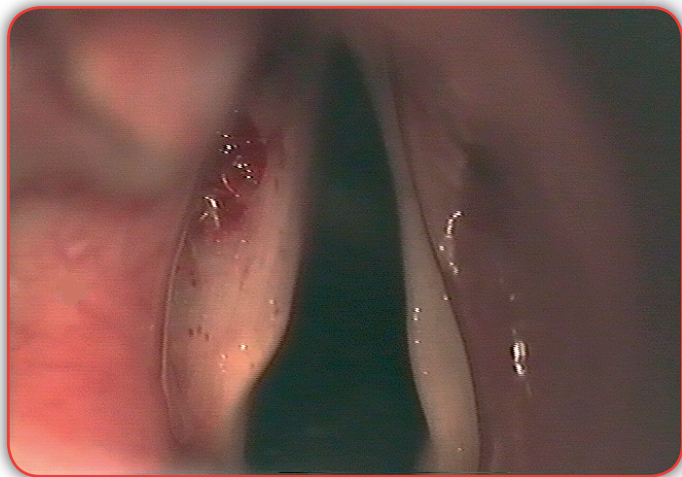


Restore

Restore Natural Speech

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 both unilateral laryngeal paralysis.



The implantation procedure creates a soft, permanent mucosal elevation.

The advantages over conventional therapy are clear:

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

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

Manufactured by



Distributed by



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1. C. Sittel, ET AL. Textured Polydimethylsiloxane Elastomers in the Human Larynx: Safety and Efficiency of Use. J. Biomed Mater Res. (Appl. Biomater) 53:646-650, 2000

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VOX® Implants
Injectable Bulking Agent


For Vocal Cord Rehabilitation



CE
0473

VOX[®] Implants

Technical Data Sheet

PRODUCT NAME:	VOX [®] Implants
CE MARK:	Yes,  0473
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, non-pyrogenic, 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 6 weeks of a previous 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 trilaminar double pouch enclosed in a box.

STORAGE CONDITIONS

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

ORDERING INFORMATION

Catalog Number	Product Description	Procedure Requirements
VOX-010	VOX Vocal Cord Rehabilitation Kit <ul style="list-style-type: none">• 1 VOX Implants, 1 ml (VOX-1.0)• 1 Malleable needle (VMN-720)	1 kit
AD	Reusable Administration Device <ul style="list-style-type: none">• Includes syringe adapter	1 device

