Implants for vocal fold augmentation

**RADIESSE™ Voice Products**

The **RADIESSE™ Voice** injectable implant contains synthetic calcium hydroxylapatite (CaHA) microspheres, which have a diameter of 25-45 μm, suspended in an aqueous resorbable carrier gel. The carrier gel contains glycerin, Sodium Carboxymethylcellulose, and sterile water. The product is injectable through a 25-gauge needle. **RADIESSE™ Voice** provides vocal fold augmentation with results that typically last up to 12 months or more.¹, ²

The **RADIESSE™ Voice Gel** injectable implant contains synthetically derived polymers, with no CaHA microspheres, and it is suitable for short term vocal fold augmentation in patients where reversible nerve damage is suspected, or in patients wishing a short term augmentation before deciding to have a longer term augmentation done with **RADIESSE™ Voice**.

**RADIESSE™ Voice and RADIESSE™ Voice Gel implants are sold with either a malleable trans-oral needle or a non-coring percutaneous needle.**

Trans-oral needle
- 25 cm long overall
- 16-gauge malleable shaft
- P/N 9010 M1

Trans-oral needle tip
- 24-gauge, 1 cm tip
- Marker at 5mm

Percutaneous needle
- 1.5", 25-gauge
- P/N 9007 M1

Percutaneous needle tip
- Non-coring Huber point

**Unique Mechanism of Action**

Over time the **RADIESSE™ Voice** implant carrier gel is resorbed and the calcium hydroxylapatite particles support in-growth of new collagen. The durable calcium hydroxylapatite microspheres degrade slowly for a long-lasting effect. The implant remains soft after injection and does not ossify.

In clinical testing and routine clinical use for vocal fold augmentation for over 7 years, no implant migration or evidence of granuloma formation has been observed.¹⁻⁴

**Histology studies demonstrate deposition of new collagen around CaHA microspheres over an extended time course. Collagen fibers stain red, while other tissue elements appear more yellow.⁵**

**NOTE: RADIESSE™ Voice has a lower injection force if warmed and therefore may flow easier through the transoral needle. See “Instructions for Use” for complete information.**

Vocal Fold Augmentation Treatment

Injection Techniques

Introduction

RADIESSE™ products can be injected through a 25-gauge needle in the operating room or in the office using a trans-thyroid cartilage, trans-cricothyroid membrane or thyrohyoid approach2,3.

Optimal Injection Location and Volume

- Vocal fold injections should be at the level of the vocal process
- Lateral to/or in the thyroarytenoid muscle (TA muscle)
- Depth of the vocal fold injection should be approximately 5-7 millimeters
- No pre-set vocal fold injections volume. The vocal fold injection volume should be done strictly on immediate clinical observation and approximately 10-15% over correction is recommended

General Injection Pearls

- Connect needle (notice alignment of green dot when using the trans-oral needle). See Figures 1 and 2
- Needle is delivered straight–bend to fit patient anatomy and physician preference
- Prime needle (~0.18 cc dead volume for trans-oral needle).
- Notice start and end volume to determine volume injected

In-Office Percutaneous Injection

- Transnasal endoscopic guidance
- Local anesthesia recommended
- Needle has non-coring “Huber” tip

Operating Room Trans-oral Injection

- Direct laryngoscopy or micro-laryngoscopy
- Similar to autologous fat injections but less over correction required (10-15%)

In-office Trans-oral Injection

- Topical anesthesia required (drip onto larynx)