Document Number: AnchorMan LAAC-MDR- CH2.1/ Attachment 1

Revision: A

Instructions for Use

AnchorMan®

Left Atrial Appendage Closure System

AnchorMan® Left Atrial Appendage Closure System

Instructions for Use

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

CE 2797

Change History

CHANGES FROM PREVIOUS VERSION OF THIS DOCUMENT:

Revision	Summary of Changes	Author	Date
A	New document	Xing, Xin	Dec 16th, 2023

1 DEVICE DESCRIPTION

1.1 Device component description

The AnchorMan® Left Atrial Appendage Closure System consists of a Closure Device and a Delivery Catheter. The AnchorMan® Closure Device is a self-expanding nitinol (nickel-titanium alloy) structure with a polyethylene terephthalate (PET) porous membrane on the proximal face. The Closure Device is constrained within the Delivery Catheter until the deployment in the LAA. The Delivery Catheter mainly consists of a 12 Fr reinforced catheter and a core wire. The Delivery Catheter permits closure device placement in the left atrial appendage (LAA) via femoral venous access and interatrial septum crossing into the left atrium. The Closure System is shown in Figure 1. The AnchorMan® Closure Device is designed to be permanently implanted at or slightly distal to the ostium (opening) of the LAA to trap potential emboli before they exit the LAA.

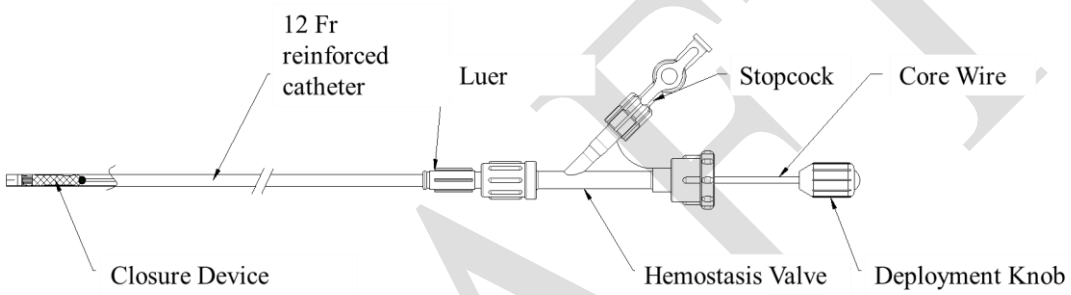


Figure 1 Construction of AnchorMan® LAA Closure System

The AnchorMan® Closure System is available in six sizes as shown in Table 1.

Table 1 AnchorMan® Closure System Sizes

Sizes	Closure Device Diameter	Delivery Catheter Working Length	Delivery Catheter Outer Diameter
FL35	35 mm	850 mm	12 Fr
FL32	32 mm	850 mm	12 Fr
FL29	29 mm	850 mm	12 Fr
FL26	26 mm	850 mm	12 Fr
FL23	23 mm	850 mm	12 Fr
FL20	20 mm	850 mm	12 Fr

- Closure Device

The Closure Device (Figure 2) is comprised of a nitinol frame, a Ti threaded insert, a PET fabric, sutures and a dowel pin. The sizes of AnchorMan® Closure Device is shown in Table1.

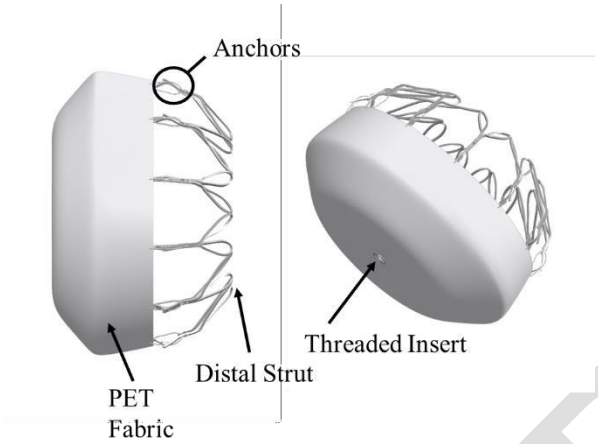


Figure 2 Anchorman® Closure Device

- Delivery Catheter

Delivery Catheter consists of a 12 Fr reinforced catheter, a Luer connector, a hemostasis valve, a stopcock, a core wire and a deployment knob. The working length of 12 Fr reinforced catheter is 850 mm.

1.2 Material

The AnchorMan® Closure Device is a self-expanding nitinol structure with a PET fabric on the proximal face. Materials and material amounts in the Closure Device are listed in Table 2 below. Materials are the same for all Closure Device. But the amounts listed below represent the 35mm Closure Device, which contains the highest amount of each material.

Table 2 Closure Device Materials

Material	Amount (g)
Nitinol alloy	0.346
Titanium	0.014
PET	0.113

2 HOW SUPPLIED

STERILE: FOR SINGLE USE ONLY. This product is sterilized with ethylene oxide (EO). 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 Closure System
- One (1) Instructions for Use

- One (1) Implant card

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

3 INTENDED PURPOSE

The AnchorMan® Closure System is intended for percutaneous, transcatheter closure of the left atrial appendage to prevent thrombus embolization from the left atrial appendage.

4 INDICATIONS

The AnchorMan® Closure System is intended to prevent thrombus embolization from the left atrial appendage in patients with non-valvular atrial fibrillation (NVAF) who have a CHA2DS2-VASc score ≥2, and eligible or ineligible for anticoagulation therapy.

5 TARGET POPULATIONS

The AnchorMan® Left Atrial Appendage Closure 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.

6 CONTRAINDICATIONS

Do not use the AnchorMan® Left Atrial Appendage Closure 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 Table 3: AnchorMan® Closure Device Selection).
- The patient has a known hypersensitivity to nickel.
- Any of the customary contraindications for other percutaneous and cardiac catheterization interventional procedure.

7 CLINICAL BENEFITS

In patients with NVAF (who have high stroke risk and a contraindication to anticoagulation therapy or are still at increased risk for stroke after receiving long-term standard anticoagulation therapy), the use of AnchorMan® Left Atrial Appendage Closure System 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

8 WARNINGS

- AnchorMan® Left Atrial Appendage Closure 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.
- Implantation of 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.

9 PRECAUTIONS

Implantation of 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.

9.1 General Precautions

1) The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying the Closure Device.
2) The AnchorMan® Closure System are supplied STERILE. For single use only. Do not reuse, reprocess or resterilize.
3) 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.
4) The AnchorMan® Closure Device has not been studied in patients under the age of 18.
5) Device selection should be based on accurate LAA measurements obtained using fluoro and echocardiography imaging guidance (TEE reccomended) in multiple angles.
6) Antithrombotic therapy should be performed according to clinical practice and relevant guidelines prior to scheduled procedure.
7) Patients should be fully heparinized throughout the procedure with an active clotting time (ACT) of 250-350s after transseptal puncture.

8) Fluoro and TEE should be used when implanting the Closure Device.

9) Do not release (i.e., unscrew) the Closure Device unless release criteria (Step14) are satisfied.

10) The potential for device embolization exists with cardioversion <30 days following device implantation. Verify Device position post cardioversion.

11) Appropriate post-procedure antithrombotic therapy should be followed according to the patient's condition, diagnosis and treatment routine and relevant guidelines.

12) Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.

9.2 Magnetic Resonance Imaging (MRI)

Non-clinical testing has demonstrated the AnchorMan® Closure Device is MR Conditional. A patient with the Closure Device can be scanned safely immediately after placement of this implant, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Maximum spatial gradient field of 12800 Gauss/cm
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2.0 W/kg (normal operating mode only)

Under the scan conditions defined above, the AnchorMan® Closure Device is expected to produce a maximum temperature rise of less than 1.6 ℃ after 15 minutes of continuous scanning with the static magnetic field of 1.5 Tesla; and 2.5 ℃ after 15 minutes of continuous scanning with the static magnetic field of 3.0 Tesla.

In non-clinical testing, an image artifact can be present. MR image quality may be compromised if the area of interest is relatively close to the AnchorMan® Closure Device. Optimization of MR imaging parameters is recommended.

10 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 dislodgement
- Device embolization

- Device fracture
- Large amount of residual leak

11 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 Access System (MicroPort CardioAdvent)

12 OPERATOR'S INSTRUCTIONS

12.1 Pre-Procedural Instructions

A baseline measurement by means of appropriate imaging modality should be performed to verify that an AnchorMan® Closure Device may be implanted.

12.1.1 Perform the following through multiple imaging views (0 °~135 °sweep).

- Assess LAA size/shape, number of lobes in LAA, and location of lobes to ostium.
- Confirm the absence of thrombus (use Color Doppler assessment and echo contrast as necessary).

12.1.2 Record LAA ostium and LAA depth measurements. Measure the LAA ostium width and LAA depth at approximately these angles.

- at 0 °measure from coronary artery marker to a point approximately 2 cm from tip of the "limbus".
- at 45 °measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus".
- at 90 °measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus".
- at 135 °measure from top of the mitral valve annulus to a point approximately 2 cm from tip of the "limbus".

Measured maximum LAA ostium width must be ≥15.0 mm and <32 mm to accommodate available Closure Device sizes.

Note: The maximum LAA ostium and LAA depth measurements determine Closure Device size selection.

12.2 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 closure system from the protective sheath and HDPE board and inspect it for kinks, bends and other damage. Do not use the product if any damage is noted.

12.3 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.

12.3.1 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

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

12.3.3 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.

12.3.4 Advance an AnchorMan® Access System over guidewire into left atrium (LA). As the Access Sheath distal end 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.

12.3.5 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.

12.3.6 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. Use Table 3 as a guide.

Table 3 AnchorMan® Closure Device Selection

Max LAA Ostium Width and/or Deployed Closure Device Diameter(mm)	Closure Device Diameter(mm)
26.3-31.5	35
24.0-28.8	32
21.8-26.1	29
19.5-23.4	26
17.3-20.7	23
15.0-18.0	20

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.

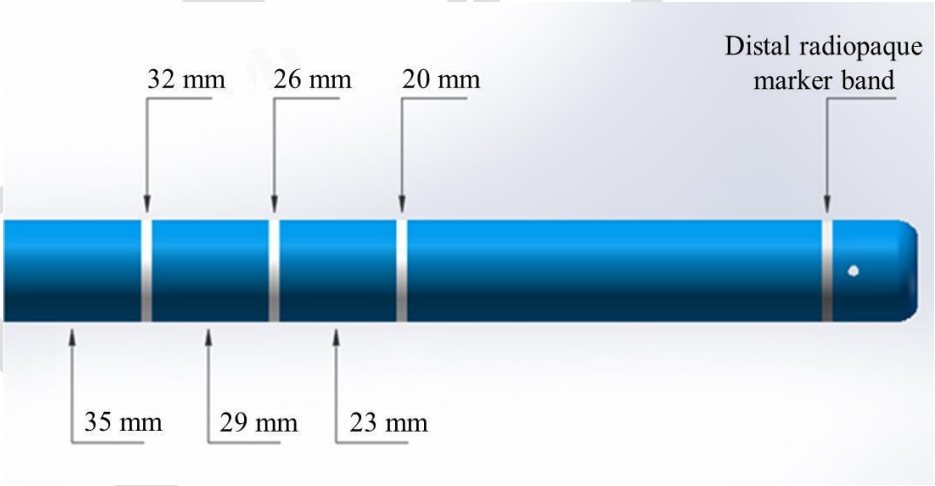


Figure 3 Radiopaque marker bands of Access Sheath

12.3.7 Prepare AnchorMan® Closure System.

Note: If sterile barrier has been compromised in any way, or Closure System appears damaged, DO NOT USE.

A. Remove Closure System under sterile conditions.

B. Inspect prior to use to ensure there is no damage to hemostasis valve, catheter connections, or Closure Device.

C. Confirm that the distal tip of the Closure Device is aligned with marker band on Delivery Catheter.

Caution: Do not allow AnchorMan® Closure Device to protrude to prevent damage to the Closure System.

D. Flush Closure System with saline, removing all air and maintaining fluid throughout system. Open and flush hemostasis valve.

Note: To avoid introducing air, apply pressurized saline bag to sideport of Access Sheath, or submerge Access Sheath hub in saline. Saline may be dripped from Delivery Catheter during introduction into Access Sheath by injecting through flush port.

12.3.8 Loosen the hemostasis valve of access sheath allowing bleed back before inserting the prepared Closure System.

Note: Hemostasis valve should spin freely (fully open).

12.3.9 To avoid introduction of air slowly advance Closure System into Access Sheath under fluoro guidance.

Note: Use caution when introducing Closure System to prevent damage to cardiac structures.

12.3.10 Under fluoroscopic guidance, align most distal marker band on Delivery Catheter with most distal marker band on Access Sheath. Once marker bands are aligned, stabilize Delivery Catheter, retract Access Sheath, and snap together to create the Access Sheath/Closure System Assembly.

12.3.11 Using fluoro and TEE confirm position of Closure System tip before deploying the Device.

Note: To inject contrast, flush catheter or measure power injector pressure while inserting Closure System into Access Sheath. Contrast syringe or manifold must be attached to flush port of Delivery Catheter. If using a power injector, the maximum pressure **should not** exceed 100 psi.

12.3.12 If repositioning is required, unsnap and slowly remove Closure System from Access Sheath. If necessary reinsert pigtail catheter to reposition Access Sheath. Reinsert Closure System as described in Steps 9 and 10.

12.3.13 Deploy AnchorMan® Closure Device by loosening valve on Closure System and holding deployment knob stationary while retracting Assembly to completely deploy Device. Leave core wire attached.

12.3.14 Closure Device release criteria.

A. **Position:** Plane of maximum diameter of the Closure Device should be at or just distal to and spans entire LAA Ostium.

Note: Closure Device position in relation to the LAA ostium may vary based on individual patient anatomy and the echocardiographic imaging view (TEE recommended).

B. **Anchor:** Gently pull back then release deployment knob to visualize movement of Closure Device and LAA together.

C. **Seal:** Ensure all lobes of the LAA are distal to Closure Device and sealed (e.g., no leak >5 mm).

D. **Size (compression):** Measure plane of maximum diameter of Closure Device. The compression

ratio should meet the requirement, i.e. the deployed closure device diameter is 75~90% of the closure device size. Use Table 3 as a guide.

12.3.15 Partial Closure Device Recapture.

Note: Partially recapture and redeploy AnchorMan® Closure Device if too distal to LAA ostium

A. Advance tip of Access Sheath/Closure System Assembly up to Closure Device (do not unsnap). Fix deployment knob position with right hand and gently advance Access Sheath/Closure System Assembly over shoulders of Device. Position right thumb against Delivery Catheter for stability. Resistance will be felt as Device shoulders collapse. Continue to advance Assembly up to but not past fixation anchors. When resistance is felt a second time (anchor contact), stop, tighten hemostasis valve.

Note: If Closure Device is retrieved past fixation anchors, recapture fully and replace Closure System.

B. Reposition Access Sheath/Closure System Assembly proximately and re-deploy by holding deployment knob and retracting Access Sheath until Closure Device is completely deployed. Leave core wire attached.

Warning: Do not release the AnchorMan® Closure Device from the core wire if the Closure Device does not meet release criteria (Step 14).

12.3.16 Fully Closure Device recapture.

Note: Fully recapture the Closure Device if too proximal or does not meet release criteria. AnchorMan® Access System and Closure System are for single use only. Do not reuse or resterilize

A. Advance tip of Access Sheath/Closure System Assembly up to face of Closure Device (do not unsnap).

B. Fix deployment knob with right hand and gently advance Access Sheath/Closure System Assembly over shoulders of Device. Position right thumb against Closure System for stability. Resistance will be felt as Closure Device shoulders collapse. Continue to advance Assembly until Closure Device is completely collapsed and recaptured (past anchors) into the Closure System.

C. Withdraw Closure Device until distal end is proximal to marker band. Then tighten hemostasis valve.

D. Unsnap Closure System from Access Sheath while maintaining Access Sheath position. Slowly remove Closure System.

E. Insert pigtail catheter to reposition Access Sheath in LAA if necessary.

F. Repeat Steps 7-14 with new Closure System.

12.3.17 AnchorMan® Closure Device Release.

Confirm proper position, anchor, size and seal, and then advance Assembly to face of Closure Device. Rotate deployment knob counterclockwise 3-5 full turns. Confirm core wire is disconnected.

12.3.18 Remove Access Sheath and Delivery Catheter based on parameters for hemostasis.

12.3.19 Use standard of care for post-procedure bleeding at access site.

13 POST-PROCEDURE PRECAUTIONS

1. Appropriate post-procedure antithrombotic therapy should be followed according to the patient's condition, diagnosis and treatment routine and relevant guidelines.

2. At 45 days and at 3 months after implantation, perform imaging to assess the AnchorMan® Closure Device (TEE recommened):

- Confirm absence of intra-cardiac thrombus.
- Perform color Doppler assessment to include the device/LAA border at approximate TEE angles.
- Measure any residual leak around the device into the LAA if necessary.

3. Prescribe appropriate endocarditis prophylaxis for 6 months following the Closure Device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.

14 USE BY

Under store requirements conditions, the "Use by" of AnchorMan® Left Atrial Appendage Closure System is 3 years. Device is a permanent implantable device and has been tested for fatigue resistance for a minimum of 10 years; however, the materials of the device are nondebiodegradable and are intended to last for the lifetime of the patient.

15 DATE OF MANUFACTURE

Refer to the label.

16 DISCLAIMER

Shanghai MicroPort CardioAdvent Co., Ltd. indicates definitely that AnchorMan® Left Atrial Appendage Closure 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 sizes, 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.

17 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) 6974565Z0214S5
- The following patients material is available for this product:

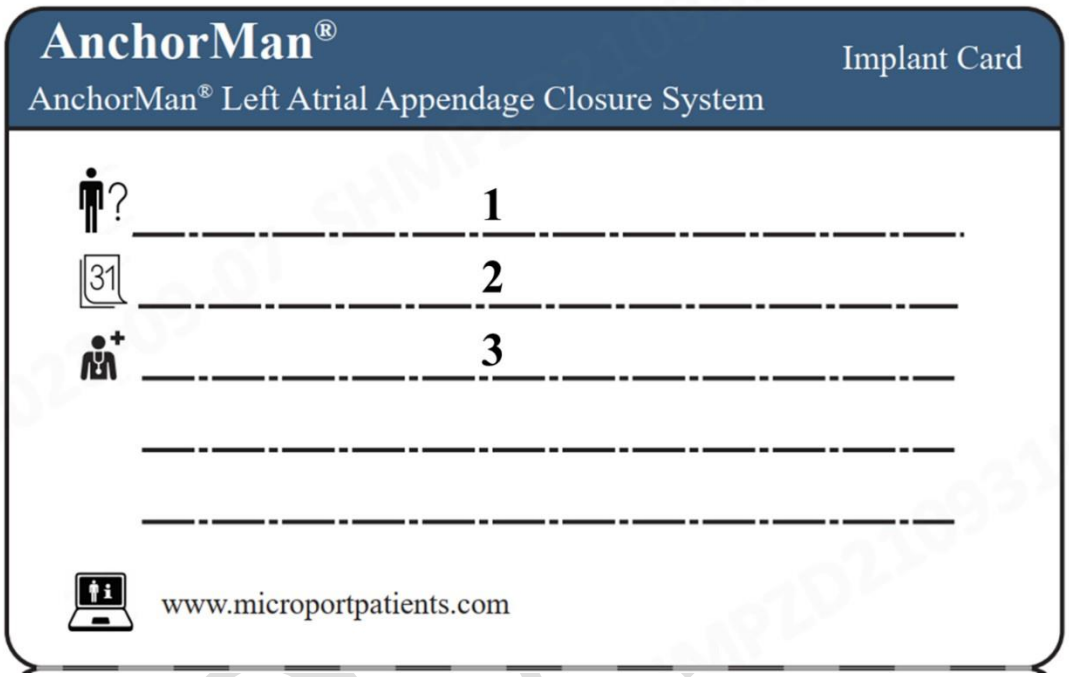
  Online patient information guide: www.microportpatients.com

18 HOW TO COMPLETE AN IMPLANT CARD (IC)

1 Name of the patient or patient ID. To be filled by the healthcare institution/provider.

2 Date of implantation. To be filled by the healthcare institution/provider.

3 Name and address of the healthcare institution/provider. To be filled by the healthcare institution/provider.



1)		Do not re-use
2)		Consult instructions for use
3)		Keep dry
4)		Keep away from sunlight
5)	LOT	Batch Code
6)	STERILE EO	Sterilized using ethylene oxide
7)		Do not use if package is damaged
8)	1	CONTENT: 1
9)		Date of manufacture

10)		Use by date
11)		Do not resterilize
12)		MRI conditional
13)		Catalogue number
14)		Authorized representative in the European Community/European Union
15)		Medical device
16)		Single sterile barrier system
17)		Unique device identifier
18)		Patient Name or patient ID
19)		Date of implantation
20)		Name and Address of the implanting healthcare institution/provider
21)		Information website for patients

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