

RADIESSE[®] for Hands Implementation Guide

Inside your E-Media Kit you will find tools to promote your practice as a Certified Injector of RADIESSE[®] for Hands. These promotional assets are designed to help you effectively reach your patients with an introduction to RADIESSE for Hands while driving them to your practice for treatment as a recognized Certified Injector.

Your E-Media Kit includes:

- RADIESSE for Hands Certified Injector Emblem
- RADIESSE for Hands Digital Web Banners (static and customizable)
- RADIESSE for Hands Talking Points
- RADIESSE for Hands Before and After Pictures
- RADIESSE for Hands Brand Logo
- RADIESSE for Hands Package Photo
- RADIESSE for Hands Consumer Video

Please remember that with any of these pieces the RADIESSE for Hands Important Safety Information (ISI) or the combined RADIESSE ISI for Face and Hands must be displayed. For details, please refer to the Terms of Use Document provided with the E-Media Kit.

RADIESSE for Hands Certified Injector Emblem

In this folder, you will find the Certified Injector (CI) emblem. This icon may be used on all digital and print promotions to identify your practice as a RADIESSE for Hands Certified Injector. Several of the pieces included in this E-Media Kit already feature the Certified Injector emblem.

RADIESSE for Hands Digital Web Banners

This E-Media Kit contains four different versions of digital banners designed for practice web platforms.

Within the E-Media Kit are **three static banners** in different sizes:

- 745 x 310 static banner
- 300 x 300 static banner

The static banners have non-customizable text but feature a customizable URL link which, when any portion of the banner is clicked, may link to a page on your website via the customized URL.

RADIESSE for Hands Digital Web Banners (Continued)

To customize:

Update the URL link to your website by changing the existing RADIESSE for Hands URL to the URL of your choice.

To upload:

Copy the HTML file and upload it to the page on your practice website where you want to display the banner.

The E-Media Kit also contains **one customizable banner**:

- 745 x 310 customizable banner

The customizable banner allows you to update your practice information, including physician name, phone number and website (both the display URL and the actual URL on your website that the email will link to).

To upload:

Copy the HTML file and upload it to the page on your practice website where you want to display the banner.

RADIESSE for Hands Talking Points

This folder contains a Word document designed for use on your practice website. It introduces and describes to your patients the benefits of RADIESSE for Hands. The text recognizes your practice as a RADIESSE for Hands Certified Injector and is easily customizable.

To incorporate this text into your own written media, update your practice information, including physician name, phone number, and website, and upload the text to a page on your practice website that you have dedicated to RADIESSE for Hands.

RADIESSE for Hands Before and After Pictures

Displaying RADIESSE for Hands Before and After photos on your website is one of the best ways to show your patients what they can expect when they receive a treatment. We have provided you multiple sets of Before and After photos for you to choose from.

RADIESSE for Hands Brand Logo

The RADIESSE for Hands logo may be used on your website alongside text from the provided talking points to add an element of design and further promote this treatment to patients.

RADIESSE for Hands Package Photo

The RADIESSE Package Photo is meant to establish RADIESSE brand recognition with your patients and may be used on your website.

RADIESSE for Hands Consumer Video

The RADIESSE for Hands Consumer Video is provided to you to promote RADIESSE for Hands in your practice. You may place this video on your website or social media platform, use it in newsletters or as an office loop, e.g. in the waiting room. For your convenience three file sizes have been provided for your varied use.

Indication:

RADIESSE[®] injectable implant is FDA-approved for hand augmentation to correct volume loss in the dorsum of the hands.

RADIESSE[®] IMPORTANT SAFETY INFORMATION

Contraindications:

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

Warnings:

Introduction of product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft tissue fillers, for example inject the product slowly and apply the least amount of pressure necessary. Rare but serious adverse events associated with the intravascular injection of soft tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care practitioner specialist should an intravascular injection occur.

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[®].

The safety and effectiveness of RADIESSE in the following situations has not been established:

- Use in the lips.
- In patients with very severe loss of fatty tissue with marked visibility of veins and tendons.
- Volumes over 3 cc of RADIESSE[®] per hand in a treatment session.

Avoid injection into veins or tendons in the hand, as this may weaken tendons and cause tendon rupture or cause embolization or thrombosis.

Injection into the dorsum of the hand may cause adverse events that last for more than 14 days, and may result in temporary difficulty performing activities (48% of study patients reported this adverse event). Fitzpatrick Skin Types IV-VI may have an increased risk (68% of Fitzpatrick Skin Types IV-VI reported this event). RADIESSE[®] may cause nodules, bumps or lumps in the dorsum of the hand (12% reported this event) and can last up to 1 year.

Increased bruising is associated with higher volume injection. Retreatment with RADIESSE[®] of volumes greater than approximately 1.6cc per hand in a treatment session can result in increased adverse events (redness, pain, swelling, and difficulty performing activities).

Precautions:

In order to minimize the risk of potential complications, this product should only be used by healthcare practitioners who have appropriate training, experience and who are knowledgeable about the anatomy at and around the injection site. Healthcare practitioners should fully familiarize themselves with the product, the product educational materials and the entire package insert.

The safety and effectiveness of RADIESSE in the following situations has not been established:

- In patients with diseases, injuries or disabilities of the hand
- beyond 3 years in the face and 1 year in the hand
- Interactions between RADIESSE[®] with drugs or other substances or implants
- Use during pregnancy, or in breastfeeding women
- In the dorsum of the hand in patients under 26 years old and over 79 years old
- In patients with increased susceptibility to keloid formation and hypertrophic scarring
- With concomitant dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures

RADIESSE[®] contains calcium hydroxylapatite (CaHA) particles that are radiopaque and are clearly visible on CT Scans and may be visible in standard, plain radiography.

As with all transcutaneous procedures, RADIESSE[®] injectable implant injection carries a risk of infection.

Care should be used in treating patients with autoimmune disease affecting the hand, hand implants, Dupuytren's contracture, history of hand tumor, vascular malformations, Raynaud's disease and patients at risk for tendon rupture.

Use of RADIESSE[®] in the dorsum of the hand may result in significant swelling of the dorsum of the hand.

The effects of RADIESSE[®] injection on hand function is uncertain.

Patients who are using medications that can prolong bleeding, such as aspirin or warfarin, may experience increased bruising or bleeding at the injection site.

Patients with a history of previous herpetic eruption may experience reactivation of the herpes.

Patients should minimize strenuous activity and 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.

Adverse Events:

Common adverse events observed in the clinical study of RADIESSE[®] injected into the dorsum of the hand include bruising, redness, swelling, pain, itching, nodule or bumps/ lumps, difficulty performing activities, loss of sensation and other local side effects.



Information on adverse events from post-market surveillance of RADIESSE[®] are included in the Instructions for Use (IFU) and Patient Information Guide (PIG) based on an assessment of seriousness and potential causal relationship to RADIESSE[®]. Please see the IFU and PIG available on www.radiesse.com for a complete list of these events.

To report a problem with RADIESSE[®], please call MyMerz Solutions at 1-844-469-6379.

For complete Safety Information please refer to the [Instructions for Use at Radiesse.com](http://www.radiesse.com).
Rx only

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