

Dry Eye Disease & Meibomian Gland Dysfunction

Fast Facts

Tears are necessary for maintaining the ocular surface and for providing clear vision.¹ Dry Eye Disease is a condition in which a person is unable to produce an adequate quality or quantity of tears to lubricate and nourish the eye. If untreated, severe Dry Eye can result in damage to the surface of the eye with the potential to cause vision impairment.²

More than **340 million** people suffer from dry eye globally³

Symptoms²

- Burning, dryness, itching or aching sensations
- Fatigued, sore or heavy eyes
- Eye redness
- Light sensitivity
- Blurred vision

Meibomian Gland Dysfunction



MGD affects approximately **86%** of dry eye patients⁵

Tears are made up of three layers. The aqueous layer is the watery layer that nourishes the eye. The mucin layer contains mucous that helps to bind the aqueous layer to the surface of the eye. The lipid layer is made up of oils produced by the Meibomian glands found in the eyelids; it helps prevent evaporation and acts as a barrier to the environment.¹

Meibomian Gland Dysfunction (MGD) is an abnormality of the Meibomian gland that blocks the secretion of oils. Without sufficient oil production, tears evaporate quickly causing Dry Eye.⁴ MGD is highly prevalent among ophthalmic patients.⁵

Diagnosis & Treatment

An eye doctor can diagnose MGD during a thorough eye exam and determine the best treatment options for a patient based on their particular needs. The Johnson & Johnson Vision MGD product portfolio technologies allow physicians to evaluate meibomian gland health, and treat MGD with a 12-minute, in-office treatment.⁴

Imaging	Treatment
<p>LipiScan™: Images meibomian gland structure efficiently⁶</p> <p>LipiView® II: Measures lipid layer thickness, captures blink rate and partial blinks, and images meibomian gland structure efficiently.⁷</p>	<p>LipiFlow®: A cleared electronic medical device for MGD shown to restore gland function by applying simultaneous heat and pressure to the eyelid to remove gland contents and obstructions while at the same time protecting delicate structures of the patient's eye.⁸</p>

¹Dry Eye. American Optometric Association. <https://www.aoa.org/patients-and-public/eye-and-vision-problems/glossary-of-eye-and-vision-conditions/dry-eye> ²Facts About Dry Eye. National Eye Institute. <https://nei.nih.gov/health/dryeye/dryeye> ³Understanding Dry Eye Syndrome. All About Vision. <http://www.allaboutvision.com/conditions/dryeye-syndrome.htm> ⁴Market Scope 2016 Dry Eye Report ⁵Lemp, M. A., Crews, L. A., Bron, A. J., Foulks, G. N., & Sullivan, B. D. (2012). Distribution of Aqueous-Deficient and Evaporative Dry Eye in a Clinic-Based Patient Cohort. *Cornea*, 31(5), 472-478. doi:10.1097/ico.0b013e318225415a ⁶Lemp, M.A., Crews, L.A., Bron, A.J., Foulks, G.N., & Sullivan, B.D. (2012). Distribution of Aqueous-Deficient and Evaporative Dry Eye in a Clinic-Based Patient Cohort. *Cornea*, 31(5), 472-478. ⁷Nichols KK, Foulks GN, Bron AJ, Glasgow BJ, Dogru M, et al. (2011) The international workshop on Meibomian gland dysfunction: executive summary. *Invest Ophthalmol Vis Sci* 52: 1922-1929 [PMC free article] [PubMed] ⁸Lemp, M.A., Crews, L.A., Bron, A.J., Foulks, G.N., & Sullivan, B.D. (2012). Distribution of Aqueous-Deficient and Evaporative Dry Eye in a Clinic-Based Patient Cohort. *Cornea*, 31(5), 472-478. ⁹Understanding Dry Eye Syndrome. All About Vision. <http://www.allaboutvision.com/conditions/dryeye-syndrome.htm> ¹⁰Tear Film. American Academy of Ophthalmology. <https://www.aao.org/eye-health/anatomy/tear-film> ¹¹Meibomian Gland Dysfunction (MGD): The Cause Of Your Dry Eyes? All About Vision. <http://www.allaboutvision.com/conditions/meibomian-gland.htm>

Indications and Important Safety Information

LIPIFLOW® Thermal Pulsation System

INDICATIONS FOR USE: The LipiFlow System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including Meibomian Gland Dysfunction (MGD), also known as Evaporative Dry Eye or Lipid Deficiency Dry Eye.

CONTRAINDICATIONS: Do not use the LipiFlow System in patients with the following conditions. Use of the device in patients with these conditions may cause injury. Safety and effectiveness of the device have not been studied in patients with these conditions.

- Ocular surgery within prior 3 months, including intraocular, oculo-plastic, corneal or refractive surgery procedure
- Ocular injury within prior 3 months
- Ocular herpes of eye or eyelid within prior 3 months
- Active ocular infection (e.g., viral, bacterial, mycobacterial, protozoan, or fungal infection of the cornea, conjunctiva, lacrimal gland, lacrimal sac, or eyelids including a hordeolum or sty))
- Active ocular inflammation or history of chronic, recurrent ocular inflammation within prior 3 months (e.g., retinitis, macular inflammation, choroiditis, uveitis, iritis, scleritis, episcleritis, keratitis)
- Eyelid abnormalities that affect lid function (e.g., entropion, ectropion, tumor, edema, blepharospasm, lagophthalmos, severe trichiasis, severe ptosis)
- Ocular surface abnormality that may compromise corneal integrity (e.g., prior chemical burn, recurrent corneal erosion, corneal epithelial defect, Grade 3 corneal fluorescein staining, or map dot fingerprint dystrophy)

PRECAUTIONS: The Activator or Activator II (Disposable) may not fit all eyes, such as eyes with small palpebral fornices. Use of the LipiFlow System in patients with the following conditions may result in reduced treatment effectiveness because these conditions may cause ocular symptoms unrelated to cystic meibomian glands and require other medical management. Safety and effectiveness of the device have not been studied in patients with these conditions.

- Moderate to severe (Grade 2-4) allergic, vernal or giant papillary conjunctivitis
- Severe (Grade 3 or 4) eyelid inflammation (e.g., blepharochalasis, staphylococcal blepharitis or seborrheic blepharitis). Patients with severe eyelid inflammation should be treated medically prior to device use
- Systemic disease conditions that cause dry eye (e.g., Stevens-Johnson syndrome, vitamin A deficiency, rheumatoid arthritis, Wegener's granulomatosis, sarcoidosis, leukemia, Riley-Day syndrome, systemic lupus erythematosus, Sjögren's syndrome)
- Taking medications known to cause dryness (e.g., isotretinoin (Accutane®) and systemic antihistamines)
- Esthetic eyelid and eyelash procedures (e.g., blepharoplasty, lash extensions, eyelid tattooing)

In addition, the treatment procedure may loosen previously inserted punctal plugs, which may worsen the patient's dry eye symptoms.

POTENTIAL ADVERSE EFFECTS: Potential adverse effects that may occur as a result of the procedure include, but are not limited to, the onset or increase in

- Eyelid/eye pain requiring discontinuation of the treatment procedure
- Eyelid irritation or inflammation (e.g., edema, bruising, blood blister, dermatitis, hordeolum or chalazion)
- Ocular surface irritation or inflammation (e.g., corneal abrasion, conjunctival edema or conjunctival injection (hyperemia))
- Ocular symptoms (e.g., burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance, sensitivity to light)

Potential serious adverse events (defined as permanent impairment or damage to a body structure or function or necessitates medical or surgical intervention to preclude permanent impairment or damage to a body structure or function) that are not anticipated because of the device mitigations to prevent occurrence include:

- Thermal injury to the eyelid or eye, including conjunctiva, cornea or lens
- Physical pressure-induced injury to the eyelid
- Ocular surface (corneal) infection

LipiView® II Ocular Surface Interferometer

INDICATIONS FOR USE: The LipiView II Ocular Surface Interferometer is an ophthalmic imaging device that is intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of:

- Specular (interferometric) observations of the tear film. Using these images, LipiView II measures the absolute thickness of the tear film lipid layer.
- Meibomian glands under near-infrared (NIR) illumination.
- The ocular surface and eyelids under white illumination.

CONTRAINDICATIONS: Contraindications are conditions in which the device should not be used because the risk of use clearly outweighs any benefit. No contraindications have been identified for LipiView II.

PRECAUTIONS: The following patient conditions may affect the interferometry assessment of a patient's tear film using LipiView II:

- Use of ophthalmic drops such as artificial tear lubricants, ointments, and medications. Advise patients not to instill oil-based ophthalmic drops (e.g., Soothe®, Restasis®, Systane Balance®) for at least 12 hours prior to device use and not to instill ointments for at least 24 hours prior to device use. Wait at least four (4) hours after the instillation of all other ophthalmic drops prior to device use.
- Soft or rigid contact lens wear. Advise patients to remove contact lenses at least four hours prior to device use.
- Use of oil-based facial cosmetics around the eye.
- Eye rubbing.
- Recent swimming in a chlorinated pool. Advise patients not to swim for at least 12 hours prior to device use.
- Any ocular surface condition that affects the stability of the tear film. These conditions include disease, dystrophy, trauma, scarring, surgery, or abnormality.

POTENTIAL ADVERSE EFFECTS: There are no known or anticipated adverse effects associated with use of this device.

LipiScan™ Dynamic Meibomian Imager

INDICATIONS FOR USE: LipiScan™ Dynamic Meibomian Imager (DMI) is an ophthalmic imaging device intended for use by a physician in adult patients to capture, archive, manipulate and store digital images of the meibomian glands.

CONTRAINDICATIONS: Contraindications are conditions in which the device should not be used because the risk of use clearly outweighs any benefit. No contraindications have been identified for the LipiScan.

PRECAUTIONS: Precautions provide information regarding any special care to be exercised by the practitioner for the safe and effective use of the device, as described below. Caution: Disinfect the surfaces of the chin rest, forehead rest and Handheld Near Infrared (IR) Lid Everter with isopropyl alcohol immediately prior to use and prior to storage to prevent cross-contamination and patient infection.

POTENTIAL ADVERSE EFFECTS: There are no known or anticipated adverse effects associated with use of this device.