Bionnovation
biomateriais

Beta TCP Bionnovation

Synthetic Bioceramics

Bionnovation Produtos Biomédicos LTDA.
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MADE IN BRAZIL / INDÚSTRIA BRASILEIRA / INDUSTRIA BRASILEÑA

www.bionnovation.com.br

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

45ºC
-5ºC
Limite de Temperatura
Límite de temperatura
Temperature limitation

Prazo de Validade
Fecha de Fabricación
Date of Manufacture

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

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

Fabricante
Fabricante
Manufacturer

Manter seco
Mantenga seco
Keep dry

65%
35%
Limite de umidade
Límite de humedad
Humidity limitation

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

Não reutilizar
No reutilizar
Do not reuse

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

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

DESCRIPTION AND ACTION FOUNDATIONS

Pure phase (Ca3(PO4)2) Beta-Tricalcium Phosphate (ß-TCP) is a synthetic and reabsorbable granulated ceramic, made from Calcium Hydroxide (Ca(OH)2), Phosphoric Acid (H3PO4) and Sucrose (C12H22O11). It is used as a matrix to replace or modify the bone tissue, since it has an identity, in terms of composition, with the bone matrix and allows restoring that tissue through the osteoconduction process.

Biodegradable and biocompatible material, being partially reabsorbed between 6 and 15 weeks after the implant depending on the porosity, chemical structure and size of the particle. The resorption of Beta TCP are organized by hydrolytic mechanism that guides the physical disintegration

Calcium phosphate ceramics have deserved a place of high light among the so-called bioceramics due to their lack of local or systemic toxicity, absence of foreign body response or inflammations and apparent ability to link itself to the host tissue. Such positive characteristics maybe explained by the chemical nature of those materials, which since they are basically formed bycalcium and phosphate ions, they actively take part in the ionic balance between the biological fluid and the ceramics.

The physico-chemical similarity of the Beta TCP with bone tissue facilitates the process of recognition and osteoblast signaling that favors the remodeling process and new bone formation.

The reabsorption of the material representing that degradation is caused by dissolution, which depends on the material's solubility product and the local pH in the physiological mean, through the physical disintegration in to smaller particles and, also, through biological factors, such as phagocytosis, the presence of leukocytes and of chemical mediators that cause a reduction of the local pH.

The application of Beta Tricalcium Phosphate (ß-TCP) allows restoring the bone tissue through the osteoconduction process.

PRODUCT'S COMPOSITION

Synthetic and reabsorbable granulated ceramic, made from Calcium Hydroxide (Ca(OH)2), Phosphoric Acid (H3PO4) and Sucrose (C12H22O11)

INDICATIONS AND PURPOSE OF USE

Beta TCP is a synthetic bioceramics, elective for regenerative techniques in Periodontology, Implantology, Orthopedics or medical and dental surgeries that require bone neoformation. Is a biomaterial used in bone grafting procedures, in reconstruction in bone walls defects, traumatic or degenerative, sinus floor elevation, periodontal or alveolar bone filling and osteotomies, as well as the preservation and preparation of the implant site. In case of medical procedures are used in orthopaedics and Traumatology for cases such as muscle-skeletal tumors fixes, rachimedular and cervical spine trauma. In the event of medical procedures, they are used in orthopedics and traumatology in cases such as muscleskeletal tumors corrections, spinal cord traumatisms and cervical spine.

PRECAUTIONS, RESTRICTIONS, WARNINGS

1. STERILE - as long as maintained the integrity of the packaging, period of validity and storage conditions.
2. Professional use only Is the responsibility of the dentist or doctor their prior training to use this product. Only qualified professionals with expertise in surgical techniques and procedures necessary for proper use of the product should make use of TCP Beta. The use of incorrect surgical techniques may cause discomfort as painful sensation, hypoesthesia, edema.
3. PROHIBITED RESTERILIZE AND REPROCESS - If resterilized or reprocessed may occur change at the physical chemical properties and crystallinity levels of Beta TCP causing foreign body reaction.
4. PROHIBITED REUSE - If reused or used with expired validity, may cause irritation, infection, inflammation and other adverse events, compromising the health and safety of the patient. Bionnovation does not recommend reuse, re-processing or resterilization, discard it as current legislation for medical waste.
5. The use of the product with surgical techniques and inadequate biosecurity conditions may damage the patient leading to unsatisfactory results.
6. Always sterilize the tools before using them.
7. The clinical and radiographic evaluation must be done prior to surgery, to help the correct treatment planning. Determination of bone quality and quantity, repairs and anatomical structures and analysis of neighboring teeth.
8. In all surgeries involving beta TCP particles must be observed proper techniques used for asepsis and antisepsis.
9. The abuse of alcohol, tobacco, drugs, steroids or lack of proper oral hygiene can significantly impair the success of the treatment.
10. All potential adverse effects as dehiscence, inflammation, bone loss, hemorrhage, must be previously informed to the patient.
11. It is supplied in sterile condition and once opened should be used in aseptic conditions. Should always work with sterile fields, appropriate instruments to the procedure and in good condition in order to eliminate sources of infection and damage to the product.
12. Beta TCP should be used only for the purpose for which it is intended.
13. If occur complications impossible to be controlled, tissue inflammation or evidence of infection is recommended the immediate removal of the material.
14. Beta TCP is provided in sterile double packaging (25 kGy gamma radiation). Provided that the package integrity is not compromised in any way, it will save the sterile product up to 3 years from the date of sterilization.
15. There are no restrictions as to maximum amount of product that can be deployed. The amount will be determined by the professional after analyzing the size of the surgical site.
16. The surgeon should evaluate the indication in patients who are carriers of diseases or are making use of medication that may alter the repair metabolism.
17. The remainder of the packaging material should not be reused, reprocessed or resterilized, discard it mischaracterized as current legislation for medical waste, do not discard contaminated products in household waste.
18. 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.
19. Beta TCP was developed in order to prevent that its use does not compromise the clinical condition of patients as well as their safety.

Note: we recommend that the identification stickers that come with the product be attached to the patient's documentation: clinical record of the patient, the report delivered to the patient, product sales invoice, vendor control and control of the surgeon in charge, ensuring the complete traceability of the product.

CONTRA INDICATIONS

- Beta TCP, as well as all the other biomaterials, should not be placed on an existing active infection or in any other degenerative disease that might affect the biomaterial's placement.
- It must not beutilizedinpatientsthatare notable, under the clinical point of view, to besubmitted toamedical or odonthological intervention. Such as, for example,inpatientswithuncompensated diabetes.
- Beta TCP is not indicated for odontopediatric patients.
- It's contraindicated for procedures different from those recommended in item "Use Indication".
- Beta TCP should not be exposed to the external medium.

STERILIZATION

The sterilization of the biomaterial Beta tricalcium phosphate (β-TCP) is performed by Gamma radiation.

PRE AND POST-SURGICAL CARES

A The pre-surgical evaluation, the correct indication of materials and the employment of compatible techniques and procedures, as well as the post-surgical follow-up and controls, are fundamental to achieve the desired results.

-Pre-Surgical: All the patients that will be submitted to a surgical procedure must be care fully examined and evaluated with the purpose of determiningtheir clinical and radiographic state, as well astheir dental, bone, or adjacent soft tissue deficitsthatmightinfluencethefinal resultof theintervention.

- Post-Surgical: The product must not be exposed to the mouth environment after the the immediate postoperative. There must be a good coaptation of the surgical snip borders, in order not to be any contamination, which would compromise the surgery's result. Exposure to the mouth environment drastically reduces the absorption time. Please, not ethe post-surgical cares for the surgical procedures. Painkillers, antibiotics, or rest for 24-48 hours may be prescribed, varyingas a functionof theprocedureandof theprofessional technical conduct.

SPECIAL CONDITIONS FOR THE PRODUCT'S STORAGE AND TRANSPORTATION, CONSERVATIONAND/ORHANDLING

- Storage and Transportation: Transport and store the product away from direct sunlight, and from heat or humidity sources. Keep it at a temperature between -5° C and 45° C and free from humidity. If the indicated temperature or humidity limit is exceeded, please discard the product. Keep the packaging sealed until its utilization time. In the case of a violated packaging or if the validity term has expired, please discard the product.

Please, verify the integrity of the same before using it. 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. Discard any mischaracterized product according to the applicable legislation for hospital waste, or return the damaged packages to the factory, including the device.

- Conservation and Handling: - In case of any alteration in the Beta TCP characteristic that might have mischaracterized it, please discard it according to the applicable legislation for hospital waste, or return the damaged packages to the factory, including the device.

COMMERCIAL PRESENTATION FORMS

Content: 01 glass flask identified with an adhesive label, as the primary packaging, with y.yy g of Beta TCP (Beta Tricalcium Phosphate - $Ca_3(PO_4)_2$), a synthetic compound obtained from Calcium Hydroxide, sealed with a butyl rubber lid and sealed with aluminum seal, packaged in blister and sealed with Tyvec®, and one adhesive identification label, 05 numbered adhesive labelswithinformation onthe product's traceability, which mustbe annexed to thepatient's clinical history, an opinion deliveredto thepatientin theproduct's sale fiscal note, supplier's controlandcontrol by the responsible surgeonandfinal packaging, heavy stock and sealed cardboard box, and 02 adhesive labelsannexed to thelid (01) andon the side (01) of thebox.

Synthetic and reabsorbable granulated ceramic with particles size from 0.1 to 0.5 mm, 0.6 to 1.0 mm, 1.1 to 1.5 mm, 1.6 to 2.0 mm, 2.1 to 2.5 mm and 2.6 to 3.0 mm, conditioned in vials in quantities of 0,5 g - 1,0 g - 1,5 g - 2,0 g - 2,5 g - 3,0 g - 3,5 g - 4,0 g - 4,5 g - 5,0 g - 6,0 g 7,0 g - 8,0 g - 9,0 g - 10,0 g - 15,0 g

USE INSTRUCTIONS

1. The bone region to receiving the biomaterial should be exposed and curetted, Decorticated or pierced for exposure of organic matrix and removed all compromised tissue. To facilitate application to the surgical site may be used conventional instruments such as curettes, spatulas, plastic or metal applicators.
2. The product is bonded by blood as it is being applied. The product should NOT be moistened in saline solution. For being a too thin biomaterial with easy flowing, the dentist or doctor in charge should evaluate the implant, controlling homeostasis to avoid product flow.
3. Add autogenic bone, collected during surgery, in order to facilitate the process of new bone formation.
4. Ensure the maximum contact between the bone replacement material and the receiver bone, with complete filling of space and good compression.
5. Reposition the flap on the grafted area and make sure that the coverage of the surgical site is full. Suturing in order to stabilize the area, but without tension.
6. There can be no exposure of the biomaterial, because it is critical to surgical success and to avoid contamination of the area.

CARE WHEN DISCARDING THE PRODUCT

The product's disposal must comply with the environmental and biosafety lawsin force. Do not discard contaminated products in the general waste.