INJECTION VOCAL FOLD AUGMENTATION

Radiesse™ Voice

Radiesse™ Voice Gel
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CLINICALLY PROVEN RESULTS

• Proven effective – in clinical testing with 12-month follow-up, the majority of patients treated with RADIESSE™ Voice reported their voice was greatly or significantly improved.²
• Proven safe – no long-lasting granuloma formation or major complications have been reported.²
• Proven long-lasting – results with RADIESSE™ Voice typically last more than 12 months.²
• Results with RADIESSE™ Voice Gel have been shown to last up to 3 months.⁷

CONVENIENT AND EASY-TO-USE

• No preparation or mixing – supplied ready-to-use in a 1.0 cc syringe with injection needle.
• No refrigeration – store at room temperature.
• No allergy testing – contains no animal or human components.
• No waiting – injection can be performed in-office in 30 minutes or less.

CONSISTENT, PREDICTABLE, STABLE CORRECTION

• Made from synthetic materials with extensive history of biocompatibility.
• Consistent, predictable correction.
• No evidence of implant migration.¹,²,³
TWO FORMULATIONS FOR EVERY CONTINGENCY

RADIËSSE™ Voice is an injectable implant containing synthetic Calcium Hydroxylapatite (CaHA) microspheres, which have a diameter range of 25 µm to 45 µm suspended in an aqueous gel carrier and is injectable through a 25-gauge needle. RADIËSSE™ Voice provides long lasting vocal fold augmentation and has been shown to be effective up to 12 months.²

RADIËSSE™ Voice Gel is an injectable implant containing synthetically derived polymers, and no CaHA microspheres, suitable for short term vocal fold augmentation, in patients where reversible nerve damage is suspected, or in patients wishing a short term augmentation before making a decision to have a long term augmentation done with RADIËSSE™ Voice.

UNIQUE MECHANISM OF ACTION

Over time the carrier gel in RADIËSSE™ Voice is resorbed and the CaHA particles support in-growth of new collagen. The durable CaHA microspheres degrade slowly over years for a long-lasting effect.⁸

In both clinical testing and clinical use, no implant migration or evidence of long-term granuloma formation have been observed.¹²³

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.⁸
OPERATING ROOM TRANS-ORAL INJECTION

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

OPTIMAL INJECTION LOCATION AND VOLUME

- Vocal fold injections should be at the level of the vocal process
- 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

CONNECT NEEDLE (notice alignment of green dot) See Figures 1 and 2
- Needle is delivered straight–bend to fit patient anatomy and physician preference
- Prime needle (~0.18 cc dead volume)
- Notice start and end volume to determine volume injected

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.
IN-OFFICE PERCUTANEOUS INJECTION

- Transnasal endoscopic guidance
- Local anesthesia
- Needle has non-coring “Huber” tip
- Prime needle
- Notice start and end volume to determine volume injected

See “Instructions for Use” for complete information.
IN-OFFICE THYROID INJECTION

- Transnasal endoscopic guidance
- Local anesthesia
- Notice start and end volume to determine volume injected

See "Instructions for Use" for complete information.
IN-OFFICE TRANS-ORAL INJECTION

- Topical anesthesia (drip onto larynx)
- Connect needle (notice alignment of green dot) See Figures 1 and 2
- Needle is delivered straight–bend to fit patient anatomy and physician preference
- Prime needle (~0.18 cc dead volume)
- Notice start and end volume to determine volume injected

See “Instructions for Use” for complete information.
PEER-REVIEWED JOURNAL ARTICLES


COMPOSITION
By volume RADIÉSSE™ Voice is approximately 30% Calcium Hydroxylapatite (CaHA) and 70% carrier gel. The carrier gel contains glycerin, Sodium Carboxymethylcellulose, and sterile water. RADIÉSSE™ Voice Gel contains the same carrier gel without CaHA microspheres.

PACKAGING
RADIÉSSE™ Voice and RADIÉSSE™ Voice Gel are pre-filled in a latex-free polycarbonate syringe in a volume of 1.0 cc.
The syringe is packed in a foil pouch enclosed in a product box.

STORAGE
Store at ambient temperature of 15-32°C (59-90°F).

CATALOG NUMBER
- RADIÉSSE™ Voice: PN 8044M0 (USA) 8044M2 (Europe)
- RADIÉSSE™ Voice Gel: PN 8602M0 (USA) Not currently available in Europe

INJECTION NEEDLES
- Transoral injection needle (9010M1): 25 cm long, 16-gauge malleable needle shaft
  1 cm needle tip (24-gauge) with marker at 5 mm

- Percutaneous needle (9001M1): 25-gauge, 1.5 in long with non-coring Huber point

See “Instructions for Use” for complete information.