous hypochlorite solution and sodium chloride Using physiological saline solution is prohibited due to its corrosive effect on stainless steels.
Water quality: The water to be used for decontamination(pre-disinfection), cleaning, rinsing and sterilisation must comply with the regulations and standards in force.

Protocol

Decontamination (pre-disinfection) :
Decontamination must be carried out as close as possible to the site of use immediately after each intervention. It is imperative that dirt is prevented from drying on the material (< 2 hours). Completely immerse the previously disassembled devices and instruments in a compatible decontaminating solution that does not bind the proteins (neutral pH without aldehyde), according to the recommendations of the manufacturer (concentration, soak time). Low-frequency ultrasound bath soaking is recommended (make sure that cutting tools do not bump into each another). The decontaminating solution must be replaced after each use in order to prevent its saturation.
Cleaning : Cleaning may be carried out manually using a brush (e.g. soft nylon brush) in the decontamination bath.
Rinsing – Drying : Cleaning will be followed immediately by abundant rinsing with demineralised or osmosis-purified water; then the products must be meticulously dried prior to beginning the sterilisation process. Manual drying is preferred (complete the drying process with medical-grade compressed air).
Packaging : Regardless of the cleaning method is used, the material must be packaged immediately in order to avoid any new contamination. In the event of sterilisation on metal mesh trays, double wrapping paper must be used for packaging purposes. In case of late packaging (> 2 hours), cleaning may be reconsidered.
Sterilisation : Recommended steam sterilization cycles in the US: 132°C (270°F) for 4 minutes. Drying time 20 minutes. The use of dry heat is prohibited. Use a sterilization double pouch that is FDA-cleared for the indicated cycle.
Return: After the instrument has been used in the event of a loan it must be returned to BIOTECH DENTAL, after it has been cleaned and decontaminated. It is incumbent upon the healthcare institution or the practitioner to ensure that the cleaning/sterilisation process is effectively implemented (equipment, materials and operator) and achieves the desired result. Under no circumstances will BIOTECH DENTAL be held liable for improper sterilisation due to the loaned instrument.

9. HANDLING AND STORAGE

The products must be handled and stored carefully in order to ensure prevention of contamination and deterioration prior to any surgical intervention. Storage must be performed with care in a suitable, dry and clean location. They must not be exposed to direct sunlight, ionising radiation, extreme temperatures, particulate contamination, or be in contact with or close proximity to products that may have a corrosive effect. The lifecycle of devices can be compromised by carelessness during handling or improper protection of the instruments.

10. DISPOSAL

The disposal of medical waste must comply with applicable legislation. The professional who produces waste will be responsible for sorting between infectious waste and waste which is compatible with household waste.

11. MRI SAFETY INFORMATION

MR Conditional

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with a Kontact™ Dental Implant System device can be scanned safely in an MR system under the following conditions:

Given potential instability during the implant healing period, it is recommended that MRI scans take place 6 months after implant surgery.

Device Name	Kontact™ Dental Implant System
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

12. DESIGN PARAMETERS

Design limitation parameters for CAD/CAM titanium base abutments, CAD/CAM premill abutments (titanium blanks), hand-milled FitPost abutments are included in the following tables.
For CAD/CAM titanium base abutments, BIOTECH DENTAL recommends to use zirconia mesostructure material that conforms to ISO 13356, Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (YTZP) and CemPlant Implant cement to affix the zirconia superstructure.

12.1 CAD/CAM TITANIUM BASE ABUTMENTS (ZIRCONIA PORTION)

Min Gingival Height (mm)	Max Gingival Height (mm)	Min Prosthetic Diameter (mm)	Max Prosthetic Diameter (mm)	Min Zirconia Wall Thickness (mm)	Max Post Correction Angle °	Min Post Height (mm)	Max Post Height (mm)	Abutment Height (mm)
0.7	4.3	3.9	6.4	0.5	0	4	12	15

Titanium Base Gingival Height (mm)	Zirconia Min Gingival Height (mm)	Zirconia Max Gingival Height (mm)	Total Max Gingival Height (mm)
0.7	0	4.3	5
1	0	4	5
2	0	3	5
3	0	2	5
4	0	1	5
5	0	0	5

12.2 PREMILL ABUTMENTS (TITANIUM BLANKS)

Implant Platform Diameter (mm)	Min Gingival Height (mm)	Max Gingival Height (mm)	Min Gingival Diameter (mm)	Max Gingival Diameter (mm)	Min Wall Thickness (mm)	Max Post Correction Angle °	Min Post Height (mm)	Max Post Height (mm)	Abutment Height (mm)
3.0	0.5	5.0	3.9	6.4	0.45	15	4	12	15
3.6 and larger	0.5	5.0	3.9	6.4	0.55	30*	4	12	15

* 22° maximum correction angle with Kontact™ implants

12.3 FITPOST ABUTMENTS

Min Wall Thickness (mm)	Min Post Correction Angle °	Max Post Correction Angle °	Min Post Height (mm)	Max Post Height (mm)	Max Abutment Height (mm)
0.55	0	30*	4	8	13

* 22° maximum correction angle with Kontact™ implants

For additional information please contact the manufacturer
Please consult our website Biotechdentalusa.com/mc and/or the restorative manual for more information about the milling centers.

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