Bionnovation
implantes

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Non-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


Código do Produto
Código del Producto
Product Code


Número do Lote
Número de Partida
Batch Number

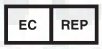

Prazo de Validade
Fecha de Fabricación
Date of Manufacture


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


Manter seco
Mantenga seco
Keep dry


Não reutilizar
No reutilizar
Do not reuse


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


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


Fabricante
Fabricante
Manufacturer


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

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. After the implants' installation, the need for the correct transfer of the implant's position and synchronicity with the prosthetic attachment leads to the production of many different components, such as the pillars, protractors, provisory components, detached definitive bolts, among others.

The dental implants (registered separately, registration nº: 10392710007 and sold separately) are devices inserted inside patients' jawbone bone tissues or maxilla, with the purpose of replacing the roots of the lost teeth. Titanium, the implants' raw material, naturally produces a layer of oxides able to attract cells from the surrounding tissue that, induced by this physical-chemical process, tend to be deposited on the most external layer of the metal, attaching the implant in the bone tissue and allowing for the installation of implant-supported dental prostheses. Titanium is a material that has been used for many years to replace body parts, due to the biocompatibility verified between that material and the body tissues. Titanium is not only used to replace lost limbs and teeth, but also for the manufacturing of auxiliary prosthetic components for treatments with dental implants.

The Non-Sterile Prosthetic Components family of products is composed by the components below, and the prosthesis may be directly attached on implants or on the intermediary pillar:

a) Molding protractor: made of Titanium-Aluminum-Vanadium alloy - ASTM F136, the molding protractor has the purpose of transferring the implant's or the intermediary pillar's position into the prosthetic operation model. The protractor allows for the reproduction of the angles and of the exact location of the implant or of the intermediary pillar for the operation model, from its waxing until the final prosthesis' making. There are 2 (two) molding techniques that use protractors, the open molder and the closed molder ones, and such techniques vary according to the choice made by the responsible professional.

The molding protractor can be used in prostheses attached directly on implants or in prostheses attached on the intermediary pillar.

• For prostheses attached directly on implants: the protractor is positioned directly on the implant, transferring the implant's exact position into the prosthetic operation model.

• For prostheses attached on the intermediary pillar: the protractor is positioned on the intermediary pillar, transferring the exact position of the pillar into the prosthetic operation model. For protractors on intermediary pillars there are also the rotating and non-rotating attachments.

b) Provisory Components and Titanium Pillar: type of temporary prosthesis used while making the definitive prosthesis or while one waits for tissue repair after the implant's installation, or used as a definitive pillar for the definitive prosthesis. Both have rotating and non-rotating attachments and can be made directly on implants or on the intermediary pillar.

The pillars and components come with a detached definitive bolt used to attach the prosthesis, thus avoiding any movement of the prosthesis and decreasing the risk of implant loss and bacterial growth in prostheses attached directly on implants or in prostheses attached on the intermediary pillar.

• For prostheses attached directly on implants: the provisory component and the titanium pillar are positioned directly on the implant.

• For prostheses attached on the intermediary pillar: the provisory component and the titanium pillar are positioned on the intermediary pillar.

c) Definitive Pillar: pillar used to make the definitive prosthesis with the purpose of customizing the prosthesis' anatomy. Both can be positioned directly on the implant's prosthetic platform - For prostheses attached directly on implants or on the intermediary pillar - for prostheses attached on the intermediary pillar. The pillars come with a detached definitive bolt used to attach the cemented or bolted prosthesis, thus avoiding any movement of the prosthesis and decreasing the risk of implant loss and bacterial growth in prostheses attached directly on implants or in prostheses attached on the intermediary pillar.

• For prostheses attached directly on implants: the pillar is positioned directly on the implants and the prosthesis can be cemented or bolted.

For the bolted prostheses, the pillars are bolted on the implants and the pillars may be calcinable (fully calcinable plastic cylinder) - plastic or injected Ucla (product not liable to registration, because it doesn't get in touch with the patient before casting), or a partially calcinable pillar with base made of chromium cobalt alloy - Ucla CoCr (registered separately under n° 10392710013 and sold separately).

For cemented prostheses, the pillars are cemented on the implants that use titanium pillars – Tiprep Pillar, to make the definitive prosthesis.

• For prostheses attached on the intermediary pillar: the cylinder is positioned on the intermediary pillar to make the definitive prosthesis. The prosthesis on the intermediary pillar is bolted, and it may be calcinable - fusible plastic or injected component, or partially calcinable with base made of chromium cobalt alloy - Ucla CoCr (registered separately under n° 10392710013 and sold separately).

Other components

- Protection Cover (intermediary pillar): made of titanium, it guides the adequate repair of the peri-implant gingival tissue, molding the space occupied by the dental prosthesis on the patient's gum.
- Metallic Capsule (overdenture): made of titanium, it's used together with the retention ring (polymer) to attach the overdenture prosthesis.

Accessories

The accessories of the Non-Sterile Prosthetic Components family of products are exclusive for each component, and are not sold separately (they are only sold separately in the case of replacement). Only in the case of locks that are sold separately and are registered separately (registration n° 10392710022)

1. Protractor pin, used to fasten the impression coping into the molder.
2. The locks for the installation of prosthetic components are available in the manual, torque meter, and counter-angle models.
3. Retention ring – o'ring (overdenture): An accessory of the metallic capsule, it's used to retain the overdenture on the round pillar, thus avoiding its movement. The rings have a natural wear as a function of their utilization, and therefore constantly verify the prosthesis' adaptation and if necessary replace the retention ring for a new one.

PRODUCT COMPOSITION

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

INDICATIONS AND PURPOSE OF USE

After the implants' installation, the need for the correct transfer of the implant's position and synchronicity with the prosthetic attachment, leads to the production of many different non-sterile components and the prosthesis can be attached directly on implants or on the intermediary pillar, and the family of components are defined below:

a) Molding protractor: made of Titanium-Aluminum-Vanadium alloy - ASTM F136, the molding protractor has the purpose of transferring the implant's or the intermediary pillar's position into the prosthetic operation model. The protractor allows for the reproduction of the angles and of the exact location of the implant or of the intermediary pillar into the operation model, from their waxing to the final prosthesis' making. There are 2 (two) molding techniques that use protractors, the open molder and the closed molder ones, and such techniques vary according to the choice made by the responsible professional.
The molding protractor can be used in prostheses attached directly on implants or in prostheses attached on the intermediary pillar.
• For prostheses attached directly on implants: the protractor is positioned directly on the implant, transferring the implant's exact position into the prosthetic operation model.
• For prostheses attached on the intermediary pillar: the protractor is positioned on the intermediary pillar, transferring the exact position of the pillar into the prosthetic operation model. For protractors on intermediary pillars there are also the rotating and non-rotating attachments.

b) Provisory Components and Titanium Pillar: type of temporary prosthesis used while making the definitive prosthesis or while one waits for tissue repair after the implant's installation, or used as a definitive pillar for the definitive prosthesis. Both have rotating and non-rotating attachments and can be made directly on implants or on the intermediary pillar.
The pillars and components come with a detached definitive bolt used to attach the prosthesis, thus avoiding any movement of the prosthesis and decreasing the risk of implant loss and bacterial growth in prostheses attached directly on implants or in prostheses attached on the intermediary pillar.
• For prostheses attached directly on implants: the provisory component and the titanium pillar are positioned directly on the implant.
• For prostheses attached on the intermediary pillar: the provisory component and the titanium pillar are positioned on the intermediary pillar.

c) Definitive Pillar: pillar used to make the definitive prosthesis with the purpose of customizing the prosthesis' anatomy. Both can be positioned directly on the implant's prosthetic platform - For prostheses attached directly on implants or on the intermediary pillar - for prostheses attached on the intermediary pillar. The pillars come with a detached definitive bolt used to attach the cemented or bolted prosthesis, thus avoiding any movement of the prosthesis and decreasing the risk of implant loss and bacterial growth in prostheses attached directly on implants or in prostheses attached on the intermediary pillar.
• For prostheses attached directly on implants: the pillar is positioned directly on the implants and the prosthesis can be cemented or bolted.
For the bolted prostheses, the pillars are bolted on the implants and the pillars may be calcinable (fully calcinable plastic cylinder) - plastic or injected Ucla (product not liable to registration, because it doesn't get in touch with the patient before casting), or a partially calcinable pillar with base made of chromium cobalt alloy - Ucla CoCr (registered separately under n° 10392710013 and sold separately).
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The treatment with implants is indicated to all the cases that require the replacement of lost dental elements. The purpose of the treatment is the placement of dental prostheses to recover esthetic elements and the chewing function.
The choice of diameter and height of the pillars must comply with the quantity of soft tissue available and anatomical accidents, through a previous visual analysis. The indication is based on the diameter of the prosthetic platform, which is the surface where the implant is connected into the prosthetic component.

PRECAUTIONS, RESTRICTIONS AND WARNINGS
1. NON STERILE- Non Sterile Prosthetic components are supplied non-sterile, observe the appropriate asepsis techniques.
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 Non Sterile Prosthetic components.
3. DO NOT REUTILIZE AND REPROCESS IT - if it is reutilized 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..
4. An incorrect surgical technique may lead to discomfort, such as a painful sensation, hypoesthesia and edema.
5. In all surgeries involving the non 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. 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.
8. The Non 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.
9. 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 HYPERLINK "mailto:sac@bionnovation.com.br" **sac@bionnovation.com.br**.

10. 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.
11. 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.
12. 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.
13. The Non Sterile Prosthetic components should not be placed on existing active infection or in case of any other degenerative disease.
14. 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.
15. 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.
- 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

The Bionnovation non-sterile prosthetic components can be conditioned in unitary form or in sets, as follows:
Unitary form
A non-sterile prosthetic component, 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 casing a sealed high basis weight cardboard box, and 01 adhesive labels annexed.
Set:
An unit of the non-sterile prosthetic component with detached definitive bolt, 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 casing a sealed high basis weight cardboard box, and 01 adhesive.

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.