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CYTOPLAST

Regenerative Barrier Membranes

INSTRUCTIONS FOR USE

INTRODUCTION

The user of Osteogenics Biomedical products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Osteogenics Biomedical disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use or installation of Osteogenics products. **IMPORTANT**: Read this entire package insert prior to use and follow all instructions carefully. Improper handling, preparation, surgical technique or postoperative care may adversely affect the safety and/or performance of the membrane.

DESCRIPTION

Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membranes are composed of proprietary 100% polytetrafluoroethylene sheet, reinforced with a titanium frame embedded between two layers of PTFE. PTFE is a biologically inert and tissue compatible material. Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membranes are a high-density sheet with a surface structure and porosity suitable to prevent integration and passage of bacteria within the interstices of the material, and simultaneously facilitate adhesion of host cells to the material.

Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membranes are designed to reduce the migration and establishment of gingival soft tissue derived cells into bony defects thus providing a more favorable environment for neovascularization and bone derived cells to repopulate and repair the defect. Since space-making is critical to this procedure, the membrane is sufficiently stiff to prevent spontaneous collapse but supple enough to conform easily to tissue contours and reduce perforations of overlying soft tissue.

INDICATIONS

Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membranes are a temporarily implantable material (non-resorbable)

for use as a space-making barrier in the treatment of periodontal defects.

CONTRAINDICATIONS

Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membranes are not designed for use under load bearing conditions.

WARNINGS

Barrier membranes should be used only with stable endosseous implants, and the long term safety and effectiveness of maintaining endosseous implants in regenerated osseous tissue on alveolar ridges has not been determined.

CAUTIONS

- U.S.A. Federal Law restricts the sale, distribution or use of this device to, by or on the order of a licensed practitioner.
- Do not use if package has been opened or damaged prior to use.
- Do not reuse or re-sterilize Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membranes.
- Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membranes should not be used in the presence of active infection.

ADVERSE REACTIONS

None reported.

MEMBRANE INSERTION

Carefully open the outer tray of the double blister and aseptically remove the sterile inner tray containing the Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membrane in the sterile field. The sterile barrier membrane can then be removed from the sterile inner tray for usage during the surgical procedure. Handle the membrane only with sterile surgical gloves, which have been washed in sterile water to remove the talc, or with sterile atraumatic forceps. The membrane may be cut to the desired configuration. Titanium is easily cut with sharp scissors. After trimming, there should be no sharp corners or rough edges. Note: For best results with textured material, place dimples side up towards gingival tissue. To enhance space-making capability, the material may be curved over the fingertips or a sterile instrument handle to create a dome shape, if desired. The membrane should be trimmed to extend 3-4mm beyond the defect margins to provide adequate protection of the bone defect and enhance membrane stability. The membrane should be trimmed to remain at least 1 mm from adjacent, uninvolved teeth. Care should be exercised

during placement of the membrane to prevent delamination. Trimming of the membrane close to the titanium frame or excessive bending of the frame can increase the risk of delamination. Sections of the membrane that become delaminated during placement should not be used. In rare instances, the titanium frame may perforate through the PTFE material during handling. If this occurs, the membrane should not be used.

If additional stability is desired, the membrane may be stabilized with sutures, surgical tacks or screws. The use of a non-resorbable monofilament suture is recommended by the manufacturer. Loss of tensile strength during the initial 2-week healing period can lead to premature membrane exposure.

Adequate flap release must be accomplished in order to achieve a tension-free closure if primary closure is desired. Vertical incisions, if used, must be remote from the location of the membrane. A double layer closure, with a deep layer of horizontal mattress sutures followed by a standard wound closure with interrupted sutures, is recommended.

MEMBRANE EXPOSURE

Depending on the size and complexity of a given defect, maintenance of primary closure may be required for predictable bone regeneration. If primary closure is desired, and premature exposure of the membrane occurs, the manufacturer recommends following recognized published protocols for management and prevention of PTFE membrane exposures.

MEMBRANE REMOVAL

When removal is desired, the membrane may be easily removed, if exposed, by grasping with forceps and gently removing it from the tissue. Anesthesia may be provided to enhance patient comfort, but is usually not necessary. If primary closure is obtained at placement, surgical exposure may be required for removal.

Following membrane removal, the regenerated tissue will re-epithelialize within 14 to 21 days to complete the initial healing process. However, final bone maturation will not occur for 6 to 12 months. This time frame should be considered in treatment planning cases involving heavy prosthetic loading of regenerated bone.

AVAILABILITY

Cytoplast® Ti-250/Ti-150 Non-Resorbable Barrier Membranes are provided sterile in a variety of shapes and sizes, and are titanium reinforced.

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

M	Manufacturer
H	Use By
D	Do Not Reuse
Y	Attention, See Instructions For Use
L	Do Not Use if Package is Damaged
IQ	Method of Sterilization Using Ethylene Oxide
15: 30:	Store at room temperature
B	Do Not Resterilize
g	Lot Number
h	Catalog Number
P	Authorized Representative in the European Community

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