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 Biomedical 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 mesh.

DESCRIPTION
RPM™ Reinforced PTFE Mesh is composed of proprietary 100% polytetrafluoroethylene (PTFE) sheet, reinforced with a titanium frame embedded between two layers of PTFE. PTFE is a biologically inert and tissue compatible material. RPM™ Reinforced PTFE Mesh is a high-density sheet manufactured with circular macropores to allow direct contact between the bone graft and the periosteum. Direct contact between the periosteum and bone graft allows naturally occurring revascularization and infiltration of cells.

The PTFE mesh is designed to maintain space and conform to tissue contours and to aid in the reconstruction and augmentation of the alveolar ridge, maxilla, and mandible.

INDICATIONS
RPM™ Reinforced PTFE Mesh is a temporarily implantable material (non-resorbable) indicated for stabilization and support of bone grafts in alveolar bony defect sites.

CONTRAINDICATIONS
1. RPM™ Reinforced PTFE Mesh should not be used in the presence of active infection.
2. RPM™ Reinforced PTFE Mesh is not designed for use under load bearing conditions.

WARNINGS
1. RPM™ Reinforced PTFE Mesh should be used only with stable endosseous implants.

PRECAUTIONS
1. USA Federal Law restricts the sale, distribution or use of this device to, by or on the order of a licensed practitioner.
2. Do not use if package has been opened or damaged prior to use.
3. Do not reuse or re-sterilize RPM™ Reinforced PTFE Mesh.
4. Safety and effectiveness in pregnant women, nursing women, and children have not been established.

ADVERSE REACTIONS
None known.

MRI SAFETY INFORMATION
Non-clinical testing has demonstrated that the RPM™ Reinforced PTFE Mesh is 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 RPM™ Reinforced PTFE Mesh is 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.

MESH INSERTION
Carefully open the outer tray of the double blister and aseptically remove the sterile inner tray containing the RPM™ Reinforced PTFE Mesh in the sterile field. The sterile PTFE mesh can then be removed from the sterile inner tray for usage during the surgical procedure. *Handle the mesh only with sterile surgical gloves that have been washed in sterile water to remove the talc, or with sterile atraumatic forceps.* The mesh 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 mesh should be trimmed to extend 3-4 mm beyond the defect margins to provide adequate protection of the bone defect and enhance mesh stability. The mesh should be trimmed to remain at least 1 mm from adjacent, uninvolved teeth. Care should be exercised during placement of the mesh to prevent delamination. Trimming of the mesh close to the titanium frame or excessive bending of the frame can increase the risk of delamination. Sections of the mesh 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 mesh should not be used.

If additional stability is desired, the mesh may be stabilized with surgical screws, tacks, or sutures.

Adequate flap release must be accomplished in order to achieve a tension-free closure. Vertical incisions, if used, must be remote from the location of the mesh.

A double layer closure, with a deep layer of horizontal mattress sutures followed by a standard wound closure with interrupted sutures, is recommended. 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 mesh exposure.

MESH EXPOSURE

Due to macroporosity, maintenance of primary closure is required for predictable bone regeneration. If premature exposure of the mesh occurs, the manufacturer recommends following recognized published protocols for management of PTFE membrane exposures.

MESH REMOVAL

The mesh is not intended to remain in place as a permanent implant and should therefore be removed following the bone regeneration procedure. A maximum duration of implantation of 12 months is recommended. When removal is desired, the mesh may be removed, following surgical exposure, by grasping with forceps and gently removing it from the tissue. In the case of separation/delamination of the three mesh layers during removal, ensure that all three layers are removed.

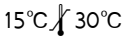
Bone maturation will not occur for 6 to 12 months. This time frame should be considered in treatment planning cases involving heavy prosthetic loading of regenerated bone.

AVAILABILITY

RPM™ Reinforced PTFE Mesh is provided sterile in a variety of shapes and sizes, and is 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
	Sterilized Using Ethylene Oxide
	Temperature Limit 15 - 30°C (59 – 86°F)
	Do Not Resterilize
	Lot Number
	Catalog Number
	MR Conditional
	Consult Instructions for Use

 Osteogenics Biomedical, Inc.

4620 71st Street, Bldg. 78-79
Lubbock, TX 79424 USA
www.osteogenics.com

PN 2531
Revised 2016-03
Ref: OBI IFU-037