


### Patient Information Leaflet (PIL)


This leaflet contains important information about your implant. **You should speak to your doctor if you have any concerns or questions.**


All implantable medical devices have risks and benefits. Follow the advice from your healthcare team, even if it differs from the information contained in this leaflet. Please read this information carefully and keep it for future reference.

The name and number of your implant can be found on the patient implant card that has been provided by your doctor.

**OLYMPUS** Patient Implant Card

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(If place patient identification here)  
Patient information can be found at [www.olympus.com.au](http://www.olympus.com.au)

Device name \_\_\_\_\_

Model number \_\_\_\_\_

Batch / Lot number \_\_\_\_\_

Manufactured by:  
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Miyoshi-cho, Tokyo 192-8507, JAPAN, [www.olympus-global.com](http://www.olympus-global.com)  
 Olympus A&ME, Inc. 1950 Louisiana Avenue North, Brookpark, Ohio  
44142, USA, <http://medical.olympusamerica.com>

### Intended Use

The Olympus Vocal Cord Medialisation system (VoCoM) is intended to treat a paralysed vocal cord with poor vocal quality, with or without aspiration by moving the paralysed vocal cord towards the middle. This is aimed at improving voice quality and the ability to swallow liquids.

### Implant Description

The VoCoM system of implants and stabilizing spacers, known as shims, are made from dense hydroxyapatite, a calcium phosphate biomaterial that has a similar composition to human bone.

### Information for Safe Use

This implant can only be inserted by your doctor.

You should follow your doctor's advice after your treatment. Discuss any questions or concerns with your doctor.

This device can be used with other surgical implants. You should always let your doctor know about any previous surgeries and treatments.

### Expected Lifetime and Follow Up

VoCoM is a permanent implant.

Periodic follow up with your doctor is recommended to evaluate device efficiency and check for possible complications.

### Adverse Effects and Reporting

Your doctor will provide information about the benefits, risks and side effects of your treatment. Please talk to your doctor if you have concerns.

Possible adverse effects may include:

- Infection
- Fistula inside the larynx
- Bruising or swelling that can compromise the airway
- Unsatisfactory voice
- Aspiration and difficulty swallowing
- Airway obstruction

### Reporting adverse effects

If you wish to report any adverse effects you believe are a result of your treatment with this implant, please speak with your medical team or report the information to the Olympus Quality and Regulatory Department:

Email: [oaz-ra@olympus.com](mailto:oaz-ra@olympus.com)

Phone: 1300 132 992

You may also wish to contact the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

### Australian Sponsor

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Patient Information:

<https://www.olympus.com.au/company/en/home/patient-information-leaflets.html>