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essential

Bonefill®

Bone Graft

Bionnovation Produtos Biomédicos LTDA.
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Prazo de Validade
Fecha de Fabricación
Date of Manufacture

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


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


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

Limite de Temperatura
Límite de temperatura
Temperature limitation


Data de Fabricação
Fecha de Fabricación
Date of Manufacture


Fabricante
Fabricante
Manufecturer

Código do Produto
Código del Producto
Product Code

Número do Lote
Número de Partida
Batch Number


Manter seco
Mantenga seco
Keep dry

Não reesterilizar
No reesterilizar
Do not resterilize

DESCRIPTION AND ACTION FOUNDATIONS

Bonefill – Materials for bone graft, natural bone mineral extracted from bovine femur, is an implantable dental biomaterial used in bone failure reconstructions where remodeling or bone neoformationis desired.
The purified osteoconductive mineral structure is produced from natural bone through a multiphase purification process, complying with the safety regulations established by the control agencies. The fresh bone is crushed, receiving a sequence of baths that solubilize the organic structures such as, for example, remaining cells, fibers and proteins, with only the mineral portion remaining this way in order to avoid the induction of possible immunogenic processes in the body. The products constituted by mineralized bovine bone is has an expected incorporation of 6 to 9 months.
Due to the natural origin, Bonefill – Materials for Bone Graft is comparable to the mineral and morphological structure of the human mineralized bone, it is biocompatible, does not present cytotoxicity, acute systemic toxicity, sub-chronic toxicity, carcinogenicity and it is not a sensitizing product (ISO 10993-1).
Bonefill – Materials for bone graft, are available in the following models: Bonefill and Bonefill Mix in granule form and Bonefill Porous, available in granules and blocks. The granules are presented in glass vials packed in blister and box and the blocks are packed in blister and box.
Bonefillis produced through the decalcification process of the cortical portion of bovine bones, Bonefill Porous is produced through the same decalcification process applied to the spongy portion of bovine bones and Bonefill Mix is produced through the decalcification process applied to the spongy and cortical portion of bovine bones (approximate ratio of 70:30).
The mineralized inorganic bone matrix of the Bonefill has a porous macro and micro structure similar to the human cortical and spongy bones. In granulate form, Bonefill, Bonefill Porous and Bonefill Mix act as osteoconductive mechanism promoting bone growth and regeneration. With time, the Bonefillis partially remodeled through the action of osteoclasts and osteoblasts, being a viable alternative to autologous bone in defects suitable for its use and indication.
In Bonefill Porous, due to the high number of connection pores and the natural composition, there is the formation and growth of new bone at the implant site. Bonefill Porousblockis incorporated in the receiving bed through a bone consolidation mechanism comparable to the biological principles of the consolidations of fracture, obtained through the formation of new bone connected to the receiving bone /implant interface.

PRODUCT'S COMPOSITION

Bonefill – materials for bone graftmanufactured from natural bone extracted from bovine femur

INDICATIONS AND PURPOSE OF USE

Bonefill – materials for bone graft is recommended for filling of bone defects and for volumetric increase in the following situations: increase/reconstructions of alveolar crests, filling of post-extraction cavities, filling of cavities produced by post-surgery treatment interventions of cysts, granulomas and other lytic, oral and maxillofacial and dental pathologies, preparation of implant and filling sites of bone dehiscence, besides bone grafts in maxillary sinuses and in the periodontal area it can be used in filling bone defects and to support the membrane during guided bone regeneration.

PRECAUTIONS, RESTRICTIONS, WARNINGS

1.STERILE – as long as the integrity of the pack, expiry date and storage conditions are maintained.
2.EXCLUSIVE PROFESSIONAL USE – the prior qualification for use of this product is under the responsibility of the dentist. Only skilled professionals with knowledge of surgical techniques and the necessary procedures for the appropriate use of the product should make use of Bonefill – materials for bone graft. The use of incorrect surgical techniques may cause discomfort such as painful sensation, hypoesthesia and/or edema. The size of the particles should not be changed.
3.RE-STERILIZATION AND REPROCESSING IS FORBIDDEN – If re-sterilized or reprocessed, change in the physical and chemical properties and crystalline levels of Bonefill – materials for bone graft may occur, causing foreign body reaction.
4.REUSE IS FORBIDDEN – If reused or used after the expiry date, the sterilization and functioning are no longer guaranteed, and it may cause irritation, inflammation and other adverse events, affecting the health and safety of the patient. Bionnovation does not recommend the reuse, reprocessing or re-sterilization; dispose according to the effective legislation for hospital wastes.
5.The use of the product with inappropriate surgical techniques and biosafety can affect the patient, leading to dissatisfactory results.
6.Always sterilize the instruments before using them.
7.The clinical and radiographic assessment should be performed prior to the installation surgery to help the correct planning of the treatment. Determination of bone quality and quantity, repairs and anatomical structures and analysis of the neighboring teeth.
8.In all operations involving Bonefill – materials for bone graft, the appropriate asepsis and antisepsis techniques should be observed.
9.The abusive use of alcohol, tobacco, drugs, corticoids or lack of appropriate oral hygiene can significantly compromise the success of the treatment.
10.All the potential adverse effects like dehiscence, inflammation, hemorrhage, should be previously informed to the patient.
11.It is supplied in sterile state and after opened it should be used under aseptic conditions. Always work with sterile fields and instruments appropriate for the procedure and in good state of conservation in order to eliminate sources of infection and damages to the product.
12.Bonefill – materials for bone graft should only be used for the purpose for which it is intended.
13.In the case of complications that are impossible to control, inflammations of the tissue or evidence of infection, the immediate removal of the material is recommended.
14.Bonefill – materials for bone graft is supplied in a double sterile pack (Gamma Radiation 25 kGy). As long as the integrity of the pack is not compromised in any way, it will keep the product sterile for up to 3 years as from the date of sterilization.
15.There are no restrictions regarding the maximum quantity of product that can be implanted. The quantity will be determined by the professional after analyzing the size of the surgical bed.
16.The surgeon should assess the indication in patients with diseases or that make use of medication that may alter the repair metabolism.
17.the remaining packaging material should not be reused, resterilized or reprocessed, dispose of it featureless according to the effective legislation for hospital waste, not disposing contaminated products in common waste.
18.In cases of adverse effects on the patient, the professional responsible should immediately contact SAC Bionnovation (customer service) on **0800 770 3824** or e-mail **sac@bionnovation.com.br.** Bionnovation Produtos Biomédicos is responsible for notifying ANVISA (National Health Surveillance Agency) of relevant occurrences according to the internal technovigilance procedure.
19.Bonefill – materials for bone graft was developed to prevent its use from compromising the clinical condition and safety of patients.
20. The surgeon is recommended to keep a follow-up report of the evolution of the case together with the results.
21.All the bone substitutes of bovine origin of the Bonefill – materials for bone graft line are manufactured with animal bones from herd tracked by the SISBOV system. According to the geographical risk classification issued by the International Zoosanitary Code and by the Scientific Steering Committee of the European Community (SSCEC August 2005), Brazil is free from Bovine Spongiform Encephalopathy (BSE). However, according to ordinance 516/97, even with Brazil declaring to be free from Bovine Spongiform Encephalopathy, and the processing to which the products are subjected are known to be efficient in the inactivation of the causing agent of BSE and the animals used for the production of the Bonefill – materials for bone graft line are registered in the Brazilian bovine and bubaline identification and certification system – SISBOV, all products of bovine origin, even if remote, have the risk of BSE transmission. In cases of appearance of symptoms of Creutzfeldt-Jakob Disease (CJD), the health professional should notify the health authority.
22.We recommend attaching the adhesive identification labels supplied with the product to the patient's documentation: patient clinical record, report submitted to the patient, sales invoice of the product, supplier control and control of the surgeon responsible, ensuring the complete traceability of the product.

23.Bonefill – materials for bone graft does not completely substitute and does not have the osteogenic properties of the autologous bone. Therefore, it should be used in bone defects that promote suitable nutrition to the graft in order for its osteoconductive activity to take place.
24. The professional is recommended to check the general health condition of the patient, observing situations and pathologies that may lead to a surgical risk and reduced potential of success in the bone formation. E.g.: Uncontrolled metabolic dysfunctions like diabetes, osteomalacia, thyroid dysfunction, severe liver or kidney failure, patients with prolonged use of corticoids, autoimmune diseases, patients subjected to radiotherapy, and heavy smoking.
25.To ensure the regeneration of the bone, Bonefill – materials for bone graft should only be implanted in vital bone tissue and in direct contact with the host bone. It is recommendable to use barriers or membranes over Bonefill – materials for bone graft, complying with the recommendations of the bone regeneration techniques.
26.For extensive defects, the addition of autologous bone is recommendable. Bonefill – materials for bone graft does not substitute and does not have the properties of the autologous bone.
27.After implanting the biomaterial, a waiting period of 6 to 9 months should be observed for the dental implant procedure, or when the implant occurs simultaneously with the graft, the same waiting period should be observed.
28.The increase of the ridge of the material depends on the volume and nutritional power of the receiving site bone.
29.Despite al the in vivo and in vitro toxicity and biocompatibility tests not showing secondary responses, incompatibility reactions to Bonefill – materials for bone graft cannot be completely excluded. Possible undesirable reactions may occur in the sequence of any surgery, including edema on the surgical site, hemorrhage, site inflammation, bone loss, infection or pain.
30.Pregnancy and Lactation: There is no data available on the use of the product during pregnancy and lactation. For safety reasons, pregnant or nursing mothers should not be treated with Bonefill – materials for bone graft. The safety and efficacy of Bonefill – materials for bone graft were not investigated in children prior to their skeletal maturity.
31.The professional should assess the characteristics of the bone support suitable for implanting since bone density is a variable and determining factor in the planning and execution of endosteal implants. Each type of density has different advantages and disadvantages, which will determine the most suitable planning. The bone density influences the surgical technique and time of healing. Therefore, the prior knowledge of the bone density becomes an indispensible factor for correct planning.
According to MISCH, C.E (1998), there are 5 groups of bone density, independent of the region in the dental arch, based on the macroscopic characteristics of the cortical (external portion of the bone) and the trabecular bone (internal portion of the bone):
D1 Dense cortical bone;
D2 Has dense cortical and thick trabecular bone;
D3 Thin cortical bone and thin trabecular bone
D4 Thin trabecular bone;
D5 Non-mineralized bone, immature
Depending on the location and time an area remained edentulous, its density will be variable. However, there are areas where the types of bones are most commonly found: D1 is found in the atrophic anterior mandible; D2 is found in the region of the anterior mandible, posterior mandible and anterior maxilla; D3 is found in the region of the anterior maxilla, posterior maxilla, posterior mandible and osteoplasty in D2 bone; and D4 is found in the region of the posterior maxilla. Ideally, the surgeon should establish a post-operative control protocol, including measures taken during observed situations.
The surgeon is also recommended to keep a follow-up report of the evolution of the case together with the results.
Note: There are no load restrictions for the product.

CONTRA INDICATIONS
1.Bonefill – materials for bone graft, like all other biomaterials, should not be placed in existing active infection or in any other degenerative disease that alters the quality of the material. It should be used with special precaution in patients with acute or chronic infection in the surgical site (e.g.: cysts, osteomyelitis, acute necrotizing ulcerative periodontitis, acute sinusitis)
2.It should not be used in patients that, under the clinical point of view, cannot be subjected to a dental intervention. Such as patients with uncompensated diabetes.
3.Bonefill – materials for bone graft is not indicated for pediatric dental patients .
4.It is contraindicated in procedures different from that recommended in the item "Intended Use"
5.Bonefill – materials for bone graft, should not be exposed to the outside environment.

STERILIZATION
Bonefil – materials for bone graft is supplied STERILE (Gamma Radiation 25kGy), provided the package integrity is not compromised.
PRE AND POST-SURGICAL CARES
In the pre-operative assessment, the correct indication of the materials and the use of compatible techniques and procedures, as well as follow-up and post--operative controls, are imperative for the desired results.

Pre-Operative Cares: All patients that will be subjected to a surgical procedure should be closely examined and assessed to determine the clinical radiographic condition, as well as the dental or bone or adjacent soft tissue deficits that may influence the final result of the intervention.

Post-Operative Cares:Analgesics, antibiotics, rest during the first 24 to 48 hours can be prescribed, varying based on the procedure and professional technical conduct.The product should not be exposed to the oral environment during the immediate post-operative period. There should be good coaptation of the edges of the surgical flap in order to prevent exposure of the Bonefill – Materials for bone graft, which will compromise the result of the surgery. The exposure to the oral environment drastically reduces the absorption time.

SPECIAL CONDITIONS FOR THE PRODUCT'S STORAGE AND TRANSPORTATION, CONSERVATION AND/OR HANDLING

StorageandTransportation:
Store and transport away from direct sunlight, sources of heat (keep at room temperature of 15 - 25°C) and humidity. Keep the pack sealed until time of use. Ensure the integrity of the pack before use. Do not use if the sterile pack is open or damaged or has an expired sterilization date in order to avoid possible contamination. Dispose of the uncharacterized product according to the effective legislation for hospital wastes or return the damaged packs and device to the manufacturing plant.

COMMERCIAL PRESENTATION FORMS

Bonefill, Bonefill Porous and Bonefill Mix (Granules)
Primary Packaging: Glass vial with rubber cap and aluminum seal.
Secondary packaging: Blister sealed with Tyveck® and adhesive identification label
Final Packaging: Sealed high grammage cardboard box with 2 labels attached to the cover (1) and to the front part (1) of the box. It includes 5 adhesive labels with information for traceability of the product that should be attached to the clinical record of the patient, report submitted to the patient, to the sales invoice of the product, supplier control and control of the surgeon in charge.

Bonefill Porous (Blocks)
Primary packaging: Blister sealed with Tyveck® and adhesive identification label
Final Packaging: Sealed high grammage cardboard box with 2 labels attached to the cover (1) and to the front part (1) of the box. It includes 5 adhesive labels with information for traceability of the product that should be attached to the clinical record of the patient, report submitted to the patient, to the sales invoice of the product, supplier control and control of the surgeon in charge.

USE INSTRUCTIONS
When using Bonefill – Materials for bone graft in its various presentations, the professional should observe the general surgical principles of sterile handling and prophylactic medication of the patient, completely eliminating the granulation tissue and preparing the receiving bed with bone perforations to promote blood nutrition.
The incisions should produce flaps of the soft tissue without damages, with enough flexibility to completely cover the implanted biomaterial, free from stress during the suturing procedure.In case the flaps are not enough to cover, the professional should make additional incisions on the periosteum to release and increase the flexibility of the soft tissue for covering.
The Guided Bone Regeneration techniques strongly recommend the use of membranes and barriers.In the same way, Bonefill – Materials for bone graft should be isolated from the soft tissues with a barrier that promotes the osteoconductive mechanism of its particles.

Bonefill, Bonefill Porous and Bonefill Mix (Granules)
1.It should be placed in the defect using sterile instruments (curettes or spatulas), without the mandatory need for prior hydration.
2.Modeling in situcan be performed with a spatula or another suitable instrument chosen by the surgeon.
3.It is advisable to cover the granulated biomaterial with a membrane or barrier according to the protocols of the regenerative techniques should avoid competition of the soft tissues and maintain the stabilization of the material.

Bonefill Porous (Block)
BonefillPorous Block is presented in pre-manufactured measurements and shapes by Bionnovation. To use, remove from the pack and model it giving the desired shape for the region to be implanted. For modeling, scissors, hemostatic forceps or drills can be used.
1. BonefillPorous block is presented in pre-manufactured measurements and shapes by Bionnovation.
2. Observe the preparation of the area and use of suitable sterile scrub of the surgeon, assistants and patient for a sterile procedure.
3. Using sterile gloves remove the block from the pack and model it with the aid of scissors, hemostatic forceps or drills, giving the desired shape for the region to be implanted.
4. Before applying the product, the receptor bone region of the biomaterial must be exposed and curetted, decorticated or perforated to produce bleeding and nutrition of the graft. Areas impaired with injuries must be carefully treated with the removal of the impaired tissue. It is at the discretion of the surgeon to use the graft in areas that are infected and with the presence of suppuration. Bionnovation does to indicate its use in critical infectious conditions.
5. Irrigate the site before placing the graft.
6. After exposure, creation of nutrition and bleeding of the receptor area, the Bonefill block can be attached with the aid of a graft and fixation screw, providing greater stability to the bone block.
7. Ensure maximum contact between the bone substitute material and the receptor bone, with complete filling of the space. The Bonefill particles can be used to help fill the spaces.
8. Reposition the flap over the grafted area and ensure the complete covering of the surgical bed. There can be no exposure of the biomaterial because it is essential for the surgical success and to avoid contamination of the area.
9. Like in any Bone Regeneration technique, Bionnovation strongly recommends the use of membranes or barriers that promote cellular exclusion.
10. For all regeneration techniques, the surgeon must be very cautious when displacing flaps in order not to damage the soft tissues and periosteum. The health of these is very important in the prevention of early exposure of the implanted materials.

Special instructions for use in periodontal correction procedures
A basic requirement for a well successful periodontal treatment includes the control of any bacterial infection as well as careful oral hygiene. Therefore, it is advisable to have a health promotion and oral preparation phase prior to the surgical implant procedures, combined with instructing the patients regarding the oral hygiene maintenance procedures. Also, carry out a careful treatment of the periodontal lesion (scraping, root planing, decontamination and debridement) before the implant. The application of the granulated biomaterial in the bone defects should be followed by the use of barrier or membrane for good tissue regeneration.

CARE WHEN DISCARDING THE PRODUCT
The product's disposal must comply with the environmental and biosafety lawsin force. Do notdiscardcontaminatedproducts in the general waste.