

MERZ AESTHETICS®

RADIESSE®

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RADIESSE® for the Correction  
of Wrinkles in the Décolleté

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# PATIENT INFORMATION GUIDE

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**Caution:** Federal law restricts this device to sale by or on the order of a licensed healthcare professional.

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

- Only you and your doctor can decide whether RADIESSE® is right for you. Other treatments are available to correct wrinkles, and you may discuss these treatment options with your doctor.
- Please read all the information in this guide and discuss any questions with your doctor before you are treated with RADIESSE®.

**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 or correct wrinkles.

## Microspheres

Round particles of CaHA which are smaller than grains of salt.

## Opaque

Not able to be seen through, not transparent or clear.

## Topical

A cream or ointment applied on top of the skin and affecting only the area to which is it applied.

Note that terms in the glossary are underlined throughout this guide

## ABOUT RADIESSE®

### What is RADIESSE®?

RADIESSE® is an opaque, white colored material made up of CaHA microspheres in a water based gel injected into the skin to smooth away wrinkles such as those in the décolleté. 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 into your skin to smooth away wrinkles such as those in the décolleté.<sup>1</sup>

### How does it work?

When used in the décolleté, RADIESSE® is first diluted in a 1:2 ratio with sterile saline (1.5 mL of RADIESSE® + 3 mL saline). The diluted product is then injected into the skin with a thin, flexible cannula to smooth décolleté wrinkles.

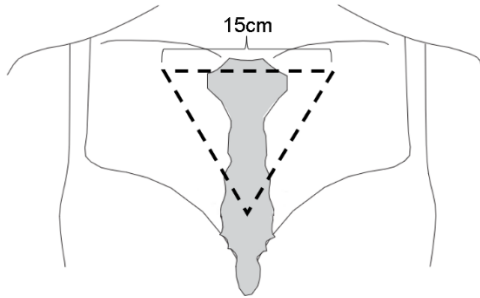
Your doctor will inject the product into your skin to make the wrinkles shallower and smoother. RADIESSE® will not correct the underlying causes of wrinkles.

<sup>1</sup> See the device IFU for further information

## PROCEDURAL INFORMATION

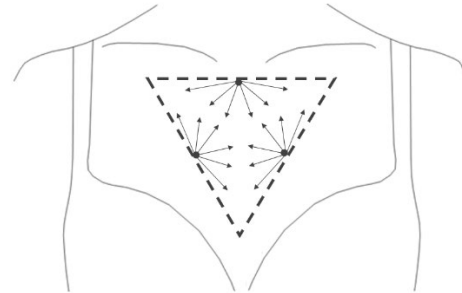
### Where is the injection made?

RADIESSE® is injected in the décolleté area defined in the image below. This triangular area is in the mid upper chest, with the upper limit just below where your collarbones meet the top of your chest, extends out to the middle of each collarbone on the sides, and ends at the top of the natural crease between the breasts.



### How will the injections take place?

Your doctor will prepare the product for your procedure by diluting RADIESSE® in a 1:2 ratio with sterile saline. Your doctor will mark the décolleté area and proceed to inject the diluted RADIESSE® using a flexible cannula into the layer of tissue just below the skin, as shown below.



## 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®. To avoid complications and unsatisfactory results, RADIESSE® should not be used if:

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

### What are some Warnings to consider?

It is important to share your medical information with your doctor. Together you can make an informed decision as to whether RADIESSE® is right for you. Because use could result in significant injury, RADIESSE® should not be used in the following cases:

- **Warning:** One of the risks of using RADIESSE® 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.
- Radiesse® should not be used in any person with active skin inflammation or infection in or near the treatment area until the inflammation or infection has been controlled.
- Injection procedure reactions have been observed consisting mainly of short-term (i.e. < 7 days) bruising, redness and swelling.
- Safety of Radiesse® injected into the breast tissue has not been studied. One of the risks with using this product is the unintentional injection into the breast tissue. It is unknown if the dermal filler injected into the chest area interferes with imaging (e.g., ultrasound, mammograms, magnetic resonance imaging (MRI), computed tomography (CT) scans, and standard plain radiography (x-rays)) of your breast tissue or the chest area. Radiesse® is not intended to be injected into breast tissue. In a clinical study, the mammograms and breast ultrasounds of patients who had been injected in the décolleté with Radiesse® were assessed by qualified radiologists. The radiologists determined that Radiesse® was not present on any of the images they reviewed.

## 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.

- You should limit the exposure of the treated area to sun or heat exposure for 24 hours after treatment or until any initial swelling and redness has resolved.
- The CaHA microspheres of RADIESSE® are visible on CT scans and it is unknown if RADIESSE® injected in the chest area is visible in ultrasound, mammograms, magnetic resonance imaging (MRI), computed tomography (CT) scans or standard plain radiography (x-rays). Tell your doctor, as well as your radiologist and/or imaging technician, that you have had
  - RADIESSE® injected in your chest area so that they are aware it is present when they are looking at your ultrasound, mammograms, MRI, CT scans or x-rays. In a clinical study, the mammograms and breast ultrasounds of patients who had been injected in the décolleté with RADIESSE® were assessed by qualified radiologists. The radiologists determined that RADIESSE® was not present on any of the images they reviewed.
  - The safety of RADIESSE® in patients under 22 years of age has not been established.
  - Tell your doctor about medicines you are taking because patients who are using medications that can prolong bleeding, such as aspirin or warfarin, may, as with any injection, experience increased bruising or bleeding at the injection site.

## SAFETY INFORMATION (continued)

- 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.
- Tell your doctor if you have had dermal therapies 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.
- No studies on the interactions of Radiesse® with drugs or other substances or implants have been conducted, and the risks are unknown.
- 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.

## What are possible side effects?

In the clinical studies of RADIESSE<sup>®</sup>, most side effects were mild in nature (uncomfortable). The most common side effects are swelling, redness, pain, bruising and itching. These side effects are also seen with other dermal filler injection procedures.

- RADIESSE<sup>®</sup> injection carries a risk of infection.
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with RADIESSE<sup>®</sup>, swelling may occur at the implant site. This also applies if you receive RADIESSE<sup>®</sup> injection before the skin has healed after a laser or chemical peel.
- You may be able to feel the RADIESSE<sup>®</sup> material in your skin for some time after your treatment. It may feel firm if you touch the area that was injected. This feeling will go away over the next several weeks.

## What potential complications should my doctor tell me about?

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

### What potential complications should my doctor tell me about? (continued)

Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

Based on information reported to Merz about the use of RADIESSE<sup>®</sup>, your physician may recommend additional interventions after RADIESSE<sup>®</sup>: antibiotics, anti-inflammatories, corticosteroids, antihistamines, 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 improve décolleté wrinkles and will provide a more youthful appearance to the décolleté.

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

Although treatment effects will differ from person to person, in a clinical study, 71.2% (about 83 out of 116 patients) showed improvement in their décolleté wrinkles 24 weeks after their first treatment with RADIESSE®. Over half of subjects in the study continued to show improvement 60 weeks after their first treatment injection.

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

RADIESSE® was shown to improve the appearance of the décolleté by reducing wrinkles in the skin as reported by patients and doctors.

## ABOUT THE PROCEDURE

### Do the injections hurt?

Injection may cause some discomfort during and after the procedure. You and your doctor may decide to numb the treatment area with a topical or injected anesthetic to further 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.
- 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 Radiesse® diluted with saline into the skin using a thin, flexible cannula until you have received the desired correction.
- Your doctor may gently massage the treatment area to ensure the product is evenly distributed.

## ABOUT THE PROCEDURE

### After Treatment:

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

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

In a clinical study on the use of RADIESSE® in the décolleté, patients underwent three treatment sessions spaced six weeks apart, with some patients undergoing an additional optional retreatment 24 weeks after the third treatment. The number of treatments required to get the look you want depends on your décolleté 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.

