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essential

CE 0434

Surgitime non Resorbable

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STERILE EO
Esterilizado por óxido de etileno
Estéril por óxido de etileno
Sterilized using ethylene oxide

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

40ºC
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

35% 65%
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

The Surgitime Non Resorbable are 100% biocompatible membranes, synthetic origin, they have memory and may be pre-molded to the bone defect. Considered as barriers for tissue regeneration, they are utilized in regenerative techniques both in the medical and in the odonthological areas. Because of its consistence and facility of access on the receptor place, exempt the use of fixatives, such as screws and tacks, which significantly decrease the problems on the post-surgery immediately, such as contamination with generation of fistula and abscesses.

The Surgitime Non Resorbable or mechanical barriers for Guided Tissue Regeneration (GTR) are used to prevent migration of cells from epithelial and connective tissues, what would cause bone growth inhibition, thus providing a proper space for the formation of a natural fibrin structure, which is the bone tissue precursor. The membrane prevents competition between connective tissue and bone, and has the purpose of isolating bone grafts promoting tissue regeneration. They come in different lengths and widths, providing adequate choices and uses for each surgical procedure.

In odonthological procedures, it's necessary to undertake a second surgery to withdraw them, and they may remain in site for at least 21 days, the time necessary to start osteoconduction.

COMPOSITION

Poly-tetra-fluoro-ethylene

INDICATIONS AND PURPOSE OF USE

The Surgitime non Resorbable are destined to regenerative techniques in periodontics, implantology, orthopedics, neurosurgery or any medical and odonthological surgical procedure that requires a mechanical barrier, such as the treatment of horizontal and vertical periodontal defects, new bone formation in alveolar ridges, protection against epithelial invagination in sinus elevation procedures, and formation of proximal areas around odonthological grafting. The Surgitime non Resorbable devices keep the grafting material in position, without any prejudice to the properties of both, they also keep the clot in the surgical site (in case it does not utilize any biomaterial), they segregate cells and microorganisms that might interfere with bone neoformation, and allow for good vascularization and nutrition of the grafting material. They are available in many different formats to provide better adaptation to the receptor site, and they may also be freely conformed through the help of scissors or a sterile scalpel.

PRECAUTIONS, RESTRICTIONS, 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 non Resorbable. 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.
4. PROHIBITED REUSE - If reused or used with expired validity, may cause irritation, inflammation and other adverse events, compromising the health and safety of the patient.
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 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. In all surgeries involving Surgitime non Resorbable must be observed proper techniques used for asepsis and antisepsis.
9. The abuse of alcohol, tobacco, drugs, steroids or lack of proper oral hygiene can significantly impair the success of the treatment.
10. All potential adverse effects as dehiscence, inflammation, bone loss, hemorrhage, must be previously informed to the patient.
11.They are supplied in sterile condition and once opened should be used in aseptic conditions. Should always work with sterile fields, appropriate instruments to the procedure and in good condition in order to eliminate sources of infection and damage to the product.
12. Surgitime non Resorbable should be used only for the purpose for which it is intended.
13. The Surgitime non Resorbable exposure may occur in dental procedures, when no perfect adaptation to the receiving bed or the covering tissues occurs.
14. We also recommend in odonthological procedures a second surgery to remove Surgitime. Surgitime's withdrawal varies according to the choice and under the responsibility of the professional surgeon.
15. If occur complications impossible to be controlled, tissue inflammation or evidence of infection is recommended the immediate removal of the material.
16. Surgitime non Resorbable is provided in sterile double packaging (Ethylene Oxide - ETO). Provided the packaging's integrity has not been somewhat compromised, it will keep the product sterile for up to 3 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. The surgeon shall evaluate its indication to patients diagnosed with diseases or that use a medication that might change the reparation metabolism
19. 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.
20. 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.
21.Surgitime non Resorbable was developed in order to prevent that its use does not compromise the clinical condition of patients as well as their safety.
22.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.

CONTRA INDICATIONS

1. Surgitime non Resorbable like all the other membranes, should not be placed on existing active infection or in case of any other degenerative disease that can affect membrane 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 Surgitime non Resorbable to the environment.

STERILIZATION

Surgitime non Resorbable is supplied as a STERILE product (Ethylene Oxide - ETO). Providing the package integrity is kept.

PRE AND POST-SURGICAL CARES

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: All the patients that will be submitted to a surgical procedure must be carefully 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 the final result of the intervention.
Post-Surgical: The product must not be exposed to the mouth environment after the immediate post-operative. May be good coaptation of the surgical flap edges, in order to not be exposed membrane which compromise the outcome of the surgery. The exposure to the mouth environment may cause the accumulation of bacterial plaque on the membrane surface, if not followed near.
Please, note the post-surgical cares for the surgical procedures. Painkillers, antibiotics, or rest for 24-48 hours may be prescribed, differing a function of the procedure and of the professional technical conduct. The product must not be exposed to the mouth environment after the immediate post-operative.

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

Storage and Transportation

Store and transport the product away from direct sunlight, and from heat and humidity. Keep the packaging sealed until its utilization time. 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

In case of any alteration in the Surgitime non Resorbable characteristic that might have mischaracterized it, please discard it according to the applicable legislation for hospital waste, or return the damaged packages to the factory, including the device.

COMMERCIAL PRESENTATION FORMS

Surgitime non Resorbable is available in different lengths, widths and thickness, in order to fulfill the many different clinical needs.

USE INSTRUCTIONS

1. Place the package contents on a sterile surgical field.
2. Detach the flap so that later the membrane 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 membrane.
4. Cut the membrane in a suitable size, with the aid of a sterile pair of scissors, aiming maximum adaptation.
5. Adapt the membrane to the site, observing its margins. All of it should be over soft tissue and without folds.
6. Re-place the flap over the membrane.
7. Suture without involving the membrane. Only in cases of use for medical field, the membranes 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 membrane can be removed once its purpose is accomplished.

CARE WHEN DISCARDING THE PRODUCT

The product's disposal must comply with the environmental and biosafety lawsin force. Do not discard contaminated products in the general waste.