

Vox[®]

IMPLANTS

Injectable Bulking Agent for Vocal Cord Rehabilitation

The VOX[®] Implants implantation procedure is a safe, simple and effective method of restoring natural speech.

By producing medial displacement to allow apposition by the normal vocal cord, VOX implantation may be an ideal primary treatment for unilateral laryngeal paralysis.

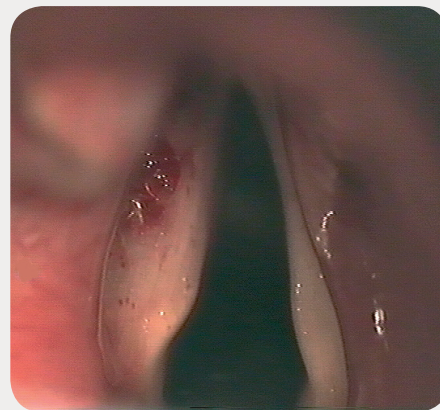
The advantages over conventional therapy are clear:

- » Microlaryngoscopic product placement
- » Daycase procedure capability
- » Minimally invasive
- » Non-migratory
- » Long-lasting results

“Endoscopic injection of textured PDMS particles leads to permanent augmentation of human vocal fold volume.”¹

Restore Natural Speech


The implantation procedure creates a soft, permanent mucosal elevation.



Product Information

Catalog Number	Product Description	Procedure Requirements
VOX-1.0	VOX Implants 1 ml unit	1 unit
VMN-720	Malleable needle 7 Fr. External Malleable Catheter x 241 mm long with 20 Ga. Needle x 7 mm long	1 needle
AD	Reusable Administration Device Includes syringe adapter	1 device

Technical Data Sheet

Product Name:	VOX [®] Implants
CE Mark:	Yes,  0344
Class:	IIb (European Union)
Latex-free:	Yes
Raw Materials:	Polydimethylsiloxane Elastomer, Polyvinylpyrrolidone (PVP), Water
Catalog Ref:	VOX-1.0
Sterilization Type:	Irradiation
Shelf Life:	2 years

Description

VOX Implants consists of latex-free, nonpyrogenic, solid, white-coloured, irregularly textured, medical grade silicone elastomer implants, suspended in a gold-coloured hydrogel carrier and packaged in a clear polycarbonate syringe. Single use only.

Indications

VOX Implants are indicated for unilateral vocal cord rehabilitation.

Contraindications

VOX Implants use in vocal cord rehabilitation is contraindicated in the following conditions:

- » Potential for spontaneous return of normal function
- » Within 12 weeks of a previous VOX treatment
- » Acute inflammation, infection, malignancy or any rapidly advancing disease
- » Bilateral vocal cord paralysis

Packaging

VOX Implants is pre-filled in latex-free, polycarbonate syringes to a volume of 1.0 ml. Each syringe is packaged in a trilaminate double pouch enclosed in a box.

Storage Conditions

Store at an ambient temperature of 15–30°C.

Distributed by



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1. Sittel, C., et al. (2000). Textured Polydimethylsiloxane elastomers in the human larynx: safety and efficiency of use. *J. Biomed Mater Res. (Appl. Biomater)* 53, 646-650.

For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each VOX product or online at www.cogentixmedical.com. VOX is a registered trademark. VOX is manufactured by Uroplasty LLC. ©2017 Cogentix Medical. All rights reserved. 15009C 02/17

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