



Solvos
Medical

Renú[®] Voice Injectable implant

Cost-effective Calcium Hydroxylapatite (CaHA)
for vocal fold injection augmentation



- 1.5cc pre filled syringe
- longevity 12-18 months
- 100% biodegradable
- Ergonomically shaped finger grips syringe
- Controlled viscosity, consistently
- Easy to inject
- 2-year shelf life

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RENÚ[®] VOICE

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Cost-effective Calcium Hydroxylapatite (CaHA) for vocal fold injection augmentation

RENÚ[®] VOICE is an injectable vocal fold implant intended for long-term augmentation. RENÚ[®] VOICE is a buffered hydrogel containing synthetic Calcium Hydroxylapatite (CaHA) particles 25 to 45 microns in size. The implant can be injected percutaneously or with a trans-oral needle supplied separately.

RENÚ[®] VOICE is provided in sterile ready-to-use 1.5cc syringes. No skin or allergy testing is required. RENÚ[®] VOICE is designed to be easy to use and placed under direct observation allowing for exact control of volume delivered.

Indications Renú[®] Voice

RENÚ[®] VOICE is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue-bulking agent. RENÚ[®] VOICE injection augment the size of the displaced or deformed vocal fold so that it may meet the opposing vocal fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulty may be an urgent indication.

Tips and Tricks for injections with Renú[®] Voice

Placement and volume delivered should comply with suggested guidelines:

- Trans-oral needle is delivered straight – bend needle to fit patient anatomy and physician preference
- Prime needle (0.28cc dead volume), Notice start and end volume in syringe to determine injected volume
- Vocal Fold injections should occur at the level of the vocal process
- Vocal Fold injections should be deep and lateral to/or in the TA muscle
- Vocal Fold Injections should be at a depth of 5 -7 mm, see depth markers at trans-oral needle



- Observe the injection; after 0.2ml tissue should start bulking. If not, re-confirm location.
- Vocal Fold Injections should be under direct clinical observation; an over-correction of 15 – 20% is suggested
- Consider voice rest of 3 days



Injection techniques Renú[®] Voice

RENÚ[®] VOICE Injection Options

- Trans-Oral (Operating Room-OR)
- Trans-Oral (Office based)
- Percutaneous (Office based)

Operating Room (OR) Trans-Oral Injection

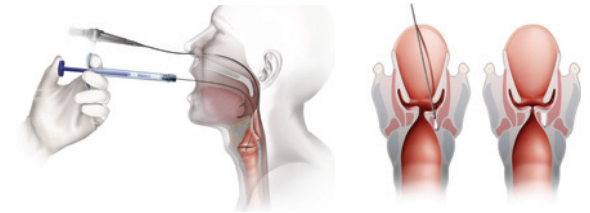
- Visualization via direct laryngoscopy or micro-laryngoscopy
- Inject with approximately 15 – 20% over correction



Operating Room Trans Oral Injection

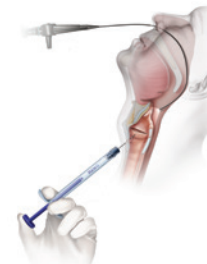
Office Based Trans-Oral Procedure

- Topical anesthesia (dripped on larynx)
- Attach appropriate needle to RENÚ[®] VOICE
- Prime needle with RENÚ[®] VOICE (dead volume equals ≈0.28cc)
- Special Note – record syringe starting and ending volume for exact volume delivered to patient.



Trans Oral Calcium Hydroxylapatite (CaHA) Injection

Percutaneous injections



Cricothyroid Cartilage approach



Thyroid Cartilage approach



Thyrohyoid approach

Clinical articles

Peer-Reviewed Journal Articles

- * Rosen, C.A., J. Gartner-Schmidt, (et al.), **"Vocal fold augmentation with calcium hydroxylapatite (CaHA)."** Otolaryngology Head and Neck Surgery (2007) 136, 198-204
- * Rosen CA, Gartner-Schmidt J, Casiano R, Anderson TD, Johnson F, Remacle M, Sataloff RT, Abitbol J, Shaw G, Archer S, Zraick RI. **"Vocal fold augmentation with calcium hydroxylapatite: twelve-month report."** Laryngoscope. 2009 May;119(5):1033-41. doi: 10.1002/lary.20126.
- * Carroll TL, Rosen CA. **"Long-term results of calcium hydroxylapatite for vocal Fold augmentation."** Laryngoscope. 2011 Feb;121(2):313-9. doi: 10.1002/lary.21258. Epub 2011 Jan 13.
- * Mallur PS, Morrison MP, Postma GN, Amin MR, Rosen CA. **"Safety and efficacy of carboxymethylcellulose in the treatment of glottic insufficiency."** Laryngoscope. 2012 Feb;122(2):322-6. doi: 10.1002/lary.21930. Epub 2012 Jan 18.
- * Sulica L, Rosen CA, Postma GN, Simpson B, Amin M, Courey M, Merati A. **"Current practice in injection augmentation of the vocal folds: indications, treatment principles, techniques, and complications."** Laryngoscope. 2010 Feb;120(2):319-25. doi: 10.1002/lary.20737.

Note: These studies were done with Prolarynx™ Plus or Prolarynx Gel (Formerly Radiesse® Voice or Radiesse gel, Merz) but are relevant since Renu® Voice and Renu® Gel are substantially equivalent products and contain the same components in the equivalent formulations. Radiesse® and Prolarynx™ are registered trademarks or trademarks of Merz North America.

Order information



REF: 08-015-04-VOI Renu® Voice Calcium Hydroxylapatite Implant 1.5cc pre-filled syringe

REF: 12-000-00-ND1 ENT (transoral) Needle 24G needle tip 9/8" overall length 16G malleable shaft

REF: 12-000-00-ND2 Percutaneous needle 23G needle 2 3/8" length

REF: 08-000-04-SET Renu® Voice + ENT (transoral) needle Injection kit

REF: 08-000-05-SET Renu® Voice + Percutaneous needle Injection kit

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