**Frequently Asked Questions**

**IS A SKIN TEST REQUIRED?**
No pre-testing is required due to Radiesse’s unique natural product formulation and biocompatibility profile.

**ARE THERE ANY SIDE EFFECTS?**
There are few reported side effects. However, some common injection-related reactions may occur, such as edema, swelling, pain, itching, disorientation and tenderness at the injection site.

**CAN RADIESSE BE INJECTED OVER OTHER IMPLANTS?**
Radiesse should not be implanted in patients with other implants or materials still in place.

**IS RADIESSE PERMANENT?**
No. The gel carrier dissipates over a few months allowing for new tissue infiltration. The CaHA particles gradually break down and are metabolized over several years.

**DO I NEED TO OVER-CORRECT?**
No, Radiesse requires a one-to-one correction, providing more augmentation per cc than other products that do require over-correction to achieve an optimal outcome.

**HOW DOES RADIESSE WORK?**
Radiesse’s CaHA microspheres are suspended within a gel carrier. The gel carrier is replaced with natural soft-tissue ingrowth. The microspheres provide a scaffolding for natural tissue infiltration and growth.

**WILL RADIESSE BECOME HARD OR NOTICEABLE TO TOUCH?**
No, Radiesse will remain soft and pliable and will take on the characteristics of the surrounding tissue.

**HOW LONG CAN I STORE RADIESSE?**
Radiesse can be stored at room temperature for up to two years in its original sealed packaging.

**HOW LONG WILL RADIESSE LAST?**
The microspheres of CaHA have been shown to last up to seven years clinically. In facial applications, Radiesse should provide a correction that lasts around two years.

**IS RADIESSE APPROVED?**
Yes, Radiesse has CE Mark certification for facial plastic surgery, among others, and a number of U.S. marketing clearances.

**HOW MANY TREATMENTS WILL PATIENTS REQUIRE?**
Some patients may achieve an optimal correction on their first injection. For other patients, variability in the rate of tissue in-growth following resorption of the gel carrier may require a touch-up to achieve an optimal correction.

Radiesse is used world wide for soft tissue augmentation and enhancement. This easily injectable material is specifically designed to offer physicians and their patients a safe and effective long lasting treatment.
HISTORY:
10 Years of development at Bristol-Myers Squibb
Scientifically based formulation
Extensively established biocompatibility and safety
Clinical verification of safety and efficacy

Biocompatible: Microspheres of calcium hydroxylapatite (CaHA), a major component of bone, suspended in a carrier gel of sodium carboxymethylcellulose, glycerine and water. No mixing or special handling required.

Durable microspheres degrade slowly and naturally for a longer lasting effect.

25 to 45 micron size microspheres are uniformly shaped and sized for consistent placement with no history of migration.

The microspheres slowly degrade through natural mechanisms without foreign body reaction.

Even dispersion of microspheres form scaffolding for natural infiltration of the surrounding tissue.

No human or animal derived components.

Clinical Development

CE Approved Indications:
- Facial Plastic Surgery
- Stress Urinary Incontinence
- Vesicoureteral Reflux
- Vocal Fold Medialization

FDA Approved Indications:
- Vocal Fold Medialization
- Radiographic Tissue Marking
- Dental Intrarabittoral Defects and Oral/Maxillofacial Defects

Clinical Studies Planned or Underway:
- Stress Urinary Incontinence
- Vesicoureteral Reflux
- Vocal Fold Medialization
- Tissue Bulking for HIV Lipodystrophy

3 Year Durability (SUI Pilot Study)

Clinical Studies Planned or Underway:

Nasolabial Folds

Before
After (6 months)

Radial Lip Lines

Before
After (6 weeks)

Facial Contouring Uses
- Nasal alar folds
- Post-rhinoplasty defects
- Marionette Lines
- Vermillion Border of the Lip

Technique

- Use a 1:1 correction factor
- Do NOT overinject
- Inject in the mid-to-deep dermis near the junction of the subcutaneous tissue
- 25 to 27 gauge needle
- Multiple injection sessions (2 - 3) for optimal correction may be necessary
- Smaller amounts of material injected over multiple sessions may allow a more efficient tissue ingrowth
- Use topical anesthetic or blocks for pain management
- Set patient expectations appropriately

Technique Considerations

- Use approximately 0.3 cc of Radiesse total
- Under-inject this area with 27 gauge 1/2” needle
- Use a tunneling technique to create adequate injection space (2 to 3 passes)
- Vertical retrograde threading injections of no more than 0.05 cc each
- Do not inject submucosally under wet vermilion or mucosa
- Massage and mold area immediately

Nasolabial Folds

Before
After (6 months)

Indications

- A typical injection of Radiesse is 0.7 cc (0.35 cc for each side).
- May vary from patient to patient
- Vertical retrograde linear threading injections of 0.05 cc each (or serial puncture) is commonly used
- Inject material with bevel of needle down in the mid dermis (approximately three threads adjacent to each other)
- If additional material is needed, inject slightly deeper to create an additional layer that will bolster the fold
- Inject shorter threads with fanning technique near top of fold if needed
- Massage and mold area immediately

Vermillion Border of the Lip

Before
After (6 months)

Radial Lip Lines

Before
After (6 weeks)