Bionnovation
implantes

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CE 0434

Sterile
Prosthetic Components

EC REP

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MADE IN BRAZIL / INDÚSTRIA BRASILEIRA / INDUSTRIA BRASILEÑA

www.bionnovation.com.br

Data de Fabricação
Fecha de Fabricación
Date of Manufacture

REF
Código do Produto
Código del Producto
Product Code

LOT
Número do Lote
Número de Partida
Batch Number

Prazo de Validade
Fecha de Fabricación
Date of Manufacture

Manter afastado do sol
Mantener fuera de la luz solar
Keep away from sunlight

Consulte as instruções de utilização
Consulte las instrucciones de utilización
Refer to instructions for use

CE 0434
Marcação CE para Comercialização na Comunidade Européia
Marca CE para Comercialización em la Comunidad Europea
CE Mark for European Community Market

Manter seco
Mantenga seco
Keep dry

Não reutilizar
No reutilizar
Do not reuse

EC REP
Representante europeu autorizado
Representante europeo autorizado
Authorised representative in the european comunity

STERILE R
Produto esterilizado por radiação gama
Producto esterilizado por radiación gama
Product sterilized through gamma rays

Não utilizar se a embalagem estiver danificada
No usar si el paquete está dañado
Do not use if package damaged

Fabricante
Fabricante
Manufacturer

DESCRIPTION AND FOUNDATIONS FOR ACTION

The Bionnovation prosthetic components are used to make partial or multiple prostheses to be affixed through a bolt on dental implants. The dental implants are devices inserted inside patients' jawbone bone tissues or maxilla, with the purpose of replacing the roots of the lost teeth.

The Sterile Prosthetic Components family of products is composed by the components below:

I. Intermediary Pillars:

a)Conic Pillar (Straight or Angular): it's an intermediary pillar utilized between the graft and the prosthesis, composed of two parts: a ring-shaped body and a detached definitive bolt. It has variations in relation to the grafts' prosthetic interfaces, and it may be Internal hexagon, External hexagon or Cone Morse. In the prosthetic fitting there is a hexagon that provides the installed prosthesis with an anti-rotational characteristic.

The conic pillar prosthetic component is available in straight or angular formats and at different heights, thus correcting the inclination of installed grafts. It's only indicated for bolted prostheses, either unitary or multiple prostheses.

b)Mini Conic Pillar (Straight or Angular): the mini straight conic pillar is a pillar intermediary utilized between the graft and the prosthesis, composed of 1 (one) single part: a ring-shaped body and connected bolts, while the mini angular conic pillar is composed of two parts: a ring-shaped body and a detached definitive bolt. It has variations in relation to the grafts' prosthetic interfaces, and it may be Internal hexagon, External hexagon or Cone Morse.

The prosthetic mini conic pillar mini component is available in straight or angular formats and in different heights, thus correcting the inclination of installed grafts. It's only indicated for bolted prostheses, either unitary or multiple prostheses.

II.Definitive Pillars

a)Spherical Pillar: utilized for overdenture retention (total prosthesis), the spherical pillar is a definitive pillar with a cylindrical shape indicated to be bolted on the graft and to receive or support the total prosthesis over the same through fastening.

b)Universal Pillar (straight or angular): it's a definitive pillar utilized to make a definitive prosthesis with the purpose of customizing the prosthesis' anatomy, and it's available in straight or angular formats, with or without indexer (hexagon) and at different heights, both gingival and coronary (4.0 and 6.0 mm). The Universal Pillar is positioned directly over the Cone Morse type graft platform and comes with a universal pillar bolt.

III.Definitive Detached Bolt: Bolt utilized to fix the prosthesis (cemented or bolted) directly over the graft or over the intermediary pillar, thus avoiding prosthesis movement and decreasing the risk of graft loss and bacterial growth.

IV.Bolt for Universal Pillar (straight and angular): Bolt utilized to fix the universal pillar directly over the Cone Morse type graft, thus avoiding pillar movement.

V.Healer: Cylindrical pillar with settlement platform according to each graft model (External and Internal Hexagon and Cone Morse). It's indicated for the soft tissue's healing period and to protect the graft thus avoiding mucous invasion on the graft. After healing it may be replaced by one of the pillars, according to the prosthetic solution chosen by the professional physician.

PRODUCT COMPOSITION

The Bionnovation Sterile Prosthetic Components are made of titanium ASTM F136.

INDICATIONS AND PURPOSE OF USE

The Sterile Prosthetic Components family of products is composed by the components below:

I. Intermediary Pillars:

a)Conic Pillar (Straight or Angular): it's an intermediary pillar utilized between the graft and the prosthesis, composed of two parts: a ring-shaped body and a detached definitive bolt. It has variations in relation to the grafts' prosthetic interfaces, and it may be Internal hexagon, External hexagon or Cone Morse. In the prosthetic fitting there is a hexagon that provides the installed prosthesis with an anti-rotational characteristic.

The conic pillar prosthetic component is available in straight or angular formats and at different heights, thus correcting the inclination of installed grafts. It's only indicated for bolted prostheses, either unitary or multiple prostheses.

b)Mini Conic Pillar (Straight or Angular): the mini straight conic pillar is a pillar intermediary utilized between the graft and the prosthesis, composed of 1 (one) single part: a ring-shaped body and connected bolts, while the mini angular conic pillar is composed of two parts: a ring-shaped body and a detached definitive bolt. It has variations in relation to the grafts' prosthetic interfaces, and it may be Internal hexagon, External hexagon or Cone Morse.

The prosthetic mini conic pillar mini component is available in straight or angular formats and in different heights, thus correcting the inclination of installed grafts. It's only indicated for bolted prostheses, either unitary or multiple prostheses.

II.Definitive Pillars

a)Spherical Pillar: utilized for overdenture retention (total prosthesis), the spherical pillar is a definitive pillar with a cylindrical shape indicated to be bolted on the graft and to receive or support the total prosthesis over the same through fastening.

b)Universal Pillar (straight or angular): it's a definitive pillar utilized to make a definitive prosthesis with the purpose of customizing the prosthesis' anatomy, and it's available in straight or angular formats, with or without indexer (hexagon) and at different heights, both gingival and coronary (4.0 and 6.0 mm). The Universal Pillar is positioned directly over the Cone Morse type graft platform and comes with a universal pillar bolt.

III.Definitive Detached Bolt: Bolt utilized to fix the prosthesis (cemented or bolted) directly over the graft or over the intermediary pillar, thus avoiding prosthesis movement and decreasing the risk of graft loss and bacterial growth.

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V.Healer: Cylindrical pillar with settlement platform according to each graft model (External and Internal Hexagon and Cone Morse). It's indicated for the soft tissue's healing period and to protect the graft thus avoiding mucous invasion on the graft. After healing it may be replaced by one of the pillars, according to the prosthetic solution chosen by the professional physician.

The following components for exclusive use of laboratory are required for prosthesis making:

- Analogs: used as a replacement of the implants in the model.
- Components calcinable: fusible components or pillars used as molds for casting permanent prosthesis.

The choice of the diameter and height of the pillars should respect the amount of soft tissue available and anatomical accidents, through visual prior analysis. The indication is through the diameter of the prosthetic platform, that is the surface where make the connection of the implant with the prosthetic component.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

1. STERILE- The product is sterile as long as package integrity, validity term and storage conditions are observed.
2. USE BY PROFESSIONALS ONLY - The making of prostheses on dental implants requires a specific professional specialization. Only qualified professionals with expertise in surgical techniques and procedures necessary for proper use of the product should make use the Sterile Prosthetic components family.
3. DO NOT RESTERILIZE, REUTILIZE AND REPROCESS IT - if it is reutilized, resterilized or reprocessed its physical chemical, properties may be altered, leading to foreign body reaction, change in dimensional features there may be non-adaptation, loosening of the component (bolt), bolt fracture, periodontitis – inflammation of the periodontium due to the accumulation of residues and peaceful settlement of the prosthesis. Bionnovation does not recommend its reutilization, reprocessing, or resterilization, so discard the product according to the applicable legislation for hospital waste, do not discard contaminated products in the general waste.
4. An incorrect surgical technique may lead to discomfort, such as a painful sensation, hypoesthesia and edema.
5. In all surgeries involving the sterile prosthetic components please observe the appropriate asepsis and antisepsis techniques.
6. Abuse of alcohol, tobacco, chemical dependency and corticosteroids or inappropriate oral hygiene may significantly compromise the success of treatment
7. The Sterile Prosthetic components are provided in sterile packaging (gamma radiation). Provided the packaging's integrity has not been somewhat compromised, it will keep the product sterile for up to 4 years to be counted as of the sterilization date.
8. In cases of adverse effects occurring in patients, the responsible must contact immediately with the SAC Bionnovation (Customer Service) by the number **0800 707 3824** or by e-mail **sac@bionnovation.com.br**. The Bionnovation Biomedical Products is responsible for notifying the ANVISA (Health Surveillance Agency) about the relevant occurrences according to internal technovigilance procedure.
9. The Sterile Prosthetic components were developed in order to prevent that its use does not compromise the clinical condition of patients as well as their safety.
10. Inspect all and any device before use, in order to visually verify that it is not damaged. In case of impact and if it has scratches, cracks or dents of great intensity, which can impair the product smooth operation, please contact immediately the Bionnovation SAC (Customer Service) via the **0800 770 3824** or email **sac@ bionnovation.com.br.**
11. Careful clinical and radiographic evaluations are necessary for the correct planning of the treatment, which must take into consideration the most adequate prosthetic options regarding chewing force balance, occlusal adjustment, esthetics and other factors related to the prosthesis' good performance. The exchange of information between the surgeon, the prosthodontist, and the laboratory technician is critically important for the treatment's success.
12. Patients should be informed in advance on all potential adverse effects such as dehiscence, inflammation, hemorrhage. In cases of adverse effects occurring in patients, the responsible must contact immediately with the SAC Bionnovation (Customer Service) by the number **0800 770 3824** or by e-mail **sac@bionnovation. com.br.** The Bionnovation Biomedical Products is responsible for notifying the ANVISA (Health Surveillance Agency) about the relevant occurrences according to internal technovigilance procedure.
13. The maximum possible torque in the definitive detached bolts is of 20Ncm for the MP bolt and of 32Ncm for the SP/RP/WP bolts, thus avoiding possible fractures.
14. The Sterile Prosthetic components should not be placed on existing active infection or in case of any other degenerative disease.
15. It must not be utilized in patients that are not able, under the clinical point of view, to be submitted to a medical or odonthological intervention. Such as, for example,in patients with uncompensated diabetes.
16. The use of the product under inadequate surgical techniques and biosafety conditions may harm the patient leading to unsatisfactory results. Always sterilize the surgical instruments before using them. One should always work with sterile fields, instruments appropriate for the procedure and in good upkeep condition, in such a way to eliminate infection sources and damages caused to the components by an inappropriate instrumentation.

Note: We recommend that the identification adhesive labels that come with the product is annexed to the documentation to be delivered to the patient, to the clinical protocol and to the fiscal documentation that will generate a collection.

PRE AND POST-OPERATIVE CARE

Pre-Operative Care: The component must be used only for the purpose it has been designed for. All the patients who might be submitted to a surgical procedure must be carefully examined and evaluated, with the aim of determining their clinical and radiographic state, as well as if there is any bone deficit or adjacent soft tissue that might influence the final result of the intervention. They also require a previous evaluation in order to minimize situations that might compromise the treatment's success or even the patient's safety.

Post-Operative Care: Only painkillers and rest may be prescribed during the first 24-48 hours, varying as a function of the procedure and of the patient's activity, as determined by the responsible professional.

SPECIAL STORAGE AND TRANSPORTATION, CONSERVATION AND/OR PRODUCT HANDLING CONDITIONS.

Storage and transportation

Transport and store it away from direct sunlight and sources of heat or humidity. Keep it at ambient temperature. Keep the packaging sealed until its utilization time. Please, verify the integrity of the same before using it.

Conservation and handling

- Do not use it if the sterile package has been opened, or if it's damaged, or if the sterilization validity date has expired in order to avoid possible contamination. It is provided on the sterile condition and once opened should be used on aseptic conditions.
- The manufacturer is not liable for damages which may occasionally occur in the product and with consequences to the patient, due to its mishandling or improper use.

COMMERCIAL PRESENTATION FORMS

A sterile prosthetic component, that is sterilized by gamma radiation, packaged in blister sealed with Tyveck® as primary packaging and with an identification adhesive label, 03 adhesive labels with information to track the product that must be annexed to the clinical protocol in the document to be delivered to the patient, and in the fiscal documentation that generates a collection, and as final packaging a sealed high basis weight cardboard box, and 02 adhesive labels annexed to the lid (01) and to the frontal part (01) of the box.

INSTRUCTIONS OF USE

The making of prostheses on dental implants requires a specific professional specialization. It will be the dental surgeon's or the prosthodontist's responsibility to make sure they've been previously qualified to use this product.

Careful clinical and radiographic evaluations are necessary for the correct planning of the treatment, which must take into consideration the most adequate prosthetic options regarding chewing force balance, occlusal adjustment, esthetics and other factors related to the prosthesis' good performance. The exchange of information between the surgeon, the prosthodontist, and the laboratory technician is critically important for the treatment's success.

CARE WHEN DISCARDING THE PRODUCT

The product's disposal must comply with the applicable environmental and biosafety laws. Do not discard contaminated products in the general waste. Discard any mischaracterized product according to the applicable legislation for hospital waste, or return the damaged packages to the factory, including the device.