



## 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, discoloration 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 DO I PURCHASE RADIESSE?

Please contact BioForm Medical Europe at the number provided on the back of this brochure.

### 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?

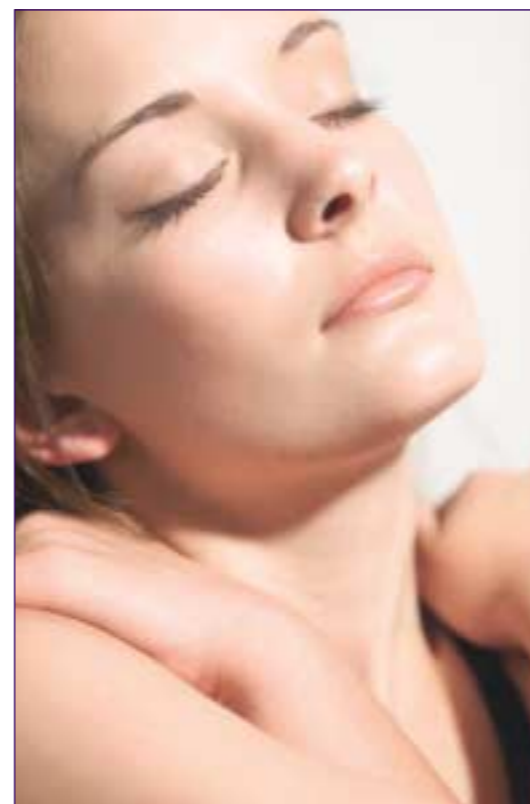
Yes, Radiesse has CE Mark certification for facial plastic surgery, among others, and a number of U.S. marketing clearances.

### 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.

**Radiesse 1 cc Syringe**  
**Reference No: 8044M2**



**"The most NATURAL injectable choice for facial tissue augmentation"**



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BIOFORM  
MEDICAL

# Radiesse™

## Long Lasting Injectable Filler



## Featuring

- Calcium Hydroxylapatite Microspheres
- Long History of Safe Clinical Use
- Biocompatibility - No Skin Test Required
- Proven Experience in Durable Facial Contouring

**The Next Generation of Tissue Augmentation**



## Preclinical Studies

### HISTORY:

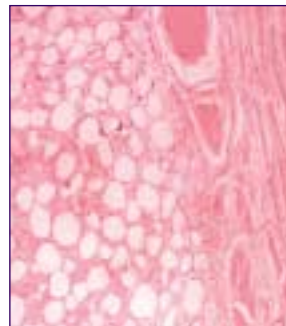
- 10 Years of development at Bristol-Myers Squibb
- Scientifically based formulation
- Extensively established biocompatibility and safety
- Clinical verification of safety and efficacy



**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.

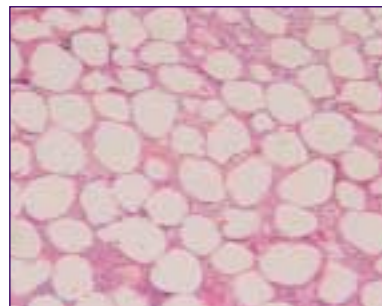


25 to 45 micron size microspheres are uniformly shaped and sized for consistent placement with no history of migration.

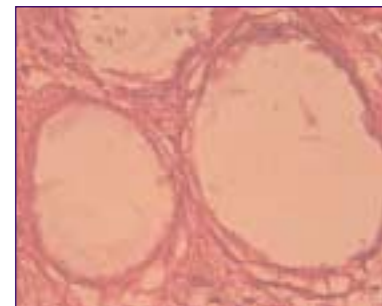
The microspheres slowly degrade through natural mechanisms without foreign body reaction.

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

No human or animal derived components.

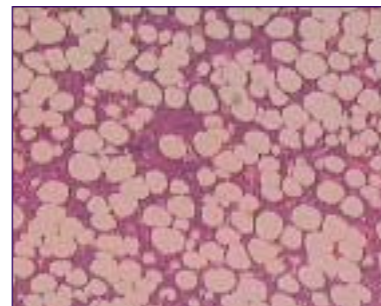


Histology  
12 months  
40x magnification



Histology  
36 months  
100x magnification

*Canine Urethral Mucosa*



- Tissue infiltrates around microspheres.
- Macrophages actively remove the gel carrier.



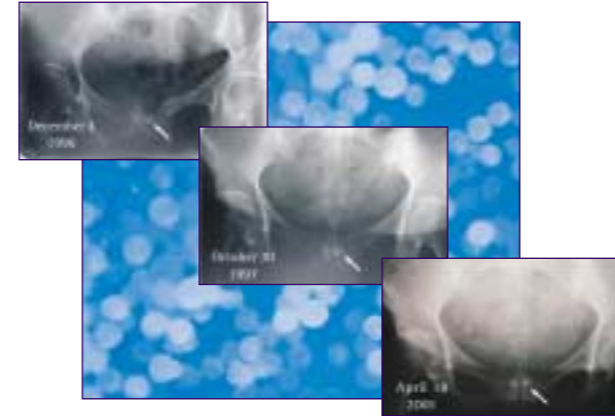
## Clinical Development

### CE Approved Indications:

- Facial Plastic Surgery
- Stress Urinary Incontinence
- Vesicoureteral Reflux
- Vocal Fold Medialization

### FDA Approved Indications:

- Vocal Fold Medialization
- Radiographic Tissue Marking
- Dental Intraosseous Defects and Oral/Maxillofacial Defects



5 Year Durability  
(SUI Pilot Study)

### Clinical Studies Planned or Underway:

- Stress Urinary Incontinence
- Vesicoureteral Reflux
- Nasolabial Folds
- Vocal Fold Medialization
- Tissue Bulking for HIV Lipoatrophy



## Technique

### Facial Contouring Uses

- Nasolabial Folds
- Post-rhinoplasty defects
- Marionette Lines
- Vermillion Border of the Lip
- Radial Lip Lines
- Chin & Cheek Augmentation
- Tear troughs

### Technique Considerations

- 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



## Indications

### Nasolabial Folds



Before



After (6 weeks)

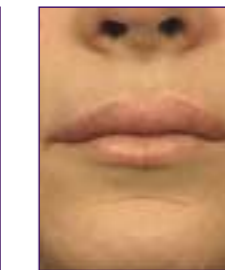


- A typical injection of Radiesse is 0.7 cc (0.35 cc for each side). May vary from patient to patient
- Vertical retrograde linear threading injections of 0.05 cc each (or serial puncture) is commonly used
- Inject material with bevel of needle down in the mid dermis (approximately three threads adjacent 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)

- Use approximately 0.5 cc of Radiesse total (0.3 cc for top and 0.2 cc for bottom)
- Inject the lip sequentially in each quadrant
- Start injection at corner of lip or just outside the lip toward the Cupid's bow
- Horizontal retrograde threading injections of no more than 0.05 cc each approximately 2 to 3 mm apart
- Inject material with bevel of needle down in along vermilion border to the white roll
- Do not inject submucosally under wet vermilion or mucosa
- Massage and mold area immediately

### Radial Lip Lines



Before



After



- Use approximately 0.3 cc of Radiesse total
- Under-inject this area with 27 gauge 1/2" needle
- Start injection at the white roll, using a tunneling technique to create adequate injection space (2 to 3 passes)
- Vertical retrograde threading injections of no more than 0.025 cc each
- Do not inject into the lip muscle
- Massage and mold area immediately