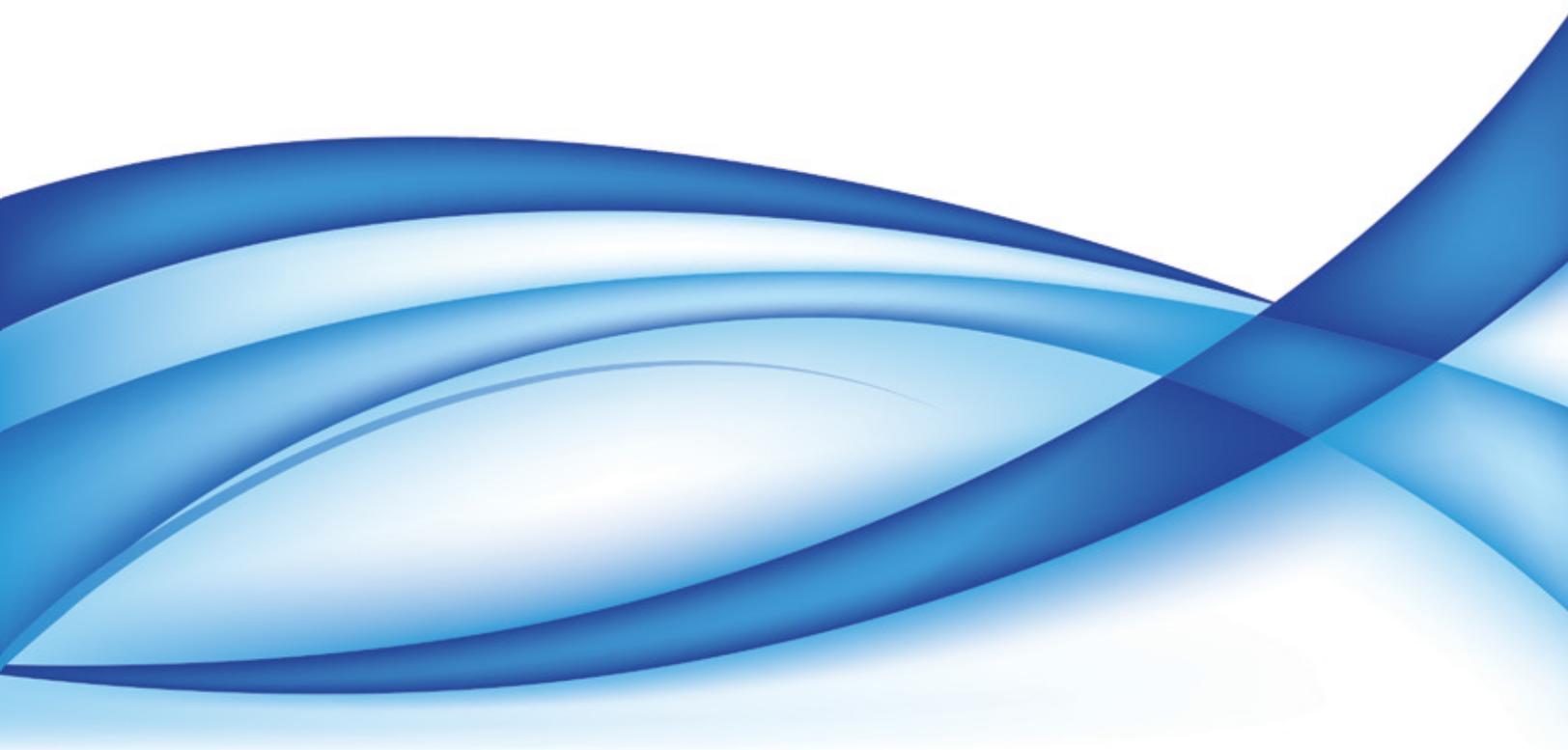




# PUNCTAL PLUG MANUAL



# TABLE OF CONTENTS

<b>OASIS Medical</b>	03
<b>Customer Service</b>	04
<b>Product Overview</b>	05
<b>Patient Education Materials</b>	08
<b>FORM FIT® Intracanalicular Plugs</b>	09
<b>SOFT PLUG® Flow Control Plugs</b>	11
<b>SOFT PLUG® Silicone Punctal Plugs</b>	12
<b>SOFT PLUG® Extended Duration Plugs</b>	16
<b>SOFT PLUG® Extended Duration 180 Plugs</b>	18
<b>SOFT PLUG® Collagen Plugs</b>	20
<b>Instruments</b>	22

**A company founded on exceptional standards.** Founded in 1987 by Norman Delgado and headquartered near Los Angeles, OASIS Medical, Inc is a specialty manufacturer of eye care products and surgical supplies, instruments, and disposables. For 28 years, OASIS has been manufacturing a broad range of products for use in cataract, refractive, dry eye and retinal disease for domestic and international sale.

## **Our Philosophy**

OASIS is a continuous improvement company deeply committed to truth in its business approach, relationships, and products based on our foundation of accountability. We welcome feedback from customers and our team to evolve as a pro-active company.

## **Our Investment**

OASIS invests in the long term through our strategic partnering relationships with Eye Care Providers. This investment helps the Doctor improve the quality of the patient's eye care experience. As consultants we are willing to invest time and equip the Doctor with how our approach can assist their Practice. This strategy allows OASIS to thrive by being relevant through focusing on the patient care experience and efficiency of the individual practice.

## **Our Solution Based Products**

Our values of integrity and quality guide our commitment to solution-based products that enhance the patient care. From the beginning, OASIS has been a practice-based company focused on building the Dry Eye and Surgical practice through the various tools we offer.

## **Our Approach**

OASIS is committed to offering informed, relevant solutions based on truth. To do this, we listen first and ask questions to understand an issue at cause. Our professionalism is demonstrated by our ability to think different. We lead with a consultative approach that is flexible and seeks to add value. It looks to address issues rather than only sell a product. It is strategic rather than tactical. Our goal is to create a partnership for OASIS and the Doctor so that both parties achieve a win.

## **Our Commitment**

In addition to an unwavering commitment to continuous improvement, truth, accountability, strategic relationships, a consultative approach, a quality eye care experience, solution-based products, being relevant, and professionalism, we are committed to a win-win approach to all that work with OASIS. Our commitment extends to a positive cash flow, profitability, financial security, and long-term sustainability.

**TO FIND OUT MORE ABOUT OASIS MEDICAL PLEASE VISIT [WWW.OASISMEDICAL.COM](http://WWW.OASISMEDICAL.COM)**

# CUSTOMER SERVICE

## **CUSTOMER SERVICE HOURS:**

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

## **EMAIL:**

[customerservice@oasismedical.com](mailto:customerservice@oasismedical.com)

## **USA TOLL-FREE:**

844.820.8940 (PHONE)  
800.631.7210 (FAX)

## **MAIN:**

909.305.5400 (PHONE)  
909.305.6897 (FAX)

## **OASIS® POLICY:**

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

## **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 service or your local OASIS Representative to review the clinic's needs. No minimum orders.

## **RETURNED MERCHANDISE POLICY:**

Unopened items returned for credit must be accompanied by an RMA (returned material authorization) and the 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:

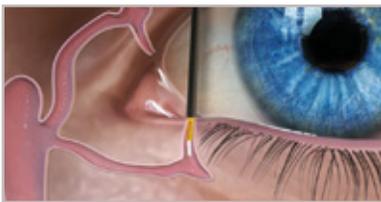
1. Shipped the product in error.
2. The product packaging or crating is damaged in transit before it is accepted.
3. The product does not perform as indicated.
4. The product does not meet industry quality standards related to performance specifications and data submissions required by the FDA or FDA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

## FORM FIT® Hydrogel Plugs

### One-size solution intracanalicular plug intended for long-term occlusion.

FORM FIT plugs are made of hydrogel that absorbs tear fluid and swells to 97% water content. They are soft and comfortable and fill the proximal canalicular cavity with a gelatinous material once they hydrate. They can be easily removed by irrigation of the tear duct. US Patent 5,116,371

- Fully hydrated within 10 minutes
- 2mm length, 0.3mm diameter
- No foreign body sensations
- No special storage needed
- Sterile, preloaded in inserter
- Easily removed via irrigation of the tear duct



Insertion



Immediately after insertion



10 minutes after insertion

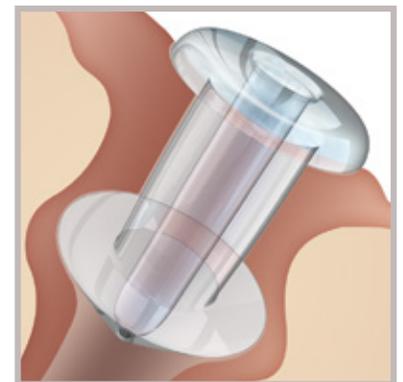
Product Name	Qty	Description	Ref #
FORM FIT Canalicular Plug 10pk	10	One size	6303
FORM FIT Canalicular Plug 2pk	2	One size	6303-T

## SOFT PLUG® Flow Control Plugs

### Soft silicone intended for long term occlusion and partial drainage.

The distinctive low-profile cap combined with a softer, flexible silicone maximizes patient comfort. The inserter provides greater control and minimizes potential for accidental release of the plug. The plug is designed with a center channel allowing for tear flow passage. SOFT PLUG Flow Control plugs are removable with forceps.

- Available in 3 sizes
- 2 plugs per box
- For partial occlusion with partial tear drainage
- Sterile, preloaded on inserter



Product Name	Qty	Description	Size	Ref #
SOFT PLUG Flow Control 2pk	2	Petite	0.6mm	6612-FC
SOFT PLUG Flow Control 2pk	2	Small	0.7mm	6613-FC
SOFT PLUG Flow Control 2pk	2	Medium	0.8mm	6614-FC

# PRODUCT OVERVIEW

## SOFT PLUG® Silicone Plugs

### Soft silicone intended for long-term occlusion.

The distinctive low-profile cap combined with a softer, flexible silicone maximizes patient comfort. The inserter provides greater control and minimizes potential for accidental release of the plug. SOFT PLUG Silicone Plugs are removable with forceps.

- Low-profile cap intended to reduce dislocation
- Dilator tip included on inserter
- Available in five sizes
- Sterile, preloaded on inserter in 2-pack or 6-pack dispenser box
- Sterile, non-loaded Economy Pack with 2 inserters and 10 trays of 2 plugs each



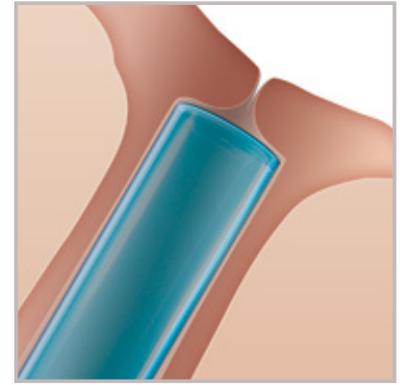
Product Name	Qty	Description	Size	Ref #
SOFT PLUG Preloaded Silicone 2pk	2	Micro	0.4mm	6610
SOFT PLUG Preloaded Silicone 2pk	2	Mini	0.5mm	6611
SOFT PLUG Preloaded Silicone 2pk	2	Petite	0.6mm	6612
SOFT PLUG Preloaded Silicone 2pk	2	Small	0.7mm	6613
SOFT PLUG Preloaded Silicone 2pk	2	Medium	0.8mm	6614
SOFT PLUG Preloaded Silicone 6pk	6	Micro	0.4mm	6610-D
SOFT PLUG Preloaded Silicone 6pk	6	Mini	0.5mm	6611-D
SOFT PLUG Preloaded Silicone 6pk	6	Petite	0.6mm	6612-D
SOFT PLUG Preloaded Silicone 6pk	6	Small	0.7mm	6613-D
SOFT PLUG Preloaded Silicone 6pk	6	Medium	0.8mm	6614-D
SOFT PLUG Silicone Economy Pack	20	Micro	0.4mm	6610-EP
SOFT PLUG Silicone Economy Pack	20	Mini	0.5mm	6611-EP
SOFT PLUG Silicone Economy Pack	20	Petite	0.6mm	6612-EP
SOFT PLUG Silicone Economy Pack	20	Small	0.7mm	6613-EP
SOFT PLUG Silicone Economy Pack	20	Medium	0.8mm	6614-EP

## SOFT PLUG® Extended Duration Plugs

**Intended for temporary occlusion for up to 3 months.**

Soft Plug Extended Duration plugs are absorbable canalicular occluders that are an economical and effective option for transient dry eye symptoms before or after surgery, seasonally, etc.

- Pre and post-surgical use
- Available in 4 sizes and variety pack
- 2mm length
- Sterile, insert with forceps



Product Name	Qty	Size	Ref #
SOFT PLUG Extended Duration Plugs 20pk	20	0.2mm	6402-A
SOFT PLUG Extended Duration Plugs 20pk	20	0.3mm	6403-A
SOFT PLUG Extended Duration Plugs 20pk	20	0.4mm	6404-A
SOFT PLUG Extended Duration Plugs 20pk	20	0.5mm	6405-A
SOFT PLUG Extended Duration Plugs 40pk	40	0.2mm	6402
SOFT PLUG Extended Duration Plugs 40pk	40	0.3mm	6403
SOFT PLUG Extended Duration Plugs 40pk	40	0.4mm	6404
SOFT PLUG Extended Duration Plugs 40pk	40	0.5mm	6405
SOFT PLUG Extended Duration Plugs Variety Pack	20	1 pair 0.2mm, 3 pairs 0.3mm, 4 pairs 0.4mm, and 2 pairs 0.5mm	6400V

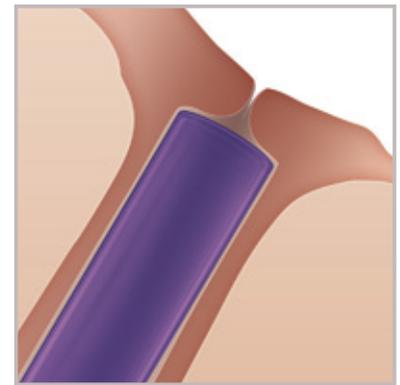
## SOFT PLUG®

### Extended Duration 180 Canalicular Plugs

**Medium term or extended duration Punctal Plugs dissolve in up to 6 months.**

Soft Plug Extended Duration plugs are absorbable canalicular occluders that are an economical and effective option for transient dry eye symptoms before or after surgery, seasonally, etc.

- Pre and post-surgical use
- Available in 3 sizes and variety pack
- 2mm length
- Sterile, insert with forceps



Product Name	Qty	Size	Ref #
<b>NEW!</b> SOFT PLUG Extended Duration 180 Canalicular Plugs 20pk	20	0.3mm	6203-A
<b>NEW!</b> SOFT PLUG Extended Duration 180 Canalicular Plugs 20pk	20	0.4mm	6204-A
<b>NEW!</b> SOFT PLUG Extended Duration 180 Canalicular Plugs 20pk	20	0.5mm	6205-A
<b>NEW!</b> SOFT PLUG Extended Duration 180 Canalicular Plugs 40pk	40	0.3mm	6203
<b>NEW!</b> SOFT PLUG Extended Duration 180 Canalicular Plugs 40pk	40	0.4mm	6204
<b>NEW!</b> SOFT PLUG Extended Duration 180 Canalicular Plugs 40pk	40	0.5mm	6205
<b>NEW!</b> SOFT PLUG Extended Duration 180 Canalicular Plugs Variety Pack	20	3 pairs 0.3mm, 4 pairs 0.4mm, 3 pairs 0.5mm	6200V

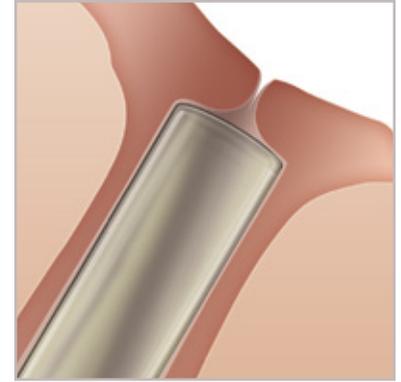
# PRODUCT OVERVIEW

## SOFT PLUG® Collagen Plugs

Intended for temporary occlusion to evaluate patient acceptance.

SOFT PLUG collagen plugs are placed in the canaliculus to temporarily block tear drainage in order to determine patient response to plugs. They last for up to 5 days.

- For diagnostic use
- Available in 3 sizes
- Absorbable material lasts 2-5 days.
- 2mm length
- Proprietary finish simplifies insertion
- Sterile, insert with forceps



Product Name	Qty	Size	Ref #
SOFT PLUG Collagen Plugs	60	0.2mm	6502
SOFT PLUG Collagen Plugs	60	0.3mm	6503
SOFT PLUG Collagen Plugs	60	0.4mm	6504

## PATIENT EDUCATION MATERIALS

Product Name	Ref #
 <p>Oasis TEARS Brochure (2011)</p>	6544C
 <p>Surgical Oasis TEARS Brochure (2011)</p>	LIT-6540
 <p>Dry Eye Products Patient Brochure (2017)</p>	LIT-DEP-PB
 <p>Oasis TEARS Point-of-Purchase Display (2017)</p>	LIT-OT-POP

Product Name	Ref #
 <p>Dry Eye Symptoms Wall Chart (2015)</p>	LIT-DES-WC
 <p>Punctal Plug Wall Chart (2014)</p>	LIT-WCDE
 <p>Oasis TEARS RX Pad, with OASIS contact information</p>	LIT-OTRX-W

# FORM FIT® HYDROGEL PLUGS

## LONG - TERM OCCLUSION

### 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.

A small amount of lubricant may be used on the punctum in order to facilitate insertion across the punctum.

### HOW TO USE:

- Caution: Patency of the canaliculus should be determined prior to insertion of the OASIS Medical Form Fit® Intracanalicular Plug. OASIS Irrigating Kit may be used.
- The plug comes pre-loaded in a disposable inserter, verify that the white OASIS Medical Form Fit® Intracanalicular Plug has not fallen out of the inserter during shipping.
- Place the amber colored tip portion of the inserter through the punctum
- Squeeze the inserter to push the plug from the inserter tip into the canaliculus
- The top edge of the plug should sit below the punctum opening
- Forceps may be used to further push the plug into desired placement
- Care should be used not to perforate the punctum or canaliculus during the insertion of the OASIS Medical Form Fit® Intracanalicular 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

### CONTRAINDICATIONS:

OASIS Medical Form Fit® Intracanalicular 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 canalicular plug, the plug should be removed.

### REMOVAL:

- Should it be necessary to remove OASIS Medical Form

Fit® Intracanalicular Plug:

- Flush the mucus-like gel plug from the canaliculus using a syringe filled with sterile saline
- Place an lacrimal cannula on the tip of the syringe
- Position the tip of the lacrimal cannula through the punctal
- Gently flush the canaliculus with sterile saline

### PRECAUTIONS:

- Do not re-sterilize the OASIS Medical Form Fit® Intracanalicular Plug by any method.
- Use only sterile intraocular irrigation solutions when required.
- Do not store the OASIS Medical Form Fit® Intracanalicular Plug 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 mucus-like plug from the canaliculus and allow the infection to clear.
- A new plug may be inserted into the canaliculus after the infection clears.

The OASIS Medical Form Fit® Intracanalicular 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.**

# FORM FIT® HYDROGEL PLUGS

## LONG - TERM OCCLUSION

### 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® Intracanalicular Plug is fully hydrated?**

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

**Q: Can the OASIS Medical Form Fit® Intracanalicular Plug be removed?**

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

**Q: How long will the OASIS Medical Form Fit® Intracanalicular Plug Last?**

A: The OASIS Medical Form Fit® 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 FLOW CONTROL PLUGS

## LONG - TERM OCCLUSION

### DESCRIPTION:

The OASIS Medical Soft Plug® Flow Control Silicone Plug is designed to be inserted into the punctal opening for long term occlusion and partial drainage. Each punctum plug is molded from medical grade silicone.

- The OASIS Medical Soft Plug® Flow Control Silicone Plug has a thin head portion designed to remain outside the punctum and rest on the eyelid.
- The central shaft portion of the plug has a smaller diameter than the head portion and is designed to fit through the punctal opening.
- The nose portion of the plug has a larger diameter which is designed to fit in the canaliculum in order to retain the plug in the punctum.

### 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 punctum 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 .5 mm and .6 mm tips
- The other with .7 and .8 mm tips
- Sterilization Case for both sizing gauges

### HOW TO SIZE:

- Start with the smallest gauge size (0.5mm)
- 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 punctual 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 eye may have different size punctum; therefore it is useful that the punctum of both eyes are measured.

### DILATION:

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 Silicone Punctum Plug comes preloaded on a disposable inserter or in a convenient bulk pack with inserters included.

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
4. Gently insert the plug into the punctum until the cap is flush with the punctual opening
5. You may rotate the inserter during insertion. This will ease insertion and properly position the inserter in your hand for plug release
6. When the plug is properly inserted, gently squeeze and withdraw the inserter to release the plug
7. 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

### INDICATIONS FOR USE:

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

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

# SOFT PLUG® SILICONE FLOW CONTROL PLUGS

## LONG - TERM OCCLUSION

OASIS Medical Soft Plug® Flow Control Silicone Plug may be used in the treatment of dry eye syndrome and the dry eye component of various ocular surface diseases such as:

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

When indicated, the OASIS Medical Soft Plug® Flow Control Silicone Plug may be used after surgery of the eye to prevent complications due to dry eye and to enhance the retention of ocular medications on the eye.

Patients experiencing dry eye related contact lens problems may also be aided by Silicone Punctum Plugs.

### **CONTRAINDICATIONS:**

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

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

### **REMOVING THE PLUGS**

#### **WHEN & WHY:**

If the patient experiences irritation, infection, or epiphora after insertion of a Silicone Punctum Plug, the plug should be removed.

#### **HOW TO REMOVE THE PLUG:**

- Remove the plug by grasping the shaft of the plug below the exposed head with forceps
- Pull the plug out of the punctal opening using a gentle rocking motion
- The plug should not be removed by grasping the exposed head

#### **CAUTIONS:**

Care should be used not to perforate the punctum or canaliculus during insertion of the OASIS Medical Soft Plug® Flow Control Silicone 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.

The OASIS Medical Soft Plug® Flow Control Silicone 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.**

# SOFT PLUG® SILICONE PLUGS

## LONG - TERM OCCLUSION

### DESCRIPTION:

The OASIS Medical Soft Plug® Silicone Punctum Plug is designed to be inserted into the punctal opening in order to block tear drainage through the canaliculus.

- Each punctum plug is molded from medical grade silicone.
- The OASIS Medical Soft Plug® Silicone Punctum Plug has a thin head portion designed to remain outside the punctum and rest on the eyelid.
- The central shaft portion of the plug has a smaller diameter than the head portion and is designed to fit through the punctal opening.
- The nose portion of the plug has a larger diameter which is designed to fit in the canaliculus in order to retain the plug in the punctum.

### 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 Soft Plug® Punctum Plug Sizing System**.

The OASIS punctum 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 0.5 mm and 0.6 mm tips
- The other with 0.7 and 0.8 mm tips
- Sterilization Case for both sizing gauges

### HOW TO SIZE:

- Start with the smallest gauge size (0.5mm)
- 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 eye may have different size punctum; therefore it is useful that the punctum of both eyes are measured

### DILATION:

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 Punctum Plug comes pre-loaded on a disposable inserter or in a convenient bulk pack with inserters included.

For the **bulk packed plugs (only)**

- Position the tip of the disposable inserter into the guide slot in the plug holder
- Move the inserter forward to load the silicone plug onto the inserter wire
- Proceed with steps 1-7 below...

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
4. Gently insert the plug into the punctum until the cap is flush with the punctal opening
5. You may rotate the inserter during insertion. This will ease insertion and properly position the inserter in your hand for plug release
6. When the plug is properly inserted, gently squeeze and withdraw the inserter to release the plug
7. 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 PLUGS

## LONG - TERM OCCLUSION

### INDICATIONS FOR USE:

The OASIS Medical Soft Plug® Silicone Punctum Plug is intended for use in patients experiencing dry eye symptoms such as:

- 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 diseases such as:

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

When indicated, the OASIS Medical Soft Plug® Silicone Punctum Plug may be used after surgery of the eye to prevent complications due to dry eye and to enhance the retention of ocular medications on the eye.

Patients experiencing dry eye related contact lens problems may also be aided by Silicone Punctum Plugs.

### CONTRAINDICATIONS:

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

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

### REMOVING THE PLUGS

#### WHEN & WHY:

If the patient experiences irritation, infection, or epiphora after insertion of a Silicone Punctum Plug, the plug should be removed.

#### HOW TO REMOVE THE PLUG:

- Remove the plug by grasping the shaft of the plug below the exposed head with forceps
- Pull the plug out of the punctal opening using a gentle rocking motion
- The plug should not be removed by grasping the exposed head

#### CAUTIONS:

Care should be used not to perforate the punctum or canaliculus during insertion of the OASIS Medical Soft Plug® Silicone 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.

The OASIS Medical Soft Plug® Silicone 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.**

# SOFT PLUG® SILICONE PLUGS

## LONG - TERM OCCLUSION

### FREQUENTLY ASKED QUESTIONS

**Q: How much do I dilate to insert the silicone punctal plug?**

A: The best results and lowest dislocation rates are obtained by using little to no dilations

**Q: What is the most common size silicone Soft Plug® used?**

A:

- 0.4mm = 3%
- 0.5mm = 24%
- 0.6mm = 36%
- 0.7mm = 27%
- 0.8mm = 10%

**Q: Can I determine the size of Silicone Plug to use by the size of the Collagen Plug used?**

A: There is no correlation since they are placed in two different locations

**Q: How long will the Silicone Plugs Last?**

A: Silicone plugs are “semi-permanent”; they will last until removed or dislocated.

# SOFT PLUG® EXTENDED DURATION PLUGS

## TEMPORARY OCCLUSION, UP TO 3 MONTHS

### DESCRIPTION:

The OASIS Medical SOFT PLUG® Extended Duration Intracanalicular Plug is a short term plug (up to 3 months based on results obtained in an animal study) designed to be inserted through the punctal opening in 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 Intracanalicular Plug is made from an absorbable copolymer of glycolic acid and trimethylene carbonate and dyed with D&C Green Number 6. The plugs are supplied sterile, two plugs per package.

### 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.

### HOW TO USE:

- Prior to insertion of a SOFT PLUG® Extended Duration Intracanalicular Plug, 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 foam holder using grooved forceps (available from OASIS Medical).
- A small amount of lubricant, sterile saline or artificial tears may be used on the plug in order to facilitate insertion through the punctum.
- Insert the SOFT PLUG® Extended Duration Intracanalicular 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.

### INDICATIONS FOR USE:

The SOFT PLUG® Extended Duration Intracanalicular Plug is

intended for temporary use in patients experiencing dry eye symptoms such as:

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

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 Intracanalicular Plug 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 SOFT PLUG® Extended Duration Intracanalicular Plug is contraindicated for patients with known sensitivities or allergies to:

- Glycolic acid
- Trimethylene carbonate
- Patients who are experiencing epiphora
- Patients who are experiencing inflammation of the eye lid
- Patients who are tearing secondary to dacryocystitis with mucopurulent discharge

### CAUTION:

The SOFT PLUG® Extended Duration 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.

Care should be used not to perforate the punctum or canaliculus while inserting the SOFT PLUG® Extended Duration Intracanalicular Plug. 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 Intracanalicular Plug, 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.

# SOFT PLUG® EXTENDED DURATION PLUGS

## TEMPORARY OCCLUSION, UP TO 3 MONTHS

**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 PLUGS

## TEMPORARY OCCLUSION, UP TO 6 MONTHS

### DESCRIPTION:

The OASIS Medical SOFT PLUG® Extended Duration 180 Canalicular Plug is a mid-term implant 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 absorbable 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® 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:

The SOFT PLUG® Extended Duration 180 Canalicular Plug is 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<sup>®</sup> EXTENDED DURATION 180 PLUGS

## TEMPORARY OCCLUSION, UP TO 6 MONTHS

### WARNINGS:

DO NOT USE IF PACKAGE IS OPEN OR DAMAGED.

Sterility may be compromised or moisture may shorten the shelf life of the plugs.

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 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 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.

Store at room temperature 25°C (77°F). Do not freeze.

# SOFT PLUG® COLLAGEN PLUGS

## TEMPORARY OCCLUSION/EVALUATION

### DESCRIPTION:

The OASIS Medical Collagen Intracanalicular Plug is designed to be inserted through the punctal opening in the canaliculus in order to block tear drainage through the lacrimal drainage system.

- The Collagen Intracanalicular Plugs are made from an absorbable bovine suture material.
- The plugs are 2mm long and are packaged 6 plugs per sterile pack.

### 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.

### HOW TO USE:

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 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, sterile saline or artificial tears may be used on the plug in order to facilitate insertion through the punctum
- During implantation avoid getting the plug wet as this will cause it to expand

### 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
- Red lid margin
- Recurrent chalazions
- Recurrent corneal erosion
- Filamentary 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, or 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.

### 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.**

# SOFT PLUG® COLLAGEN PLUGS

## TEMPORARY OCCLUSION/EVALUATION

### FREQUENTLY ASKED QUESTIONS

**Q: Which size Collagen Plug should I use?**

A: The largest you can insert without dilation.

**Q: Which Collagen Plug size is the most commonly used?**

A: The 0.3mm collagen plug is used over 50% of the time.

**Q: How long will the Collagen Plug last?**

A: Collagen Plugs will last up to 5 days.

# 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 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



Glendora, CA, USA

(844) 820-8940 (USA Toll Free) | (909) 305-5400  
 oasis@oasismedical.com | www.oasismedical.com

LIT-PP-PHM Rev.2 11/2017