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INSTRUCTIONS FOR USE

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 were 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 materials used in periodontics, implantology and any other 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 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 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

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

Warnings / Precautions / Interactions

PTFE Regenerative Membranes should be used only from members of experienced surgical teams. The use of the product under inadequate surgical techniques and bio-safety 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 PTFE Regenerative Membrane is recommended.

Sterilization

A 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 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*

: *Batch Number*

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

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