COMPONENTS PROSTHETIC STERILE BIO

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.: 10392710008
Technical Responsible: Gustavo Telli Athaide CREA SP 5069918500
Technical Product Name: Dental Implant Components (2101397)
Trade Name: Prosthetic Components Sterile Bio

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 GROUNDS OF ITS OPERATION AND ACTION, ITS CONTENT OR COMPOSITION, WHEN APPLICABLE, AS WELL AS RELATIONS WITH ACCESSORIES AIMED AT WORK WITH THE PRODUCT.

The Bio prosthetic components are used for the preparation of dental prostheses that will be fixed on dental implants. Bone-integrated implants are devices inserted into the bone tissue of mandible or jaws of partially or totally edentulous patients with the purpose of replacing the roots of the missing teeth.

The family of Sterile Prosthetic Components consists of the following components:

I. Intermediate Abutments:

a) **Mini Conical Abutment (Straight or Angled):** The straight mini conical abutment is an intermediate abutment used between the implant and the prosthesis, composed of 1 (one) single part: ring-shaped body and bolt connected, already the angled mini conical abutment is composed of two parts: ring-shaped body and final loose screw. It has variations in relation to the prosthetic interfaces of the implants, being it can be, Cone Morse.

The prosthetic component mini conical abutment is available in a straight or angled format and at different heights, correcting the inclination of the installed implants. It is indicated only for screwed prostheses, being single or multiple prostheses.

II. Definitive Abutments

a) **Spherical abutment:** used for overdenture retention (total prosthesis), the spherical abutment is a definite abutment with cylindrical shape indicated to be screwed in the implant and receive or support the total prosthesis over it by means of buttoning.

b) **Universal abutment (straight or angled):** it is a definitive abutment used to make the definitive prosthesis with the purpose of customizing the prosthesis anatomy, it is available in a straight or angled format, with or without indexer (hexagon) and at different heights, both gingival as coronary (4.0 and 6.0mm). The Universal Abutment is positioned directly on the platform of the Morse Cone Implant and comes with a universal abutment screw.

III. Definitive Independent Screw

A) **Screws for Abutment:** Screw used to fix the prosthesis (cemented or screwed) directly on the implant or on the intermediate abutment, thus avoiding the movement of the prosthesis and reducing the risk of implant loss and bacterial growth.

B) Screw for Mini Conical Abutment: Screw used to fix the mini conical abutment directly over the implant, thus avoiding the movement of the prosthesis and reducing the risk of implant loss and bacterial growth.

IV. Healing Cap:

Cylindrical abutment with seating platform according to each implant model (Morse Cone). It is indicated for the healing period of the soft tissue and for protection of the implant avoiding invasion of the mucosa in the implant. After healing can be replaced by one of the abutments, according to the prosthetic solution chosen by the professional.

2. COMPOSITION

The Bio Prosthetic Components are produced in titanium ASTM F136 Aluminum Vanadium.

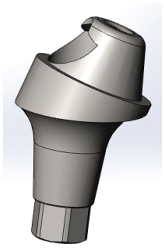
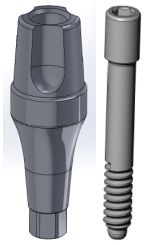
3. FORMS OF COMMERCIAL PRESENTATION

A Sterile Prosthetic Component packed in rigid and transparent blister pack (PETG), sealed with Tyveck® surgical grade paper (high density polyethylene fibers) and in secondary packaging made of triplex paper with attached adhesive label for product identification. Sterile Prosthetic Component is accompanied by 03 adhesive labels with information for traceability of the product that must be attached to the clinical report, in the document to be delivered to the patient, and product sales invoice.

Sterile Prosthetic Component is offered in three types of fitting: Cone Morse (CM). They are available in different formats, diameters and heights, in order to meet different clinical needs.

List of Sterile Prosthetic Components Models

DEFINITIVE ABUTMENT	
 **Spherical abutment CM**	Spherical abutment CM 0,0 mm Spherical abutment CM 0,8 mm Spherical abutment CM 1,5 mm Spherical abutment CM 2,0 mm Spherical abutment CM 3,0 mm Spherical abutment CM 4,0 mm

 **Mini Conical Abutment CM**	Mini Conical Abutment CM 0,0 mm Mini Conical Abutment CM 0,8 mm Mini Conical Abutment CM 1,5 mm Mini Conical Abutment CM 2 mm Mini Conical Abutment CM 3 mm Mini Conical Abutment CM 4 mm
 **Angled Mini Conical Abutment CM**	Angled Mini Conical Abutment CM 0,8 X 17 Angled Mini Conical Abutment CM 1,5 X 17 Angled Mini Conical Abutment CM 3,0 X 17 Angled Mini Conical Abutment CM 0,8 X 30 Angled Mini Conical Abutment CM 1,5 X 30 Angled Mini Conical Abutment CM 3,0 X 30
 **Universal Abutment with Index (4,0 mm)**	Universal Abutment CM 3,5 x 0,0 x 6,0 mm with index Universal Abutment CM 3,5 x 0,8 x 6,0 mm with index Universal Abutment CM 3,5 x 1,5 x 6,0 mm with index Universal Abutment CM 3,5 x 2 x 6,0 mm with index Universal Abutment CM 3,5 x 3 x 6,0 mm with index Universal Abutment CM 3,5 x 4 x 6,0 mm with index Universal Abutment CM 4,5 x 0,0 x 6,0 mm with index Universal Abutment CM 4,5 x 0,8 x 6,0 mm with index Universal Abutment CM 4,5 x 1,5 x 6,0 mm with index Universal Abutment CM 4,5 x 2 x 6,0 mm with index Universal Abutment CM 4,5 x 3 x 6,0 mm with index

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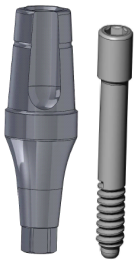
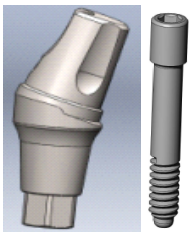
 **Universal Abutment with index (6,0 mm)**	Universal Abutment CM 4,5 x 4 x 6,0 mm with index
 **Angled Universal Abutment with index (4,0 mm)** 	Angled Universal Abutment 18° 3,5x1,5x6,0mm with index Angled Universal Abutment 18° 3,5x2,5x6,0mm with index Angled Universal Abutment 18° 3,5x3,5x6,0mm with index Angled Universal Abutment 18° 4,5x1,5x6,0mm with index Angled Universal Abutment 18° 4,5x2,5x6,0mm with index Angled Universal Abutment 18° 4,5x3,5x6,0mm with index Angled Universal Abutment 30° 3,5x1,5x6,0mm with index Angled Universal Abutment 30° 3,5x2,5x6,0mm with index Angled Universal Abutment 30° 3,5x3,5x6,0mm with index Angled Universal Abutment 30° 4,5x1,5x6,0mm with index Angled Universal Abutment 30° 4,5x2,5x6,0mm with index Angled Universal Abutment 30° 4,5x3,5x6,0mm with index

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Angled Universal Abutment with index (6,0 mm)	
HEALING ABUTMENTS	
 **Healing Abutment CM**	Healing Abutment CM 3,5 mm with profile of 0,0 mm Healing Abutment CM 3,5 mm with profile of 0,8 mm Healing Abutment CM 3,5 mm with profile of 1,5 mm Healing Abutment CM 3,5 mm with profile of 2,0 mm Healing Abutment CM 3,5 mm with profile of 3,0 mm Healing Abutment CM 3,5 mm with profile of 4,0 mm Healing Abutment CM 4,5 mm with profile of 0,0 mm Healing Abutment CM 4,5 mm with profile of 0,8 mm Healing Abutment CM 4,5 mm with profile of 1,5 mm Healing Abutment CM 4,5 mm with profile of 2,0 mm Healing Abutment CM 4,5 mm with profile of 3,0 mm Healing Abutment CM 4,5 mm with profile of 4,0 mm
SCREWS	
 **Definitive Screw CM**	Definitive Screw CM 0,0 Definitive Screw CM 0,8 Definitive Screw CM 1,5 Definitive Screw CM 2,0 Definitive Screw CM 3,0 Definitive Screw CM 4,0
	Screw for Universal Abutment 0,0 mm Screw for Universal Abutment 0,8 mm Screw for Universal Abutment 1,5 mm Screw for Universal Abutment 2,0 mm Screw for Universal Abutment 3,0 mm

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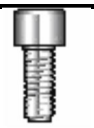
 **Screw for Universal Abutment**	Screw for Universal Abutment 4,0 mm
 **Screw for Angled Universal Abutment**	Screw for Angled Universal Abutment 1,5 mm Screw for Angled Universal Abutment 2,5 mm Screw for Angled Universal Abutment 3,5 mm
 **Prosthetic screw CM**	Prosthetic screw CM

4. INDICATION, PURPOSE OR USE INTENDED FOR THE PRODUCT

The family of Sterile Prosthetic Components consists of the following components:

I. Intermediate Abutments:

a) **Mini Conical Abutment (Straight or Angled):** The straight mini conical abutment is an intermediate abutment used between the implant and the prosthesis, composed of 1 (one) single part: ring-shaped body and bolt connected, already the angled mini conical abutment is composed of two parts: ring-shaped body and final loose screw. It has variations in relation to the prosthetic interfaces of the implants, being Internal Morse Cone.

The prosthetic component mini conical abutment is available in a straight or angled format and at different heights, correcting the inclination of the installed implants. It is indicated only for screwed prostheses, being single or multiple prostheses.

II. Definitive Abutments

a) **Spherical abutment:** used for overdenture retention (total prosthesis), the spherical abutment is a definite abutment with cylindrical shape indicated to be screwed in the implant and receive or support the total prosthesis over it by means of buttoning.

b) **Universal abutment (straight or angled):** it is a definitive abutment used to make the definitive prosthesis with the purpose of customizing the prosthesis anatomy, it is available in a straight or angled format, with or without indexer (hexagon) and at different heights, both gingival as coronary (4.0 and 6.0mm). The Universal Abutment is positioned directly on the platform of the Morse Cone Implant and comes with a universal abutment screw.

III. Definitive Independent Screw

a) Screw for Abutment

Screw used to fix the prosthesis (cemented or screwed) directly on the implant or on the intermediate abutment, thus avoiding the movement of the prosthesis and reducing the risk of implant loss and bacterial growth.

b) **Screw for Mini Conical Abutment:** Screw used to fix the mini conical abutment directly over the implant, thus avoiding the movement of the prosthesis and reducing the risk of implant loss and bacterial growth.

IV. Healing Cap (Healing Abutment)

Cylindrical abutment with seating platform according to each implant model (Morse Cone). It is indicated for the healing period of the soft tissue and for protection of the implant avoiding invasion of the mucosa in the implant. After healing can be replaced by one of the abutments, according to the prosthetic solution chosen by the professional.

In order to make the prostheses, the following components are exclusively necessary for laboratory use (they cannot be CE marked, since they do not come in contact with the patient):

- Analogues: used as replacements for implants in the model.
- Casting components: abutments or fusible components used as molds for the casting of definitive prostheses.

The choice of the diameter and height of the abutments should comply with the amount of available soft tissue and the anatomical accidents, through previous visual analysis. The indication happens through the diameter of the prosthetic platform which is the surface where the connection of the implant with the prosthetic component occurs.

5. RESTRICTIONS, SPECIAL PRECAUTIONS AND CLARIFICATIONS ON THE USE OF THE MEDICAL PRODUCT:

1. STERILE - provided that the integrity of the packaging, shelf life and storage conditions are maintained.

2. Prosthetic components should be used only for their intended purpose.

3. Sterile prosthetic components are supplied sterilized by Gamma radiation method. As long as the integrity of the packaging is not compromised in any way, it will keep the product sterile for up to 5 years from the sterilization date.

4. In cases of Adverse Effects occurring with the patient, the professional in charge should contact the SAC Bio Health immediately (Customer Service) by phone **+55 1440092400** or e-mail sac@implante-bio.com.br. A *Bio Health do Brasil LTDA* and all others involved (dentists, patients and physicians) are responsible for notifying ANVISA (National Health Surveillance Agency) of the relevant occurrences according to the internal technovigilance procedure, through the website www.anvisa.gov.br/notivisa.

5. If 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 S.L by phone +34 931407240 and/or contact the plant and by sac@implante-bio.com.br. Please remember 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's website: http://ec.europa.eu/health/medical-devices/links/vigilance_contact_points_en.htm .

6. The installation keys are attached to the top of the component, which must fit perfectly between the two. In order to avoid deformations in the fittings and connections. In addition to allowing the transport of the same from the packaging to the surgical bed of installation. The keys must undergo a process of decontamination and sterilization before use, under the responsibility of the professional.

7. The prosthetic components were developed in such a way as to avoid their use compromising patients' clinical status as well as their safety.

8. During implant installation, factors such as quantity, density and bone defects are considered for the surgical positioning of the implants;

9. The longevity of an implant dependents on the biomechanical concepts that will occur when an installed prosthesis comes into function.

6. PRECAUTIONS AND WARNINGS

1. PROFESSIONAL USE ONLY - The manufacture of dental prostheses requires specific professional specialization. It is the responsibility of the dental surgeon or the prosthetist that he or she has been trained beforehand to use this product in order to observe the adequate load of prosthetic occlusion.

2. PROHIBITED TO REUSE, RESTERILIZE OR REPRODUCE - The product may not be reused, resterilized or reprocessed. If reused, there may be: non-adaptation, loosening of the component (screw), screw fracture, periodontitis - inflammation of the periodontium due to accumulation of residue and peaceful settlement of the prosthesis, leading to active infections. After use discard it in accordance with current legislation for hospital wast.

3. The use of the product with surgical technique and inadequate biosafety conditions may harm the patient leading to non-satisfactory results.

4. Always sterilize the surgical instruments before using them.

5. Careful clinical and radiographic evaluations are necessary for proper treatment planning, which should take into consideration the most suitable prosthetic options for masticatory strength balance, occlusal adjustment, aesthetics and other factors related to the good performance of the prosthesis. The exchange of information between the surgeon, the prosthodontist and the laboratory technician is of paramount importance for the success of the treatment.

6. In all operations involving sterile prosthetic components, observe suitable asepsis and antisepsis techniques.

7. Abusive use of alcohol, tobacco, drugs, steroids or lack of proper oral hygiene can significantly impair the success of the 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 good condition in order to eliminate sources of infection and deformations in the protective fittings;

9. Do not use if the packaging is broken or expired. Return the damaged packages and the device to the plant.

10. 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.

11. Incorrect choice of a prosthetic component may result in its failure: the incorrect choice of a mini abutment for its height and inclination may directly affect the success of a rehabilitation. Choices of shallow straps in areas of deep healing can lead to the occurrence of chronic inflammatory processes and eventual peri-implantitis. Already straps higher than this fabric can compromise the aesthetic appearance of the case especially in previous areas present in the smile.

12. Torques for the installation of sterile prosthetic components are recommended:

PRODUCT	MODELS
	BioMORSE
Mini Conical Abutment	20 Ncm
Spherical Abutment	20 Ncm
Screw for Mini Conical Abutment	20 Ncm
Universal Abutment (Screw for Universal Abutment)	20Ncm
Screw for Abutment	20 Ncm
Screw for Mini Conical Abutment	20 Ncm
Healing Cap	10 Ncm

13. The dissipation of charge around the implant may allow a healthy bone tissue physiology or may be the pathological factor of its degeneration.

Note: We recommend that the identification adhesive labels that accompany the product be attached to the patient's documentation, patient's clinical report and product sales invoice.

10. ADVERSE EFFECTS

All adverse effects must be previously reported to the patient.

The following complications associated with the surgical treatment are mentioned as adverse effects:

1. Dehiscence, inflammation, infection, bone loss, hemorrhage, fracture or loss of implant;

11. Contraindications

1. It is not indicated for patients with blood disorders such as diabetes mellitus or uncompensated periodontal disease.

2. Contraindicated for procedures other than those recommended in the item "indication, purpose or use for which the product is intended".

3. Prosthetic components should not be placed in an existing active infection or in any other degenerative disease that affects the placement of the components without proper control.

12. INSTRUCTION FOR USE

The preparation of prostheses on dental implants requires a specific professional specialization. It is the responsibility of the dental surgeon or the prosthetist to have prior training in using this product.
Careful clinical and radiographic evaluations are necessary for proper treatment planning, which should take into consideration the most suitable prosthetic options for masticatory strength balance, occlusal adjustment, aesthetics and other factors related to the good performance of the prosthesis. The exchange of information between the surgeon, the prosthodontist and the laboratory technician is of paramount importance for the success of the treatment.

13. STORAGE, PRESERVATION OR USE CONDITIONS FOR THE MEDICAL PRODUCT

13.1 Storage and transportation

Convey and store away from direct sunlight, sources of heat or moisture, in a clean and waste-free environment. Store at room temperature. Transport should be done in the original packaging and avoid damage to it.

13.2 Storage and Handling

EXCLUSIVE USE OF PROFESSIONAL - The product should be handled only by dentists and professionals with knowledge of implant / prosthesis techniques.
Keep the sealed packaging, open the packaging only at the time of use.

14. PRE- AND POSTOPERATIVE CARE

14.1. Preoperative Care

The component shall be used only for its intended purpose. All patients undergoing surgical procedure should be carefully examined and evaluated for determination of radiographic and physical status, as well as bone deficit or adjacent soft tissue that could influence the final 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 patient safety.

14.2. Postoperative Care

Analgesics and rest may be prescribed only in the first 24-48 hours, varying according to the procedure and the patient's activity, determined by the professional's technical conduct.
The professional should recommend observation regarding prosthetic mobility, occlusal forces may lead to loosening of prosthetic fixation, and periodic control should be performed according to professional recommendation.

15. HANDLING WITH THE PRODUCT DISPOSAL

Disposal should be in accordance with applicable environmental and biosafety laws. Do not dispose of contaminated products in general waste.

LEGAL WARRANTY TERM

(according to the Consumer Protection and Protection Code: Law 8,078 of September 11, 1990)

The company ***Bio Health do Brasil LTDA***, in compliance with Art. 26 of Law 8,078, September 11, 1990, hereby establishes the right of the consumer to complain about apparent defects or easy inspection of all products manufactured and marketed by the consumer for a period of 90 days, counting from of the actual delivery date of the products.

In the case of occult addiction, the expiring term begins when the defect becomes evident, as provided in Paragraph 3 of Art. 26 of Law 8.078.

In order for this Legal Warranty Term to be effective, the consumer must observe the conditions described below:

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

Do not allow misuse as well as improper use 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 Instructions for Use