IMPLANTABLE SURGICAL MESH
SURGITIME TITANIUM (TITANIUM MESH)
VALID FOR ALL COUNTRIES EXCEPT BRAZIL
PROFESSIONAL USE ONLY

Manufacturer/Distributor in Brazil:
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ANVISA REGISTRATION No: 10392710028
Technical Manager: Gustavo Telli Athaide CREA SP 5069918500
Technical Product Name: Implantable Surgical Mesh (2701074)
Trade Name: Surgitime Titanium (titanium mesh)
Sterilization Method: Gamma Radiation

Keep out of the sun

Keep dry

Do not use if the packaging is damaged

See instructions for use

Temperature Limit

Do not reuse

Do not resterilize

Product sterilized by gamma radiation

Expiration date

Manufacturing date

Lot

Reference / code

1. DETAILED DESCRIPTION OF THE MEDICAL PRODUCT, INCLUDING THE FUNDAMENTALS OF ITS OPERATION AND ACTION, ITS CONTENT OR COMPOSITION, WHEN APPLICABLE, AS WELL AS A LIST OF ACCESSORIES INTENDED TO INTEGRATE THE PRODUCT.

Surgitime Titanium (titanium mesh) is a non-absorbable titanium mesh made of commercially pure Titanium (ASTM F-67/EN ISO 5832-2) that helps in bone neoformation, acting as a biological barrier, preventing the migration of epithelial cells connective tissue and/or bacteria that would cause the inhibition of bone growth.

Surgitime Titanium provides biocompatibility, an occlusive property, has permeability allowing the transmission of nutrients, ease of use, as it is very malleable and can be trimmed to adapt to surgical sites. It has the ability to maintain an intact regenerative space and the possibility of vascularization of the bidirectional graft (periosteum and endosseum). It is designed to aid in the three-dimensional reconstruction of alveolar bone defects and facilitate bone replacement through proper fixation of replacement material.

Because it has memory, it can be pre-molded to the defect and fixed with Bionnovation Screws for graft and fixation to the bone surface (they do not come with the product, they are sold separately, and for exclusive use), however there is no need to use the Screw for grafting for that the titanium mesh performs its function. The fixation decision varies according to the choice and conduct of the professional who uses it.

The titanium mesh conforms to the tissue contours and still has enough rigidity to maintain the space over the bone defect and the covering tissue. It is important to use Surgitime Titanium temporarily to promote a suitable environment, allowing the body to use its natural healing potential and regenerate lost or absent tissue.

The removal of Surgitime varies according to the choice and responsibility of the professional, for removal of surgitime Titanium a second surgery is necessary for its removal. In cases of premature exposure of Surgitime titanium, it should be considered that the minimum permanence of the mesh should correspond to the beginning of osteoconduction, which takes place, on average, in 21 days. Furthermore, it is suggested to keep the mesh for 60 days, which corresponds to the time when the graft is self-sustained, as long as it manages to control the inflammatory and infectious process. Otherwise it must be removed.

2. COMPOSITION

Surgitime Titanium (titanium mesh) is made with grade I Pure Titanium sheet in accordance with ASTM F-67 and EN ISO 5832-2.

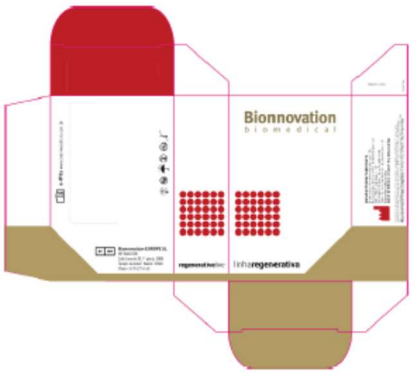
3. FORMS OF COMMERCIAL PRESENTATION

Surgitime Titanium (titanium mesh) is available in different lengths, widths, thicknesses and hole diameters in order to meet different clinical needs.

Contents: 01 unit of Surgitime Titanium film, non-absorbable barrier produced with Pure Titanium Grade 1 ASTM F67, 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 adhesive identification label, 05 adhesive labels numbered with information for product traceability that must be attached to the patient's clinical record, report delivered to the patient, in the note product sales tax, supplier control and control of the surgeon in charge and final packaging, sealed heavyweight cardboard box, and 02 adhesive labels attached to the lid (01) and front (01) of the box. This package is compatible with sterilization in Gamma Radiation, and the Quality Control guarantees the integrity of the pre- and post-sterilization sealed.

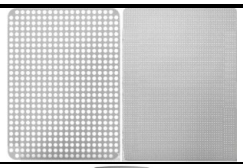
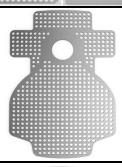
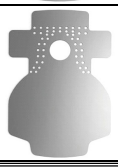
Primary Package

Blister and Tyveck® (with identification tag)



Final Packaging

3.1. LIST OF MODELS FROM SURGITIME TITANIUM (TITANIUM MESH)

	Models (length x width)	Holes Diameters	mesh thickness	
	Surgitime Titanium 34,0 mm x 25,0 mm		0,04 mm	0,08 mm
		0,15 mm	16565	16473
		0,85 mm	16472	16698
	Surgitime Titanium 3DF 18 mm x 12 mm	0,35 mm	-	161256
	Surgitime Titanium 3DL 18 mm x 12 mm	0,35 mm	-	161261

3.2. CODES AND DESCRIPTION OF SURGITIME TITANIUM (TITANIUM MESH)

16472 SURGITIME TITANIUM 34,0 x 25,0 x 0,04 HOLE 0,85mm

16473 SURGITIME TITANIUM 34,0 x 25,0 x 0,08 HOLE 0,15mm
16565 SURGITIME TITANIUM 34,0 x 25,0 x 0,04 HOLE 0,15mm
16698 SURGITIME TITANIUM 34,0 x 25,0 x 0,08 HOLE 0,85mm
161256 SURGITIME TITANIUM 3DF18 x 12 x 0,08 HOLE 0,35 mm
161261 SURGITIME TITANIUM 3DL18 x 12 x 0,08 HOLE 0,35mm

4. INDICATION, PURPOSE OR USE FOR WHICH THE PRODUCT IS INTENDED

Surgitime Titanium (titanium mesh) is indicated for regenerative dental procedures (periodontics, maxillofacial, implant dentistry), mainly for bone reconstructions. Surgitime titanium, also known as mechanical barriers for GBR - guided bone regeneration, helps in bone neoformation, acting as a barrier that prevents the migration of epithelial cells and connective tissue, avoiding competition with the bone graft, promoting adequate space for formation of a natural fibrin framework, precursor of bone tissue. Titanium meshes are an excellent vehicle for maintaining the dimensions of the desired alveolar crest bone augmentation. Once exposed, Surgitime prevents large graft loss, as there is an epithelial closure around the mesh. In cases of premature exposure of Surgitime titanium, the minimum permanence of the mesh should be considered, corresponding to the beginning of osteoconduction, which occurs, on average, in 21 days. Furthermore, it is suggested to keep the mesh for 60 days, which corresponds to the time when the graft is self-sustained, as long as it manages to control the inflammatory and infectious process. Otherwise it must be removed. The Surgitime Titanium (Titanium Mesh) has shapes in rectangles, variable thicknesses and specific holes. Surgitime titanium (titanium mesh) is still a barrier even with the biggest holes.

Titanium meshes with **0.15mm** perforation are indicated for bone reconstructions where intense blockage of soft tissue cell activity and selective permeability for microvascularization is required. They are used when applying inorganic bone grafts, with particle size ranging from 0.04 to 0.08mm in thickness.

Titanium meshes with **0.85mm** perforation are used in bone regeneration procedures to keep the graft material in position for tissue neoformation. They are applied to organic

and fresh grafts, as well as to maintain space for the techniques of using collagen blends associated with growth factors.

Surgitime Titanium and its thickness: The thinnest screens (0.04 mm) are used for tissue insulation purposes. Thicker screens (0.08 mm) are used when a structure and maintenance of architecture and regenerative space are desired. They are also used in reconstructive procedures as bone wall substitutes.

The Surgitime titanium 3DL and 3DF are customized membranes and have a special pre-formed and three-dimensional custom design for the GBR technique, it does not need a Graft Screw accessory, as it has a 2.5 mm hole that allows direct fixation on the implant through the Implant Cover, Healing Caps or Healing Caps, which can be used in HE, HI and CM implants. The holes measuring 0.35 mm prevent the displacement or migration of the Bone Graft material, but allow the diffusion of blood into the graft, with the use of the Graft Screw at the discretion of the professional, as well as the tenda screw DM 6.0, 9.0, 12.0 or 15.0 mm, sold separately.

5. INSTRUCTIONS FOR USE

1. Place the contents of the package on the sterile surgical drape.
2. Displace the flap so that the mesh later extends by at least 2 mm from the area to be protected.
3. Using the aseptic surgical techniques applicable to the case, prepare the mesh receiving bed.
4. If necessary, cut the mesh to the appropriate size with the aid of sterile scissors, aiming at maximum adaptation to the work area.
5. Adapt the mesh to the field, leaving it flat, carefully observing its edges. It should be completely under soft tissue and wrinkle free.
6. Reposition the flap over the mesh.
7. Suture without wrapping the mesh.
8. The use of surgical cement is optional for the surgeon in charge.

9. Surgitime Titanium (titanium mesh) must be removed after fulfilling its intended function.

6. PRECAUTIONS, RESTRICTIONS, WARNINGS, SPECIAL CARE AND CLARIFICATIONS ABOUT THE USE OF THE MEDICAL PRODUCT, AS WELL AS ITS STORAGE AND TRANSPORTATION.

6.1. PRECAUTIONS, RESTRICTIONS, WARNINGS SPECIAL CARE AND CLARIFICATIONS ABOUT THE USE OF THE MEDICAL PRODUCT.

1. STERILE - provided that the integrity of the packaging, expiration date and storage conditions are maintained.
2. Surgitime Titanium (titanium mesh) is supplied sterile, observe proper asepsis and antisepsis techniques.
3. Surgitime Titanium (titanium mesh) must only be used for its intended purpose.
4. Surgitime Titanium (titanium mesh) is supplied in a double sterile package (25 kGy Gamma Radiation). As long as the integrity of the package is not compromised in any way, it will keep the product sterile for up to 4 years from the date of sterilization.
5. MAGNETIC RESONANCE (MR) - SAFETY INFORMATION Surgitime Titanium has not been evaluated for safety in the MR environment. It has not been tested for heating, migration, in the RM environment. The safety of Bionnovation products in the RM environment is unknown. Scanning a patient with this device can result in interference and image changes generated during the process that can result in image artifacts that cause misinterpretation of results.
6. In cases of adverse effects occurring in the patient, the responsible professional must immediately contact the SAC Bionnovation (Customer Service) through 0800 770 3824 or e-mail sac@bionnovation.com.br . Bionnovation Produtos Biomédicos is responsible for notifying ANVISA (Agency for Sanitary Surveillance) of relevant occurrences according to the internal technovigilance procedure.

7. If any adverse patient effects occur due to the use of our products in the European community, countries should contact our authorized representative Bionnovation Europe SL by phone +34 931407240 and/or contact the factory by e- mail sac@bionnovation.com.br. Remembering that professionals are responsible for reporting adverse events to local authorities within the European Union. Health surveillance contact points are listed on the European Commission website: http://ec.europa.eu/health/medical-devices/links/vigilance_contact_points_en.htm.
8. Surgitime Titanium (titanium mesh) was developed in order to prevent its use from compromising the clinical status of patients as well as their safety.

Note: We recommend that the numbered identification adhesive labels that accompany the product be attached to the patient's documentation: patient's clinical record, report delivered to the patient, product sales invoice, supplier control and control of the responsible surgeon, ensuring complete traceability the same

6.2. *PRECAUTIONS AND WARNINGS*

1. PROFESSIONAL USE ONLY - It is the dentist's or physician's responsibility to previously train themselves to use this product. Only qualified professionals with knowledge of surgical techniques and procedures necessary for the proper use of the product should use Surgitime Titanium (titanium mesh). Using incorrect techniques for screw placement can lead to screw failure and substantial loss of adjacent bone.
2. PROHIBITED RESTERILIZATION AND REPROCESSING- be reprocessed may occur changing the physicochemical properties causing foreign body reaction. The resterilization, mainly in an autoclave, changes the quality of the product, and there may also be changes in the quality of the titanium alloy
3. REUSE PROHIBITED – the mesh suffers loads when deployed, making it fragile. If reused or used with an expired expiration date, it may cause irritation, infection, inflammation and other adverse events, compromising the patient's health and safety. Bionnovation does not recommend reuse, reprocessing or resterilization, dispose of it in accordance with current legislation for hospital waste. .

4. The use of the product with inadequate surgical techniques and biosafety conditions may harm the patient, leading to unsatisfactory results.
5. ALWAYS STERILIZE THE INSTRUMENTS BEFORE USING THEM.
6. The clinical and radiographic evaluation must be done prior to the installation surgery, to assist in the correct planning of the treatment. Determination of bone quality and quantity, repairs and anatomical structures and analysis of neighboring teeth.
7. The abusive use of alcohol, tobacco, drugs, corticoids or the lack of proper oral hygiene can significantly impair the success of the treatment.
8. It is supplied sterile and once opened must be used in aseptic conditions. Always work with sterile fields, instruments suitable for the procedure and in good condition in order to eliminate sources of infection and damage to components caused by inadequate instrumentation.
9. All potential adverse effects such as dehiscence, inflammation, infection, bone loss, hemorrhage, fracture or implant loss must be informed in advance to the patient. The implantation of Surgitime Titanium can cause discomfort such as painful sensation, hypoesthesia and edema.
10. The mesh may be exposed when there is no perfect adaptation to the receiving bed or the tissues.
11. We also recommend in dental procedures a second surgery to remove Surgitime. Surgitime's withdrawal varies according to the professional's choice and responsibility.
12. Osseointegration may occur if Surgitime Titanium (titanium mesh) is used with autogenous bone graft, making its removal difficult.
13. If uncontrollable complications, tissue inflammation or evidence of infection arise, immediate removal of the material is recommended.
14. There are no restrictions on the maximum amount of product that can be used. The amount will be determined by the professional after analyzing the size of the surgical bed.

15. The Surgitime Titanium must be molded according to the bone anatomy and must not be bent at sharp angles, scratched or deformed. Once used and molded, it must not be molded again, as it may result in failure of the product's function.
16. The correct handling of Surgitime Titanium is of great importance, and should be handled only when necessary, excessive modifications or molding in the mesh can contribute to its breakage and/or deformation.
17. When material sensitivity (allergy) is suspected, all appropriate tests should be performed prior to mesh placement.
18. The surgeon should evaluate the indication in patients who are carriers of diseases or who use medication that may alter the repair metabolism.
19. The rest of the packaging material should not be reused, resterilized or reprocessed, dispose of it in an uncharacterized way according to current legislation for hospital waste, do not discard contaminated products in common waste.

6.3. *ADVERSE EFFECTS*

All adverse effects must be previously informed to the patient. The following complications associated with the surgery are cited as adverse effects:

1. Dehiscence, inflammation, infection, discomfort, painful sensation, hypoesthesia, localized swelling, and/or abnormal sensation due to the presence of the device.

6.4. CONTRAINDICATIONS

1. Surgitime Titanium (titanium mesh), like all other meshes, should not be placed on existing active infection or any other degenerative disease that affects mesh placement.
2. It should not be used on patients who are not fit, from a clinical point of view, to undergo a dental intervention. For example, in patients with uncompensated diabetes.

3. Contraindicated for procedures other than those recommended in the item "Indication for Use"
4. Surgitime Titanium (titanium mesh) should not be used for bone mobilization, aiding in osteosynthesis and gathering bone fragments from a fracture. If used, the screw may fracture, as well as its non-adaptation to the plate due to the difference in the screw profile.

6.5. PRE AND POST-OPERATIVE CARE

In the preoperative evaluation, the correct indication of materials and the use of compatible techniques and procedures, as well as the follow-up and postoperative controls, are essential for the desirable results.

6.5.1. PRE-OPERATIVE CARE

All patients who will undergo a surgical procedure must be carefully examined and evaluated, with a view to determining the clinical and radiographic status, as well as dental deficits or deficits in adjacent bone or soft tissue that may influence the final outcome of the intervention.

6.5.2. POST-OPERATIVE CARE

Surgitime titanium should not be exposed to the oral environment in the immediate postoperative period. There must be good coaptation of the edges of the surgical flap, so that the meshes are not exposed, which could compromise the result of the surgery. Exposure to the oral environment can cause the accumulation of bacterial plaque on the mesh surface.

Observe post-operative care for surgical procedures. Analgesics, antibiotics, rest for the first 24-48 hours may be prescribed, depending on the procedure and professional technical conduct.

6.6. SPECIAL CONDITIONS FOR THE STORAGE AND TRANSPORTATION, CONSERVATION AND/OR HANDLING OF THE PRODUCT.

6.6.1. STORAGE AND TRANSPORTATION

Transport and Store the product away from direct sunlight and heat (maximum temperature: 15 -25 ° C and humidity. Keep the package sealed until use. Ensure its integrity before use. Do not use if the sterile package is opened or damaged or has expired sterilization expiration date to avoid possible contamination Discard the uncharacterized product according to current legislation for hospital waste or return the damaged packages and the device included to the factory.

6.6.2. CONSERVATION AND HANDLING

Any alteration that occurs on the surface or shape of the mesh must be discarded in an uncharacterized way according to current legislation for hospital waste or return the damaged packages and the device included to the factory.If there is an impact and it has scratches, cracks or dents of great intensity that can impair the smooth functioning of the product or the presence of broken packaging it must be discarded and a new one must be purchased.

Bionnovation® recommends complying with current environmental and biosafety laws. Do not dispose of contaminated products in common waste.

SINGLE USE PRODUCT - PROHIBITED REPROCESSING
MANUFACTURER RECOMMENDS SINGLE USE
DESTROY AFTER USE

LEGAL WARRANTY TERM

(in accordance with the Consumer Protection and Defense Code: Law 8.078, of September 11, 1990)

The company Bionnovation Produtos Biomédicos LTDA, in compliance with Art. 26 of Law 8.078, of September 11, 1990, hereby guarantees the consumer's right to complain about apparent defects or easy verification of all products. manufactured and marketed, for a period of 90 days from the date of effective delivery of the products. In the case of a hidden

defect, the statute of limitations begins when the defect becomes evident, as provided for in Paragraph 3 of Article 26 of Law 8.078.

For this Legal Warranty Term to take effect, the consumer must observe the conditions described below:

Do not allow unauthorized persons to handle the materials in question.

Do not allow misuse or misuse of the materials in question.

Follow all instructions for use in detail, as well as the precautions described in the User Manual or Instructions for Use.

We declare the information presented in this Model Instructions for Use to be true.