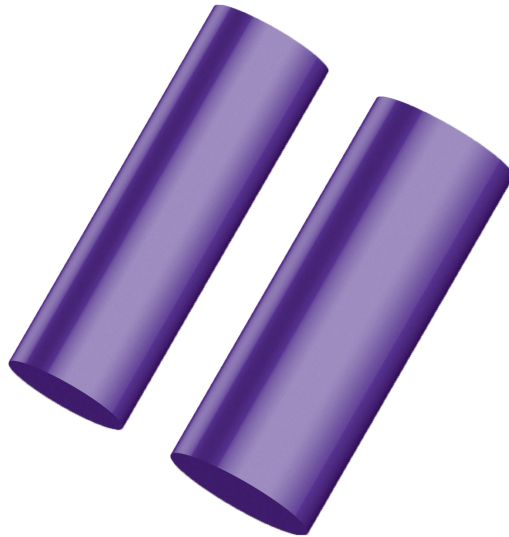




EN **VISIPLUG® DISSOLVABLE LACRIMAL PLUGS**
PATIENT INFORMATION LEAFLET



DISSOLVABLE VISIPLUG® LACRIMAL PLUGS

1638, 1639, 1657, 1658, 1638-C, 1639-C



WHAT IS THIS LEAFLET?

This leaflet answers some common questions about Summit Medical, LLC Dissolvable VisiPlug Lacrimal Plugs. It does not contain all the available information. It does not take the place of talking to your surgeon/doctor.

All medical devices and implants have risks and benefits. Your surgeon/clinician weighed the risks of using Dissolvable VisiPlug Lacrimal Plugs against the expected benefits.

Follow your surgeon/clinician's advice even if it differs from what is in this leaflet.

WHAT IS A VISIPLUG?

The Dissolvable VisiPlug Lacrimal Plug is a piece of dissolvable medical suture placed by a surgeon/physician into the tear duct to prevent moisture from leaving the surface of the eye.

WHO USES VISIPLUGS?

VisiPlugs 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.

HOW DO VISIPLUGS WORK?

VisiPlugs are inserted into the tear ducts of the eye by a qualified surgeon/physician to restrict the natural lubricating tears from being pumped off the eye. VisiPlugs may be used:

- As a diagnostic aid to determine the potential effectiveness of ocular 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

HOW LONG WILL THE VISIPLUG REMAIN IMPLANTED?

VisiPlugs have a medium-term degradation rate of approximately 180 days. VisiPlugs are dissolvable and will pass through the body's digestive tract.

WHAT IS A VISIPLUG TUBE MADE OF?

Summit Medical VisiPlugs are made from Polydioxanone (PDO).

IS IT SAFE TO HAVE AN MRI SCAN WHILE THE VISIPLUG IS IMPLANTED?

Yes, VisiPlugs are MR safe devices.

HOW TO READ YOUR IMPLANT CARD?

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.



WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS?

- 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

WHEN TO CONTACT A HEALTHCARE PROVIDER?

See a physician if you experience any side effects/risks listed above. If initial symptoms persist, device may require attention from a physician.

HOW TO REPORT ADVERSE EFFECTS?

If you wish to report any adverse effects you believe are a result of VisiPlugs, please report the information to Summit Medical at customerservice@innoviamedical.com

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.

Reports may also be made directly to the appropriate Government Health Authority where you are based, including:

Australia: Therapeutic Goods Administration via the website: <https://www.tga.gov.au/reporting-adverse-events>



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