Instruction for Use

AVAILABILITY

OpenTex-TR Non-Resorbable ePTFE Membrane is sterile and available in a variety of sizes.

DEVICE DESCRIPTION

OpenTex-TR Non-Resorbable ePTFE Membrane is composed of 100% expanded polytetrafluoroethylene (ePTFE) sheet and grade 1 titanium plate, which are biologically inert and tissue compatible.

ePTFE sheet of OpenTex-TR Non-Resorbable ePTFE Membrane is designed to have a suitable surface structure and porosity to prevent integration and passage of bacteria within the interstices of the material, while maintaining space for host cells adhesion to the device.

OpenTex-TR Non-Resorbable ePTFE Membrane is designed to provide a favorable environment for neovascularization and healing of defects, through repopulating the bone derived cells and protecting the bony defects from migration of the gingival tissue derived cells. Since the adequate space-maintenance is critical to this procedure, the membrane is sufficiently stiff to prevent spontaneous collapse, but also flexible enough to easily conform to tissue contours and reduce perforations of overlying soft tissue.

INDICATIONS

OpenTex-TR Non-Resorbable ePTFE Membrane is a temporary implantable material (non-resorbable) for use as a space-making barrier for periodontal defects.

CONTRAINDICATIONS

1. OpenTex-TR Non-Resorbable ePTFE Membrane is not designed for use under load bearing conditions.
2. Do not use in patients who suffer from mental and/or physical illness.

WARNINGS

1. If the membrane is not removed within 30 days as indicated, it may be difficult to remove due to the adhesion between the membrane and tissue.
2. If side effects occur, appropriate treatment must be provided including reoperation.
3. Appropriate treatment should be given if any signs of active infection and/or potential infection are detected at the treatment site.
4. If allergic reaction or hypersensitivity to ePTFE material at the treatment site is diagnosed, appropriate treatment should be provided including the membrane removal.
5. OpenTex-TR Non-Resorbable ePTFE Membrane shall be used only with stable endosseous implants. However, the long-term safety and effectiveness of maintaining endosseous implants in regenerated osseous tissue on alveolar ridges has not been determined.

PRECAUTIONS

1. Use for medical purpose only.
2. Do not use if the membrane is damaged or has been altered in any way.

3. Handle with appropriate surgical instruments.
4. Care should be taken in order to avoid any risk of contamination. Do not use if there is any possibility of contamination.
5. Practitioner must check with patients to see if they have any special conditions such as diabetes, which may require special care.
6. Patients should be informed of factors that can adversely affect treatment such as heavy drinking, excessive movement and/or external impact on the surgical site.
7. OpenTex-TR Non-Resorbable ePTFE Membrane is designed for use only under the supervision of well-trained professionals.
8. OpenTex-TR Non-Resorbable ePTFE Membrane is designed for single use only. Reuse of this medical device bears the risk of patient cross-contamination.

SIDE EFFECT

Below is the list of potential adverse events that are known to be associated with ePTFE barrier membrane use in dental applications.

1. Gingival inflammation
2. Poor healing
3. Localized infection

MEMBRANE INSERTION

Carefully take out the OpenTex-TR Non-Resorbable ePTFE Membrane. Handle the membrane only with sterile surgical gloves, which have been washed in sterile water to remove any talc, or with sterile atraumatic forceps. The membrane may be trimmed to the desired configuration, and there should be no sharp corners or rough edges after trimming.

Note: The membrane should be trimmed to extend 3-4 mm beyond the defect margins to provide an appropriate 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

Membrane should be removed between 15 to 29 days after surgery. When exposed, the membrane should be gently removed from the tissue by grasping with appropriate surgical instruments. Anesthesia may be provided to enhance patient comfort, but usually, it is not necessary. If gingival soft tissue grows into surgical site or membrane, incision of soft tissue is necessary in order to remove the membrane.

After removal of the membrane, the regenerated tissue will re-epithelialize within 2~4 weeks to complete the initial healing process. When planning for cases involving heavy prosthetic loading of regenerated bone, it is expected to take 6~12 months for final bone maturation to occur.

STORAGE

OpenTex-TR Non-Resorbable ePTFE Membrane should be stored at the temperature between 10~25℃ in a dry place.

OpenTex-TR Non-Resorbable ePTFE Membrane should be kept away from direct sunlight

DISPOSAL
The used membrane must be disposed in an appropriate receptacle with the designated label on.
OpenTex-TR Non-Resorbable ePTFE Membrane must be handled or applied only by trained and qualified professionals who have read and understand this instruction for use thoroughly.

SYMBOLS GLOSSARY

	Do not reuse		Catalogue number
	Method of sterilization		Attention, see instruction for use
	Do not resterilize		Use by
	Manufacturer		CE mark and identification number of notified body
	EU Representative		Lot number
	Temperature limit		Do not use if package is damaged
	Keep away from sunlight	Rx Only	Prescription only

Manufactured by:
Purgo Biologics Inc.
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