

**INDICATIONS FOR USE - EpiCare-DUO™**

The Light Age, Inc. EpiCare-DUO™ Laser System is intended for use in general and plastic surgery, dermatology, and podiatry for the treatment of vascular lesions, benign pigmented lesions, for removal of dark tattoo inks and reduction of hypertrophic and keloid scars, hair removal, and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hair regrowth after a treatment regime on all skin types (Fitzpatrick I-VI including tanned skin.)

**Intended Use**

**755nm** – Specifically the 755 nm mode is indicated

- Hair removal, and stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles on all skin types (Fitzpatrick I-VI) including tanned skin. Permanent hair reduction is defined as long-term stable reduction in the number of hair regrowth after a treatment regime. The number of hairs re-growing must be stable over a time greater than the duration of the complete growth cycle of hair follicles, which varies from 4-12 months according to body location. Permanent hair reduction does not necessarily imply the elimination of all hairs in the treated area.
- Treatment of vascular lesions
- Treatment of benign pigmented lesions.
- Treatment of wrinkles.

**1064nm** –

- Removal of unwanted hair, for stable long term or permanent hair reduction on all skin types Fitzpatrick I-VI including tanned skin.
- Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemoangioma, warts, telangiectasia, rosacea, venus lake, leg veins, and spider veins and poikiloderma of civatte. Coagulation and hemostasis of soft tissue.
- Benign cutaneous lesions such as warts, scars striae and psoriasis.
- Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.
- Pigmented lesion size reduction in patients with lesions who would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Treatment of pseudofolliculitis barbae (PFB).
- Treatment of wrinkles including but not limited to periocular wrinkles and perioral wrinkles.

**Safety and Efficacy**

In the nearly one decade of use with over 1 million treatments performed, the EpiCare™ product family has been proven to be clinically safe with no reports of significant patient or operator injury.