MERZ AESTHETICS®

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

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.

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

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, other substances, or implants have 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

N = 113 Subjects

Side Effect	Number and Percent (%) of Patients Reporting Side Effects
	Number (N) / Percentage (%)
Swelling	N = 112; (99%)
Pain	N = 104; (92%)
Redness	N = 92; (84%)
Bruising	N = 84; (74%)
Difficulty Performing Activities	N = 52; (46%)
Itching	N = 52; (46%)
Loss of Sensation	N = 17; (15%)
Bumps/Lumps	N = 7; (6%)
Hematoma (blood clot in the tissue)	N = 1; (0.9%)

*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% (14 out of 113 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.

- A post approval study was conducted to evaluate the effect of RADIESSE® on hand X-Rays to determine if RADIESSE® would obscure the visualization of the bones. The purpose of the PAS is to provide a radiological evaluation of hands after implantation with RADIESSE® to evaluate if implantation interferes with radiological assessment by obscuring the bones of the hand. The study enrolled 20 qualifying subjects at least 22 years of age with moderate to very severe volume loss in the dorsum of their hands based on the Merz Hand Grading Scale (MHGS), 10 with moderate to severe volume loss (MHGS grades 2 and 3) and 10 with very severe volume loss (MHGS grade 4). Subjects were in the study for approximately 24 months. Subjects were treated with RADIESSE® in the dorsum of the hands after baseline X-rays, and had the opportunity to receive up to three (3) repeat treatments over 2 years of follow-up. The retreatment interval was every six months as agreed upon by the treating investigator and the subject.
- The Protocol executed the following schedule for Subject Visits

  1- If a subject only received the initial treatment; there were a total of 7 in-office clinic visits, 3 X-ray visits, and 1 follow-up phone call.

  2- For each of the 3 optional retreatments received, there was an additional follow-up phone call (72-hours post injection).

  3- The fourth X-ray visit was only required at Month 12 if obscuration was present in the 6 month X-ray, and

  4- The fifth X-ray visit was only conducted if a subject received all 4 total treatments of RADIESSE® in this study.

- X-Rays were taken at multiple time points in the study and although RADIESSE® was visible in the X-Ray it did not obscure hand bones.
- Side effects reported by patients in this study were similar to those reported in the original clinical study of RADIESSE® in the hands.

Have there been adverse events reported through postmarket surveillance?

Table 2. Subject reported Post Approval Study Adverse Events

N = 20 Subjects

Event	# of subjects with event	% of subjects treated
Swelling	20 (100.0%)	100.0%
Redness	18 (90.0%)	90.0%
Bruising	17 (85.0%)	85.0%
Pain	16 (80.0%)	80.0%
Difficulty performing activities requiring the hands	9 (45.0%)	45.0%
Itching	8 (40.0%)	40.0%

The following adverse events have been identified during post-approval use of RADIESSE®. Because they are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to RADIESSE®. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to RADIESSE®: (skin) infection, loss of aesthetic effect, product displacement/migration, allergic reaction including serious reaction, hives, rash, itch, superficial and deep skin swelling, inflammation, tissue damage, nodules, skin hardening, redness, skin discoloration, pustule, hair loss, tingling, drooping of the upper eyelid, pain, headache, asymmetry (treatment area), abscess, herpetic infection including herpes simplex and herpes zoster, bruising, blanching, blistering, dizziness, festoons, flu-like symptoms, muscular weakness or tingling, rapid breathing, decreased blood flow, swelling of lymph tissue, nausea, swelling of the tissue surrounding the heart, scarring, sensitivity to cold, blocking/narrowing of blood vessels including in the eye, double vision, visual impairment/blindness, facial muscle paralysis.

Based on information reported to Merz about the use of RADIESSE®, your physician may recommend additional interventions after RADIESSE®: antibiotics, anti-inflammatories, corticosteroids, anti-histamines, analgesics, massage, warm compress, excision, drainage, and surgery. This information does not constitute and is not intended to be medical advice, a recommendation on how to treat an adverse event or an exclusive list of possible interventions. Your physician should always evaluate each individual case, and independently determine what treatments(s), if any, are right for you.

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)

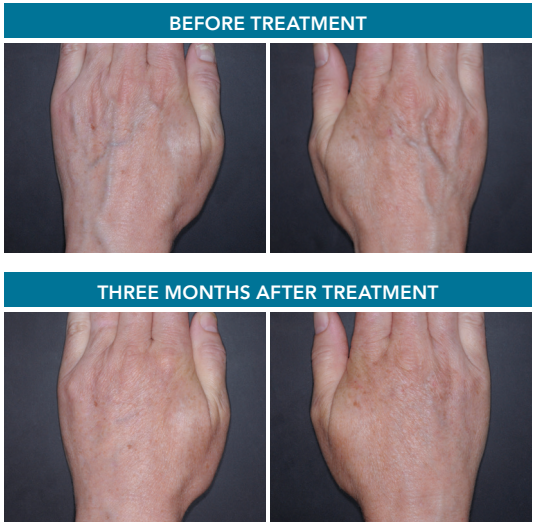
For patients that received a second treatment, the number of patients that had at least 1-point improvement was:

- 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



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 844.469.6379 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 844.469.6379.

QUESTIONS FOR MY DOCTOR

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