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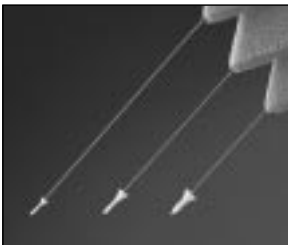
## MADE IN USA

U.S. Patent Nos.: 4,660,546; 5,049,142;  
5,053,030; 5,163,959; 5,171,270;  
5,723,005; EP0,522,008  
Other Patents Pending

## FOR PROFESSIONAL USE ONLY

# OPAQUE Herrick Lacrimal Plug®

Instructions For Use



## INTRODUCTION

OPAQUE Herrick Lacrimal Plugs are designed for maximum ease of insertion without punctal dilation or topical anesthesia.

The non-dissolvable plugs:

- Are effective in the horizontal canaliculi.
- Never touch the eye.
- Are comfortable after placement.
- Cannot be rubbed out of the punctum.

The plugs may be placed in the superior and/or inferior punctum as a unilateral or bilateral procedure.

## INDICATIONS

OPAQUE Herrick Lacrimal Plugs may be used in the treatment of:

- Dry Eye symptoms: dryness, redness, itching, burning, intermittent tearing or foreign body sensation.
- For treatment of ocular dryness secondary to contact lens use.
- To enhance the efficacy of topical ocular medications.
- After surgery to prevent complications due to Dry Eyes.
- For the Dry Eye component of: conjunctivitis, keratitis, corneal ulcer, pterygium blepharitis, red lid margins, recurrent chalazion, corneal erosion, filamentary keratitis and other eye diseases.

OPAQUE Herrick Lacrimal Plugs are indicated by the patient's positive response to The Lacrimal Efficiency Test™ with dissolvable plugs (Lacrimedics).

## CONTRAINDICATIONS

**Tearing secondary to canalicular obstruction (epiphora), Dacryocystitis with/without mucopurulent discharge.**

In patients with suspected epiphora, use lacrimal irrigation or probing (at least 10 days prior to plug insertion) to rule out pre-existing canalicular obstruction.

## PACKAGING

OPAQUE Herrick Lacrimal Plugs are medical grade silicone (2 per box), are provided sterile, and premounted on an insertion tool.

Sizes include 0.3mm, 0.5mm and 0.7mm (shaft) diameters. The "collapsible bell" on each plug is approximately 0.85mm, 1.40mm and 1.95mm in diameter respectively.

0.5mm plugs are appropriate for most adults, while 0.3mm plugs are typically utilized in pediatric patients. Use 0.7mm plugs when 0.5mm plugs will not stay in position.



Store product at room temperature or between -10 and +25 degrees Centigrade. Temperatures may move above and below these values temporarily (i.e. during transport) without harm.

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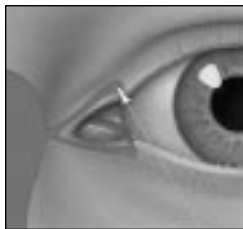


fig. 1

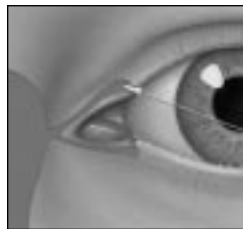


fig. 2

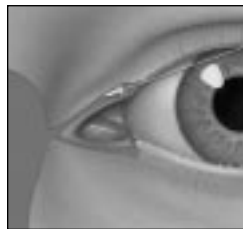


fig. 3



fig. 4



fig. 5

## INSERTION

**To optimize the patient's response and minimize unwanted epiphora, place plugs into superior canaliculi first.**

**a.** Inspect the patient's puncta to determine which size plug to use.

**b.** Remove the sterile packet from the box, peel back the lid (exposing the plug and insertion tool) and hold in your hand like a pencil.

**c.** While using magnifying loupes or a slit-lamp, have the patient look away from the point of insertion and evert the eyelid with your finger or cotton-tipped applicator.

**d.** Guide the tip of the plug partially into the vertical canaliculus until the collapsible bell rests on the punctum (fig. 1).

**e.** Move the top of the insertion tool laterally until it is parallel with the lid margin (fig. 2). This straightens the angle between the vertical and horizontal canalculus allowing for easier insertion.

**f.** Advance the plug (toward the nose) completely through the punctum (fig. 3). As the plug passes into the vertical canalculus it will collapse upon itself. Once beneath the punctum the bell will reopen.

**g. Advance the plug three to five millimeters beyond the punctal opening** to ensure that it has been positioned beyond the vertical canalculus **into the horizontal canalculus.**

**h.** Withdraw the insertion tool from the punctum, being careful not to touch the eye, and inspect the tool to confirm that the plug has been released.

**i.** Reinsert the insertion tool as if

repeating steps **c** through **h**. This will ensure that the plug is inserted properly and not lodged in the angle between the vertical and horizontal canalculus.

Should the plug remain on the insertion tool after steps **c** through **h**, use sterile forceps to remove and remount the plug on the tool and repeat steps **c** through **i**.

After placement, the plug will migrate several millimeters where it becomes lodged in the medial horizontal canalculus (fig. 4).

For maximum benefit, after placement of the OPAQUE Herrick Lacrimal Plug in the upper punctum, **retest the inferior punctum with dissolvable plugs to determine if OPAQUE Herrick Lacrimal Plugs should be placed inferiorly.**

Follow steps **a** through **i** for placement of plugs into inferior canaliculi.

## REMOVAL

"Pressure" saline irrigation with the *TruPro™ Lacrimal Cannula* (fig. 5) or *West Lacrimal Cannula* (combines irrigation and probing), are the preferred methods for plug removal. Probing the canalculus should always be followed with saline irrigation.

These procedures are intended to advance the plug through the nasolacrimal duct into the nose or throat where it eventually leaves the body.

In rare cases, surgical methods may be appropriate to achieve plug removal.

Patients experiencing irritation or tearing after plug insertion may benefit from shallow probing (3 to 5 mm *only*) or repositioning of the plug within the horizontal canalculus.

## CAUTIONS/CONSIDERATIONS

Lacrimal/Punctal Occlusion enhances the efficacy of ocular topical medications. After insertion of OPAQUE Herrick Lacrimal Plugs use a single drop of topical antibiotic to prevent complications related to plug insertion.

## SEEING OPAQUE PLUGS

**Anytime after insertion, or during removal procedures, use a simple light source to transilluminate the eyelid, and visualize the location and movement of OPAQUE Herrick Lacrimal Plugs.**

## DISCLOSURE

Patients being treated with Lacrimal/Punctal Occlusion should first be informed about benefits and risks and alternative treatments. Have patients sign an **Informed Consent Form** (sample available from Lacrimedics) to document receipt of this information.

**ALWAYS READ THESE INSTRUCTIONS BEFORE USE**