

**RADIESSE® Dermal Filler**  
**to add fullness to the back of the hands**

**PATIENT INFORMATION GUIDE**

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This guide will help you decide whether treatment with RADIESSE on the back of the hand is right for you. This information does not take the place of a discussion with your doctor. This guide will answer some questions you may have about RADIESSE treatment on the back of the hand.

- Only you and your doctor can decide whether RADIESSE is right for you. The information provided in this guide is only for the hands.
- Please read all the information in this guide and discuss any questions with your doctor before you are treated with RADIESSE on the back of the hand
- RADIESSE is also available to correct facial wrinkles and folds and you may want to discuss these other treatment options with your doctor. A separate guide is available for RADIESSE treatments to correct wrinkles and folds in the face.

Keep this information. You may want to read it again.

## **GLOSSARY**

(Note that terms in the glossary are underlined throughout this guide)

Anesthetic: a substance that reduces sensitivity to pain

Calcium Hydroxylapatite (CaHA): a substance that is naturally in the body. CaHA is part of what makes up bone and teeth. The CaHA found in RADIESSE is a man-made form of the CaHA found naturally in your body.

Dermal filler: a substance that is injected in the skin to create a smoother and/or fuller appearance in the hands

Necrosis: death of one or more cells, or of a portion of tissue or organ of the body, resulting from irreversible damage to cells.

Microspheres: round particles of CaHA which are smaller than grains of salt

Opaque: not able to be seen through, not transparent or clear

Tendon: a non-stretchy fibrous cord or band in the body that connects muscle to a bone or other structure inside the body

Topical: a cream or ointment applied on top of the skin and affecting only the area to which is it applied

Touch-up: an additional injection of a small amount of dermal filler usually given about 2 weeks to 1 month after the first injection for treatment of the hands. A touch-up treatment may be needed to get the desired cosmetic result.

## **ABOUT RADIESSE**

### **What is RADIESSE?**

RADIESSE is an opaque, white colored injectable dermal filler that is made up of CaHA microspheres in a water-based gel. RADIESSE is non-animal based and free from animal protein. Before you are injected, you do not have to be tested to see if you are allergic to RADIESSE.

**What is RADIESSE used for?**

RADIESSE is injected under your skin on the back of your hands (not your palms) to add volume to lessen the visibility of veins and tendons in your hands due to loss of fullness.

**How does it work?**

RADIESSE is injected under the skin with a thin needle to plump the skin and add volume to the back of your hands. RADIESSE will not correct the underlying causes of loss of fullness in the hands. RADIESSE will not be injected into your wrist or fingers.

**SAFETY INFORMATION****Are there any reasons why I should not receive RADIESSE?**

Your doctor will ask about your medical history to determine if you are a good candidate for injection of RADIESSE. In order to avoid complications and unsatisfactory results, RADIESSE should not be used if:

- You have severe allergies marked by a history of severe reactions (anaphylaxis), or history or presence of multiple severe allergies. Use of this product may result in an allergic reaction.
- You have had a severe reaction (hypersensitivity) to any of the components (CaHA, sterile water, sodium carboxymethylcellulose, glycerin). Use of this product may result in an allergic reaction.
- You have a bleeding disorder.

**What are some Warnings to consider?**

It is important that you tell your doctor about your medical history. Together, you can make an informed decision as to whether RADIESSE is right for you. Because the use of RADIESSE can result in a significant injury, you should understand the risks:

- One of the risks with using this product is unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin. If you have changes in your vision, signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms, or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion), white appearance of the skin, or unusual pain during or shortly after treatment, you should notify your health care practitioner immediately.
- Do not use RADIESSE if you have an active skin inflammation or infection on or near the hand until the inflammation or infection has been controlled.

RADIESSE has not been studied in patients with very severe loss of fatty tissue with marked visibility of veins and tendons. The safety of RADIESSE in this patient population is unknown.

**What precautions should my doctor tell me about?**

The following are important treatment considerations for you to discuss with your doctor and understand in order to help avoid unsatisfactory results and complications.

- Minimize strenuous activity and limit exposure of the treated area to sun or heat exposure for 24 hours after treatment. These activities may cause increased swelling and redness in your hand.
- The CaHA microspheres of RADIESSE are visible on CT scans and may be visible in standard, plain radiography (x-rays). Tell your doctor, as well as your radiologist, that you have had RADIESSE injected in your hands so that they are aware it is present when they are looking at your CT scans or x-rays. It is presently unknown if RADIESSE could interfere with diagnosis of a hand injury on imaging studies.
- The effect of RADIESSE on hand function is uncertain.
- The risk of using RADIESSE in the back of the hand in patients with diseases, injuries or disabilities of the hand has not been studied. Since the side effects are not known, tell your doctor if you have an autoimmune disease affecting the hand, if you have one or more hand implants, if you have Dupuytren's contracture, if you have a history of hand tumor, if you have some malformation of the blood vessels, Reynaud's disease, and you have been told that you are at risk for tendon rupture.
- Tell your doctor if you are or think you might be pregnant. Tell your doctor if you are breastfeeding. The safety of RADIESSE for use during pregnancy, or in women who are breastfeeding has not been established.
- Tell your doctor your age. The safety of RADIESSE injection in hands of patients under 26 years or over 79 years has not been studied.
- Tell your doctor about all the medicines you are taking. Some medicines can increase bruising or bleeding after RADIESSE injection.
- Tell your doctor if you have had dermal therapies on your hands such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures. The safety of RADIESSE with these procedures has not been evaluated in controlled clinical trials and the risks are not known.
- Tell your doctor if you have a history of herpes. Injection of RADIESSE into patients with a history of herpes can activate herpes.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars) and/or skin over or under pigmentation. The safety of RADIESSE in patients who scar easily has not been studied. Use in these patients may result in additional scars and changes in skin pigmentation.
- No studies of interactions of RADIESSE with drugs, or other substances, or implants have not been studied and the risks are unknown.

**What are possible side effects?**

- In a clinical study of RADIESSE for hand injection, the majority of the patients (79% or 79 out of 100) had side effects that were mild or moderate in nature. The most common side effects were related to the injection procedure itself and usually lasted less than or equal to 14 days. Based on the clinical study, the likelihood of experiencing a side effect after treatment with RADIESSE reported by patients is shown in Table 1.

**Table 1**  
**Percent of Patient Reported Side Effects After Treatment**

Side Effect	Percent (%) of Patients Reporting Side Effects
Swelling	99% (99 out of 100 people)
Pain	92% (92 out of 100 people)
Redness	81% (81 out of 100 people)
Bruising	73% (73 out of 100 people)
Difficulty Performing Activities	48% (48 out of 100 people)
Itching	46% (46 out of 100 people)
Loss of Sensation	15% (15 out of 100 people)
Bumps/Lumps	6% (6 out of 100 people)*
Hematoma (blood clot in the tissue)	1% (1 out of 100 people)

\*This percentage does not include side effects reported by physicians. The total percent of patients that had nodules, bumps, or lumps in the study was reported to be 12% (12 out of 100 people).

- In the clinical study of RADIESSE for hand injection, the percent of patients that reported a side effect lasting longer than 14 days after treatment were:
  - Swelling (29%; 29 out of 100 people)
  - Pain (25%; 25 out of 100 people),
  - Bumps/lumps (7%; 7 out of 100 people)
  - Difficulty performing activities (6%; 6 out 100 people)
  - Redness (6%; 6 out of 100 people)
  - Itching (3%; 3 out of 100 people)
  - Bruising (3%; 3 out of 100 people)
  - Hematoma (1%; out of 100 people)
- RADIESSE injection carries a risk of infection that may be treated with antibiotics. If you experience an infection and it does not resolve with antibiotics, surgery may be needed to remove RADIESSE.
- You may feel RADIESSE material in your skin after your treatment. It may feel firm if you touch the area that was injected. This feeling should go away over several weeks.
- Injection of RADIESSE in the back of your hand may result in temporary difficulty in performing activities (see Table 1 for details). If you have a dark skin tone there is an increased risk for this side effect.

- Radiesse may cause bumps or lumps in your hand (see Table 1 for details). This side effect may last up to a 1 year.
- The higher the amount of Radiesse that is injected in the back of your hand, the more likely you could have a side effect. This may include increased chances of bruising, swelling, pain, redness and difficulty performing activities.
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with Radiesse, swelling may occur at the implant site. This can also happen if you receive a Radiesse injection before the skin has healed after a laser treatment or chemical peel.

## **BENEFITS of Radiesse**

### **What will Radiesse accomplish?**

It will temporarily provide fullness to the back of the hands.

### **How long do treatment effects last?**

Treatment effects will differ for each person. In a clinical study, 113 patients were injected with no more than 3.0 mL of Radiesse on the back of each hand. The average injection was 2.5 mL per hand.

After 6 months from the initial injection, patients were given the opportunity to have a second treatment of Radiesse. In general, the amount of the second injection was significantly less than the first treatment (average of 1.6 mL per hand).

The effectiveness of Radiesse on correcting volume loss in the hands was evaluated by a 5 point scale that ranged from 0-4. In this scale, 0 is described as “no loss of fatty tissue, no visibility of veins or tendons” and 4 is described as “a very severe loss of fatty tissue and marked visibility of veins and tendons.”

The results of the study showed that Radiesse was effective in correcting volume loss in the hands. For patients that received only one injection, the number of patients that showed at least 1-point improvement was:

- At 3 months: 77% (77 out of 100 people)
- At 9 months: 71% (71 out of 100 people)
- At 12 months: 68% (68 out of 100 people)

For patients that received a second treatment, the number of patients that had at least 1-point improvement was:

- 82% (82 out of 100 people) after 3-months from the second injection
- 89% (89 out of 100 people) after 6-months from the second injection.

### **What are some benefits of Radiesse that have been shown in clinical studies?**

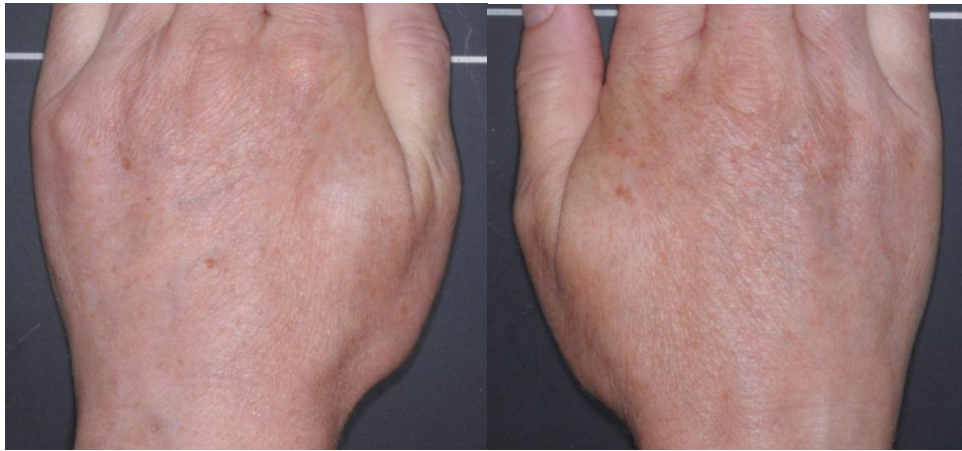
Radiesse has been shown to improve the appearance of the hands by adding fullness to the back of the hands, as reported by both patients and doctors.

Fullness of the back of the hands 3 months after treatment

**BEFORE TREATMENT**



### THREE MONTHS AFTER TREATMENT



On a 5-point scale, both hands were improved by 2 points.  
Individual results may vary.

## ABOUT THE PROCEDURE

### Do the injections hurt?

Injections may cause some discomfort during and after the procedure. Radiesse is injected in small amounts using a very fine needle. You and your doctor may also decide to numb the treatment area with a topical or injected anesthetic to reduce your discomfort.

### What can I expect to happen at a treatment session?

Note that each doctor may have a different process for assessing and treating patients. The following is an example of what you would experience with a typical procedure:

#### Before treatment:

- Your doctor will answer all of your questions and prepare you for the treatment. You can use the space at the end of this Guide to write down your questions before you see your doctor.
- Your doctor will ask you questions about your medical history.
- Remove all jewelry such as rings before injection. Do not put on jewelry until your hands are no longer swollen.
- Your doctor will clean the area where the injections will be given.

- You and your doctor will determine if a topical or local anesthetic is needed.

**During Treatment:**

- Your doctor will inject small amounts of RADIESSE into the skin in multiple areas across the back of your hand using a thin needle until you have received the desired correction.
- Your doctor may gently massage the treatment area to ensure the product is evenly distributed.

**After Treatment:**

- Your doctor may periodically apply an ice pack to the treatment area to help reduce swelling.
- Your doctor will give you specific after-treatment care instructions.

**How many treatments are required to get the look I want?**

The number of treatments required to get the look you want depends on your hands and your personal treatment plan.

Your doctor will decide with you the number of treatment sessions you will need and the amount of RADIESSE you will need at each treatment session. A touch-up treatment may be required to get the desired outcome.

## **ADDITIONAL INFORMATION**

**What should I do if I have a problem after a RADIESSE treatment? When should I call my doctor?**

If you believe that you have experienced a problem related to your RADIESSE treatment, you should call your doctor. You may also call Merz North America during normal business hours at 1-866-862-1211 to report any side effects.

**What should I do if I have additional questions?**

For further questions and information, please call Merz North America at 1-866-862-1211.

## **QUESTIONS FOR MY DOCTOR**

Use the lines below to write down questions you may want to discuss with your doctor.



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