

Patient Access Program Application Form

PATIENT INFORMATION (to be filled out by patient)

Name of Patient	Date of Birth		
Address	City	State	Zip
Phone Number	Alternative Phone Number		

Please complete the following information:

1. Patient's ANNUAL income, including social security and pension benefits: \$ _____
(Patient: Please include supporting documentation such as W2, 1099 or similar form)
2. The product use for this patient is consistent with the following FDA-approved indication for RADIESSE :
 RADIESSE[®] is intended for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus. Yes No
3. Does patient qualify for insurance coverage for RADIESSE in a public program? Yes No
If yes, patient is not eligible for assistance program

RADIESSE is a prescription filler to help with the restoration and/or correction of facial fat loss in adults with HIV.
Please refer to Important Safety Information on page 3.

PATIENT STATEMENT AND AUTHORIZATION

By signing this document, I hereby give my consent to my healthcare provider and Merz North America, Inc. (Merz North America) , including their representatives and vendors, to obtain, use and disclose information about my health insurance coverage and income for purposes of determining my eligibility for the RADIESSE Patient Assistance Program (PAP). The parties authorized to disclose such information also include my health insurer, employer(s), and any of my healthcare providers.

I understand that Merz North America reserves the right to modify or discontinue the RADIESSE Patient Assistance Program and its eligibility criteria at any time without further notice to me. I have read this document and understand it. The information I have provided above, including my income and insurance information, is complete and accurate. I represent that I am not eligible for and do not have any form of insurance for RADIESSE.

Patient's Signature	Date
---------------------	------

Check box if you consent to Merz contacting you directly.

Patient Access Program Application Form

PRACTICE INFORMATION

Physician's Name _____ Specialty _____

Facility Name _____ Account# (if new customer - leave blank) _____

Address (PRODUCT SHIPMENT PURPOSES) _____ City _____ State _____ Zip _____

Phone Number _____ Fax Number _____

Provide one of the following:

DEA # _____ NPI # _____ State and State License # _____

Office Contact Name _____ Contact Phone Number _____

Email _____

INDICATION

RADIESSE[®] has been approved for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus.

RADIESSE is a prescription filler to help with the restoration and/or correction of facial fat loss in adults with HIV. **Please refer to Important Safety Information on next page.**

NUMBER OF SYRINGES REQUESTED (1.5cc per syringe) for the patient listed on the next page:

1 2 3 4 5 6

LICENSED PRACTITIONER STATEMENT:

I agree to administer the RADIESSE injectable implant provided under this application only to the patient listed below for the FDA-approved indication listed above and for no other purpose. I certify that the product provided hereunder will not be resold nor offered for sale, trade or barter and will not be returned for credit. To the best of my knowledge, the patient for whom I am requesting RADIESSE under this application has no insurance coverage, whether private or governmental, for RADIESSE treatment. I understand that Merz North America reserves the right to modify or discontinue the Patient Access Program and its eligibility criteria at any time without further notice.

Name of Patient for whom product is being requested _____

Licensed Physician's Signature _____ Date _____

For Internal Use Only: (circle as appropriate, sign and date)					
Approved	Not Approved	Training Confirmed: Yes / No	Price per 1.5 cc syringe: \$80 / \$120 / \$ _____		
				Signature	Date

RADIESSE[®]

VOLUMIZING FILLER

INDICATION

RADIESSE[®] has been approved for restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with human immunodeficiency virus.

RADIESSE IMPORTANT SAFETY INFORMATION

Contraindications: RADIESSE injectable implant is contraindicated for patients with known hypersensitivity to any of the components, severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; and patients with bleeding disorders.

Warnings: Use of RADIESSE in any person with active skin inflammation or infection in or near the treatment should be deferred until the inflammatory or infectious process is controlled. Do not overcorrect (overfill) a contour deficiency with RADIESSE because the depression should gradually improve within several weeks as the treatment effect of RADIESSE occurs. The safety and effectiveness for use in the lips has not been established.

Precautions: RADIESSE contains calcium hydroxylapatite, radiopaque particles, that are visible on CT Scans and may be visible in standard radiography. Patients using medications that can prolong bleeding, such as aspirin or warfarin, may experience increased bruising or bleeding at the injection site. Patients should minimize exposure of the treated area to extensive sun or heat exposure for approximately 24 hours after treatment or until any initial swelling and redness has resolved.

RADIESSE is for one-time, Single Patient Use Only. Do not use if needle is bent. Do not re-shield used needles. Discard needles and syringes as potential biohazards. If mixing RADIESSE with lidocaine, use within 2 hours of mixing.

Safety of RADIESSE beyond 3 years; in the periorbital area; with concomitant dermal therapies or other drugs or implants; in patients with susceptibility to keloid formation and hypertrophic scarring; in pregnancy, in breastfeeding females or in patients under 18 years has not been established. As with all transcutaneous procedures, there is a risk of infection with RADIESSE. Patients with a history of herpetic eruption may experience reactivation of herpes.

Adverse Events: The most common serious adverse events from post market surveillance include necrosis, allergic reaction, edema and infection. The most common physician reported adverse events (>5%) with RADIESSE included contour irregularity, edema and ecchymosis. The most common patient reported adverse events (>5%) with RADIESSE include ecchymosis, edema, erythema, pain, pruritis, contour irregularity and lumps. Common adverse events with RADIESSE are generally mild in nature.

For Instructions for Use Document and Complete Safety Information please go to www.radiesse-fl.com or call Merz Customer Service at 866-862-1211.