TH.KAZANTZIDIS S.A
Industrial Area
611 00 Kilkis - Greece
Phone 23410 71991
Fax 23410 71979
E-mail:info@medipac.gr

INSTRUCTIONS FOR USE

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 were 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 materials used in periodontics, implantology and any other 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 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 can be removed from the sterile inner tray for use, during the surgical procedure.

Clinical judgment must be used for selecting patients who will benefit from tissue regeneration, for selecting and implanting the appropriate configuration for the defect, and for 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. The final bone maturation will **not occur,** unless 6 up to 12 months have passed.

Contraindications

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

Warnings / 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 uncontrolled complications, tissue inflammation, or evidence of infection occur, it is recommended that the material should be immediately removed.

A second surgery to remove Ti-PTFE Regenerative Membrane is recommended.

Sterilization

A Ti-PTFE Regenerative Membrane is 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 re-sterilized.

Storage

Store below 25 °C, away from direct heat and moisture. Never use after expiration date.

Symbols used in labeling

 : *Date of production*

 : *Do not reuse*

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

 : *See instructions for use*

 : *Use until Year & Month*

: *Store at temperature*

: *PHTHALATE FREE*

REF : *Product Number*

LOT : *Batch Number*

CE0653 : *Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC*
mark and identification number of notified body.

REV.03.2020