

# INSTRUCTIONS FOR USE FOR:

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RESOLUT<sup>®</sup> ADAPT<sup>®</sup>

REGENERATIVE MEMBRANE



RESOLUT<sup>®</sup> ADAPT<sup>®</sup> LT

REGENERATIVE MEMBRANE

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## BIOABSORBABLE

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en

English

bg

Български

cz

Čeština

dk

Dansk

nl

Nederlands

ee

Eesti

fi

Suomi

fr

Français

de

Deutsch

gr

Ελληνικά

hu

Magyar

it

Italiano

lt

Lietuvių

no

Norsk

pl

Polska

pt

Português

ro

Română

sk

Slovenčina

es

Español

se

Svenska

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**INSTRUCTIONS FOR USE FOR:  
GORE RESOLUT® ADAPT® Regenerative Membrane  
and  
GORE RESOLUT® ADAPT® LT  
Regenerative Membrane****AVAILABILITY**

The GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane are provided STERILE for single use only. 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 RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane have been sterilized by gamma irradiation, and should be stored at room temperature.

**INDICATIONS FOR USE**

GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane are bioabsorbable, implantable materials intended to aid in the healing of periodontal and bone defects. They may also be used as membranes for bone graft containment. When used over a bone graft, GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane provide a stable barrier to prevent migration of bone graft material and provide a favorable environment for bone regeneration. When used in the treatment of non-spacemaking defects, GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane may be used in combination with spacemaking bone graft materials (e.g., autogenous bone, bone substitutes).

GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane may be used for augmentation around immediately placed endosseous implants or existing endosseous implants (e.g., dehiscence and fenestration defects, extraction sockets); for ridge augmentation with future implantation of endosseous implants; and for sinus procedures (e.g., sinus window, sinus lift).

**CONTRAINDICATIONS**

There are currently no known contraindications to the use of GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane.

**DESCRIPTION**

GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane are provided STERILE for single use only. GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane have been sterilized by gamma irradiation. The membranes should be handled using sterile gloves and / or atraumatic instruments and placed onto a sterile field. A sterile, non-implantable template (with holes) is included to assist in sizing the implantable membrane.

GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane are composed of a microporous structure of synthetic bioabsorbable glycolide and trimethylene carbonate copolymer fiber. GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane are designed to be a passive barrier that allow the exclusion of epithelial and gingival connective tissue from the defect site so that only the desirable cells repopulate the space, allowing regeneration to occur.

The membranes are designed to protect the defect space in order to establish an environment favorable for regeneration and drape smoothly over the defect margin.

GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane are degraded via hydrolytic and enzymatic pathways. The polymer components have a history of use as bioabsorbable sutures, membranes, and implantable devices, which have been found to be biocompatible and nonantigenic.

*In vitro* and *in vivo* studies indicate that the GORE RESOLUT® ADAPT® LT Regenerative Membrane remains substantially intact for 16 - 24 weeks and gradually bioabsorbs thereafter.

GORE-TEX® Suture is provided for use with GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane to close soft tissues. It is a nonabsorbable, monofilament ePTFE suture that has been expanded to produce a porous microstructure (approximately 50% air by volume). GORE-TEX® Suture provides excellent handling properties and elicits minimal tissue response. These qualities make GORE-TEX® Suture the preferred suture for use with GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane.

## CAUTIONS

- DO NOT resterilize GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane.
- GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT 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.
- Defects with severe horizontal bone loss and with little remaining periodontal ligament and cementum or defects that do not allow for creation and maintenance of a space, exhibit characteristics which may reduce the amount of regeneration possible. Therefore, clinicians should carefully consider the therapeutic benefit before attempting to treat these types of defects.
- Flap management is essential for use of these products. Every effort should be made to minimize damage to the flap while maintaining blood flow.

## SURGICAL IMPLANTATION INFORMATION

Clinical judgment must be used in selecting patients for guided tissue regeneration and treating patients post-operatively. 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 regenerative therapy.

## PRECAUTIONS

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 RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane have 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 patient's physician prior to treatment.

**The sterile template is not for permanent implantation.**

When using GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane in conjunction with adjunctive materials, the clinician should follow all instructions and cautions provided by each manufacturer.

## **SURGICAL CONSIDERATIONS AND REMINDERS**

- Maintain sterile field throughout procedure.
- Prepare full thickness flaps.
- Preserve interdental papillae (when treating periodontal defects).
- Excise pocket epithelium (when treating periodontal defects).
- Thoroughly scale and plane the root surface, and debride the defect of any granulosomatous tissue (when treating periodontal defects).
- Minimize salivary contamination of the membrane and surgical site.
- Completely cover the defect area with the membrane. Trim membrane, if necessary, allowing for complete defect coverage.
- The membrane should extend 2 - 3 mm beyond defect margins.
- Preserve a space under the membrane and if necessary use spacemaking bone graft materials (e.g., autogenous bone, bone substitutes).
- Adapt the margins of the membrane to the alveolar bone.
- Stabilization of the membrane is essential for the regenerative outcome. Use of a resorbable suture as a ligature is recommended when transgingival configurations are used to treat periodontal defects.
- Make every attempt to obtain primary closure over the membrane.

## **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.
    - Gentle mechanical plaque control.
    - 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.
- 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.
- Exposed membrane should be frequently monitored and may be removed post-operatively at the clinician's discretion, however, material exposure should not interfere with regeneration.
- GORE RESOLUT® ADAPT® Regenerative Membrane and GORE RESOLUT® ADAPT® LT Regenerative Membrane are bioabsorbed by the body tissues and do not need to be removed after healing has occurred.
- If complications (exposure, infection, inflammation) develop which cannot be controlled by standard post-operative treatments, the membrane may be removed at the clinician's discretion. Removal of the membrane may require curettage and should be accompanied by thorough flushing with sterile saline.
- It is recommended not to debride the site for at least one year following guided tissue regeneration.

## **EVALUATION OF RESULTS**

- Gain in attachment level, decreased probing pocket depth, and overall health of the site are effective measurements of determining success of the periodontal 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 regenerative therapy include thermal sensitivity, gingival recession, flap sloughing, resorption, resorption or ankylosis of the treated root, some loss of crestal bone height, perforation or abscess formation, infection, pain, swelling, inflammation, gingival irregularities, and complications associated with the use of anesthesia.

Depending on the type and severity of the complication, as judged by the clinician, membrane 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.

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**DEFINITIONS**

Use By



Attention, See Instructions for Use



Do Not Re-Use

REF

Catalogue Number

LOT

Batch Code

EC REP

European Authorized Representative

STERILE

Contents sterile unless package has been opened or damaged.

STERILE EO

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

STERILE R

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

Do Not Resterilize

▼ Reverse Cutting Needle

Rx

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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Worldwide*

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