Occlutech

Interventional Systems
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SHARING EXPERTISE

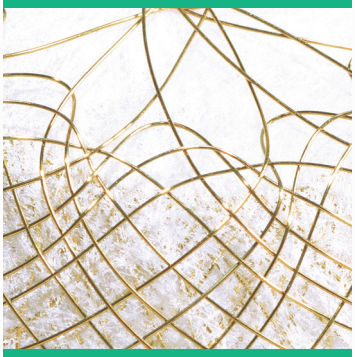
Occlutech® ASD Occluder

Intended for Percutaneous Transcatheter Closure of Ostium Secundum Atrial Septal Defects

Deliver Confidently.

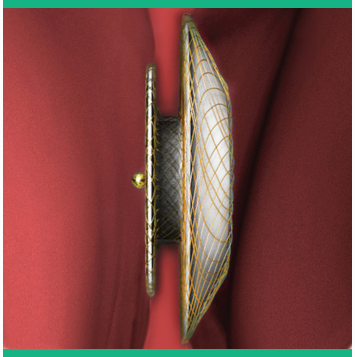
Occlutech® ASD Occluder

Design characteristics allow you to confidently deliver the Occlutech ASD Occluder.

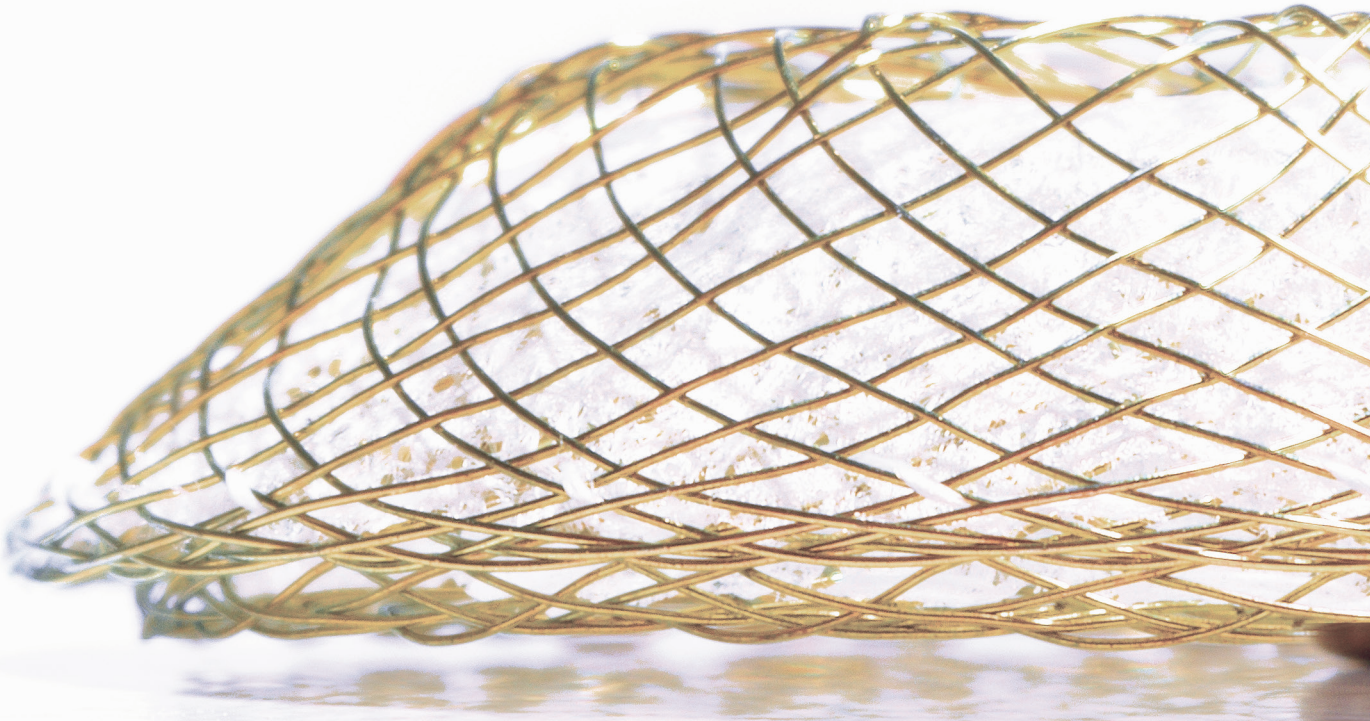


Titanium oxide-covered nitinol is biocompatible [1,2]

Ultra-thin PET-patches facilitate endothelization [2]

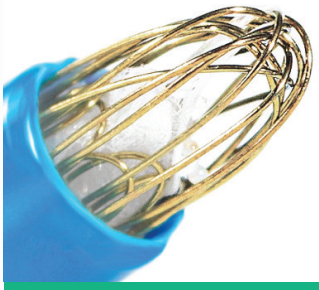


Closure of atrial septal defects from 6 to 33 mm [3]



Delivery system is intuitively designed

Bioptome-like jaw creates a reliable lock between pusher and occluder [4,5]



Less material at the left atrial disk combined with flexible wires produces a conformable atraumatic device [2]

Occlutech® ASD Occluder

Increased Feasibility

The Occlutech ASD Occluder is designed with less material at the left atrial disc which allows it to develop into a round shape during left atrial deployment. This minimizes the risk of the device prolapsing across the atrial septum. [4,5]

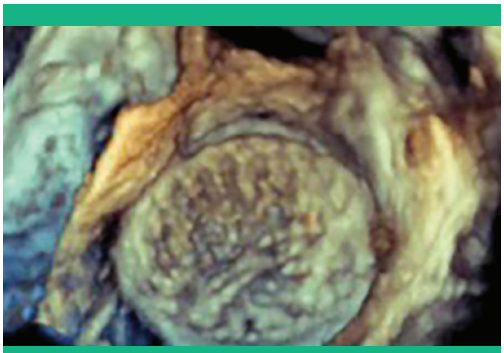
Optimal Septal Alignment

The Occlutech ASD Occluder is designed with a unique ballshaped hub which allows a 45-degree implantation angle, reducing tension during right-side deployment. This minimizes the risk of device jump upon release. [4,5]

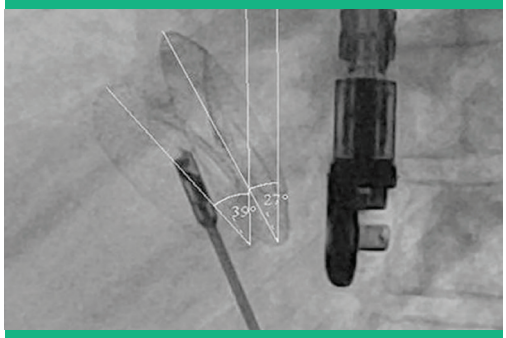
Clinical Benefits

Peer-reviewed studies have concluded that transcatheter closure of isolated ostium secundum atrial defects using the Occlutech® ASD Occluder is safe and effective with proven outcomes. [1-7]

- Significantly higher rate of successful device placement at first attempt at 99.1% [3]
- Significantly reduced mean procedure and fluoroscopic time compared to other devices [5,7]
- Demonstrated a lower rate of supraventricular arrhythmias [7]
- A meta-analysis for atrial septal defect devices documented no reports of device fracture [7]
- Proven suitable for a large variety of patients including small children (<15 kg) and deficient rim anatomies [4,5]



3D TEE image of an implanted Occlutech ASD Occluder



45 degrees of angulation of Occlutech ASD Occluder using Occlutech Pistol Pusher

References

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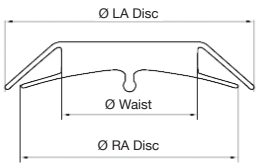
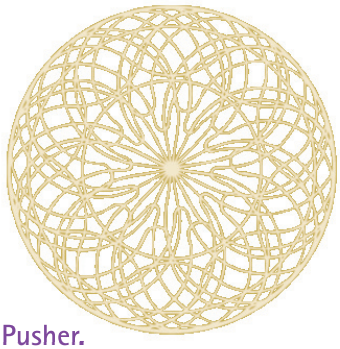
Occlutech® ASD Occluder

Ordering Information

Ø LA Disc: Diameter of distal disc [mm] (Left Atrial)
Ø RA Disc: Diameter of proximal disc [mm] (Right Atrial)
Ø Waist: Waist Diameter [mm]





The Occlutech ASD Occluder is packaged together with its compatible Occlutech Pistol Pusher.

Material Number	Description	Ø Waist (mm)	Ø LA Disc (mm)	Ø RA Disc (mm)	Defect Size (mm)	Sheath Size (F)	Size-Matched Compatible Occlutech Pistol Pusher*
37ASD06P	Occlutech ASD Occluder Procedure Pack 6mm	6	16.5	12.5	5 < D ≤ 6	7	
37ASD07P	Occlutech ASD Occluder Procedure Pack 7mm	7.5	18	14	6 < D ≤ 7.5	7	
37ASD09P	Occlutech ASD Occluder Procedure Pack 9mm	9	20.5	16.5	7.5 < D ≤ 9	7	
37ASD10P	Occlutech ASD Occluder Procedure Pack 10mm	10.5	22	18	9 < D ≤ 10.5	7	
37ASD12P	Occlutech ASD Occluder Procedure Pack 12mm	12	27	23	10.5 < D ≤ 12	9	
37ASD13P	Occlutech ASD Occluder Procedure Pack 13mm	13.5	28.5	24.5	12 < D ≤ 13.5	9	
37ASD15P	Occlutech ASD Occluder Procedure Pack 15mm	15	30	26	12 < D ≤ 15	9	
37ASD16P	Occlutech ASD Occluder Procedure Pack 16mm	16.5	31.5	27.5	15 < D ≤ 16.5	9	
37ASD18P	Occlutech ASD Occluder Procedure Pack 18mm	18	33	29	15 < D ≤ 18	9	
37ASD19P	Occlutech ASD Occluder Procedure Pack 19mm	19.5	34.5	30.5	16.5 < D ≤ 19.5	10	
37ASD21P	Occlutech ASD Occluder Procedure Pack 21mm	21	36	32	18 < D ≤ 21	11	
37ASD24P	Occlutech ASD Occluder Procedure Pack 24mm	24	39	35	21 < D ≤ 24	11	
37ASD27P	Occlutech ASD Occluder Procedure Pack 27mm	27	42	38	24 < D ≤ 27	12	
37ASD30P	Occlutech ASD Occluder Procedure Pack 30mm	30	45	41	27 < D ≤ 30	12	
37ASD33P	Occlutech ASD Occluder Procedure Pack 33mm	33	48	43	30 < D ≤ 33	12	

**Color defines compatible Occlutech Pistol Pusher for respective Occlutech ASD Occluder. To facilitate size-matching between the Occlutech ASD Occluder implant and its compatible Occlutech Pistol Pusher, the color of the Occlutech Pistol Pusher's handle is the same as the color-code sticker placed on the Tyvek pouch as well as on the outer box for the Occlutech ASD Occluder.*

Instructions for Use

Indications for Use and Area of Application

The Occlutech® ASD Occluder is a medical device intended for transcatheter closure of ostium secundum-type atrial septal defects (ASD). Patients indicated for ASD closure have:

- Echocardiographic evidence of ostium secundum-type ASD,
- Clinical evidence of right ventricular (RV) volume overload (hemodynamically significant left-to-right shunt with Qp / Qs ≥ 1.5 or RV enlargement).

Contraindications

The Occlutech ASD Occluder is contraindicated for the following:

- Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
- 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.
- 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.
- Any patient known to have demonstrated intracardiac thrombi on echocardiography (especially left atrial or left atrial appendage thrombi).
- 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.
- 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.

Warnings

- The Occlutech ASD Occluder must be implanted exclusively by physicians trained in its use and experienced with interventional transcatheter ASD closure techniques.
- Physicians who implant the Occlutech ASD Occluder must be able to recognize, assess and manage procedure-associated emergencies. On-site cardiac surgical support with corresponding personnel must be available.
- The use of improperly size-matched devices could seriously affect hemodynamics and optimal results. Before using this device, physicians shall carefully review the hemodynamic parameters as well as sizing information printed on the labels of the Occlutech ASD Occluder and its accessories (OPP and Occlutech Delivery Set III (ODS III)). Physicians shall also review the sizing and compatibility chart in section 5.1 (Table 1: Device Sizes and Recommended Occlutech Delivery Sets) before starting a procedure. Careful consideration shall be given to ensure accurate size matching of its accessories with the corresponding device (i.e. review of device labels and color-coding).
- Before using the Occlutech ASD Occluder, the physician shall carefully review section 9 (Implantation Procedure) including relevant instructions therein on connecting the Occlutech ASD Occluder to the OPP. If a secure connection between the Occlutech ASD Occluder and OPP is not verified as described, disconnection of the device from the pusher may occur and the Occlutech ASD Occluder may embolize causing a life-threatening situation.
- The Occlutech ASD Occluder should not be used with delivery systems other than those recommended in section 5.1 (Table 1: Device Sizes and Recommended Occlutech Delivery Sets).
- After deployment and release of the Occlutech ASD Occluder, complications such as device dislocation or embolization may occur as a result of erroneous positioning or sizing of the device. These complications can present a life-threatening situation to the patient.
- An embolized Occlutech ASD Occluder must be retrieved using a snare and a larger delivery sheath. An emergency kit for the retrieval of the Occlutech ASD Occluder must be available in the catheterization laboratory during the procedure.
- The Occlutech ASD Occluder should only be released from the OPP after the physician has confirmed that the device is positioned correctly. This should be determined by performing fluoroscopy and/or Transesophageal (TEE) or Intracardiac Echocardiography (ICE) to visualize the Occlutech ASD Occluder and to confirm that the device is positioned properly.
- While still connected to the OPP, the Occlutech ASD Occluder can be retrieved or re-positioned using the recommended ODS III.
- The Occlutech ASD Occluder must be used exclusively in accordance with this IFU and its implantation is to be carried out as described in this IFU.
- The physician shall inspect all packaging and labels of all devices before opening and follow the Instructions for Use. If the product box or sterile packaging is damaged in any manner, the Occlutech ASD Occluder shall be considered as unsterile and should not be used.
- The physician shall not use this device or any of its components if a seal appears to be broken (contents may not be sterile); if the label appears marked with text or symbols other than those on the label shown in this IFU or if the label is illegible, inappropriate, or absent.
- The physician shall not use this device or any of its components after the "use by" (expiration) date.
- The Occlutech ASD Occluder and OPP is intended for single use only, and is not suitable for re-sterilization. As soon as the Occlutech ASD Occluder and OPP devices are removed from the sterile packaging and used, they are contaminated. Re-use or re-sterilization may compromise the structural integrity of the devices, lead to device failure, and result in patient injury, illness or death.
- If, after inspection by the physician, the Occlutech ASD Occluder appears damaged or does not appear to function properly, the device is not suitable for implantation.
- Patients with a rim < 5 mm from the aortic root may have a higher risk of erosion and if closed using a device, they will require closer follow up. Patients with rim sizes < 5 mm to the coronary sinus, inferior vena cava rim, an atrioventricular valve, or the right upper pulmonary vein may have a higher risk of device embolization and it is best to avoid doing such cases.
- Patients should be advised to avoid strenuous physical activity for a period of at least 2 weeks after device implantation.
- The Occlutech ASD Occluder contains nitinol, an alloy of nickel and titanium. Patients allergic to nickel and/or titanium and/or nickel/titanium-based materials may suffer an allergic reaction to this device. Certain allergic reactions can be serious. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials. Patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty in breathing, or inflammation of the face or throat.

Precautions

- Patients with body weight < 8 kg might be at higher risk for complications.
- The use of a single Occlutech ASD Occluder device to repair multiple ASDs might bear a risk of inadequate closure or residual shunts. Cryptogenic stroke caused by ASD related left circulatory embolism has not been clinically evaluated for the Occlutech ASD Occluder. The use of this device has not been studied in patients with patent foramen ovale.
- Use standard interventional cardiac catheterization techniques to place the Occlutech ASD Occluder.
- Placement of the Occlutech ASD Occluder may impact future cardiac interventions, for example transseptal puncture and mitral valve repair.

Refer to the Occlutech ASD Occluder and Occlutech Pistol Pusher Instructions for Use for complete prescribing indications, contraindications, warnings and precautions.

Occlutech® ASD Occluder is a registered trademark of Occlutech Holding AG.

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The Occlutech ASD Occluder, Occlutech Pistol Pusher and Occlutech Delivery Set III are intended for single use only.

For more information, please contact your representative or call 877-836-2228.

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