

ATRISORB® FreeFlow™

Bioabsorbable Guided Tissue Regeneration (GTR)
Barrier



INSTRUCTIONS FOR USE

ATRISORB® FreeFlow™

Bioabsorbable Guided Tissue Regeneration (GTR) Barrier

Manufactured by TOLMAR Inc.
Fort Collins, CO 80526
Distributed by
Zila Therapeutics, Inc.

To Order Call: 1-800-228-5595
www.atridox.com



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Coe-Pak™ is a trademark of G.C. America, Inc.



See Instructions for Use

REF

Catalog Number



Expiration Date
Good through end of month indicated

30°C 86°F
15°C 59°F

Storage Temperature



Do Not Reuse

STERILE R

Radiation

LOT

Lot Number

ATRISORB® FreeFlow™ Bioabsorbable Guided Tissue Regeneration (GTR) Barrier

Formulation Description

The ATRISORB® FreeFlow™ Bioabsorbable Guided Tissue Regeneration (GTR) barrier is formed using a flowable polymeric formulation composed of poly(DL-lactide) (PLA) dissolved in *N*-methyl-2-pyrrolidone (NMP).

Device Description

The ATRISORB® FreeFlow™ GTR barrier contains foil pouches each containing single-patient use syringes of 0.5g ATRISORB® polymer formulation, and general use stainless steel cannulae for application of the formulation.

Mechanics

The ATRISORB® FreeFlow™ GTR barrier functions as a guided tissue regeneration barrier by isolating the regenerative surgical site from the adjacent gingival connective tissue and epithelium. This facilitates population of the surgical site with cells from the periodontal ligament and adjacent alveolar bone that lead to regeneration.

Storage

15° - 30° C (59° - 86° F)

How Supplied

The ATRISORB® FreeFlow™ GTR barrier is supplied as sterile, single-patient use syringes.

ATRISORB® FreeFlow™ GTR Barrier - Indications

ATRISORB® FreeFlow™ GTR barrier is indicated for the surgical treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures. ATRISORB® FreeFlow™ GTR barrier is not intended for use in defects outside the indications statement.

ATRISORB® FreeFlow™ GTR Barrier - Contraindications

Patients who are allergic to NMP or PLA should not be treated with this product. The ATRISORB® FreeFlow™ GTR barrier is contraindicated in those situations where general periodontal surgery should not be performed. There are currently no known additional contraindications to the use of the ATRISORB® FreeFlow™ GTR barrier.

ATRISORB® FreeFlow™ GTR Barrier - Evaluation of Treatment Effects

The duration of treatment for Guided Tissue Regeneration (GTR) is the same as conventional regenerative periodontal surgery; standard clinical practice has defined this time period as 12 months. If after 12 months, the treatment using the ATRISORB® FreeFlow™ GTR barrier has not been successful, retreatment may be considered.

ATRISORB® FreeFlow™ GTR Barrier - 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, perforations or abscess formation, infection, pain, gingival irregularities, and complications associated with the use of anesthesia.

ATRISORB® FreeFlow™ GTR Barrier - Precautions

The ATRISORB® FreeFlow™ GTR barrier has not been clinically tested in pregnant women.

The ATRISORB® FreeFlow™ GTR barrier has not been clinically evaluated in patients with conditions involving extremely severe defects with very little remaining periodontium.

The ATRISORB® FreeFlow™ GTR barrier has not been clinically tested for use in the regeneration of alveolar bone, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants.

The ATRISORB® FreeFlow™ GTR barrier cannot be resterilized. Do not use if pouches have been previously opened or damaged, or if the cannulae heat stakes are broken.

The ATRISORB® FreeFlow™ GTR barrier has not been clinically tested in immunocompromised patients (such as patients immunocompromised by diabetes, chemotherapy, radiation therapy, or infection with HIV).

Instructions for Use Preparations for Application of the ATRISORB® FreeFlow™ GTR Barrier

This guide provides detailed instructions for formation of the ATRISORB® GTR barrier using the FreeFlow™ application (in situ) method.

Patient Selection

Patients selected for GTR should be free from medical disorders that are general contraindications for periodontal surgical treatment. They should have established their willingness and ability to perform adequate oral hygiene. Smoking may affect outcomes following periodontal surgery. Treatment of patients who smoke is at the discretion of the clinician.

Defect Selection

The ATRISORB® FreeFlow™ (in situ) technique requires the use of bone replacement graft material.

Regenerative therapy should only be performed in defects where a reasonable likelihood of success exists. When treating furcation defects, Class II furcation defects are often considered good candidates for GTR treatment. However, size, defect morphology, and location of these defects vary considerably, and as a result, the predictability of success in these areas may be quite variable. When treating intrabony sites, defects deeper than 3 mm have greater potential for regeneration.

Based on these factors, general guidelines for defect selection are as follows:

Favorable

Class II furcation defects, intrabony defects deeper than 3 mm

Less Favorable

Class III furcation defects, horizontal defects (0-walled), and shallow intrabony defects

Presurgical Treatment

Oral Hygiene Instructions

Before undergoing GTR surgery, patients should receive oral hygiene instruction and demonstrate a willingness and ability to perform adequate plaque control.

Scaling and Root Planing

Scaling and root planing are generally recommended prior to surgery. The resulting improvement in tissue health will aid flap reflection and manipulation.

Presurgical Medication

Antimicrobial oral rinses such as chlorhexidine should begin the day before the planned surgery. At the discretion of the clinician, antibiotics may begin the day before surgery as well. Use of antibiotics should follow recommendations in standard clinical practice.

ATRISORB® FreeFlow™ GTR Barrier Formation FreeFlow™ Application (In Situ) Method

1. Perform standard full-thickness flap surgery including debridement of soft tissue, and scaling and planing of the root surface (including the furcation region, if involved). Assure that flap reflection is adequate to provide sufficient access for placement of the barrier.
 2. Fill the defect with bone replacement graft material as per manufacturer's instructions.
 3. Firmly twist a blunt-ended cannula onto the syringe and bend cannula to an appropriate angle. Expel air from the syringe.
 4. Tilt the patient's head to facilitate barrier placement. Appropriate head position is one that takes advantage of gravity in placing the barrier.
 5. Assure through evacuation that the surgical field remains as saliva-free and hemorrhage-free as possible taking care not to disturb the bone replacement graft.
 6. Hold the cannula tip 1 - 2 mm away from the graft and apply the fluid polymer from the syringe so there is a continuous flow of polymer.
 7. Express the polymer from the syringe to cover the graft and defect site. The polymer should cover the graft, be in intimate contact with the tooth surface, and extend slightly over the adjacent alveolar bone.
 8. Mist the barrier with a fine spray of sterile water or saline (i.e., from the highspeed or ultrasonic handpiece) for approximately 10 - 20 seconds to facilitate the initial "set" of the barrier.
 9. Inspect the precipitating barrier. If additional polymer is required it can be added from the syringe in the manner previously described. The newly added polymer is then "set" with the sterile water or saline spray.
 10. Do not disturb the barrier after it has been placed and formed. Close the surgical wound with sutures.
11. Place periodontal dressing at the surgical site.

Barrier Exposure

Some barrier exposure may occur during the initial healing. The exposed material should not be trimmed because of the possibility of disrupting the healing tissue and/or site. Instruct the patient to keep the exposed material clean by applying chlorhexidine directly to the site twice daily with a cotton tip applicator. Generally, this material will disappear by 6 to 8 weeks following surgery due to absorption or attrition.

The granulation tissue that forms at the surgical site under the barrier may cause barrier displacement. In these cases, it is recommended that, if necessary, periodontal dressing such as Coe-Pak™ periodontal dressing be replaced weekly to assure that the barrier remains in place through the first 4 weeks.

Postoperative Considerations

Postsurgical Care

It is imperative that regenerative sites be kept free of plaque accumulation. Also, mechanical disruption of the healing site should be avoided. The following recommendations are made:

1. For 8 weeks following surgery, the patient should not clean the treated area by brushing, flossing, using a toothpick, or other interdental cleaning techniques.
2. During this period, rinsing or direct application with an anti-infective agent such as chlorhexidine, is strongly recommended. After this 8 week period, mechanical tooth cleaning can resume.
3. Professional removal of supragingival plaque should be performed every week for 4 weeks, then bi-weekly through 8 weeks.
4. Probing the surgical site for treatment evaluation and subgingival scaling should not be done until at least 6 months following surgery.

ATRISORB® FreeFlow™ GTR Barrier - Use of Antibiotics

Antibiotic therapy is provided at the discretion of the clinician and should adhere to recommended regimens in standard clinical practice. Antibiotic coverage is often provided following regenerative surgeries as part of postoperative care. In cases of postsurgical infection or abscess, it may be necessary to remove the ATRISORB® FreeFlow™ GTR barrier depending on the severity of the complication.