

NEW

ATRISORB Direct and ATRISORB-D Direct

Bioabsorbable GTR-barriers

Direct application - Individual Fit - Reliable stability



Unique post-operative wound management¹

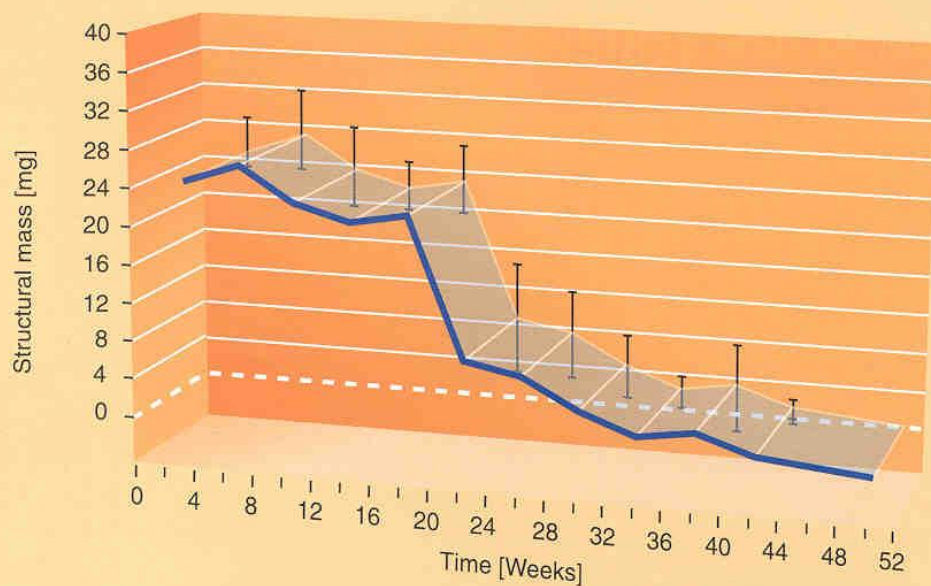
ATRISORB Direct

ATRISORB Direct is a bioabsorbable, guided tissue regeneration barrier that isolates gingival connective tissues and prevents epithelial downgrowth into the intrabony defect. It supports the regeneration of the periodontal ligament and alveolar bone²⁻¹².

The ATRISORB Direct barrier is customformed directly at the surgical site from a free flow polymer formulation gel. It is applied right over bone replacement graft with a cannula using a direct *in situ* technique. This method creates a more intimate contact of the barrier with the root surface and minimizes the handling of the polymer: you get a barrier with less risk of bacterial infection for your patient. ATRISORB Direct conforms perfectly to the defect morphology within the surgical field. No need for stabilizing sutures as ATRISORB Direct adheres to the tooth and surrounding bone. The applied polymer gel hardens into a semisolid barrier when sprayed with sterile water or saline. Unlike other barriers ATRISORB Direct is absorbable and does not need to be removed. The barrier retains its structural mass for 20 weeks after placement. Complete bioabsorption within 12-14 months³.

ATRISORB Direct: Flowable - Individual - Safe

Reliable stability



Degradation of ATRISORB over time

The flowable gel hardens into a biodegradable semisolid barrier when sprayed with sterile water or saline. ATRISORB is *in situ* stable over a period of 20 weeks. Bioabsorption is completed within 12-14 months³.



Syringe A
715mg Atrigel® Polymer
Formulation

ATRISORB-D Direct

ATRISORB-D Direct incorporates the same unique features of ATRISORB Direct. Additionally it contains 4% Doxycycline, a locally effective broad-spectrum antibiotic.

A major post operative risk associated with GTR surgery is bacterial colonization of the barrier with anaerobic bacteria or specific pathogens. Various studies support the importance of decreasing colonization of GTR membrane surfaces with anaerobic bacteria in order to more positively influence wound healing at the surgical site. Atrisorb-D Direct is a flowable barrier containing doxycycline.

ATRISORB-D Direct provides doxycycline locally, at the surgical site, over a period of 7 days following surgery at a concentration 200 times greater than that seen with systemic delivery. The presence of the antibiotic inhibits bacterial growth on the barrier. A well-controlled multi-center clinical study showed that the use of ATRISORB-D Direct resulted in statistically superior reductions in bacterial growth on the barrier for at least 6 weeks after surgery and barrier placement¹. ATRISORB-D Direct helps manage the post operative risks associated with GTR.

ATRISORB-D Direct = Less bacteria on the barrier

Reduction of bacteria in percent: 7 days after barrier placement

A. actinomycetemcomitans	-100%
P. gingivalis	-100%
P. intermedia/P.nigrescens	-100%
B. forsythus	-100%
F. Nucleatum	-99,6%
C. rectus	-99,9%
Total anaerobes	-94,8%

Atrisorb-D Direct provides statistically superior reduction in total anaerobes and suspected periodontal pathogens at multiple time points¹.

ATRISORB-D Direct

For unique post-surgical wound management

- ➔ Significant reduction of bacterial colonization on the barrier²
- ➔ Prevention of post-operative infections
- ➔ Improved outcome

gel® Polymer
ion

How to use ATRISORB

1

For product preparation of ATRISORB-Direct and ATRISORB-D Direct please see package insert.

2



Perform standard full thickness flap surgery including debridement of soft tissue and scaling and planing of the root surface.

3



If available, you can fill the defect with patient's own bone, before adding the bone graft material.

4



Loosely fill the defect with bone graft replacement material and place with light incremental pressure. Holding the cannula tip one to two millimeters away from the graft, apply the ATRISORB polymer.

5



Polymer should cover the graft by initial contact with the tooth surface and extend approximately 3 millimeters over the adjacent alveolar bone. Spray the polymer with sterile water or saline for about 10-20 seconds to set the barrier.

6



Inspect barrier for complete coverage, adding more polymer if necessary. Suture flap to completely cover the area.

ATRISORB Direct

A unique flowable barrier

- Customformed over bone graft to cover defect
- Unique fit because barrier adapts to each defect morphologically
- Bioadhesive: stays in place without fixing
- Sets quickly in contact with saline
- One syringe treats multiple sites

Adaptable - Reduces inventory costs

- One barrier forms to fit all defects
- Multiple sites in one session
- Helps to cut down inventory costs
- No trimming or handling of pre-formed standard barriers

Bioabsorbable with reliable stability

- No second surgery needed to remove ATRISORB
- Complete absorption in 12-14 months

ATRISORB-D Direct

with 4% Doxycycline

- Doxycycline is a broadspectrum antibiotic.
- The presence of the antibiotic over 7 days following surgery protects the barrier from bacterial colonization¹.
- It reduces the risk of the post operative barrier infection during the first week after surgery. Facilitated post-operative care for dentist as well as for patient. The prevention of barrier infection contributes to improve the outcome of GTR-surgery.



NE

ATRISORB DIRECT products are indicated for the surgical treatment of periodontal defects to aid in the regeneration and integration of tissue components in GTR/GBR procedures^{2,9}. They are registered as medical devices. Directly applied as a viscous gel over bone graft material the ATRISORB DIRECT barriers are formed "in situ".



ATRISORB® DIRECT



ATRISORB®-D DIRECT - American Packaging

The clinical safety and efficacy in the use of ATRISORB DIRECT in GTR and GBR is backed by solid evidence in more than 20 preclinical and clinical studies.

- 1) A well controlled clinical study demonstrated that ATRISORB-D Direct provided statistically superior reductions in total anaerobes and suspected periodontal pathogens at multiple timepoints in comparison to Atrisorb Direct. Data on file. ATRIX Laboratories Inc.
- 2) Polson AM, et al. Healing patterns associated with an ATRISORB DIRECT barrier in GTR. Compendium on Continuing Education in Dentistry 1993; XIV No. 9: 1152-1171
- 3) Coonts B, et al. Biodegradation and biocompatibility of a GTR barrier membrane formed from a liquid polymer material. Biomaterial applications 1998.
- 4) Polson AM, et al. GTR in human furcation defects after using a biodegradable barrier: A multi-center feasibility study. J Periodontol 1995; 66: 377-385
- 5) Polson AM, et al. Periodontal healing after GTR with ATRISORB Direct barriers in beagle dogs. Int J Periodont Rest Dent 1995; 15: 575-589
- 6) Garrett S, et al. Periodontal regeneration in naturally occurring Class II furcation defects in beagle dogs after GTR with bioabsorbable barriers. J Periodontol 1997; 68: 536-544
- 7) Stoller NH, Johnson L, et al. The use of ATRISORB Direct bioabsorbable barrier during GTR. Postgraduate Dentistry 1997; Vol. 4, No. 2
- 8) Garrett S, et al. Clinical use of the ATRISORB DIRECT GTR barrier. Postgraduate Dentistry 1997; Vol. 4, No. 2
- 9) Rosen P, et al. In situ barrier formation. Int J Periodont Rest Dent 1998
- 10) Polson AM, et al. Initial study of GTR in Class II furcation defects after use of a biodegradable barrier. Int J Periodont Rest Dent 1995; 1:43-55
- 11) Rosen P, Reynolds MA Polymer-assisted regenerative therapy: case reports of 22 consecutively treated periodontal defects with a novel combined surgical approach; J Periodontol 1999; 70 (5): 554-561
- 12) Rosen P, Reynolds MA, Bowers GM A technique report on the in situ application of ATRISORB Direct as a barrier for combination therapy; Int J Periodont Rest Dent 1998; 18 (3): 249-255
- 13) Jepsen K, et al. Bewertung einer neuen resorbierbaren GTR-Membran in der Rezessionsbehandlung; Deutsche Zahnärztliche Zeitschrift 56 (2001) 4.
- 14) Jepsen S., et al. Evaluation of a New Bioabsorbable Barrier for Recession Therapy: A Feasibility Study; J Periodontol; Sept 2000
- 15) Rosen P, Reynolds MA Guided bone regeneration for dehiscence and fenestration defects on implants using an absorbable polymer barrier, J Periodontol, 2001 Feb; 72 (2): 250-6

ATRIX Laboratories, Inc. is a speciality pharmaceutical company focused on advanced drug delivery. ATRIX is currently developing a diverse portfolio of proprietary products, including oncology, pain management, dermatology and dental products. The company also applies its proprietary technologies to new chemical entities or to extend patent life of existing products. The goal is to make pharmaceutical products more effective with less side-effects and treatments more efficient and patient friendly.



Ihr neuer Vertriebspartner:

curasan

Lindigstraße 4
63801 Kleinostheim
Zentrale: 0 60 27 / 46 86-0
Bestellfax: 0 60 27 / 46 86 19

Atrix Laboratories GmbH Hessenring 119-121 D-61348 Bad Homburg Germany
More information about ATRISORB Tel +49 6172 92 58 81 Fax +49 6172 92 58 50 info@atrixlab.de
Order Fax +49 6151 66 715 73

ATRISORB DIRECT and ATRISORB-D Direct are registered trademarks of ATRIX Laboratories Inc.