

# Tear Duct Occluder™

FDA Approved Device Patient Labeling  
21 CFR 886.5838

## 1. Descriptive Information

### Purpose

Tear Duct Occluder™ is indicated to temporarily occlude the nasolacrimal ducts in adult patients to reduce outflow through the nasolacrimal ducts. Improvement and/or deleterious effect(s) of concomitant ocular medication use has not been established with clinical data. Caution: Federal law restricts this device to sale by or on the order of a licensed eye care professional.

### Warning

This device has not been evaluated for pediatric use.  
Do not use this device for more than 5 minutes at a time.  
Do not use this device in case of open globe, post-surgery, infection, and inflammation.  
Stop using this device should the skin, in contact with the device, develop irritation.  
It is not known if this device eases the “tear duct occlusion” effort, thereby enabling the user to concurrently perform other activities (such as driving), therefore increasing compliance.

### Precaution

Do not use this device if you use anti-coagulants as use of this device may cause bruising.  
Do replace the device every 6 months. Over-use may lead to device fracture and/or excessive Velcro wear and tear.

### Risks and benefits

The device should fit the nasal aspect of the patient’s orbital rim seamlessly. Improper fit of the device will render the device non-functional. The device should not be worn continuously for more than 5 minutes. Prolonged wearing may produce soreness in the area under pressure by the device. The device should be replaced every 6 months. Extensive use beyond prescribed period may cause the metal frame to fracture and/or diminish the ability of the Velcro to grip properly.

### Description

Tear Duct Occluder™ has the “look and feel” of a spectacle frame. Figure 1 shows that Tear Duct Occluder™ is made of a specific carbon steel wire that is rigid enough to maintain the shape of the frame during normal use yet soft enough to be bendable by hand. This material characteristic enables this device be fully adjustable to fit individual patients. The skin contact portions of the frame are covered with silicone rubber (which is Latex free) to improve comfort and increase the coverage over the nasolacrimal ducts.

## 2. Operating Information

### Fitting Adjustments

The device should fit the nasal aspect of orbital rims seamlessly, firmly, and comfortably. You are required to consult your licensed eye care professional regarding the fit. Your licensed eye care professional should check your nasolacrimal drainage reduction while you are wearing the device via the simplified dye disappearance test described later in this label.

Figure 1 depicts the user wearing the device. The frame width can be adjusted by bending two frontal segments. The nose pad bridge can be bent to fit the width of user’s nose. The temple length is adjusted by sliding the temple hook inside the holding tube so that the temple hook can reach behind the user’s ear. Figure 2 depicts the anatomic site for applying the nose pad. The nose pad sits across the nasolacrimal duct along the orbital rim area. Figure 3 depicts the use of the device.

### Pressure adjustment

The nose pad pressure is adjusted by first wrapping the Velcro around the back of the head, as shown in Fig 3, then reducing the Velcro length by one centimeter. This level of tightness will produce approximate 1.6 psi of pressure on the nasolacrimal ducts which can reduce the drainage through the nasolacrimal ducts. If the Velcro length reduction deviates from 1 centimeter, the pressure produced will deviate as well but is capped at 3.9 psi by the yield stress limit of the device’s frame. After the tightness adjustment, the user should mark the tightened Velcro position for future reference. A small variation in Velcro tightness will not significantly affect the drainage reduction function which can be verified by the dye disappearance test. The curvature of the nose pad should be adjusted to make at least 1 inch of linear contact to the skin area at the nasal aspect of orbital rim. The curvature can be adjusted to fit shallower or deeper set eyes. Decrease the curvature for shallower set eyes. Increase the curvature for deeper set eyes. Make sure the nose pad bridge is pointing vertically away from the face.

### Directions for Use

Fig. 3 depicts the use of this device. The device is to be used for 5 minutes at a time.

### Maintenance

Over time, the nose pad silicone tube may be coated with some deposit. This layer of deposit may or may not be visible. It is advisable to clean it weekly with an alcohol patch or moistened facial tissue. The service life of this device is expected to be 6 months or when the Velcro fabric becomes loose or shows signs of wear and tear, whichever comes first.

### Storage

The device should be placed on an open surface or hung on the wall with no objects pressing against it.

### Failure time and Failure mode

The Velcro fabric of the device is likely to begin loosening after 6 months of use. Depending on the number of times that the device is used, the failure time may be longer or shorter than 6 months. The failure mode is when the Velcro fabric shows sign of wear and tear.

### Dispose of the device

This device does not contain hazardous materials and may be disposed as household trash.

## 3. Troubleshooting

If you accidentally twist the frame or you feel:

- a. uneven pressure points along the nose pad/skin contact area,
- b. uncomfortable wearing the device,

you should return the device to the licensed eye care professional for refitting and confirmation that the device is functional via the simplified dye disappearance test described later in this label.

## 4. Additional Information

### Physician’s Information

Tear Duct Occluder™ is indicated to temporarily occlude the nasolacrimal ducts in adult patients to reduce outflow through the nasolacrimal ducts.

The most important technological characteristic of Tear Duct Occluder™ is the specific carbon steel wire that is rigid enough to maintain the shape of the frame during normal use yet soft enough to be bendable by hand. This characteristic enables this device to be fully adjustable to fit individual patients. The skin contact portions are

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covered with silicone rubber (which is Latex free) to improve comfort and increase the coverage area over the nasolacrimal ducts.

The occlusion pressure is accomplished via fastening a pair of Velcro bands around the back of the head. A licensed eye care professional should work with the patient to fit the device to avoid too much pressure (a safety risk) or too little pressure (an efficacy concern). The device is designed to deform at 3.9 psi of pressure, which is safe for skin to tolerate. The licensed eye care professional should review the fit of the device with the patient and check the occlusion effect of the device using the simplified dye disappearance test described later in this label.

## Simplified Dye Disappearance Test

The purpose of the test is to check if the outflow through nasolacrimal ducts is significantly reduced due to wearing Tear Duct Occluder™. A licensed eye care professional should perform the test and assess the result during a routine clinical visit for patients using the Tear Duct Occluder™. The test procedure is to first let the patient wear the device and then use a wet fluorescein strip with balanced salt solution or saline to instill fluorescein into the conjunctival fornices of each eye. Then continuously observe the film of the tear with the cobalt blue filter of the slit lamp. Persistence of significant dye particularly asymmetric clearance of the dye from the tear meniscus over a 5 minute period, indicates an obstruction during that period.

Two eyes were tested on one subject with this simplified dye disappearance test by a licensed eye care professional to verify temporary nasolacrimal duct occlusion. The outcome was that persistence of dye was achieved bilaterally for 5 minutes. No adverse events were reported.

## Warranty

Innovatex Inc. warrants this product to be free from defects on material and workmanship for a period of one (1) year from the original purchase. If this product is found to be defective, excluding normal wear and tear, Innovatex Inc. will replace it free of charge. To claim the warranty, mail the sale receipt to Innovatex Inc., 150 Buckskin Drive, Weston, MA 02493.

## User Assistance

INNOVATEX Help Phone: 1-(508)259-5200  
info@TearDuctOccluder.com  
www.TearDuctOccluder.com  
Address: 150 Buckskin Drive, Weston, MA 02493 USA  
If you notice any adverse events while using the device (e.g., bruising, soreness, or corneal abrasion) please report them to INNOVATEX INC. and FDA through MedWatch at 1-800-332-1088 or the internet at: <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>.

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INNOVATEX INC.  
Weston, MA 02493 USA  
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2/17/2017

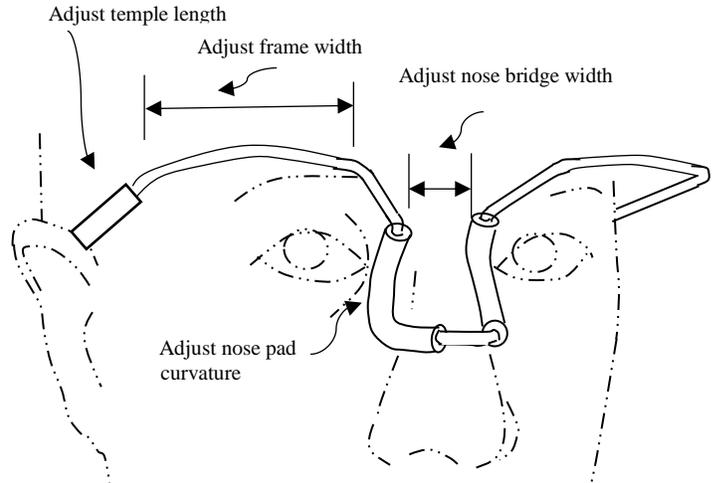


Fig. 1 – Fitting device on face

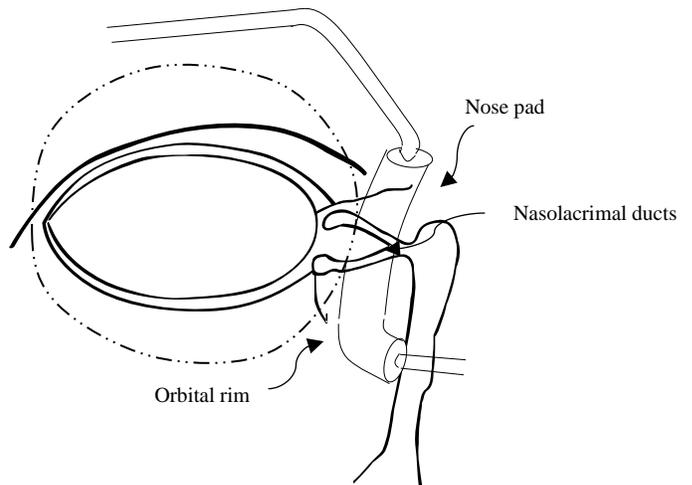


Fig. 2 – Nose pad sitting across nasolacrimal ducts

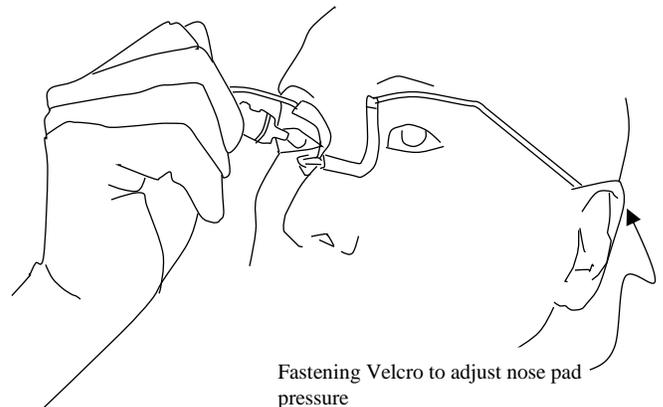


Fig. 3 - Use of the device