

## **Informed Consent for the LipiFlow® Treatment**

### **INTRODUCTION**

Please read this consent form carefully. Take time to ask as many questions as you want so that you can decide if there are any words or information you do not clearly understand.

### **NATURE AND PURPOSE OF TREATMENT**

Dry eye is a common problem that may result in symptoms of eye discomfort, blurred vision and possible damage to the surface of the eye. People with dry eye symptoms use different methods to ease their discomfort. For some people, relief of their dry eye symptoms is incomplete because there is a lack of the oily layer of the tear film. The tear film is the lining of tears that lubricates the eye surface. The tear film consists of a mucus layer, a water layer and an oily layer. The outer oily layer keeps the inner tear layers on the eye surface. The oily layer is produced by eyelid glands, called meibomian glands, which release oils from openings along the lining of the eyelids. These eyelid glands can become blocked so that there is not enough oily layer in the tear film, which can lead to dry eye symptoms.

The LipiFlow® System is a medical device used by a doctor to apply warmth and massage to the eyelids to allow the oils from the blocked eyelid glands to flow into the tear film. During an eye examination, the doctor conducts testing to determine if the LipiFlow® System is a treatment option for a patient with blocked eyelid glands and associated dry eye symptoms.

### **LipiFlow® Device Description**

The LipiFlow® System is approved by FDA. The LipiFlow® System provides controlled warmth and massage to the eyelids. The doctor places the device around and behind the eyelids. The device rests gently on the eye, similar to a contact lens but it does not touch the cornea, the clear front surface of the eye. The LipiFlow® System directs the controlled warmth to the inner eyelid surface while protecting and insulating the eye from the warmth. The temperature of warmth applied by the LipiFlow® System is slightly above normal body temperature, and below the level that will cause a burn to the eyelid or eye based on prior animal and human clinical studies. The LipiFlow® System also applies controlled massage to the outer eyelid surface to release oils from the blocked eyelid glands into the tear film.

\_\_\_\_\_ **INITIALS**

You will be seated for the treatment. Your doctor will put numbing drops into your eyes to make your eyes more comfortable. Your doctor will fit the device around and behind your eyelids. You will be asked to keep your eyelids closed during the procedure to ensure that the device is in the proper position to treat the eyelid glands.

During treatment, you will feel warmth and a pressure sensation on your eyelids. The treatment will take 12 minutes for each eye. At all times, your doctor will monitor the treatment process. At the end of the treatment, your doctor will remove the device from your eyelids and examine your eyes.

You may experience minor eye irritation or discomfort from the procedure lasting a few minutes.

### **Potential risks associated with the LipiFlow® Device Treatment**

Potential adverse events that have been identified for the LipiFlow® treatment procedure may include onset of or increase in:

- eye or eyelid pain
- eyelid swelling
- eyelid irritation
- stye or inflammation of the glands in the eyelid
- scratch on the front surface of the eye
- swelling of the conjunctiva (clear lining of the eyelid and eye)
- eye symptoms of burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance and sensitivity to light

In addition, if you have punctal plugs inserted in your eyes, the treatment procedure may loosen the plugs, which may worsen your dry eye symptoms.

The LipiFlow® System has been used in prior clinical studies and the following adverse events have been reported: moderate eye/eyelid pain, eyelid irritation, stye, inflammation of the eyelid glands, and onset or increase in eye redness. All of these events were transient and resolved within a day to 2 weeks. Medical treatment was provided for the eyelid irritation, stye, and inflammation of the eyelid glands.

\_\_\_\_\_ **INITIALS**

Serious adverse events that would result in persistent or significant disability are not anticipated with use of the LipiFlow® System because device safety features have been put into place to reduce these risks. Serious risks that are possible but unlikely to occur include:

- burn or injury to the eyelid or eye related to the temperature of warmth applied by the device
- permanent mechanical injury to the eyelid from the eyelid pressure applied by the device
- eye infection

No serious adverse events have been reported in prior clinical studies of the LipiFlow® System.

### **ALTERNATIVE TREATMENTS**

**Other alternatives to the use of the LipiFlow® System include:**

- Topical pharmaceutical medicines for dry eye and/or blocked eyelid glands
- Punctal plugs made of silicone or collagen inserted in the tear duct in the eye
- Cauterization of the opening of the tear duct in the eye
- Manual expression of your eyelid glands
- Warm compress therapies and eyelid scrubs

### **POTENTIAL BENEFITS**

There is no guarantee that you will receive any medical benefit as a result this of 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.

With the clinical information available today, the positive results of this treatment are known to last 9-18 months. It may be necessary to repeat the LipiFlow® treatment annually.

\_\_\_\_\_ **INITIALS**

I understand and I acknowledge that no guarantees have been made to me concerning the results of the LipiFlow® procedure.

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Patient Name

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Date

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Patient Signature

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Date

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Witness Name

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Date

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Witness Signature

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Date