OsseoGuard® Non-Resorbable PTFE Barrier Membrane

Patient Information Leaflet (*For Australian market only)*

What is in this leaflet?

This leaflet answers some common questions about OsseoGuard® Non-Resorbable Polytetrafluoroethylene (PTFE) Barrier Membrane.

Your dental surgeon has been provided additional information and can answer any additional questions you may have.

What is OsseoGuard® Non-Resorbable PTFE Barrier Membrane?

OsseoGuard® Non-Resorbable PTFE Barrier Membrane is composed of proprietary 100% polytetrafluoroethylene sheet. PTFE is a biologically inert and tissue compatible material. OsseoGuard® Non-Resorbable PTFE Barrier Membrane is 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.

OsseoGuard® Non-Resorbable PTFE Barrier Membrane is 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.

What is OsseoGuard® Non-Resorbable PTFE Barrier Membrane used for?

OsseoGuard® Non-Resorbable PTFE Barrier Membrane is a temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.

How is OsseoGuard® Non-Resorbable PTFE Barrier Membrane used?

This product can only be implanted surgically by a qualified dental surgeon.

When must OsseoGuard® Non-Resorbable PTFE Barrier Membrane not be used?

There are no known contraindications to using this product.

Adverse Reactions

None reported

Reporting adverse events

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If you wish to report any adverse event you believe is a result of your implanted medical device, please talk with your dental surgeon or the manufacturer:

Manufacturer:

Quality
Osteogenics Biomedical, Inc.
4620 71st Street, Bldg. 78-79
Lubbock, TX 79424, USA

Reports may also be made directly to the Therapeutic Goods Administration via the website:

www.tga.gov.au/reporting-problems

***Note to the dental surgeon**:*

It is a regulatory requirement in Australia to provide the Patient Implant Card and Patient Information Leaflet to the patient.

Model No: NTXR2530-4, NTXR1224-10, TXR2530-1, TXR2530-4, TXR1224-1, TXR1224-10