

# PUNCTAL PLUG MANUAL



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OASIS Medical is a US based manufacturer and distributor of vision care solutions serving the eye care industry for over 37 years.

As a privately owned business, OASIS Medical is nourishing and sustaining the eye care community for the long term.

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# **CUSTOMER SERVICE**

### **CUSTOMER SERVICE HOURS:**

7:00 AM - 4:30 PM (Pacific Standard Time) Monday - Friday, excluding holidays.

**USA TOLL-FREE:** (844) 820 8940 (Phone) (800) 631 7210 (Fax)

# **OASIS® POLICY:**

OASIS® Medical offers a 100% satisfaction guarantee to customers and patients.

**EMAIL:** customerservice@oasismedical.com

MAIN: (909) 305 5400 (Phone) (909) 305 6897 (Fax)

# TRAINING OR PRODUCT QUESTIONS?

Please call customer service or your local OASIS Representative to schedule a training.

# **INITIAL STOCKING STRATEGY:**

Based on the clinic's experience with Dry Eye Patients a one month supply is recommended. Please contact customer servive or y our local OASIS Representative to review the clinics needs. No minimum orders.

# **RETURNED MERCHANDISE POLICY:**

Unopened items returned for credit must be accompanied by an RMA (Returned Material Authorization) and reason for the return. RMAs are requested through your OASIS Representative or through Customer Service.

Please contact OASIS for a return material authorization.

# ALLOWANCE SCHEDULE FOR ACCEPTABLE RETURNS:

The following conditions must be met to obtain 100% credit:

- 1. Shipped the product in error.
- 2. The product packaging or crating is damaged in transit before it is accepted.
- 3. The product does not perform as indicated.
- 4. The Product does not meet industry quality standards related to performance specifications and data submissions required by the FDA or FDA approval of the product.
- 5. The product is outdated or expired when delivered.
- 6. OASIS Medical gives prior written approval.

# **FORM FIT**<sup>®</sup> HYDROGEL CANALICULAR PLUGS

## LONG TERM OCCLUSION

FORM FIT<sup>®</sup> is truly a one size plug solution. Once inserted into the canaliculus, FORM FIT<sup>®</sup> hydrates in approximately 10 minutes. As it hydrates, FORM FIT<sup>®</sup> increases in size until it completely fills the vertical canalicular cavity.

### **HOW IT WORKS**

FORM FIT<sup>®</sup> is made of a safe and biocompatible hydrogel material that expands into a soft, pliable, gelatinous material when it contacts tear film. FORM FIT<sup>®</sup> securely conforms to the vertical canaliculus so there is no need for a cap on the end of the plug. This greatly increases patient comfort and decreases foreign body sensation.

### DETAILS

- Hydrates in approximately 10 minutes
- Easily removed via irrigation of the tear duct
- Biocompatible, no foreign body sensation
- Sterile
- Conveniently pre-loaded in inserter
- 0.3mm, one size fits all









Ref #	QTY/Box	Product Name	Diameter
6303 <sup>†</sup>	10pk	FORM FIT Hydrogel Canalicular Plug	0.3mm
6303-T†	2pk	FORM FIT Hydrogel Canalicular Plug	0.3mm

# SOFT PLUG® SILICONE PUNCTUM PLUGS

## LONG TERM OCCLUSION

The distinctive low-profile cap combined with a softer, flexible silicone maximizes patient comfort. Now available with two inserter options. SOFT PLUG<sup>®</sup> Silicone Punctum Plugs are removable with forceps per instruction for use.





## DETAILS

- Pen-Style Inserter with dilator tip 1pk, 2pks, 6pks
- Original Inserter with dilator tip 1pk, 2pks, 6pks, 20pks
- Sterile, preloaded on inserter in 1pk, 2pks, 6pks dispenser box
- Low-profile cap intended to reduce dislocation
- Economy pack includes 20 plugs. Holders equipped with an alignment slot for quick loading



**Original Inserter** 

Pen-Style Inserter

Original Inserter Ref #	Pen-Style Inserter Ref #	QTY/Box	Product Name	Diameter
6610-S <sup>†</sup>	7710-S‡	1pk	SOFT PLUG Silicone, Preloaded, Micro	0.4mm
6611-S <sup>†</sup>	7711-S‡	1pk	SOFT PLUG Silicone, Preloaded, Mini	0.5mm
6612-S†	7712-S‡	1pk	SOFT PLUG Silicone, Preloaded, Petite	0.6mm
6613-S <sup>†</sup>	7713-S‡	1pk	SOFT PLUG Silicone, Preloaded, Small	0.7mm
6614-S <sup>†</sup>	7714-S‡	1pk	SOFT PLUG Silicone, Preloaded, Medium	0.8mm
6610 <sup>+</sup>	7710 <sup>‡</sup>	2pk	SOFT PLUG Silicone, Preloaded, Micro	0.4mm
6611 <sup>†</sup>	7711‡	2pk	SOFT PLUG Silicone, Preloaded, Mini	0.5mm
6612 <sup>†</sup>	7712 <sup>‡</sup>	2pk	SOFT PLUG Silicone, Preloaded, Petite	0.6mm
6613 <sup>+</sup>	7713 <sup>‡</sup>	2pk	SOFT PLUG Silicone, Preloaded, Small	0.7mm
6614 <sup>†</sup>	7714 <sup>‡</sup>	2pk	SOFT PLUG Silicone, Preloaded, Medium	0.8mm
6610-D <sup>†</sup>	7710-D <sup>‡</sup>	6pk	SOFT PLUG Silicone, Preloaded, Micro	0.4mm
6611-D <sup>†</sup>	7711-D‡	6pk	SOFT PLUG Silicone, Preloaded, Mini	0.5mm
6612-D <sup>†</sup>	7712-D‡	6pk	SOFT PLUG Silicone, Preloaded, Petite	0.6mm
6613-D <sup>†</sup>	7713-D‡	6pk	SOFT PLUG Silicone, Preloaded, Small	0.7mm
6614-D <sup>†</sup>	7714-D‡	6pk	SOFT PLUG Silicone, Preloaded, Medium	0.8mm
6610-EP		20pk	SOFT PLUG Silicone, Economy Pack, Micro	0.4mm
6611-EP		20pk	SOFT PLUG Silicone, Economy Pack, Mini	0.5mm
6612-EP		20pk	SOFT PLUG Silicone, Economy Pack, Petite	0.6mm
6613-EP		20pk	SOFT PLUG Silicone, Economy Pack, Small	0.7mm
6614-EP		20pk	SOFT PLUG Silicone, Economy Pack, Medium	0.8mm



# LONG TERM OCCLUSION WITH PARTIAL DRAINAGE

The distinctive low-profile cap combined with a softer, flexible silicone maximizes patient comfort. The inserter minimizes potential for accidental release of the plug. Plug is designed with a center channel allowing for partial tear flow. SOFT PLUG® Flow Control Plugs are removable with forceps (per instruction for use).



### DETAILS

- Available in 1pk and 2pks
- Sterile, preloaded on inserter

Silicone

For partial occlusion with limited tear drainage

Original Inserter Ref #	Pen Inserter Ref #	QTY/Box	Product Name	Diameter
6612-SFC <sup>†</sup>		1pk	SOFT PLUG Flow Control, Preloaded, Petite	0.6mm
6613-SFC <sup>†</sup>		1pk	SOFT PLUG Flow Control, Preloaded, Small	0.7mm
6614-SFC <sup>†</sup>		1pk	SOFT PLUG Flow Control, Preloaded, Medium	0.8mm
6612-FC <sup>†</sup>	7712-FC <sup>‡</sup>	2pk	SOFT PLUG Flow Control, Preloaded, Petite	0.6mm
6613-FC <sup>+</sup>	7713-FC <sup>‡</sup>	2pk	SOFT PLUG Flow Control, Preloaded, Small	0.7mm
6614-FC <sup>†</sup>	7714-FC <sup>‡</sup>	2pk	SOFT PLUG Flow Control, Preloaded, Medium	0.8mm

# SOFT PLUG® COLLAGEN INTRACANALICULAR PLUGS

## **TEMPORARY OCCLUSION**

The Collagen Plugs have a smooth proprietary finish that simplifies insertion of the plug. Collagen Plugs are ideal for short-term, diagnostic, and postsurgical occlusion.

### DETAILS

- Absorbable material lasts 2-5 days
- Proprietary finish simplifies insertion
- Evaluate patient acceptance
- Insert with forceps

- 2mm length
- Sterile

Ref #	QTY/Box	Product Name	Diameter
6502	60 per box	SOFT PLUG Collagen Intracanalicular Plug	0.2mm
6503	60 per box	SOFT PLUG Collagen Intracanalicular Plug	0.3mm
6504	60 per box	SOFT PLUG Collagen Intracanalicular Plug	0.4mm



## **MEDIUM TERM OCCLUSION FOR UP TO 3 OR 6 MONTHS**

SOFT PLUG® Extended Duration Plugs are absorbable canalicular occluders that are an effective option for transient dry eye symptoms before or after surgery, seasonally, etc. and for patients seeking to experience non-permanent options of punctal occlusion.

### DETAILS

- Pre and post-surgical use
- Sterile
- Insert with forceps
- 2mm length







Ref #	QTY/Box	Product Name	Diameter
6210-A‡	20pk	NEW! SOFT PLUG Extended Duration 180-T Tapered Canalicular Plug	Tapered 0.6mm – 0.25mm
6210‡	40pk	NEW! SOFT PLUG Extended Duration 180-T Tapered Canalicular Plug	Tapered 0.6mm – 0.25mm
6203-A <sup>†</sup>	20pk	SOFT PLUG Extended Duration 180 Canalicular Plug	0.3mm
6204-A <sup>†</sup>	20pk	SOFT PLUG Extended Duration 180 Canalicular Plug	0.4mm
6205-A†	20pk	SOFT PLUG Extended Duration 180 Canalicular Plug	0.5mm
6203 <sup>†</sup>	40pk	SOFT PLUG Extended Duration 180 Canalicular Plug	0.3mm
6204 <sup>†</sup>	40pk	SOFT PLUG Extended Duration 180 Canalicular Plug	0.4mm
6205 <sup>†</sup>	40pk	SOFT PLUG Extended Duration 180 Canalicular Plug	0.5mm
6200V†	20pk	SOFT PLUG Extended Duration 180 Canalicular Plug, Variety Pack	3 pair 0.3mm, 4 pair 0.4mm, 3 pair 0.5mm
6402-A <sup>†</sup>	20pk	SOFT PLUG Extended Duration Plug	0.2mm
6403-A†	20pk	SOFT PLUG Extended Duration Plug	0.3mm
6404-A <sup>†</sup>	<b>2</b> 0pk	SOFT PLUG Extended Duration Plug	0.4mm
6405-A <sup>†</sup>	20pk	SOFT PLUG Extended Duration Plug	0.5mm
6402 <sup>†</sup>	40pk	SOFT PLUG Extended Duration Plug	0.2mm
6 <b>403</b> †	40pk	SOFT PLUG Extended Duration Plug	0.3mm
6404 <sup>†</sup>	40pk	SOFT PLUG Extended Duration Plug	0.4mm
6405 <sup>†</sup>	40pk	SOFT PLUG Extended Duration Plug	0.5mm
6400V†	20pk	SOFT PLUG Extended Duration Plug, Variety Pack	1 pair 0.2mm, 3 pair 0.3mm, 4 pair 0.4mm, 2 pair 0.5mm

# PATIENT EDUCATION MATERIALS

### Available at no charge.

Place order with OASIS Customer Service.

	Product Name	Ref #			Product Name	Ref #
ARE YOUR EYES DRY, HURNING, BRY, HURNING, WATERY? VOU AND HAVE DRY EYE	Patient Dry Eye Brochure (2008)	P6520		<section-header><section-header><section-header><list-item><section-header><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item><list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></list-item></section-header></list-item></section-header></section-header></section-header>	Dry Eye Symptoms Wall Chart (2015)	LIT-DES-WC
Instant and Long-lasting Relief of Dry Eye Symptoms	Oasis TEARS Brochure (2011)	6544C		<section-header><section-header><text><text><image/></text></text></section-header></section-header>	Punctal Plug Wall Chart (2014)	LIT-WCDE
ILINYING EYE SURGERYT	Surgical Oasis TEARS Brochure (2011)	LIT-6540	•	EYE CARE RECIMEN	Oasis TEARS RX Pad, with OASIS contact information	LIT-OTRX-W
ABOUT DRY EYE				Improve the intervention     Improve the intervention	Oasis TEARS RX Pad, plain	LIT-OTRX
Don't ignore your DRY EYE SYMPTOMS	Dry Eye Products Patient Brochure (2015)	LIT-DEP-PB		The path to DRY EYE RELIEF doesn't have to be difficult. Dent ignore your DRY EYE SYMPTOMS WITCH STATUS	Oasis TEARS Point-of- Purchase Display (2015)	LIT-OT-POP

# FORM FIT® HYDROGEL PLUGS LONG-TERM OCCLUSION

### **DESCRIPTION:**

The OASIS Medical Form Fit® Canalicular Plug is designed to be inserted through the punctal opening in order to block tear drainage through the canaliculus. The Form Fit® canalicular plug is provided as a semi-rigid rod of polyvinyl pyrrolidinone (PVP) based hydrogel measuring approximately 0.3mm diameter by 2.5mm long. Upon contact with fluids, the plug will slowly swell to approximately 3 times its initial size to form a soft, mucus-like gel.

Each Form Fit® Canalicular Plug is supplied sterile, in dry form, in a disposable inserter. The product is gamma sterilized and sterility is guaranteed unless the packaging is opened or otherwise compromised. The Expiration Date is provided on the label and the Form Fit® canalicular plug should not be used after this date.

### **INDICATIONS FOR USE:**

The OASIS Medical Form Fit® canalicular plug is intended for use in patients experiencing dry eye symptoms such as:

Redness

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- Burning
- Reflex tearing
- Itching or foreign body sensations which can be relieved by occluding the punctum.

The Form Fit® canalicular plug may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases. When indicated, the Form Fit® canalicular plug may be used after ocular surgery to prevent complications due to dry eye and to enhance the retention of topical ocular medications on the eye. Patients experiencing dry eye related contact lens problems may also be aided by the Form Fit ® canalicular plug.

### **CONTRAINDICATIONS:**

The OASIS Medical Form Fit® Canalicular Plug is contraindicated for patients experiencing:

- Epiphora.
- Inflammation of the eye lid.
- Tearing secondary to dacryocystitis with mucopurulent discharge.

If the patient experiences irritation, infection, or epiphora after insertion of the Form Fit® canalicular plug, the plug should be removed.

### **INSERTION:**

- Anesthetize the area of the punctum with either a topical anesthetic instilled into the conjunctival sac or an anesthetic soaked, cotton tipped applicator held against the punctum for 30 seconds. A small amount of lubricant may be used on the punctum in order to facilitate insertion across the punctum.
- Caution: Patency of the canaliculus should be determined prior to insertion of the Form Fit® plug.
- The OASIS Medical Form Fit® canalicular plug comes preloaded in a disposable inserter.
- Verify that the white Form Fit® plug has not fallen out of the inserter during shipping.
- Place the brown tip portion of the inserter through the puncta and squeeze the inserter to push the plug from the inserter tip into the canaliculus.
- The top edge of the plug should lie below the punctum opening.
- Forceps may be used to further push the Form Fit® canalicular plug to obtain the desired placement.

### **REMOVAL:**

Should it be necessary to remove the Form Fit® canalicular plug:

- Flush the mucus-like, gel plug from the canaliculus using a syringe filled with saline.
- Place an injection cannula on the tip of the syringe.
- Position the tip of the injection cannula through the puncta.
- Gently flush the canaliculus with saline.

# FORM FIT® HYDROGEL PLUGS LONG-TERM OCCLUSION

# **PRECAUTIONS:**

- Do not re-sterilize the Form Fit® canalicular plug by any method.
- Use only sterile intraocular irrigation solutions when required.
- Do not store Form Fit® canalicular plugs in excessively humid environments.
- During implantation avoid getting the plug wet as this will cause it to expand. Avoid touching the plug or inserter tip to the patient's eyelid prematurely.
- Should an infection occur in the canaliculus, flush the mucuslike plug from the canaliculus and allow the infection to clear. A new Form Fit® plug may be inserted into the canaliculus after the infection clears.
- Care should be used not to perforate the punctum or canaliculus during the insertion of the Form Fit® canalicular plug. Perforation may cause pain, increase the risk of infection, and cause the plug to fall out more easily due to an enlarged punctal opening or infection. If perforation occurs, delay the placement of the plug until the wound heals.
- The Form Fit® canalicular plug may enhance the effects of ocular medications used on the eye.
- Depending on the type of medications being used, dosage may need to be reduced accordingly.

DO NOT REUSE. This is a single use, disposable, device that cannot be properly cleaned and re-sterilized.

FEDERAL LAW (USA) restricts this device to sale by or on the order of a physician.

# FREQUENTLY ASKED QUESTIONS

#### Q: How does the hydrogel plug work?

A: Once inserted in the punctum, the dry hydrogel plug will absorb tear fluids and will expand to fill and conform to the vertical canaliculus.

## Q: How long until the OASIS Medical Form Fit<sup>®</sup> Intracanalicular Plug is fully hydrated?

A: The plug will swell up to 3 times its size within 45 seconds and become fully hydrated over a 10 minute period.

# Q: Can the OASIS Medical Form Fit<sup>®</sup> Intracanalicular Plug be removed?

A: Yes, it can be removed by flushing balanced salt solutions (BSS) through the lacrimal system with a lacrimal cannula.

# Q: How long will the OASIS Medical Form Fit<sup>®</sup> Intracanalicular Plug last?

A: The OASIS Medical Form Fit<sup>®</sup> Intracanalicular Plug is designed for long-term occlusion or until removed by irrigation.

#### Q: How do you know if the plug is still there?

A: It has been suggested by experienced physicians to place a drop of fluorescein by the punctum, if it pools and does not drain this is an indicator that the plug is still in place.

# Q: Has the hydrogel material been used by other manufacturers?

A: No. This is a patented product unique to OASIS and no other company has used this form of hydrogel for punctal occlusion.

# SOFT PLUG® SILICONE AND FLOW CONTROL PUNCTUM PLUGS LONG-TERM OCCLUSION

### **INTENDED USE:**

The OASIS® Medical SOFT PLUG® Silicone and Flow Control Punctum Plugs are intended to be inserted into the punctal opening by a certified physician to totally or partially block tear drainage through the canaliculus.

### **DESCRIPTION:**

The OASIS® Medical SOFT PLUG® Silicone and Flow Control Punctum Plugs are made from medical grade silicone are available in two styles: the original, OASIS® Medical SOFT PLUG® Silicone, with a closed nose portion which blocks flow through the punctal opening, and the SOFT PLUG® Flow Control, with an opening through the nose portion which allows flow through the punctal opening.

The OASIS® Medical SOFT PLUG® Silicone and Flow Control Punctum Plugs have a thin cap portion designed to remain outside the punctum and rest on the eyelid. The head portion of the plug is conical with a larger diameter designed to fit in the canaliculus to anchor the plug in the punctum. The central shaft portion of the plug has a smaller diameter than the head and cap portions and is designed to fit through the punctal opening. In practice, the plug insertion procedure is generally recognized as a non-sterile procedure. Oasis Medical sterilized its plugs to provide the best quality product possible.

## **ANESTHESIA:**

Anesthetize the area of the punctum with either a topical anesthetic instilled into the conjunctival sac or an anesthetic soaked, cotton tipped applicator held against the punctum for 30 seconds.

### **PROPER SIZING:**

Determine the proper plug size prior to dilation using the OASIS Punctum Plug Sizing System.

The OASIS Punctal Plug Sizing System is designed to allow the user to fit the plug for maximum comfort and retention. A properly fitted punctum plug will be more comfortable to the patient, less likely to dislocate and easier to remove should the need arise.

The gauging set consists of two stainless steel instruments:

• One with .5mm and .6mm tips

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- The other with .7 and .8 mm tips
- Sterilization Case for both sizing gauges

### HOW TO SIZE:

- Determine the proper plug size prior to optional dilation.
- Start with the smallest gauge size (.5 mm).
- Gently insert the head of the gauge into the punctum, being careful not to go beyond the neck.
- When entering and leaving the punctal opening, the gauge head should slightly flex the punctal ring.
- If there is no resistance to the gauge, the next larger size should be tried.
- The gauge size is too large if there is substantial resistance and the tip is difficult to insert.
- The proper plug size is found when the punctal opening flexes moderately when the gauge is inserted and removed and the gauge tip is "snug" when in the punctum.
- In some patients, the left and right eyes may have different size punctum, therefore it is useful that the punctum of both eyes are measured.

### **DILATION (OPTIONAL):**

If dilating, gently dilate the punctum and quickly insert the silicone plug. If the plug is not inserted within 15 to 30 seconds, the dilation may need to be repeated.

### **INSERTION:**

The OASIS Medical Soft Plug® Silicone Plug comes preloaded on a disposable inserter.

The pre-loaded plug is sterile and individually mounted on a disposable inserter ready to use.

- 1. Use the inserter to position the plug across the punctum.
- 2. Lubrication of the plug with saline solution or artificial tears eases insertion.
- 3. Grasp the inserter on the non-compressible side to avoid compressing the plug out of the wire.
- 4. Gently insert the plug into the punctum until the cap is flush with the punctal opening.
- 5. When the plug is properly inserted, gently squeeze and withdraw the inserter to release the plug.
- 6. Observe and verify proper placement of the punctum plug:
- The nose of the plug should be beyond the punctum.
- The shaft of the plug should go through the punctum.
- The head of the plug should be outside the punctum and resting snug against the eyelid.

# SOFT PLUG® SILICONE AND FLOW CONTROL PUNCTUM PLUGS LONG-TERM OCCLUSION

# INDICATIONS FOR USE:

The OASIS Medical Soft Plug® Flow Control Silicone Plug is intended for use in patients experiencing dry eye symptoms:

- Redness
- Burning
- Reflex tearing
- Itching
- Foreign body sensation

Silicone Punctum Plugs may be used in the treatment of dry eye syndrome and the dry eye component of various ocular surface disease such as:

- Corneal ulcers
- Conjunctivitis
- Pterygium
- Blepharitis
- Keratitis
- Red lid margins
- Recurrent chalazions
- Recurrent coneal erosion
- Filamentry keratitis
- And other external eye diseases

Other patients that may benefit are:

- Cataract patients
- Patients with arthritis
- Patients medicated for hypertension
- Contact wearers of any age
- Seasonal allergy sufferers
- Patients who live in dry climates, or spend extended periods in air conditioning
- Any others who suffer from dry irritation. It is reasonable that eye drops of many kinds would be more effective if retained on the surface of the eye, rather than drained into the sinus.

## **CONTRAINDICATIONS:**

The OASIS Medical Soft Plug® Flow Control Silicone Plug is contraindicated for patients experiencing:

- Inflammation of the eye lid
- Tearing secondary to dacryocystitis with mucopurulent discharge

## **CAUTIONS:**

Care should be used not to perforate the punctum or canaliculus during insertion of the Silicone Punctum Plug. Perforation may cause pain, increase the risk of infection and cause the plug to fall out easier due to an enlarged punctal opening or infection. If perforation occurs, delay the placement of the plug until the wound heals.

Inadequate or excessive forces, or improper technique used to insert the plug into punctum may cause loss of plug, lodging of plug beyond punctum into canaliculus, patient discomfort, or injury.

Patient intervention such as forceful rubbing of eyelids may result in dislodging of the plug.

The OASIS® Medical SOFT PLUG® Silicone Punctum Plug may enhance the effect of ocular medication used on the eye. Depending on the type of medications being used, dosage may need to be reduced accordingly.

DO NOT REUSE. This is a single use, disposable, device that cannot be properly cleaned and resterilized.

DO NOT USE if product is beyond the "use-by date".

DO NOT USE if the sterile packaging is damaged. After use it should be properly disposed of according to medical waste guidelines of your facility.

While not necessary, additional patient care information is available on www.oasismedical.com.

Federal law (USA) restricts this device to sale by or on the order of a physician.

# SOFT PLUG® EXTENDED DURATION TEMPORARY OCCLUSION, UP TO 3 MONTHS

### **DESCRIPTION:**

The OASIS Medical SOFT PLUG®, Extended Duration is a short term plug (less than 3 months based on results obtained in an animal study) designed to be inserted through the punctal opening into the canaliculus in order to block tear drainage through the lacrimal drainage system. This residency time falls between the absorbable collagen plugs, which are completely absorbed after several days, and the permanent intracanalicular plug, which is designed to remain in the canaliculum indefinitely.

SOFT PLUG®, Extended Duration are made from an absorbable copolymer of glycolic acid and trimethylene carbonate and dyed with D&C Green Number 6. They are available in four diameters. The plugs are supplied sterile, two plugs per package, so that a plug can be placed into each canaliculus.

### **INDICATIONS FOR USE:**

The SOFT PLUG® Extended Duration is intended for temporary use in patients experiencing dry eye symptoms such as:

- Redness
- Burning
- Reflex tearing
- Itching
- Foreign body sensations

They may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases.

When indicated, the SOFT PLUG® Extended Duration may also be used after surgery on the eye to prevent complications due to dry eye and to enhance the retention of ocular medication on the eye.

### **CONTRAINDICATIONS:**

The OASIS Medical SOFT PLUG® Extended Duration is contraindicated for patients with known sensitivities or allergies to glycolic acid or trimethylene carbonate and for patients who are experiencing:

- Epiphora
- Inflammation of the eye lid
- Tearing secondary to dacryocystitis with mucopurulent discharge
- The plug is not intended for prophylactic use and should only be prescribed if dry eye symptoms are present

### **INSERTION:**

- Prior to insertion of a SOFT PLUG® Extended Duration, inspect the patient's punctum to determine the appropriate diameter plug to use. Punctal sizing instruments are available from OASIS Medical.
- Open the sterile Tyvek pouch and remove the appropriate diameter plug from the blue foam holder using jeweler's forceps.
- A small amount of lubricant may be used on the plug or punctum in order to facilitate insertion across the punctum.
- Insert the SOFT PLUG® Extended Duration part way through the punctal opening while grasping the plug with the forceps. Release the plug and use the tip of the forceps to push the plug the rest of the way through the punctal opening and into the canaliculus.

Email international@oasismedical.com

# SOFT PLUG<sup>®</sup> EXTENDED DURATION TEMPORARY OCCLUSION, UP TO 3 MONTHS

# **CAUTION:**

- The OASIS Medical SOFT PLUG® Extended Duration may enhance the effect of ocular medication used on the eye.
  Depending on the type of medications being used, dosage may need to be reduced accordingly.
- Care should be used not to perforate the punctum or canaliculus while inserting the SOFT PLUG® Extended Duration. Perforations may cause pain and increase the risk of infection. If perforation occurs, delay the placement of the plug until the wound heals.
- If patient experiences irritation, infection, or epiphora after insertion of a SOFT PLUG® Extended Duration, the plug should be removed. Saline irrigation or probing may be used to expel the plug through the lacrimal drainage system into the nose or throat.

DO NOT REUSE. This is a single use, disposable, device that cannot be properly cleaned and re-sterilized.

Federal law (USA) restricts this device to sale by or on the order of a physician.

# FREQUENTLY ASKED QUESTIONS

# Q: How long will the Extended Duration Plug last?

A: Extended Duration Plugs last up to 3 months.

# SOFT PLUG® EXTENDED DURATION 180 CANALICULAR PLUG TEMPORARY OCCLUSION, UP TO 6 MONTHS

## **DESCRIPTION:**

The OASIS Medical SOFT PLUG® Extended Duration 180 Canalicular Plug is designed to be inserted through the punctal opening into the canaliculus in order to block tear drainage through the lacrimal drainage system for approximately 180 days.

SOFT PLUG® Extended Duration 180 Canalicular Plugs are made from degradable polydioxanone monofilament colored violet with D&C No. 2. The plugs are 2.0mm long and available in 0.3mm, 0.4mm and 0.5mm diameters. The plugs are supplied sterile, two plugs per package, so that a plug can be placed into each canaliculus.

# INDICATIONS FOR USE:

The SOFT PLUG<sup>®</sup> Extended Duration 180 Canalicular Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to:

- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Temporarily enhance the efficacy of topical medications or ocular lubricants,
- Temporarily treat contact lens intolerance secondary to dry eye,
- Temporarily treat dry eye after ocular surgery, and
- Determine the potential effectiveness of permanent occlusion.

## **CONTRAINDICATIONS:**

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The SOFT PLUG<sup>®</sup> Extended Duration 180 Canalicular Plugs are contraindicated for:

- Patients with known sensitivities or allergies to polydioxanone,
- Patients who are experiencing epiphora, canaliculitis, infectious conjunctivitis, or dacryocystitis with mucopurulent discharge.

## **INSERTION:**

- Prior to insertion, inspect the patient's punctum to determine the appropriate diameter plug to use. Punctal sizing instruments are available from OASIS Medical.
- Apply a topical anesthetic to the eyelid prior to insertion of the plug.
- Open the sterile Tyvek and foil pouches and remove the appropriate diameter plug from the foam holder using sterile jeweler's forceps.
- A small amount of lubricant may be used on the plug or punctum in order to facilitate insertion across the punctum.
- Insert the plug part way through the punctal opening while grasping the plug with the forceps. Release the plug and use the tip of the forceps to push the plug the rest of the way through the punctal opening and into the canaliculus.
- Following insertion, inspect the punctal opening to ensure the plug is below the punctal opening.

# POTENTIAL RISKS / ADVERSE REACTIONS OF IMPLANTATION:

- Tearing of the punctum or puncture of the canaliculus during insertion,
- Infection related to insertion,
- Excessive epiphora,
- Infection related to contamination trapped in the canaliculus due to insertion of a plug,
- Allergic reaction to polydioxanone resulting in irritation, itching, or swelling,
- Possible need to surgically remove a plug that cannot be flushed out of the canaliculus.

# SOFT PLUG® EXTENDED DURATION 180 CANALICULAR PLUG TEMPORARY OCCLUSION, UP TO 6 MONTHS

### WARNINGS:

- **DO NOT USE IF PACKAGE IS OPEN OR DAMAGED.** Sterility may be com promised or moisture may shorten the shelf life of the plug.
- **DO NOT REUSE.** This is a single use, disposable, device that cannot be properly cleaned and re-sterilized.
- Canalicular plugs may enhance the effect of ocular medications used on the eye. Depending on the type of medications being used, dosage may need to be reduced accordingly.
- Care should be used not to tear the punctum or puncture the canaliculus while inserting the plug. Perforations may cause pain and increase the risk of infection. If perforation occurs, delay the insertion of the plug until the wound heals.
- If the patient experiences irritation, infection, or epiphora after insertion, the plug should be removed. Saline irrigation may be used to expel the plug through the lacrimal drainage system into the nose or throat.

## **CAUTIONS:**

• Federal law (USA) restricts this device to sale by or on the order of a physician.

### **STORAGE:**

• Store between 0°C and 35°C (32°F to 95°F). Keep dry.

## FREQUENTLY ASKED QUESTIONS

### Q: How long will the Extended Duration Plug last?

A: Extended Duration 180 Plugs last up to 6 months.

# SOFT PLUG® EXTENDED DURATION 180-T TAPERED CANALICULAR PLUG TEMPORARY OCCLUSION, UP TO 6 MONTHS

### **DESCRIPTION:**

The OASIS Medical SOFT PLUG<sup>®</sup> Extended Duration 180-T Tapered Canalicular Plugs are designed to be inserted through the punctal opening into the canaliculus in order to block tear drainage through the lacrimal drainage system for approximately 180 days.

These Plugs are made from degradable polydioxanone monofilament colored violet with D&C No. 2. The tapered plugs are available in 0.6mm diameter. The plugs are supplied sterile, two plugs per package, so that a plug can be placed into each canaliculus.

### **INDICATIONS FOR USE:**

The SOFT PLUG<sup>®</sup> Extended Duration 180-T Canalicular Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to:

- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Temporarily enhance the efficacy of topical medications or ocular lubricants,
- Temporarily treat contact lens intolerance secondary to dry eye,
- Temporarily treat dry eye after ocular surgery, and
- Determine the potential effectiveness of permanent occlusion.

### **CONTRAINDICATIONS:**

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The SOFT PLUG<sup>®</sup> Extended Duration 180-T Tapered Canalicular Plugs are contraindicated for:

- Patients with known sensitivities or allergies to polydioxanone,
- Patients who are experiencing epiphora, canaliculitis, infectious conjunctivitis, or dacryocystitis with mucopurulent discharge.

#### **INSERTION:**

- Prior to insertion, inspect the patient's punctum to determine the appropriate diameter plug to use. Punctal sizing instruments are available from OASIS Medical. It is recommended that the 0.6mm punctal gauge be used to determine if the tapered canalicular plug will fit through a smaller opening.
- Apply a topical anesthetic to the eyelid prior to insertion of the plug.
- Open the sterile Tyvek and foil pouches and remove the appropriate diameter plug from the foam holder using sterile jeweler's forceps.
- A small amount of lubricant may be used on the plug or punctum in order to facilitate insertion across the punctum.
- Insert the plug part way through the punctal opening while grasping the plug with the forceps. Release the plug and use the tip of the forceps to push the plug the rest of the way through the punctal opening and into the canaliculus.
- Following insertion, inspect the punctal opening to ensure the plug is below the punctal opening.

# POTENTIAL RISKS / ADVERSE REACTIONS OF IMPLANTATION:

- Tearing of the punctum or puncture of the canaliculus during insertion,
- Infection related to insertion,
- Excessive epiphora,
- Infection related to contamination trapped in the canaliculus due to insertion of a plug,
- Allergic reaction to polydioxanone resulting in irritation, itching, or swelling,
- Possible need to surgically remove a plug that cannot be flushed out of the canaliculus.

# SOFT PLUG® EXTENDED DURATION 180-T TAPERED CANALICULAR PLUG TEMPORARY OCCLUSION, UP TO 6 MONTHS

### WARNINGS:

- **DO NOT USE IF PACKAGE IS OPEN OR DAMAGED.** Sterility may be com promised or moisture may shorten the shelf life of the plug.
- **DO NOT REUSE.** This is a single use, disposable, device that cannot be properly cleaned and re-sterilized.
- Canalicular plugs may enhance the effect of ocular medications used on the eye. Depending on the type of medications being used, dosage may need to be reduced accordingly.
- Care should be used not to tear the punctum or puncture the canaliculus while inserting the plug. Perforations may cause pain and increase the risk of infection. If perforation occurs, delay the insertion of the plug until the wound heals.
- If the patient experiences irritation, infection, or epiphora after insertion, the plug should be removed. Saline irrigation may be used to expel the plug through the lacrimal drainage system into the nose or throat.

## **CAUTIONS:**

• Federal law (USA) restricts this device to sale by or on the order of a physician.

### **STORAGE:**

• Store between 0°C and 35°C (32°F to 95°F). Keep dry.

# FREQUENTLY ASKED QUESTIONS

### Q: How long will the Extended Duration Plug last?

A: Extended Duration 180-T Plugs last up to 6 months.

# SOFT PLUG® COLLAGEN INTRACANALICULAR PLUG TEMPORARY OCCLUSION, EVALUATION

### **DESCRIPTION:**

The OASIS Medical Collagen Intracanalicular Plug is designed to be inserted through the punctal opening into the canaliculus in order to block tear drainage through the lacrimal drainage system. The Collagen Intracanalicular Plugs are made from an absorbable suture material. The plugs are 2 mm long and available in multiple sizes: SOFT PLUG® COLLAGEN plugs are available in 0.2 mm diameter, 0.3 mm diameter, and 0.4 mm diameter. There are six plugs per package so that a plug can be placed in each canaliculus and two are left over in case a plug is dropped or mishandled.

### **INDICATIONS FOR USE:**

The OASIS Medical Collagen Intracanalicular Plug is intended for temporary use in patients experiencing dry eye symptoms such as:

- Redness
- Burning
- Reflex tearing
- Itching
- Foreign body sensations

Collagen Intracanalicular Plugs may be used in the treatment of dry eye syndrome and the dry eye components of various ocular surface diseases such as:

- Corneal ulcers
- Conjunctivitis
- Pterygium
- Blepharitis
- Keratitis

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- Red lid margins
- Recurrent chalazions
- Recurrent corneal erosion
- Filamentry keratitis
- And other external eye diseases

When indicated the Collagen Intracanalicular Plug may be used after surgery on the eye to prevent complications due to dry eye and to enhance the retention of ocular medications on the eye.

#### **CONTRAINDICATIONS:**

The OASIS Medical Collagen Intracanalicular Plug is contraindicated for patients:

- With known sensitivities or allergies to bovine collagen or for patients who are experiencing epiphora
- Inflammation of the eye lid
- Tearing secondary to dacryocystitis with mucopurulent discharge

If the patient experiences irritation, infection, or epiphora after insertion of a Collagen Intracanalicular Plug, saline irrigation or probing may be used to expel the plug through the lacrimal sac into the nose or throat. However, these symptoms should be resolved when the implant dissolves.

#### **INSERTION:**

- Prior to insertion of a Collagen Intracanalicular Plug, inspect the patient's punctum to determine the appropriate size plug to use.
- Remove the appropriate diameter plug from the foam plug holder using jewelers forceps.
- Insert the plug part way through the punctal opening while grasping the plug with the forceps.
- Release the plug and use the tip of the forceps to push the plug the rest of the way through the punctal opening and into the canaliculus.
- A small amount of lubricant may be used on the plug in order to facilitate insertion across the punctum.

# SOFT PLUG® COLLAGEN INTRACANALICULAR PLUG TEMPORARY OCCLUSION, EVALUATION

### WARNINGS:

- DO NOT USE IF PACKAGE IS OPEN OR DAMAGED. Sterility may be com promised or moisture may shorten the shelf life of the plug.
- **DO NOT REUSE.** This is a single use, disposable, device that cannot be properly cleaned and re-sterilized.

### **CAUTIONS:**

- Care should be used not to perforate the punctum or canaliculus while inserting the Collagen Intracanalicular Plug. Perforation may cause pain and increase the risk of infection. If perforation occurs, delay the placement of the plug until the wound heals.
- The OASIS Medical Collagen Intracanalicular Plug may enhance the effect of ocular medication used on the eye.
  Depending on the type of medications being used, dosage may need to be reduced accordingly.
- Federal law (USA) restricts this device to sale by or on the order of a physician.

# **INSTRUMENTS**





Product Name	Description	Ref #
Lacrimal Irrigation Kit	One 3ml syringe and one 25g x 1 1/8" lacrimal cannula, curved, open end. Sterile.	4003-IK
Sizing Gauge	0.5mm and 0.6mm tips	6625
Sizing Gauge	0.7mm and 0.8mm tips	6627
Sizing Gauge Set	Includes both instruments and sterilization tray	6630
Castroviejo Lacrimal Dilator	Double ended, 14cm	6640
Straight Jeweler's Forceps	Straight #3	6643
Curved Jeweler's Forceps	Curved #7	6647
Grooved Forceps	For the insertion of Extended Duration & Collagen Plugs	6648
Lacrimal Intubation Set	23g	6001
Lacrimal Intubation Set with Retrieval Device	23g	6004
Lacrimal Intubation Kit	27g	6004-27
Lacrimal Cannula	21g X 1-1/2", Curved, Open End	6005
Lacrimal Cannula	21g X 1-1/2", Straight, Closed End	6006
Lacrimal Cannula	25g X 1-1/2", Curved, Closed End	6007
Lacrimal Cannula	19g/23g X 1-1/2", Straight	6008
Lacrimal Cannula	26g X 1-1/8", Curved, Open End	6010

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