

INSTRUCTIONS FOR USE FOR:



RESOLUT[®] XT

REGENERATIVE MEMBRANE

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INSTRUCTIONS FOR USE FOR: GORE RESOLUT® XT Regenerative Membrane

INDICATIONS FOR USE

GORE RESOLUT® XT Regenerative Membrane is a bioabsorbable, implantable material intended to aid in the healing of periodontal defects. It may also be used as a membrane for bone graft containment. When used over a bone graft, GORE RESOLUT® XT Regenerative Membrane provides a stable barrier to graft material migration and provides a favorable environment for bone regeneration. GORE RESOLUT® XT 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® XT Regenerative Membrane.

DESCRIPTION

GORE RESOLUT® XT Regenerative Membrane is provided STERILE in a variety of configurations and sizes, 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® XT Regenerative Membrane has been sterilized by gamma irradiation, and should be stored at room temperature. The membrane 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® XT Regenerative Membrane is composed of a porous structure of synthetic bioabsorbable glycolide and trimethylene carbonate copolymer fiber and an occlusive membrane of synthetic bioabsorbable glycolide and lactide copolymer. GORE RESOLUT® XT Regenerative Membrane is designed to be a passive barrier that allows 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 membrane is designed to be stiff enough to create and maintain a protected defect space in order to establish an environment favorable for regeneration, yet supple enough to drape smoothly over the defect margin.

GORE RESOLUT® XT Regenerative Membrane is degraded via hydrolytic and enzymatic pathways. The polymer components have a history of use as bioabsorbable sutures, surgical meshes, and implantable devices, which have been found to be inert and nonantigenic. *In vitro* and *in vivo* studies indicate that GORE RESOLUT® XT Regenerative Membrane remains essentially unchanged for eight to ten weeks and gradually bioabsorbs thereafter.

CAUTIONS

- DO NOT resterilize GORE RESOLUT® XT Regenerative Membrane.
- GORE RESOLUT® XT 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 this product. 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, selecting and implanting the appropriate configuration for the defect, 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 guided tissue regeneration.

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® XT 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 patient's physician prior to treatment. **The sterile template is not for permanent implantation.**

When using GORE RESOLUT® XT 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.
- Excise pocket epithelium.
- Thoroughly scale and plane the root surface, and debride the defect of any granulomatous tissue.
- Minimize salivary contamination to 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.
- Adapt the margins of the membrane to the alveolar bone.
- Stabilize the membrane.
- 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 may be removed postoperatively any time at the clinician's discretion, however, membrane exposure should not interfere with regeneration.
- GORE RESOLUT® XT Regenerative Membrane is bioabsorbed by the body tissues and does not need to be removed after periodontal healing has occurred.

- In the event of tissue inflammation or evidence of infection, and at the clinician's discretion, the membrane may be removed. GORE RESOLUT® XT Regenerative Membrane undergoes hydrolytic and enzymatic breakdown during bioabsorption and, therefore, loses its structural integrity. 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

- Sites treated with GORE RESOLUT® XT 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 of determining 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, 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 RESOLUT® SUTURE

DESCRIPTION

Braided GORE RESOLUT® synthetic absorbable surgical sutures are composed of the homopolymer of glycolic acid and coated with POLYCAPROLATE® Coating System, a copolymer of glycolide and epsilon-caprolactone.

The POLYCAPROLATE® Coating System is inert, noncollagenous and nonantigenic.

The sutures are sterile, inert, noncollagenous and nonantigenic. GORE RESOLUT® Sutures are available in the undyed natural beige color.

GORE RESOLUT® Sutures meet all requirements established by the United States Pharmacopoeia (USP) and European Pharmacopoeia (EP) for synthetic absorbable surgical sutures.

INDICATIONS

GORE RESOLUT® Sutures are indicated for use as absorbable sutures in general soft tissue approximation and / or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neural tissue.

ACTIONS

GORE RESOLUT® Sutures elicit a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of GORE RESOLUT® Sutures occur by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized by the body. The absorption process begins as a loss of tensile strength followed by a loss of mass. Subcutaneous implantation studies in rats indicate GORE RESOLUT® Sutures retain approximately 65% of the original tensile strength at two weeks post implantation, with approximately 35% remaining at three weeks. Animal studies demonstrate absorption of GORE RESOLUT® Sutures is essentially complete between 60 and 90 days.

CONTRAINDICATIONS

The use of this suture is contraindicated in patients with known sensitivities or allergies to its components.

These sutures, being absorbable, should not be used where extended approximation of tissue is required.

WARNINGS

Do not resterilize. Sterile unless packaging has been opened or damaged. Discard open unused sutures. Store at room temperature. Avoid prolonged exposure to extreme temperatures.

Users should be familiar with surgical procedures, techniques, suture size choice, and tensile strength profiles involving absorbable sutures before employing GORE RESOLUT® Sutures for wound closure. The risk of wound dehiscence may vary with the site of application and the suture material used.

Acceptable surgical practice must be followed with respect to the management of contaminated or infected wounds.

The use of these sutures may be inappropriate in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing.

The use of supplemental nonabsorbable sutures should be considered by the surgeon in closure of sites which may undergo expansion, stretching, or distension or which may require additional support.

As with any foreign body, prolonged contact with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

PRECAUTIONS

Under some circumstances, notably orthopaedic procedures, immobilization by external support may be employed at the discretion of the surgeon.

Topical or skin sutures which must remain in place longer than seven days may cause localized irritation and the external portion should be snipped off, when indicated.

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

As with any suture material, adequate knot security requires the accepted surgical technique of flat, square ties with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Care should be exercised when knotting sutures used in continuous mass or layered closure of the abdomen, i.e., non-slip locking knots should be used at both ends of the continuous closure.

The commonly used looped-to-strand knot during termination of a running suture is a configuration which may lead to slippage. Extreme care must be utilized to ensure that multiple square knots are well secured.

Dispose of contaminated suture and packaging materials utilizing standard hospital procedures and universal precautions for biohazardous waste.

During suturing, care should be taken to avoid damage to the surgical needle from handling. Grasp the needle in an area one-third to one half of the distance from the attachment end to the point. Grasping near the point could result in damage to the functional integrity or fracture of the needle. Grasping at the attachment area could cause breakage of the needle barrel or the suture in the attachment area. Reshaping needles may result in decreased resistance to bending and breaking. To avoid inadvertent needle stick injury, which may result in transmission of blood-borne pathogens, the user should exercise caution during handling of surgical needles and consider use of PROTECTPOINT™ modified taper needles where appropriate.

ADVERSE EVENTS

Adverse events associated with the use of this device include: wound dehiscence; variable rates of absorption over time (depending on the type of suture used, the presence of infection and the tissue site); failure to provide adequate wound support in closure of sites where expansion, stretching, or distension occur, unless additional support is supplied; failure to provide adequate wound support in elderly, malnourished or debilitated patients or in patients suffering from cancer, anemia, obesity, diabetes, infection or other conditions which may delay wound healing; tissue granulation or fibrosis; wound suppuration and bleeding, as well as sinus formation; infected wounds; moderate tissue inflammatory response characteristic of foreign body response; calculus formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs; and transitory local irritation.

Needle breakage during surgery may result in extended anesthesia and/or surgical time, retention of foreign body in the patient, and / or additional surgery.

HOW SUPPLIED

GORE RESOLUT® Suture is available sterile and is undyed.

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

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



Taper Point Needle

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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*Creative Technologies
Worldwide*

W. L. GORE & ASSOCIATES, INC.

Flagstaff, Arizona 86004 • USA

Order Information: Tel.: 928.526.3030

Tel.: 800.528.8763

Technical Information: Tel.: 928.779.2771

Tel.: 800.437.8181

For international contact and additional
product information, visit

www.goremedical.com

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