



## Instructions For Use

### DESCRIPTION

The ComfortTip punctal occluder is designed to provide reduction or elimination of tear drainage through the inferior or superior puncta, thus maintaining lubricating tears on the surface of the eye. The ComfortTip is available in four sizes (x-small, small, medium, and large).

### INDICATIONS FOR USE

The ComfortTip is for use in patients with dry eye symptoms.

### CONTRAINDICATIONS

Contraindications include, but are not limited to, eye infections, sensitivity or allergies to the occluder material and/or materials used in the manufacture of the device, blockage/infection of the lacrimal systems, inflammation of the eyelid, and epiphora.

### PRECAUTIONS

The ComfortTip may enhance the effect of ocular medications in the eye. Depending on the type of medication being used the dose may need to be altered accordingly. Conditions such as blepharitis or ocular surface inflammation should be treated prior to use of punctal plugs. If the patient experiences irritation, infection, or epiphora after insertion, the occluder should be removed.

### POTENTIAL ADVERSE EFFECTS

The following complications may occur:

- Epiphora
- Foreign body sensation
- Pyogenic granuloma
- Infection of the lacrimal system
- Washout
- Punctal erosion
- Plug dislodgement or migration possibly requiring surgical intervention

### PRODUCT FEATURES

Each box contains two individually packaged sterile ComfortTip punctal occluders preloaded on inserters for single use only. The ComfortTip is manufactured from medical grade silicone.

### PROPER SIZING

Proper sizing can be determined by using a 0.3mm gauge. If the gauge tip is snug in the punctum, then a small size occluder is required. If there is no resistance to the gauge then the next larger size should be tried. If resistance is extremely tight, an x-small size occluder should be used.

punctal opening	proper size	item number
0.2mm to 0.3mm	X-Small	2003
0.3mm to 0.5mm	Small	2005
0.6mm to 0.8mm	Medium	2008
0.9mm to 1.0mm	Large	2010

### PRIOR TO INSERTION

Patients with intermittent tearing should receive probing and irrigation with a sterile irrigation solution to rule out pre-existing canalicular obstruction.

### STORAGE

Store at 15-30° Celsius. Temperatures may move above and below these values temporarily (i.e. during transport) without harm.

### WARNINGS

The ComfortTip punctal occluder is intended for single use. Do not reuse. If the sterile packaging is damaged or opened, sterility is not guaranteed and the occluder should be discarded. U.S. federal law restricts the sale of this device by or on the order of a physician.

### DOCUMENTATION

Each box contains Instructions For Use and two peel-off patient chart labels for your ease and convenience.

# ComfortTip™

PUNCTAL OCCLUDER

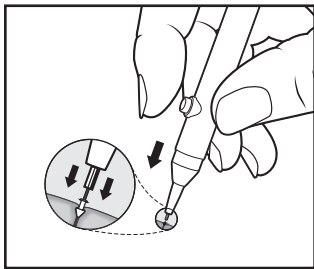


Figure "a"

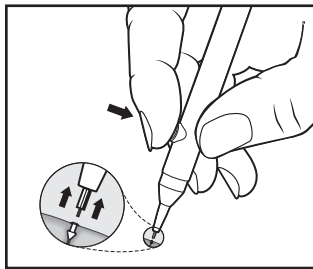


Figure "b"

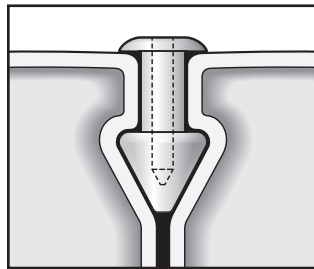


Figure "c"

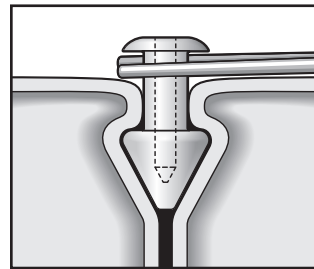


Figure "d"

## INSERTION

1. Anesthetize the area of the punctum with a topical anesthetic placed in the conjunctival sac.
2. Apply a drop of saline solution or artificial tears onto the ComfortTip plug to help ease insertion.
3. Position the insertion instrument by placing the forefinger on the release button of the inserter and placing the occluder end of the insertion instrument over the patient's (superior or inferior) punctum.

4. Vertically insert the ComfortTip by positioning the occluder into the punctum until the cap is flush with the punctal opening. *Figure "a"*
5. When the occluder is properly seated, depress the release button and withdraw the insertion instrument. *Figure "b"*
6. Verify that the occluder is properly placed by confirming that the cap is flush with the punctal opening. *Figure "c"* After insertion, monitor the placement and integrity of the occluder to determine if/when the occluder may need to be replaced.

## REMOVAL

Should removal be indicated, grasp the vertical shaft of the occluder underneath the exposed cap with sterile forceps. Gently pull upward until the plug is removed. *Figure "d"*

## STERILIZATION

ComfortTip sterile preloaded punctal occluders are packaged in individual trays, two per box. The date of expiration should be confirmed prior to use. If the expiration date has lapsed the occluder should be discarded.

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