SURGITIME NON ABSORBABLE

BIONNOVATION PRODUTOS BIOMÉDICOS LTDA

VALID FOR ALL COUNTRIES, EXCEPT BRAZIL

Manufacturer / Distributor in Brazil:

BIONNOVATION PRODUTOS BIOMÉDICOS LTDA.

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ANVISA REGISTRATION No.: 10392710009

Technical Responsible: Gustavo Telli Athaide CREA-SP 5069918500

Technical Product Name: Regenerating Membranes (2701065)

Trade name: Surgitime Non-Resorbable

Sterilization method: Ethylene Oxide

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 ethylene oxide

Expiration date

Manufacturing date

Lot

Reference / code

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

Surgitime Non Absorbable, composed by PTFE is 100% biocompatible, synthetic, animal-free membranes. They are considered as barriers for guided tissue regeneration (GTR) and guided bone regeneration (GBR) used in regenerative techniques in dental areas. The membranes have memory and can be pre-molded to the defect, and fixed with Bionnovation® Screw for Graft and Fixation to the bone surface (not included with the product, sold separately and have own registration), however there is no need to use of screws to Surgitimes perform their function.

The Surgitime Non Absorbable or mechanical barriers to guided tissue regeneration (GTR) and/or guided bone regeneration (GBR), have function to prevent the migration of epithelial cells and connective tissue which would cause inhibition of bone growth, promoting adequate space for the formation of a natural fibrin framework, bone tissue precursor. The membranes provide a space between the flap and the bone tissue, with the purpose of tissue insulation favoring its growth. They have different lengths, widths, thicknesses that allow the choice and proper use of each surgical procedure.

The membranes need a second surgery to remove them, being able to remain at least 28 days - time to the start osteoconduction.

2. COMPOSITION

Polytetrafluoroethylene - non-biodegradable synthetic material used as a mechanical barrier in bone grafting.

3. FORMS OF PRESENTATION IN MARKET OF THE MEDICAL PRODUCT

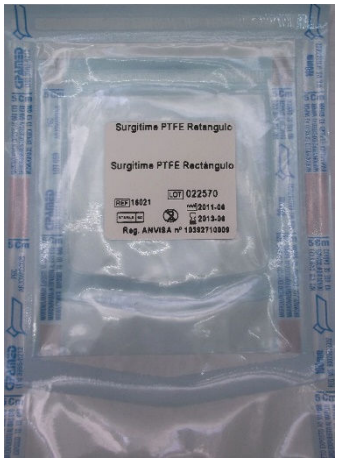
Content: 01 unit ofsheet of Surgitime Non-Absorbable, manufactured with polytetrafluoretylene, in different sizes with xx,x cm (length) X yy,y cm (width) x w,ww mm (thickness), packaged in two thermal sealant type envelopes (with sealer) and self-sealing (double-sided tape) made with surgical grade paper and PET / PP film as primary and secondary packaging, compatible with ethylene oxide sterilization (ETO), and with adhesive label of identification: 05 adhesive label with information for traceability of the product should be attached on medical chart of the patient, patient report, invoice for the sale of the product, control of the supplier and control of the surgeon responsible.

The final packaging consists of box of high grammage sealed cardboard, and adhesive labels 02 attached to the cover (01) and front (01) of the box.

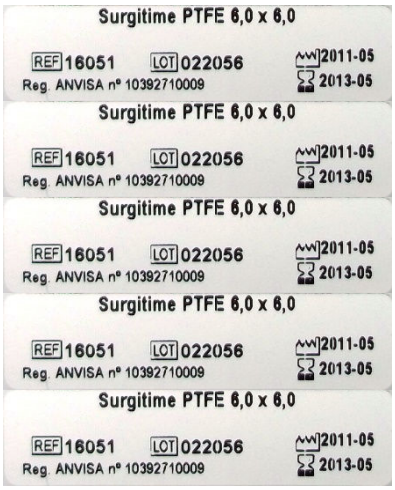
See annex: Table of Surgitime Non Absorbable: reference code, description (Surgitime PTFE), length of the membrane (*xx,x cm),* width of membrane *(yy,y cm)* andthickness of membrane *(w,ww mm).*

Surgitime NonAbsorbable

Final package of Bionnovation:
Box of cardboard



Primary and Secondary packaging:
Thermal sealant envelope and identification label



Identification Labels: Ensure total product traceability

Identification Label

Relation of Surgitime Non-Absorbable Models

16021	SURGITIME PTFE 30 x 20 x 0,1 MM
16022	SURGITIME PTFE TRAPEZE
16023	SURGITIME PTFE "H"
16044	SURGITIME PTFE 30 x 20 x 0,25 MM
16527	SURGITIME PTFE TRAPEZE 0,25 MM
16528	SURGITIME PTFE "H" 0,25 MM
16534	SURGITIME PTFE 30 x 20 x 0,50 MM
16535	SURGITIME PTFE TRAPEZE 0,50 MM
16536	SURGITIME PTFE "H" 0,50 MM

4. INDICATION, PURPOSE OR USE INTENDED FOR THE PRODUCT

The Surgitime Non Absorbable is intended for regenerative techniques in periodontics and implantology or any dental surgical procedure that requires a mechanical barrier, such as treatment of horizontal and vertical periodontal defects, formation of new bone in the alveolar ridge, protection against epithelial invagination in sinus lift procedures and formation of proximal areas around dental implants. Surgitime Non Absorbable maintains the grafting material in position, without impairing the properties of both, keeps the clot in the surgical site (if it does not use a biomaterial), prevents the migration of cells and microorganisms that may interfere in the new bone formation and allows good vascularization and nutrition for the material of grafting. They are available in different formats for better adaptation to the recipient site, and can be shaped with the aid of a sterile scalpel or scalpel.

5. INSTRUCTION FOR USE

1. Place the contents of the package over the sterile surgical field;
2. Cut the flap so that the membrane extends beyond at least 2 mm to the area to be protected;
3. Using aseptic surgical techniques applicable to the case, prepare the membrane receptor bed;
4. Cut the membrane in the appropriate size with the aid of a sterile scissors, aiming at maximum adaptation;
5. Adapt the membrane to the field, paying attention in edges. It should be completely under soft tissue and no folds;
6. Reposition the flap over the membrane;
7. Suture without wrapping the membrane;

8. The use of surgical cement is optional to the surgeon responsible;
9. Antibiotic medication, Painkillers or anti-inflammatory drugs may be used post-operatively;
10. The membrane may be removed after it has fulfilled its intended function;
11. It is suggested for the removal of the membrane that it should be detached from the tissues through the movement of tissue divulsion, that is, careful detachment clamping to avoid its fragmentation. Vigorous traction should be avoided.

6. PRECAUTIONS, RESTRICTIONS, WARNINGS, SPECIAL CARE, CLARIFICATIONS ON THE USE OF MEDICAL PRODUCT, STORAGE, TRANSPORT AND PRODUCT DISPOSAL

1. STERILE - since it kept the integrity of the packaging, shelf life and storage conditions;
2. The Surgitime Non Absorbable is supplied in sterile double packaging (ETO). Since the package integrity is not compromised in any way, save the sterile product to 5 years from the sterilization date;
3. The Surgitime Non Absorbable be used only for the purpose intended for;
4. Surgitime Non-Absorbable is not intended for alveolar preservation after extraction;
5. Surgical flaps poorly positioned, thin and/or tensioned and the lack of adequate adaptation to the surgical bed may result in post-surgical complications such as early exposure;
6. The Surgitime Non Absorbable were developed in order to prevent its use does compromise the clinical condition and safety of patients;
7. In cases of adverse effects occurring in the patient, the professional responsible should contact immediately the Bionnovation® SAC (Customer Service) through **0800 770 3824** or email **sac@Bionnovation.com.br**. The Bionnovation® Biomedical Products and all others involved (**dentists, patients and doctors**) are responsible for notifying the ANVISA (National Health Surveillance Agency - Brazil) about the relevant events as internal procedure for technical surveillance www.anvisa.gov.br/notivisa;

8. Should any adverse effects occur with the patient on 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 and by email sac@bionnovation.com.br . Recalling that professionals are responsible for reporting adverse events to local authorities within the European Union, health monitoring contact points are listed on the European Commission website: http://ec.europa.eu/health/medical-devices/links/vigilance_contact_points_en.htm.

6.1. WARNINGS AND RESTRICTIONS

1. PROFESSIONAL USE ONLY – It is the responsibility of the dental surgeon yours prior training to use this product. Only qualified professionals with knowledge in surgical techniques and procedures for proper use of the product should use the Surgitime Non Absorbable. The use of incorrect surgical techniques may cause discomfort such as painful sensation, hypoaesthesia, edema;
2. PROHIBITED TO RE-STERILISE AND REPROCESS – If re-sterilized or reprocessed may change the physicochemical properties causing foreign body reaction;
3. PROHIBITED REUSE - If reused or used with date of validity expired may cause irritation, inflammation and other adverse events, compromising the health and safety of the patient. Bionnovation® does not recommend reuse, reprocessing or resterilization, dispose of it according to current legislation for hospital waste;
4. The use of the product with surgical techniques and inadequate biosafety conditions may harm the patient leading to unsatisfactory results;
5. ALWAYS STERILIZE SURGICAL 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, as well determine bone quality and quantity, repairs, anatomical structures and in analysis of adjacent teeth;
7. In all operations involving the Surgitime Non Absorbable must be observed appropriate aseptic and antiseptic techniques;
8. The abuse of alcohol, tobacco, drugs, steroids or lack of proper oral hygiene can significantly impair the success of treatment;
9. It is supplied in a sterile condition and once opened should be used in aseptic conditions. It should always work with sterile fields, appropriate and in good condition instruments in order to eliminate sources of infection and damage caused to the product;
10. We also recommend in dental procedures a second surgery for removal of Surgitime. The removal of Surgitime vary according to choice and the professional responsibility but it must remain at least 28 DAYS and not exceeding 06-08 months for the removal, at which time it enables subsequent

reopening procedures for implants placement or prosthetic components, if there is simultaneous implantation to bone regeneration;

11. If Surgitime Non-Absorbable remains in a time superior to that indicated of 08 months, the membrane may undergo hydrolysis making it difficult to remove;
12. For the removal of the membrane should be avoided vigorous traction of the same, so as not to break it during the procedure;
13. If there is membrane fragmentation, it is suggested that a superficial curettage of the area be done in order to remove all product;
14. The Surgitime Non-Absorbable should not be exposed to the oral environment in the immediate postoperative period.
15. In cases of premature exposure to Surgitime PTFE, it is suggested that the membrane remain in place for until the beginning of osteoconduction, i.e. about 28 days, provided it can control the inflammatory and infectious process. Otherwise, of complications arise impossible to be controlled, as tissue inflammation or evidence of infection is recommended an immediate removal of the material;
16. There are no restrictions on the maximum amount of product that can be implanted. The amount will be determined by the professional after analyzing the size of the surgical bed;
17. The surgeon should evaluate the indication of Surgitime use in patients with diseases or who use medications that may alter the repair metabolism;
18. The rest of the material should not be reused, resterilized or reprocessed. Dispose of it in uncharacteristic way as legislation for hospital waste, and do not discard contaminated products in normal waste.
19. 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.

Note: We recommend that the 05 adhesive labels that accompany the product be attached to the patient's documentation: patient's clinical report, report delivered to the patient, product sales invoice, supplier control and responsible surgeon control ensuring complete traceability of the product.

6.2. ADVERSE EFFECTS

All potential adverse effects should be informed in advance to the patient. The following complications associated with surgery are listed as adverse effects: Dehiscence, inflammation, bone loss, hemorrhage and membrane exposure when there are not perfect adaptation to the recipient bed or covering tissues and should be withdrawn immediately because should not be intentionally expose.

6.3. CONTRAINDICATIONS

1. Surgitime Non-Absorbable, like all other membranes, should not be placed in existing active infection or any other degenerative disease that affects membrane placement;
2. It should not be used in patients who are not clinically fit to undergo dental intervention. As for example, in patients with uncompensated diabetes;
3. Contraindicated for other procedures than those recommended in the item "Indication of Use";
4. Bionnovation Surgitime Non-Absorbable is not intended for procedures where the patient does not have complete bone formation.

6.4. SPECIAL CONDITIONS OF STORAGE AND TRANSPORTATION, CONSERVATION AND / OR PRODUCT HANDLING.

6.4.1. Storage and Transportation

Transport and store the product away from direct sunlight, and from heat. (Maximum temperature: 15 -25° C and humidity). Keep the package sealed until the moment of use. Make sure of the integrity of it before use. Do not use if sterile package be opened or damaged or validity date expired to avoid possible contamination.

Disposal the product mischaracterized according legislation for medical waste or return the damaged package and the included device to the Factory.

6.4.2 Conservation and manipulation

Any membrane with surface changed should be disposed according to legislation for medical waste or return the damaged package and the included device to the Factory.

7. PRE– and POST-OPERATIVECARES

In the preoperative evaluation, the correct indication of the materials and the use of techniques and compatible procedures, as well as monitoring and postoperative controls are essential to the desirable results.

7.1 PREOPERATIVE CARE

All patients who will be undergo the surgical procedure should be carefully examined and evaluated in order to determine the clinical and radiographic condition, as well as bone deficit or adjacent soft tissue that may influence the outcome of the intervention.

7.2 POSTOPERATIVE CARE

The product should not be exposed to the oral environment in the immediate postoperative period. There should be good coaptation of the surgical flap edges in order to avoid exposing the membrane, which will compromise the result of the surgery. The exposure to the oral cavity may cause bacterial plaque accumulation on the membrane surface.

Observe postoperative care for surgical procedures. Painkillers, antibiotics and rest for 24-48 hours may be prescribe, varying according to the procedure and the professional technical conduct.

8. PRODUCT DISPOSAL CARE

"All products and materials used in the surgery to implants/ biomaterials installation can endanger the health of those who handle them. Therefore, after surgery all materials used should be disposed of in contaminated waste and follow the procedures of storage and dispose in accordance with current legislation.

The Bionnovation® recommends obey the environmental and current biosafety laws (classification as RDC 306) - Dispose of all contaminated waste material (identified as contaminated waste - white bag, resistant to rupture and leakage, impermeable according to NBR 9.191/2000 of ABNT) and follow the procedures of external storage and collection according to Conama Resolution No. 237/97."

9. CUSTOMER SERVICE

In cases of doubts, complaints and/or suggestions, Bionnovation provides the Customer Service (SAC) to the professional responsible contact by phone **0800 770 3824** or email **sac@Bionnovation.com.br**.The Bionnovation Biomedical Products and all others involved (dentists, patients and doctors) are responsible for notifying the ANVISA (National Health Surveillance Agency - Brazil) on the relevant events as internal procedure for technical surveillance.

LEGAL GUARANTEE TERM

(According to the Protection and Defense of Consumer Code: Law 8.078 of September 11, 1990).

In compliance with Article 26 of Law 8.078, of September 11, 1990, the ***Bionnovation Biomedical Products LTD*** company establishes the right of the consumer to complain about apparent defects or about easy verification of all products manufactured and marketed by it for a period of 90 days from the effective date of delivery of the products.

In the case of hidden defects, the decadential period starts when the defect is evidenced, as provided in Paragraph 3 of Article 26 of Law 8.078.

In order for this Legal Guarantee 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 the improper use as well as misuse of the materials in question.

Follow all the guidelines for use, as well as the care described in the User Manual or Instructions for Use.

We declare true the information presented in this Model of Instructions for Use