

VeraPlug™

Nonsterile Bulk
Punctal Occlusion System

Description

The VeraPlug™ 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. Each VeraPlug™ punctal occluder is molded from medical grade silicone. The VeraPlug™ is available in four sizes (small, medium, large and x-large) and is packaged nonsterile, ten pairs per box.

Indications for Use

The VeraPlug™ is for use in patients with dry eye syndromes.

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 VeraPlug™ may enhance the effect of some ocular medications in the eye. Depending on the type of medication being used the dose may need to be altered accordingly. If the patient experiences irritation, infection or epiphora after the insertion of the VeraPlug™, the occluder should be removed.

Potential Adverse Events

The following complications may occur:

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

Product Features

Each box contains ten pairs of VeraPlug™ punctal occluders for single use only. The VeraPlug™ is manufactured from implant grade silicone.

Proper Sizing

The VeraPlug™ punctal occluder is available in four sizes: small, medium, large and x-large. To determine the proper size, begin with the smallest VeraPlug™ gauge (0.5mm) and insert the head of the gauge into the punctal opening. The gauge should fit snugly with a small amount of resistance. If the gauge enters the punctal opening with no resistance, the next larger size gauge should be tried in the same manner. Repeat this process until the proper size VeraPlug™ is determined based on the sizing chart shown.

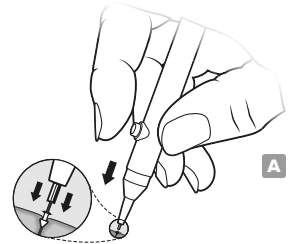
PUNCTAL OPENING	BEST FITTING GAUGE	PROPER VERAPLUG™ SIZE
0.4mm to 0.6mm	0.5mm	BNS-1001 Small
0.6mm to 0.7mm	0.6mm	BNS-1002 Medium
0.7mm to 0.8mm	0.7mm	BNS-1003 Large
0.8mm to 1.0mm	0.8mm	BNS-1004 X-Large

Sterilization

Remove the occluders to be sterilized from the bag using forceps. Grasp the occluder at the shaft, place into an autoclavable pouch and seal. The VeraPlug™ can be sterilized using steam gravity type sterilization. The cycle temperature is 121°C (259°F) and cycle time is 30 minutes. The dry time is an additional 30 minutes. The entire cycle meets a SAL (Sterility Assurance Level) of 10⁻⁶.

Loading

Load the sterilized occluder onto the inserter using forceps. Grip the occluder by its shaft and carefully guide the inserter wire into the hole on the occluder cap. Secure the occluder on the inserter wire by placing the forceps onto the nose portion of the plug and pushing gently. The occluder is properly loaded when the wire has reached the end of the shaft to the point where it begins to taper.

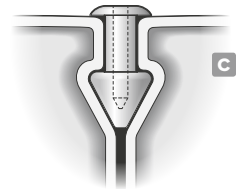
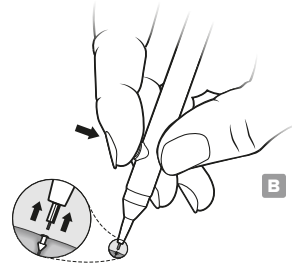


Prior to Insertion

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

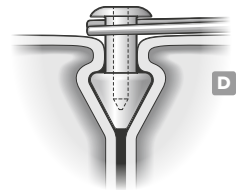
Insertion

- 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 VeraPlug™ 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 VeraPlug™ 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**



Storage

Store at room temperature.

Warnings

The VeraPlug™ punctal occluder is intended for single use. Do not reuse. Do not autoclave the inserter. 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 10 labels for your ease and convenience.

Authorized Representative

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