

FCI Ophthalmics

Prolong™

Long Term Absorbable Plug



Manufactured for FCI Ophthalmics

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DESCRIPTION:

The FCI Prolong long term absorbable plug lasts up to 3 months (based on results obtained in an animal study) and is designed to be inserted through the punctal opening into the canaliculus in order to block tear drainage through the lacrimal drainage system. This residency time falls between the short term absorbable collagen plugs, which are completely absorbed after several days, and the permanent punctal plug, which is designed to remain in the punctum indefinitely.

Prolong plugs are made from an absorbable copolymer of glycolic acid and trimethylene carbonate and dyed with D&C Green Number 6. They are available in three diameters. The plugs are supplied sterile, two plugs per pouch.

INDICATIONS FOR USE:

Prolong plugs are intended for temporary use in patients experiencing dry eye symptoms such as redness, burning, reflex tearing, itching, or foreign body sensations which can be relieved by blockage of the canaliculus. They may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases.

When indicated, Prolong plugs may also be used after surgery on the eye to prevent complications due to dry eye and to enhance the retention of ocular medication on the eye.

CONTRAINDICATIONS:

The FCI Prolong long term absorbable plug is contraindicated for patients with known sensitivities or allergies to glycolic acid or trimethylene carbonate and for patients who are experiencing epiphora, inflammation of the eye lid, or tearing secondary to dacryocystitis with mucopurulent discharge. The plug is not intended for prophylactic use and should only be prescribed if dry eye symptoms are present.

INSERTION:

Prior to insertion of a Prolong plug, inspect the patient's punctum to determine the appropriate diameter plug to use.

Open the sterile Tyvek pouch and remove the appropriate diameter plug from the blue foam holder using jeweler's forceps.

A small amount of lubricant may be used on the plug or punctum in order to facilitate insertion across the punctum.

Insert the Prolong plug part way through the punctal opening while grasping the plug with the forceps. Release the plug and use the tip of the forceps to push the plug the rest of the way through the punctal opening and into the canaliculus.

CAUTION:

The FCI Prolong long term absorbable plug may enhance the effect of ocular medication used on the eye. Depending on the type of medications being used, dosage may need to be reduced accordingly.

Care should be used not to perforate the punctum or canaliculus while inserting the Prolong plug. Perforations may cause pain and increase the risk of infection. If perforation occurs, delay the placement of the plug until the wound heals.

If patient experiences irritation, infection, or epiphora after insertion of a Prolong plug, the plug should be removed. Saline irrigation or probing may be used to expel the plug through the lacrimal drainage system into the nose or throat.

Federal law (USA) restricts the device to sale by or on the order of a physician.