OsseoGuard®

Non-Resorbable d-PTFE, Titanium-Reinforced Barrier Membranes

INSTRUCTIONS FOR USE

INTRODUCTION

The user of OsseoGuard® TR250/150 products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. The manufacturer 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 OsseoGuard® TR250/150 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

OsseoGuard® TR250/TR150 PTFE Membranes are composed of proprietary 100% polytetrafluoroethylene high-density sheet, reinforced with a titanium frame embedded between two layers of PTFE. PTFE is a tissue compatible material. OsseoGuard® TR250/TR150 PTFE Membranes are designed to reduce epithelial downgrowth to maintain space for bone to grow into, 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

OsseoGuard® TR250/TR150 PTFE Membranes are a temporarily implantable material (non-resorbable) indicated for use as a space-making barrier in the treatment of alveolar and periodontal bony defects sites.

Periodontal defects include different defect shapes, sizes, and clinical scenarios, all resulting from periodontal disease and loss of periodontium, including bone. These defect types can include small intrabony defects, such as furcation defects, to larger defects where periodontal disease has resulted in the loss of a tooth or multiple teeth.

Alveolar defects include any bony defect found *within the alveolus*, both in the mandible and the maxilla, such as extraction sites, partially resorbed ridges due to edentulism, defects as a result of trauma, defects as a result of cysts, cancer, or other abnormalities such as fibrous dysplasia, and bony defects around implants.

CONTRAINDICATIONS

OsseoGuard® TR250/TR150 PTFE Membranes are not designed for use under load bearing conditions.

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 OsseoGuard® TR250/TR150 PTFE Membranes. Safety and effectiveness following reuse or re-sterilization of the OsseoGuard® TR250/TR150 PTFE Membranes has not been established.
- OsseoGuard® TR250/TR150 PTFE Membranes should not be used in the presence of active infection.

ADVERSE REACTIONS

None reported.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that OsseoGuard® TR250/TR150 PTFE Membranes are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the OsseoGuard® TR250/TR150 PTFE Membranes are expected to produce a maximum temperature rise of less than 2.3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 3 mm from the implant when imaged with a gradient echo pulse sequence and a 3.0 T MR system.

MEMBRANE INSERTION

Carefully open the outer tray of the double blister and aseptically remove the sterile inner tray containing the OsseoGuard® TR250/TR150 PTFE 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 that could irritate or perforate the overlying soft tissue. 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. Because OsseoGuard® TR250/TR150 PTFE Membranes are composed of PTFE sheet, reinforced with a titanium frame embedded between the two layers of PTFE, aggressive trimming can result in separation of the layers, i.e. delamination. 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 choice of fixation type and device is left to the discretion of the surgeon.

Although the choice of suture is left to the discretion of the surgeon, 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
The membrane is not intended to remain in place as a permanent implant and should therefore be removed following completion of bone regeneration. A maximum duration of implantation of 12 months is recommended. When removal is desired, the membrane may be easily removed, if exposed, by grasping with forceps and gently removing it from the surgically-treated site. 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 of the membrane from the surgical site.

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
OsseoGuard® TR250/TR150 PTFE 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.

	Manufacturer
	Use By
	Do Not Reuse
	Caution
	Do Not Use if Package is Damaged
STERILE EO	Sterilized Using Ethylene Oxide
15°C 30°C	Temperature Limit 15 - 30°C (59 – 86°F)
	Do Not Resterilize
LOT	Lot Number
REF	Catalog Number
MR	MR Conditional
	Consult Instructions for Use
Rx only	Federal (USA) law restricts this device to sale by or on the order of physician

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PN 2694
Revised 2023-01
Ref: OBI IFU-057