



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™ Regentex Non-Resorbable Barrier Membranes are composed of proprietary 100% polytetrafluoroethylene sheet. PTFE is a biologically inert and tissue compatible material. Cytoplast™ Regentex 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™ Regentex 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™ Regentex Non-Resorbable Barrier Membranes are a temporarily implantable material (non-resorbable) for use as a spacemaking barrier in the treatment of periodontal defects.

CONTRAINDICATIONS

Cytoplast™ Regentex 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™ Regentex Non-Resorbable Barrier Membranes. Safety and effectiveness following reuse or re-sterilization of the Cytoplast™ Regentex Non-Resorbable Barrier Membranes has not been established.
- Cytoplast™ Regentex 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™ Regentex 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. After trimming, there should be no sharp corners or rough edges. Note: For best results when using textured material, place dimples side up towards gingival tissue. To enhance space-making capability, the material may be stretched over the fingertips or a sterile instrument handle to create a dome shape, if desired. The membrane should be trimmed to extend 3-4 mm 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. If additional stability is desired, the membrane may be stabilized with sutures, surgical tacks or screws.

MEMBRANE REMOVAL

The membrane is not intended to remain in place as a permanent implant and should therefore be removed following the bone regeneration procedure. Membrane may be removed after 21-28 days. 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 will 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™ Regentex Non-Resorbable Barrier Membranes are provided sterile in a variety of shapes and sizes, and have been shown to be pyrogen-free.

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

	Manufacturer
	Use By
	Do Not Reuse
	Caution
	Do Not Use if Package is Damaged
	Sterilized Using Ethylene Oxide
	Temperature Limit 15 - 30°C (59 – 86°F)
	Do Not Resterilize
	Lot Number
	Catalog Number
	Consult instructions for use

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