Tear Duct Occluder ™

Medical Device Patient Labeling

1. Descriptive Information

Purpose

Tear Duct Occluder™ is the brand name of FDA approved Nasolacrimal Compression Device and is indicated to temporarily occlude the nasolacrimal ducts (tear ducts) in adult patients to reduce outflow through the nasolacrimal ducts. Federal law restricts this device to sale by or on the order of a licensed eyecare professional.

Warning

Stop using this device should the skin, in contact with the device, develop irritation.
Continue wearing for more than 30 minutes may produce soreness in the area under pressure by the device.

Precaution

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.
Do not use this device if you use anti-coagulants as use of this device may cause bruising.
Do not use the device beyond 1 year of service life as it may lead to excessive wear and tear of silicone sleeves as well as Velcro tapes thus pose the risk of unable to fasten the device to produce adequate pressure to occlude tear ducts.

Risks and benefits

The device should fit the nasal aspect of your orbital rim firmly. Improper fit will render the device function suboptimal.

Description of the device

Tear Duct Occluder™ has the "look and feel" of a spectacle frame. Figure 1 shows that Tear Duct Occluder™ is made of a specific grade of stainless-steel alloy which is rigid enough to maintain a factory set nose pad geometry during normal use yet flexible enough to allow some adjustments and protect against over pressure. This nose pad geometry is designed to be "one size fits all" but the nose pad gap is adjustable, as needed. The skin contact portions of the frame are covered with Latex free silicone rubber to improve comfort and be more adaptable the surface curve- over the tear ducts.

2. Operating Information

Fitting Adjustments

Figure 1 depicts a patient wearing the device. The nose pad curve and angle were factory set and not adjustable. The nose pad gap will fit most people but may be adjusted by squeezing them closer or pulling them apart. The upper part of nose pads should fit the space next to the corners of the eyes by the nose (but do not touch the corner of eyes, or else, it would cause a pinch.) The lower part of nose pads should fit across the lower nose base. Temple length should fit most of the people but may be adjusted by sliding the temple hook inside the temple sleeve so that the temple hook can reach behind the user's ears. Figure 2 depicts the anatomic site for applying the nose pad where the nose pad sits across the tear duct along the orbital rim area.

Pressure adjustment

Fog 3 shows that the nose pad pressure is adjusted by first wrapping the Velcro around the back of the head and then reducing the Velcro length by approximate one centimeter. The pressure produced may vary but will not exceed 3.4 psi, as it is limited by the elasticity of the device frame. If you feel uncomfortable then the Velcro strap may be too tight. You could loosen the strap until you feel comfortable. A comfortable pressure is around 1.6 psi and this pressure is sufficient to occlude the tear ducts to reduce the outflow. A small variation in pressure is allowed.

Directions for Use

Fig. 3 depicts the use of this device. Step by step use instructions are:

1. Put on the device (adjust nose pad gaps across the nose, as needed).
2. Wrap Velcro straps around the back of your head and then reduce the strap`s length by 1 cm.
3. Put eyedrops into the eyes (alternatively you may put in eyedrops before putting on the device. But by doing so the tear duct occlusion effectiveness may be compromised slightly). You may keep your eyes open.
4. Remove the device 5 minutes later.

Maintenance

Over time, the nose pad silicone sleeves may be coated with some eyedrops 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. Depending on the frequency of use, the temple sleeves may become enlarged over time and unable to grab temple hook effectively. To cope with this problem, 2 replacement temple sleeves are included in the product package to prolong the device usable life. The service life of this device is expected to be 1 year or when the Velcro fabric becomes loose or shows signs of wear and tear, or temple sleeve becomes enlarged again after replacement, 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 is likely to begin loosening after 1 year of use. Depending on the number of times that the device is used, the failure time may be longer or shorter than 1 year. 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 feel uncomfortable while wearing the device, it is likely the nose pad geometry or the upper and/or lower nose pad gaps across the nose was disturbed by accidental pressing, such as packing for travel. You can restore the nose pad gap by following the fitting adjustment procedure. It is possible to restore the nose pad curve and angle by bending it back until you feel comfortable to wear again. However, improper adjustment of nose pad curve and angle could result in uneven nose pad surface causing uncomfortable wearing and possible leaking. If you feel the device is comfortable to wear after adjustments, then you should replace the device.

If you experience minor dysgeusia (bitter aftertaste) which suggests that the device either does not fit or the Velcro strap is not firmly fastened. You should adjust the device as stated in the Operating Information Section to minimize the dysgeusia.

4. Additional Information

For Licensed Eyecare Professionals:

Tear Duct Occluder temporarily occludes the tear ducts via compressing the tear ducts externally.

Unlike the generic Nasolacrimal Compression Device requiring nose pad curve fitting adjustment, Tear Duct Occluder has a unique nose pad curve geometry that fits almost all human races without needing custom adjustment.

The occlusion pressure is accomplished via fastening a pair of Velcro bands around the back of the head. A physician 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 3.4 psi of pressure, which is safe for skin to tolerate. You should review the device fitting with the patient and, at your discretion, the occlusion effect of the device may be checked via a simplified dye disappearance test described below:

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™. An ophthalmologist 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 board-certified ophthalmologist 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 (or shipping paper) 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.

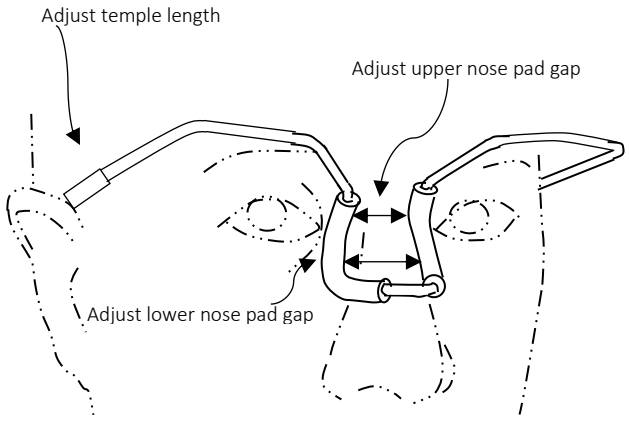

Fig. 1 – Fitting device to the nose width

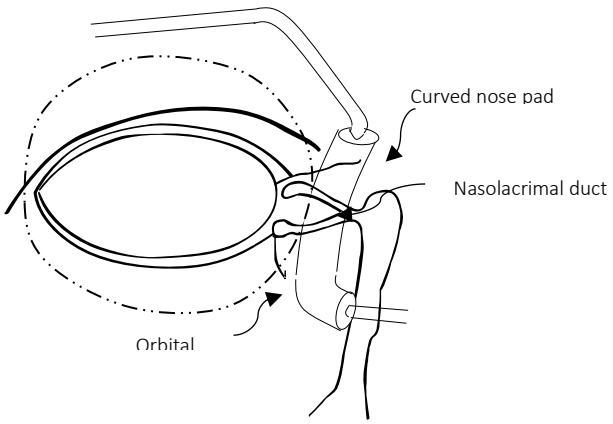

Fig. 2 – Nose pad sitting across nasolacrimal duct

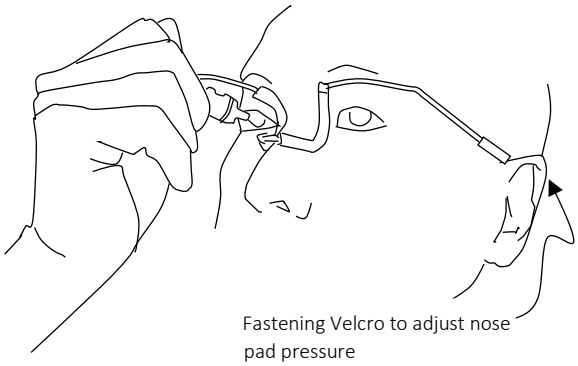

Fig. 3 - Use of the device

Date of FDA approval:
INNOVATEX INC.
Weston, MA 02493 USA
Printed in U.S.A.
12/17/2020