

# Olympus Ossicular Replacement

**Brand Name(s):** Applebaum, Attic Defect, Austin, Black Oval-Top, Black Spanner, Bojrab, Brackman, CAP, Causse, Cawthorne, De La Cruz, Dornhoffer, Drum-to-Stapes, Fisch-Type, Fluroplastic, Goldenberg, Grate, Grote, Haberman, House-Type, Kartush, Mangham, Mass Eye & Ear, McGee, Micron PORP, Modified PORP, Off-Centred, Platinum Ribbon, Richards, Ronis, Sanna, Scheer, Schuknecht, Shea, Sheehy-Type, SMart Piston, SMart 360, SMart De La Cruz, Strasnick, Tantalum, Tilt-Top, Trapeze Ribbon, Velegrakis, Wehrs.

## 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. 2011 100-04-070,  
Hachioji-shi, Tokyo 188-8502, JAPAN, www.olympus-global.com  
 Olympus AOML, Inc. 9500 Louisiana Avenue North Brooklyn Park,  
MN 55410, USA, https://medical.olympusamerica.com

## Intended Use

The Olympus Ossicular Replacement Implant is placed in the middle ear to replace the portion of the ossicular chain that is no longer functioning correctly.

## Implant Description

The ossicular chain, otherwise known as the middle ear, consists of three bones (ossicles) – the malleus, incus and stapes. The ossicles help conduct and amplify outside sound to the inner ear. The Olympus Ossicular Replacement Implant is available in different designs for the replacement of any, or all, of the bones in the ossicular chain.

Your doctor has selected an implant based on your specific requirements. It may be made from stainless steel, titanium, nitinol, tantalum, platinum, polyethylene, fluroplastic, Plasti-Pore, hydroxylapatite, HAPEX, nickel, or a combination of these materials.

## 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.

Keep your ear clean and dry until the dressings are removed and healing is completed.

Depending on your treatment, the implant may contain metals. You will have been given an MRI Identification Patient Card by your doctor. Please keep this for future reference and let your doctor know about any previous surgeries and treatments.

## Expected Lifetime and Follow Up

The Olympus Ossicular Replacement Implant is a permanent replacement for damaged bones in the middle ear.

## 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:

- Postoperative hearing loss due to surgical trauma
- Inflammation and damage to the membranes
- Inflammation of the inner ear
- Dizziness
- Incus necrosis
- Infection
- Implant displacement
- Malleus fixation
- Tissue irritation caused by allergy or sensitivity to implant material
- Postoperative bleeding
- Infection and facial nerve paresis/paralysis

## 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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Phone: 1300 132 992

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

Patient Information:

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