

# INFORMED CONSENT AND RELEASE TO EXPERIENCE iLUX® DRY EYE TREATMENT DEVICE

## Family Vision Care

By signing below I, \_\_\_\_\_, acknowledge that I have unilaterally requested and hereby consent to have a Family Vision Care employee who has been trained to utilize the iLux device administer the iLux® device on myself. I understand the iLux® device is indicated for the application of localized heat and pressure therapy in adult patients with chronic disease of the eyelids, including Meibomian Gland Dysfunction (MGD), also known as evaporative dry eye.

I also understand the use of the iLux device is contraindicated for the following conditions: persons (i) whose pupils have been pharmaceutically dilated, (ii) who have undergone ocular surgery within the last 3 months, (iii) who have experienced ocular injury or trauma, chemical burns, or limbal stem cell deficiency within the last 3 months, (iv) who have had active ocular herpes zoster or simplex of eye or eyelid or a history of these within the last 3 months, (v) who have had cicatricial lid margin disease identified via slit lamp examination, active ocular infection, active ocular inflammation or history of chronic, recurrent ocular inflammation within the last 3 months, (vi) who have ocular surface abnormality that may compromise corneal integrity, lid surface abnormalities that affect lid function in either eye, aphakia or permanent makeup or tattoos on their eyelids, moderate to severe allergic, vernal or giant papillary conjunctivitis, severe eyelid inflammation, systemic disease conditions that cause dry eye, or (vii) who are taking medications known to cause dryness.

**Precautions:** Punctal plugs — the treatment procedure may loosen previously inserted punctal plugs, which may worsen the patient's dry eye symptoms.

I acknowledge proparacaine will be administered to numb my eyes before beginning treatment with iLux. I have considered the following precautions regarding this drug: **Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Long-term studies in animals have not been performed to evaluate carcinogenic potential, mutagenicity, or possible impairment of fertility in males or females.

**Pregnancy:** Animal reproduction studies have not been conducted with proparacaine. It is also not known whether proparacaine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Proparacaine hydrochloride should be administered to a pregnant woman only if clearly needed.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when proparacaine hydrochloride is administered to a nursing woman.

I also understand potential adverse effects may include eyelid/eye pain requiring discontinuation of the treatment procedure, eyelid irritation or inflammation, temporary reddening of the skin, ocular surface irritation or inflammation and ocular symptoms.

By signing below, I am confirming that I am voluntarily agreeing to undergo administration of the iLux device and confirming that I do not have any of the above conditions, considered the precautions regarding proparacaine and understand the potential adverse events that can occur as a result of treatment with the iLux device.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Treatment Personnel Signature: \_\_\_\_\_ Date: \_\_\_\_\_