



CoCr/Plastic Non-Sterile Prosthetic Components



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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



Mantener 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



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



Mantener seco
Mantenga seco
Keep dry



Não reutilizar
No reutilizar
Do not reuse



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



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.

Osseointegration is a process of dynamic interaction between the metallic surface of implants and bone tissue. Titanium naturally produces a layer of oxides able to attract cells from adjacent tissue that are induced by such physical-chemical process and tend to deposit on the outer layer of metal, thus fixating the implant to the bone tissue and allowing for the application of implant-supported prosthesis.

The CoCr/Plastic Non-Sterile Prosthetic Components family of products is composed by the components below:

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 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

Nota: Bionnovation CoCr/Plastic Non-Sterile Prosthetic Components are used as integrated abutments and subsequently comes into contact with the patient to prosthesis construction.

Accessories

Hexagonal screw and square screw

PRODUCT COMPOSITION

Bionnovation CoCr/Plastic Prosthetic Components are made of Polyacetal (Polyoxymethylene) and Cobalt-Chrome alloy band.

INDICATIONS AND PURPOSE OF USE

The implant treatment is indicated for all cases there is a need to replace lost dental elements. The purpose of treatment is the placement of dental prostheses for restoration of aesthetics and masticatory function.

After the implants' installation, the need for the correct transfer of the implant's position and synchronicity with the prosthetic attachment as well as various aesthetic options where the need for casting metal or metal-free, leads to the production of components defined as follows:

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

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

To prosthesis construction are still needed the following components of laboratory use only (they are not subject to registration, because doesn't come in contact with the patient):

- 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. The Micro Platforms (MP) and Small (SP) are indicated for replacement of upper and lower lateral incisors and lower central incisors. Regular Platform (RP) is indicated for replacement of lateral and central incisors, canines, premolars and upper or lower molars. Wide Platform (WP) is indicated for replacement of upper and lower premolars and molars.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

1. NON STERILE- CoCr/Plastic 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 CoCr/Plastic 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 CoCr/Plastic 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 **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 odontological 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.

16. 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.

Note: To have a safe combination, Abutments should be used in accordance with the connection and implant platform.

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

A CoCr/Plastic non-sterile prosthetic components with screw, 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 casing, 01 adhesive label annexed .

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.

