



Pellevé® / PelleFirm® RF Skin Treatment System Contraindications

As a patient, it is important that you understand the possible results and risks of **radiofrequency (RF) skin treatment with Pellevé® or PelleFirm® handpieces (Pellevé)**. Please read this document carefully. Before signing this document, ask your doctor or the clinician providing the treatment (Clinician) about any aspect of this document or the procedure that you do not understand.

Pellevé System equipment may present a hazard to patients with active implanted devices (e.g. pacemakers, defibrillator, cochlear implant, diabetic pump, etc.) or inactive metal implants (e.g. artificial jaw/joint, metal IUDs, etc.) that are near the treatment area. Tell your clinician if you have any metal or active implants.

Since ongoing patient feedback is required during treatment, if you have any nerve insensitivity to heat in the treatment area, you should not be treated with Pellevé.

Tell your clinician if you have a history or current symptoms of any of the following conditions PRIOR to being treated. Your clinician will determine if you are a candidate for the procedure at this time.

- Skin disease in the treatment area
- Active cut, wound, or infection in the treatment area, including cold sores
- Collagen or vascular disease (e.g. scleroderma)
- Autoimmune disease (e.g. rosacea, eczema, severe dermatitis, or lupus)
- Any disease that inhibits pain sensation

Tell your clinician if you have a history of or are currently taking any of the following prescriptions PRIOR to being treated. Your clinician will determine if you are a candidate for the procedure at this time.

- Oral steroids
- Topical steroids in the treatment area
- Oral Isotretinoin (Accutane®)
- Tretinoin (Retin-A®),
- Glycolic or Salicylic Acid
- Any medication that can cause dermal hypersensitivity or affect skin characteristics

Wait at least two weeks after neurotoxin or filler for Pelleve.

Pellevé equipment is unstudied and unknown for pregnant or lactating patients, patients with autoimmune disease, diabetes, or herpes simplex. All patients are different and exact results of the treatment(s) cannot be predicted or guaranteed.

During Treatment

If the eyelids are to be treated directly plastic, non-conductive eye shields will be used to cover your eyes.

All jewelry and makeup, including lotions, eyeliner and eye shadow should be removed from the treatment area prior to treatment.

Cut, wounded or infected skin should not be treated as this could promote infection and injury.

Ensure you are well hydrated prior to treatment. With good hydration, the tissue is more responsive to heat.

Excessive hair in the treatment area will need to be removed (shaved or closely trimmed) prior to treatment as heating may be compromised. Thick facial hair should be clean shaven.

During the treatment you should feel warmth and heat and provide ongoing feedback to the individual performing the treatment. Therefore no anesthetic (local, oral, or systemic) should be used prior to or during the treatment. Additionally, if you have nerve insensitivity to heat anywhere in the treatment area, you should not be treated. Inadequate or impaired feedback may lead to burns or injury. Ongoing feedback should be provided by you to the individual performing the treatment to ensure a safe and effective treatment.

Slight discomfort may be experienced while undergoing treatment due to the strong heating sensation generated. Typically the discomfort is mild and temporary during the procedure and localized within the treatment area. **Inform the clinician immediately if you experience any pain or a burning sensation.**

After Treatment

Studies indicate the possible side effects are usually treatment site related and include mild discomfort during the procedure localized within the treatment area. Mild swelling and redness may occur which typically goes away within 2 to 24 hours. There is the possibility that additional risk factors of radiofrequency skin treatments exist that are not yet known.

Possible Risks

Risks associated with Pellevé are well known and include:

- Mild swelling post-treatment
- Mild redness post-treatment

Swelling and redness are temporary in nature and typically resolve quickly. As with any radiofrequency treatment, burning is also possible. In order to avoid a burn, it is important that you tell your clinician if the treatment becomes too hot.