

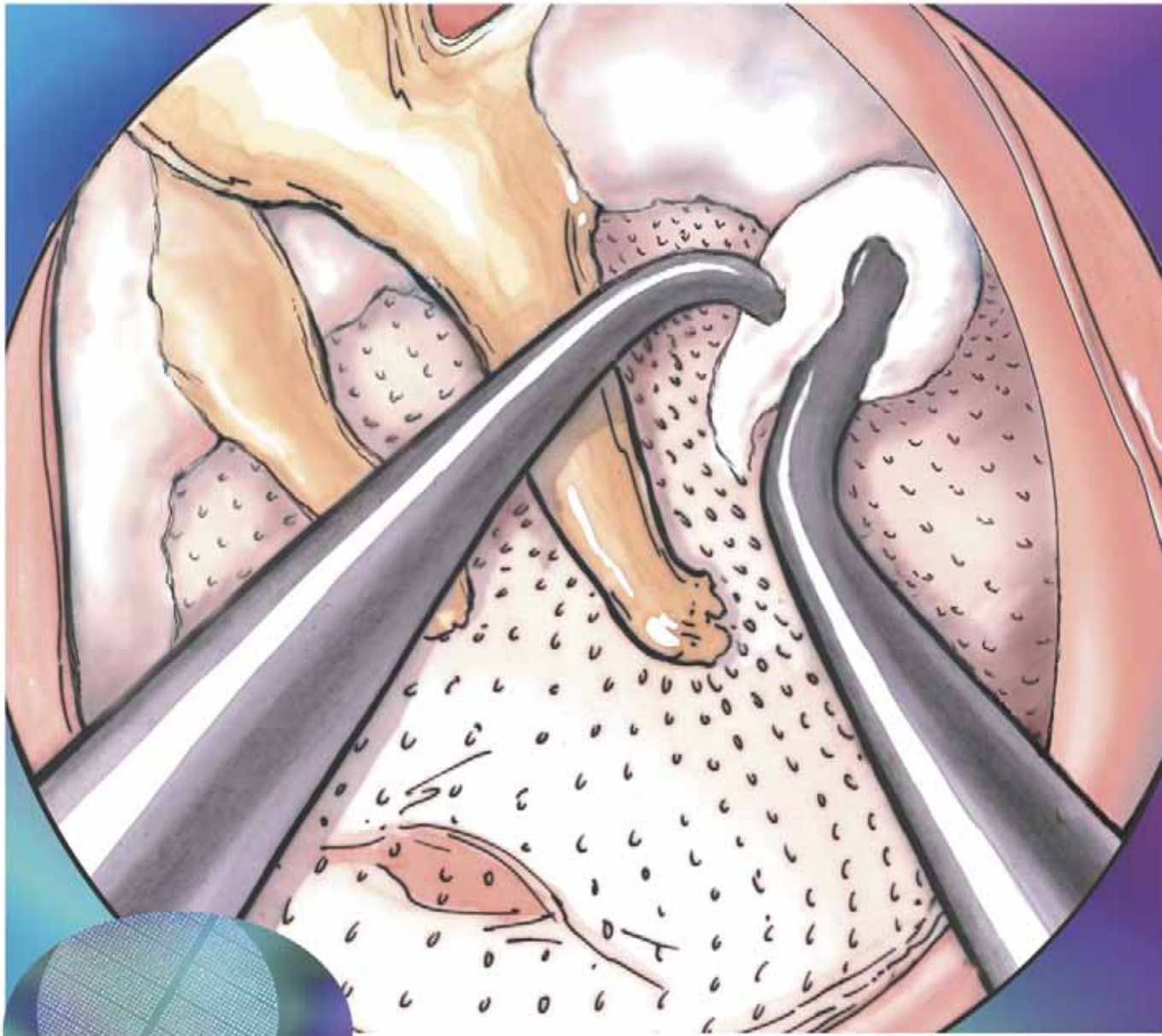


Medtronic

XOMED

SURGICAL TECHNIQUE

EpiDisc™ Otologic Lamina and MeroGel® Otologic Packing



*Krueger "H.A.T." Hyaluronic Acid Tympanoplasty
Technique, Presented by Wesley O. Krueger, MD*

Philosophy

Little has changed in otologic surgery techniques and materials over the past few decades. The most frequently documented complications include middle ear adhesions/fibrosis, dense fibrous capsule formation in response to silicone or fluoroplastic sheeting in the middle ear, and chronic granular inflammation of the tympanic membrane graft and canal wall. It is hoped that integrating the use of two unique otologic devices created from HYAFF[®], an esterified form of hyaluronic acid, during canalplasty, myringoplasty, tympanoplasty, and stapes and mastoid surgery, will address many of the problems encountered by the otologic surgeon.

Hyaluronic Acid

Hyaluronic acid is a naturally occurring linear polysaccharide and is found in high concentrations in the extracellular matrix, particularly the synovial fluid and vitreous humor of the eye. It plays a significant role in the body during the repair process, mediating cell adhesion, differentiation, motility and blood vessel growth.

Hyaluronic acid has a well established biocompatibility profile, is bacteriostatic¹, and plays a bioactive role in the process of regenerative vs. reparative wound healing in fetuses.² Over 30 million patients have been treated with various Hyaluronic acid devices, including devices that help to reduce the incidence and severity of postoperative adhesions in abdominopelvic surgery.¹ In middle ear surgery, Hyaluronic acid has been shown to improve the natural healing of the mastoid cavity following tympanoplasty, and to help reduce connective tissue formation.^{2,3}

Surgical Technique

When performing a myringoplasty or tympanoplasty, EpiDiscs (EpiFilm[®] Otologic Lamina Discs) and MeroGel Otologic Packing are utilized to separate mucosal surfaces to help minimize the formation of adhesions. This assists the natural healing process and assists with re-epithelialization of the canal and lateral surface of the graft.

Figure 1

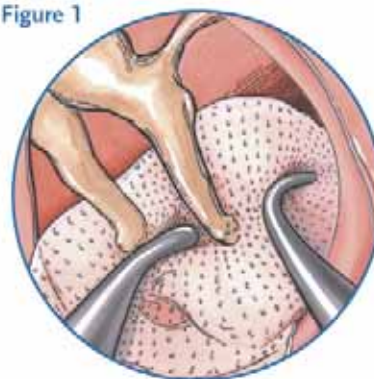


Figure 2

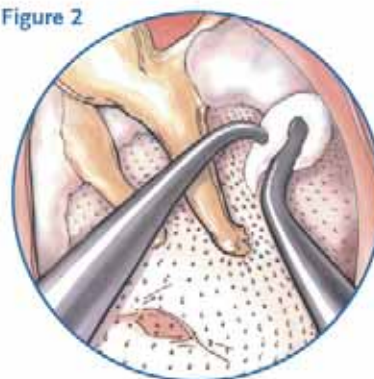
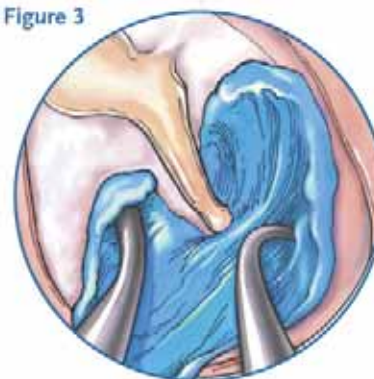


Figure 3



The EpiDisc Otologic Lamina is a thin, implantable scaffold made from esterified Hyaluronic acid, HYAFF, in an 8 mm diameter disc configuration making it ideal for placement on the promontory during tympanoplasty and also as a scaffold on the TM during myringoplasty or tympanoplasty procedures. EpiFilm Otologic Lamina, 2.5 cm x 2.5 cm, is a larger version of EpiDisc that is useful for surgical procedures where more material is needed to cover larger surface areas of mucosa or exposed bone.

The MeroGel Otologic Packing is a space-occupying biomaterial with a soft, cotton-like structure that can be used to pack the middle ear space to separate mucosal surfaces and support the tympanic membrane graft and can also be used as a dissolvable external ear packing to support the external ear canal skin.

In the Krueger H.A.T. Technique, an EpiDisc is placed on the promontory (Figure 1). Small pieces of MeroGel Otologic Packing are hydrated with an antibiotic solution and placed in the middle ear cavity in order to help support the tympanic membrane graft (Figure 2).

A dried and trimmed temporalis fascia graft is then placed in an overlay fashion under and around the malleus handle and on top of the tympanic membrane annulus (Figure 3). Once the temporalis fascia graft has been properly placed, a second EpiDisc is placed to cover the entire graft area (Figure 4). The 40-80 micron diameter microperforations in the EpiDisc allow fluid exudates to egress from the surface of the graft. The EpiDisc Otologic Lamina and MeroGel Otologic Packing typically dissolve in 6-8 weeks when used in the middle ear.

Figure 4

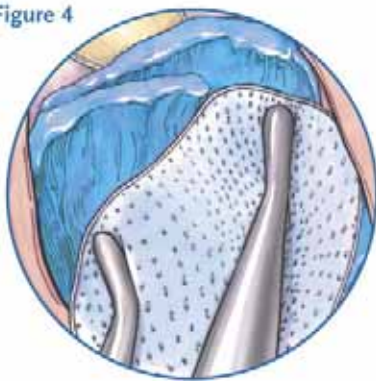
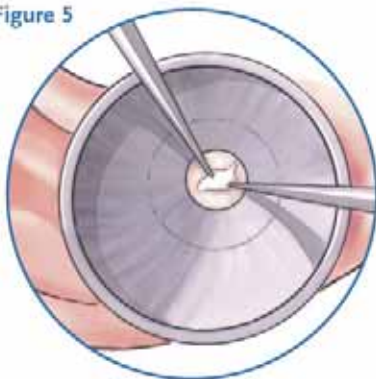


Figure 5



Finally, the external ear canal is packed with MeroGel. The amount of material typically needed is available in the larger version of MeroGel, 4 cm x 4 cm, which is the MeroGel Nasal Dressing/Sinus Stent and Otologic Packing. Small pieces are selectively used and rolled into the desired shape, hydrated and packed into the ear canal to the meatus (Figure 5). Post-operative care is the same as with other packings and preparations, such as keeping the ear dry. An advantage of the MeroGel material is that it will dissolve when hydrated with some consistency. Typically, three weeks following the surgery the patient applies antibiotic drops to the ear canal twice daily and the MeroGel will dissolve approximately two weeks after hydration.

Ordering Information

14-17100	EpiDisc Otologic Lamina, 8mm disc	2/box	NEW
14-17000	EpiFilm Otologic Lamina, 2.5cm x 2.5cm	1/box	
15-17100	MeroGel Otologic Packing, 1cm x 5cm	1/box	NEW
15-17000	MeroGel Nasal Dressing Sinus Stent/ Otologic Packing, 4cm x 4cm	1/box	
15-17002	MeroGel Nasal Dressing Sinus Stent/ Otologic Packing, Double Pack	2/box	

Studies

1. Pirnazar P., et al, 1999, "Bacteriostatic Effects of Hyaluronic Acid", J. Periodontol, 70:370-374.
2. Longaker M. T., et al. 1991, "Studies in Fetal Wound Healing. A Prolonged Presence of Hyaluronic Acid Characterized Wound Fluid", Annals of Surgery, 213:292-296.
3. Grainger D. A., et al, 1991, "The Use of Hyaluronic Acid Polymers to Reduce Postoperative Adhesions: J. Gynecol. Surg. 7:97-101.
4. Martini A., Morra B., "An Open, Controlled, Randomized, Multicenter Study to Evaluate the Clinical Performance and Safety of HYAFF 11 Otomembrane in the Healing Process of Mastoid Cavity in Patients Suffering from Chronic Cholesteatomatous Otitis Media", *In preparation for publication.*
5. Laurent C., Hellstrom S., Stenfors L., 1986, "Hyaluronic Acid Reduces Connective Tissue Formation in Middle Ears Filled with Absorbable Gelatin Sponge: An Experimental Study", Am. J. Otolaryn., 7:181-186.

Nota Bene: The technique description herein and the use of instructions for the related procedures are made available by Medtronic Xomed Surgical Products, Inc. to the health care professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which, in the health care professional's judgment, addresses the needs of the individual patient.



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