

***iLux*® MGD Treatment System**

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. Do not use the *iLux*® Device in patients with the following conditions: Patients whose pupils have been pharmaceutically dilated; patients who have undergone ocular surgery within prior 12 months; patients with ocular injury or trauma, chemical burns, or limbal stem cell deficiency (within prior 3 months); patients with active ocular herpes zoster or simplex of eye or eyelid or a history of these within prior 3 months; patients with cicatricial lid margin disease; patients with active ocular infection, active ocular inflammation or history of chronic, recurrent ocular inflammation within prior 3 months; patients with an ocular surface abnormality that may compromise corneal integrity; patients with lid surface abnormalities that affect lid function in either eye; patients with aphakia; or patients with permanent makeup or tattoos on their eyelids. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Use of the *iLux*® Device is not recommended in patients with the following conditions: moderate to severe allergic, vernal or giant papillary conjunctivitis; severe eyelid inflammation; systemic disease conditions that cause dry eye; in patients who are taking medications known to cause dryness; or patients with punctal plugs. 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 (e.g., corneal abrasion, conjunctive edema or conjunctival injection (hyperemia)), and ocular symptoms (e.g., burning, stinging, tearing, itching, discharge, redness, foreign body sensation, visual disturbance, sensitivity to light). Please refer to the User Manual for a complete list of contraindications, instructions for use, warnings and precautions for the *iLux*® Device.