

# Home Use Radio-Frequency Device for Peri-Orbital Wrinkles Clinical Trial Inclusion & Exclusion Criteria. Please Read Carefully

## Inclusion Criteria

- Having visible lines and wrinkles in the peri-orbital region of the face (eyes)
- Healthy male and female subjects age 30 - 65 years of age
- Skin type I to VI ( all population skin colors)
- Willingness to sign informed consent, follow the treatment and maintenance schedule and post-treatment care instructions
- For females only - Must be either post-menopausal or surgically sterilized, or using a medically acceptable form of birth control at least three months prior to enrollment

## Exclusion Criteria

- Previously treated in the eye area within the past 6 months using energy based device for facial skin treatment
- Pregnant or planning to become pregnant, having given birth less than 3 months ago, and/or breast feeding
- Having an electrical implant in the treated area, such as metal plates or injected chemical substance such as silicone
- Known photosensitivity
- Use of substances that's cause photosensitivity within 6 weeks of treatment
- Use of retinoid, antioxidants or skin nourishing supplements in medical concentration within 2 months of treatment
- Use of isotretinoin (Accutane) within 4 months of treatment or during the study
- Having received a facial dermabrasion or chemical pee within three months
- having received Botox/collagen/fat injections or other methods of augmentation with injected or implanted material within 6 months
- Undergone a resurfacing procedure, face lift or eyelid surgery within a year of treatment
- Undergone any other surgery in the treated area within 6 months of treatment
- History of keloids scarring or of abnormal wound healing
- Suffering from significant skin conditions or inflammatory skin conditions in the treated area
- Having any active eye disease/disorder or experiencing uncontrollable twitches in the treated area or its proximity
- History of immunosuppressant/immune deficiency disorders (including HIV infection or AIDS)
- Having a known anticoagulative or thromboembolic condition or taking anticoagulation medications one week prior to and during the treatment course
- Having undergone any form of treatment for active cancer, or having a history of skin cancer or pre-malignant pigmented lesions
- Suffering from significant concurrent illness, such as cardiac disorders, diabetes (type I or II) lupus or porphyria
- Recently tanned in area to be treated and/or unable or unlikely to refrain from tanning during the study