











## SYMBOLS USED FOR LABELING

-  Product Code
-  Caution—Refer to Accompanying Documents
-  Consult instructions for use
-  Do Not Reuse
-  Use by
-  Sterilized using irradiation
-  Do Not Resterilize
-  Lot Code
-  Manufacturer
-  Do not use if package is damaged

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

To reorder product, please contact your local distributor or sales representative at:



### Surgical Specialties Corporation

100 Dennis Drive  
Reading, PA 19606 USA  
Telephone: 732 626-6466

877 991-1110 (USA and Canada only)

Fax: 610 404-4010

[www.Sharpoint.com](http://www.Sharpoint.com)

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## ULTRAPLUG™ TEMPORARY COLLAGEN PUNCTAL PLUGS

P/N 03-4279R2

## ULTRAPLUG™ TEMPORARY COLLAGEN PUNCTAL PLUGS

### DESCRIPTION

UltraPlug™ Collagen 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 UltraPlug™ Collagen Plug is composed of purified collagen, derived from the serosal layer of bovine intestines.

The plugs are supplied sterile, six plugs per package and ten packages per box. Each box contains one size (diameter) plug. Available sizes (diameter) are: 0.2mm, 0.3mm, and 0.4mm. All plugs are 2.0mm in length. A variety pack containing all three diameters (24 plugs each) is also available. Each device is intended for single use. **DO NOT RESTERILIZE.**

### INTENDED USE

UltraPlug™ Collagen Plugs are designed to be inserted through the punctal opening into the canaliculus to block tear drainage through the lacrimal drainage system.

### INDICATIONS

Collagen plugs may be used in the treatment of Dry Eye Syndrome and the dry eye components of various ocular surface diseases such as corneal ulcers, conjunctivitis, pterygium, blepharitis, keratitis, red lid margins, recurrent chalazions, recurrent corneal erosion, filamentary keratitis and other external eye diseases. When indicated, UltraPlug™ Collagen 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 UltraPlug™ Collagen Plugs.

### CONTRAINDICATIONS

UltraPlug™ Collagen Plugs are contraindicated for patients allergic to bovine collagen or

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 UltraPlug™ Collagen Plugs, a saline irrigation or a probe may be used to expel the plug through the lacrimal sac into the nose or throat. Presence of the plug may alter the prescribed effect of eye drop medications due to the reduction or elimination of tear drainage via the punctum.

### PATIENT PREPARATION

Inspect the patient's punctum to determine the appropriate size (diameter) plug prior to insertion of UltraPlug™ Collagen 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. The UltraPlug™ Punctal Gauge/Dilator Set (REF: PAK-101, sold separately) is recommended to accurately size the punctum.
- 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 UltraPlug™ Collagen Plugs is essentially completed between 7 and 10 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 UltraPlug™ Silicone Punctal Plugs.

### CAUTIONS

U.S. Federal Law restricts this device for sale by or on the order of a physician. Care should be used not to perforate the punctum or canaliculus while inserting the UltraPlug™ Collagen 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 UltraPlug™ Collagen 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.