LACRIVERA

INSTRUCTIONS FOR USE

STERILE EO

CE 0086

VeraPlug™ FlexFit™

Sterile Preloaded
Punctal Occlusion System

Description

The VeraPlug™ FlexFit™ 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™ FlexFit™ punctal occluder is molded from medical grade silicone. The VeraPlug™ FlexFit™ is available in four sizes (x-small, small, medium, and large) and is packaged sterile, two per box. Each occluder is sterile, preloaded on an inserter.

Indications for Use

The VeraPlug™ FlexFit™ 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™ FlexFit™ 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 the insertion of the VeraPlug™ FlexFit," the occluder should be removed.

Potential Adverse Events

The following complications may occur:

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

Product Features

Each box contains two individually packaged sterile VeraPlug™ FlexFit™ punctal occluders preloaded on inserters for single use only. The VeraPlug™ FlexFit™ is manufactured from implant 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.

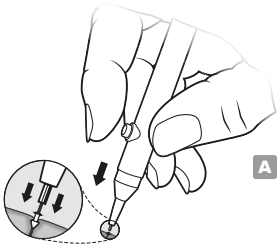
PUNCTAL OPENING	PROPER FLEXFIT™ SIZE	ITEM NUMBER
0.2mm to 0.3mm	X-Small	VFF-5000
0.3mm to 0.5mm	Small	VFF-5001
0.6mm to 0.8mm	Medium	VFF-5002
0.9mm to 1.0mm	Large	VFF-5003

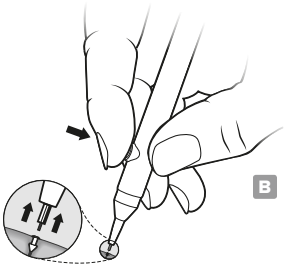
Prior to Insertion

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

Insertion

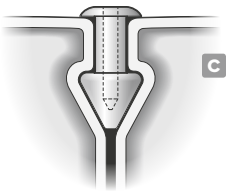
1. Anesthetize the area of the punctum with a topical anesthetic placed in the conjunctival sac.
2. Apply a drop of saline solution or artificial tears onto the VeraPlug™ FlexFit™ to help ease insertion.
3. Position the insertion instrument by placing the forefinger on the release button of the inserter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

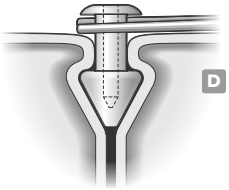
VeraPlug™ FlexFit™ sterile preloaded punctal occluders are offered in individual trays, two per box. The date of expiration should be confirmed prior to use. If the expiration date has lapsed the occluder should be discarded.

Storage

Store at 15-30° Celsius.

Warnings

The VeraPlug™ FlexFit™ punctal occluder is intended for single use. Do not reuse. If the sterile packaging is damaged or opened sterility is not guaranteed and the VeraPlug™ FlexFit™ 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 labels for your ease and convenience.

Authorized Representative

EC REP

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