Tear Duct Occluder®

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 this device beyond 1 year of service life as it may lead to excessive wear and tear of silicone sleeves as well as Velcro band 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. It is made of a specific grade of stainless-steel alloy which is rigid enough to maintain a factory set nose pad shape during normal use yet flexible enough to allow some adjustments and protection against over pressure. The nose pad curve and its angle from the frontal frame were designed to be "one size fit 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 adaptable to the surface curve over the tear ducts.

2. Operating Information

Fitting Adjustments

Because of the unique nose piece design, the device will fit most patients except, in very rare case, some patients having very wide nose. Allowable adjustments are widening the distances between two nose pieces across the nose as shown in Fig. 1. The nose pad should fit the surface next to the corners of the eyes by the nose. Fig. 2 shows the anatomic site for positioning the nose pad on the orbital rim area. The nose pad curve and its angle from the frontal frame were factory set and are not adjustable. Temple length should fit most of the people but may be adjusted by sliding the temple hook on the frame so that the temple hook can reach behind the patient's ears. Generally, patients can recognize the fitness. If doctor wants to check the fitness, a dye disappearance test describe in the Additional Information Section may be used.

Pressure adjustment

Fog 3 shows that the nose pad pressure is adjusted by first wrapping the Velcro band around the back of the head and then reducing the Velcro band length by approximate 1 cm. The pressure produced can be between 1.6 psi to maximum 3.4 psi. The maximum pressure is capped by the elasticity of the device frame. You should adjust the tightness of the band until you feel comfortable to wear the device. A minimum pressure of 1.6 psi is required to occlude the tear ducts to reduce the outflow.

Directions for Use

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

1. Put on Tear Duct Occluder, adjust nose pad gaps as needed. Wrap Velcro band around the back of your head and then reduce the band length by 1 cm.
2. Pull the lower eyelid down to form a pocket to receive eyedrops.
3. Put eyedrops into the eyelid pocket by aiming at the center of the eye.
4. Wait for 5 minutes and then remove the device. You may keep your eyes open during this period.

Alternatively, you may put in eyedrops first before putting on the device. However, by doing so the tear duct occlusion would be less effective.

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 that the nose pad shape was disturbed by accidental pressing, such as packing for travel. It is possible to restore the nose pad shape by bending it back until you feel comfortable to wear again. However, improper adjustment of nose pad shape could result in uncomfortable wearing and possible leaking. If you feel the device is uncomfortable to wear after adjustments, it is likely the adjustment is incorrect, and you may need to readjust or replace the device.

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

4. Additional Information

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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, this new Tear Duct Occluder has a unique nose piece design that fits most patients without needing adjustments.

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. Patients usually can verify the correct fitting by lake of dysgeusia taste after instillation of eyedrops but 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. Weston, MA 02493 USA

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.

Printed in U.S.A.
03/23/2024

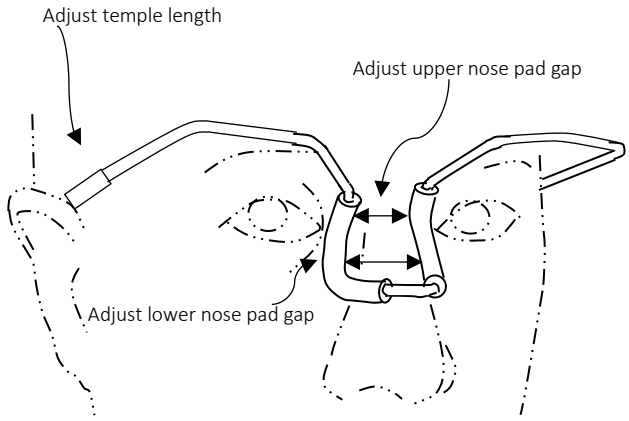

Fig. 1 – Fitting device to the nose width

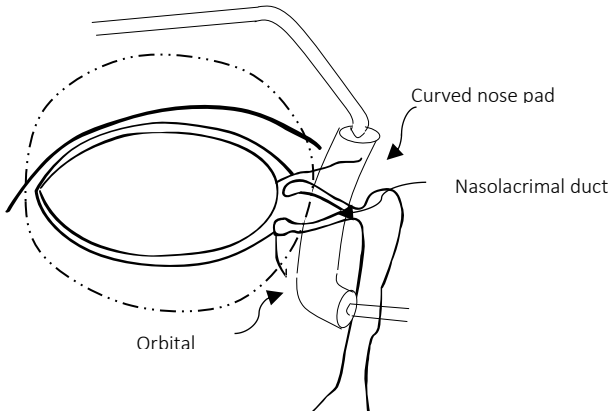

Fig. 3 - Use of the device