Doc ID: P17F08.009.02_ Printing file_Implant Card Leaflet_ PFO

Occlutech

IMPLANT CARD LEAFLET

1 **2**

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

Occlutech PFO Occluder
The implanted product, Figulla Flex II PFO Occluder, is used to close the Patent Foramen Ovale (PFO) which is a flap-like hole in the heart between the upper chambers (in the atrial septum). This hole is important during fetal development and normally closes at birth or within the first year. This congenital heart defect is fairly common and occurs in about 25% of the population. An open PFO is not necessarily a concern, it can stay uneventful and even unrecognized. However it has been shown that in some people, an unclosed PFO can cause an increased risk of strokes, migraines or other diseases.

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:
Occlutech GmbH
Winzerlaer Straße 2
07745 Jena, Germany