SUMMIT medical

AN INNOVIA MEDICAL COMPANY

EN CS DA NL FI FR DE EL IT LV LT NO PL PT ES SR SV TR

DISSOLVABLE VISIPLUG® LACRIMAL PLUG Instructions for Use

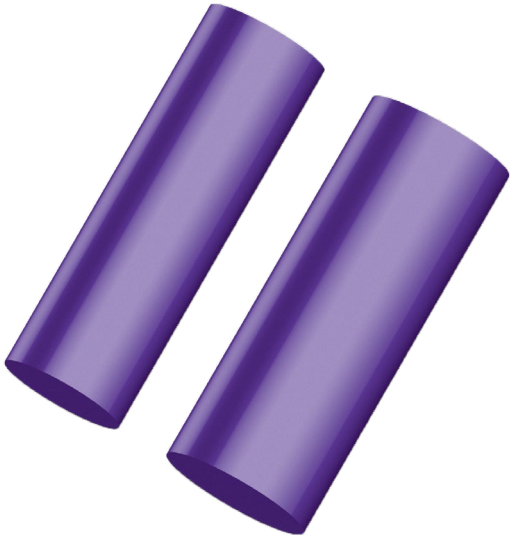
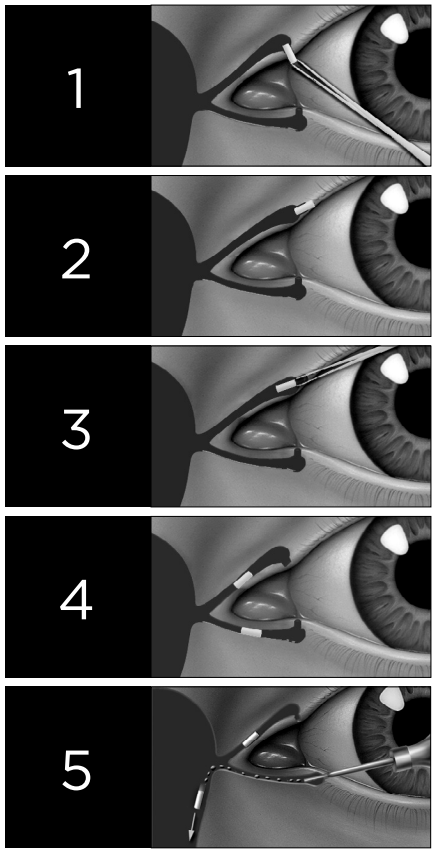


TABLE OF CONTENTS /



DISSOLVABLE VISIPLUG® LACRIMAL PLUG

EN

Read Before Use

INTRODUCTION
The Dissolvable VisiPlug® Lacrimal Plug is an ophthalmic device commonly referred to as a lacrimal plug, placed by a practitioner into the lacrimal duct to restrict the natural lubricating tears from being pumped off the eye. Lacrimal Plugs are prescribed for temporary treatment of certain eye conditions collectively referred to as 'Lacrimal System Dysfunction' or 'Dry Eye Syndrome' and other conditions of tear insufficiency.

Dissolvable Plugs:
• Are intended to treat Dry Eye Syndrome
• Are effective in the horizontal canaliculi
• Never touch the eye
• Are comfortable after proper placement, and will not fall out of the punctum

Punctal dilation and topical anesthesia are not usually required for insertion.

INDICATIONS FOR USE
Dissolvable VisiPlug Lacrimal Plugs may be used:
• As a diagnostic aid to determine the potential effectiveness of Occlusion Therapy with non-dissolvable plugs.
• To temporarily enhance the efficacy of topical medications or ocular lubricants.
• After ocular surgery to prevent complications due to dry eyes.
• To evaluate treatment of ocular dryness secondary to contact lens use.
• In the treatment of Dry Eye Syndrome and the dry eye components of varying Ocular Surface Diseases.

INTENDED USER & PATIENT TARGET GROUP
The devices are intended to be inserted by suitably qualified ophthalmic surgeons/physicians. The patient population is determined by the surgeon/physician in accordance with the intended use.

CONTRAINDICATIONS
This device is not designed, sold, or intended for use except as indicated or prescribed by a physician. Below are examples where Dissolvable VisiPlug Lacrimal Plugs may not be the therapy of choice:
• Chronic tearing (epiphora) secondary to canalicular obstruction
• Dacryocystitis with or without mucopurulent discharge.

PACKAGING AND STORAGE CONDITIONS
Dissolvable VisiPlug Lacrimal Plugs are made of polydioxanone and are provided in a Tyvek pouch which acts as the sterile barrier, two plugs per pouch. After sterilization the devices are packaged inside a moisture barrier pouch with a desiccant as the plugs moisture sensitive. Physicians are encouraged to keep VisiPlugs within the moisture barrier until such time they are ready to be used.

INTENDED LIFETIME OF THE DEVICE
Dissolvable VisiPlug Lacrimal Plugs have a medium term degradation rate of approximately 180 days.

BEFORE INSERTION
Dissolvable VisiPlug Lacrimal Plugs are available in two sizes: 0.4mm & 0.5mm. The 0.4mm plugs are appropriate for use with most adult patients; use 0.5mm when 0.4mm plugs will not stay in position.

A physician must use medical judgement and consider a patient's medical history prior to implanting a Dissolvable VisiPlug Lacrimal Plug. Pathologic conditions for which VisiPlugs are indicated include, but are not limited to:
• Patients with pre-existing intermittent tearing should receive pressure irrigation to rule out canalicular obstruction.

INSERTION
A. Inspect the patient's punctum to determine which size plug to use.
B. Remove a sterile packet from the box, peel open the pouch and remove the foam holder.
C. While using magnifying loupes or a slit-lamp, have the patient look away from the point of insertion.
D. Use a jeweler's forceps to remove one of the plugs from between the grooves in the foam holder.
E. Apply traction with a cotton tip applicator to evert the eyelid and clearly view the punctum.
F. Guide the plug partially into the punctum and release the forceps (Fig. 1).
G. Apply lateral traction with the cotton tip applicator to straighten the angle between the vertical and horizontal canaliculus (Fig. 2).
H. Use the tips of the forceps to push the plug out of sight into the horizontal canaliculus (Fig. 3).
I. Blinking and normal tear flow cause the plug to migrate down into the horizontal canaliculus (adjacent to the common canaliculus).
J. Repeat the same procedure for each remaining punctum. After insertion, inspect each punctum to ensure the plugs are not sticking out (Fig. 4). Unused plugs should be discarded.

Plug insertion (Fig.1-4) is the same for inferior and superior puncta.

FOLLOWING PLACEMENT
Patients should feel little or no discomfort following plug placement.

For patients experiencing irritation or epiphora after plug insertion, use a sterile probing device to confirm proper placement within the horizontal canaliculus (4-6mm beneath the punctum).

Use a single drop of topical antibiotic to prevent complications related to plug insertion.

WARNINGS
During insertion be careful not to perforate the canaliculus with the jeweler's forceps. Perforation can increase the risk of infection. If perforation occurs, delay plug insertion until the wound heals.

This device is designed, intended and distributed for single use only. DO NOT RE-STERILIZE OR REUSE THE DEVICE. There are no data to support the sterility and functionality of the device after reprocessing.

EN

Do not use if package is damaged. Please contact the manufacturer with the product code and lot number listed on the device and dispose of the package in accordance with the "Disposal" section of this instruction for use.

VisiPlugs are moisture sensitive devices and will begin degradation when exposed to ambient air. Premature degradation of the lacrimal plugs may decrease the length of treatment.

IMPLANT REMOVAL
Pressure irrigation (Fig. 5) is the preferred method for plug removal. In rare cases, when this method proves unsuccessful, surgical removal may be required.

DISPOSAL
VisiPlug devices leave the body through the digestive tract via natural waste. Any unused product should be disposed of via clinical waste in accordance with local procedures. If unused, product in original packaging which has exceeded the declared shelf life should be removed from packaging and disposed of as clinical waste.

EXPECTED CLINICAL BENEFITS AND PERFORMANCE CHARACTERISTICS
- The Dissolvable VisiPlug Lacrimal Plugs provide temporary occlusion of the tear drainage system and have a medium term degradation rate of approximately 180 days.
- A summary of safety and clinical performance can be found at the following link, when available via EUDAMED: https://ec.europa.eu/tools/eduamed/#/screen/home.

POSSIBLE ADVERSE EFFECTS
- Infection
- Canaliculitis
- Tearing or Perforation of the canaliculus
- Eye watering or excessive tearing (epiphora)
- Irritation, itching, swelling, or pain
- Need to surgically remove plug that doesn't flush out of canaliculus

MATERIALS: POLYDIOXANONE AND D&C VIOLET #2 (<0.25%)

STERILITY
Lacrimal plugs are provided terminally sterilized by ethylene oxide (EO) gas. The product is sterile in an undamaged, unopened package.

Adhesive product labels are included on the pouch for use on patient and hospital records.

INCIDENT REPORTING
Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the FDA or the competent authority of the Member State in which the user and/or patient is established.

PATIENT IMPLANT CARD: INSTRUCTIONS FOR COMPLETION
All steps are to be completed by the healthcare provider.
1. Implantation date
2. Patient name or identification number
3. Healthcare institution/provider name and address
4. Remove device information sticker from pouch label and adhere to this card in the space provided
5. Provide patient with completed implant card, which provides a link to the patient information leaflet

FOR PROFESSIONAL USE ONLY.
RX ONLY

TO ORDER, REQUEST INFORMATION, OR REPORT PRODUCT PERFORMANCE, CONTACT YOUR LOCAL DISTRIBUTOR, OR:
Summit Medical LLC.
ATTN: Customer Service
815 Vikings Parkway, Suite 100
St. Paul, MN 55121
Tel: 1.888.229.2875 | 651.789.3939
Fax: 1.888.229.1941 | 651.789.3979
E-mail: customerservice@innoviamedical.com
WWW: https://summitmedicalusa.com/

® Indicates U.S. Trademark Registration.

SYMBOL REFERENCE KEY	
	Consult instructions for use
	Quantity
	Caution: US Federal law restricts this device to sale by or on the order of a physician
	Catalog Number
	Lot Number
	Use By
	Sterilized using Ethylene Oxide
	Distributor
	Manufacturer
	Caution
	Do not use if package is damaged and consult instructions for use
	Single Sterile Barrier System and Single Sterile Barrier System with protective packaging outside
	Peelable Label
	Unique device identifier
	Date and country of manufacture (made in the US)
	Medical device
	Do not reuse
	Do not resterilize
	Keep Dry
	Keep away from sunlight
	Upper limit of temperature
	Patient identification

SYMBOL REFERENCE KEY	
	Date of implantation
	Health care centre or doctor
	Patient information
Not made with natural rubber latex.	

AN INNOVIA MEDICAL COMPANY

Summit Medical LLC
815 Vikings Parkway, Suite 100
St. Paul, MN 55121 | USA

P: 1-888-229-2875 | +1 651-789-3939
F: 1-888-229-1941 | +1 651-789-3979
www.summitmedicalusa.com

IFU-26753 | RevA | NOV2022