

INSTRUCTIONS FOR USE FOR:



REGENERATIVE
MEMBRANE

en

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fi

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de

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es

Español

gr

Ελληνικά

se

Svenska

INSTRUCTIONS FOR USE

GORE-TEX® Regenerative Membrane

AVAILABILITY

GORE-TEX® Regenerative Membrane is provided STERILE in a variety of configurations and sizes, in both non-reinforced and titanium reinforced configurations. Provided that the package is not compromised in any way, the package will serve as an effective sterile barrier until the "Use By" (expiration) date printed on the box. GORE-TEX® Regenerative Membrane should be stored in a cool, dry environment.

INDICATIONS FOR USE

GORE-TEX® Regenerative Membrane is intended to provide a mechanism for the ingrowth of new hard and soft tissues into bony defects surrounding teeth and to augment ingrowth of hard and soft tissues on alveolar ridges.

CONTRAINDICATIONS

GORE-TEX® Regenerative Membrane is a passive, non-load bearing material. It is NOT intended for use in load-bearing, articulating situations such as temporal mandibular joint reconstruction.

DESCRIPTION

GORE-TEX® Regenerative Membrane is surgically placed beneath the muco-periosteum to aid in the regenerative healing of (1) bone or (2) bone / periodontal ligament defects of the oral cavity. The material is designed to be a passive barrier which excludes epithelial and gingival connective tissue from the defect site so that only the desirable cells repopulate the space, allowing regeneration to occur.

The material is designed to be stiff enough to create and maintain a protected defect space into which new attachment or bone can form, but supple enough to drape smoothly over the defect margin. It is non-absorbable, thereby allowing for predictable isolation of the defect site.

GORE-TEX® Regenerative Membrane is composed of expanded polytetrafluoroethylene (ePTFE). ePTFE is recognized for its inertness and tissue compatibility. ePTFE is a matrix of PTFE nodes and fibrils in a microstructure that can be varied in porosity to address the clinical and biological requirements of its intended applications.

GORE-TEX® Regenerative Membrane is provided STERILE in a variety of shapes and sizes, in both non-reinforced and titanium reinforced configurations. The titanium reinforced configurations are more space-creating and shape-maintaining. Transgingival (GTPM) Configurations of GORE-TEX® Regenerative Membrane are for use only in transgingival applications and Submerged (GTAM) Configurations of GORE-TEX® Regenerative Membrane are for use only in submerged applications.

OPENING THE PACKAGE

Carefully open the pouch and gently remove the paper pouch, which contains the GORE-TEX® Regenerative Membrane. The material should be handled using sterile gloves or atraumatic instruments and placed onto a sterile field. Keep in a cool, dry storage environment.

CAUTIONS

- USA Federal law restricts the sale, distribution or use of this device to, by, or on the order of a physician.
- Do not resterilize GORE-TEX® Regenerative Membrane. Material is designed for one-time use only.
- GORE-TEX® Regenerative Membrane should not be placed where active infection exists. Prior to placement, the surgeon should be confident that any active or recent infection has been properly treated.

- In cases of failing endosseous implants, no controlled study results are currently available. There are concerns about the etiology of endosseous implant failure and the appropriate method for resolving any accompanying infection. Therefore, the treatment of failing endosseous implants should be considered experimental.
- GORE-TEX® Regenerative Membrane is NOT intended as a permanent implant when placed through intra-oral incisions. It is designed to facilitate the regeneration of specific oral tissue.

Ideally material that is placed in a submerged application should remain in place three to nine months or until bone regeneration is complete. However, if exposed, it is recommended that shorter term removal (at approximately four to twelve weeks) be accomplished to avoid compromising the regenerative result.

In transgingival applications, four to twelve weeks is the recommended removal timeframe. Again, early removal may be appropriate in the event of a complication.

Long-term porous biomaterial implants, placed via intra-oral incisions, have been associated with infections and exfoliation. In order to reduce the potential for post-operative infection, GORE-TEX® Regenerative Membrane should be removed after the material has performed its intended function. Early removal should always be considered if the site becomes compromised in any manner which cannot be controlled by standard post-operative treatments.

SURGICAL IMPLANTATION INFORMATION

Clinical judgment must be used in selecting patients who will benefit from guided tissue regeneration, selecting and implanting the appropriate configuration for the defect, and treating patients postoperatively. These topics are discussed widely in the literature and have been published in peer-reviewed journals.

Good oral hygiene practices of the patient both pre- and post-operatively will help in the success of guided tissue regeneration.

PRECAUTIONS

The long-term safety and effectiveness of using GORE-TEX® Regenerative Membrane in conjunction with bone filling materials has not yet been established. When using GORE-TEX® Regenerative Membrane in conjunction with adjunctive materials, the clinician should follow all instructions and cautions provided by each manufacturer.

If endosseous implants are involved, GORE-TEX® Regenerative Membrane should only be used in combination with a stable implant and not in lieu of achieving primary implant stability. The long-term safety and effectiveness of maintaining endosseous implants in regenerated osseous tissue has not yet been determined.

There are patients who have medical conditions which put them at increased risk for complications following periodontal surgery. Patients with a heart valve or other prosthetic device, heart valve defects (i.e., heart murmur, prolapsed mitral valve, history of rheumatic heart disease, etc.) or uncontrollable diabetes are specific examples.

Additionally, GORE-TEX® Regenerative Membrane has not been tested in patients with a history of connective tissue disease or steroid use either at the time of treatment or for a one year period prior to treatment. Because there is no information on these types of patients, the clinician should assess the risk and benefit for these patients and consider consulting with the patients' physician prior to treatment.

SURGICAL CONSIDERATIONS AND REMINDERS

- Maintain sterile field throughout procedure.
- Prepare a full thickness flap.
- Preserve interdental papillae.
- Excise pocket epithelium.
- Thoroughly scale and plane the root surface, and debride the defect of any granulomatous tissue.
- Minimize salivary and other contamination to the material and surgical site.
- Trim material, if necessary, allowing for adequate defect coverage.
- Completely cover the defect area with the material.
- Completely cover the material when possible.
- Preserve a space under the material.
- Adapt the margins of the material to the alveolar bone.
- Stabilize the material.
- Make every attempt to obtain primary closure over the material.
- For the titanium reinforced configuration, shape the titanium reinforced material to conform to the contours of the defect site and the adjacent bone, and avoid trimming the material within 1 mm of the titanium “frame”.

POST-OPERATIVE REMINDERS

As with any oral surgical procedure, careful post-operative management is important for optimal healing. This should include:

- Oral hygiene maintenance plan as prescribed by the clinician. This may include a gentle mechanical plaque control or a chemical plaque control such as chlorhexidine.
- Instructions on flossing or brushing as prescribed by the clinician.
- Close patient monitoring and professional prophylaxis (no pumice) at least every other week for the first eight weeks.
- Subsequent exposure of the material is expected. DO NOT attempt to cover material that has become exposed. Exposure of the material should not interfere with regeneration if closely monitored.
- Exposed material may be removed any time post-operatively at the clinician’s discretion.
- Ideally, GORE-TEX® Regenerative Membrane should stay in place at least four to twelve weeks. Sutures should be removed one to two weeks post-operatively.
- Post-operative management may also include antibiotic therapy at the clinician’s discretion. Systemic antibiotics have been shown in the literature to help reduce post-operative complications.
- If complications develop which cannot be controlled by standard post-operative treatments, immediate material removal is recommended.
- For the titanium reinforced configurations, if the material is well integrated with tissue, be careful that the layers of material do not separate during removal.
- It is recommended not to debride the site for at least one year following guided tissue regeneration.
- In the event of tissue inflammation or evidence of infection, and at the clinician’s discretion, the material may be removed.

EVALUATION OF RESULTS

- Sites treated with GORE-TEX® Regenerative Membrane should not be probed for at least six months.
- Gain in attachment level, decreased probing pocket depth and overall health of the site are effective measurements for determining the success of the procedure.
- Radiographs can be taken to evaluate bone fill 12 to 18 months post-surgery. Regenerative healing has been shown to continue over this timeframe.

ADVERSE REACTIONS

Possible complications with any periodontal surgery include thermal sensitivity, gingival recession, flap sloughing, resorption or ankylosis of the treated root, some loss of crestal bone height, perforation or abscess formation, pain, swelling, inflammation, infection, gingival irregularities, and complications associated with the use of anesthesia.

Depending on the type and severity of the complication, as judged by the clinician, material removal or antibiotic therapy may be indicated (please refer to section on post-operative reminders).

Gore-TEX® SUTURE

The GORE-TEX® Suture is a nonabsorbable, monofilament ePTFE suture that has been expanded to produce a porous microstructure (approximately 50% air by volume). GORE-TEX® Suture has been shown in clinical trials to elicit minimal tissue response. GORE-TEX® Suture is EtO sterilized.

INDICATIONS

The GORE-TEX® Suture is indicated for use in all types of soft tissue approximation, including use in cardiovascular surgery and dura mater repair. It is recommended for use where reduced suture line bleeding during cardiovascular anastomotic procedures is desired.

CONTRAINDICATIONS

This device is contraindicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.

WARNINGS

For **single use** only. Do not resterilize. Sterile unless packaging has been opened or damaged. The safety and effectiveness of this suture in peripheral neural, microsurgical and ophthalmic applications have not been established. Tissue invasion of the GORE-TEX® Suture can result in attachment of the suture to the tissue it penetrates. Such attachment may make removal of the GORE-TEX® Suture difficult.

PRECAUTIONS

Misuse of this suture, like any other suture, can result in severe injury or death to the patient. As with any suture, care should be taken to avoid damage when handling. Avoid crushing or crimping the suture with surgical instruments or exposing the suture to sharp edges. Do not grasp the needle on the crimped area where the thread is attached in order to avoid compromise of needle attachment strength. Knot security requires standard surgical technique of flat and square ties with additional throws as indicated by surgical circumstances and the experience of the surgeon. Uneven tensioning of a well formed square knot may result in an unsecure knot. Not U.S.P./Not E.P.

DEFINITIONS

Use By



Attention, See Instructions for Use



Do Not Re-Use



Catalogue Number



Batch Code



European Authorized Representative



Contents sterile unless package has been opened or damaged.

Contents sterile unless enclosed package has been opened or damaged.
Sterilized by ethylene oxide.Contents sterile unless enclosed package has been opened or damaged.
Sterilized by irradiation.

Do Not Resterilize

▼ Reverse Cutting Needle



Taper Point Needle

R_x Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.



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