

Patient informed consent form

For acne treatment with AviClear™

(NOTE: THIS PATIENT INFORMED CONSENT TEMPLATE IS PROVIDED “AS IS” AND IS INTENDED FOR INFORMATIONAL PURPOSES ONLY. THIS TEMPLATE MAY NOT MEET ALL STATE AND FEDERAL LEGAL OR REGULATORY REQUIREMENTS FOR USE WITH PATIENTS. PHYSICIANS USING THIS TEMPLATE ARE RESPONSIBLE FOR ENSURING THAT THE INFORMED CONSENT FORM USED WITH PATIENTS MEETS ALL APPLICABLE STATE AND FEDERAL LEGAL AND REGULATORY REQUIREMENTS, AND ARE ENCOURAGED TO CONSULT WITH THEIR ATTORNEY.)

I hereby authorize _____ or _____, under Dr. _____ supervision to treat my acne using AviClear™. I acknowledge that my provider has diagnosed me with mild, moderate, or severe acne. I understand that multiple treatments may be required. Although rare, it is possible the result will be minimal or may not help at all.

The procedure may result in the following adverse experiences or risks:

- **Discomfort:** Mild to moderate discomfort is typical during treatment.
- **Erythema and edema:** Mild to significant erythema (redness) and mild to moderate edema (swelling) are common during or developing within several minutes of treatment. Erythema typically resolves within 20 min to several hours, and edema typically resolves within several hours to a day; however, both can last for several days. Application of cold packs immediately after treatment may reduce the severity and duration of both. Swelling and/or redness that develops a few days after treatment, especially if accompanied by warmth, should be evaluated by the treating physician.
- **Transient acne flareups:** Mild flareups of inflammatory acne lesions are common after treatment. Flareups have been reported by up to 44% and 50% of subjects enrolled in clinical studies conducted with the AviClear Laser System with moderate and severe inflammatory acne vulgaris prior to treatment, respectively. If acne flareups occur, they typically maximize 2 to 5 days after treatment and resolve over 2 to 3 weeks; however, acne flareups can continue at perceptible levels for several more weeks.
- **Temporary skin dryness:** Temporary mild skin dryness is common after treatment and has been reported by up to 22% of female and 13% of male subjects enrolled in clinical studies conducted with the AviClear Laser System. If skin dryness occurs, it is normally noticed 1-2 days after treatment and typically resolves in a few days to 2 weeks with application of topical skin moisturizers (e.g., CeraVe®, Cetaphil®); however, it can persist up to 4 weeks.
- **Blisters:** Mild to moderate blisters developing during or within several hours of treatment are uncommon but have been reported. If blisters do develop, care should be taken not to disturb or unroof the blisters to prevent oozing and possible infection. Oozing from blisters that are disturbed or unroofed lasting more than a day should be evaluated by the treating physician.
- **Crusting/scabbing:** Mild crusting or scabbing is rare but has been reported as typically following blistering. If crusting/scabbing occurs, the crusts/scabs should be allowed to natural slough, without picking, to minimize the likelihood of skin pigmentation changes.
- **Hyperpigmentation:** Brown darkening of the skin (hyperpigmentation) can occur either following blistering or crusting, or as a result of inflammation during the recovery period. If it occurs, it may last for one to several months before normal pigmentation levels return. Hyperpigmentation is very rarely permanent. Your treating physician may recommend topical skin-lightening products to accelerate the return to normal pigmentation levels.
- **Skin texture changes:** Transient texture changes are rare and usually resolve with time.
- **Infection:** Despite good wound care, pain, swelling, oozing, and fever can indicate the development of an infection. Topical and/or oral antibiotics may be necessary.

- **Scarring:** Scarring is a rare occurrence, but it is a possibility whenever the skin's surface is disrupted. To minimize the chances of scarring, it is important that patients follow all posttreatment instructions provided by their healthcare provider. Good post-treatment care will help reduce the possibility of scarring.
- **Hypopigmentation:** Lightening or loss of skin pigment (hypopigmentation) is very rare. Transient hypopigmentation lasting several weeks has been reported following crusting/ scabbing. Permanent hypopigmentation has not been reported; however, it is a possible adverse event, especially in patients with a history of vitiligo or pigmentary disorders.
- **Altered hair growth:** The use of lasers that heat the pilosebaceous unit may affect both the sebaceous gland and structures of the hair follicle. Therefore, it is possible that treated areas may exhibit altered hair growth in the future.

I acknowledge the following points have been discussed with me:

- This treatment is not meant to prophylactically treat acne.
 - A flare-up can occur in clear skin.
- Potential benefits of the treatment of acne, including the possibility that the procedure may not work for me
- Alternative treatments, such as topical or oral medications or even surgery
- Reasonably anticipated health consequences if the procedure is not performed
- Possible complications/risks involved with the proposed procedure and subsequent healing period

For women of childbearing age: By signing below I confirm that I am not pregnant and do not intend to become pregnant at any time during the course of treatment. Furthermore, I agree to keep Dr. _____ and staff informed should I become pregnant during the course of treatment.

Photographic documentation will be taken. I hereby do ___do not___ authorize the use of my photographs for teaching purposes.

ACKNOWLEDGMENT

BY MY SIGNATURE BELOW, I ACKNOWLEDGE THAT I HAVE READ AND FULLY UNDERSTAND THE CONTENTS OF THIS INFORMED CONSENT FORM FOR TREATMENT OF ACNE, AND THAT I HAVE HAD ALL MY QUESTIONS ANSWERED TO MY SATISFACTION BY MY HEALTHCARE TEAM.

Signature-Patient or Guardian	Print Name/Relationship	Date
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Signature-Witness	Print Name	Date
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