Occlutech

INSTRUCTIONS FOR USE

Occlutech® Pistol Pusher

INSTRUCTIONS FOR USE

OCCLUTECH PISTOL PUSHER

TABLE OF CONTENTS

1. PRODUCT DESCRIPTION 2
2. INDICATION FOR USE 3
3. CONTRAINDICATIONS 3
4. WARNINGS 4
5. ADVERSE EVENTS 5
6. HANDLING 5
   - ***6.1. Preparation 5***
   - ***6.2. Introducing the Delivery Sheath 7***
7. STORAGE CONDITIONS 9
8. DISPOSAL 9
9. WARRANTY 9
10. GLOSSARY OF SYMBOLS 9

1. PRODUCT DESCRIPTION

The Occlutech Pistol Pusher is a medical device compatible with the Occlutech Atrial Septal Defect Occluder (Occlutech ASD Occluder) and applications with special cardiac catheters in the human heart.

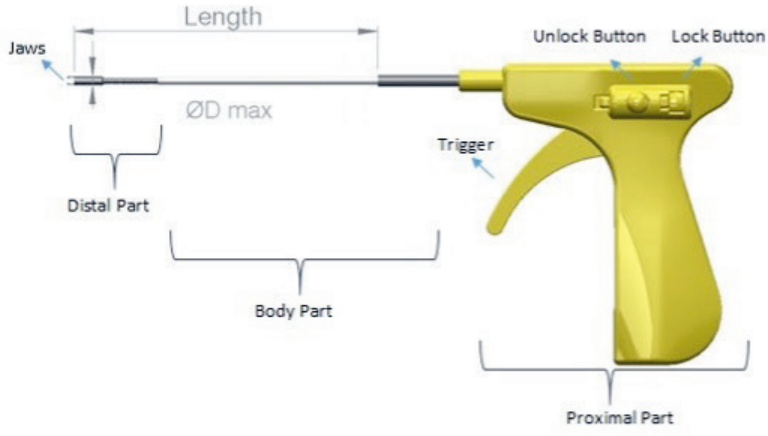


Figure 1: Representative image of Occlutech Pistol Pusher and its proximal, body and distal parts.

The Occlutech Pistol Pusher is composed of proximal body and distal parts. The distal part consists of titanium alloy jaws and a stainless-steel container while the body part is polymer laminated stainless steel coil. The proximal parts of the Occlutech Pistol Pusher largely contains plastic components. The jaws and container mechanism - grab and secure the ball connector of the compatible Occlutech ASD Occluder, allow retraction of the Occlutech ASD Occluder into the ODS III and advancement to the implant area. The proximal part has a trigger for releasing the compatible Occlutech ASD Occluder and a locking mechanism for locking the system to prevent unintentional release.

The Occlutech Pistol Pusher is available in different sizes for compatibility with the Occlutech ASD Occluders.

For compatibility between the Occlutech Pistol Pusher, Occlutech Delivery Set III (ODS III) and Occlutech ASD Occluder, see the Occlutech ASD Occluder Instructions for Use (IFU), (Table 1. Device Sizes and Recommended Occlutech Delivery Sets).

Physicians must also carefully read the IFU of the Occlutech ASD Occluder provided within the same product box.

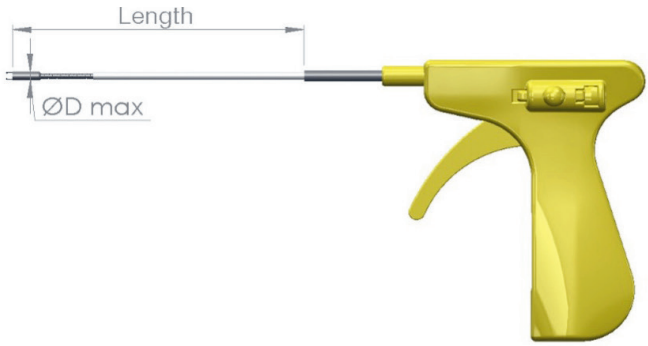


Table 1: Recommended Occlutech Pistol Pusher with compatible ODS III and internal diameters.

Occlutech Pistol Pusher article number (with color codes)	Length [cm]	Jaw container outer diameter ØDmax [mm]	Minimum internal diameters of compatible delivery systems*
38PP125 Light blue	120	2.13	6F (2.16 mm)
38PP165 Yellow	120	2.73	8F (2.83 mm)
38PP185 Purple	120	2.93	9F (3.03 mm)
38PP210 Blue	120	3.23	10F (3.33 mm)

**Based on compatibility testing performed with ODS III (Article no. 98DSXXX)*

2. INDICATION FOR USE

The Occlutech Pistol Pusher is a percutaneous, transcatheter pusher system designed for the delivery of the Occlutech ASD Occluder to the implantation area. It is used via a minimally invasive catheter delivery system technique.

3. CONTRAINDICATIONS

For contraindications, please see the IFU of the Occlutech ASD Occluder.

4. WARNINGS

For Procedure

- The Occlutech Pistol Pusher shall not be used with ODS III other than those listed in Table 1. Furthermore, the correct size of the Occlutech Pistol Pusher and compatible ODS III must be followed. Should the recommended size-matched systems not be followed, the device may be damaged and/or serious adverse events can occur.

- The Occlutech Pistol Pushers shall only be used in connection with the Occlutech ASD Occluder!
- The Occlutech Pistol Pushers are supplied sterile for single use!
- Prior to the application the Occlutech Pistol Pusher must be checked for functionality, distal tip surface properties and damage!
- Only intact and sterile Occlutech Pistol Pushers should be used!
- The Occlutech Pistol Pusher should only be used once!
- Compare the size of the Occlutech Pistol Pusher with the size of the ODS III!
- Before use ensure that the sticker color on the procedure pack as well as the occluder pouch matches with the color of the Occlutech Pistol Pusher proximal part!

- The Occlutech Pistol Pusher shall be used exclusively by physicians, who are trained in this type of cardiac treatment and experienced in the process of 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.
- In cases where the “Handling” (section 6) is not followed and the “Warnings” (section 4) are overlooked, severe complications can occur.
- Disconnection of the Occlutech Pistol Pusher from the Occlutech ASD Occluder can occur undetected, resulting in Occlutech ASD Occluder embolization during implantation. This presents a life-threatening situation for the patients.
- The Occlutech Pistol Pusher is only recommended for the Occlutech ASD Occluder.

Labeling and Packaging

Identifications for the Occlutech Pistol Pusher including correct labeling should be verified before proceeding. The following are considerations:

- Occlutech Pistol Pusher packaging damaged. This can impair sterility.
- Occlutech Pistol Pusher marked by an illegible or inappropriate label.
- Occlutech Pistol Pusher for which the labeling is missing.

If the packaging box or double plastic pouches are damaged in any way, the Occlutech Pistol Pusher shall be considered unsterile and should not be used.

If, after inspection by the physician, the Occlutech Pistol Pusher appears damaged or does not appear to function properly, it is not suitable for use and the distributor should be contacted.

Re-use

- The Occlutech Pistol Pusher is intended for single use only. The Occlutech Pistol Pusher and the Occlutech ASD Occluders are not suitable for re-sterilization. As soon as the Occlutech Pistol Pusher is used, it is contaminated. Re-use of a contaminated Occlutech Pistol Pusher, may cause a high risk of injury to the patient, including sepsis.

5. ADVERSE EVENTS

The adverse events that may occur during or after a procedure include but are not limited to:

- Cardiac arrhythmia
- Formation of blood clots, vascular injury and occlusion due to existing vascular calcification and heart disease
- Unintentional injuries to the heart
- Injuries to the blood vessels
- Bleeding or secondary bleeding in the heart or pericardium due to injury of the heart
- Infection via the point of introduction
- Pulmonary embolism
- Arterial embolism
- Cardiac tamponade
- Perforation
- Cardiac arrest
- Damage of heart valves and other structures
- Death

For compatible Occluder-related adverse events, please see the Occlutech ASD Occluder IFU.

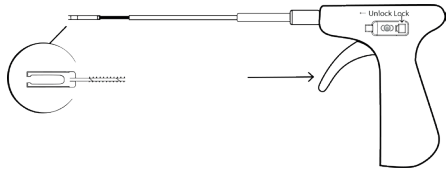
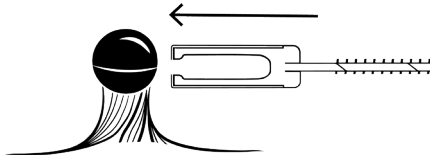
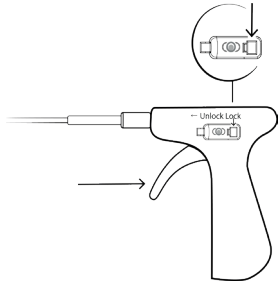
6. HANDLING

6.1. Preparation

Note: Prior to the application, the Occlutech Pistol Pusher shall be checked for functionality (opening and closing of the jaws), the parts shall not contain any burr marks or sharp edges nor be curved or oppressed. The surface of the distal tip should be smooth and not roughened or damaged. All delivery sheaths and related equipment should be flushed and deaired according to local practice before insertion into the patient.

1. Remove the Occlutech Pistol Pusher and compatible ODS III (delivery sheath and loader) from its sterile packaging and check for device functionality. Flush the loader assembly via the side port with three-way stopcock ensuring it is free of air prior to use.
2. Insert the distal end (jaw-container) of the Occlutech Pistol Pusher through the hemostasis valve of the loader.
3. Remove the compatible Occlutech ASD Occluder from its sterile packaging and check for occluder integrity. Follow the instructions in Table 2, on how to connect the Occlutech ASD Occluder to the Occlutech Pistol Pusher.

Table 2: Occlutech ASD Occluder-Occlutech Pistol Pusher Connection Instructions

3a. Open the jaws of the Occlutech Pistol Pusher. The Occlutech Pistol Pusher come in "Un-lock" position. Be sure that the 'Unlock button' is in the correct unlock position.	Pull the trigger of the Occlutech Pistol Pusher while the pusher cable is in a straight position. 
3b. Connect the open jaws of the Occlutech Pistol Pusher to the Occlutech ASD Occluder's ball connector. **Note:** After connecting the Occlutech Pistol Pusher to the Occlutech ASD Occluder, ensure that the occluder can rotate freely. If not, disconnect and re-connect the Occlutech ASD Occluder to the Occlutech Pistol Pusher.	
3c. Secure the Occlutech ASD Occluder - Occlutech Pistol Pusher connection. **Note:** A secure occluder - Occlutech Pistol Pusher connection is required to prevent any unintentional release of the occluder from the Occlutech Pistol Pusher.	Push the 'Lock' button of the Occlutech Pistol Pusher to its 'Locked' position while the pusher cable is in a straight position. 

Note: Be sure that the Occlutech Pistol Pusher is in 'Locked' position before pulling the Occlutech ASD Occluder into the loader.

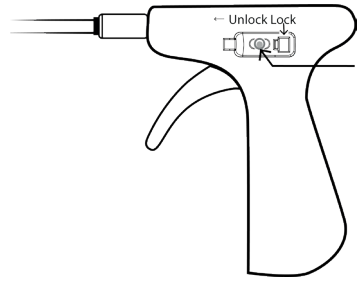
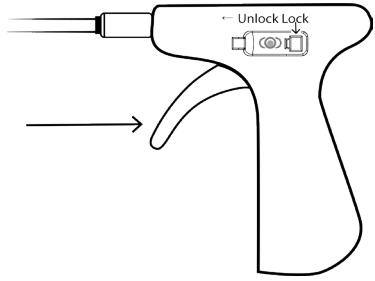
4. The Occlutech ASD Occluder is now attached to the Occlutech Pistol Pusher and shall be pulled into the loader while both the occluder and loader (distal end) are immersed in a sterile heparinized saline solution.
5. The following steps constitute a potential risk of introducing air into the ODS III, 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.

6.2. Introducing the Delivery Sheath

Note: See the Occlutech ASD Occluder IFU for detailed information on the Occlutech ASD Occluder implantation procedure.

1. Ensure that there is no air in the delivery sheath and the loader, as there is a risk of air embolism. Secure the loader by screwing the swivel ring tightly on the delivery sheath.
2. 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 Occlutech Pistol Pusher. Use x-ray guidance to visualize the occluder advancement up to the distal end of the delivery sheath which should be positioned in the left atrium.
3. Once in place, the left atrial disc of the Occlutech ASD Occluder is opened by carefully advancing the Occlutech Pistol Pusher 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 delivery sheath towards the atrial septum until resistance is felt. Maintain the relationship between the OPP and the delivery sheath while withdrawing the system, until the left atrial disc is engaged with the septum. TEE, TTE or ICE imaging should be used to confirm proper positioning of the left atrial disc at this time.
4. 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 Occlutech Pistol Pusher cable, while keeping the Occlutech Pistol Pusher cable in a stable position until the occluder has been completely deployed. Do not disconnect the Occlutech ASD Occluder from the Occlutech Pistol Pusher.
5. If the optimal fit and positioning of the occluder has been established and confirmed by use of TEE, TTE, fluoroscopy or ICE, then the Occlutech Pistol Pusher can be safely disconnected (see the Occlutech ASD Occluder IFU for detailed occluder implantation).
6. Follow the instructions in Table 3, to release the occluder from the Occlutech Pistol Pusher.

Table 3: Releasing the Occlutech ASD Occluder from the Occlutech Pistol Pusher.

6a. Unlocking the Occlutech ASD Occluder-Occlutech Pistol Pusher connection.	Move the 'Unlock' button on the handle of the Occlutech Pistol Pusher to its 'Unlocked' position. 
6b. Open the jaws and disconnect / release the Occlutech ASD Occluder.	Slowly pull the trigger mechanism located on the handle at the proximal Occlutech Pistol Pusher end. 

7. After the Occlutech ASD Occluder has been disconnected, the delivery sheath together with the Occlutech Pistol Pusher and the loader can be entirely retracted and discarded (see section 8. Disposal).

Due to the anatomy of the heart, circumstances may arise where the geometric arrangement of the Occlutech ASD Occluder and the Occlutech Pistol Pusher is unfavorable and as such, the release is made more difficult. To solve the problem, slide the Occlutech Pistol Pusher forward slightly and attempt to release by turning the fixture between the Occlutech Pistol Pusher and the Occlutech ASD Occluder.

Ensure that the jaws of the Occlutech Pistol Pusher do not penetrate into the cardiac tissue/occluder tissue and only carry out this procedure under X-ray screening.

7. STORAGE CONDITIONS

Temperature: 5°C – +30°C (41 to 86 °F).

Do not place objects on the instruments and/or their packaging!

Do not store in the vicinity of a chemicals, disinfectants or radiation!

Do not expose the instrument to direct or indirect sunlight or other ultraviolet radiation!

No complaints can be made with respect to improperly stored instruments.

8. 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 in the corresponding collection containers for recycling purposes.

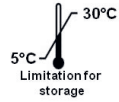
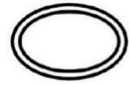
9. WARRANTY

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.

10. 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		BATCH CODE

STERILE EO	STERILIZED USING ETHYLENE OXIDE	REF	CATALOGUE NUMBER
∅	DIAMETER [MM]	SN	SERIAL NUMBER
	USE BY DATE		STORE DRY & AWAY FROM SUNLIGHT
Quantity 1	QUANTITY		TEMPERATURE LIMIT
Rx Only	FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.		DOUBLE STERILE BARRIER SYSTEM
	DOUBLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE		

Occlutech Tıbbi Ürünler San. Ve Tic. Ltd. Şti
Yeşilköy SB Mah., E Blok Sok.
Occlutech Apt. No: 6
34149 Bakırköy / Istanbul, Türkiye

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: P17F03.014.02