






IMPLANT CARD LEAFLET



	<p>EN: Complete the required lines on the Implant Card using a waterproof pen.</p>
	<p>EN: Give the Implant Card and the Implant Card Leaflet to the patient.</p>
	<p>EN: MR conditional, for details refer to manufacturer website.</p>

Occlutech ASD Occluder

The implanted product, Figulla Flex II ASD Occluder, is used to close an Atrial Septal Defect (ASD). ASD is a birth defect in the septum between the right and left atrium, the two smaller up-per chambers of the heart. As the blood pressure on the left side is usually higher than on the right side, this leads to continuous blood flow across the ASD-hole from the left to the right side. A volume overload of the right heart can have serious consequences. It can lead to enlargement of the right heart, heart failure and hypertension in the lung arteries over years. Therefore, ASDs of significant size are usually closed to avoid serious long-term consequences, even though the patient in younger age might not feel any type of discomfort.

The product is made of nitinol mesh, PET patches and medical suture and has no lifetime limitation.

After the procedure

Your physician will provide you with a check-up schedule, usually with the following intervals:

- Day after the implantation
- After 1, 3 and 6 months. During check-ups, your physician will confirm the proper placement of the device using standard hospital diagnostic methods e.g., echocardiography.

Things to think about after the procedure

- Take all the medication as recommended by your physician.
- Avoid physical strain for a minimum of 2 weeks.
- Carry your implant card.
- If you experience any symptoms of shortness of breath or chest pain at any time, seek medical care immediately.

Travelling

The device will not set-off any metal detectors at an airport security scan.

Magnetic resonance imaging (MRI)

An MRI scan of 1.5 and 3 Tesla are tested conditionally safe under specific settings and is possible to perform immediately after the procedure. Please tell your radiologist prior to an MRI scan that you carry an implant.

NOTE: For Australia only. Any serious incident that occurs in relation to the implant should be reported to the manufacturer and to the Therapeutic Goods Administration (TGA) at complaints@occlutech.com and www.tga.gov.au/reporting-adverse-events, respectively.

Manufacturer:

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