



To order, request information, or report product performance, contact your local distributor, or:

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MADE IN USA

Manufactured under license from R.S. Herrick, II U.S. Patent No. 7,404,825

FOR PROFESSIONAL USE ONLY R× ONLY

Dissolvable VisiPlug® Lacrimal Plugs

Instructions For Use

INTRODUCTION

The *Dissolvable* VisiPlug Lacrimal Plug provides temporary occlusion of the tear drainage system.

Dissolvable Plugs:

- Are effective in the horizontal canaliculi
- Never touch the eye
- Are comfortable after proper placement, and will not fall out of the punctum

Punctal dilation and topical anesthesia are not usually required for insertion.

INDICATIONS

Dissolvable VisiPLug Lacrimal Plugs may be used:

- As a diagnostic aid to determine the potential effectiveness of Occlusion Therapy with non-dissolvable plugs.
- To temporarily enhance the efficacy of topical medications or ocular lubricants
- After ocular surgery to prevent complications due to dry eyes.
- To evaluate treatment of ocular dryness secondary to contact lens use
- In the treatment of Dry Eye Syndrome and the dry eye components of varying Occular Surface Diseases.

CONTRAINDICATIONS

Chronic tearing (epiphora) secondary to canalicular obstruction, Dacryocystitis with or without mucopurulent discharge.

BEFORE INSERTION

Patients should be given a complete eye examination with thorough history. Patients reporting one or more symptoms on a Symptoms Checklist (available from Lacrimedics) should be given the Lacrimal Efficiency Test™ with dissolvable test plugs.

Patients with pre-existing intermittent tearing should receive pressure irrigation (with the TruProTM Cannula from Lacrimedics) to rule out canalicular obstruction.

PACKAGING

Dissolvable VisiPlug Lacrimal Plugs are made of polydioxanone and are provided sterile, two plugs per pouch.

Dissolvable VisiPlug Lacrimal Plugs are available in two sizes: 0.4mm & 0.5mm. The 0.4mm plugs are appropriate for use with most adult patients; use 0.5mm when 0.4mm plugs will not stay in position.

Dissolvable VisiPlug Lacrimal Plugs have a medium term degradation rate of approximately 180 days.

This device is designed, intended and distributed for single use only. DO NOT RE-STERILIZE OR REUSE THE DEVICE. There are no data to support the sterility and functionality of the device after reprocessing.

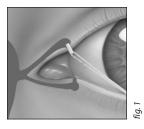
Authorized European Representative: (NOT A DISTRIBUTOR) Obelis s.a. Bd. Général Wahis 53, 1030 Brussels, Belgium. Tel: +32.2.732.59.54 Fax: +32.2.732.60.03 email: mail@obelis.net





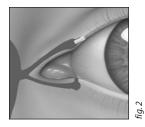






INSERTION

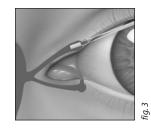
- a. Inspect the patient's punctum to determine which size plug to use.
- **b.** Remove a sterile packet from the box, peel back the lid and remove the foam holder.
- c. While using magnifying loupes or a slit-lamp, have the patient look away from the point of insertion.
- d. Use a jeweler's forceps to remove one of the plugs from between the grooves in the foam holder.
- e. Apply traction with a cotton tip applicator to evert the eyelid and clearly view the punctum.
- f. Guide the plug partially into the punctum and release the forceps (Fig. 1).
- g. Apply lateral traction with the cotton tip applicator to



straighten the angle between the vertical and horizontal canaliculus (Fig.2).

- **h.** Use the tips of the forceps to push the plug out of sight into the horizontal canaliculus (Fig. 3).
- i. Blinking and normal tear flow cause the plug to migrate down into the horizontal canaliculus (adiacent to the common canaliculus).
- j. Repeat the same procedure for each remaining punctum. After insertion, inspect each punctum to ensure the plugs are not sticking out (Fig. 4). Unused plugs should be discarded.

Plug insertion (Fig.1-4) is the same for inferior and superior puncta.

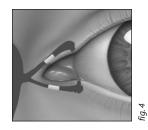


FOLLOWING PLACEMENT

Patients should feel little or no discomfort following plug placement.

For patients experiencing irritation or tearing after plug insertion, use a sterile probing device such as the Williams Intracanalicular Plua Positionina Tool (WIPPT) to confirm proper placement within the horizontal canaliculus (4-6mm beneath the punctum).

Use a single drop of topical antibiotic to prevent complications related to plug insertion.

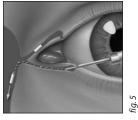


CONSIDERATIONS

During insertion be careful not to perforate the canaliculus with the jeweler's forceps. Perforation can increase the risk of infection. If perforation occurs, delay plug insertion until the wound heals.

DISCLOSURE

Before using **Dissolvable** VisiPlug Lacrimal Plugs, patients should be informed about benefits, risks, and alternatives. Have patients sign an Informed Consent Form (sample form available from Lacrimedics) to document receipt of information.



Seeina Dissolvable VisiPlua Lacrimal Plugs

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

REMOVAL

Pressure irrigation with the *TruPro™ Cannula* (Fig.5) or with the West Lacrimal Cannula (combines irrigation and probing) is the preferred method for plug removal. In rare cases, when this method proves unsuccessful, surgical removal may be required.



Storage Temperature





ALWAYS READ THESE INSTRUCTIONS BEFORE USE