INQ 027rev03 / 04-11-2015

essential

CE 0434

Hydroxyapatite

EC REP

Bionnovation Biomedical A.B.
Welandergatan 24
S-41656 Gothenburg Sweden
Phone 0303773325

Bionnovation Produtos Biomédicos LTDA.
Rua Laureano Garcia, 1-275 –CEP: 17039-760
Bauru - SP • Fone 55-14 4009 2400 • SAC 0800 770 3824
CNPJ 73.191.090/0001-19 • IE 209.444.766.117
Resp. Técnico: Roselaine dos Santos Pinto Marques - CRQ-IV 04488952
MADE IN BRAZIL / INDÚSTRIA BRASILEIRA / INDUSTRIA BRASILEÑA

www.bionnovation.com.br

Manter seco
Mantenga seco
Keep dry

Não reesterilizar
No reesterilizar
Do not resterilize

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

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

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

Fabricante
Fabricante
Manufecturer

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

-5°C 40°C
Limite de Temperatura
Límite de Temperatura
Temperature Limitation

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

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

DESCRIPTION AND ACTION FOUNDATIONS
Hydroxyapatite, Ca10(PO4)6(OH)2 is a hydrated calcium phosphate, a majority component (about 95%) of the mineral phase of human bones and teeth. It is used by the body to compound the skeleton, due to its capacity to act as a reserve of calcium and phosphorus. Owing to its chemical similarity with the mineral phase of bone tissues it becomes one of the most biocompatible materials ever known, favoring the bone growth where it is located (osteoconductive), setting up chemical bonds between it and the bone tissue (bioactive), allowing the proliferation of fibroblasts, osteoblasts and other bone cells, which do not differentiate from the bone surface indicating the high surfasse chemical similarity.
The hydroxyapatite allows integration of bipolar type alloys, causing water molecules and also proteins and collagen to be absorbed at the surface thus inducing tissue regeneration.
The application of Hydroxyapatite allows the bone tissue restoration through the osteoinduction process.

ACCESSORIES
Not applicable

COMPOSITION
The Hydroxyapatite from Bionnovation is manufactured from reactions in aqueous systems by precipitation where one of these reactions consists of adding, by dropping, Calcium Hydroxide Ca(OH)2 and Phosphoric Acid H3PO4, resulting in round, radiopaque particles in several sizes, which assist in the bone cell development.

INDICATIONS AND PURPOSE OF USE
Hydroxyapatite based biomaterials have been largely used as bone replacement. Hydroxyapatite is a bone graft material successfully used in orthopedic, cranio-maxillofacial and odontologic surgeries. It is recommended to repair defects of the base of the skull, spinal fusion, and for orthopedic use, it is also used for bone grafts around dental implants and hip mettalic prostheses.

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 Hydroxyapatite. The use of incorrect surgical techniques may cause discomfort as painful sensation, hypoesthesia, edema. The size of the particles should not be changed.
3. PROHIBITED RESTERILIZE AND REPROCESS - If resterilized or reprocessed may occur change at the physical chemical properties and crystallinity levels of Hydroxyapatite causing foreign body reaction.
4. PROHIBITED REUSE - If reused or used with expired validity, may cause irritation, inflammation and other adverse events, compromising the health and safety of the patient.
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 Hydroxyapatite 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. Hydroxyapatite 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. Hydroxyapatite 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. Hydroxyapatite 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
1. Hydroxyapatite, 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.
2. It must not be utilized in patients that are notable, under the clinical point of view, to be submitted to a medical or odonthological intervention. Such as, for example, in patients with uncompensated diabetes.
3. Hydroxyapatite is not indicated for odontopediatric patients.
4. It's contraindicated for procedures different from those recommended in item "Use Indication".
5. Hydroxyapatite should not be hydrated before the use. It should be taken directly to the recipient surgical bed

STERILIZATION
Hydroxyapatite is supplied STERILE (Gamma Radiation 25kGy), provided the package integrity is not compromised.

PRE AND POST-SURGICAL CARES
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 carefully examined and evaluated with the purpose of determining their clinical and radiographic state, as well as their dental, bone, or adjacent soft tissue déficits that might influence the final result of the intervention.
Post-Surgical: Please, note the post-surgical cares for the surgical procedures. Painkillers, antibiotics, or rest for 24-48 hours may be prescribed, varyingas a function of the procedure and of the professional technical conduct. The product must not be exposed to the mouth environment after the the immediate post operative. 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.

SPECIAL CONDITIONS FOR THE PRODUCT'S STORAGE AND TRANSPORTATION, CONSERVATION AND/OR HANDLING
STORAGE AND TRANSPORTATION
Store and transport the product away from direct sunlight, and from heat. (temperature between -5 and 40°C) and humidity. Keep the packaging sealed until its utilization time. 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 Hydroxyapatite 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
Hydroxyapatite granules
Primary packaging: glass flask sealed with a butyl rubber lid and sealed with aluminum seal, may contain 01-05 units.
Secondary packaging: blister and sealed with Tyveck®, and one adhesive identification label.
Final packaging: a sealed high grammage cardboard box, and 02 adhesive labels, one placed on the lid (01) and the other one on the frontal part (01) of the box, accompanied by 05 adhesive labels with information on the product's traceability

Hydroxyapatite as block
Primary packaging: blister and sealed with Tyveck®, and one adhesive identification label.
Final packaging: a sealed high grammage cardboard box, and 02 adhesive labels, one placed on the lid (01) and the other one on the frontal part (01) of the box, accompanied by 05 adhesive labels with information on the product's traceability

USE INSTRUCTIONS
1. The bone area that will receive the biomaterial should be opened and scraped with a curette, decorticated or perforated for exposure of organic matrix and the whole jeopardized tissue should be removed. Conventional instruments such as curettes, spatulas, plastic or metallic applicators can be used so as to ease the application at the surgical site.
2. The product is bonded by blood as it is being applied. The product should NOT be moistened in saline solution.
3. Add autogenic bone, collected during surgery, in order to facilitate the process of new boné 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.