# Vera90<sup>™</sup> EXTENDED WEAR SYNTHETIC ABSORBABLE PUNCTAL PLUG



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## Vera90™ EXTENDED WEAR SYNTHETIC ABSORBABLE PUNCTAL PLUG

#### DESCRIPTION

Vera90™ Extended Wear Punctal Plugs are intended for temporary use with 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. The Vera90™ Extended Wear Punctal Plug is made from synthetic absorbable suture material. E-Caprolactone-L-Lactide copolymer (PCL). The plug is provided dyed violet with D&C Violet #2 and is coated with a calcium sterate, a noncollagenous and nonantigenic coating.

The plugs are supplied sterile, two plugs per package, ten packages per box. Each box contains one size plug. Available sizes (diameter) are: 0.2mm, 0.3mm, 0.4mm and 0.5mm. All plugs are 2.0mm in length. Each device is intended for single use. DO NOT RESTERILIZE.

#### INTENDED USE

Vera90™ Extended Wear Punctal Plugs are designed to be inserted through the punctal opening into the canaliculus to block tear drainage through the lacrimal drainage system.

#### INDICATIONS

Vera90™ Extended Wear Punctal Plugs may be used in the treatment of Dry Eye Syndrome and the dry eye components of various ocular surface diseases. When indicated, Vera90™ Extended Wear Punctal Plugs may be used after ocular surgery to prevent complications due to dry eye and to enhance the retention of ocular medications. Patients experiencing ocular dryness secondary to contact lens use may also be aided by Vera90™ Extended Wear Punctal Plugs.

#### CONTRAINDICATIONS

Vera90™ Extended Wear Punctal Plugs are contraindicated for patients who are experiencing epiphora, inflammation of the eyelid, or tearing secondary to dacryocystitis with mucopurulent discharge. If the patient experiences irritation or epiphora after insertion of Vera90™ Extended Wear Punctal Plugs, a saline irrigation or a probe may be used to expel the plug through the lacrimal sac into the nose or throat.

#### PATIENT PREPARATION

Inspect the patient's punctum to determine the appropriate size (diameter) plug prior to insertion of

Vera90™ Extended Wear Punctal Plugs. As a guideline, the measured punctal opening less 0.2mm may indicate an approximate diameter of the canaliculus. Physician experience should ultimately determine the proper sizing of the canaliculus.

#### DIRECTIONS FOR USE

- · Inspect the patient's punctum to determine the appropriate size (diameter) punctal plug to use.
- · Inspect the sterile package integrity. Check the expiration date.

# DO NOT USE IF THE PACKAGE IS OPEN. DAMAGED OR EXPIRED.

- · Remove the appropriate diameter plug from the plug holder using jewelers' forceps.
- · A small amount of lubricant may be used on the plug in order to facilitate insertion.
- While holding the plug with the forceps, place the plug partially through the punctal opening.
- · 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.
- · Following insertion, inspect the punctal opening to ensure the implant is below the punctal opening.

# ADDITIONAL INFORMATION

Effective occlusion in the first days after insertion is dependent on the size of the patient's punctal opening and the size plugs used. Absorption of Vera90™ Extended Wear Punctal Plugs is essentially completed between 60 and 180 days. The patient may experience rapid improvement of dry eye symptoms after initial placement, followed by a return of previous discomfort. Such signs of temporary improvement suggest that the patient may benefit by permanent, yet reversible punctal occlusion with Silicone Punctal Plugs.

#### CAUTIONS

U.S. Federal Law restricts this device for sale by or on the order of a physician. Care should be taken not to perforate the punctum or canaliculus while inserting the Vera90™ Extended Wear Punctal Plugs, Perforation may cause pain and increase the risk of infection. If perforation occurs, delay the placement of the plug until the wound heals. Presence of the Vera90™ Extended Wear Punctal Plug may alter the prescribed effect of eye drop medications due to the reduction or elimination of tear drainage via the punctum.

#### PRECAUTIONS

Contents are sterile if individual package is unopened and undamaged. Do not use if package has been previously opened or damaged. DO NOT RESTERILIZE.

#### STORAGE

Ambient conditions apply. Do not expose to extreme temperatures.

## SYMBOLS USED FOR LABELING

REF

Product Code Caution-Refer to Accompanying Documents

Consult instructions for use Do Not Reuse

Do Not Resterilize



Use by

STERILE[E0] Sterilized using ethylene oxide



Lot Code Manufacturer



Do not use if package is damaged

RyOnly CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.