BIO CLASSIC DENTAL IMPLANTS

BIO HEALTH DO BRASIL LTDA

VALID FOR ALL COUNTRIES, EXCEPT BRAZIL

Manufacturer / Distributor in Brazil:
BIO HEALTH DO BRASIL LTDA.
R. Laureano Garcia, 1-275 ·
Distrito Industrial II · Bauru SP · 17039-760
Tel 14 4009 2400 · SAC 0800 770 3824
Indústria Brasileira
www.implante-bio.com.br

CE
2460

EC REP **Bionnovation Europe S.L**
NIF B66633330
Calle Enmedio, 20 1a Planta 28850
Torrejón de Ardoz Madrid, España
Phone + 34 615371648

ANVISA Registration nº:10392710007
Technical Responsible: Gustavo Telli Athaide **CREA-SP** 5069918500
Technical Product Name: Dental Implants (Osseointegrable) (2701125)
Trade name: Dental Implants Bio Classic

Keep out of the sun

Keep dry

Do not use if the packaging is damaged

See instructions for use

Temperature Limit

Do not reuse

Do not resterilize

Product sterilized by gamma radiation

Expiration date

Manufacturing date

Lot

Reference / code

1. DETAILED DESCRIPTION OF THE MEDICAL PRODUCT, INCLUDING THE FUNDAMENTALS OF ITS OPERATION AND ITS ACTION, ITS CONTENTS OR COMPOSITION, IF APPLICABLE, AS WELL AS LIST OF ACCESSORIES INTENDED TO INTEGRATE THE PRODUCT.

Osseointegrated dental implants are devices inserted into the bone tissue of mandibles and / or maxillary of partially or totally edentulous patients in order to replace the roots of the missing teeth and even support single or multiple dentures.

The titanium, raw material of the implants, is a biocompatible and non-cytotoxic material that naturally produces a layer of oxides capable of attracting bone cells from adjacent tissue and then induced by this physicochemical process, tend to deposit in the external layer of the metal, securing the implant to the bone tissue. Titanium also allows the installation of implant-supported dental prostheses.

Bio Classic Dental Implants are subjected to a surface corrosion treatment, Supex. The Supex treatment provides a rough texture to the metal, which facilitates the migration of bone cells and increases the area of contact between implant and tissue, accelerating the osseointegration process and the dynamic interaction process between the metal surface of the implants and the tissue Bone.

The Bio Classic Dental Implant family has implants with Conical and Cylindrical formats. In the case of dental implants CM Biomorse the torque is applied directly on the implant, dispensing the use of assemblers.

List of accessories that should integrate the Bio Dental Implants

	**Cover cap -** It avoids waste deposit and even gum invagination in the implant's internal thread. Models: CM BIOMORSE	**Cover cap Models:** Cover cap CM Biomorse
	**Bushing** –Implant Fixation in the package (plastic tube), support, it avoids damaging the product.	

BIO Health do Brasil LTDA
Rua Laureano Garcia, 1-275 - Distrito Industrial II - CEP 17039-760 - Bauru/SP BRASIL
Tel.: 55 14 4009 2400 / SAC: 0800 770 3824

1.1 DENTAL IMPLANTS WITH BIOMORSE

Dental implants Biomorse have an accurate internal conic format, which during installation of the abutment into the implant promotes a close adaptation between the interposed surfaces, acquiring a mechanical resistance similar to a single piece.

It is considered the internal retention system of the prosthetic element on the implant, employing the mechanical friction between the prosthetic component's contact surface and the implant's internal wall.

Implants with Biomorse have been developed to improve the biomechanical properties of the implant/pillar prosthetic sets, and to reduce the incidence of the mechanical problems found in the internal and external hexagon systems.

The connections provide a better adaptation between the prosthetic component and the implant, reducing micro-gap between component and implant, reducing the peri-implant bone reabsorption levels, also providing a better mechanical stability for the pillar, minimizing the occurrence of micro-moves. The micro-moves cause an increase in the incidence of relaxation and screw fractures. The Biomorse implants have a better anti-rotational fixation with indexer and greater resistance through the implant/pillar set fixed with a screw because the close link between both of them practically provides a mechanical response similar to a single body one and the incidence of mechanical complications are low. The Biomorse has greater ability to support horizontal loads because it has a higher interposition surfaces between the implant and the abutment, also has better stability of bone and gum tissues (discreet absorption).

The internal geometry of implants is comprised of a hexagon whose function is to convey the insertion torque to the implant. This internal torque system avoids the use of an assembler, eliminating the need of making transversal grooves on the implant's platform, decreasing bacterial proliferation and facilitating prosthesis hygiene.

The **Biomorse XP** implants have cut chambers at 120°, micro threads with round profile, double thread (faster installation), internal hexagon fitting for installation and anti-rotational fitting for the prosthesis, active conic apex to facilitate installation and lack of smooth collar. As regards the **Biomorse EZ** implants, they have cut chambers in the shape of a helix, micro threads with round profile, double threads with variable levels, spirals with high cutting power, and conicity in the internal part of the thread (conic core), and lack of smooth collar. **Biomorse SWE** implants have cutting chambers with through holes, micro threads with rounded profile, double threads with varying levels, coils with high cutting

power, taper in the inner part of the thread (conical core) and absence of smooth collar. Check recommended maximum torques according to **table 4.**

IMPLANTCM BIOMORSE CONICAL	IMPLANTCM BIOMORSE XP	IMPLANT CM BIOMORSE EZ
		

WARNING: The images above are merely illustrative. They do not represent the actual surface dimensions and characteristics of the product.

Table 1 - Biomorse Classic, Conical and SWE Dental Implants. Available in diameters and lengths

Ø	3,50	3,80	4,00	4,30	4,50	5,00	5,50
LENGTHS	7,0	7,0 mm	7,0 mm	7,0 mm	7,0 mm	7,0 mm	7,0 mm
	8,5	8,5 mm	8,5 mm	8,5 mm	8,5 mm	8,5 mm	8,5 mm
	10,0	10,0	10,0	10,0	10,0	10,0	10,0
	11,5	11,5 mm	11,5 mm	11,5 mm	11,5	11,5	11,5
	13,0	13,0 mm	13,0 mm	13,0	13,0	13,0	13,0
	15,0	15,0	15,0	15,0	15,0	15,0	15,0
	18,0	18,0	18,0	18,0	18,0	18,0	18,0
	21,0	21,0	21,0	21,0	21,0	21,0	21,0

Accessories integrating and exclusive of the Biomorse Implants:

Bush;

Cover cap.

List of optional accessories exclusive to the installation of the Biomorse implant (sold separately, do not accompany the product and have separate registration).

Wrenches for Implant with Cone Morse type connection	
 **Long** **Short**	**Wrenches for Biomorse Torque** – used for installation and application torque in the implant. The Wrenches for Biomorse torque follow an internal design for adaptation in a Bio torque wrench.
 **Long** **Short**	**Biomorse contra-angle wrenches –** used for installation and application torque in the implant with surgical engine (counter - angle). The fittings of Contra-angle **Biomorse contra-angle wrenches** are in accordance with ISO 1797- Dentistry - Shanks for rotary and oscillating instrument, in which their manufacture is monitored.
Assembler of the Biomorse Implant with Morse Cone	
	**Assembly -** Morse Cone Wrench for contra-angle adapted to the Biomorse implant. Longitudinal cut, featuretofitting in the cervical region

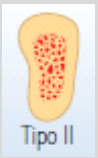
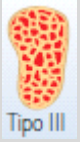
BIO Health do Brasil LTDA
Rua Laureano Garcia, 1-275 - Distrito Industrial II - CEP 17039-760 - Bauru/SP BRASIL
Tel.: 55 14 4009 2400 / SAC: 0800 770 3824

The Biomorse implant must be installed with the contra-angle only until obtaining a torque of 32Ncm and then the ratchet must be used.

Table 2 - Indication of Use Biomorse Implants.

Implants	Indications
Biomorse XP	-Used for single or multiple rehabilitations; - Type of bone classification for installation (recommendation): Ø 3.5mm: Bone type I, II, III and IV - Indicated for all teeth except molars; Ø 4.0 mm: Bone typeI, II, III and IV – Indicated for all teeth except lateral incisors and lower incisors; Ø 5.0 mm: Bone typeIII and IV- Indicated for molars.
Biomorse EZ	-Used for single or multiple rehabilitations; - Indicated for post-extraction installations; - Type of bone classification for installation (recommendation): Ø 3.5mm: Bone type I, II, III and IV- Indicated for all teeth except molars; Ø 4.0 mm: Bone type I, II, III and IV- Indicated for all teeth except lateral incisors and lower incisors; Ø 5.0 mm: Bone type III and IV- Indicated for molars.
Biomorse	-Used for single or multiple rehabilitations; - Indicated for post-extraction installations; - Type of bone classification for installation (recommendation): Ø 3.5mm: Bone type I, II, III and IV- Indicated for all teeth except molars; Ø 4.0 mm: Bone type I, II, III and IV- Indicated for all teeth except molars; Ø 5.0 mm: Bone type III and IV- Indicated for molars.
Biomorse SWE	-Used for single or multiple rehabilitations; - Indicated for post-extraction installations; - Type of bone classification for installation (recommendation): Ø 3.5mm: Bone type I, II, III and IV- Indicated for all teeth except molars; Ø 4.0 mm: Bone type I, II, III and IV- Indicated for all teeth except lateral incisors and lower incisors; Ø 5.0 mm: Bone type III and IV- Indicated for molars.

Table 3 - Bone classification

	Bone type I	Bone type II	Bone type III	Bone type IV
				
Implants with CM Biomorse	•	•	•	•

1.2. Recommended Implant Installation Torques:

The Bio Classic dental implant family has tapered and cylindrical shapes. In the case Biomorse and Biomorse SWE implants, the torque is applied directly over the implant, eliminating the use of fitters. The insertion torques of the implants vary between 45N.cm and 55 N.cm, according to the table below:

Table 4 - Maximum recommended torque according to implant type.

Implant Type	Platform / model	Recommended maximum torque (N/cm)
Biomorse Implant	**Biomorse Implant**	45 N/cm
	Biomorse XP Implant	45 N/cm
	Biomorse EZ Implant	45 N/cm
	Biomorse SWE Implant	45 N/cm

1.3. Drill Protocol

It is a professional choice the sequence of installation drills according to the previous evaluation of the implant to be used, for choosing the sequence of drills Bio Health recommends tables 1.3.1 Biomorse Implant, the choice of drill diameter influences stability and primary fixation of the implant, the drilling depth must be in accordance with the planned implant length.

1.3.1 Biomorse Implant

Drill Protocol	Biomorse			Biomorse XP			Biomorse EZ		
	Ø3,50mm	Ø4,00mm	Ø5,00mm	Ø3,50mm	Ø4,00mm	Ø5,00mm	Ø3,50mm	Ø4,00mm	Ø5,00mm
Lance Drill	X	X	X	X	X	X	X	X	X
Helicoidal Drill Ø2,2	X	X	X	X	X	X	X	X	X
Conic Drill Ø2,8	X	X	X	X	X	X	X	X	X

Conic Drill Ø3,2	X	X	X	X	X	X		X	X
Conic Drill Ø3,6		X	X		X	X			X
Conic Drill Ø4,4			X			X			X

2 COMPOSITION

Bio Implants are produced with grade 4 titanium, according to the Standard ASTM F67 e ISO 5832-2.

3 FORMS OF PRESENTATION IN MARKET OF THE MEDICAL PRODUCT

Content:01 dental implant vv, ww, x,xx mm X yy,yy mm, machined with titanium G4 alloy, fixed to the protection and support bushing, packed in plastic tube with silicone cap containing a cover cap (ww) as primary package. As a secondary package, the product is packaged in rigid and transparent blister pack (PETG film) sealed with surgical grade paper Tyveck® (high density polyethylene fibers) and in tertiary package, a box made of cardboard triplex with attached adhesive label for Product Identification. There are three adhesive labels with information for traceability of the product that must be attached to the medical record, in the document to be delivered to the patient and in the tax documentation that generates the charge. **See annex:** Bio Classic Dental Implant family table: Model (vv); Platform (ww), diameter (x, xx mm), length (yy, yy mm) and cover cap (ww).

4. INDICATION, PURPOSE OR USE INTENDED FOR THE PRODUCT, ACCORDING TO MANUFACTURER'S RECOMMENDATIONS

Treatment with implants is indicated for cases where there is a need for replacement of lost dental elements. The purpose of the treatment is the installation of dental prostheses to recover aesthetics and masticatory function.

The choice of implant diameter, length and platform should respect bone quantity and quality, prosthetic space, as well as anatomical repairs, through previous radiographic and clinical analyzes.

The indication is through the diameter of the prosthetic platform, ie the surface where the connection of the implant with the prosthetic component occurs.

The criteria for choosing implants and implant platforms that will be installed are the responsibility of the specialized professional.

5. INSTRUCTIONS FOR USE OF MEDICAL PRODUCT

1. The planning should also take into consideration the prosthetic options most appropriate to the masticatory forces balance, occlusal adjustment, esthetics and other factors related to the good performance of the prosthesis. The exchange of information between the dental surgeon, the prothesis specialist and the laboratory technician is important for the success of the treatment.
2. After implant installation, the surgeon should evaluate the initial stability to determine if the implants may or may not receive immediate function.
3. Surgeries should be performed with special care about refrigeration, which should be done continuously with saline solution, gradual increase of drill diameter and low speeds because the high heat can cause permanent damage to host tissue and the consequent loss of implant. The milling sequence indicated for each implant diameter is described in table 5 below.
4. Implants with External Hexagon (EH) and Internal Hexagon (IH) are in the public domain.

6. RESTRICTIONS, SPECIAL CARE AND CLARIFICATIONS ON THE USE OF MEDICAL PRODUCT, STORAGE, TRANSPORT AND PRODUCT DISPOSAL

1. STERILE - provided that an integrity of the package, shelf-life and storage conditions are maintained;
2. Implants should only be used for their intended purpose;
3. The implants are supplied in sterile double packaging (25 kGy Gamma Radiation). Since the integrity of the package is not compromised in any way, save the sterile product to 5 years from the date of sterilization;
4. In cases of Adverse Effects occurring in the patient, the responsible professional should contact the SAC Bio Health immediately (Customer Service) by phone **0800 770 3824** or email sac@implante-bio.com.br. Bio Health do brasil Ltda and all others involved (dentists, patients and physicians) are responsible for notifying ANVISA (Sanitary Surveillance Agency - Brazil) of the relevant occurrences according to internal technovigilance procedure, by the website www.anvisa.gov.br/notivisa;
5. Should any adverse effects occur with the patient on the use of our products in the European Community, countries should contact our authorized representative Bionnovation Europe SL by phone +34 931407240 and / or contact the factory and by email sac@implante-bio.com.br . Recalling that professionals are responsible for reporting adverse events to local authorities within

the European Union, health monitoring contact points are listed on the European Commission website: http://ec.europa.eu/health/medical-devices/links/vigilance_contact_points_en.htm.

6. Bio Dental System are Developed in order to avoid its use compromising patients' clinical status and safety;
7. The bone region to be implanted must be exposed and prepared (drilled) with appropriate drills to receive the implant. The milling sequence indicated for each implant diameter is described in table below:

Table 5 - Milling Sequence for Bio Classic Dental Implants

Ø 3,50 mm	Ø Ø 4,00 mm	Ø 5,00 mm
Lance	Lance	Lance
Helical Ø 2,20 mm	Helical Ø 2,20 mm	Helical Ø 2,20 mm
Helical Ø 2,80 mm	Helical Ø 2,80 mm	Helical Ø 2,80 mm
ConicØ3,20 mm	ConicØ3,20 mm	ConicØ3,20 mm
	ConicØ3,60 mm	ConicØ3,60 mm
	ConicØ4,00 mm	ConicØ4,00 mm
		ConicØ4,20 mm
		ConicØ4,40 mm

OBS: The cutters should be replaced regularly to maintain cutting efficiency. They do not accompany the product, sold separately.

The sequence of drills may vary according to the bone quality presented in radiographic planning.

6.1. WARNINGS AND RESTRICTIONS

1. PROFESSIONAL USE ONLY – Bio Classic Dental Implants should be implanted only by dentists and professionals with knowledge of implant techniques;
2. PROHIBITED TO REUSE, REPROCESSING OR RESTERILIZE: If reused, resterilized or reprocessed, oxidation may occur on the surface of the implant, with fibrointegration occurring instead of osseointegration. Bio does not recommend re-use, resterilization or reprocessing. Disposal should be in accordance with applicable environmental and biosafety laws. Do not dispose of contaminated products in normal household waste;
3. The use of the product with inadequate surgical techniques and biosafety conditions may harm the patient leading to unsatisfactory results;
4. Always sterilize surgical instruments before using them;

5. Careful clinical and radiographic evaluations are necessary for the correct planning of the treatment as well as for the verification of anatomical structures that must be observed before the perforation. An adequate margin of safety adjacent to other teeth and vital structures should be preserved;
6. In all operations involving dental implants observe the appropriate techniques of asepsis and antisepsis;
7. Abusive use of alcohol, tobacco, drugs, steroids or lack of proper oral hygiene can significantly impair the success of treatment;
8. It is supplied in the sterile state and after opened should be used under aseptic conditions. Always work with sterile fields, instruments appropriate to the procedure and in a good state of conservation in order to eliminate sources of infection;
9. If uncontrollable complications, tissue inflammation or evidence of infection arise, immediate removal of the implant is recommended;
10. Implants with Ø 2.9mm are indicated for lower incisors and unitary prosthesis. The use in areas not indicated can fractures the implant. Dental professional is responsible by use;
11. The installation of the CM Biomorse implant should always be parallel, without angles and installed 2mm below the crest;
12. The surgeon should evaluate the indication in patients who are carriers of diseases or who use medications that may alter the repair metabolism;
13. If there is an impact and it has scratches, fissures or dents of great intensity that may impair the proper functioning of the product, it must be discarded and a new one must be purchased. The impact can cause damage to the platform and dimensional characteristics.
14. MAGNETIC RESONANCE (MR) - SAFETY INFORMATION The Bio Implants has not been evaluated for safety in the MR environment. It has not been tested for heating, migration, in the MR environment. The safety of products Bio in the MR environment is unknown. Scanning a patient with this device can result in injury to the patient with tissue damage due to radiofrequency-induced heating and metallic implants can result in image artifacts that cause misinterpretation of results.
15. There are no contraindications for implant placement in elderly patients, as long as the previous evaluation (anamnesis), quantity and sufficient bone quality are respected.

6.2. ADVERSE EFFECTS

All potential adverse effects should be informed in advance to the patient.

The following complications associated with surgery are listed as adverse effects:

1. Dehiscence, inflammation, bone loss, hemorrhage, allergic reaction, fracture and / or implant loss;
2. There may be no osseointegration or subsequent loss of the implant in cases where there is no quality or quantity of bone.
3. Incorrect surgical technique may cause discomfort such as painful sensation, hypoaesthesia and edema.
4. The implants can cause interference or distortion in the images, in magnetic resonance imaging.

6.3. CONTRAINDICATIONS

1. Implants should not be placed in existing active infection or any other degenerative disease that affects the placement of implants;
2. It should not be used in patients who are not clinically fit to undergo dental intervention. As for example, in patients with blood disorders such as Diabetes Mellitus and uncompensated periodontal disease;
3. Bio implants is not intended for procedures where the patient does not have complete bone formation (patients pediatric);
4. Contraindicated for other procedures besides of recommended in "Intended Use"
5. Is safe for implants a waiting period of 6 to 8 weeks should be enough to allow the implant to be held securely in the tissue, which should be safe for MRI scan.

6.4. PRE– and POST-OPERATIVECARES

In the preoperative evaluation, the correct indication of the materials and the use of techniques and compatible procedures, as well as monitoring and postoperative controls are essential to the desirable results.

PREOPERATIVE CARE

The anamnesis must be made so that the dentist knows the patient's health history and condition, the surgeon must evaluate the indication in patients who have pre-existing diseases such as Diabetes Melitus and periodontal disease or who make use of medication that can alter reparational

metabolism, preferably patients who will undergo implant placement will be accompanied by a person who can drive.

All patients who will be undergo the surgical procedure should be carefully examined and evaluated in order to determine the physical and radiographic condition, as well as bone deficit or adjacent soft tissue that may influence the outcome of the intervention.

Also, they need a prior evaluation in order to minimize situations that could compromise the success of the treatment or even the safety of the patient.

POSTOPERATIVE CARE

Observe postoperative care for surgical procedures. Painkillers, antibiotics and rest for 24-48 hours may be prescribe, varying according to the procedure and the professional technical conduct.

Immediately after surgery to install the implant the patient should avoid any activity that requires excessive physical effort, do not smoke, do not drink alcoholic drinks, use ice pack press, ingest cold or icy foods. Pain, swelling, discomfort, phonetic difficulties and inflamed gingiva may be reactions of the surgical procedure. If these reactions persist the surgeon should be consulted. Guide the patient about the need to follow-up after surgery, alerting the importance of strictly obeying all guidance on care, nutrition, prescription of medicines, and special care with the patient's oral hygiene. The period for removing the suture must be longer than 7 days depending on the type of suture used determined in the professional's surgical planning.

Depending on the lifetime of use of the implants, it is recommended that the professional assess the conditions of the implant and prosthesis, including accessories, abutments and crowns to check the need for adjustments or removal after a long period of use. The stability of the implants can be compromised due to loosening of fixation between implants and prostheses, so they must be evaluated by the professional after long periods, in case of any deviation, the professional should evaluate the best procedure, which can be replaced if necessary.

Instruct the patient as to the need for a professional medical monitoring annual to assess osseointegration and prosthesis placement. The professional in charge is responsible for providing these guidelines.

7. CONDITIONS OF STORAGE, CONSERVATIONOR HANDLING OF MEDICAL PRODUCT.

7.1. STORAGE AND TRANSPORTATION

Transport and store the product away from direct sunlight, and from heat (maximum temperature: 15 -25° C and humidity .Keep the package sealed until the moment of use. Make sure of the integrity of it before use. Do not use if sterile package be opened or damaged or validity date expired to avoid possible contamination. Disposal the product mischaracterized according legislation for medical waste or return the damaged package and the included device to the Factory.

7.2. CONSERVATION AND MANIPULATION

In case of any change in the characteristics of the implants, discard it in a discharacterized way according to current legislation for hospital waste orreturn the damaged package and the included device to the Factory.

8. PRODUCT DISPOSAL CARE

The disposal of the product must comply with environmental laws and existing biosafety. Do not dispose of contaminated products in normal waste.

LEGAL GUARANTEE TERM

(According to the Protection and Defense of Consumer Code: Law 8.078 of September 11, 1990).

In compliance with Article 26 of Law 8.078, of September 11, 1990, the ***Bio Health do Brasil LTDA*** company establishes the right of the consumer to complain about apparent defects or about easy verification of all products manufactured and marketed by it for a period of 90 days from the effective date of delivery of the products.

In the case of hidden defects, the decadential period starts when the defect is evidenced, as provided in Paragraph 3 of Article 26 of Law 8.078.

In order for this Legal Guarantee Term to take effect, the consumer must observe the conditions described below:

Do not allow unauthorized persons to handle the materials in question.

Do not allow the improper use as well as misuse of the materials in question.

Follow all the guidelines for use, as well as the care described in the User Manual or Instructions for Use.

We declare true the information presented in this Model of Instructions for Use