



**PATIENT INFORMATION FOR LIPIFLOW® TREATMENT
(Treatment for Meibomian Gland Dysfunction / Evaporative Dry Eye)**

The information in this document is to help you decide whether or not to have a LipiFlow® Treatment. Please carefully read this document in its entirety. Ask your doctor any questions that you may have about the information in this document prior to having a LipiFlow® Treatment.

INTRODUCTION

The surface of the eye is covered in a lining of tears called the tear film. The tear film is made up of three layers: a Lipid (oil) layer which lubricates and prevents evaporation of the tears; an Aqueous (water) layer, which nourishes and protects the eye surface; and a Mucin layer, which adheres to the eye. Since the tear film is exposed directly to the air, the protective lipid layer is essential to maintaining a healthy tear film on the eye. When the protective lipid layer of the tear film is lacking, the eye surface can become irritated and dry eye symptoms can occur.

Evaporative Dry Eye is a disease that results from not having enough lipid in the tear film to protect the eye. Evaporative dry eye is most often caused by a blockage or obstruction of the eyelid glands, called the Meibomian Glands, which produce the lipid layer of the tear film. Meibomian Gland Dysfunction is a disease that results from the formation of plugs inside the glands, which obstruct gland openings and limit the lipid secreted by the glands into the tears.

WHAT IS THE LIPIFLOW® SYSTEM?

The LipiFlow® System is a medical device used by a doctor to apply heat and pressure to the eyelids to allow the lipids from the blocked eyelid glands to flow into the tear film. Your doctor will determine if the LipiFlow® System is an appropriate treatment option you based on a complete exam of your eye health, including evaluation for blocked glands and associated dry eye symptoms.

WHAT ARE THE INDICATIONS FOR LIPIFLOW® TREATMENT?

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.

WHAT ARE ALTERNATIVE TREATMENTS FOR MGD AND EVAPORATIVE DRY EYE?

Possible alternative treatments for MGD and evaporative dry eye include:

- Manual expression of your eyelid glands by your doctor.
- Warm compress therapy and eyelid hygiene using scrubs and manual massage.

- Topical prescription medications
- Over-the-counter tear replacements and lubricants for dry eye.
- Punctal plugs made of silicone or collagen inserted in the tear ducts.
- Cauterization (sealing) of the opening of the tear duct in the eye.

WHAT SHOULD I EXPECT DURING A LIPIFLOW® TREATMENT?

The 12-minute treatment will begin with you either resting in a reclined chair or lying comfortably on a table in a procedure room. Your doctor will place 1-2 drops of a mild anesthetic in the eye(s) to be treated. Your doctor will gently fit the LipiFlow® (Disposable) eyepiece under your eyelids. You will be asked to close your eyes gently around the eyepiece and keep them closed. The LipiFlow® will be activated. You will begin to feel both gentle pressure and warmth on your eyelid. The eyepiece will become gradually warmer on your eyelids. Once the temperature reaches a therapeutic range, the device will maintain this temperature for 2 minutes at a constant pressure. This is when the glands are being brought to the appropriate temperature to begin melting the blockages within the glands. At the end of the 2 minutes, the pressure will be released briefly. Next, the temperature will be maintained but the pressure will go through different modes, including slow increasing pressure and pulsation, for several cycles throughout the remaining 10 minutes of treatment. This is done to facilitate removing the blockages from the glands.

WHAT ARE THE CONTRAINDICATIONS OF THE LIPIFLOW® TREATMENT?

The LipiFlow® System should **not** be used 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. Ask your doctor if you have any of the following conditions.

- Recent eye surgery, eye injury or a *Herpes* infection of the eye or eyelid, or chronic recurrent eye inflammation within the prior 3 months
- Current eye infection or eye inflammation
- Eyelid abnormality that affects eyelid function
- Eye surface abnormality that may affect the integrity of the eye surface

WHAT ARE THE PRECAUTIONS REGARDING LIPIFLOW® TREATMENT?

The eyepiece used for treatment (Disposable) may not fit all eyes, such as eyes with small eyelid anatomy. Use of the LipiFlow® System is **not** recommended in patients with the following conditions. Patients with these conditions may have reduced treatment effectiveness because these conditions may cause eye symptoms unrelated to cystic meibomian glands. Safety and effectiveness of the device have not been studied in patients with these conditions. Ask your doctor if you have any of the following conditions.

- Moderate to severe allergy in the eye
- Severe eyelid inflammation. Patients with severe eyelid inflammation should be treated medically prior to device use.
- Systemic disease conditions that cause dry eye
- Taking medications known to cause dryness

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

WHAT ARE THE WARNINGS REGARDING LIPIFLOW® TREATMENT?

You should be aware of the following warnings related to the LipiFlow® System.

- Federal law restricts this device to sale by or on the order of a licensed physician.
- You should be under direct supervision during the entire length of treatment
- Remove contact lenses prior to treatment. You can resume contact lens wear one hour after completion of treatment unless there is an adverse effect, as determined by you and your doctor. In the event of an adverse effect such as, eye surface irritation, inflammation or discomfort, your doctor will advise you when to resume contact lens wear following resolution of the effect.
- Do not to attempt to remove the eyepiece (Disposable) from your eye during treatment
- Keep your eyelids closed during treatment. If your eyelids are not closed, the eyepiece (Disposable) will not be in the proper position to provide appropriate treatment of your eyelids.
- In case of discomfort, your doctor can reduce the pressure applied to your eyelids or pause the treatment at any time.

WHAT ARE THE RISKS AND POTENTIAL ADVERSE EFFECTS OF THE LIPIFLOW® TREATMENT?

There is no guarantee that you will receive any medical benefit as a result of the LipiFlow® treatment. It is possible that your dry eye symptoms and blocked eyelid glands will improve. It is also possible that your condition will remain the same or worsen.

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

- Eyelid or eye pain requiring discontinuation of the treatment procedure;
- Eyelid irritation or inflammation (for example, eyelid swelling, itching, stye);
- Eye surface irritation or inflammation (for example, scratch on the eye surface, swelling of the eye surface or eye redness); and
- Eye symptoms (for example, burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance, sensitivity to light).

Potential serious adverse events that are **not** anticipated because of the device mitigations to prevent occurrence include:

- Heat-related injury to the eyelid or eye;
- Physical pressure-induced injury to the eyelid; and
- Eye surface infection.

In addition, the LipiFlow® treatment may involve risks that are unforeseeable. There is always the possibility that you will have an adverse event or problem that is currently unknown and unexpected. You should discuss any questions or concerns you might have with your doctor. If you experience any problems during the treatment, it is important that you tell your doctor.

Patient's Name

Patient's Signature / Date

Doctor's Signature / Date