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Occlutech® ASD Occluder

Implantation Guide

The Occlutech ASD Occluder is a permanent cardiac implant intended to be delivered by a percutaneous, transcatheter procedure and to close ostium secundum-type atrial septal defects.

Deliver Confidently.

Occlutech® ASD Occluder

Implantation Guide

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NOTE: This Implantation Guide does not replace the Instructions for Use of the Occlutech ASD Occluder, Occlutech Pistol Pusher or Occlutech Delivery Set III. Always consult the Instructions for Use before use of the devices.

Occlutech® ASD Occluder

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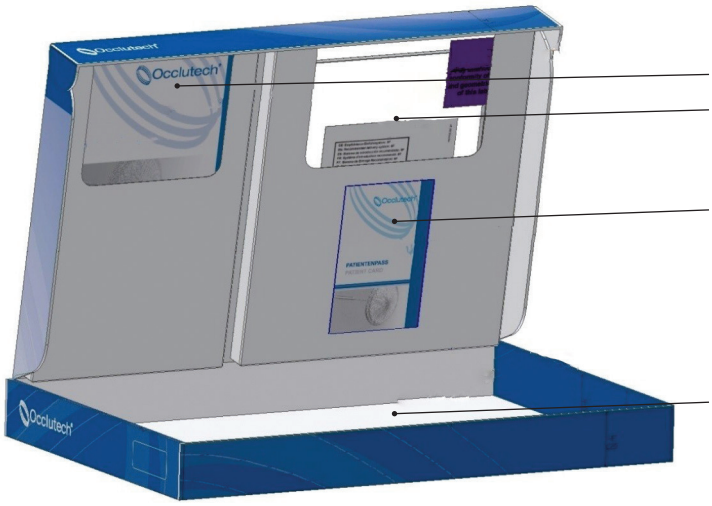
Occlutech ASD Occluder

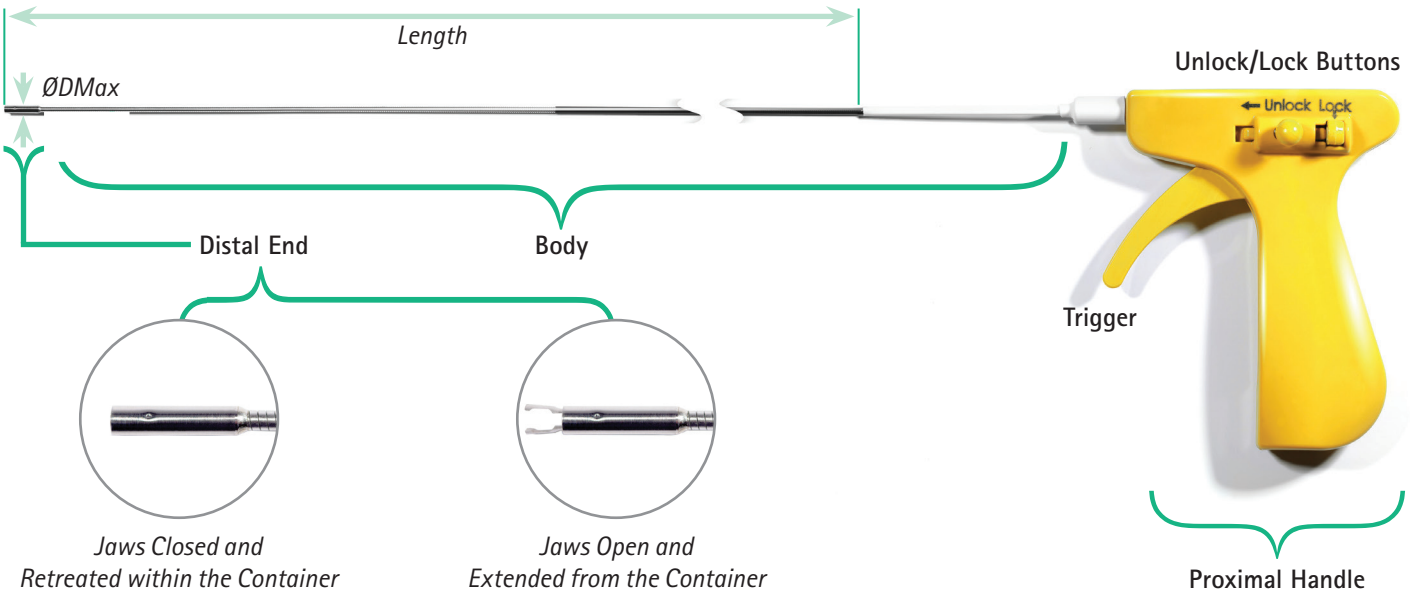
The Occlutech Atrial Septal Defect (ASD) Occluder is a permanent cardiac implant intended to be delivered by a percutaneous, transcatheter procedure and to close atrial septal defects of type ostium secundum. The Occlutech ASD Occluder is designed with highly flexible wires that allow the device to collapse, be pulled into a delivery sheath, and return to its original shape once it is deployed at the implantation site. The Occlutech Pistol Pusher (OPP) is a percutaneous, transcatheter pusher system used for the delivery of the Occlutech ASD Occluder to the implantation site. The Occlutech ASD Occluder is packaged together with its compatible Occlutech Pistol Pusher.

Occlutech® Pistol Pusher

The Occlutech Pistol Pusher is composed of a proximal handle, body and distal end. The proximal handle is manufactured from plastic components. The body is a polymer-laminated stainless-steel coil, while the distal section consists of a stainless-steel jaw container and titanium alloy jaws. The proximal handle has a trigger which allows the jaws to extend from and retreat within the jaw container, in addition to grabbing and securing the ball-connector of the Occlutech ASD Occluder. The proximal handle also contains buttons which lock and unlock the jaws in order to prevent unintentional release of the occluder.

Occlutech Process Pack





The Occlutech® Pistol Pusher (OPP) is offered in a length of 120 cm and is manufactured with four different jaw sizes for compatibility with the different ball-connectors located on the proximal disc of the Occlutech® ASD Occluder. To facilitate size-matching between the Occlutech ASD Occluder and its compatible Occlutech Pistol Pusher, the color of the OPP handle is the same as the color-coded sticker on the Tyvek Pouch of the Occlutech ASD Occluder, as well as the outer box.

Occlutech Pistol Pusher Color Code	Length (cm)	Minimum Inner Diameter of Compatible Delivery Sheath (mm)	Jaw Container Outer Diameter (mm)
	120	2.23 *(7 Fr)*	2.13
	120	2.83 *(8 Fr)*	2.73
	120	3.03 *(9 Fr)*	2.93
	120	3.33 *(10 Fr)*	3.23

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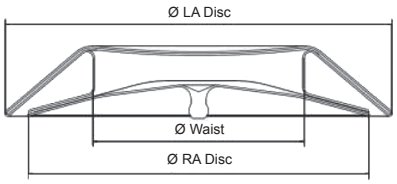
Device Sizing and Selection:

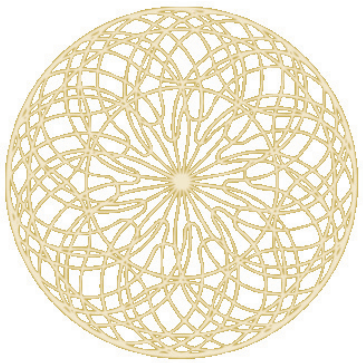
Based on precise ASD measurement and device-related sizing information, select an appropriate Occlutech ASD Occluder. The Occlutech ASD Occluder is packaged together with its size-matched Occlutech® Pistol Pusher (OPP).

Ø LA Disc: Diameter of distal disc [mm] (Left Atrial)

Ø RA Disc: Diameter of proximal disc [mm] (Right Atrial)

Ø Waist: Maximum Waist Diameter [mm]





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

*Color defines compatible Occlutech Pistol Pusher for respective Occlutech ASD Occluder.

Compatible Accessories:

Prepare a compatible loader and sheath for proper delivery of the Occlutech® ASD Occluder. The Occlutech® Delivery Set III (ODS III) consists of a braided sheath with three-way stopcock on a side port, dilator and loader. The ODS III is compatible with the Occlutech ASD Occluder and recommended per the IFU.

Material Number	Description	Size-Matched Compatible OPP*	Sheath Size (Fr)	ODS III Material Number	ODS III Loader Usable Length (mm)	ODS III Sheath Usable Length (mm)	ODS III Distal Angle (°)
37ASD06P	Occlutech ASD Occluder Procedure Pack 6 mm		7	98DS007	85	790	45
37ASD07P	Occlutech ASD Occluder Procedure Pack 7 mm		7	98DS007	85	790	45
37ASD09P	Occlutech ASD Occluder Procedure Pack 9 mm		7	98DS007	85	790	45
37ASD10P	Occlutech ASD Occluder Procedure Pack 10 mm		7	98DS007	85	790	45
37ASD12P	Occlutech ASD Occluder Procedure Pack 12 mm		9	98DS009	125	790	45
37ASD13P	Occlutech ASD Occluder Procedure Pack 13 mm		9	98DS009	125	790	45
37ASD15P	Occlutech ASD Occluder Procedure Pack 15 mm		9	98DS009	125	790	45
37ASD16P	Occlutech ASD Occluder Procedure Pack 16 mm		9	98DS009	125	790	45
37ASD18P	Occlutech ASD Occluder Procedure Pack 18 mm		9	98DS009	125	790	45
37ASD19P	Occlutech ASD Occluder Procedure Pack 19 mm		10	98DS010	125	790	45
37ASD21P	Occlutech ASD Occluder Procedure Pack 21 mm		11	98DS011	165	790	45
37ASD24P	Occlutech ASD Occluder Procedure Pack 24 mm		11	98DS011	165	790	45
37ASD27P	Occlutech ASD Occluder Procedure Pack 27 mm		12	98DS012	165	790	45
37ASD30P	Occlutech ASD Occluder Procedure Pack 30 mm		12	98DS012	165	790	45
37ASD33P	Occlutech ASD Occluder Procedure Pack 33 mm		12	98DS012	165	790	45

*Color defines compatible Occlutech Pistol Pusher for respective Occlutech ASD Occluder.

Occlutech® ASD Occluder

Implantation Guide

Device Preparation and Implantation

1

Connect Occlutech ASD Occluder to the Occlutech Pistol Pusher

Based on precise ASD measurement and device-related sizing information, select an appropriate Occlutech ASD Occluder and the size-matched recommended ODS III. Remove the Occlutech ASD Occluder and Occlutech Pistol Pusher (OPP) from its sterile packaging. Check device integrity and OPP functionality.

Insert the distal end (jaw container) of the OPP through the hemostasis valve of the loader (Fig. 1).

The Occlutech ASD Occluder has a ball-connector that will seat within the jaws of the OPP. Pull the trigger (Fig. 2) of the OPP to extend and open jaws, then place the jaws around the ball-connector of the device. (Fig. 3).

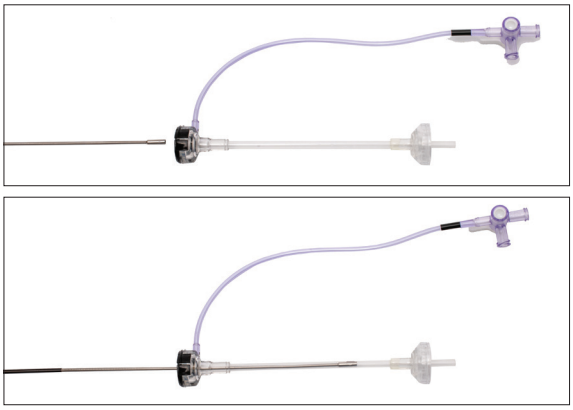


Figure 1: Insertion of OPP through loader.

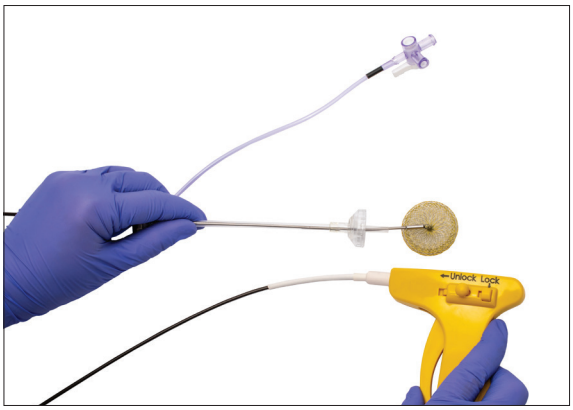


Figure 2: Depicts trigger pulled close to OPP handle in order to extend and open the jaws.

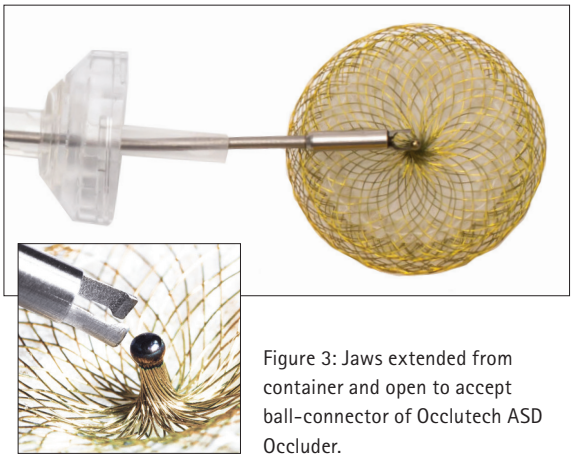


Figure 3: Jaws extended from container and open to accept ball-connector of Occlutech ASD Occluder.

Allow the trigger to return to its initial position (Fig. 4), which secures the device by closing and retracting the jaws (Fig. 5).

Push the 'LOCK' button on the OPP while ensuring that the black cable is in a straight position. Ensure that the Occlutech® ASD Occluder is securely connected to the OPP by gently rotating the device clockwise. Gently pull on the Occlutech ASD Occluder to ensure a secure connection to the OPP.

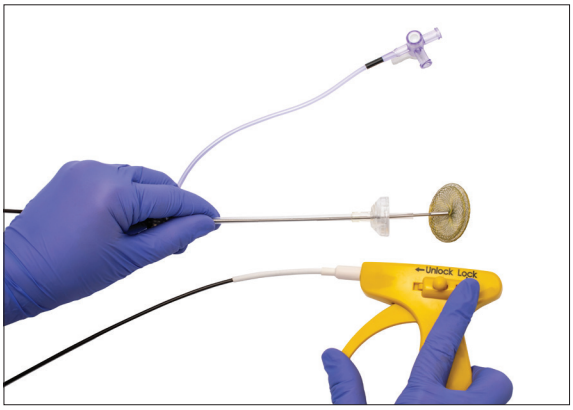


Figure 4: Depicts trigger on OPP handle returned to initial position in order to retract the jaws and a finger on the "Lock" button.

Note | The Occlutech ASD Occluder / OPP connection must be securely locked to prevent accidental release of the device. The "LOCK" mechanism is flush when in the "locked" position and protrudes when in the "unlocked" position.

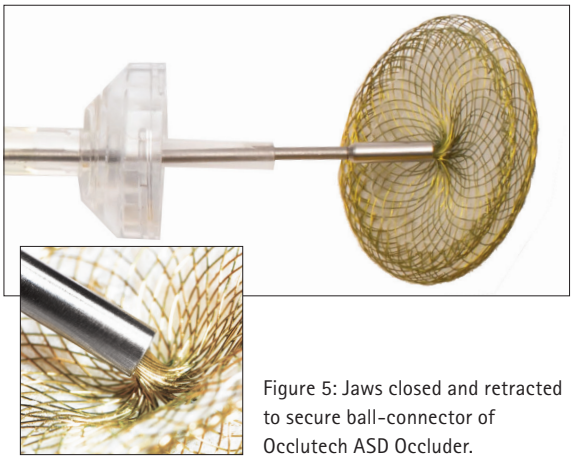


Figure 5: Jaws closed and retracted to secure ball-connector of Occlutech ASD Occluder.

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2

Load Occlutech ASD Occluder into the Compatible Loader

The Occlutech ASD Occluder and delivery system should be properly prepared for intracardiac placement through flushing (de-airing).

With the Occlutech ASD Occluder attached to the OPP, pull the device into the loader of the ODS III system, while both the device and loader (distal end) are immersed in a sterile heparinized saline solution (Fig. 6).

Note | Ensure the OPP is in a locked position before pulling the device into the loader.

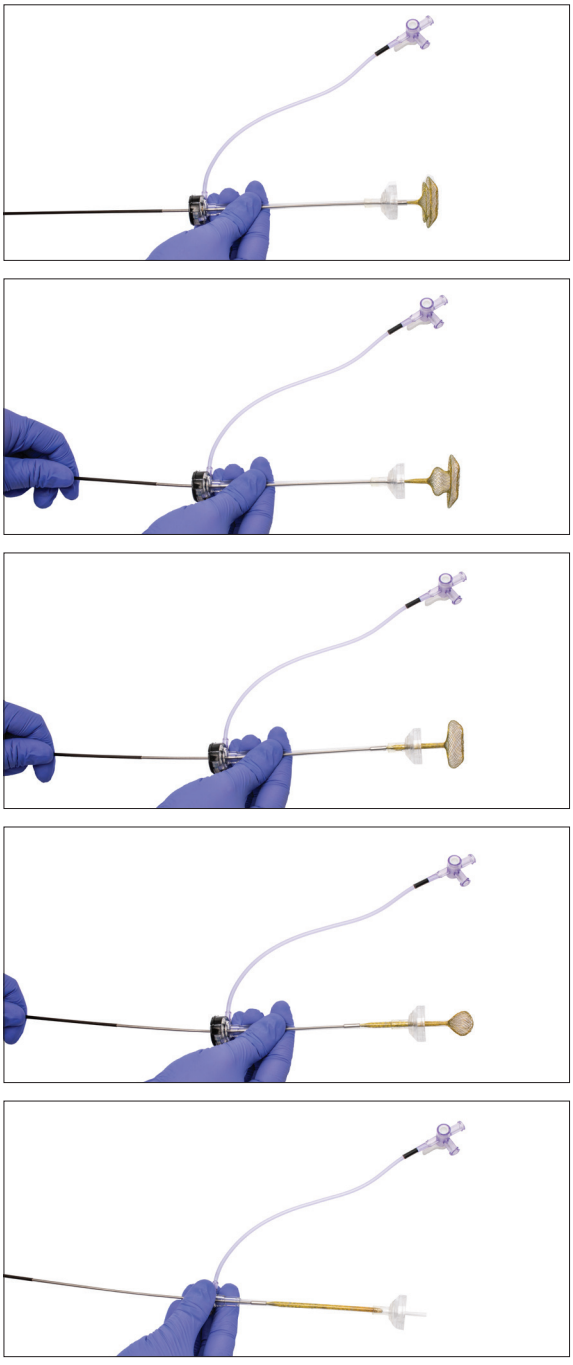

Figure 6: Images depict Occlutech ASD Occluder collapsing and being pulled into loader until it is fully retracted within the loader.

Note | The following step constitutes a potential risk of introducing air into the delivery system, which may lead to an air embolism. It is important to ensure that all air bubbles are removed from the loader and the delivery sheath as described.

After the Occlutech® ASD Occluder has been completely retracted into the loader, the loader device assembly must be thoroughly flushed using the sterile heparinized saline solution to remove any air bubbles by using a full 20 mL syringe connected to the side port of the loader (Fig. 7). Gently advance and retract the Occlutech ASD Occluder within the loader several times until properly flushed and prepared for intracardiac placement.

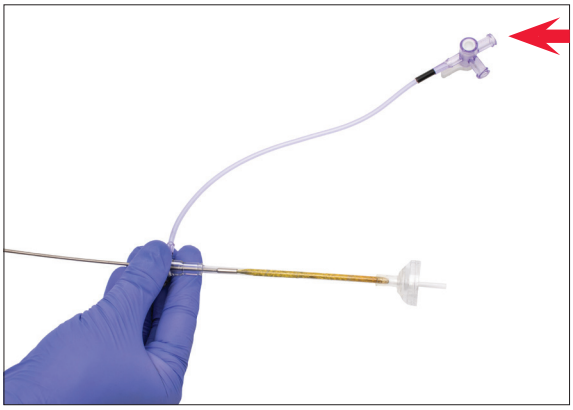

Figure 7: Side port of loader where syringe should attach (red arrow).

3

Connect Loader and Delivery Sheath

Secure the loader by pushing it through the proximal valve of the delivery sheath until it cannot be pushed further (Fig. 8 and Fig. 9). Once the loader device assembly is connected to the delivery sheath, the Occlutech ASD Occluder can be pushed from the loader to the delivery sheath by advancing the cable of the OPP.

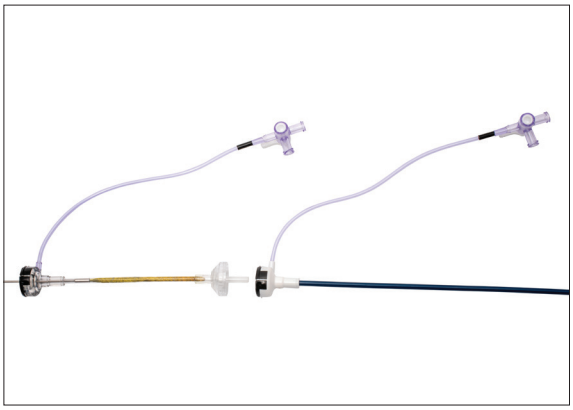

Figure 8: Depiction of loader adjacent to proximal valve of delivery sheath.

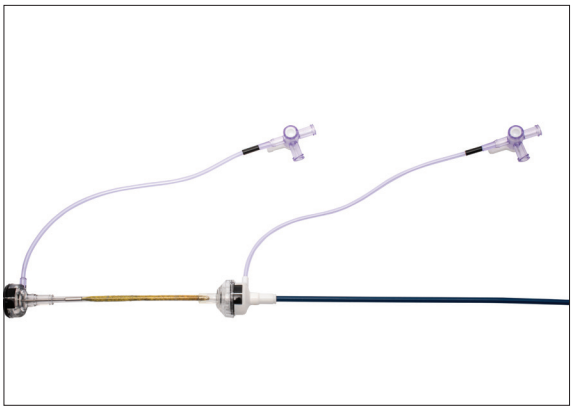

Figure 9: Depiction of loader connected to the proximal valve of the delivery sheath.

Occlutech® ASD Occluder

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4

Deployment of the Occlutech ASD Occluder

Use x-ray guidance to visualize the Occlutech ASD Occluder advancement up to the distal end of the delivery sheath, which should be positioned in the left atrium.

Once in place, the left atrial (LA) disc of the Occlutech ASD Occluder is deployed by carefully advancing the cable of the OPP towards the distal end of the delivery sheath (Fig. 10).

After the LA disc has been successfully deployed in the left atrium, it is pulled carefully together with the sheath towards the atrial septum. Maintain the relationship between the OPP and the delivery sheath while withdrawing the system, until the LA disc is engaged with the septum. An elastic resistance with pulse-synchronized movements will be observed when reaching the septum.

Note | TEE, TTE or ICE imaging should be used to confirm proper positioning of the LA disc at this time.

The delivery sheath should now have been withdrawn into the right atrium. Upon confirmation that the LA disc is engaged with the septum and the delivery sheath is in the right atrium, the right atrial disc of the Occlutech ASD Occluder is opened in the right atrium. Gently retract the delivery sheath over the OPP cable, while keeping the OPP cable in a stable position until the device has been completely deployed. Do not disconnect the Occlutech ASD Occluder from the OPP (Fig. 11 and Fig. 12).

Correct positioning of the Occlutech ASD Occluder must be confirmed through a combination of fluoroscopic analysis and/or echocardiography.

Note | If the Occlutech ASD Occluder does not adequately fit upon deployment, a correction of its position must be considered (see Notes for Troubleshooting). If repositioning of the device cannot be achieved, or a significant shunt remains, the Occlutech ASD Occluder should be withdrawn back into the delivery sheath and removed. The distributor should be contacted.

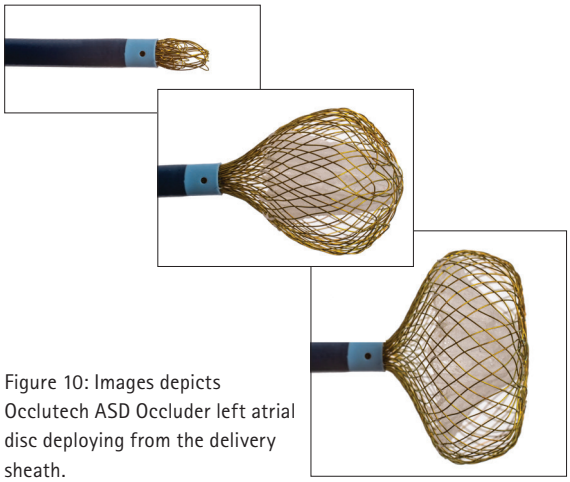

Figure 10: Images depicts Occlutech ASD Occluder left atrial disc deploying from the delivery sheath.

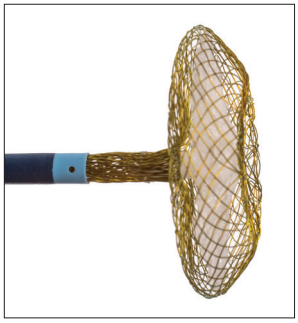

Figure 11: Image depicts the Occlutech ASD Occluder as it is pulled back to septum and initial deployment in the left atrium.

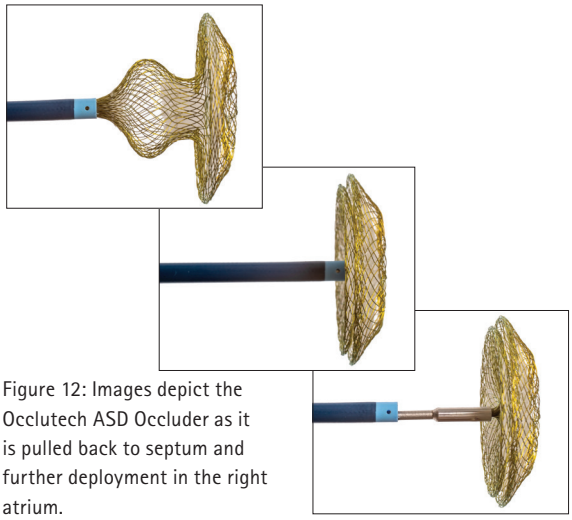

Figure 12: Images depict the Occlutech ASD Occluder as it is pulled back to septum and further deployment in the right atrium.

5

Disconnect the Occlutech® ASD Occluder Device

If the optimal fit and positioning of the Occlutech ASD Occluder has been established and confirmed by use of TEE, TTE, fluoroscopy or ICE, then the OPP can be safely disconnected.

To disconnect the Occlutech ASD Occluder, slide the 'UNLOCK' button following the direction of the arrow on the OPP and slowly pull the trigger – the jaws will extend and open, thereby releasing the ball-connector (Fig. 13). The physician should only disconnect the Occlutech ASD Occluder from the OPP once proper positioning of the device has been confirmed using fluoroscopic or echocardiographic imaging.

After the Occlutech ASD Occluder has been disconnected, the delivery sheath together with the OPP can be entirely retracted and discarded.

Figure 13: Depiction of thumb on the "UNLOCK" button which unlocks the OPP connected to the Occlutech ASD Occluder.

Note | Do not release the device from the OPP if the Occlutech ASD Occluder does not conform to its original configuration, if the device position appears unstable or if the device interferes with any adjacent cardiac structures such as the superior vena cava (SVC), pulmonary vein (PV), mitral valve (MV), coronary sinus (CS) or aorta (AO). In this case, the device position must be corrected (see Notes for Troubleshooting). If it is not possible to improve the position of the Occlutech ASD Occluder, the device must be removed and the distributor should be contacted.

Notes for Troubleshooting

Incorrectly Positioned Device

If the Occlutech ASD Occluder is not properly positioned after deploying both discs and has not been disconnected from the OPP, a correction of the position is required. To do so, the device must be completely withdrawn into the delivery sheath. Thereafter, another attempt to place and position the Occlutech ASD Occluder can be made. If positioning of the device cannot be improved, the Occlutech ASD Occluder should be withdrawn completely into the delivery sheath by retracting the OPP and removed. The distributor should be contacted.

Misconfigured Device

If the Occlutech ASD Occluder does not develop its intended shape during positioning, the device must be withdrawn completely into the delivery sheath by retracting the OPP. The Occlutech ASD Occluder should be removed and the distributor should be contacted.

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Indication 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 are 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 sets 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 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 the Occlutech ASD Occluder 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.

Occlutech is a registered trademark of Occlutech Holding AG.
Refer to the Occlutech ASD Occluder, Occlutech Pistol Pusher and Occlutech Delivery Set III Instructions for Use for complete prescribing indications, contraindications, warnings and precautions.
The Occlutech ASD Occluder, Occlutech Pistol Pusher and Occlutech Delivery Set III are intended for single use only.

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