



OCCLUTECH PDA OCCLUDER
PATIENT INFORMATION LEAFLET

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| Name of device | Occlutech PDA Occluder |
| Intended purpose | Occlutech PDA Occluder, is used to close a patent ductus arteriosus (PDA). PDA is a defect where a neonate's ductus arteriosus fails to close after birth and remains open (patent). Normally the heart's left side only pumps blood to the body, and the right side only pumps blood to the lungs. In a person with PDA, extra blood gets pumped from the body artery (aorta) into the lung (pulmonary) arteries. If the PDA is large, the extra blood being pumped into the lung arteries makes the heart and lungs work harder and the lungs can become congested. PDA is one of the most common congenital heart defects and is much more common among premature babies and infants with genetic disorders than others. In many children the PDA will sometimes shrink and go away without any help. Most defects close within two years without treatment being necessary. |
| Intended patient | Occlutech PDA Occluder, is intended (used) in patients who have a patent ductus arteriosus (PDA). |
| Contraindications (when the device should not be used) | <ul style="list-style-type: none"> • “silent ductus”:serious pulmonary hypertension (<i>a type of high blood pressure that affects the arteries in the lungs</i>). • presence of a known coagulation (<i>inability to form blood clots</i>) disorder. • thrombus (<i>blood clot</i>) at the position allocated for the implantation. • a vein thrombosis (<i>blood clot formation in the blood flow</i>) in the blood vessels chosen for the introducing system. • an active infection (active endocarditis (<i>inflammation of the inner layer of the heart's chambers and valves</i>) or other infections causing bacteremia (<i>bacteria in the blood</i>)) or history of endocarditis within 3 months from procedure. • nitinol intolerance (nickel or titanium). • contrast medium intolerance. • patients who have a vascular system (which is used to access the defect) which is too small to admit the required sheath. |
| Warnings and precautions | <p>If you experience any symptoms of shortness of breath or chest pain at any time, seek medical care immediately.</p> <p>Magnetic Resonance Imaging (MRI)</p> <p>Carriers of an Occlutech PDA 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.</p> <p>Nickel and/ or titanium allergy</p> <p>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.</p> |

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| | 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 | <ul style="list-style-type: none"> • Active infection, including endocarditis (<i>inflammation of the inner layer of the heart's chambers and valves</i>). • Air embolism (<i>when air bubbles enter the vessels</i>). • Allergic reactions (dye, drug, or device). • Aortic obstruction (<i>blocked or clogged artery</i>). • Apnea (<i>interruption of breathing</i>). • Arrhythmias (<i>irregular heartbeat</i>). • Bleeding. • Cardiac or vessel perforation (<i>damage in the heart or vessels</i>). • Cardiac tamponade (<i>buildup of sac fluid in the sac around the heart</i>). • Chest pain or palpitations (<i>when your heartbeat becomes more noticeable</i>). • Death. • Device embolization. • Fever. • Headache / Migraine. • Hyper- (<i>high blood pressure</i>) or hypotension (<i>low blood pressure</i>). • Iatrogenic (<i>unintentional complication</i>) coarctation (<i>narrowing</i>) of the aorta. • Intervention for device removal. • Myocardial infarction (<i>heart attack</i>). • Patients with Nickel allergy: the implant may elicit allergic reactions. • Pericardial effusion (<i>build-up of fluid in the sac around the heart</i>). • Peripheral embolism (<i>blockage of the surrounding vessels in the body</i>). • Pleural effusion (a buildup of fluid between the layers of tissue that line the lungs and chest cavity). • Pulmonary embolism (<i>sudden blockage of the vessels in the lungs</i>). • Stroke or TIA (<i>a stroke that only lasts a few minutes</i>). • Thrombus (<i>blood clot</i>) at site of implantation. |
| After the procedure | <p>Your physician will provide you with a check-up schedule, usually with the following intervals:</p> <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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 | <p>If you experience any of the following:</p> <ul style="list-style-type: none"> • symptoms of shortness of breath or • chest pain at any time <p>contact your physician or the ward immediately.</p> |
| 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 |

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| | (TGA) at complaints@occlutech.com and https://www.tga.gov.au , respectively. |
| Manufacturer name and address: | Occlutech Tıbbi Ürünler San. ve Tic. Ltd. Şti Yeşilköy SB Mah., E Blok Sok. Occlutech Apt. No: 6 34149 Bakırköy / İstanbul, Turkey |

Occlutech PDA Occluder Product List

| | Occlutech PDA Occluder REF no. | Ø Disc [mm] | Ø Waist [mm] | Ø Shank [mm] | Length L [mm] |
|---------------------|--------------------------------|-------------|--------------|--------------|---------------|
| Standard PDA | 42PDA05 | 9 | 3.5 | 5 | 4.25 |
| | 42PDA06 | 10 | 4 | 6 | 5.00 |
| | 42PDA07 | 11 | 5 | 7 | 6.05 |
| | 42PDA08 | 13 | 6 | 8 | 6.30 |
| | 42PDA10 | 16 | 8 | 10 | 7.00 |
| | 42PDA12 | 18 | 10 | 12 | 12.00 |
| | 42PDA15 | 20 | 12 | 15 | 14.00 |
| | 42PDA18 | 24 | 14 | 18 | 16.00 |
| PDA with long shank | 43PDA05L | 9 | 3.5 | 5 | 7.00 |
| | 43PDA06L | 10 | 4 | 6 | 7.50 |
| | 43PDA07L | 11 | 5 | 7 | 8.50 |
| | 43PDA08L | 13 | 6 | 8 | 9.00 |
| | 43PDA10L | 16 | 8 | 10 | 10.50 |



The Occlutech PDA Occluder from the side.