OsseoGuard® Non-Resorbable PTFE Titanium-Reinforced 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) Titanium-Reinforced 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 Titanium-Reinforced Barrier Membrane?

OsseoGuard® Non-Resorbable PTFE Titanium-Reinforced Barrier Membrane is 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.

Osseoguard® Non-Resorbable PTFE Titanium-Reinforced 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.

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

OsseoGuard® Non-Resorbable PTFE Titanium-Reinforced 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 Titanium-Reinforced Barrier Membrane used?

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

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

There are no known contraindications to using this product.

Adverse reactions

None reported

Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that OsseoGuard® Non-Resorbable PTFE Titanium-Reinforced Barrier Membrane 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)

Please share this information with your healthcare provider.

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 supply the Patient Implant Card and Patient Information Leaflet to the patient.

Model No: TR250AE-1, TR250AE-2, TR250AEY-1, TR250AEY-2, TR250PE-1, TR250PE-2, TR250SMT-1, TR250SMT-2, TR250P-1, TR250P-2, TR250LGT-1, TR250LGT-2, TR250PN-1, TR250PN-2, TR250PW-1, TR250PW-2, TR250LF-1, TR250LF-2, TR250RAX-1, TR250RAX-2, TR250RAK-1, TR250RAK-2, TR250TCS-1, TR250TCS-2, TR250TCL-1, TR250TCL-2, TR250PR-1, TR250PR-2, TR250RAKL-1, TR250RAKL-2, TR150AE-1, TR150AE-2, TR150AEY-1, TR150AEY-2, TR150PE-1, TR150PE-2, TR150SMT-1, TR150SMT-2, TR150P-1, TR150P-2, TR150LGT-1, TR150LGT-2, TR150PN-1, TR150PN-2, TR150PW-1, TR150PW-2, TR150LF-1, TR150LF-2, TR150RAX-1, TR150RAX-2, TR150RAK-1, TR150RAK-2, TR150TCS-1, TR150TCS-2, TR150TCL-1, TR150TCL-2, TR150PR-1, TR150PR-2, TR150RAKL-1, TR150RAKL-2

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