LipiFlow Informed Consent

LipiFlow Thermal Pulsation System

- The LipiFlow is a 12- minute bilateral procedure
- Initial anesthetic drop will be administered
- Contoured design vaults the cornea and protects the eye from any heat or pressure
- As a result, the obstructed meibum is liquefied and pushed up and out of the gland orifices
- By the simultaneous heat and a gentle pulsatile pressure to the upper and lower eyelids that helps to unblock and evacuate the stagnant debris from the glands.

Recommended LipiFlow Instructions

- Remove contact lenses prior to treatment. You may resume contact lens wear one hour after completionof treatment unless there is an adverse effect. As determined by the physicianor patient.
- Do not attempt to remove the Activator (eyepiece) from your eye during the treatment. In case of discomfort, we can pause the treatment to re-position the Activator (eyepiece).
- Keep eyelids closed during the treatment. If your eyelids are not closed the Activator (eyepiece) will not be in the proper position to provide appropriate treatment to the eyelids.

Precautions

- 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.
    - 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)
- The Activator (eyepiece) may not fit all eyes, such as eyes with small palpebral fornices
- Procedure may loosen previously inserted punctal plugs, which may worsen the patient's dry eye symptoms.
- Esthetic eyelashes may become unglued

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 or Ocular herpes of eye or eyelid within prior 3 months
- 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)

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

Patient Name (printed)_____

Patient Signature_____ Date_____