Occlutech

INSTRUCTIONS FOR USE

Occlutech® ASD Occluder

INSTRUCTIONS FOR USE

OCCLUTECH ASD OCCLUDER

TABLE OF CONTENTS

1. PRODUCT DESCRIPTION 2
2. INDICATION FOR USE AND AREA OF APPLICATION 2
3. CONTRAINDICATIONS 2
4. WARNINGS 2
5. PRECAUTIONS 4
   5.1. Device Size 4
   5.2. Pre-Implantation Check 5
   5.3. Procedural 6
   5.4. Post-Implant 6
   5.5. Use in Specific Populations 6
6. MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION 7
7. POTENTIAL ADVERSE EVENTS 7
   7.1. Tissue Erosion 8
8. CLINICAL SUMMARY 8
   8.1. Summary of Premarket Clinical Study 8
   8.1.1. Study Population Demographics and Baseline Parameters 9
   8.1.2. ASD Sizing and Device Selection 10
9. IMPLANTATION PROCEDURE: DIRECTIONS FOR USE 14
   9.1. Required Accessories (not included in the Occlutech ASD Occluder Procedure Pack) 14
   9.2. Recommended Imaging Tools 14
   9.3. Recommended Measurement of Defect and Device Sizing 14
   9.4. Implantation 15
   9.5. Notes for Troubleshooting 18
10. STORAGE CONDITIONS 18
11. DISPOSAL 19
12. WARRANTY 19
13. GLOSSARY OF SYMBOLS 19

1. PRODUCT DESCRIPTION

The Occlutech Atrial Septal Defect (ASD) Occluder is a percutaneous transcatheter closure device, consisting of 2 nitinol wire mesh discs connected by a waist section and polyethylene terephthalate (PET) patches. The PET patches, sewn into the wire mesh, are intended to stop the blood flow through the ASD as well as optimize tissue growth. The design properties of the Occlutech ASD Occluder allow transcatheter implant of the device. The Occlutech ASD Occluder is packaged with its compatible Occlutech Pistol Pusher (OPP), Instructions for Use (IFU) and Patient Implant Card.

2. 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).

3. 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.

4. 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.

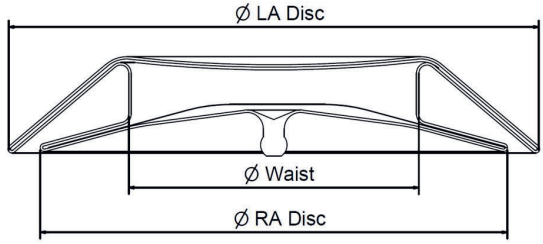
- The Occlutech ASD Occluder contains nitinol, an alloy of nickel and titanium. Patients allergic to nickel and/or titanium and/or nickel/titanium-based materials may suffer an allergic reaction to this device. Certain allergic reactions can be serious. Prior to implantation, patients should be counseled 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.

5. 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.

5.1. Device Size

A suitable Occlutech ASD Occluder is determined by the ASD assessment (see section 9.3 Recommended Measurement of Defect and Device Sizing) and the device-related sizing information in **Table 1** in relation to **Figure 1.**



Ø LA: Left Atrial Disc Diameter

Ø RA: Right Atrial Disc Diameter

Ø Waist: Maximum Waist Diameter

Figure 1: Schematic picture of the Occlutech ASD Occluder

Table 1: Device Sizes and Minimum Recommended Occlutech Delivery Sets Size

Occlutech ASD Procedure Pack Article no.	Atrial Septal Defect Size (D) [mm]	Ø Waist [mm]	Ø LA Disc [mm]	Ø RA Disc [mm]	Occlutech Pistol Pusher Article no.	Minimum Occlutech Delivery Set III [F]*
37ASD06P	5 < D ≤ 6	6	16.5	12.5	38PP125 (light blue)	6
37ASD07P	6 < D ≤ 7.5	7.5	18	14	38PP125 (light blue)	6
37ASD09P	7.5 < D ≤ 9	9	20.5	16.5	38PP125 (light blue)	7
37ASD10P	9 < D ≤ 10.5	10.5	22	18	38PP125 (light blue)	7
37ASD12P	10.5 < D ≤ 12	12	27	23	38PP165 (yellow)	8
37ASD13P	12 < D ≤ 13.5	13.5	28.5	24.5	38PP165 (yellow)	8
37ASD15P	12 < D ≤ 15	15	30	26	38PP165 (yellow)	8
37ASD16P	15 < D ≤ 16.5	16.5	31.5	27.5	38PP165 (yellow)	8
37ASD18P	15 < D ≤ 18	18	33	29	38PP165 (yellow)	8
37ASD19P	16.5 < D ≤ 19.5	19.5	34.5	30.5	38PP165 (yellow)	9
37ASD21P	18 < D ≤ 21	21	36	32	38PP185 (purple)	10
37ASD24P	21 < D ≤ 24	24	39	35	38PP185 (purple)	10
37ASD27P	24 < D ≤ 27	27	42	38	38PP210 (blue)	11
37ASD30P	27 < D ≤ 30	30	45	41	38PP210 (blue)	11
37ASD33P	30 < D ≤ 33	33	48	43	38PP210 (blue)	12

*ODS III Article No: 98DSXXX.

5.2. Pre-Implantation Check

Prior to introducing the Occlutech ASD Occluder in the patient, it is recommended to check whether the device reverts to its original shape after it has been pulled in and pushed out of the loader while immersed in a sterile heparinized saline solution. If the Occlutech ASD Occluder does not revert to its intended shape, it is not suitable for implantation and (see section 9. Implantation Procedure). The physician shall inspect the device prior to its use and check the following:

- OPP size is correct as matched by the label color codes,
- Occlutech ASD Occluder can be properly connected to the OPP,
- Occlutech ASD Occluder can be released from the OPP by operating the release mechanism,
- Occlutech ASD Occluder is firmly attached to the OPP by gently pulling the device a few times and ensuring the Occlutech ASD Occluder can rotate freely.

In case any of these criteria are not met, the physician should select another device.

5.3. Procedural

- This device should only be used by physicians who have been trained in transcatheter techniques and are able to determine suitable patients for procedures using this device.
- Although the device is designed to be used only by experienced users (physicians, professional health care personnel), physicians should participate in the physician training program for new customers to ensure that all implanting physicians are trained on the use of the Occlutech ASD Occluder.
- Standard endocarditis prophylactic therapy should be administered during the procedure.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this device.
- Patient is administered Aspirin 48 hours prior to the procedure, based on patient weight, at a dose of 3 – 5 mg / kg per day.
- Maintain a recommended minimum active clotting time (ACT) of 200 seconds prior to device insertion and throughout the procedure.
- If TEE is used, the patient‘s esophageal anatomy must be adequate for placement and manipulation of the TEE probe.

5.4. Post-Implant

- Patients should be treated with antiplatelet/anticoagulation therapy (such as aspirin) for 6 months post-implant. The decision to continue antiplatelet/anticoagulation therapy beyond 6 months is at the discretion of the physician.
- Patients should take appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at the discretion of the physician.
- Clinical follow-up with a cardiologist, including visualization of the Occlutech ASD Occluder such as the use of echocardiograms, are recommended at the time of implant, 1-day post-implant, pre-discharge and again at 1 month, 2 months, 6 months, and 12 months post-implant. Immediate follow-up with a cardiologist with the onset of any new symptoms suggestive of erosion or impending erosion, and routine clinical follow-up annually thereafter.

5.5. Use in Specific Populations

- Pregnancy - Care should be taken to minimize the radiation exposure to the fetus and the mother.

- Nursing mothers - There has been no quantitative assessment of the presence of leachables from the device/procedure in breast milk, and the risk to nursing mothers is unknown.

6. MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

MR
Conditional

Non-clinical testing has demonstrated that the Occlutech ASD Occluder is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3 T only,
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m),
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (Normal Operating Mode).

Under the scan conditions defined above, the Occlutech ASD Occluder is expected to produce a maximum temperature rise of 3ºC after 15 minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the Occlutech ASD Occluder when imaged with a gradient echo pulse sequence and a 3 T MRI system.

7. POTENTIAL ADVERSE EVENTS

Potential adverse events associated with the device or implant procedure include, but are not limited to, the following:

- Air embolism
- Allergic reactions
- Anesthesia reactions
- Apnea
- Arrhythmias
- AV-Fistula
- Bleeding (hemorrhage) requiring treatment
- Cardiac / vascular perforation
- Cardiac tamponade
- Death
- Embolization (peri & post procedural)
- Esophageal injury
- Femoral access complication
- Fever
- Hematoma
- Hypertension or Hypotension
- (Immediate) surgical interventions
- Infections, including endocarditis
- Pericardial effusions
- Pericarditis
- Post-pericardiotomy syndrome
- Pseudo aneurysm
- Pulmonary edema
- Seizure
- Stroke
- Tissue erosion
- Thrombus formation on device
- Thrombosis
- Valvular regurgitation

7.1. Tissue Erosion

Tissue erosion refers to the erosion or abrasion of the tissue of the atrium, primarily in the area of the roof of either or both atria, and/or the adjacent aortic root (non-coronary sinus). Tissue erosion, while rare, is a surgical emergency due to the occurrence or impending risk of hemodynamic instability resulting from cardiac tamponade and may lead to severe morbidity or death. Absence of the anterior superior (aortic) rim and device oversizing may be related to the causation of erosion due to the increased likelihood of device-tissue contact in the dynamic anatomic area at highest risk for erosion.

8. CLINICAL SUMMARY

The Occlutech ASD Occluder is identical to the Figulla Flex II ASD Occluder and was clinically evaluated as Figulla Flex II ASD Occluder in pre-market clinical trial.

8.1. Summary of Premarket Clinical Study

The Figulla Flex II ASD Occluder was assessed in a prospective, international, multicenter randomized controlled trial to investigate the efficacy and safety of the Figulla Flex II ASD Occluder compared to that of the Amplatzer Atrial Septal Occluder (ASO) for transcatheter ASD closure of secundum type. A total of 176 patients were randomized to receive the Figulla Flex II (n=116) or the Amplatzer ASO (n=60) in a 2:1 ratio, respectively. One patient was randomized to the Figulla Flex II ASD Occluder group but was excluded from the analysis because a non-study device was implanted.

The study was performed according to ISO14155 (GCP) and the Declaration of Helsinki in 7 study centers throughout Germany and France. The primary efficacy endpoint was early efficacy success rate, which was defined as the rate of a successful placement of the device, and successful closure of the defects without major complication, surgical reintervention, device embolization or moderate or large residual shunt the day after procedure but no later than 36 hours after the procedure.

An early success rate of 94.8% in the Figulla Flex II ASD Occluder group versus 88.1% in the Amplatzer ASO group (p-value = 0.000066) was achieved. This trial showed statistically significant non-inferior early success for the Figulla Flex II ASD Occluder compared with the Amplatzer ASO. Major complication rates at 36 hours, 6-months, and 12-months are provided below.

Study Design

Occlutech conducted a randomized, controlled, multi-center, open trial to investigate the efficacy and safety of the Figulla Flex II ASD Occluder family compared to that of a control device (the Amplatzer ASO) for transcatheter ASD closure of secundum-type. This study was performed according to ISO14155 (GCP) guidelines and the Declaration of Helsinki in 7 study centers throughout Germany and France from October 2012 to July 2015. Upon reaching the non-inferiority (vs. the Amplatzer ASO) endpoint during a planned interim analysis (75% of patients were enrolled), an independent Data and Safety Monitoring Board (DSMB) recommended the early termination of the study.

The **inclusion criteria** for patient recruitment into the study included:

- echocardiographic evidence of secundum-type ASD,
- defect diameter of < 38 mm,
- left-to-right shunt with a Qp / Qs ratio of ≥ 1.5: 1 or the presence of right ventricular volume overload as assessed by TTE or clinical symptoms due to the ASD,
- > 5 mm distance from the ASD margins to the coronary sinus, arterio-ventricular valves, and right upper pulmonary vein as measured by echocardiography.

The **key exclusion criteria** were:

- multiple ASDs which could not adequately be covered by the devices,
- associated congenital cardiac anomalies that required cardiac surgery,
- other ASD types, like ostium primum or sinus venosus ASDs, or
- partial anomalous pulmonary venous drainage,
- pulmonary vascular resistance above 7 wood units,
- right and/or left ventricular decompensation with ejection fraction of <30%,
- body weight < 8 kg.

8.1.1. Study Population Demographics and Baseline Parameters

Major demographic data and medical history of the patient cohort are shown below in **Table 2** and **Table 3.**

Table 2: Demographic Summary by Treatment Group

Parameter	Figulla Flex II ASD Occluder (N=115)	Amplatzer ASO (N=60)
Mean Age (years) (SD) Min, Max	20.4 (18.89) 3, 79	21.1 (20.77) 3, 77
Gender n (%) Male Female	39 (33.9%) 76 (66.1%)	21 (35.0%) 39 (65.0%)
Mean Weight (kg) (SD) Min, Max	45.8 (27.16) 13, 104	47.0 (29.48) 13, 125
Ages 2-17 years Mean Weight (kg) Min, Max	N = 70 27.6 13, 70	N = 38 28.7 13, 73
Ages ≥18 years Mean Weight (kg) Min, Max	N = 45 74.1 45, 104	N = 22 78.6 54, 125
Mean Height (cm) (SD)	143.0 (27.77)	143.3 (26.87)

Table 3: Patient Medical History by Treatment Group

Most Common Medical History – Body System	Figulla Flex II ASD Occluder (N=115) n (%)	Amplatzer ASO (N=60) n (%)
Congenital/Chromosomal Abnormality[1]	115 (100.0)	60 (100.0)
Any Past and/or Concomitant Diseases or Past Surgeries/Interventions	115 (100.0)	60 (100.0)
Circulatory System	69 (60.0)	33 (55.0)
Head, Eyes, Ears, Nose, Throat	25 (21.7)	12 (20.0)
Respiratory System	21 (18.3)	13 (21.7)

[1] ASD was considered a congenital abnormality, so all patients have this condition.

8.1.2. ASD Sizing and Device Selection

Device size was selected based predominantly on the stretched ASD diameter using a sizing balloon, “Stop-Flow Technique” and standard imaging methods. Mean ASD size in both groups is reported in Table 4 below.

Table 4: ASD Size

ASD Size	Figulla Flex II ASD Occluder (N=115)	Amplatzer ASO (N=60)
Mean MM (SD)	16.02 +/- 4.878	15.07 +/- 5.550
[range]	[4.0, 31.0]	[5.3, 29.0]

8.1.3. Performance

Procedural and fluoroscopy exposure time (Table 5), successful acute device placement (Table 6), successful defect closure and level of residual shunt (Table 7), and were assessed as device performance evaluations.

Table 5: Evaluation of Device Performance

Parameter	Figulla Flex II ASD Occluder (N=115)	Amplatzer ASO (N=59)
Mean Duration of Procedure (min)	47.8 (35.22)	53.8 (41.16)
Mean Fluoroscopy Time (min) (SD)	2.4 (4.40)	3.7 (5.99)

Table 6: Acute Device Placement Success

Parameter	Figulla Flex II ASD Occluder (N=115)	Amplatzer ASO (N=59)
Successful Device Placement	115/115 (100%)	57/59 (96.7%)

After device placement, an echo evaluation was performed to determine closure status. Results below are from the Central Lab read. Six patients did not have Central Lab reads completed and therefore were not evaluable.

Table 7: Residual Shunt Post Implant

Residual shunt	Figulla Flex II ASD Occluder (N=115)	Amplatzer ASO (N=59)
n	110 (100.0)	58 (100.0)
No Shunt	99 (90.0)	48 (82.8)
Trivial	4 (3.6)	2 (3.4)
Small	4 (3.6)	4 (6.9)
Moderate	3 (2.7)	3 (5.2)
Large	0	1 (1.7)

8.1.4. Effectiveness and Safety Results

Device Efficacy

Primary Efficacy Results

The primary efficacy endpoint was early efficacy success rate, which was defined as the rate of a successful placement of the device, and successful closure of the defects without major complication, surgical re-intervention, device embolization or moderate or large residual shunt the day after procedure but no later than 36 hours after the procedure. The assessments showed statistically non-inferior early success for the Figulla Flex II ASD Occluder compared with the Amplatzer ASO.

The early success rates are presented in **Table 8.**

Secondary Efficacy Results

Secondary efficacy endpoints were:

a) the rate of closure success (residual shunt ≤ 2 mm, assessed by an echocardiography core laboratory) within 6 months after the procedure, without the need for surgical repair.

The secondary efficacy endpoint results are presented in **Table 8.**

Table 8: Primary and Secondary Endpoints- Closure Success Rate

Assessment	Occlutech ASD Occluder (N=115)	Amplatzer ASO (N=59)	
Primary Efficacy Results	109/115 (94.8%)	52/59 (88.1%)	p-value 0.000066
Secondary Efficacy Results	94/115 (81.7%)	42/59 (71.2%)	95% CI -2.99, 24.10

8.1.5. Safety

The safety assessment was performed with data at 36 hours, 6- and 12-months post implantation (Table 9). Safety events of interest included the following:

- Major complications rate at 6- and 12-months post procedure
- Minor complications rate at 6-months and 12-months post procedure
- All other device or procedure related adverse events at 6- and 12-months post procedure.

Major complications were defined as stroke, cardiac perforation with tamponade, endocarditis, repeat surgery, death, pericardial effusion with tamponade, arrhythmia requiring major treatment, and device embolization requiring surgery. Minor complications were defined as device embolization requiring percutaneous treatment, arrhythmia requiring medical therapy, vascular access site complications.

Table 9: Major Complication Rates

	Figulla Flex II ASD Occluder	Amplatzer ASO
Major complication rate 36 hours Patients (%)	3/115 (2.61 %)	4/60 (6.67 %)
Major complication rate 6 months Patients (%)	5/99 (5.05 %)	6/49 (12.25 %)
Major complication rate 12 monthsPatients (%)	6/76 (7.90 %)	6/39 (15.39 %)

Table 10: Number (%) of Patients with Most Frequent Treatment-emergent Adverse Events (≤5 % for any group)

	Figulla Flex II ASD Occluder (N= 115)	Amplatzer ASO (N= 60)
	n (%)	**n (%)**
Total Patients with Any TEAE	82 (71.3)	43 (71.7)
Adverse Event		
Headache	13 (11.3)	8 (13.3)
Related study device[a]	0 (0.0)	0 (0.0)
Related study procedure[b]	1 (0.9)	1 (1.7)
Hematoma	13 (11.3)	3 (5.0)

	Figulla Flex II ASD Occluder (N= 115)	Amplatzer ASO (N= 60)
Related study device[a]	1 (0.9)	0 (0.0)
Related study procedure[b]	12 (10.4)	2 (3.3)
Chest pain	9 (7.8)	2 (3.3)
Related study device[a]	2 (1.7)	2 (3.3)
Related study procedure[b]	2 (1.7)	0 (0.0)
Vomiting	6 (5.2)	5 (8.3)
Related study device[a]	0 (0.0)	0 (0.0)
Related study procedure[b]	0 (0.0)	2 (3.3)
Palpitations	7 (6.1)	2 (3.3)
Related study device[a]	0 (0.0)	0 (0.0)
Related study procedure[b]	0 (0.0)	0 (0.0)
Epistaxis	7 (6.1)	1 (1.7)
Related study device[a]	1 (0.9)	1 (1.7)
Related study procedure[b]	0 (0.0)	0 (0.0)
Infection	3 (2.6)	4 (6.7)
Related study device[a]	0 (0.0)	0 (0.0)
Related study procedure[b]	0 (0.0)	0 (0.0)
Groin pain	3 (2.6)	3 (5.0)
Related study device[a]	0 (0.0)	0 (0.0)
Related study procedure[b]	3 (2.6)	3 (5.0)
Respiratory tract infection	2 (1.7)	3 (5.0)
Related study device[a]	0 (0.0)	0 (0.0)
Related study procedure[b]	0 (0.0)	0 (0.0)
Device dislocation	1 (0.9)	3 (5.0)
Related study device[a]	0 (0.0)	3 (5.0)
Related study procedure[b]	1 (0.9)	3 (5.0)
Bronchitis	1 (0.9)	3 (5.0)
Related study device[a]	0 (0.0)	0 (0.0)
Related study procedure[b]	0 (0.0)	0 (0.0)

TEAE=treatment-emergent adverse event.

[a] Related study device=at least possibly related to study device.

[b] Related study procedure=at least possibly related to study procedure.

9. IMPLANTATION PROCEDURE: DIRECTIONS FOR USE

The Occlutech ASD Occluder is intended for transcatheter delivery. To minimize the risk of adverse events occurring, the following manufacturer's recommendations must be reviewed before implantation of the device.

The Occlutech ASD Occluder shall only be implanted by an experienced and trained physician, and in a specialized catheterization laboratory.

9.1. Required Accessories (not included in the Occlutech ASD Occluder Procedure Pack)

- Occlutech Delivery Set III (ODS III)
- Guide wire
- Appropriate accessories to manage potential adverse events.

9.2. Recommended Imaging Tools

- X-ray, fluoroscopy
- TEE or ICE (recommended before, during and after implantation. If TEE is used, the patient's esophageal anatomy must be adequate for the placement and manipulation of the TEE probe).

9.3. Recommended Measurement of Defect and Device Sizing

Warning: 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. Sizing shall be based on echocardiographic assessment of type, size and number of atrial septal defects and matched with the sizing information printed on the labels of the Occlutech ASD Occluder and its accessories (OPP and ODS III).

Physicians shall review the sizing and compatibility chart (see 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 Occlutech ASD Occluder (i.e., review of device labels and color-coding).

1. Access the right femoral vein and perform a routine right heart catheterization.
2. Assess the secundum ASD simultaneously either by TEE or ICE resulting in a comprehensive echocardiographic study of all aspects of the ASD anatomy, including location, size, presence of additional defects and adequacy of the Superior/Superior Vena Cava rim; Anterior-Superior/ Aortic rim; Inferior/Inferior Vena Cava and Coronary Sinus rim; and Posterior rim.
3. Select a guide wire (0.035"-0.038"), and with the use of a multipurpose catheter (e.g., 5-French) cross the atrial septal defect and place the guide wire in the upper pulmonary vein.
4. Prepare an appropriate sizing balloon according to the manufacturer`s guideline.
5. Remove the multipurpose catheter.
6. Advance the sizing balloon using the over-the-wire technique into the heart and place it across the ASD under fluoroscopic and echocardiographic guidance.
7. Defect sizing should be performed using the "stop-flow-technique": The TEE/ICE ultrasound probe shall be in place and color doppler mode activated to visualize the ASD shunt flow. Inflate the balloon by inserting diluted X-ray contrast medium (typically 1:2 concentration) over the side port of the balloon. The left-to-right shunt ceases and a clearly defined waist becomes visible as observed by color-Doppler TEE/ICE.
8. Perform precise ASD measurement by echocardiographic and/or fluoroscopic visualization of indentation made by the ASD margins (ASD margins can be measured if the balloon is displayed in the long axis during imaging). Ideally, two orthogonal measurements are taken to evaluate the potentially ellipsoidal shape of the ASD. If reference measurements are required to calibrate the x-ray quantification, markers are visible on the balloon catheter. Please refer to the manufacturer`s guidelines for further details on additional imaging techniques.
9. All borders, so called "rims" and distances to surrounding structures shall be measured.

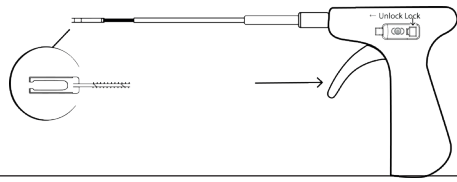
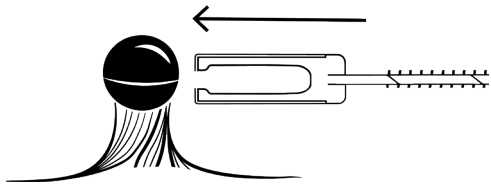
Warning: Improper evaluation of the ASD bears the risk of erosion. Deficient retro-aortic rim <5 mm ("naked aorta"), or a deficient superior rim significantly increases the risk of erosion.

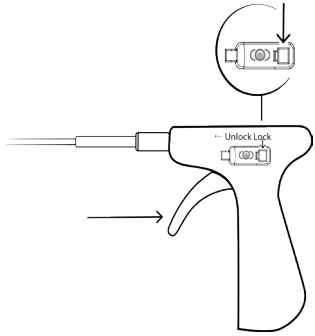
9.4. Implantation

1. Based on precise ASD measurement and device-related sizing information (see section 5.1. Table 1: Device Sizes and Minimum Recommended Occlutech Delivery Sets Size), select an appropriate Occlutech ASD Occluder and the size-matched recommended ODS III.
2. Unpack and prepare the ODS III as described in its IFU.
   Flush the loader assembly via the side port with three-way stopcock ensuring it is free of air prior to use.
   Percutaneous delivery shall be performed using the over-the-wire method, with the use of the dilator. Delivery sheath placement shall be performed under the guidance of imaging methods, like TEE, fluoroscopy or ICE.
3. After positioning of the delivery sheath in the left atrium, the guide wire and dilator can be entirely removed.

   Warning: Do not abruptly remove the dilator from the left atrium as the risk for causing an air embolism can occur.
4. Remove the OPP and the Occlutech ASD Occluder from its sterile packaging and check for device integrity and pusher functionality.
5. Place the Occlutech ASD Occluder in a bowl filled with a sterile heparinized saline solution. Follow the instructions in Table 11, to connect the Occlutech ASD Occluder to the OPP.
6. Insert the distal end (jaw-container) of the OPP through the hemostasis valve of the loader.

Table 11: Occlutech ASD Occluder-OPP Connection Instructions

6a. Open the jaws of the OPP (see pusher IFU for detailed device components and descriptions). The OPP is provided in the "Un-lock" position. Be sure that the 'Unlock button' is in the correct 'Unlock' position.	Pull the trigger of the OPP while the pusher cable is in a straight position. 
6b. Connect the open jaws of the OPP to the Occlutech ASD Occluder's ball connector. **Note:** After connecting the OPP to the Occlutech ASD Occluder, make sure that the occluder can rotate freely. If not, disconnect and re-connect the Occlutech ASD Occluder to the OPP.	

6c. Secure the Occlutech ASD Occluder-OPP connection. **Note:** A secure device-OPP connection is required to prevent any unintentional release of the occluder from the OPP. Gently pull on the Occlutech ASD Occluder to ensure a secure connection to the OPP.	Push the 'Lock' button of the OPP to its 'Locked' position while the pusher cable is in a straight position. 

7. The Occlutech ASD Occluder is now attached to the OPP and shall be pulled into the loader while both the occluder and loader (distal end) are immersed in a sterile heparinized saline solution.
8. The following steps constitute a potential risk of introducing air into the ODS III, 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-occluder 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.
9. Introducing the catheter: Make sure that there is no air in the delivery sheath and the loader, as there is a risk of air embolism.
10. Once the loader-occluder assembly is connected to the delivery sheath, the Occlutech ASD Occluder can be pushed from the loader into the delivery sheath by advancing the OPP. 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.
11. Once in place, the left atrial disc of the Occlutech ASD Occluder is opened by carefully advancing the OPP towards the distal end of the delivery sheath. After the left atrial disc has been successfully deployed in the left atrium, it is pulled carefully together with the sheath towards the atrial septum until resistance is felt. TEE, TTE or ICE imaging should be used to confirm proper positioning of the left atrial disc at this time.
12. Upon confirmation that the left atrial disc is engaged with the septum and the delivery sheath is in the left 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.
13. Correct positioning of the Occlutech ASD Occluder must be confirmed through a combination of fluoroscopic analysis and/or echocardiography.
14. If the Occlutech ASD Occluder does not adequately fit upon deployment, a correction of its position must be considered (see section 9.5. 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.

15. 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 from the Occlutech ASD Occluder (see Table 12).

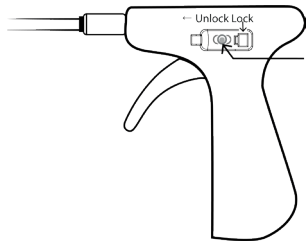
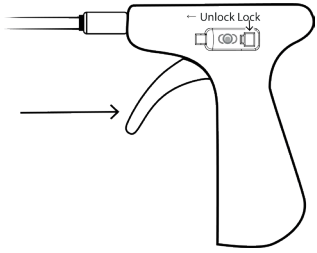
    Note: Do not disconnect the Occlutech ASD Occluder from the OPP if the occluder does not conform to its original configuration, if the device position appears unstable, or if the device interferes with any adjacent cardiac structures such as:

    - the superior vena cava (SVC),
    - pulmonary vein (PV),
    - mitral valve (MV),
    - coronary sinus (CS)
    - aorta (AO).

In this case, the device position must be corrected. see section 9.5. Notes for Troubleshooting. If it is not possible to improve the position of the Occlutech ASD Occluder, the device must be removed and discarded.

Note: The physician should only disconnect the Occlutech ASD Occluder from the OPP once proper positioning of the device has been confirmed using echocardiographic imaging.

Table 12: Releasing the Occlutech ASD Occluder from the OPP.

15a. Unlocking the Occlutech ASD Occluder-OPP-connection.	Move the 'Unlock' button to the handle of the OPP to its 'Unlocked' position. 
15b. Open the jaws and disconnect / release the Occlutech ASD Occluder.	Slowly pull the trigger mechanism located on the handle at the proximal OPP end. 

16. After the Occlutech ASD Occluder has been disconnected, the delivery sheath together with the OPP and the loader can be entirely retracted and discarded (see section 11. Disposal).

9.5. Notes for Troubleshooting

Incorrectly Positioned Device

If the Occlutech ASD Occluder is not properly positioned after opening both discs, 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 into the delivery sheath and removed and, and distributor should be contacted.

Misconfigured Device

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

10. STORAGE CONDITIONS

- Temperature: 5 to 30 °C (41 to 86 °F).
- Store in a dry place.

11. DISPOSAL

All Occlutech devices should be disposed of properly according to the applicable regulations, guidelines or instructions on waste disposal given by the individual clinic.

Note: The empty outer and sterile packaging and IFU can be disposed separately. Put in the corresponding collection containers for recycling purposes.

12. WARRANTY

Occlutech Holding, Switzerland warrants to buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer`s instructions for use and shall be free from defects in materials and workmanship.

Occlutech Holding, Switzerland disclaims all warranties, both express and implied, including, but not limited to, any implied warranty of merchantability, fitness for a particular purpose, or non-infringement.

13. GLOSSARY OF SYMBOLS

	CAUTION		MANUFACTURER
	DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE		DATE OF MANUFACTURING
	DO NOT RESTERILIZE		CONSULT INSTRUCTION FOR USE
	DO NOT RE-USE		SERIAL NUMBER
	STERILIZED USING ETHYLENE OXIDE		CATALOGUE NUMBER
	DIAMETER [MM]		STORE DRY & AWAY FROM SUNLIGHT
	USE BY DATE		TEMPERATURE LIMIT
	FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN		QUANTITY
	MRI CONDITIONAL		DOUBLE STERILE BARRIER SYSTEM
	UNIQUE DEVICE IDENTIFIER		DOUBLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE
			NON-PYROGENIC

Occlutech GmbH
Winzerlaer Straße 2
07745 Jena, Germany

for Occlutech Holding AG
Feldstrasse 22
8200 Schaffhausen, Switzerland

Distributed by:
B. Braun Interventional Systems Inc.
Bethlehem, PA 18018-3524
Customer Service:
TEL: (877) 836-2228
FAX: (610) 849-1334

For contact and additional product information, please visit www.bisusa.com

Issue date: Rev. 02, 2025-12-18

REV: P17F03.009.02