**Comfortear® Lacrisolve™ Absorbable Punctum Plugs**

**INDICATIONS**

The Comfortear® Lacrisolve™ Absorbable Punctum Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to:

- Determine the potential effectiveness of permanent occlusion,
- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Temporarily enhance the efficacy of topical medications or ocular lubricants,
- Temporarily treat contact lens intolerance secondary to dry eye, and
- Temporarily treat dry eye after ocular surgery.

**CONTRAINDICATIONS**

Comfortear® Lacrisolve™ Absorbable Punctum Plugs are contraindicated for use in patients with known sensitivity to any one of the materials that comprise the Comfortear® Lacrisolve™ Absorbable Punctum Plugs, infectious conjunctivitis, dacryocystitis, inflammation of the eyelid, infected eyes, or epiphora.

**BEFORE INSERTION**

Patients should be given a complete eye examination with thorough history.

**Patients with pre-existing intermittent tearing should receive pressure irrigation to rule out canalicular obstruction.**

**PACKAGING**

Comfortear® Lacrisolve™ Absorbable Punctum Plugs for medium-term occlusion therapy are made of Polydioxanone and provided sterile (by EO Sterilization), two plugs per pouch, one pouch per box. Plugs are available in two sizes: 0.4mm and 0.5mm. Insert the largest size possible for maximum occlusion benefits.

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

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**To request information, or report product performance, contact:**

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**MADE IN USA**

Comfortear® is a U.S. Registered Trademark of Delta Life Science, Inc. Lacrisolve™ is a U.S. Trademark of Paragon BioTeck, Inc.

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INSERTION

a. Inspect the patient’s punctum in an effort to determine which size plug to use.

b. Remove a sterile packet from the box, peel open the pouch and remove the foam holder containing the Comfortear® Lacrisolve™ Absorbable Punctum Plugs.

c. While using magnifying loupes or a slit-lamp, have the patient look away from the point of insertion.

d. Use a jeweler’s type forcep to remove one of the plugs from between the grooves in the foam holder.

e. Apply traction with a cotton tip applicator to avert 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, approximately 4-6mm beneath the punctum (Fig. 3).

i. Blinking and normal tear flow cause the plug to migrate down into the horizontal canaliculus (adjacent to the common canaliculus).

j. Repeat the same procedure for each remaining punctum. After insertion, inspect each punctum to ensure the plugs are not protruding (Fig. 4).

FOLLOWING PLACEMENT

Patients should feel little or no discomfort following plug placement.

For patients experiencing irritation or tearing after plug insertion, consider the use of a sterile probing device to confirm proper placement within the horizontal canaliculus (4-6mm beneath the punctum).

A single drop of a suitable topical antibiotic may be instilled prophylactically in an effort to prevent complications related to plug insertion.

CONSIDERATIONS

During insertion, care should be taken so not to perforate the canaliculus with the forceps. Perforation can increase the risk of infection. If perforation occurs, delay the plug insertion until the wound heals.

DISCLOSURE

Before placing or removing the Comfortear® Lacrisolve™ Absorbable Punctum Plugs, patients should be informed about benefits, risks, and alternatives. Have patients sign an Informed Consent Form to document receipt of information.

REMOVAL

Should plug removal be required prior to the normal dissolution of the Comfortear® Lacrisolve™ Absorbable Punctum Plugs, consider pressure irrigation (Fig. 5) for plug removal. In rare cases, when this method proves unsuccessful, surgical removal may be required.

ALWAYS READ THESE INSTRUCTIONS BEFORE USE