Occlutech

FIGULLA FLEX II PFO OCCLUDER

PATIENT INFORMATION LEAFLET

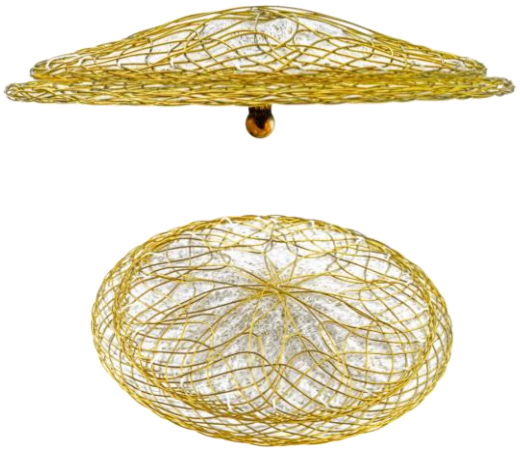
Name of device	Figulla Flex II PFO Occluder
Intended purpose	Figulla Flex II PFO Occluder, is used to close the Patent Foramen Ovale (PFO), which is a flap-like hole in the heart between the upper chambers (in the atrial septum). This hole is important during fetal development and normally closes at 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.
Intended patient	The Figulla Flex II PFO Occluder is intended to close Patent Foramen Ovale (PFO).
Contraindications ***(when the device should not be used)***	The Figulla Flex II PFO Occluder is contraindicated in the following cases: • Acute *(serious, short-term)* infection. • Adequate oral anti-coagulation therapy / platelet inhibition is not possible post-intervention *(after treatment it is not possible to maintain normal blood function with additional therapy).* • Arrhythmia *(abnormal heartbeat).* • Atrial *(upper chamber of the heart)* tumor. • Atrial thrombus *(blood clots in the upper chamber).* • Eisenmenger-syndrome *(heart condition present from birth, where high pressure in the lung arteries makes it harder for blood to flow through the lungs).* • Known coagulation disorder *(the body forms too many or too few blood clots).* • Intolerance to contrast *(substance to improve the visibility of internal body structures in MRI-scanning)* agents. • Allergies to nickel and/or titanium and/or nickel and/or titanium-related materials. • Recent pelvic venous *(vein)* thrombosis *(blood clot).* • Recent myocardial infarction *(heart attack)* or bypass surgery (*creation of a new path for blood to flow to the heart)* within the last 30 days. • Patients with insufficient distance (< 9 mm as measured by echo) from the PFO defect to the Superior Vena Cava valves and free walls of the atrium *(general incompatible neighboring cardiac structures).* • Patients whose size or condition would cause the patient to be a poor candidate choice for cardiac catheterization *(procedure in which a thin, flexible tube (catheter) is guided through a blood vessel to the heart to diagnose or treat certain heart conditions)* (e.g. too small for echocardiography imaging probe, catheter size, vasculature size, active infection, body weight < 8 kg) *(some patients are not suitable for the procedure).*

Warnings and precautions	If you experience any symptoms of shortness of breath or chest pain at any time, seek medical care immediately. **Magnetic Resonance Imaging (MRI)** Carriers of a Figulla Flex II PFO Occluder can be scanned safely in an MRI scanner of 1.5 and 3 Tesla. For a safe MRI scan, certain parameters must be considered. Therefore, please consult with your physician prior to any MRI procedures. **Nickel and/ or titanium allergy** Please let your physician know if you are allergic to nickel and/or titanium and/or nickel/titanium-based materials, since you may suffer an allergic reaction to this device. Contact your physician/ seek medical care immediately if you are experiencing an allergic reaction such as difficulty in breathing, or inflammation of the face or throat.
Adverse *(unwanted or unintended)* Events	• Air embolism *(when air bubbles enter the vessels)* • Allergic reactions • Anesthesia reactions *(a reaction to a drug or agent used to reduce pain to control unconsciousness)* • Apnea (*interruption of breathing)* • Arrhythmia *(irregular heartbeat)* • AV-Fistula *(ArterioVenous fistula is an abnormal channel or passage between an artery and a vein)* • Bleeding (hemorrhage) requiring treatment • Cardiac / vascular perforation *(damage in the heart or vessels)* • Cardiac tamponade *(buildup of sac fluid in the sac around the heart)* • Chest pain • Death • Embolization *(formation and release of a blood clot)* (peri *(before)* & post *(after)* procedural) • Esophageal *(the tube that connects the mouth to the stomach)* injury • Femoral access complication *(problem accessing an important vein in the thigh)* • Fever • Hematoma *(severe bruise)* • Hypertension *(high blood pressure)* or Hypotension *(low blood pressure)* • (Immediate) surgical interventions • Infections, including endocarditis (*inflammation of the inner layer of the heart's chambers and valves)* • Myocardial infarction *(heart attack)* • Pericardial effusions *(build-up of fluid in the sac around the heart)* • Pericarditis *(inflammation of the sac around the heart)* • Post-pericardiotomy syndrome *(an inflammatory response to heart surgery)* • Pseudoaneurysm *(when a blood vessels wall is injured and the leaking blood collects in the surrounding tissue)* • Pulmonary edema (*fluid in the lungs)* • Seizure • Septic state (*presence of an infection in the blood)* • Stroke • Tissue erosion *(loss of cells on the surface of a tissue)* • Thrombus *(blood clot)* formation on the device • Thrombosis *(blood clot formation in the blood flow)* • Transient ischemic attack (TIA) *(a stroke that only lasts a few minutes)* • Valvular regurgitation (*leaks in the heart valve(s))*

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.
Symptoms of malfunctioning	If you experience any of the following: • symptoms of shortness of breath or • chest pain at any time contact your physician or the ward immediately.
Expected device lifetime	The device is intended to be used for the lifetime of the patient.
Material	The product is made of nitinol (nickel / titanium alloy) mesh, PET (polyethylene terephthalate) patches and medical suture.
Notice of serious incident	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 https://www.tga.gov.au, respectively.
Manufacturer name and address:	Occlutech GmbH Winzerlaer Straße 2 07745 Jena, Germany

Figulla Flex II PFO Occluder Product List

Figulla Flex II PFO Occluder REF no.	Ø LA Disc [mm]	Ø RA Disc [mm]
18PFO25S	23	25
19PFO18D	16	18
19PFO25D	23	25
19PFO30D	27	30
19PFO35D	31	35



The Figulla Flex II PFO Occluder from the side and top.