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CE 0434

Surgitime Titanium

EC REP

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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

2
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) are no absorbable titanium screens made of pure titanium (ASTM F-67), that helps in bone neoformation, acting as barrier blocking an migration of epithelial cells from the connective tissue and/or bacteria that cause growth inhibition bone. They are available in two models, **Surgitime Titanium** and **Titanium Seal**

Surgitime Titanium

Surgitime Titanium provides biocompatibility, occlusive and selective property, property, has permeability, allowing the transmission of nutrients, it is easy to use because it is highly malleable and can be cut to adapt to surgical sites. It has the capacity to keep the regenerative space intact and the possibility of graft vascularization on both sides (periosteum and endosteum). It was designed to ensure the tridimensional reconstruction of alveolar bone defects and to facilitate bone replacement through suitable fixation of the replacement material.

For having memory, it can be pre-molded to the defect and fixed with Bionnovation graft and fixation screws to the bone surface (not supplied with the product, they are sold separately, and are of exclusive use), however, there is no need to use the Graft screw in order for the Titanium Mesh to exercise its function, its use varies according to the option of the professional that uses it.

The Surgitime Titanium shapes the contours of the tissue and is rigid enough to keep the space over the bone defect and the covering tissue. The temporary use of Titanium Mesh is important to promote a suitable environment, allowing the body to use its natural healing potential and to regenerate the lost of missing tissues. In cases of premature exposure of the Surgitime titanium, the minimum stay of the mesh should correspond to the onset of the osteoconduction, which occurs in an average of 21 days. Furthermore, it is suggested for the mesh to remain for 60 days, which corresponds to the time when the graft is self-supported, provided the inflammatory and infectious processes are controlled. Otherwise it should be removed.

Surgitime Titanium Seal

Surgitime Titanium Seal has excellent biocompatibility, it is fully impermeable, and it excludes the possibility of competition and invagination of the soft tissues on the grafts and bone defects.

Surgitime Titanium Seal is very flexible and can be used to cover periodontal or alveolar defects and generally does not require fixation, but if necessary, the Bionnovation graft and fixation screw accessory can be used.

For alveolar sealing procedures, **Surgitime Titanium Seal** protects the surgical wound against the invagination of the soft tissues, which promotes reabsorption of the alveolar process. Therefore, there is a statistically proven decrease of absorption reduction.

Surgitime Titanium Seal was designed to remain intentionally exposed in alveolar sealing procedures following extraction. It produces an environment for bone regeneration from blood clotting, protecting it against the invagination of the soft tissues. In cases were it is used to cover grafts, should exposure occur, chlorhexidine oral rinse solution 0.12% or chlorhexidine gel 0.20% should be used twice daily. Keep the exposed membrane in position until the graft becomes self-supported, which requires approximately 45 days.

Due to its malleability, it can be cut to adapt to the surgical sites and for being bio-electrically neutral thanks to the electrochemical passivation, it contributes to new bone growth without intercurrences.

The minimum stay necessary for the onset of osteoconduction is 21 days, and 14 days for use in the case of sealing of fresh alveoli.

LIST OF SURGITIME TITANIUM (TITANIUM MESH) ACCESSORIES

Bionnovation graft and fixation screw

The screw is made of Titanium F136 6Al 4V, the best material due to its excellent biocompatibility and resistance to corrosion in the biological environment. The shape is developed to promote stability even in spongy bone and to keep the membrane in position. It is a threaded screw, with cylindrical body, self-tapping and milled tapered tip, head with spherical surface with an insert for cross-head screwdriver

The Bionnovation Graft and Fixation Screws are implantable medical and dental devices intended for fixation and immobilization of the membranes with bone reconstruction function and they are sold separately.

It is a viable alternative that has been clinically and scientifically tested during the years for the treatment of bone tissue injuries resulting from lesions, tumor resections and dental-maxillofacial deformities. The screws can be temporary or not for fixation of the **Surgitime Titanium** and **Surgitime Titanium Seal.The screw is not indicated for fixing the plates for osteosynthesis; fracture of the screw may occur if plates are used as well as its non-adaptation due to the difference in the profile of the screw.**

It is a single use product and the raw material from which it is machined allows it to be subjected to the gamma radiation sterilization process, which is fundamental for use in clinical intervention procedures.

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 (orthopedic, it is usually applied as a element to reconstruction of orbit floor cavity and neurosurgery) and dental (periodontal, oral-maxillofacial, implantology) regenerative procedures, especially for bone reconstructions. In dental cases, we recommend a second surgery for its removal since osteointegration may occur with the autogenous bone graft because it is made of pure Titanium, thus making its removal difficult.

Surgitime Titanium (Titanium mesh), also known as mechanical barriers for GBR – Guided Bone Regeneration, aid in bone neoformation, acting as a barrier that prevents the migration of epithelial cells and connective tissue, avoiding competition with the bone graft, promoting suitable space for the formation of a natural fibrin framework, precursor of the bone tissue.

The Surgitime Titanium (Titanium mesh) are an excellent tool for maintenance of the dimensions of the desired increase of the alveolar bone crest. Once exposed, the **Surgitime Titanium** model prevents great loss of the graft because it ends up with an epithelial closure around the mesh. Regarding the **Surgitime Titanium Seal** model, the mesh continues to protect the bone graft material even when exposed due to its impermeability. Surgitime titanium (titanium mesh) are meshes easy to handle, with the function to protect blood clot from the invasion of non-osteogenic structures and direct them preventing their distortion by the pressure of adjacent tissues. Surgitime titanium (titanium mesh) remains a barrier even with bigger holes or without holes.

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 (Titanium mesh) . The use of incorrect techniques in the placement of the screws may result in their failure and substantial loss of the adjacent bone.
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 (Titanium mesh) 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. Regarding the screw, it suffers loads when implanted, making it fragile, and its reuse may result in deformation during fitting of the insertion driver, change of the thread profile and reduction of the fixation quality of the screw.
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. In dental procedures, exposure of the mesh can occur when perfect adaptation to be receiving bed or covering tissues does not occur, or when the soft tissues are too injured during detachment of the flap. The professional must be cautious during tissue maneuvers.
14. Osteointegration can occur in case the meshes are used with autogenous bone graft, hindering its removal when necessary. In dental cases, we recommend a second surgery for its removal since osteointegration may occur with the autogenous bone graft because it is made of pure Titanium, thus making its removal difficult. The removal time of the titanium mesh varies according to the option and responsibility of the professional.
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 (Titanium mesh) 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 the Surgitime Titanium (Titanium mesh) is of great importance; it should be handled only when necessary because excess modifications or modeling on the meshes can contribute to its breakage and/or deformation.
20. Suspicion and evidence of sensitivity to Surgitime Titanium (Titanium mesh) material must be verified by the professional during anamnesis and medical history. In the case of any, the professional must request for sensitivity tests prior to implanting.
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.
24. The surgeon should assess the indication in patients with diseases or that make use of medication that may alter the repair metabolism.

Note: Bionnovation suggests that the product's 5 identification adhesive labels with numbers 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 other meshes, must not be placed in regions of existing active infection or in any other degenerative disease that affects the placement of the mesh.
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". procedures. **Surgitime Titanium Seal** was designed to remain intentionally exposed in alveolar sealing procedures after extraction because it creates an environment for bone regeneration from blood clotting, protecting it against the invagination of soft tissues.
4. Do not expose the Surgitime Titanium (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. If used, fracture of the screw may occur as well as its non-adaptation in the plate due to the difference in the screw profile

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. Surgitime titanium Seal was designed to remain intentionally exposed in alveolar sealing procedures after extraction.
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 and **Surgitime Titanium Seal** are available in different lengths, widths, thicknesses and hole diameters. **Surgitime Titanium Seal** has no perforations and it is completely impermeable. It has a large variety of models in order to meet the different clinical needs.
Content: 01 Surgitime Titanium (Titanium mesh) 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,zzmm (hole diameters), in case of the **Surgitime Titanium Seal** has no perforations. It is packed blister sealed with Tyveck® and an identification adhesive label, 05 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. The Surgitime Titanium (Titanium mesh) must exceed 2mm of the grafted area in its entire length. A flap that exceeds 5mm of safety is suggested over the entire length of the Surgitime Titanium (Titanium mesh) for its passive covering.
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. In dental procedures, the mesh can be removed after performing its intended function. It is recommended to use the graft screw for fixation of the Surgitime titanium (titanium mesh)
10. The Surgitime Titanium (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.