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Sterile Disposable MemoPart™ Occluder Delivery System Ⅱ

Instructions for Use

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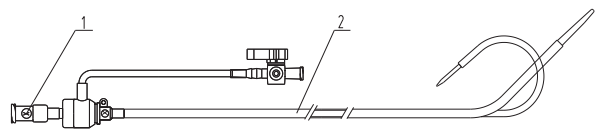
Read the following warnings, precautions and directions for use carefully.

1. Product Name

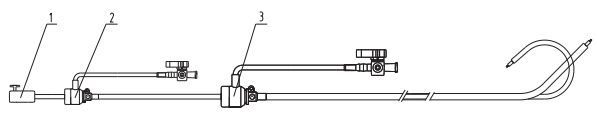
Sterile Disposable MemoPart™ Occluder Delivery System Ⅱ

2. Device Description

The Sterile Disposable MemoPart™ Occluder Delivery System Ⅱ is designed to deliver occlusion devices. The occlusion device and delivery system are shipped separately. The Sterile Disposable MemoPart™ Occluder Delivery System Ⅱ consists of a delivery sheath, dilator, loader, and pusher. The distal curve of delivery sheath and dilator come in two different shapes. The body of the delivery sheath and pusher are radiopaque for visibility under fluoroscopy.



1.Dilator 2.Delivery sheath（The assembled diagram for delivery sheath and dilator）



1.Pusher 2.Loader 3.Delivery sheath（The assembled diagram for loader, delivery sheath and pusher）

Fig1. The assembled drawings for Sterile Disposable MemoPart™ Occluder Delivery System Ⅱ

Delivery sheath — Provides a pathway through which the occlusion device is delivered
Dilator — Eases penetration of tissue and minimizes vessel trauma.
Loader — Introduces the occlusion device into the delivery sheath
Pusher — Attaches to the occlusion device to control its movement through the delivery sheath

3. Intended Use

3.1.Intended purpose
The Sterile Disposable MemoPart™ Delivery System II is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.
3.2.Disease or Medical Indications
The Sterile Disposable MemoPart™ Occluder Delivery System Ⅱ is used in the interventional treatment of congenital heart diseases that include atrial septal defects (ASD), ventricular septal defects (VSD), patent foramen ovale (PFO), or patent ductus arteriosus (PDA).
3.3.Contraindications
• Conditions which are unfavorable for cardiac catheter examination, e.g., fever.

• Presence of thrombi in the heart chambers or hemorrhagic diseases such as active ulcer.
• Any patient whose vessel or heart size is too small for cardiac catheterization or occlusion devices.
• Any patient who is infected recently.
3.4.Intended Patient Populations
This device is suitable for any patients with the target disease or medical indications except for whom with contraindications. The safety and efficacy of Sterile Disposable MemoPart™ Occluder Delivery System Ⅱ in pregnant women or men intending to father children, nursing mothers, and the immunocompromised patients has not been established.
3.5.Intended Users
The Sterile Disposable MemoPart™ Occluder Delivery System II should only be used by physicians who are trained in transcatheter defect closure techniques. The physician should determine which patients are candidates for procedures that use this device. Before use, the operator should have a full understanding of the using instruction, warnings and precautions.

4. Clinical Benefits to be Expected

• High success rate of delivery of occlusion device.
• Low incidence of related clinical adverse events.

5. Summary of Safety and Clinical Performance (SSCP)

The summary of safety and performance for the device is available on the website of Eudamed: https://ec.europa.eu/tools/eudamed by searching the Basic UDI-DI "69330523XZ0007KD".

6. Device and Combination Using Products Selection

The Sterile Disposable MemoPart™ Occluder Delivery System II is divided into two models of ASD and P/V according to the distal curve. The model ASD is indicated to deliver ASD Occluder and PFO Occluder, the other model P/V to deliver VSD Occluder and PDA Occluder. There are seven specifications for each model, see the following table for specific specifications.

Compatible device	Catalogue number	Delivery system size (French)	Inner diameter of the delivery sheath (mm)
ASD Occluder and PFO Occluder	ASD-6F	6F	2.16mm
	ASD-7F	7F	2.49mm
	ASD-8F	8F	2.84mm
	ASD-9F	9F	3.18mm
	ASD-10F	10F	3.48mm
	ASD-12F	12F	4.18mm
	ASD-14F	14F	4.84mm
PDA Occluder and VSD Occluder	P/V-6F	6F	2.16mm
	P/V-7F	7F	2.49mm
	P/V-8F	8F	2.84mm
	P/V-9F	9F	3.18mm
	P/V-10F	10F	3.48mm
	P/V-12F	12F	4.18mm
	P/V-14F	14F	4.84mm

The selection of delivery system size is based on the inner diameter of the delivery sheath. The inner diameter of the delivery sheath should match the size of the device to be introduced. When placing a device using a Sterile Disposable MemoPart™ Occluder Delivery System II, refer to the instructions for use provided with the device to determine delivery sheath compatibility. It's recommended to choose the size of delivery system as small as possible among the available sizes of occluder in accordance with the weight.

7. Warnings

• Use before the last day of the expiration noted on the product packaging.
• The delivery system is sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm.
• Do not use the delivery system if the sterile packaging is damaged or opened before use.
• Remove the dilator and delivery sheath from the patient slowly to prevent an ingress of air.
• Inspect the device for damage before use. Do not use damaged or kinked components.

8. Precautions

• The physician should exercise clinical judgement in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this delivery system.
• This device should only be used by physicians who have been trained in transcatheter techniques. The physician should determine which patients are suitable candidates for procedures using this delivery
• Patients should be anticoagulated sufficiently throughout the procedure to prevent or reduce the possibility of thrombosis and thromboembolism. Once thromboembolism is observed, apply the thrombolysis drug at once.
• The delivery sheath may be twisted in the cardiac cavity due to the twisting of the vessel lumen, which can be detected in time under X-ray. Once the delivery sheath is twisted, the guidewire should be introduced at first and this event can be solved by delivery route adjustment of delivery sheath, if needed, replace it with a new Sterile Disposable MemoPart™ Occluder Delivery System II.
• It should be ensured that the delivery sheath is pushed in over the guidewire during the procedure. Advance the delivery sheath directly may cause cardiac perforation, so the operating regulation should be strictly performed. Emergency surgery should be performed in the event of cardiac perforation.
• Confirm the compatibility with the occlusion device before use. The screw thread on the distal end of the pusher is designed to be compatible with occlusion devices produced by the manufacturer. Using this device with occlusion devices produced by other manufacturers is not recommended for the sizing may be incompatible and may result in technical failures and/or adverse events.
• Please carefully read the medical indications, contraindications, residual risks and undesirable side-effects of any medical device used in combination with this device

9. Residual Risks and Undesirable Side-effects

Residual risks and undesirable side-effects that may occur during or after a procedure using this delivery system may include but are not limited to:

• Air embolism• Arrhythmia• Arterio-venous fistula• Bleeding• Cardiac tamponade• Cardiac Perforation• Death• Device distortion/fracture (delivery system failure)• False Aneurysm
• Hematoma• Infection/endocarditis• Myocardial infarction• Nerve damage (including brachial plexus injury)• Peripheral pulse loss• Stroke• Thrombosis• Tissue or vessel trauma/damage
• Valve injury• Vascular dissection• Vascular occlusion

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

10. Directions for Use

10.1. Materials recommended for use with this device
• Occluders (CHD occlusion devices produced by SHSMA)
• Guidewire with sufficient stiffness
• Syringe
10.2. Procedure
• Perform local anesthesia for adults or general anesthesia for children.
• Perform femoral vein or femoral artery puncture according to the requirements of treatment.
• Perform routine cardiac catheter examination and determine pressure inside each cardiac chamber as well as the blood oxygen content.
• Insert the guidewire via the artery or vein and deliver the cardiac catheter to the atrium or the ventricle or the aorta along the guidewire
• Select the appropriate delivery system for the occlusion device that will be introduced through the delivery sheath.
Note: When placing a device using a Sterile Disposable MemoPart™ Occluder Delivery System II, refer to the instructions for use provided with the device.
• Inspect the sterile pouch and verify that it is unopened and undamaged.
Note: Do not use the components if the sterile barrier has been compromised.
• Gently open the sterile pouch and inspect the components for damage.
Note: Do not use damaged or kinked components.
• Wash the delivery sheath and dilator with heparin saline. Insert the dilator into the delivery sheath. Advance the dilator and delivery sheath over the guidewire to the target vessel or cardiac chamber under the guidance of DSA (Digital subtraction angiography) or ultrasonic cardiogram. Slowly remove the dilator and guidewire, leaving the delivery sheath in the vessel or cardiac chamber.
• Insert the pusher into the loader. Push out the distal end of the pusher. Connect the pusher with the occlusion device, then pull back the pusher to retract the occlusion device into the loader. Rapidly inject heparinized saline through the side arm of the loader to purge any air. Attach the distal end of the loader to the proximal end of delivery sheath. Advance the pusher and the occlusion device through the loader and delivery sheath until the occlusion device reaches the target lesion.
• Position, deploy, and detach the occlusion device according to its instruction for use.
• When the procedure is complete, slowly retract the distal end of the pusher into the delivery sheath and slowly remove the delivery sheath from the patient.

11. Disposal

• Dispose of all packaging materials appropriately according to the local laws.
• Dispose of delivery systems and accessories following standard solid biohazard waste procedures.

12. Storage and Expiry Date

• This device should be stored in a dry, clean, well-ventilated environment free of corrosive gases.
• The period of validity is three years when this product is stored under specified condition.

13. Explanation of Symbols

Symbol	Explanation of Symbol
	Manufacturer
EC REP	Authorized representative in the European Community
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number /Model number
	Double sterile barrier system and sterilized using ethylene oxide
	Do not resterilize
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	Consult instructions for use
	Caution
MD	Medical Device
UDI	Unique Device Identifier
CE 2696	CE Marking and Identification Number of Notified Body

The color of EO Sterilization indicator on the package bag turns yellow after EO sterilization.

14. Disclaimer Of Warranty And Limitation Of Remedy

Descriptions or specifications in Shanghai Shape Memory Alloy Co., Ltd printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. Shanghai Shape Memory Alloy Co., Ltd will not be responsible for any direct, incidental, or consequential damages resulting from the abnormal use of the product.