

After the procedure ...

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

- Day after the implantation
- After 1, 2, 6, and 12 months

During check ups your physician will confirm the proper placement of the device using standard hospital diagnostic methods e.g., echocardiography.³

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.³

Occlutech ASD Occluder and Magnetic Resonance Imaging

Patients carrying an Occlutech 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.³

Occlutech ASD Occluder and travelling

The device will not set off any metal detectors at an airport security scan.³

Further questions

In case of any other questions related to the device, please consult with your physician.³

About Occlutech

Occlutech is a leading provider of minimally invasive structural heart disease devices. Our products are implanted in tens of thousands of human hearts every year, avoiding surgery, while minimizing potentially fatal complications.

With more than 100,000 implants in over 80 countries, Occlutech has a product performance track record and experience of more than 15 years.

We are committed to continuously perfecting physicians' performance around the world for the benefit of their patients.

References:

1. 2016 Haas et. al. Closure of Secundum Atrial Septal Defects by Using the Occlutech Occluder Devices in More Than 1300 Patients: The IRFACODE Project: A Retrospective Case Series. Journal of Catheter and Vascular Interventions
2. 2015 Godart et. al. Transcatheter closure of atrial septal defect with the Figulla® ASD Occluder: A comparative study with the Amplatzer® Septal Occluder
3. P17.F02.029.05: Occlutech Figulla Flex II ASD Instructions For Use

For more information about Occlutech and its products visit:
www.occlutech.com

Patient Information

Perfecting Performance

Closure of Atrial Septal Defect



Occlutech International AB
Landskronavägen 2, SE-252 32 Helsingborg, Sweden
info@occlutech.com, www.occlutech.com

Occlutech Customer Service: + 46 704 33 65 26

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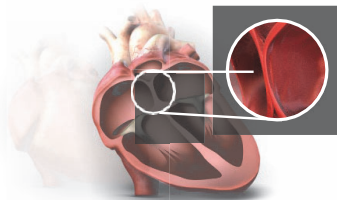




1. The Atrial Septal Defect (ASD)

An Atrial Septal Defect (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 in the lung arteries over years. Therefore, ASDs of significant size are usually closed to avoid serious long-term consequences, even though the patient of younger age might not feel any type of discomfort.¹

ASD area shown on a normal, healthy heart



2. Closing the defect

Today, closing an ASD requires no longer a surgical intervention. The minimal invasive closure is performed in a cardiac catheterization laboratory, also known as a cath lab. A thin tube (catheter) is inserted in a blood vessel in the groin and guided to the heart. The size and exact location of the ASD is measured by ultrasound (echo), x-ray or with a so-called balloon sizing catheter.²

The Occlutech ASD Occluder has two umbrella-shaped flexible discs with a connection in the middle. The device collapses down to fit into the catheter. When ejected, the shape-memory properties return the device to the two umbrella-disc shape. The discs allow a secure attachment to both sides of the atrial septum. Once in place, your physician will confirm proper placement before releasing the device and withdrawing the catheter.³

3. Device in position

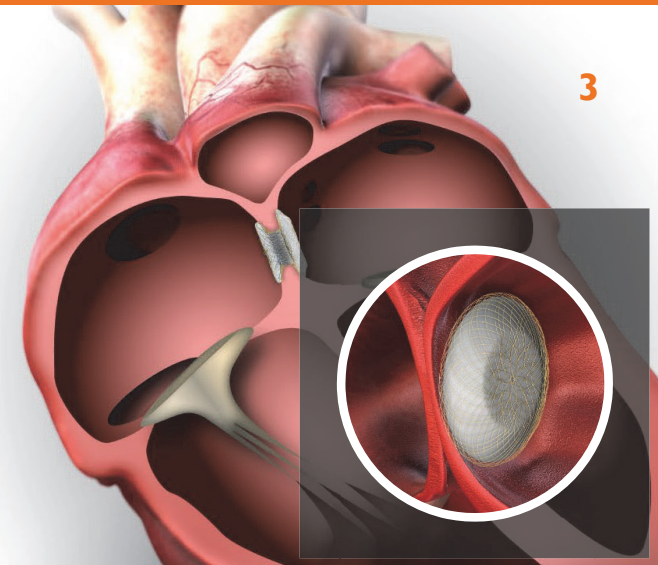
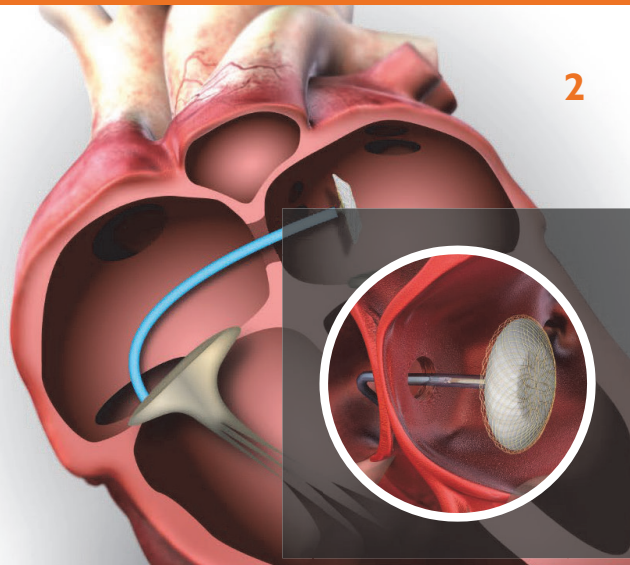
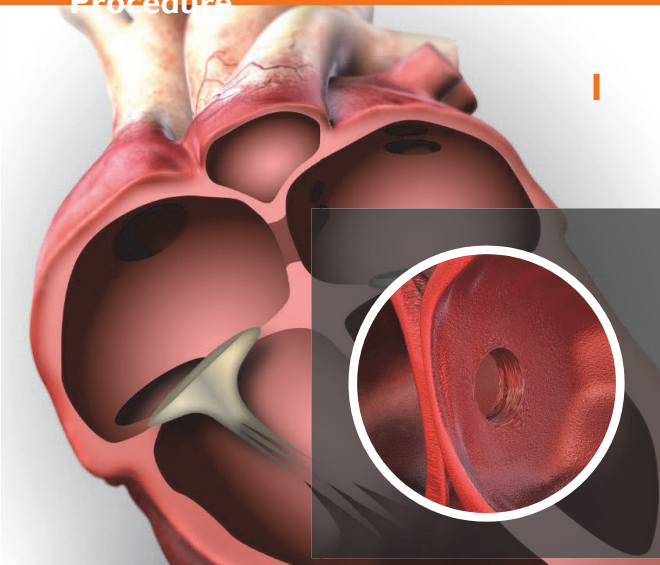
The device is now in the correct position and the defect is closed by the two discs of the device. For closing the little incision in the groin, usually no stitches are required, only a pressure bandage.

After a few months, the device will be covered by a thin layer of cells, then covered by the heart's tissue and over time the defect should be completely overgrown.³

Occlutech® ASD Occluder



Procedure



Clinical Trial Summary

Occlutech conducted a randomized, controlled, multi-center trial to assess the safety and effectiveness of the Occlutech® ASD Occluder (also called the Figulla Flex II ASD Occluder) in 176 patients who had a secundum-type atrial septal defect (ASD). Two-thirds of patients were randomly (like flipping a coin) assigned to receive the Occlutech ASD and the other one-third of patients received an FDA approved device. About 60% of the patients enrolled in the trial were between the ages of 2 to 17 years old. About 95% of patients who received the Occlutech® ASD Occluder had successful closure of their ASD. Successful closure means that patients did not have a large or moderate residual shunt or any major complications, surgical reintervention, or device embolization (movement of the device to an unintended part of the body) one day after the procedure. By 6 months, about 82% of patients' ASDs had completely closed. The study showed that the Occlutech® ASD Occluder had a very high success rate closing the ASD. Compared to the approved device group, patients treated with the Occlutech® ASD Occluder had similar rates of successful closure and procedure related complications such as headache, hematoma (bruising where the catheter is placed in the leg), irregular heartbeat, infections and unintended movement of the device.

Contraindications

The Occlutech ASD Occluder is contraindicated for patients that have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery. Additionally any patient known to have sepsis within 1 month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement, or any patient known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy, unless another antiplatelet agent can be administered for 6 months, is contraindicated. Other contraindications include patients known to have demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi), or any patient whose size (such as, too small for transesophageal echocardiography probe, catheter size) or condition (active infection, etc.) would cause the patient to be a poor candidate for cardiac catheterization. Contraindications include any patient where the margins of the defect are less than 5 mm to the coronary sinus, inferior vena cava rim, AV valves, or right upper lobe pulmonary vein. Please discuss with your Physician if any of these contraindications apply to you or the Patient.