BIO NON-STERILE PROSTHETIC COMPONENTS

BIO HEALTH DO BRASIL LTDA

VALID FOR ALL COUNTRIES, EXCEPT BRAZIL.

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ANVISA REGISTRATION No.: 10392710016
Technical Responsible: Gustavo Telli Athaide CREA SP 5069918500
Technical Product Name: Dental Implant Components (2101397)
Trade Name: Non-Sterile Bio Prosthetic Components

Keep out of the sun

Keep dry

Não utilizar se a embalagem estiver danificada

Do not use if the packaging is damaged

Temperature Limit

Do not reuse

Expiration date

Manufacturing date

Lot

Reference / code

1. Detailed description of the medical product, including the fundamentals of its operation and its action, its content or composition, when applicable, as well as a list of accessories intended to integrate the product..

Bio prosthetic components are used for the manufacture of partial or multiple prostheses that will be fixed by means of a screw over dental implants. After the installation of the implants, the need for the correct transfer of the implant position and the synchronism with the prosthetic fitting, leads to the production of several components such as the abutments, Temporary components, permanent loose screws, among others. Dental implants (registration number: 10392710007 and sold separately) are devices inserted into the bone tissue of patients' jaws or jaws, in order to replace the roots of missing teeth. Titanium, the raw material for implants, naturally produces an oxide layer capable of attracting cells from the surrounding tissue, which, induced by this physical-chemical process, tend to deposit in the outermost layer of the metal, fixing the implant in the bone tissue and allowing the installation of implant supported dental prostheses. Titanium is a material that has been used for many years as a substitute for body parts, due to the biocompatibility that exists between the material and body tissues. Titanium is not only used to replace lost limbs and teeth, but also to manufacture auxiliary prosthetic components in the treatment with dental implants.

The family of Non-sterile Prosthetic Components are for SINGLE USE and must be sterilized by autoclave before use, according to the sterilization item. consists of the components below, and the prosthesis can be directly on implants or on the intermediate abutment:

a) ***Temporary Components and Titanium Abutment:*** type of temporary prosthesis used while making the definitive prosthesis or tissue repair is expected after installation of the implant or used as a definitive abutment for definitive prosthesis. They have rotational and anti-rotational inserts and can be made directly on implants or on the intermediate abutment. The abutments and components accompany a permanent loose screw used for fixing the prosthesis, avoiding the movement of the prosthesis and decreasing the risk of implant loss and bacterial growth of the prostheses directly on implants or of the prostheses on the intermediate abutment.

For prostheses directly on implants*:* the Temporary component and titanium abutment are positioned directly on the implant.

For prostheses on the intermediate abutment*: the Temporary component and titanium abutment are positioned on the intermediate.*

b) ***Pilar Definitivo:*** abutment used in making the definitive prosthesis in order to personalize the anatomy of the prosthesis. They can be positioned directly on the implant prosthetic platform - For prostheses directly on implants or on intermediate abutments - for prostheses on the intermediate abutment. The abutments accompany a final loose screw used to fix the cemented or screwed prosthesis, avoiding the movement of the prosthesis and reducing the risk of implant loss and bacterial growth of the prostheses directly on implants or the prostheses on the intermediate abutment.

For prostheses directly on implants: the abutment is positioned directly on the implants and the prosthesis can be screwed or cemented.

For screwed prostheses, the abutments are screwed over the implants and the abutments can be calcined (plastic cylinder fully calcined) - Plastic or injected ucla (product not subject to registration, as it does not come into contact with the patient before casting), or abutment partially calcinable with base produced in chromium cobalt alloy - Ucla CoCr (registered part under n° 10392710013 and sold separately).

For cemented prostheses, the abutments are cemented on the implants using the titanium abutments - Tiprep Abutment, to make the final prosthesis.

For prostheses on the intermediate abutment: the cylinder is positioned on the intermediate pillar to make the final prosthesis. The prosthesis on the intermediate abutment is screwed and can be castable - fused plastic or injected component, or partially castable with base produced in chromium cobalt alloy - Ucla CoCr (registered part under n ° 10392710013 and sold separately).

Other components

Protection Cover (intermediate pillar)**:** made of titanium, guides the proper repair of periimplant gingival tissue, shaping the space of the denture in the patient's gums. The protective cover is also used for the protection of prosthetic components during the manufacture of prosthetics.

Metal capsule (overdenture): made of titanium is used for the fixation (fitting) of overdenture prosthesis by means of the retaining ring (polymer).

Accessories

Non-Sterile Prosthetic Component family accessories are exclusive to each component and are made available together to products. Only in the case of installation keys that are sold separately and have registration of the part (registration no. 10392710022):

The keys for installation of prosthetic components are available in manual models, for torque wrench and contra-angle.

Retaining ring - oring (overdenture): Accessory of the metallic capsule, used to retain the overdenture on the spherical pillar, preventing its movement. The rings have natural wear depending on their use, so constantly check the adaptation of the prosthesis and if necessary replace the retaining ring with a new one.

1. Composition

Non-sterile Bio Prosthetic Components are produced in titanium according to ASTM F136 (EN ISO 5832-3).

2. Forms of commercial presentation

The non-sterile Bio prosthetic components can be packaged individually or together as follows:

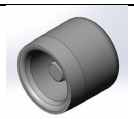
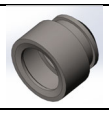
Unit form

A non-sterile prosthetic component, packed in a blister-type primary packaging (PETG film), rigid and transparent, sealed with Tyveck® surgical grade paper (high density polyethylene fibers) and in secondary envelope type packaging made of trIplex cardboard with adhesive label attached for Product Identification. Accompanying 03 adhesive labels with information for product traceability 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.

2.1. Set:

One unit of non-sterile prosthetic component with permanent loose screw, packed in a blister-type primary packaging (PETG film), rigid and transparent, sealed with Tyveck® surgical grade paper (high density polyethylene fibers) and in secondary packaging made of cardboard. triplex with adhesive label attached for product identification. Accompanying 03 adhesive labels with information for product traceability 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.

2.2. List of Non-Sterile Prosthetic Components models

Code	Description	Production description – certificate CE	Illustrative image
06524	Titanium abut biomorse 3,5x0,0mm index	TITANIUM ABUTMENT	
06525	Titanium abut biomorse 3,5x0,8mm index		
06526	Titanium abut biomorse 3,5x1,5mm index		
06527	Titanium abut biomorse 3,5x2,0 mm index		
06528	Titanium abut biomorse 3,5x3,0mm index		
06529	Titanium abut biomorse 3,5x4,0 mm index		
06540	Titanium abut biomorse 4,5x0,0 mm index		
06541	Titanium abut biomorse 4,5x0,8 mm index		
06542	Titanium abut biomorse 4,5x1,5 mm index		
06543	Titanium abut biomorse 4,5x2,0 mm index		
06544	Titanium abut biomorse 4,5x3,0mm index		
06545	Titanium abut biomorse 4,5x4,0mm index		
10039	Temporary Cylinder sem hex/ no hex/ no hex		
10040	Temporary Cylinder com hex/with hex/con hex		
12007	Protection Cover		
12003	Capsule Metallic Spheric Pilla		
12005	Calcinable Component Spheric Pillar		

3. Instructions for use

The manufacture of prostheses on dental implants requires specific professional specialization. It is the responsibility of the dental surgeon or the prosthodontist to provide them with prior training to use this product.

Careful clinical and radiographic evaluations are necessary for correct treatment planning, which must take into account the most appropriate prosthetic options for balancing masticatory forces, occlusal adjustment, aesthetics and other factors related to the good performance of the prosthesis. The exchange of information between the surgeon, the prosthetist and the laboratory technician is of fundamental importance for the success of the treatment.

3.1. Sterilization

Products must be removed from their original packaging and packaged in a thermo-seal envelope type (laminated polyester / polypropylene film);

It is recommended to follow the autoclave sterilization method:

- Use distilled water for this procedure so that the resulting steam is free of impurities.
- In a steam clave saturated under pressure, the Bio cutting instrument must remain 4 minutes, after reaching a temperature of 134 ° C and after procedures, wait 40 minutes for drying.
- Do not open the autoclave prematurely, to avoid rapid condensation;
- Do not open the autoclave quickly, letting all steam out, before the drying cycle.
- Clean the autoclave rigorously and periodically, removing dirt and any excess rust.
- It is recommended to use the component immediately after sterilization, in case of product storage keep the sterilized thermoseal packaging

4. Precautions, restrictions, warnings, special care and clarifications on the use of the medical product, as well as its storage and transportation.

4.1. Precautions, restrictions, warnings, special care and clarifications on the use of the medical device

- Do not use if the packaging is broken. Return damaged packages and the included device to the factory.

- The product cannot be reused or reprocessed. After use, dispose of it in accordance with current legislation for hospital waste. If reused, there may be non-adaptation, component loosening (screw), screw fracture, periodontitis

– inflammation of the periodontium by the accumulation of residue and peaceful settlement of the prosthesis.

- Abuse of alcohol, tobacco, drugs, steroids or lack of proper oral hygiene can significantly impair the success of treatment.

- If there is an impact on the non-sterile prosthetic components and it presents scratches, cracks or dents of great intensity, which can impair the smooth 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.

- The products are available non-sterile and sterilization is recommended before use, as indicated by the manufacturer (item 4.1- USE Instruction).

- Insertion torque higher than recommended and inadequate wrenches can cause damage to the material and render the system unusable, check the condition of the instruments to be used before each procedure. Replace the instruments in case of damage, erased markings, compromised sharpening, deformation and wear, it is recommended to check the indication of the instrument's useful life as indicated by the manufacturer.

- Insertion torque below the recommended can cause undesirable effects such as loosening of the adaptation screws, disengagement of the prosthetic components, which can cause fractures and deformations in fittings.

- It is recommended that the professional use the products of the Bio line. The use of instruments and / or implants and / or prosthetic components from other systems does not guarantee perfect function and does not warrant any warranty on the product used.

- Incorrect planning can compromise the performance of the prosthetic set (implant and prosthesis) and may present implant loss or fracture, loosening or fracture of the prosthetic screws.

- During prosthetic adaptation, make sure that the products (implant and component) are properly seated and aligned with the implant axis, avoiding locking and damage to the thread.

- MAGNETIC RESONANCE (MR) - SAFETY INFORMATION Non-sterile Prosthetic Components have not been evaluated for safety in the MR environment. It has not been tested for heating, migration, in the MR environment. The safety of Bio products in the MR environment is unknown. Scanning a patient with this device can result in interference and image changes generated during the process that can result in image artifacts that cause misinterpretation of results.

- The expiry date is indicated on the label.
- In the event of Adverse Effects on the patient, the responsible professional must immediately contact the SAC Bio Health (Customer Service) by calling 0800 770 3824 or by email sac@implante-bio.com.br. Bio Health do Brasil and all others involved (dentists, patients and doctors) are responsible for notifying ANVISA (Health Surveillance Agency) of the relevant occurrences according to the internal technovigilance procedure, through the website www.anvisa.gov.br/ notivisa.
- In case of any adverse effect with the patient on the use of our products in the European community, countries should contact our authorized representative Bio Europe SL by phone +34 931407240 and / or contact the factory and by email sac @ implante-bio .com. Bearing in mind that professionals are responsible for reporting adverse events to local authorities within the European Union, the health surveillance contact points are listed on the European Commission's website: http://ec.europa.eu/health/medical-devices/ links / vigilance_contact_points_en.htm.

Note: We recommend that the adhesive identification labels accompanying the product are attached to the documentation to be delivered to the patient, clinical record and tax documentation.

4.1.1. Torque Recommendation

Bio recommends the use of torques as indicated in the table below, the excess torque or the lack of torque can bring undesirable results.

Non-sterile Prosthetic Component	Prosthetic adaptation (docking platform)
	Biomorse
Temporary Components and Titanium Abutment	20 N.CM
Definitive Pillar	20 N.CM
Protection case	Manual

4.2. Adverse events

- Adverse events are not expected from non-sterile prosthetic components when used as indicated for use. The components are for temporary use and / or can be replaced in case of breakdowns and damages, bringing no risk to the patient's health.

- All potential adverse effects such as dehiscence, inflammation, infection, allergic reaction, fracture or loss of the implant due to poor adaptation between components must be previously informed to the patient.

4.3. Contraindications

- Contraindicated for procedures other than that recommended in "Indication of USE".
- It should not be used in patients who are not clinically able to undergo dental intervention. As, for example, in patients with diabetes Mellitus and decompensated periodontal disease;
- Non-sterile prosthetic components are not indicated in patients who do not have complete bone formation (pediatric dentists) since the placement of dental implants in these conditions is not indicated.

4.4. Special Conditions for Storage and Transport, Conservation and / or Handling of the product.

4.4.1. Storage and Transportation

- Transport and store the product away from direct sunlight and heat (maximum temperature: 15 -25 ° C and humidity). Keep the container closed until sterilization.
- Make sure the integrity of it before use. Do not use if the package is open or damaged. Dispose of the uncharacterized product in accordance with legislation for hospital waste or return the damaged packaging and the device included to the Factory.

4.4.2. Conservation and Handling

In case of changes in the characteristics of the non-sterile prosthetic components, dispose of them in accordance with current legislation for hospital waste or return the damaged packaging and the device included to the Factory.

5. Pre and Post Operative Care

5.1. Preoperative care

All patients who are going to undergo a surgical and / or prosthetic procedure must be carefully examined and evaluated, with a view to determining the radiographic and physical status, as well as the osseointegration of the implant implant that may influence the final result of the intervention. Also, they need a previous evaluation in order to minimize situations that could compromise the success of the treatment or even the safety of the patient.

5.2. Post Operative Care

- Observe postoperative care for surgical procedures. Analgesics, antibiotics and rest for the first 24-48 hours may be prescribed, varying according to the procedure and the patient's activity and the technical conduct of the responsible professional.
- It is recommended that the professional assess the conditions of the implant and prosthesis, including accessories, abutments and crowns, to verify the need for readjustments or removal after a long period of use. The stability of the implants can be compromised due to loosening of the fixation between the implants and the prostheses, and must be evaluated by the professional after long periods; in case of any deviation, the professional must evaluate the best procedure, which can be replaced, if necessary.

6. Care about product disposal

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

WARRANTY TERM

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

The company ***Bio Health do Brasil LTDA***, in compliance with Article 26 of Law 8.078, of September 11, 1990, uses this legal instrument to guarantee the consumer's right to complain about apparent defects or easy verification of all products by it manufactured and marketed, for a period of 90 days, counting from the date of effective delivery of the products. In the case of a hidden defect, the decay period begins when the defect becomes evident, as provided in Paragraph 3 of Art. 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 misuse or misuse of the materials in question. Follow all the instructions for use in detail, as well as the precautions described in the Instructions for Use electronically.

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