

# CONSENT FORM for Radiance™

Consent for Medical/Surgical Procedures and Acknowledgement of Receipt of Information

Patient's Name: \_\_\_\_\_

Today's Date: \_\_\_\_\_

[Name of State] law requires that your physician obtain your informed consent to medical and surgical treatment. In keeping with the [Name of State] state law, you are being asked to sign a confirmation that we have discussed the nature of your condition, your contemplated operation or medical procedure, the general nature of the proposed treatment/surgery, the request of the proposed treatment/surgery, the prospects for success, the reasonable therapeutic alternatives to the treatment/surgery, and the risks of such alternatives. Your physician has 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 Dr. [Physician name here] and/or associates or assistant of [his/her] choice to perform upon [Patient name] the following surgical, diagnostic, or medical procedure:

Injection of Radianceä FN (calcium hydroxylapatite microspheres in gel carrier) into lips, facial folds or lines, depressed scars, or other areas of depression. This product is not FDA approved for this procedure.

2. My diagnosis/nature of my condition for which treatment/surgery is indicated and recommended is [insert diagnosis/condition here].

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/surgery or as to cure. The possible risks include death, brain damage, quadriplegia, paraplegia, loss or loss of function of any organ, of arms or legs, disfigurement including disfiguring scars, infection or hemorrhage and the other risks of this treatment/surgery have been explained to me including the risks known to be associated with treatment/procedures as required by the [Name of State] Medical Disclosure Panel.

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

1. Poor cosmetic result, 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. Radianceä cannot be called permanent. Reabsorption of implant will probably occur. Other material risks generally associated with the treatment/procedure and particular risks, if any, associated with my complicating medical condition are: [insert risks here].

2. This is not yet FDA approved for lip augmentation or correction of depressions and lines. The effects on the body are unknown at this time. Long term effects are unknown.

3. I further authorized the doctors to perform any other procedures that in their judgment are advisable for my wellbeing. I hereby authorize and direct the above named physician and/or associate of doctor's choice or assistants to provide such additional service as they may deem reasonable and necessary including, but not limited to, the administration of any general or regional anesthetic agent, or the services of the X-Ray Department or laboratories and I hereby consent thereto.

4. Any tissue or parts surgically removed may be disposed of by the hospital in accordance with accustomed practice and I consent thereto.

I hereby state that I have read (or it has been read to me) 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 or procedures have been answered in a satisfactory manner, and that all blanks were filled in prior to my signature. THIS CONSENT FORM IS VALID UNTIL ALL OR PART IS REVOKED BY ME IN WRITING.

Date: \_\_\_\_\_ Time: \_\_\_\_\_ AM / PM

I UNDERSTAND THE EXPERIMENTAL USE OF THIS PRODUCT

Signature of Patient \_\_\_\_\_

Signature of Patient Representative \_\_\_\_\_

Witness \_\_\_\_\_ 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/surgery.

Signature of Physician \_\_\_\_\_

Order by priority when consenting to medical/surgical procedure (except for care and treatment of any mentally retarded person who is a resident of certain state operated facilities).

1. Any competent adult, age 18 or older, for himself.
2. The judicially appointed curator of a patient, if one has been appointed.
3. An agent acting pursuant to a valid mandate (power of attorney), specifically authorizing the agent to make health care decisions.
4. The patient's spouse not judicially separated.
5. An adult child of the patient.
6. Any parent whether adult or minor for his/her minor child.
7. The patient's sibling.
8. The patient's other ascendants or descendants.
9. Any person temporarily standing in loco parentis, whether formally serving or not, for the minor under his care, and guardian for his ward.

If there is more than one person within the same class above, then the consent of the majority of those members of the class available for consultation is required.