

2020 Guide to Occlusion Therapy

Dear Doctor,

Lacrimedics' proven **System of Occlusion Therapy** provides clinical and business solutions to Dry Eye and tear specialists treating Dry Eye Disease with Lacrimal and Punctal Occlusion Therapy (*when eye drops alone are not enough*).

Our **2020 Guide to Occlusion Therapy** includes office forms, billing guidance and a review of procedures and techniques to save you time, improve patient care and increase practice revenue using lacrimal and punctal Occlusion Therapy. Follow our step-by-step instructions and keep it simple for best results!

For questions or to place an order call **(800) 367-8327** from 8 AM – 4:30 PM PST, or visit our on-line store at www.Lacrimedics.com. An **Occlusion Therapy Starter Kit** can help you begin realizing the benefits of Occlusion Therapy in your practice today!

You may use an MMP-9 test to find ocular allergy, thermal pulsation treatment in MGD and tear osmolarity to aid in diagnosis, but *insist* on Lacrimedics' brand dissolvable and non-dissolvable lacrimal and punctum plugs for Occlusion Therapy in Dry Eye Disease!

Find us on Linked-In, Facebook or YouTube ("The Dry Eye Channel"). Thank you for your patronage and partnership in the medical specialty of Lacrimology!

Sincerely,



Robert Herrick, II

President

#Collagen Plugs #Dissolvable VisiPlugsTM #Opaque Herrick Lacrimal Plugs[®] #ComfortTip
#Punctal Occluder[®] #AccuFlo Punctal Occluder[®] #DoTheProcedure #Lacrimology
#PunctalOcclusionForThePeople #KeepItSimple #CPT68761 #PlugsImproveDrops

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Quality Policy and Objectives Statement

Lacrimedics designs, develops, and manufactures Occlusion Therapy devices for the treatment of Dry Eye Disease and underlying symptoms.

Lacrimedics' devices are intended for sale to and use by licensed healthcare professionals and are marketed throughout the world.

Lacrimedics is committed to providing its customers with high quality, efficiently produced products at a fair price while meeting its customers' expectations in terms of quality, delivery, and value.

Lacrimedics will meet this commitment by developing and implementing effective quality management system processes that include:

- Establishing, reviewing, and maintaining quality objectives.
- Maintaining conformance with applicable regulatory requirements
- Continuously improving our products and Quality Management System through monitoring, measuring, and analyzing processes

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Using the Dry Eye Symptoms Checklist

1. Have new patients complete a Dry Eye Symptoms Checklist to confirm the diagnosis of Dry Eye Disease and to document baseline symptoms.
2. Update each patient's Dry Eye Symptoms Checklist annually.
3. Those with one or more symptom(s) on the checklist should be evaluated with dissolvable Collagen Plugs for longer-term Occlusion Therapy.
4. Review the completed checklist and place with notations in the chart.
5. Get signed informed consent (e.g.: Request for Evaluation).
6. Monitor clinical signs and (subjective) symptoms during evaluation and treatment to confirm treatment effect and adequacy.
7. Occlusion Therapy improves tear film insufficiency in most patients with Dry Eye Disease. Others suffer from the condition from other causes such as diet, environment, or auto-immune disease. Some require surgical eyelid procedures to reduce tear evaporation and loss.
8. When baseline symptoms return, consider plug migration or loss.

Use a *Dry Eye Symptoms Checklist* liberally to expand *your* Dry Eye practice!

“Call us now, we will show you how!”

(800) 367-8327

Dry Eye Symptoms Checklist

Patient Name: _____

Date: _____

To ensure a proper Eye Health Examination indicate symptoms or conditions you now experience or have experienced during the last 12 months. Please provide complete answers where possible.

YES EYE SYMPTOMS

- Redness
- Dry Eye Feeling
- Sandy or Gritty Feeling
- Itching
- Burning
- Foreign Body Sensation
- Constant Tearing
- Occasional Tearing
- Watery Eyes
- Light Sensitivity
- Eye Pain or Soreness
- Sties, Chalazion
- Fluctuating Visual Acuity
- "Tired" Eyes
- Contact Lens Discomfort
- Contact Lens Solution Sensitivity
- Mucous Discharge

YES SECONDARY SYMPTOMS

- Sinus or Nasal Congestion
- Difficulty Breathing
- Chronic Cough
- Head Congestion
- Post-nasal Drip
- Chronic Bronchitis
- Allergy Symptoms
- Hay Fever
- Chronic Cold Symptoms
- Middle Ear Congestion
- Sneezing
- Dry Mouth or Throat
- Headaches
- Asthma Symptoms
- Heartburn or Indigestion
- Snoring
- Sleep Apnea

Circle items which you are sensitive to:

- | | |
|-------------------|------------------|
| Heaters | Dust |
| Blowers | Pollen |
| Air Conditioning | Airplane Cabins |
| Cigarette Smoke | Computer Screens |
| Smog | Sunshine |
| Contact Lens Wear | Wind |

Circle items you or a blood relative have experienced:

- | | |
|--------------|---------------------|
| Glaucoma | Diabetes |
| Tuberculosis | Rheumatoid |
| Lupus | Thyroid Disorder |
| Gout | Heart Disease |
| Cataracts | High Blood Pressure |
| Arthritis | Sjogren's Syndrome |

YES

- Do you use lubricating drops? What brand? _____
- Do you wear contact lenses How often? _____
- Are your contacts comfortable? How long have you worn them? _____
- Have you tried contacts before and quit? Why? _____
- Do you use glasses? How long have you had them? _____
- Have you ever had an eye injury? Describe the injury: _____
- Are you allergic to anything? List: _____
- Do you take any medications? List: _____

Additional comments: _____

Patient's Signature

Provider's Name

Request for Pre-authorization - Occlusion Therapy

MEDICAL NECESSITY: The patient presented at the office with signs and symptoms of Dry Eye Disease. The patient has tried lubricating eye drops or ointments, and reports having inadequate symptomatic relief.

Please provide pre-authorization for Occlusion Therapy (closure of the lacrimal punctum by plug; each).

The diagnosis of Dry Eye Disease will be confirmed using at least three different diagnostic tests, and the results charted. The patient will be evaluated by placing absorbable Collagen Plugs in all four canaliculi to determine if the signs and symptoms of Dry Eye Disease improve with Occlusion Therapy (4 - 7 days). Should a positive response occur the patient will receive longer term Occlusion Therapy using medium-term dissolvable lacrimal plugs and/or non-dissolvable lacrimal or punctum plugs in the upper or lower puncta, as indicated.

A drop of topical anesthetic will be applied to the eye(s) as needed. In the presence of epiphora, lacrimal irrigation or probing will be performed to confirm patency of the tear drainage ducts prior to plug insertion. The puncta will be examined to determine the appropriate size plugs to use.

A sterile packet will be opened, to provide the necessary plugs for insertion. Intracanalicular lacrimal plugs are advanced 4–6 mm into the horizontal canaliculus, using an intracanalicular plug positioning device. Punctal style plugs will be placed into the punctum, where they partially reside upon the surface of the eyelid.

While at the slit lamp, or with the patient reclined, the eyelid will be everted using a sterile cotton-tipped applicator/q-tip which tightens the lid margin and exposes the punctum for plug insertion. Afterward, plugs are inspected to ensure proper placement and a drop of topical antibiotic is instilled as a prophylactic step.

The patient will be advised to contact the office promptly should localized infection, discomfort or other adverse reaction occur. A follow-up office visit will be scheduled at least ten (10) days after plug insertion. Although uncommon, should undesirable effects occur after Occlusion Therapy, plugs may generally be removed non-surgically with short in-office procedures.

Diagnosis: Kerato-conjunctivitis Sicca; Tear Film Insufficiency

Procedure: Closure of the lacrimal punctum by plug; each (CPT 68761)

Patient Name: _____

Provider Signature: _____

Date: _____

Provider Name: _____

Patient Consent – Evaluation with Collagen Plugs - OT1

My provider examined me and reviewed my medical history. Given my clinical signs and subjective symptoms I have been diagnosed with **Dry Eye Disease** (or a related condition) due to insufficient or poor-quality tears on the surface of my eyes, or some other factor.

Evaluation - I have been told that **Occlusion Therapy** improves the clinical signs and symptoms of Dry Eye Disease, and that I might benefit from evaluation with Collagen Plugs. I realize these plugs will reduce tear drainage away from my eyes for 4 – 7 days and then will be absorbed by my body (requiring no removal). An antibiotic drop may be administered as a prophylactic step. If my clinical signs and symptoms improve, I understand longer term Occlusion Therapy may benefit me. At my next appointment, I will tell my provider about the good or bad outcomes I experience during the evaluation period.

Risks and Complications - I understand that watery eyes or excessive tearing may occur during evaluation or treatment with Occlusion Therapy, and that this may last for 3 days or longer due to healing of the cornea. Although uncommon, I may experience itching, irritation or infection of my eyes or eyelids; and that should I experience discomfort or plug irritation I will promptly tell my provider and return to the office for evaluation. If I develop an infection upon my eye or eyelids, I understand I may require treatment with an antibiotic.

Plug Repositioning or Removal – Collagen Plugs generally last in the tear drainage ducts for their intended term and then are absorbed by the body, requiring no removal. However, plugs can be repositioned if necessary, or removed using saline irrigation or probing of the tear drainage system.

Probability of Success - Should my symptoms improve during the evaluation with Collagen Plugs, I understand that longer term treatment with Occlusion Therapy may benefit me. If left untreated, I understand my condition will likely persist, may get worse, or lead to more severe conditions like corneal ulceration or permanent vision loss.

Alternatives to Occlusion Therapy: I realize that I may choose NOT to have this procedure at this time. I understand that: lubricating eyedrops or topical medications may provide temporary relief from my Dry Eye condition, that thermal procedures can be used to permanently close my tear drainage ducts, and that surgical eyelid procedures may be required in some patients to adequately reduce tear evaporation and loss.

Request to be evaluated for Occlusion Therapy - I understand my provider and their staff will do their best to help me. However, there has been no guarantee of the outcome either stated or implied. I have been informed about Dry Eye Disease and evaluation and treatment with Occlusion Therapy. I have been given the opportunity to ask questions, all of which have been answered to my satisfaction.

I hereby request that I be evaluated for Occlusion Therapy with absorbable Collagen Plugs.

Patient Name (Print): _____

Patient Signature: _____ Date: _____

Provider Signature: _____ Date: _____

Patient Consent – Medium-term Occlusion Therapy – OT2

My provider examined me and reviewed my medical history. Given my clinical signs and subjective symptoms I have been diagnosed with **Dry Eye Disease** (or a related condition) due to insufficient or poor-quality tears on the surface of my eyes, or some other factor. I have been evaluated for Occlusion Therapy using Collagen Plugs which caused one or more of my eye symptoms to improve.

Proposed Treatment – After my positive response to evaluation with Collagen Plugs, I have been advised that medium-term Occlusion Therapy with Dissolvable VisiPlugs may benefit me (lasts about 6 months). I understand these plugs may first be placed into my upper tear drainage ducts, and if my symptoms persist I may require evaluation or Occlusion Therapy in my lower tear drainage ducts or a more advanced treatment.

Risks and Complications - I understand I may experience watery eyes or excessive tearing during evaluation or treatment with Occlusion Therapy, and that this may last for 3 days or longer after plug insertion, due to healing of the cornea. Although uncommon, I may experience itching, irritation or infection of my eyes or eyelids. Should I experience discomfort or irritation from the plug(s) I will promptly tell my provider and return to the office for examination. If I develop an infection, I understand that I may require treatment with an antibiotic, plug repositioning, or plug removal.

Plug Repositioning or Removal – Dissolvable VisiPlugs last in the tear drainage ducts for their intended term and then simply dissolve, requiring no removal. Should discomfort occur, plugs may generally be repositioned or removed using saline irrigation or probing of the tear drainage ducts.

Probability of Success – Should my symptoms improve after medium-term Occlusion Therapy with Dissolvable VisiPlugs, I understand that I may benefit from long term Occlusion Therapy with non-dissolvable lacrimal or punctal plugs. I know there is no guarantee of treatment, that my symptoms may return in the future, and that I may ultimately require additional treatment including advanced eyelid procedures to reduce tear evaporation or loss from the eye.

Alternatives: Lubricating eyedrops or topically applied medications may provide temporary relief from the symptoms of Dry Eye Disease. Thermal procedures may be used to permanently close the tear drainage ducts. Surgical eyelid procedures may be used to reduce tear evaporation and loss. I realize I may choose NOT to receive Medium-term Occlusion Therapy at this time; and, if left untreated my condition will likely persist, get worse, or lead to more severe conditions such as corneal ulceration, or vision loss.

Request for Medium-term Occlusion Therapy with Dissolvable Lacrimal Plug - I understand my provider and their staff will do their best to help me. However, there has been no guarantee of the outcome either stated or implied. I have been informed about Dry Eye Disease and evaluation and treatment with Occlusion Therapy. I have been given the opportunity to ask questions, all of which have been answered to my satisfaction.

I hereby request that I receive Occlusion Therapy with dissolvable lacrimal plugs.

Patient Name (Print): _____

Patient Signature: _____ **Date:** _____

Provider Signature: _____ **Date:** _____

Patient Consent – Long-term Occlusion Therapy (lacrimal plug) – OT3/A

My provider examined me and reviewed my medical history. Given my clinical signs and subjective symptoms I have been diagnosed with **Dry Eye Disease** (or a related condition) due to insufficient or poor-quality tears on the surface of my eyes, or some other factor. I have been evaluated and received medium-term Occlusion Therapy which caused one or more of my eye symptoms to improve.

Proposed Treatment – After my positive response to evaluation and medium-term Occlusion Therapy, I have been advised that Occlusion Therapy with non-dissolvable lacrimal plugs in my upper tear drainage ducts may benefit me. I understand that afterwards, should my symptoms persist, I may benefit from additional medium-term or long-term (punctal) Occlusion Therapy in my lower tear drainage ducts or a more advanced treatment. An antibiotic may be administered as a prophylactic step.

Risks and Complications - I understand I may experience watery eyes or excessive tearing during evaluation or treatment with Occlusion Therapy, and that this may last for 3 days or longer after plug insertion, due to healing of the cornea. Although uncommon, I may experience itching, irritation or infection of my eyes or eyelids. Should I experience discomfort or irritation from the plug(s) I will promptly tell my provider and return to the office for examination. If I develop an infection, I understand that I may require treatment with an antibiotic, plug repositioning, or plug removal.

Plug Repositioning, Imaging or Removal – Non-dissolvable (OPAQUE) lacrimal plugs are inserted into the horizontal canaliculus of the upper eyelid. Retroillumination of the eyelid may be used to monitor these unique plugs post-insertion, or to confirm their absence after a removal procedure. Should excess tearing or discomfort occur after placement, these plugs can be either be repositioned or removed using saline irrigation or probing of the tear drainage duct, or by surgical means.

Probability of Success – My symptoms may improve after long-term Occlusion Therapy in my upper eyelids, however, should my symptoms persist I realize I may benefit from long-term Occlusion Therapy of my lower eyelids using non-dissolvable punctal plugs. I know there is no guarantee of treatment, that my symptoms may return in the future and that I may require additional treatment including advanced eyelid procedures to reduce tear evaporation or loss.

Alternatives: Lubricating eyedrops or topically applied medications may provide temporary relief from the symptoms of Dry Eye Disease. Thermal procedures may be used to permanently close the tear drainage ducts. Eyelid surgery may be used to reduce tear evaporation and loss. I realize I may choose NOT to receive Long-term Occlusion Therapy at this time; and, If left untreated my condition will likely persist, get worse, or lead to more severe conditions such as corneal ulceration, or vision loss.

Request for Long-term Occlusion Therapy with Non-dissolvable Lacrimal Plugs - I understand my provider and their staff will do their best to help me. However, there has been no guarantee of the outcome either stated or implied. I have been informed about Dry Eye Disease, and evaluation and treatment with Occlusion Therapy. I have been given the opportunity to ask questions, all of which have been answered to my satisfaction.

I hereby request that I receive Occlusion Therapy with non-dissolvable lacrimal plugs.

Patient Name (Print): _____

Patient Signature: _____ **Date:** _____

Provider Signature: _____ **Date:** _____

Patient Consent – Long-term Occlusion Therapy (punctal plug) – OT3/B

My provider examined me and reviewed my medical history. Given my clinical signs and subjective symptoms I have been diagnosed with **Dry Eye Disease** (or a related condition) due to insufficient or poor-quality tears on the surface of my eyes, or some other factor. I have been evaluated and received medium-term Occlusion Therapy which caused one or more of my eye symptoms to improve.

Proposed Treatment – After my positive response to evaluation, and medium-term Occlusion Therapy, I have been advised that Long-term Occlusion Therapy with non-dissolvable punctum plugs in my upper and / or lower tear drainage ducts may benefit me. I understand that should my symptoms persist after treatment that I may require plug adjustment, plug removal or a more advanced treatment. An antibiotic may be administered as a prophylactic step.

Risks and Complications - I understand I may experience watery eyes or excessive tearing during evaluation or treatment with Occlusion Therapy, and that this may last for 3 days or longer after plug insertion, due to healing of the cornea. Although uncommon, I may experience itching, irritation or infection of my eyes or eyelids. Should I experience discomfort or irritation from the plug(s) I will promptly tell my provider and return to the office for examination. If I develop an infection, I understand that I may require treatment with an antibiotic, plug repositioning or plug removal.

Plug Repositioning or Removal – Non-dissolvable punctum plugs are partially inserted into the punctal ring, where they remain visible post-insertion. Should excess tearing or discomfort occur after placement, these plugs can either be repositioned or removed directly from the punctum, or by surgical means.

Probability of Success – My symptoms may improve after long-term Occlusion Therapy in my upper eyelids. Should my symptoms persist, I realize I may benefit from Occlusion Therapy of my lower eyelids. I know there is no guarantee of treatment, that my symptoms may return in the future, and that I may require additional treatment including advanced eyelid procedures to reduce tear evaporation or loss.

Alternatives: Lubricating eyedrops or topically applied medications may provide temporary relief from the symptoms of Dry Eye Disease. Thermal procedures may be used to permanently close the tear drainage ducts. Surgical eyelid procedures may be used to reduce tear evaporation and loss. I realize I may choose NOT to receive Medium-term Occlusion Therapy at this time; and, If left untreated my condition will likely persist, get worse, or lead to more severe conditions such as corneal ulceration, or vision loss.

Request for Long-term Occlusion Therapy with Non-dissolvable Punctal Plugs - I understand my provider and their staff will do their best to help me. However, there has been no guarantee of the outcome either stated or implied. I have been informed about Dry Eye Disease and evaluation and treatment with Occlusion Therapy. I have been given the opportunity to ask questions, all of which have been answered to my satisfaction.

I hereby request that I receive Occlusion Therapy with non-dissolvable punctal plugs.

Patient Name (Print): _____

Patient Signature: _____ **Date:** _____

Provider Signature: _____ **Date:** _____

Patient Consent – Lacrimal Probing (repositioning a plug) – OT4

My provider examined me and reviewed my medical history. Given my clinical signs and subjective symptoms I have been diagnosed with Dry Eye Disease (or a related condition) due to insufficient or poor-quality tears on the surface of my eyes, or some other factor. I have been evaluated and treated with Occlusion Therapy. I began experiencing **excess tearing and/or plug irritation** after Occlusion Therapy.

Proposed Treatment – I understand that “shallow” lacrimal probing of the tear drainage canal and plug repositioning may relieve my condition. I understand I will receive an anesthetic as indicated, and that my doctor will then gently insert a small lacrimal probe into my tear drainage duct to reposition my lacrimal plug.

Risks and Complications - I know there is a chance that this procedure may not relieve my symptoms and that my excess tearing and/or irritation may continue. Although uncommon I may experience itching or infection of my eyes or eyelids after the procedure. Should itching occur it is usually temporary. Should lacrimal probing fail to resolve my discomfort, I will promptly return to the office for further examination and additional treatment. If I develop an infection of my eye or eyelids I will promptly return to the office where my provider may prescribe an antibiotic.

Plug Removal – Dissolvable and non-dissolvable lacrimal plugs can generally be repositioned or removed from the tear drainage ducts using lacrimal irrigation and/or probing. Non-dissolvable punctum plugs are typically removed directly from the punctum. In rare cases, surgical intervention may be necessary to remove plugs from the tear drainage system. An antibiotic may be administered as a prophylactic step.

Probability of Success - I understand “shallow” lacrimal probing is usually effective in relieving the symptoms of excess tearing and/or plug irritation after Occlusion Therapy.

Alternatives: I could choose NOT to have the procedure. With the doctor’s approval, I could choose to have lacrimal irrigation or a surgical procedure to remove the plugs from my tear drainage duct. If left untreated, I understand my condition may persist, get worse, or lead to a more severe condition such as pyogenic granuloma and/or scarring.

Request for Lacrimal Probing - I understand my provider and their staff will do their best to help me. However, there has been no guarantee of the outcome either stated or implied. I have reviewed the related materials. I have been given the opportunity to ask questions, all of which have been answered to my satisfaction. I hereby request that I receive lacrimal probing for excess tearing and/or plug irritation after Occlusion Therapy.

Patient Name (Print): _____

Patient Signature: _____ **Date:** _____

Provider Signature: _____ **Date:** _____

Patient Consent – Irrigation (lacrimal plug removal) – OT5A

My provider examined me and reviewed my medical history. Given my clinical signs and subjective symptoms I have been diagnosed with Dry Eye Disease (or a related condition) due to insufficient or poor-quality tears on the surface of my eyes, or some other factor. I have been evaluated and treated with Occlusion Therapy. I began experiencing **excess tearing and/or plug irritation** after Occlusion Therapy.

Proposed Treatment – I understand that saline irrigation with or without lacrimal probing of the tear drainage system may relieve my condition. I understand I will receive an anesthetic as indicated, and that my doctor will then gently insert an irrigating cannula into my tear drainage canal to attempt to flush the plug from my tear drainage system.

Risks and Complications - I know there is a chance that this procedure may not relieve my symptoms and that my excess tearing and/or irritation may continue. Although uncommon I may experience itching or infection of my eyes or eyelids after the procedure. Should itching occur it is usually temporary. Should saline irrigation with or without lacrimal probing fail to resolve my condition, I will promptly return to the office for further examination and additional treatment. If I develop an infection of my eye or eyelids I will promptly return to the office where my provider may prescribe an antibiotic.

Plug Removal – Lacrimal plugs can generally be repositioned with lacrimal probing or removed with irrigation of the tear drainage system (with or without probing). Non-dissolvable punctum plugs are typically removed directly from the punctum. An antibiotic drop may be administered as a prophylactic step.

Probability of Success - I understand irrigation is usually effective in dislodging and removing lacrimal plugs from the tear drainage system. In rare cases, surgical intervention may be necessary to remove lacrimal or punctal plugs from the tear drainage system.

Alternatives: I could choose NOT to have the procedure. I could request a surgical procedure to remove the plugs from my tear drainage duct. If left untreated, I understand my condition may persist, get worse, or lead to a more severe condition such as pyogenic granuloma and/or scarring.

Request for Irrigation - I understand my provider and their staff will do their best to help me. However, there has been no guarantee of the outcome either stated or implied. I have reviewed the related materials. I have been given the opportunity to ask questions, all of which have been answered to my satisfaction. I hereby request that I receive lacrimal irrigation with or without probing.

Patient Name (Print): _____

Patient Signature: _____ **Date:** _____

Provider Signature: _____ **Date:** _____

Patient Consent – Punctum Plug Removal (Forceps) – OT5B

My provider examined me and reviewed my medical history. Given my clinical signs and subjective symptoms I have been diagnosed with Dry Eye Disease or a related condition due to insufficient or poor-quality tears on the surface of my eyes (or some other factor). I have been evaluated and treated with Occlusion Therapy. I began experiencing **excess tearing and/or plug irritation** after Occlusion Therapy.

Proposed Treatment – I understand that non-dissolvable punctal plugs can be removed directly from the punctum using fine tipped forceps, and that this may relieve my condition. I understand I will receive an anesthetic as indicated, and that my doctor will then gently grasp the plug from my eyelid and remove it from my tear drainage system.

Risks and Complications - I know there is a chance that this procedure may not relieve my symptoms and that my excess tearing and/or irritation may continue. Although uncommon I may experience itching or infection of my eyes or eyelids after the procedure. Should itching occur it is usually temporary. Should plug removal fail to resolve my condition, I will return to the office for further examination and treatment. If I develop an infection of my eye or eyelids I will return to the office where my provider may prescribe an antibiotic.

Plug Removal – Non-dissolvable punctum plugs are typically removed directly from the punctum. An antibiotic drop is commonly administered as a prophylactic step.

Probability of Success - I understand punctum plug removal is usually effective, but that in rare cases, surgical intervention may be necessary to remove a punctal plug from within the tear drainage system.

Alternatives: I could choose NOT to have the procedure. I could request a surgical procedure to remove the plugs from my tear drainage duct. If left untreated, I understand my condition may persist, get worse, or lead to a more severe condition such as pyogenic granuloma and/or scarring.

Request for Punctum Plug Removal - I understand my provider and their staff will do their best to help me. However, there has been no guarantee of the outcome either stated or implied. I have reviewed the related materials. I have been given the opportunity to ask questions, all of which have been answered to my satisfaction. **I hereby request that my punctum plug be removed.**

Patient Name (Print): _____

Patient Signature: _____ Date: _____

Provider Signature: _____ Date: _____

Procedural Report - Closure of the Punctum by Plug

Evaluation with Collagen Plugs, or VisiPlugs in all four (4) puncta – OT1, OT2

MEDICAL NECESSITY: The patient presented at the office with symptoms of Dry Eye Disease. The patient had tried lubricating eye drops or ointments in the past, with inadequate relief. Three or more objective tear tests were performed (Zone-Quick, Schirmer tear test, ocular surface staining, tear film evaluation, tear meniscus evaluation, or tear film break-up-time, MMP-9, MGD, Osmolarity, etc.) and the results were charted. After observing and recording the signs and symptoms of Dry Eye Disease, and confirming the diagnosis with at least 3 diagnostic test, a decision was made to proceed with short-term Occlusion Therapy. After securing informed consent, closure of the lacrimal puncta was performed.

Patient Name: _____ Date: _____

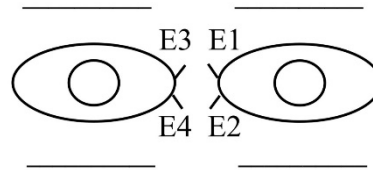
Evaluation / Treatment

Initial Diagnosis: Keratoconjunctivitis Sicca

Post Procedural Diagnosis: Same, Other: _____

Anesthesia (as needed):

- None
- Fluress .25%, one drop in conjunctival sac
- R/L eye(s): 1 gtt Tetracaine .5% instilled X _
- R/L eyes(s): 1 gtt Proparacaine instilled X __



- R/L eyes(s): Lidocaine applied over puncta via sterile cotton tipped applicator (q-tip)

Details of the procedure: Anesthetic was applied to the eye(s) as needed. In the presence of epiphora, lacrimal irrigation or probing was used to confirm the patency of the tear drainage ducts *prior* to plug insertion. The puncta were evaluated, and the appropriate size plug was identified. A sterile packet of dissolvable lacrimal plugs was opened, and the foam holder was held under magnification. Standard jeweler’s forceps, or specialty API Forceps, were used to grasp the plug and remove it from the holder. A sterile cotton-tipped applicator was used to evert the eyelid and pull laterally on the lid margin. The plug was placed half-way into the puncta, and the instrument was used to prompt the plug down until it was flush with the lid margin. The tip(s) of the forceps, or the Williams Intra canalicular Plug Positioning Tool (WIPPT), was used to advance the plug 4 - 6mm beneath the punctum into the horizontal canaliculus. The patient reported no discomfort or complications, and the procedure was terminated.

After plug insertion a prophylactic drop of topical antibiotic was instilled in the R / L eye(s). Name of antibiotic _____ @ _____ AM / PM.

The patient was advised to report back to the office promptly should any discomfort or adverse reaction develop. A follow-up appointment was scheduled after the 10-day post-op period.

Provider Name _____

Provider Signature _____

Office Information _____

Procedural Report - Closure of the Punctum by Plug

Treatment with Non-dissolvable Lacrimal/Punctum Plugs - OT3A, OT3B

MEDICAL NECESSITY: The patient presented at the office with symptoms of Dry Eye Disease, as recorded on a Dry Eye Symptoms Checklist. The patient reported having tried lubricating eye drops or ointments in the past, with inadequate symptomatic relief. The patient was evaluated with three or more objective tear tests (either Zone-Quick, Schirmer tear test, ocular surface staining, tear film evaluation, tear meniscus evaluation, or tear film break-up-time, etc.) and the results were charted. After obtaining patient consent the patient received dissolvable lacrimal plugs. After relief using dissolvable plugs, the patient was treated with non-dissolvable lacrimal or punctum plugs in the upper puncta and re-evaluated in the lower puncta.

Patient: _____ Date _____

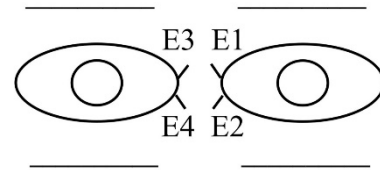
Initial Diagnosis: Keratoconjunctivitis Sicca

Post Procedural Diagnosis: Same, Other: _____

Anesthesia (as needed):

- None
- Fluress .25%, one drop in conjunctival sac
- R/L eye: 1 gtt Tetracaine .5% instilled x _____

- R/L eyes: 1 gtt Proparacaine instilled X _____
- R/L eyes(s): Lidocaine applied over puncta via sterile cotton tipped applicator (q-tip)



Details of the procedure: Anesthetic was applied to the eye(s) as needed. In the presence of epiphora, lacrimal irrigation or probing was used to confirm the patency of the tear drainage ducts *prior* to plug insertion. The puncta were evaluated, and the appropriate size plugs identified. A sterile packet was opened, and a sterile cotton-tipped applicator was used to evert the eyelid and pull laterally on the lid margin,. A pre-mounted non-dissolvable punctum plug was inserted into one or both of the superior punctum. If a lacrimal plug was used, it was inserted into the horizontal canaliculus at a 4mm depth, and the insertion instrument removed (per the Instructions for Use). Dissolvable lacrimal plugs were re-inserted into the lower puncta to evaluate the benefits of long-term Occlusion Therapy. Patients experiencing improvement were treated with medium term dissolvable or long term non-dissolvable punctum plugs in the lower puncta. The patient reported no discomfort or complications, and the procedure was terminated.

After plug insertion a prophylactic drop of topical antibiotic was instilled in the R/L eye(s). Name of antibiotic

_____ @ _____ AM / PM.

The patient was advised to report back to the office promptly should any discomfort or adverse reaction develop. A follow-up appointment was scheduled after the 10-day post-op period.

Provider's Signature _____

Provider's Name _____

Office Information _____

Procedural Report – Probing of the Lacrimal Canaliculi

Repositioning Lacrimal Plugs after Occlusion Therapy – OT4

MEDICAL NECESSITY: The patient presented at the office with symptoms of Dry Eye Disease, as recorded on a Dry Eye Symptoms Checklist. The patient reported having tried lubricating eye drops or ointments in the past, with inadequate symptomatic relief. The patient was evaluated with three or more objective tear tests (either Zone-Quick, Schirmer tear test, ocular surface staining, tear film evaluation, tear meniscus evaluation, or tear film break-up-time, etc.) and the results were charted. After securing a Request for Occlusion Therapy, the patient was evaluated and then treated with non-dissolvable lacrimal or punctum plugs. After discomfort was experienced, the patient received probing of the lacrimal canaliculi to reposition the lacrimal plug.

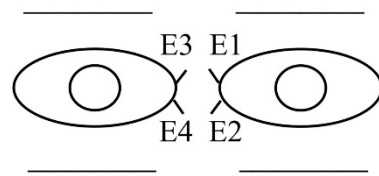
Patient: _____ Date _____

Initial Diagnosis: Keratoconjunctivitis Sicca

Post Procedural Diagnosis: Same, Other: _____

Anesthesia (as needed):

- | | |
|---|--|
| <input type="checkbox"/> None | <input type="checkbox"/> R/L eyes(s): 1 gtt Proparacaine instilled X ___ |
| <input type="checkbox"/> Fluress .25%, one drop in conjunctival sac | <input type="checkbox"/> R/L eyes(s): Lidocaine applied over puncta via sterile cotton tipped applicator (q-tip) |
| <input type="checkbox"/> R/L eye(s): 1 gtt Tetracaine .5% instilled x ___ | |



Details of the procedure: Anesthetic was applied to the eye(s) as needed. A sterile cotton-tipped applicator was used to evert the eyelid and pull laterally on the lid margin. The Williams Intracanalicular Plug Positioning Tool (WIPPT) was introduced into the punctum 2mm, and then rotated until the instrument paralleled the inner third of the lid margin, the tool was advanced 4 – 6mm, and then withdrawn. The patient reported improvement in their discomfort or complications, and the procedure was terminated.

After plug repositioning, a prophylactic drop of topical antibiotic was instilled in the R/L eye(s). Name of antibiotic _____ @ _____ AM / PM.

The patient was advised to report back to the office promptly should any discomfort or adverse reaction develop. A follow-up appointment was scheduled after the 10-day post-op period.

Provider's Signature _____

Provider's Name _____

Office Information _____

Procedural Report – Lacrimal Irrigation/Probing

Removing Lacrimal Plugs after Occlusion Therapy – OT5A

MEDICAL NECESSITY: The patient presented at the office with symptoms of Dry Eye Disease, as recorded on a Dry Eye Symptoms Checklist. The patient reported having tried lubricating eye drops or ointments in the past, with inadequate symptomatic relief. The patient was evaluated with three or more objective tear tests (either Zone-Quick, Schirmer tear test, ocular surface staining, tear film evaluation, tear meniscus evaluation, or tear film break-up-time, etc.) and the results were charted. After securing a Request for Occlusion Therapy, the patient was evaluated with dissolvable lacrimal plugs. After relief using dissolvable lacrimal plugs in the lower puncta, the patient was treated with non-dissolvable punctum plugs.

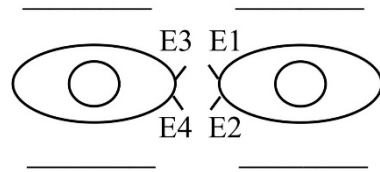
Patient: _____ Date _____

Initial Diagnosis: Keratoconjunctivitis Sicca

Post Procedural Diagnosis: Same, Other: _____

Anesthesia (as needed):

- | | |
|--|--|
| <input type="checkbox"/> None | <input type="checkbox"/> R/L eyes(s): 1 gtt Proparacaine instilled X __ |
| <input type="checkbox"/> Fluress .25%, one drop in conjunctival sac | <input type="checkbox"/> R/L eyes(s): Lidocaine applied over puncta via sterile cotton tipped applicator (q-tip) |
| <input type="checkbox"/> R/L eye(s): 1 gtt Tetracaine .5% instilled x __ | |



Details of the procedure: Anesthetic was applied to the eye(s) as needed. In the presence of epiphora, lacrimal irrigation or probing was used to confirm the patency of the tear drainage ducts *prior* to plug insertion. The punctum was evaluated, and the appropriate size plugs identified. A sterile packet was opened, and a pre-mounted non-dissolvable punctum plug was removed and positioned for insertion. As a sterile cotton-tipped applicator was used to evert the eyelid and pull laterally on the lid margin. The tip of the plug was inserted into the punctum, and the release button was pushed. After withdrawing the insertion tool, the plug was inspected to ensure that it was positioned securely and was still visible. In bilateral Dry Eye, the procedure was repeated in the opposing eye. Dissolvable lacrimal plugs were inserted into the remaining un-occluded puncta, to evaluate the need for additional treatment. The patient reported no discomfort or complications, and the procedure was terminated.

After plug insertion a prophylactic drop of topical antibiotic was instilled in the R/L eye(s). Name of antibiotic _____ @ _____ AM / PM.

The patient was advised to report back to the office promptly should any discomfort or adverse reaction develop. A follow-up appointment was scheduled after the 10-day post-op period.

Provider's Signature _____

Provider's Name _____

Office Information _____

Occlusion Therapy - Patient Self Evaluation Form

Write down a few words each day to describe good or bad changes in the symptoms you experience during evaluation or treatment with Occlusion Therapy; preferably at the same time each day (evening is best).

Day 1 _____

Day 3 _____

Day 4 _____

Day 5 _____

Day 6 _____

Day 7 _____

Day 8 _____

Day 9 _____

Day 10 _____

Day 11 _____

Day 12 _____

Day 13 _____

Day 14 _____

Patient Name: _____

Patient Signature: _____

Provider Name: _____

Date: _____

Occlusion Therapy - After Care Instructions

Following Occlusion Therapy with dissolvable or non-dissolvable lacrimal or punctum plugs, you may experience:

1. Watering or tearing eyes (usually dissipates within 72 hours)
2. Plug awareness or feeling like something was done to your eyelid
3. Temporary Itching (It's OK to rub, try a cool compress)
4. Mucous discharge

Not all patients will experience these symptoms. For those that do, the symptoms should generally resolve after a few days.

Collagen Plugs will absorb 4-7 days after insertion. Thereafter, your baseline symptoms should return. You may notice symptoms, which you were previously not aware of. Some patients will experience a dramatic change, others may not. All these responses are normal.

Call and request to be seen if you experience:

1. A foreign body sensation that won't go away. This is a sensation that something is poking you in the eye or eyelid.
2. Greenish-yellow discharge – Although some mucous discharge is normal, a significant discharge may indicate an infection.
3. Swelling and redness of tissue surrounding the eye and eyelid.

After evaluation with Collagen Plugs, we will schedule a follow-up visit to evaluate the benefits of treatment with Occlusion Therapy.

Occlusion Therapy Universal Precautions

Lacrimedics' System of Occlusion Therapy is minimally invasive and includes techniques to avoid provider contact with tears, blood, mucous membranes and other potentially infectious materials (OPIM). When an infection is present, or when contact seems unavoidable, use gloves during Occlusion Therapy.

OSHA (Occupational Safety and Health Agency) provides Universal Precautions that require all human blood and OPIM be treated "as if known to be infectious for HIV, HBV, HCV or other bloodborne pathogens". Providers should have a Blood Borne Pathogen / Infection Control Policy in effect for their practices.

Materials and Allergic Reactions

- Collagen Plugs – Bovine, absorbs in 4 – 7 days, BSE Free
- VisiPlugs – Polydioxanone, dissolve in ~ 180 days
- Non-dissolvable lacrimal and punctum plugs – medical grade silicone

Silicone breast implants are placed within body tissues in contact with blood. Problems occur when the liquid silicone in breast implant leaks into the surrounding tissue. In contrast, Lacrimedics' non-dissolvable lacrimal and punctum plugs are made from solid non-liquid silicone which cannot leak into the surrounding tissue.

It is OK for patients with lacrimal or punctum plugs to receive MRI or Ultrasound procedures.

Useful Abbreviations

OT1 – Dissolvable Lacrimal Plugs in All Four Puncta (for bilateral Dry Eye)

OT2 – Non-Dissolvable Lacrimal *or* Punctum Plugs in Upper Puncta

OT3 – Non-Dissolvable Punctum Plugs in Lower Puncta

OT4 – Repositioning Lacrimal Plugs (probing with WIPPT)

OT5 – Removing Lacrimal Plugs (probing with irrigation)*

**Removing Punctum Plugs is included in the reimbursement for insertion.*

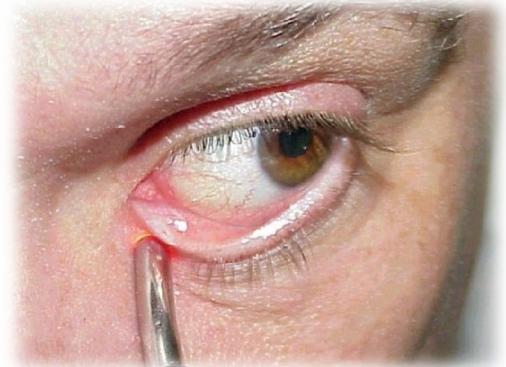
Monitoring Plugs

Direct Visualization – Observe punctal plugs within the punctum.

Symptomatic Benefits – Apart from desensitization, the benefits of Occlusion Therapy should continue if plugs remain in place. After dissolution, migration, loss, or removal, the patient’s baseline symptoms should return.

Observe (intra-canalicular) lacrimal plugs by:

Transillumination – Transilluminate the eyelid (with Lissamine Green Dye). 1) Turn room lights down and turn the transilluminator down to approximately 50% illumination (if too bright the technique will not work). 2) Ask the patient to look away from the punctum.



It is useful to advise the patient to look away from the light.

Apply a Q-tip (cotton-tipped applicator, medical-grade, wooden handle) to the dermis adjacent to the punctum and apply pressure while rolling the Q-tip away from the punctum, to evert the eyelid. After the punctum becomes available, pull laterally to tighten the skin on the eyelid. 3) Place the transilluminator tip on the dermis, 4 to 6mm medial to the punctum (backlight the plug and observe the shadow). This helps confirm plug presence and location after insertion; repositioning; or plug removal.

Blanching – 1) Apply cotton-tipped applicator (Q-tip, medical-grade, wooden handle) to the dermis, adjacent to the punctum. 2) Roll the Q-tip away from the punctum to evert the eyelid. 3) After the punctum presents itself, pull laterally to tighten the skin medial to the punctum. 4) Using a second Q-tip, apply a slight lateral (outward) tension on the conjunctiva directly over or adjacent to the location of the plug. The tissue over the plug will thin and blanch slightly, revealing the outline of the plug.

Backpressure during irrigation may indicate either a blocked canaliculus or poor technique. Insert a 15mm suture into the punctum until resistance reveals either the location or the absence of a lacrimal plug. Effective plug removal should precipitate a patients’ return to baseline symptoms.

Evaluating Tearing After Occlusion Therapy

After Occlusion Therapy with lacrimal or punctal plugs, patients may experience intermittent (reflex) or constant tearing. This can occur during the healing process, from under-treatment, improper plug positioning, or over treatment (too much blockage).

Healing

Dry Eye patients often have roughened or devitalized corneal epithelium (demonstrated during staining). The condition affects mucous membranes in and around the eyes, ears, nose, throat, sinus and respiratory systems. Dry Eye patients need time to heal after Occlusion Therapy. **Patients may experience transient, intermittent tearing after Occlusion Therapy due to healing** (lasts about 3 days).

Under Treatment

To evaluate Dry Eye patients with Collagen Plugs, occlude upper and lower puncta in tested eyes (one or more plug per puncta, largest diameter possible, with dilation and anesthesia, if necessary). Thereafter, apply Occlusion Therapy in a progressive fashion. Occlude upper puncta first to improve tear distribution, and overall wetting during the blink; this allows the lower puncta to continue removing debris, and excess tears, from the eye's surface, and reduces overtreatment. **Patients may experience persistent, intermittent tearing after Occlusion Therapy due to under treatment.** If this occurs, evaluate un-occluded puncta for additional Occlusion Therapy with Collagen Plugs.

Improper Plug Positioning

Lacrimal plugs (Collagen Plugs, VisiPlugs, Herrick Plugs) should be placed 4 – 6 mm beyond the punctum, into the horizontal canaliculus. The Williams Intracanalicular Plug Positioning Tool (WIPPT) helps ensure proper placement. **Patients may experience constant or intermittent tearing, or itching, after Occlusion Therapy due to Improper Plug Positioning.** Use the WIPPT to reposition the plug and provide symptomatic relief.

Over Treatment

To avoid overtreatment: 1) use Collagen Plugs to evaluate Occlusion Therapy in Dry Eye patients, 2) use dissolvable VisiPlugs before non-dissolvable (silicone) lacrimal or punctal plugs, 3) treat upper puncta first during progressive treatment, and 4) if symptoms persist, evaluate un-occluded puncta with Collagen Plugs. **Patients may experience persistent, constant tearing (Epiphora) after Occlusion Therapy due to overtreatment.** Should constant tearing occur, consider plug removal.

Procedural Report – Lacrimal Irrigation with/without Probing

To Clear Lacrimal Obstruction or Remove Lacrimal Plugs

MEDICAL NECESSITY: The patient reported to the office with symptoms of lacrimal obstruction and a history of treatment with dissolvable or non-dissolvable lacrimal plugs. The patient experienced undesirable symptoms (chronic tearing or discomfort) associated with plug presence. After Plug Repositioning failed to relieve the symptoms, the patient was advised to have Lacrimal Irrigation to clear the obstruction or remove resident plugs. After securing a signed Patient Request for Plug Removal, lacrimal irrigation was performed.

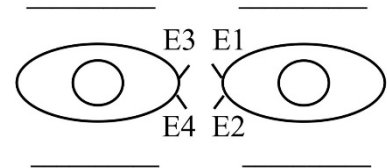
Patient: _____ **Date:** _____

Initial Diagnosis: Lacrimal Obstruction / Epiphora

Post Procedural Diagnosis: Same

Supplies Required:

- | | |
|---|--|
| <input type="checkbox"/> TruPro™ Cannula | <input type="checkbox"/> Anesthetic drops |
| <input type="checkbox"/> Cotton Tipped Applicator (Q-tip) | <input type="checkbox"/> Sterile Saline Solution |
| <input type="checkbox"/> 3CC Disposable Syringe | <input type="checkbox"/> Antibiotic Drops |
| <input type="checkbox"/> Facial Tissue | |



Details of Procedure: A sterile TruPro cannula was placed on a 3cc Syringe. After withdrawing the plunger, 3CC of sterile saline solution was placed in the syringe, and the plunger replaced. The tip of the syringe was held in an upward position and the plunger depressed to purge excess air. Instruments were pre-arranged on a tray. **One drop of topical anesthetic was administered (3X, one minute apart).** The patient was told that fluid would be advanced through their tear drainage ducts and that it would exit out the nose, or down the throat. A tissue was given to the patient to catch fluid passing out their nose. While in the exam chair, the patient was asked to look away from the punctum. A cotton-tipped applicator (Q-tip) was used to evert the eyelid and pull laterally (exposing the puncta). The tip of the cannula was partially inserted into the punctum (1 – 2mm). The instrument was rotated more than 90 degrees until the angles between the vertical and horizontal canaliculus were straightened. The cannula was advanced an additional 2mm until the flared portion of the cannula formed a tight seal at the punctum. With the instrument parallel with the inner 1/3 of the lid margin (tangential to the eye), and the lid pulled tight, the saline fluid was discharged. Upon resistance, the traction was adjusted to ensure flaccid tissue was not obstructing the lumen. The position of the syringe was modified to the point of least resistance for maximum effect. Care was taken not to point the syringe posteriorly. 2–3CC of saline was discharged through the tear drainage duct, and the patient passed fluid out the nose, or down the throat. It was determined that the obstruction had been cleared, successfully. A prophylactic drop of topical antibiotic was instilled, and the procedure was terminated.

- It was necessary to use Punctal Dilation or Lacrimal Probing in this case.

Provider Signature _____

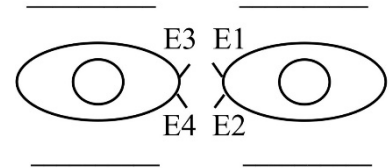
Provider Name _____

Office Information _____

Procedural Report – Punctum Plug Removal

MEDICAL NECESSITY: The patient reported to the office with epiphora, and a history of treatment with non-dissolvable punctum plugs. After ruling out Ptosis as a cause of epiphora, and confirming the plugs were appropriately positioned, the patient was advised to have the punctum plug removed. After securing a signed Patient Request for Plug Removal, Punctum Plug Removal was performed.

Patient: _____ Date: _____



Initial Diagnosis: Lacrimal Obstruction / Epiphora

Post Procedural Diagnosis: Same

Supplies Required:

- | | |
|---|---|
| <input type="checkbox"/> Jeweler’s Forceps | <input type="checkbox"/> Anesthetic drops |
| <input type="checkbox"/> Cotton Tipped Applicator (Q-tip) | <input type="checkbox"/> Antibiotic Drops |
| <input type="checkbox"/> Facial Tissue | |

Details of Procedure: Instruments were pre-arranged on a tray. While in the exam chair, the patient was asked to look away from the punctum and provided a tissue. One drop of topical anesthetic was administered, as needed. A cotton-tipped applicator (Q-tip) was used to evert the eyelid and pull laterally (exposing the punctum). Under magnification, a sterile jeweler’s forceps were used to grasp the punctum plug and remove it from the punctum. After confirming that the plug had been successfully removed from the punctum, a prophylactic drop of topical antibiotic was instilled, and the procedure was terminated.

Provider Signature _____

Provider Name _____

Office Information _____

Removing Lacrimal Plugs

When removing non-dissolvable lacrimal plugs becomes necessary, follow these steps in sequence to minimize patient risk and trauma. Once removed, additional steps are not required.

Dissolvable and non-dissolvable lacrimal plugs are generally removed using lacrimal probing and/or irrigation.

- 1) The TruPro[™] lacrimal cannula is designed to irrigate the tear drainage ducts (clear obstruction) and remove dissolvable or non-dissolvable lacrimal plugs.
- 2) The West lacrimal cannula is designed to combine lacrimal probing and irrigation, to clear obstruction), and remove dissolvable or non-dissolvable lacrimal plugs. The blunt tip eases insertion, while the length facilitates passage through the tear drainage duct. A side port allows for saline irrigation upon insertion.
- 3) After probing, follow up with lacrimal irrigation with the TruPro[™] cannula.
- 4) Canaliculotomy – A surgical procedure to open the tear drainage duct and remove the plug under direct visualization.
- 5) Dacryocystorhinostomy (DCR) - A surgical procedure to open the nasolacrimal sac (external or endo-nasal) and remove the plug under direct visualization.

TruPro Cannula - Sterilization and Cleaning

Steam Autoclave

This method is preferred for the TruPro cannula, due to its fine lumen, which can become clogged with use. Autoclave the instrument in a suitable vented-lid tray or jar (instead of wrapping).

Minimum recommended cycles:

Normal autoclave: 121^oC (250^oF)/1.4kg/cm², 20 psi for 30 minutes.

Flash autoclave: 132^oC (270^oF)/21.kg/cm², 30 psi for 5 minutes.

Cold Sterilization

Cleaning - Sometimes a cannula can become obstructed or clogged. It may be difficult to pass the solution through the instrument. Preventive care is key.

Following a procedure, immediately fill the syringe with saline and irrigate the cannula clear. Repeat with disinfectant, then complete standard cleaning and sterilization procedures. The key is managing the care of the instrument immediately after use, rather than later.

Chemical Sterilization

Chemical sterilization: Most solutions (Sporicidein, Wavicide -01, CetylCide-G, MetraCide, etc.) are effective at breaking down an organic debris obstruction, allowing easy irrigation of the cannula. Use solutions that provide sterilization and disinfection (usually requiring an overnight soak), following the manufacturer's Instructions for Use. Following the recommended soaking process, fill the syringe with saline and irrigate the cannula clear; any remaining debris should easily irrigate out. Once the obstruction is removed, complete standard cleaning and sterilization procedures.

Occlusion Therapy – Medicare and Private Insurance

Use **CPT 68761** to bill for “closure of the lacrimal punctum by plug; each” (Occlusion Therapy) in Dry Eye patients. Medicare bundles reimbursement for the service with the sterile supply. The code should be used for dissolvable and non-dissolvable plugs. Private Insurances may not bundle.

A **10-day post-op period** exists after the procedure. Repeated use of long-term dissolvable plugs instead of silicone plugs or thermal procedures must be supported by medical justification.

History of Prior Treatment – Before Using Plugs

Document that the patient presented with signs and symptoms of Dry Eye disease (recorded on a Dry Eye Symptoms Checklist), and was evaluated with at least 3 diagnostic Dry Eye tests (can include): Schirmer Tear Test.

- Zone-Quick Thread Test
- Corneal Staining
- Tear Film Break-Up-Time
- Meniscus Evaluation

Document that the patient underwent 2 to 4 weeks of conventional treatment with lubricating eye drops or ointments, and that there was little or no subjective or objective improvement during the period.

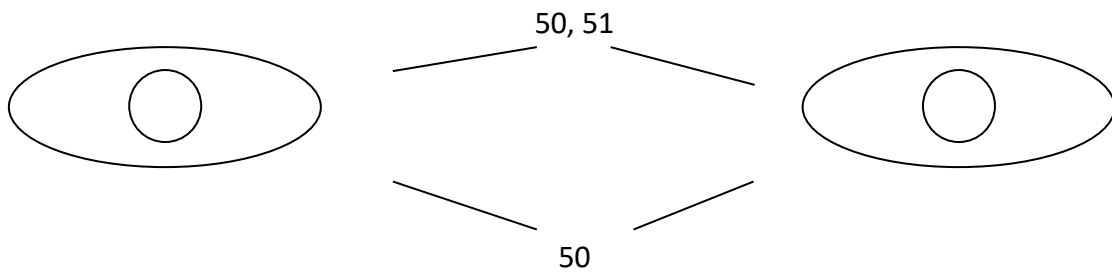
Secure a signed **Patient Request for Occlusion Therapy** (Informed Consent) when reviewing the risks, benefits, drawbacks, and alternatives to Occlusion Therapy with the patient.

When closing multiple puncta, **Medicare will allow 100% of the billing for the first punctum, and 50% for each additional punctum billed. Medicare generally pays 80% of the allowable, and the patient pays the other 20%.** Be sure to evaluate all four puncta with Collagen Plugs in bilateral Dry Eye.

Private insurance may reimburse for sterile supplies using HCPCS Code A4262 (absorbable collagen) or A4263 (non-dissolvable silicone).

Medicare Billing for Lacrimal Occlusion using 50, 51 Modifiers

CPT Procedure Code:	68761	Closure of the lacrimal punctum, by a plug, each
CPT Modifier	50	Bilateral Procedure (both eyes)
CPT Modifier	51	Multiple Procedures



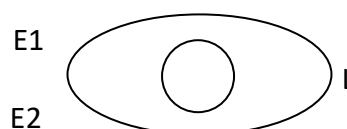
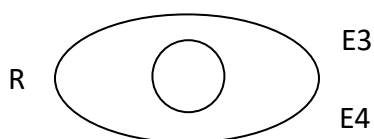
Procedure Codes

Occluded one lid	68761		
Occluded both lower lids	68761 50	or	68761 68761 51
Occluded both upper lids	68761 50	or	68761 68761 51
Occluded all four lids	68761 50 68761 50, 51	or	68761 68761 51 68761 51 68761 51
Occluded both lids, same eye	68761 68761 51		

Contact your local carrier for specific modifier/unit use.

Medicare Billing for Lacrimal Occlusion using E Modifiers

CPT Procedure Code:	68761	Closure of the lacrimal punctum, by a plug, each
HCPCS Modifier	E1	Upper left, eyelid
HCPCS Modifier	E2	Lower left, eyelid
HCPCS Modifier	E3	Upper right, eyelid
HCPCS Modifier	E4	Lower right, eyelid
CPT Modifier	51	Multiple Procedures



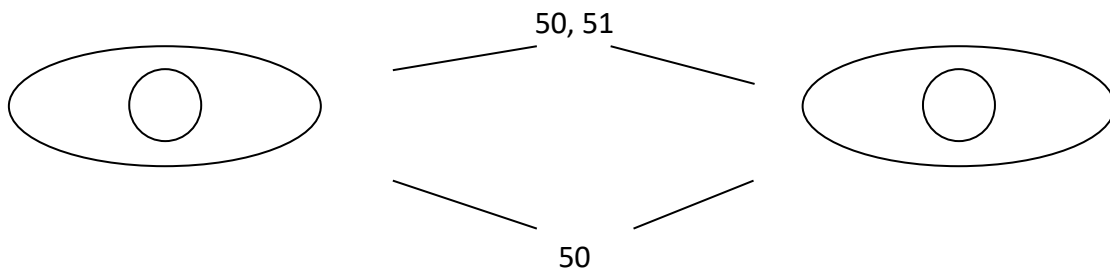
Procedure Codes

Occluded one lid	68761		
Occluded both lower lids	68761 E2 68761 E4	or	68761 E2 68761 51 E4
Occluded both upper lids	68761 E1 68761 E3	or	68761 E1 68761 51 E3
Occluded all four lids	68761 E1 68761 E2 68761 E3 68761 E4	or	68761 E1 68761 51 E2 68761 51 E3 68761 51 E4
Occluded both lids, same eye	68761 E1 68761 E2	or	68761 E3 68761 E4
or			
Occluded both lids, same eye	68761 E1 68761 51 E2	or	68761 E3 68761 51 E4

Contact your local carrier for specific modifier/unit use.

Private Insurance Billing for Lacrimal Occlusion

CPT Procedure Code:	68761	Closure of the lacrimal punctum, by plug, each
CPT Supply Code:	99070	Supplies and materials provided by the physician over and above those usually included with the office visit or other services rendered
CPT Modifier	50	Bilateral Procedure (both eyes)
CPT Modifier	51	Multiple Procedures



	<u>Procedure Codes</u>		<u>Supply Codes</u>
Occluded one lid	68761		99070 units 1
Occluded both lower lids	68761 50 68761 51	or	68761 99070 units 2
Occluded both upper lids	68761 50 68761 51	or	68761 99070 units 2
Occluded all four lids	68761 50 68761 50, 51 68761 51 68761 51	or	68761 68761 51 99070 units 4
Occluded both lids, same eye	68761 68761 51		99070 units 2

Contact your local carrier for specific modifier/unit use.

Request for Referral from Primary Care Physician

Primary Care Provider _____ Date _____

Address _____

City, State, Zip Code _____

Re: Patient Name _____

Patient ID Number _____

Dear _____,

I am writing to update you on the status of your patient, _____ and to request authorization for services. This letter provides information about the patient's history and diagnosis to document the medical necessity of the planned procedure.

_____ was seen in my office on _____ and is being treated for Dry Eye disease. At this point, the use of artificial tears and ointments is not providing adequate relief. I have discussed the option of occlusion therapy with the patient and wish to proceed with lacrimal/punctal occlusion "by plug".

Clinical Findings:

Complaints of itching, scratching _____
 Results of Schirmer's Test _____
 Tear-Break-Up-Time (TBUT) _____
 Corneal staining _____
 Results of tear assay test _____
 Other pertinent or systemic involvement _____
 Chronic problems or systemic involvement _____

Treatment History:

Date of first diagnosis _____
 Results of tears or ointments _____
 Compliance with tears and ointments _____
 Need for lacrimal/punctal plugs _____
 Other surgical options (laser, cautery, suture) _____

I feel this procedure is medically appropriate. If you agree, please sign and return this form to our office. If you need additional information in determining treatment, please do not hesitate to contact our office.

Sincerely,

 Provider's Signature

 Printed Name

 Practice Phone

 Email

 Address

 City, State, Zip Code

For reasons outlined above, I hereby refer this patient for Occlusion Therapy with plugs.

 Primary Care Physician Signature

 Date

Letter to Insurance Company Appealing Denial of Authorization for Payment

Medical Director _____ Date _____

Insurance Company _____

Address _____

City, State, Zip Code _____

Re: Patient Name _____

Patient ID Number _____

Date of Service _____

Dear _____,

I am writing in response to a recent denial of our claim(s) for lacrimal occlusion with plugs (CPT 68761). This letter will serve as a request for an appeal of your denial as well as provide additional information on which to base a favorable payment determination.

Service Description

Occlusion of the lacrimal canal with plugs involves the insertion of dissolvable or non-dissolvable plugs into the lacrimal canal. The number of plugs used depends on the severity of the condition. The plugs restrict the drainage of tears into the lacrimal system; the effect is a greater tear film on contact with the front surface of the eye and a decrease in dry eye symptoms and corneal dryness.

Indications

Symptoms of dry eye syndrome may include dryness or irritation of eyes and eyelids, scratchy sensation, reflex tearing, treatment for dry eye syndrome includes a regimen of artificial tears and lubrication ointments. For patients who do not achieve a satisfactory result from the use of drops and ointments, the insertion of lacrimal plugs is an option. Insertion of collagen plugs is performed to assess the condition and to determine if the permanent occlusion is required. The collagen plugs absorb in the lacrimal canal over the course of several days. In many, but not all cases, occlusion with permanent plugs is performed once the results of the temporary occlusion are apparent.

CPT Code

The American Medical Association has published a CPT code for this procedure: 68761 – Closure of the lacrimal punctum; by a plug, each.

Conclusion

_____ presented in our office with symptoms of Dry Eye disease. The Clinical findings supported this diagnosis. After discussing the options with the patient, it was decided that occlusion therapy with lacrimal/punctal plugs was the best course of treatment. After reviewing this information, we hope that the denial previously issued will be reversed and our claim will be honored for reimbursement. If you have any questions or need additional information to proceed with this request, please do not hesitate to contact our office.

Sincerely,

Provider's Signature

Printed Name

Practice Phone _____

Email _____

Address _____

City, State, Zip Code _____

2020 Occlusion Therapy Financial Model

Median patient volume in optometric/ophthalmic practice per year	5000	(Note #1)	
Potential Dry Eye		38%	(Note #2)
Dry Eye Patients/Year		1900	(Note #3)
Lacrimal Efficiency Test Procedure (OT1)	100%	1900 patients	
CPT 68761 Collagen Plug for the Lacrimal Efficiency Test (100% E1)	1,900	\$152.00	\$288,800
CPT 68761 Collagen Plug for the Lacrimal Efficiency Test (50% E3)	1,900	\$76.00	\$144,400
CPT 68761 Collagen Plug for the Lacrimal Efficiency Test (37.5% E2)	1,900	\$57.00	\$108,300
CPT 68761 Collagen Plug for the Lacrimal Efficiency Test (37.5% E4)	1,900	\$57.00	\$108,300
Lacrimal Efficiency Test Annual Revenue (Note #3)	per visit	\$342.00	\$649,800
Partial Long-Term Occlusion Candidates (OT2) (Note #4)	50%	950 of OT1 patients	
Lacrimedics' Herrick Lacrimal Plug or ComfortTip Punctal Occluder (100% E1)	950	\$152.00	\$144,400
Lacrimedics' Herrick Lacrimal Plug or ComfortTip Punctal Occluder (50% E3)	950	\$76.00	\$72,200
CPT 68761 Collagen Plug for the Lacrimal Efficiency Test (37.5% E2)	950	\$57.00	\$54,150
CPT 68761 Collagen Plug for the Lacrimal Efficiency Test (37.5% E4)	950	\$57.00	\$54,150
	per visit	\$342.00	\$324,900
Long-Term Occlusion Candidates (OT3)	25%	238 of OT2 patients	
CPT68761 Lacrimedics' ComfortTip Punctal Occluder (100% E2)	238	\$152.00	\$36,100
CPT68761 Lacrimedics' ComfortTip Punctal Occluder (50% E4)	238	\$76.00	\$18,050
Occlusion Therapy Annual Revenue (Note #5)	per visit	\$228.00	\$54,150
Total Annual Occlusion Therapy M.A.C.			\$1,028,850

NOTES

1. Richard C. Koval, MPA, CMPE. (2002, June 15). How does your practice compare? Healio - Ocular Surgery News. Retrieved from <https://www.healio.com/ophthalmology/news/print/ocular-surgery-news/{0fd7192e-a1ba-4a35-bd63-d07a99836902}/how-does-your-practice-compare>
2. Yu J, Asche CV, Fairchild CJ. "The economic burden of dry eye disease in the United States: A decision tree analysis." Cornea 2011; 30(4):379-87
3. In a national survey in 2011 by Harris Interactive, 69% of survey respondents who experience symptoms of Dry Eye said they had not visited an eye care professional for treatment.
4. Lacrimedics' Visiplugs for Medium Term Occlusion Therapy may be substituted for long-term silicone plugs in OT2/OT3.
5. Reimbursement figures are based on the Medicare 2019 Physician Fee Schedule. Medicare M.A.C. varies by region, check with your local provider for current data.

Working model available, kindly contact Lacrimedics for a copy.