

*The following Informed Consent Form for OptiLight IPL Treatments is suggested as a sample only. Lumenis takes no liability on this document and encourages modification to fit individual needs and practices, in order to meet local regulatory requirements.*

*Please read and initial each statement. Complete, underline or circle individual selection accordingly.*

- |   | <u>Initials</u> |
|---|-----------------|
| • I authorize Doctor _____ to perform IPL™ treatments on me in an effort to improve Dry Eye Disease due to Meibomian Gland Dysfunction  | _____           |
| • I understand that without eye protection, IPL applied near the eyes may cause severe ocular complications   | _____           |
| • I understand that there is a rare possibility of side effects or serious complications including permanent discoloration and scarring. I am aware that careful adherence to all advised instructions will help reduce this possibility  | _____           |
| • I understand the below list of short-term effects and agree to follow matching guidelines: <ul style="list-style-type: none"> <li>▪ Flaking of pigmented lesions – crusts may take 5 to 10 days to disappear and it is important not to manipulate or pick which may otherwise lead to scarring</li> <li>▪ Discomfort – during the procedure, I might experience a sensation similar to a rubber band snap which degree will vary per my skin condition and area sensitivity but that does not last long. A mild “sun-burn” sensation may follow for typically up to one hour and will be reduced with application of cooling and soothing creams</li> <li>▪ Reddening and swelling – severity and duration depend on the intensity of the treatment and the sensitivity of the area to be treated. These phenomena may be reduced with application of cooling and/or anti-inflammatory creams</li> <li>▪ Bruising may rarely occur and may last up to 2 weeks</li> </ul> | _____           |
| • I understand that sun exposure or tanning of any sort is not aligned with the pre and/or post-care instructions and may increase the chance for complications   | _____           |
| • The procedure as well as potential benefits and risks have been thoroughly explained to me and I have had all my related questions answered   | _____           |
| • Pre and post-care instructions have been discussed and are completely clear to me   | _____           |
| • I understand that results may vary with each individual and acknowledge that it is impossible to predict how I will respond to the treatment and how many sessions will be required   | _____           |
| • I consent to photographs being taken for the purpose of documenting my progress and response to the treatment and be kept solely in my medical record   | _____           |
| • I consent to photographs being used for medical education or publication with applied discretion and not revealing my identity  | _____           |
| • I agree to review the following IPL™ pre-treatment compliance checklist along with my Physician and bring accurate and updated data, to the best of my knowledge  | _____           |

For Dry Eye Disease due to Meibomian Gland Dysfunction:

Skin type of the area to be treated: I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/>			
OptiLight	Ocular surgery or eyelid surgery, within 6 months prior to the first IPL session?	NO	YES
	Neuro-paralysis in the planned treatment area, within 6 months prior to the first IPL session ?	NO	YES
	Uncontrolled eye disorders affecting the ocular surface, for example active allergies ?	NO	YES
	Pre-cancerous lesions, skin cancer or pigmented lesions in the planned treatment area ?	NO	YES
	Uncontrolled infections or uncontrolled immunosuppressive Diseases ?	NO	YES
	Ocular infections, within 6 months prior to the first IPL session ?	NO	YES
	Prior history of cold sores or rashes in the perioral area or in the planned treatment area that could be stimulated by light at a wavelength of 560 nm to 1200 nm, including: Herpes simplex 1 & 2, Systemic Lupus erythematosus, and porphyria ?	NO	YES
	Within 3 months prior to the first IPL session, use of photosensitive medication and/or herbs that may cause sensitivity to 560-1200 nm light exposure, including: Isotretinoin, Tetracycline, Doxycycline, and St. John's Wort ?	NO	YES
	Radiation therapy to the head or neck, within 12 months prior to the first IPL session ?	NO	YES
	Planned radiation therapy, within 8 weeks after the last IPL session	NO	YES
	Treatment with chemotherapeutic agent, within 8 weeks prior to the first IPL session ?	NO	YES
	Planned chemotherapy, within 8 weeks after the last IPL session ?	NO	YES
	History of migraines, seizures or epilepsy ?	NO	YES
	Tattoos in the planned treatment area ?	NO	YES
	Exposure to sun or artificial tanning during 3-4 weeks prior to Treatment ?	NO	YES
	Any remaining suntan, sunburn or artificial tanning products ?	NO	YES

My signature certifies that I duly read and understood the content of this informed consent form, and that I gave the accurate information as to my health condition. I hereby freely consent to OptiLight IPL treatments

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Name of patient (please print)

Signature of patient

Date

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Name of witness (please print)

Signature of witness

Date

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433 SE Main St  
Suite B  
Simpsonville, SC 29681  
P: 864-963-4933  
F: 864-963-4933

644 N Main St  
Suite 109  
Greenville, SC 29601  
P : 864-900-0671  
F: 864-900-0671

### **IPL PRE-TREATMENT PATIENT INSTRUCTIONS**

**The primary reason for your treatment is the improvement of Dry Eye signs and symptoms. You must know that IPL is also used for and has been shown to reduce the appearance of red and brown spots on the skin from rosacea and unwanted age spots for example. The only intention of your treatment is the improvement of the signs and symptoms of dry eye disease, ocular surface disease, and Meibomian gland dysfunction.**

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#### ***Pretreatment Patient Education***

Patients should be aware of the following prior to performing the IPL procedure:

- Results are not guaranteed
- Not all red and brown areas will disappear
- Red and brown spots removed by treatment may recur, especially with excessive sun exposure.
- Deep wrinkle lines will not be removed by the treatment.
- Adverse effects may include redness, swelling, burning, pain, crust formation, bruising, hyper-and hypo pigmentation, and scar information.
- Multiple treatment sessions (minimum of 4 consecutive separated by 2 to 3 weeks) are required for optimal results.
- Maintenance dry eye treatment will be reviewed with each patient individually.

#### ***Pretreatment Patient instructions***

- Do not take isotretinoin (Accutane) for 1 month before treatment.
- If you are tanned or have been tanning, please reschedule your appointment with the advice and direction of your doctor
- Do not apply makeup or lotions on your face the day of treatment, or be prepared to remove them to completion at our office
- If you have a history of cold sores, take your prescribed medications (Valtrex, Famvir, Zovirax) on the day before, day of and the day after treatment. **Let our doctors know prior to arrival.**
- Inform our staff before each appointment if you (1) are taking new medications or (2) have tattoos or beauty marks you do not want to be altered.
- Inform the staff immediately if the area being treated feels "too hot"

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### IPL POST TREATMENT INSTRUCTIONS

Immediately after treatment patients may notice slight redness on their eyes, eyelids, and face. This may last anywhere from several hours to three days. Patients will be given individualized eye and eyelid regimens to improve outcomes and minimize any unintended discomfort. Dryness and grittiness may be worse with in the first 1-3 treatments and especially within the first couple of days of treatment due to evacuation of diseased oil.

Pigmented areas on the skin may also appear darker. Superficial pigment may darken, dry and slough off within seven to ten days. Deeper pigment darkens, and then slowly fades as the body absorbs the remnants of damaged pigment. In addition to discussing expected post treatment sequelae, patients are given the following instructions:

- Apply sunscreen everyday (30 SPF or greater)
- If the treated area is red and irritated after treatment you may apply an ice pack or cold compresses
- In caring for the treated area, use only gentle cleansers and lotions until healing is complete. Avoid perfumes and products with alcohol or acid.
- If a blister develops, notify the office immediately for directions on how to safely manage this. Do not pick the blister or scab because a scar may form.
- Call our office if any additional problems, questions, or concerns arise.

We look forward to your feedback and follow up on this revolutionary dry eye treatment!

# Skin typing assessment quiz

One of the most important factors in deciding which Laser/IPL™ (and settings) to use is the patient skin type. Skin typing is determined by genetics, reaction of the skin to sun exposure and tanning habits. The following skin type quiz<sup>1</sup> is intended **as a sample only** to provide additional help in the evaluation of an individual skin type. *Skin typing of the area to be treated* is to be assessed. Lumenis takes no liability on that document and its content is not intended to be a substitute for professional medical diagnosis.

<b>Genetic predisposition</b>						<b>Report Score</b> ↓
<b>Score →</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	
What is the color of your eyes?	Light blue, grey, green	Blue, grey or green	Blue	Dark brown	Brownish black	.....
What is the natural color of your hair?	Sandy red	Blond	Chestnut, dark blond	Dark brown	Black	.....
What is the color of your skin (non-exposed areas)?	Reddish	Very pale	Pale with beige tint	Light brown	Dark brown	.....
Do you have freckles on non-exposed areas?	Many	Several	Few	Incidental	None	.....

**Total score for genetic predisposition:** .....

<b>Reaction to sun exposure</b>						<b>Report Score</b> ↓
<b>Score →</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	
What happens when you stay in the sun too long?	Painful redness, blistering, peeling	Blistering followed by peeling	Burns sometimes followed by peeling	Rare burns	Never had burns	.....
To what degree do you turn brown?	Hardly or not at all	Light colour tan	Reasonable tan	Tan very easy	Turn dark brown quickly	.....
Do you turn brown within several hours after sun exposure?	Never	Seldom	Sometimes	Often	Always	.....
How does your face react to the sun?	Very sensitive	Sensitive	Normal	Very resistant	Never had a problem	.....

**Total score for reaction to sun exposure:** .....

<b>Tanning habits</b>						<b>Report Score</b> ↓
<b>Score →</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	
When did you last expose your body to sun (or artificial sunlamp/self-tanning cream)?	More than 3 months ago	2-3 months ago	1-2 months ago	Less than a month ago	Less than 2 weeks ago	.....
Did you expose the area to be treated to the sun?	Never	Hardly ever	Sometimes	Often	Always	.....

**Total score for tanning habits:** .....

**Add up the total scores for each of the three sections for your Skin Type Score:** .....

<sup>1</sup> Quiz adapted from the Radiation protection (tanning units) amendment regulation by the Australian Government Health Directorate and the American Skin Cancer Foundation