

DERMIS P.C.
LAURENCE KIRWAN, M.D., Medical Director
LISA TOPHAM, R.N., Aesthetic Director

RADIANCE

Informed Consent/Acknowledgement of Receipt of Information

Patient Name: _____

Today's Date: _____

Connecticut law requires that your physician obtain your informed consent to medical treatment. In keeping with the Connecticut state law, you are being asked to sign a confirmation that we have discussed the nature of your condition, your contemplated medical procedure, the general nature of the proposed treatment, the request of the proposed treatment and the risks of such alternatives. Your physician have discussed with you the common problems or risks. We wish to inform you as completely as possible. You are also being asked to sign a confirmation that you have been given the opportunity to ask whatever questions you had and that your questions have been answered in a satisfactory manner. Please read the form carefully. Ask about everything you do not understand and we will be pleased to explain it.

1. I hereby authorize and direct Lisa Topham R.N. to perform the following medical procedure: Injection of Radiance™ FN (calcium hydroxylapatite microspheres in gel carrier) into lips, facial folds or lines, depressed scars, or other areas of depression. The product is CE approved for facial restoration and augmentation.
2. The nature of my condition for which treatment is indicated and recommended is depressions and lines of face.
3. This procedure has been explained to me. Alternative methods have also been explained to me, as have the advantages and disadvantages. The risks of not being treated have also been explained to me. I am advised that though good results are expected, the possibility and nature of complications cannot be accurately anticipated and that, therefore, there can be no guarantee as expressed or implied either as to the success or other result of treatment or as to cure. As with any implant material, possible adverse reactions that may occur include, but are not limited to, the following: inflammation, infection, fistula formation, extrusion, haematoma, seroma, induration formation, inadequate healing, skin discoloration and inadequate or excessive augmentation.
4. Safety and effectiveness during pregnancy has not been established.

An alternative to this procedure and the associated risk are not to have the injection of Radiance. Risks of having this procedure are:

1. Poor cosmetic results, extrusion, infection, unequal lips, folds, or areas of depression, possible further surgery, swelling, granuloma formation, allergic reaction, firm hard areas on lips, folds, or lines, inadequate correction of depressions, lines or lips. Radiance™ cannot be called permanent. Reabsorption of implant will probably occur. Other material risks generally associated with the treatment and particular risks, if any associated with my complicating medical condition are:

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2. This is CE approved for facial restoration and augmentation.
 3. Radiance FN requires soft tissue for easy percutaneous injection. Scar tissue and significantly compromised tissue may not accept Radiance FN appropriately.

4. Infection requiring treatment may occur at the injection site. If such infection cannot be corrected, it may become necessary to remove the implant.
5. Injection related reactions, including erythema, swelling pain, itching discoloration or tenderness, may occur at the site of the injection. These usually resolve spontaneously within one to two after the injection.
6. Nodule(s) may form requiring treatment or removal
7. Irregularity of the implant may occur which may require a surgical procedure to correct.
8. The Radiance FN injection procedure, like similar injection procedures, has small but inherent risks of infection and/or bleeding. The patient may experience slight discomfort during and following the procedure. Therefore, anesthetic techniques common with this treatment should be considered. The usual precautions associated with percutaneous injection procedures should be followed to prevent infection.

Contraindications

- Presence of acute or chronic inflammation or infection in the treated area.
- Patients with known hypersensitivity to Radiance or any of its components
- Patients prone to developing inflammatory skin conditions or those patients with a tendency to develop hypertrophic scars
- Glabellar folds
- Presence of foreign bodies such as liquid silicone or other particulate materials
- Radiance FN should not be implanted in patients while the patient is on an aspirin regimen or while taking other medications that could cause bleeding or inhibit the healing process.

I hereby state that I have read and I understand this consent and I understand the information contained in it. I have had the opportunity to ask any questions about the treatment including risks or alternatives and acknowledge that all my questions about the procedure have been answered in a satisfactory manner, and that all blanks were filled in prior to my signature. THE CONSENT FORM IS VALID UNTIL ALL OR PART IS REVOKED BY ME IN WRITING.

Date: _____ Time: _____ AM / PM

Signature of Patient: _____

Witness _____

I have provided and explained the information set forth herein and answered all questions of the patient or the patient's representative concerning treatment.

Signature of Physician: _____