Olympus Spiration™ Valve System

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.

Information about your implant can be found on the patient implant card provided by your doctor.

Intended Use

The Olympus Spiration Valve System is a device placed in the lung airway to treat severely diseased lungs in patients with emphysema or damaged lungs resulting in air leaks, by limiting airflow to the damaged areas.

Implant Description

The Olympus Spiration Valve is an umbrella-shaped one-way valve that directs airflow away from diseased or damaged parts of the lung to healthier areas. It allows trapped air and mucus to escape making breathing easier.

Multiple valves may be used in your treatment. Your doctor has selected a valve based on your needs. It is made out of the following materials:

- Nitinol
- Polycarbonate Polyurethane

Information for Safe Use

This device can only be inserted by your doctor.

It should not be used for patients who have:

- Active asthma, bronchitis or significant damage
- Known or suspected sensitivity to nickel

Please advise your doctor if you have these conditions.

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

If you suddenly feel unwell after treatment and are unusually short of breath, visit your nearest hospital immediately and inform doctors about your treatment.

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

MRI Compatibility

The Spiration Valve System is **MR Conditional**.

Please carry your implant card with you and share this information with your doctor and MRI technician prior to undergoing an MRI procedure.

Expected Lifetime and Follow Up

For Emphysema: The valves are meant to be permanently implanted in the airways, but they are also designed to be removed if necessary.

For Air leaks: The device is intended to be placed for up to 6 weeks.

Your doctor will determine whether the valve should remain in place based on the clinical need.

Follow up with your doctor as needed.

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:

- Partial or complete lung collapse
- Injury to the bronchial tubes/airways
- Bronchitis
- Tightening of the bronchial tubes/airways causing wheezing or coughing
- Worsening Chronic Obstructive Pulmonary Disease (COPD)
- Death
- Breathlessness
- Coughing up blood
- Infection
- Movement of the valve in the lung or out of the lung
- Persistent cough
- Buildup of air in the chest cavity
- Pneumonia
- Respiratory failure
- Chest pain
- Tissue reaction at the site of the valve
- Valve breakage

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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Patient Information:

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