Bionnovation
biomateriais

CE 0434

Surgitime Titanium

EC REP

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MADE IN BRAZIL / INDÚSTRIA BRASILEIRA / INDUSTRIA BRASILEÑA

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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

40°C
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

Surgitime Titanium (Titanium mesh) is a no absorbable titanium screen made of pure Titanium (ASTM F-67), that helps in bone neoformation, acting as barrier that block the migration of epithelial and connective tissue, avoiding competition with bone graft. They come in many different lengths, widths, thicknesses, and hole diameters.

The titanium mesh provides excellent biocompatibility, and occlusive property, and it's permeable allowing the transmission of nutrients, and it's easy to use, since it's very malleable and can be cut for surgical site adaptations, having the capacity to keep the regenerative space intact with the possibility of bone graft vascularization on both sides (periosteum and endosseous). It has been designed to ensure the tridimensional reconstruction of alveolar bone defects and to facilitate bone replacement through the replacement material's adequate fixation.

Since it has memory, it can be premolded into the defect and fixed with graft bolts and Bionnovation fixation on the bone surface, however it is not necessary to use a bone graft screw for the titanium mesh to exercise its function, and its use varies according to the responsible professional's options.

The titanium mesh conforms the tissue contours and also is rigid enough to keep a space on the bone defect and the overlapping tissue. It's important to use Surgitime Titanium (titanium mesh) temporarily in order to promote an adequate environment, allowing the organism to utilize its natural cicatrization potential and regenerate the lost or missing tissue.

The necessary stay for starting the osteoconduction is at least 21 days.

List of accessories that should integrate the product

Bionnovation Graft & Fixation Screw

PRODUCT COMPOSITION

Surgitime Titanium (Titanium mesh) is made of pure grade 1 Titanium according to Standard ASTM F 6 7.

INDICATION AND PURPOSE OF USE

Surgitime Titanium (titanium mesh) is indicated for medical regenerative procedures (orthopedics and neurosurgery) and odonthological (periodontics, oral and maxillofacial, implantodontics), especially for bone reconstructions. In odonthological cases we recommend a second surgery for their removal, and since they are made of pure titanium, there may be osseointegration when used with autogenic bone graft, thus hindering their withdrawal. The titanium mesh's withdrawal varies according to the responsible professional's options.

The titanium meshes, also known as mechanical barriers for GBR – Guided Bone Regeneration, help in bone neoformation, acting as biological barriers to avoid cell migration from the epithelium, the conjunctive tissue and/or bacteria that might cause bone growth inhibition, promoting an adequate space for the formation of a natural fibrin understructure, precursor of the bone tissue. It is an easily manipulated membrane which function is to protect the clot from the invasion of the nonosteogenic structures and direct it, preventing its distortion by the pressure from adjoining tissues. Surgitime titanium is anyway a barrier even with the larger holes as mentioned in the report.

Surgitime Titanium is an excellent medium for maintaining the desired crest dimensions. Once exposed, Surgitime Titanium (Titanium mesh) prevents a great loss of graft because an epithelial closure around the screen ends up occurring.

It is supplied sterile, as long as kept under the ideal storage and conservation conditions and the packing integrity has not been compromised. It is sterilized by Gamma Radiation, and should not be used in case its validity time has expired.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

1. STERILE- The product is sterile as long as package integrity, validity term and storage conditions are observed.
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 Surgitime Titanium. The use of incorrect surgical techniques may cause discomfort as painful sensation, hypoesthesia, edema.
3. DO NOT RESTERILIZE AND REPROCESS IT – if it is resterilized or reprocessed its physical-chemical properties may be altered, leading to foreign body reaction. Resterilization especially in autoclave alters the product's quality, and the titanium alloy's quality may be altered.
4. DO NOT REUTILIZE IT –the mesh is exposed to loads when implanted, becoming fragile. If it's reutilized or utilized with an expired validity date, it may lead to irritation, infection, inflammation and other adverse events, thus compromising the patient's health and safety. Bionnovation does not recommend its reutilization, reprocessing, or resterilization, so discard the product according to the applicable legislation for hospital waste.

Surgitime titanium must be in its flat form for its correct utilization, since the mesh has memory, and once it has been utilized it will never resume its original format, thus compromising its functionality.

One it has been installed with grafting screw and fixation, if it is reutilized there will be alteration in holes' diameter, thus compromising its functionality.

5. The use of the product under inadequate surgical techniques and biosafety conditions may harm the patient leading to unsatisfactory results.
6. ALWAYS STERILIZE THE SURGICAL INSTRUMENTS 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. Surgitime Titanium (Titanium mesh) is supplied sterile – so, observe the appropriate asepsis and antisepsis techniques.
9. Abuse of alcohol, tobacco, chemical dependency and corticosteroids or inappropriate oral hygiene may significantly compromise the success of treatment.
10. Patients should be informed in advance on all potential adverse effects such as dehiscence, inflammation, hemorrhage, allergic reaction.An incorrect surgical technique may lead to discomfort, such as a painful sensation, hypoesthesia and edema.
11. It is provided on the sterile condition and once opened should be used on aseptic conditions. 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.
12. Surgitime Titanium (Titanium mesh) should be used only for the purpose for which it is intended.
13. The membrane exposure may occur in dental procedures, when no perfect adaptation to the receiving bed or the covering tissues occurs.

14.In odonthological cases we recommend a second surgery for its removal, and since the product is made of pure Titanium, there may be osseointegration when used with autogenic bone graft, hindering its withdrawal. The titanium mesh's withdrawal varies according to the responsible professional's options.
15.If occur complications impossible to be controlled, tissue inflammation or evidence of infection is recommended the immediate removal of the material.
16.Surgitime Titanium (Titanium mesh) is provided in sterile double packaging (25 kGy gamma radiation). Provided the packaging's integrity has not been somewhat compromised, it will keep the product sterile for up to 4 years to be counted as of the sterilization date.
17.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.
18.Surgitime Titanium must be molded according to the bone's anatomy, and it must not be folded em sharp angles, scored or deformed. Once it has been utilized and molded, it must not be molded again, since it might lead to product function failure.
19.The correct handling of Surgitime Titanium is highly important, and it may only be handled when deemed necessary, and excessive mesh modifications or molding may lead to breakage and/or deformation.
20.The surgeon shall evaluate its indication to patients diagnosed with diseases or that use a medication that might change the reparation metabolism
21.The remaining material on the bottle may not be reused, resterilized or reprocessed. Dispose of it in a de-characterized way, according to the current legislation for hospital waste.
22.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.
23.Surgitime Titanium (Titanium mesh) was developed in order to prevent that its use does not compromise the clinical condition of patients as well as their safety.

Note: Bionnovation suggests that the product's 5 identification adhesive labels are attached to patient documentation (patient's clinical dossier, report given to the patient, sale invoice of the product, supplier control and surgeon control). This assures full product traceability through the ID code and batch printed in the labels, and prompt location of all production documents; then the product can be retained for evaluation and analysis purposes when needed.

CONTRAINDICATIONS
1. Surgitime Titanium (Titanium mesh), like all the other membranes, should not be placed on existing active infection or in case of any other degenerative disease that can affect mesh implant.
2. 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.
3. It's contraindicated for procedures different from those recommended in item "Use Indication".
4. Do not expose the titanium mesh to the environment, in dental procedures.
5. Surgitime Titanium (titanium mesh) must not be utilized for bone mobilization, as an osteosynthesis auxiliary, and to gather the bone fragments of a fracture.

STERILITY
Surgitime Titanium (Titanium mesh) is supplied in the STERILE form (Gamma Radiation). As long as the packing integrity is not impaired.

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 Cares: All the patients that will be submitted to a surgical procedure must be care fully 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 thefinal result of the intervention.
Post-Surgical Cares: The product must not be exposed to the mouth environment after the immediate post operative. A good product coaptation should exist on the surgical piece edges, so as to prevent the mesh contamination, what will jeopardize the surgery result. The exposure to the mouth medium may cause bacterial plate to accumulate on the mesh surface.
Please, not ethe post-surgical cares for the surgical procedures. Painkillers, antibiotics, or rest for 24-48 hours may be prescribed, varying as a function of the procedure and of the professional technical conduct.

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

STORAGE AND TRANSPORTATION
Transport and store the product away from direct sunlight, and from heat (maximum temperature: 40 º C and humidity (35% to 65%). Keep the packaging sealed until its utilization time. 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
Any alteration that occurs on the surface or shape of the mesh this might have mischaracterized, please discard it according to the applicable legislation for hospital waste, or return the damaged packages to the factory, including the device.

PRODUCT'S PRESENTATIONS

Surgitime Titanium (Titanium mesh), a non absorbable barrier produced from Pure Titanium, is available in different lengths, widths and hole diameters. in order to fulfill the many different clinical needs.

Content: 01 Surgitime Titanium film unit, non-absorbable barrier made of ASTM F67 Pure Titanium Grade 1, in different sizes with xx,x mm (length) X yy,y mm (width) X w,ww mm (thickness) , z,zz mm (hole diameters) in blister sealed with Tyveck® and an identification adhesive label, 05 numbered adhesive labels with information on the product's traceability, which must be annexed to the patient's medical records, to the medical opinion delivered to the patient, on the product's sale fiscal note, on the supplier's control sheet and on the responsible surgeon's control sheet, and on the 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. This packaging is compatible with sterilization by Gamma Radiation, and Quality Control ensures the sealed package's integrity pre and post-sterilization.

INSTRUCTIONS OF USE

1. Place the package contents on a sterile surgical field.
2. Detach the flap so that later the mesh exceeds at least 2 mm the area to be protected.
3. Using the aseptic surgery techniques applicable in the case, prepare the receiving bed for the mesh.
4. If necessary, cut the mesh with the help of sterile scissors in the adequate size, aiming at maximum adaptation to the work area.
5. Adapt the mesh to the field, leaving it flat, and thoroughly observing its edges. It must be completely under the soft tissue and without any fold.
6. Re-place the flap over the mesh.
7. Suture without involving the mesh. Only in cases of use for medical field, the meshes can be involved.
8. Using surgical cement is facultative to the surgeon in charge.
9. Antibiotics, painkillers or anti-inflammatory drugs may be used after surgery.
10. The titanium mesh can be removed once its purpose is accomplished.

CARE WHEN DISCARDING THE PRODUCT

The disposal of the product must comply with the environmental and bio safety laws in force. Do not discard contaminated products in the general waste.