Occlutech

FIGULLA FLEX II ASD OCCLUDER

PATIENT INFORMATION LEAFLET

Name of device	Figulla Flex II ASD Occluder
Intended purpose	The 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 upper 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 (high blood pressure) in the lung arteries over years. Therefore, ASDs of significant size are usually closed to avoid serious long-term consequences, even though you are in of younger age and might not feel any type of discomfort.
Intended patient	The Figulla Flex II ASD Occluder is intended to close atrial septal defects (ASD).
Contraindications *(when the device should not be used)*	The Figulla Flex II ASD Occluder is contraindicated 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).* • ASD defect larger than 40 mm *(too large of a defect which can not be closed with an occluder).* • ASD primum defect *(a type of defect that is not treatable with an occluder).* • Atrial *(upper chamber of the heart)* tumor. • Atrial thrombus *(blood clots in the upper chamber).* • Eisenmenger-syndrome *(birth defect where there is irregular blood flow in the heart and 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/titanium-based 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. • Shunt reversal with separated or significant right-to-left shunt *(abnormal direction of blood flow).* • 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) that is guided through a blood vessel to the heart to diagnose or treat certain heart conditions)* (e.g. too small for echocardiographic imaging probe, catheter size, vasculature size, active infection, body weight <8kg) (*some patients are not suitable for the procedure.)* • Patients with rim *(tissue surrounding the ASD defect)* sizes of < 5 mm to the coronary sinus *(large vessel)*, inferior vena cava (*large vein)* rim, an atrioventricular valve *(between the upper chambers and lower*

	chambers), or the right upper pulmonary *(lung)* vein *(abnormal circulation in the heart).*
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 ASD 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 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)* • Postpericardiotomy 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 ASD Occluder Product List

Figulla Flex II ASD Occluder REF no.	Ø Waist [mm]	Ø LA Disc [mm]	Ø RA Disc [mm]
29ASD04	4	11	9
29ASD05	5	14	11
29ASD06	6	16.5	12.5
29ASD07	7.5	18	14
29ASD09	9	20.5	16.5
29ASD10	10.5	22	18
29ASD12	12	27	23
29ASD13	13.5	28.5	24.5
29ASD15	15	30	26
29ASD16	16.5	31.5	27.5
29ASD18	18	33	29
29ASD19	19.5	34.5	30.5
29ASD21	21	36	32

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

Figulla Flex II ASD Occluder REF no.	Ø Waist [mm]	Ø LA Disc [mm]	Ø RA Disc [mm]
29ASD24	24	39	35
29ASD27	27	42	38
29ASD30	30	45	41
29ASD33	33	48	43
29ASD36	36	52	46
29ASD39	39	54	49
29ASD40	40	55	50