CONTRAINDICATIONS

Ti-PTFE Regenerative Membranes like all the other membranes, should not be placed on existing active infection.

WARNING / PRECAUTIONS / INTERACTIONS

Ti-PTFE Regenerative Membranes should be used only from members of experienced surgical teams. The use of the product under inadequate surgical techniques and biosafety conditions may harm the patient, leading to unsatisfactory results.

In case of infected wounds acceptable surgical practices should be followed. If occur complications impossible to be controlled, tissue inflammation or evidence of infection it is recommended the immediate removal of the material.

It is recommend a second surgery to remove PTFE Regenerative Membrane.

STERILIZATION

Ti-PTFE Regenerative Membranes are sterilized with Ethylenoxide gas. It is intended to be used only once and it should be discarded if its package is damaged or opened. Unused open membranes must be discarded and should not be resterilized.

STORAGE

Store bellow 25ºC, away from direct heat and moisture. Never use after expiration date.

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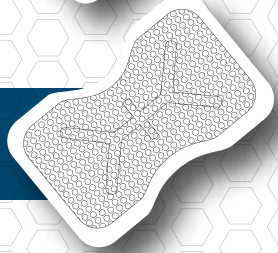
PTFE MEMBRANE

Titanium-Reinforced
Posterior Singles
20mm x 25mm

Titanium-Reinforced
Anterior Singles
14mm x 24mm



Non-Reinforced
25mm x 30mm

medipac
medical supplies

INVESTING IN
INNOVATION
& HIGH QUALITY

PTFE BARRIER MEMBRANES

Non absorbable
Sterile PTFE Regenerative Membranes

DESCRIPTION

PTFE Regenerative Membranes are sterile non absorbable membranes made from polytetrafluoroethylene (PTFE) polymer.

PTFE is a biologically inert and tissue compatible material. The PTFE Regenerative Membranes have been proved to be pyrogen free. PTFE Regenerative Membranes for Guided Tissue Regeneration (GTR)are used to prevent migration of cells from epithelial and connective tissues, what could cause bone growth inhibition, thus providing a proper space for the formation of a natural fibrin structure, which is the bone precursor.

PTFE Regenerative Membranes are manufactured according to the requirements of the European Pharmacopoeia.

INDICATIONS-USE

PTFE Regenerative Membranes are temporarily implantable material used in periodontics, implantology and any dental surgical procedure that requires a mechanical barrier. The membranes provide a mechanism for the ingrowth of new soft tissues and they are used as a space making barriers for the treatment of periodontal defects.

Carefully open the outer tray of the double blister and aseptically remove the inner sterile tray which contains the PTFE Regenerative Membrane. The sterile barrier membrane then can be removed from the sterile inner tray for usage during the surgical procedure.

Clinical judgment must be used in selecting patients who will benefit from tissue regeneration, selecting and implanting the appropriate configuration for the defect, and treating patients postoperatively.

If additional stability is desired, the membrane can be stabilized with sutures, surgical tacks and screws.

When removal is desired, the membrane can be easily removed by grasping with forceps. Anesthesia may be provided to enhance patient comfort, but is usually not necessary.

Following membrane removal, the regenerated tissue will re-epithelialize within 14 to 21 days to complete the initial healing process. However, the final bone maturation will not occur for 6 to 12 months

TITANIUM PTFE BARRIER MEMBRANES

Non absorbable
Sterile Reinforced Ti-PTFE Regenerative Membranes

DESCRIPTION

Ti-PTFE Regenerative Membranes are sterile non absorbable membranes made from polytetrafluoroethylene (PTFE) polymer reinforced with a medical grade Titanium embedded between two layers of PTFE.

PTFE is a biologically inert and tissue compatible material. The Ti-PTFE Regenerative Membranes have been proved to be pyrogen free. Ti-PTFE Regenerative Membranes for Guided Bone Regeneration (GBR) help in bone neoformation acting as biological barriers to prevent migration from 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.

Ti-PTFE Regenerative Membranes are manufactured according to the requirements of the European Pharmacopoeia.

INDICATIONS-USE

Ti-PTFE Regenerative Membranes are temporarily implantable material used in periodontics, implantology and any dental surgical procedure that requires a mechanical barrier, especially for bone reconstructions. The membranes provide a mechanism for the ingrowth of new soft and hard tissues and they are used as a space making barriers for the treatment of periodontal defects.

Carefully open the outer tray of the double blister and aseptically remove the inner sterile tray which contains the Ti-PTFE Regenerative Membrane. The sterile barrier membrane then can be removed from the sterile inner tray for usage during the surgical procedure.

Clinical judgment must be used in selecting patients who will benefit from tissue regeneration, selecting and implanting the appropriate configuration for the defect, and treating patients postoperatively.

If additional stability is desired, the membrane can be stabilized with sutures, surgical tacks and screws.

When removal is desired, the membrane can be easily removed by grasping with forceps. Anesthesia may be provided to enhance patient comfort, but is usually not necessary.

Following membrane removal, the regenerated tissue will re-epithelialize within 14 to 21 days to complete the initial healing process. However, the final bone maturation will not occur for 6 to 12 months.

SYMBOLS USED IN LABELING

25°C : Store at temperature

: Do not reuse

: See Instructions for Use

STERILE EO : Sterile unless the package is damaged or opened.
Method of Sterilization: Ethylene Oxide

REF
QTY
LOT
EXP. DATE

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CE 0653 : CE-mark and identification number of notified body.
Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC