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Revision: A

Instructions for Use

AnchorMan®
Left Atrial Appendage Access System

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Instructions for Use

Before use, please read this IFU carefully and pay more attention to all the items in Warning and Precautions!

CE 2797

Table of Content

Change History

CHANGES FROM PREVIOUS VERSION OF THIS DOCUMENT:

Revision	Description of Revision	Author	Revision Date
A	New document	Xing, Xin	Dec. 12nd, 2023

1 DEVICE DESCRIPTION

The AnchorMan® Left Atrial Appendage Access System consists of an Access Sheath and a Dilator, as shown in Figure1. The access sheath, with the aid of a dilator, can be advanced over guidewire via femoral vein and interatrial septum crossing into the left atrium. Remove the dilator and the delivery catheter preloaded with closure device can be advanced through the access sheath. The AnchorMan® Access System is compatible with AnchorMan® Left Atrial Appendage Closure System.

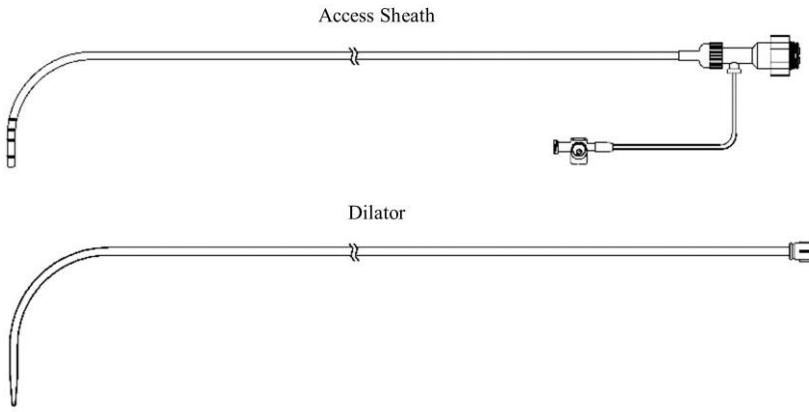

Figure1 AnchorMan® Access System

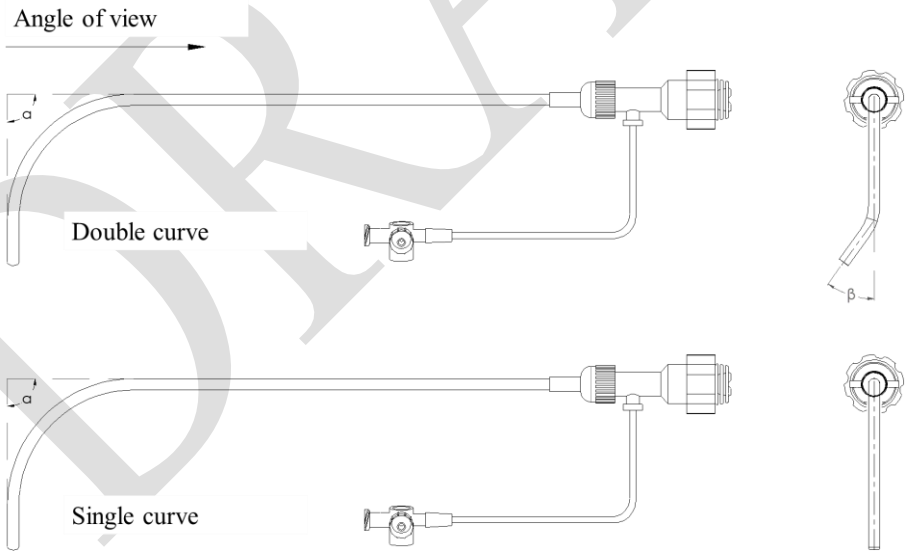

Figure2 Schematic Diagram of Access Sheath Sizes

- AnchorMan® Access System Sizes

The AnchorMan® Access System is divided into two sizes as single curve and double curve according to the different distal tip configurations of access sheath (see Figure2).

Table 1 AnchorMan® Access System Sizes

Sizes	Description	Inner diameter	Outer diameter	Working Length
Single Curve	AnchorMan® Access System with single curve distal tip configuration	12 Fr	14 Fr	770 mm
Double Curve	AnchorMan® Access System with double curve distal tip configuration	12 Fr	14 Fr	770 mm

2

2 HOW SUPPLIED

STERILE: FOR SINGLE USE ONLY. This product is sterilized with ethylene oxide (EtO).

Non-pyrogenic.

- Do not use if the package is opened or damaged.
- Do not use if labeling is incomplete or illegible.
- Do not resterilize.

CONTENTS:

- One (1) AnchorMan® Left Atrial Appendage Access System
- One (1) Instructions for Use

STORAGE: The product should be stored in a cool, dry, dark place.

3 INTENDED PURPOSE/INDICATIONS

The AnchorMan® Access System provides the femoral venous and trans-atrial septal access for AnchorMan® Closure System.

4 TARGET POPULATIONS

The AnchorMan® System (LAA Closure System and Access System) can be used for NVAF patients who are at high risk of ischemic stroke.

- The AnchorMan® System has not been studied in patients under the age of 18 year.
- The AnchorMan® System has not been studied in Pregnancy or Lactation patient.

5 CONTRAINDICATIONS

Do not use the AnchorMan® Left Atrial Appendage Access System if:

- Intracardiac thrombus is present (NOTE: If thrombus is identified in the LAA, dissolve with anticoagulation therapy before attempting to implant the AnchorMan® Closure Device).
- An atrial septal defect repair or closure device or a patent foramen ovale repair or closure

device is present.

- The LAA anatomy will not accommodate a Closure Device (see AnchorMan® Closure Device Selection Table).
- The patient has a known hypersensitivity to nickel.
- Any of the customary contraindications for other percutaneous and cardiac catheterization interventional procedure.

6 CLINICAL BENEFITS

In patients with NVAF (who are eligible or ineligible for anticoagulation therapy), the use of AnchorMan® System of devices can lead to the following clinical benefits :

- Occlude/close the LAA patency
- Prevent thrombus embolization originated from the LAA in NVAF patients
- Reduce the risk of stroke

7 WARNINGS

- AnchorMan® Left Atrial Appendage Access System is supplied STERILE. For single use only. Do not reuse or resterilize.
- Carefully inspect the sterile package. Do not use if package is damaged or unintentionally opened before use.
- Note the “Use by” date. Do not use the product after the “Use-by” date.
- Use of the AnchorMan® Access System for implantation of the AnchorMan® Closure Device should only be performed by physicians who have obtained relevant qualification.
- The device and packaging should be treated disposed of in accordance with any applicable hospital, administrative, and/or local government regulations.
- Carefully read the instruction for use (IFU) before use. Note all the warnings and precautions, otherwise accidents may happen.

8 PRECAUTIONS

Use of the AnchorMan® Access System for implantation of the AnchorMan® Closure Device should only be performed by physicians who have obtained relevant qualification, and performed at hospitals where Left Atrial Appendage Closure (LAAC) procedure is accessible.

General Precautions

- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying, recapturing, and repositioning the Closure Device.

- The AnchorMan® Access System are supplied STERILE. For single use only. Do not reuse, reprocess or resterilize.
- Careful consideration should be given to use of the Closure Device in pregnant and/or breastfeeding women due to the risk of significant exposure to X-rays and the use of anticoagulation medication.
- The use of AnchorMan® Access System for implantation of the AnchorMan® Closure Device has not been studied in patients under the age of 18.
- Antithrombotic therapy should be performed according to clinical practice and relevant guidelines prior to scheduled procedure.
- Patients should be fully heparinized throughout the procedure with an active clotting time (ACT) of 250-350s after transseptal puncture.
- Appropriate post-procedure antithrombotic therapy should be followed according to the patient's condition, diagnosis and treatment routine and relevant guidelines.
- Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.

9 ADVERSE EVENTS

Potential adverse events may be associated with the use of a left atrial appendage closure device or implantation procedure include but not limited to:

- Risks of anesthesia
- Postoperative anesthetic reactions
- TEE complications (throat swelling and pain, related site injury, hemorrhage, etc.)
- Puncture-related complications (puncture site hemorrhage, hematoma; vascular access site injury; poor wound healing; pseudoaneurysm, arteriovenous fistula, etc.)
- Allergic reactions to contrast agents/drugs or device materials
- Edema
- Fever
- Inflammation
- Hypotension
- Vasovagal reaction
- Bleeding
- Coughing blood
- Hematuria
- Reduced platelets

- Thrombosis
- Air embolism
- Systemic embolism
- Hypoxia
- Hypoxic encephalopathy
- Hemorrhagic stroke
- Ischemic stroke
- Chest pain/chest discomfort
- Valve injury
- Atrial septal defect
- Angina
- Arrhythmia
- Asystole
- Cardiac perforation
- Pericardial effusion/pericardial tamponade
- Congestive heart failure
- Pulmonary edema
- Pleural effusion
- Renal failure/kidney dysfunction
- Death
- Inability to reposition and recapture the device
- Device dislocated or dislodged
- Device embolization
- Device fracture
- Large amount of residual shunting

10 EQUIPMENT NEEDED FOR IMPLANTATION PROCEDURE

- Venous Introducer (optional)
- Standard transseptal access system
- 0.035 inch guidewire (exchange length extra support)
- 6 Fr pigtail catheter
- AnchorMan® Left Atrial Appendage Closure System (MicroPort CardioAdvent)

11 OPERATOR'S INSTRUCTIONS

11.1 Inspection Prior to Use

- Carefully inspect the sterile package. Do not use if the integrity of the sterile package has been compromised in any way.
- Do not use the product after the "Use by" date.
- Carefully remove the access system from the HDPE board and blister, and inspect it for bends, kinks, and other damage. Do not use the product if any damage is noted.

11.2 Procedural Instructions

Warning: Echocardiographic imaging (TEE recommended) should be used when implanting the device.

Note: Patients should be fully heparinized throughout the procedure with an active clotting time (ACT) of 250-350s after transseptal puncture.

11.2.1 Use standard practice to puncture vessel and insert 0.035" guidewire and vessel dilator. Use a standard transseptal access system to cross inter-atrial septum.

11.2.2 Exchange crossing sheath with exchange length extra support 0.035" guidewire. Position guidewire in left upper pulmonary vein (LUPV) or loop in left atrium.

11.2.3 Prepare an AnchorMan® Access System.

Note: Carefully inspect the sterile package and AnchorMan® Access System prior to use. DO NOT USE if the sterile barrier has been compromised in any way.

1) Remove Access Sheath and Dilator from package under sterile conditions.
2) Inspect prior to use to ensure no damage.
3) Flush Access Sheath and Dilator with saline prior to use.
4) Insert Dilator into hemostasis valve of Access Sheath until the two snap together.

Note: Do not tighten the hemostasis valve while the Dilator is inserted in the Access Sheath. The Dilator by itself will occlude the lumen of the Access Sheath creating hemostasis. Tightening the valve onto the Dilator may damage the valve threads, which can lead to subsequent difficulty in closing the valve and an incomplete seal, once the Dilator is removed.

11.2.4 Advance an AnchorMan® Access System over guidewire into left atrium (LA). As the Access Sheath nears center of LA, hold the Dilator, and advance Access Sheath into initial position in LA or ostium of LUPV.

Note: Use caution when introducing AnchorMan® Access System to prevent damage to cardiac structures.

11.2.5 Remove Dilator and guidewire, leaving Access Sheath in LA or LUPV. Allow back bleed to minimize potential for introducing air before tightening valve. Flush with saline.

Note: If continued back bleed is observed from the valve after the Dilator is removed despite attempting to close it, loosen the valve cap (counter-clockwise rotation) until the cap spins freely. Then re-attempt closure of the valve while exerting gentle toward pressure on the valve cap during closure (clockwise rotation) to ensure proper engagement of the valve thread. While these steps are being undertaken, manual occlusion of the valve opening using a gloved finger is recommended to minimize blood loss.

Note: These steps may be repeated if necessary. However, if this does not mitigate the blood leak, the user should remove and replace the AnchorMan® Access Sheath before proceeding with the procedure.

11.2.6 Confirm LAA size and select appropriate AnchorMan® closure Device.

A. Using TEE, measure LAA ostium width and LAA length in 3-4 views.

B. Choose a Closure Device based on maximum LAA ostium width recorded. Refer to AnchorMan® Closure System IFU for device selection.

Note: LAA anatomy should accommodate a single Closure Device.

Note: Record multiple angles on cine with contrast prior to advancing Access Sheath into LAA. Use fluoro guidance while advancing pigtail catheter, or Access Sheath. Stop if resistance is felt.

C. Carefully advance pigtail catheter through Access Sheath into distal portion of the LAA under fluoro guidance. Carefully advance Access Sheath over pigtail catheter until Access Sheath marker band corresponding to Device size (see Figure 3) is at or just distal to LAA ostium. Slowly remove pigtail catheter.

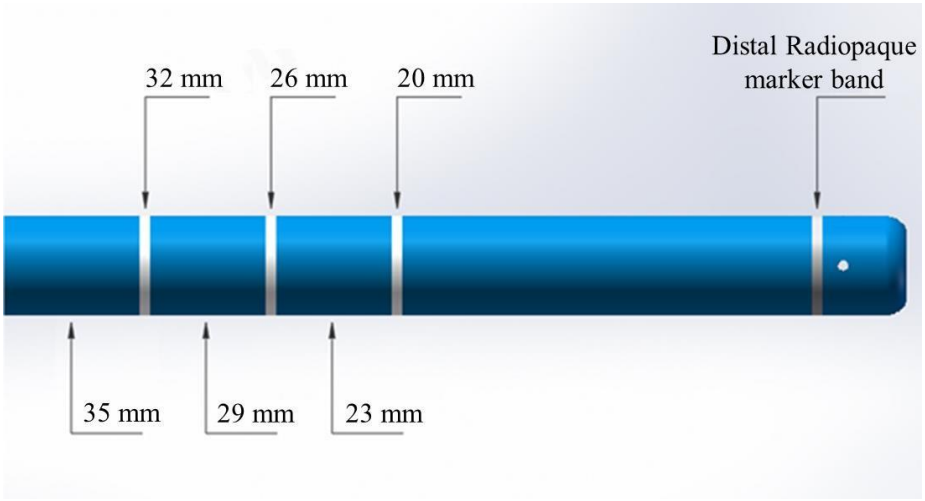

Figure 3 Radiopaque marker bands of Access Sheath

12 USE BY

Under store requirements conditions, the “Use by” of AnchorMan® Left Atrial Appendage Access System is 3 years.

13 DATE OF MANUFACTURE

Refer to the label.

14 DISCLAIMER

Shanghai MicroPort CardioAdvent Co., Ltd. indicates definitely that AnchorMan® Left Atrial Appendage Access System is intended for one time use only and makes no recommendation, indication or implication of any kind，whether expressed or implied respecting the reuse of this product. Shanghai MicroPort CardioAdvent Co., Ltd. assumes no responsibility for incident or production damages which may result from such reuse. MicroPort CardioAdvent shall not be responsible for production damages and surgical failure resulted from improper selection of product specification, erroneous operation, or human error of any kind.

AnchorMan® is a trademark of Shanghai MicroPort CardioAdvent Co., Ltd.

In case of incidents, please contact the European Authorised Representative, the Manufacturer or your local distributor.

15 SUPPLEMENTARY INFORMATION

- SSCP is available in the European database on medical devices (Eudamed), please refer to (https://ec.europa.eu/tools/eudamed)
- Basic UDI-DI: (8013) 69745565Z0217SB
- The following patients material is available for this product:

  Online patient information guide: (www.microportpatients.com)

GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELING

1)		Do not re-use
2)		Consult instructions for use
3)		Keep dry
4)		Keep away from sunlight
5)		Batch Code
6)		Sterilized using ethylene oxide
7)		Do not use if package is damaged

8)		CONTENT: 1
9)		Date of manufacture
10)		Use by date
11)		Do not resterilize
12)		Catalogue number
13)		Authorized representative in the European Community/European Union
14)		Unique device identifier
15)		Medical device
16)		Single sterile barrier system

Shanghai MicroPort CardioAdvent Co., Ltd.

Add: Room 911, Building 1, 1601 Zhang Dong Rd., ZJ Hi-Tech Park，Shanghai, 201203 P. R. China

Tel: (86) (21) 38954600

Fax: (86) (21) 50801305

Email: mpzuoxin@microport.com

Website: www.en.cardioflowmedtech.com

MicroPort Medical B.V.

Add: Paasheuvelweg 25 1105BP Amsterdam The Netherlands