

Ventilation Tubes

Brand names: *Armstrong beveled grommets, Armstrong beveled plain end, Butterfly, Collar bobbin, Donaldson, DuraVent, Shea parasol, Micron titanium bobbin, Modified T-tubes, Paparella-type, Sheehy-type, Reuter bobbin, Richards T-tubes, Rock paediatric, Shah, Jahn Hydroxyl, Shepard Grommet, Straight.*

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

Device name _____

Model number _____

Batch / Lot number _____

Manufactured by:
 Olympus Medical Systems Corp. 3501 Inabawa-cho,
Hachioji-shi, Tokyo 188-8502, Japan. www.olympus-grommets.com
 Olymus ACM, Inc. 3920 Louisiana Avenue North, Rockledge Park,
Mn 55445, USA. https://medical.olympusamerica.com

Intended Use

Olympus Ventilation Tubes are intended ventilate the middle ear following an ear infection (otitis media). The placement of the tube allows for any fluid to be eliminated as well as creating an air passage to ease pressure on the ear drum.

Implant Description

Olympus Ventilation Tubes are available in a variety of materials and shapes. Your doctor has selected a tube based on your specific requirements. It may be made from the following materials:

- Fluroplastic
- Polyethylene
- Silicone
- Pacific – phosphorylcholine (PC) coating on fluroplastic tubes
- Ultrasil Silicone
- Titanium
- Micron Titanium
- Stainless Steel

Information for Safe Use

This implant can only be inserted by your doctor.

Care should be taken to avoid water entering the ear.

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

Expected Lifetime and Follow Up

Your doctor will determine the length of time the Ventilation Tube will be implanted based on your specific requirements.

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:

- Clogging of the Ventilation Tubes
- The Ventilation Tube may fall out earlier than planned
- Infection
- Persistent perforations (tears) in the ear drum
- Irritation due to material allergy or sensitivity

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

Phone: 1300 132 992

You may also wish to contact the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

Australian Sponsor

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Phone: 1300 132 992

Website: <https://www.olympus.com.au/>

Patient Information:

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