Instructions for Use

LeSifter™ Left Atrial Appendage Closure Device

1. Device Description

1.1. Device component description

The Left Atrial ppendage (LAA) Closure Device consists of the LAA occluder and a Access System (Delivery System and Guiding System), where the occluder is pre-loaded into the Delivery System. The Guiding System include a Dilation Tube and a Guiding sheath. The Occluder and Delivery system can be introduced through the femoral vein and passed across the atrial septum to reach the left atrium for placement of the occluder into the left atrial appendage. The occluder is made of self-expanding nitinol alloy material, with its outer surface covered by a porous mesh. The product is available in 5 size options, ranging from 20mm to 35mm. The appropriate size of the occluder is selected by measuring the size of the left atrial appendage orifice using fluoroscopy (fluoroscopic imaging) and transesophageal echocardiography (TEE).

The LAA occluder is designed for permanent implantation at the orifice (opening) of the left atrial appendage or slightly distal to it, in order to intercept thrombus generated within the left atrial appendage. The implantation procedure is performed in the catheterization lab under local or general anesthesia.

1.2. Material

The LeSifter™ occluder is a self-expanding nitinol structure with a PET fabric on the proximal face. Materials and material amounts in the Occluder are listed in Table 1 below. Materials are the same for all Occluder . But the amounts listed below represent the 35mm Occluder, which contains the highest amount of each material.

Table 1 Occluder Materials

Material	Amount (g)
Nickel-titanium alloy (Nitinol)	0.225
316LVM	0.068
Polyethylene terephthalate (PET)	0.128

2. Intended Use

The Lesifter™ Device is intended for percutaneous, transcatheter closure of the left atrial appendage.

3. Indications For Use

The Lesifter™ Device is indicated 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.

4. Intended User

Intended users of the LeSifterTM left atrial appendage Occluder are interventional cardiologists and/or electrophysiologists who are proficientin percutaneous procedures, transseptal procedures, the imaging modality utilized.

5. Intended patient population

The LeSifter™ Device is an option that may be considered in patients to reduce the risk of cardioembolism from the LAA.Selection among available treatment options must first take into account whether anticoagulation is indicated to reduce the risk of stroke based on CHA2DS2-VASc scores. Next, in a patient who is deemed by their physicians to be suitable for anticoagulation therapy, physicians and patients should consider the rationale for implantation of the LeSifter™ Device as an alternative to long-term anticoagulation therapy. Specific factors may include one or more of the following:

- A history of major bleeding while taking anticoagulation therapy.
- The patient's prior experience with oral anticoagulation (if applicable).
- A medical condition, occupation, or lifestyle placing the patient at high risk of major bleeding secondary to trauma. Some studies of patients with a history of falls, or at risk for falls and head trauma, have shown that the benefits of anticoagulation therapy to reduce the risk of stroke outweigh the risk of major, life-threatening bleeding. An individualized benefit and risk assessment should be made in such patients.
- The presence of indication(s) for long-term anticoagulation therapy, other than non-valvular atrial fibrillation (e.g. mechanical heart valve, hypercoagulable states, recurrent deep venous thrombosis).

6. Contraindications

Do not use the LeSifter™ Device if:

- Intracardiac thrombus is present (NOTE: If thrombus is identified in the LAA, dissolve with anticoagulation therapy before attempting to implant the LeSifter™ 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 LeSifter™ occluder.
- 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 LeSifter™ Left Atrial Appendage Closure Device 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

- LeSifter™ Left Atrial Appendage Closure Device 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 LeSifter™ occluder 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 LeSifter™ occluder 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 LeSifter™ Closure Device is 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 LeSifter™ 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 (Step16) 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.

10. Adverse Events

Potential adverse events which may be associated with the use of a left atrial appendage Occluder or implantation procedure include but are 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 accesssite 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
- Atrialseptal 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

There may be other potential adverse events that are unforeseen at this time.

11. MRI Safety information

Non-clinical testing has demonstrated that the LeSifter™ device is MR Conditional.

A patient with the LeSifter™ device can be safely scanned in an MR system under the following conditions:

- Static magnetic fields of 3.0 Tesla (3.0T)
- Maximum spatial gradient field of 5.8 T/m (580 G/cm)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 1.6°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends radially up to 10 mm from the device when imaged with a gradient echo pulse sequence in a 3.0T MR system

12. Operation Instructions

12.1. Pre-Procedural Instructions

A baseline measurement by means of appropriate imaging modality (either cardiac CT or TEE) should be performed to verify if a LeSifter™ Device can be implanted and preselect the appropriate occluder size.

① Perform the following through multiple imaging views:

- Measure the LAA length and width at the ostium.
- Assess LAA size/shape,number of lobes in LAA,and location of lobes to ostiun.
- Confirm the absence of thrombus.

Note： If using TEE,measure the LAA ostium at approximately these angles as anatomy permits:

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

② Determine the greatest width (i.e.diameter) measurement.

③ Record LAA ostium width and LAA depth measurements. Use Table 2 as a guide for size selection.

Measured maximum LAA ostium width must be ≥14.0mm and≤32.0mm to accommodate available Occluder sizes.

Note： Successful device sizing is dependent on multiple imaging views.

Note： The maximum LAA ostium width and depth measurements determine Occluder size selection.

Table 2 :LeSifter™ Device Selection

Model	Max LAA Ostium Width(mm)	Occluder Size(mm)
YFDQ-20-1/ YFDQ-20-2	14~18	20
YFDQ-24-1/ YFDQ-24-2	17~21	24
YFDQ-27-1/ YFDQ-27-2	19~24	27
YFDQ-31-1/ YFDQ-31-2	22~28	31
YFDQ-35-1/ YFDQ-35-2	25~32	35

12.2. Equipment Needed for implantation Procedure

- Venous Introducer (optional)
- Standard transseptal access system
- 0.035 in (0.89mm) guidewire (exchange length support)

- 5F(1.7mm) or 6F(2.0mm) angioraphic pigtail catheter

12.3. Implantation Procedure

Note: Patient should start aspirin prior to scheduled procedure and continue daily.

Note: Fluoroscopic (fluoro) and echocardiographic imaging should be used when implanting the device.

Note: Patients should be fully heparinizad throughout the procedure with a recommended minimum active clotting time (ACT) of 200 seconds-300 seconds after transseptal puncture.

1) Use standard percutaneous techniques to puncture femoral vein and insert 0.035 in (0.89 mm) guidewire and vessel Dilation Tube. Use a standard, commercially available transseptal access system to cross inter-atrial septum.
2) Exchange crossing sheath with exchange length extra support 0.035 in (0.89 mm) guidewire. Position guidewire in left upper pulmonary vein (LUPV) or loop in left atrium.
3) Prepare a Guiding System.

Note: Inspect sterile package and Guiding System prior to use. If sterile barrier, labeling, packaging, or device have been compromised in any way, DO NOT USE.

A. Remove Guiding Sheath and Dilation Tube from package under sterile conditions.

B. Inspect prior to use to ensure no damage.

C. Flush Guiding Sheath and Dilation Tube with saline prior to use.

D. Ensure hemostasis valve is fully open. Insert Dilation Tube into hemostasis valve of Guiding Sheath until the two snap together.

4) Advance a Guiding System over guidewire into left atrium (LA). As the Guiding Sheath nears center of LA, unsnap the Guiding Sheath from the Dilation Tube, hold the Dilation Tube, and advance the Guiding Sheath into initial position in LA or ostium of LUPV.

   Precaution: Use caution when introducing Guiding System to prevent damage to cardiac structures.

5) Ensure hemostasis valve is fully open, remove Dilation Tube and guidewire, leaving Guiding Sheath in LA or LUPV. Allow back bleed to minimize potential for introducing air before tightening valve. Flush the Guiding Sheath with saline.

   If continued back bleed is observed from the valve after the Dilation Tube 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 forward

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 Guiding Sheath before proceeding with the procedure.

6) Carefully advance pigtail catheter through Guiding Sheath into distal portion of the LAA under fluoro guidance. Obtain angiographic views of the LAA.

Note: If user notices kink in Guiding Sheath , user should remove and replace Guiding Sheath before proceeding with procedure.

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

7) Confirm LAA size and confirm appropriate occluder model. There is clinical evidence to support the use of TEE or intracardiac echocardiography (ICE) and fluoroscopy to guide LAAC implantation.

A. Perform the following through multiple imaging views:

- Measure the LAA length and width at the ostium.
- Assess LAA size/shape, number of lobes, and location of lobes relative to the ostium.
- Confirm the absence of thrombus.

Note: If using TEE, measure the LAA ostium at approximately these angles as anatomy permits:

- 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.”

Note: In the ICE-LAA study, physicians obtained at least two orthogonal (short axis and

long axis) views of the LAA when using ICE from the left atrium to document the position, compression, leak, and record the tug test to comply with the PASS™ (Position, Anchor, Size, and Seal) device release criteria (refer to Step 16). These two views were further defined as:

- Short-Axis View (also called mid LA/PV view): with the ICE probe positioned in the mid LA, near or at the ostium of the left superior pulmonary vein. This resembles the 0-90° view on TEE.
- Long-Axis View (also called supra mitral view): a posterior flex, 90° rotation, and slight advancement of the probe toward the superior aspect of the mitral valve will delineate the long axis view of the LAA, which resembles the 90-135° view on TEE.

If using ICE imaging, visualize the LAA with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the LAA anatomy, as well as the PASS criteria.

B. Confirm occluder based on maximum LAA ostium width recorded. Use Table 2 as a guide.

Note: LAA anatomy should accommodate a single occluder as described in Table 2.

Note: These values are based on TEE and can be utilized with ICE. Other imaging modalities may vary.

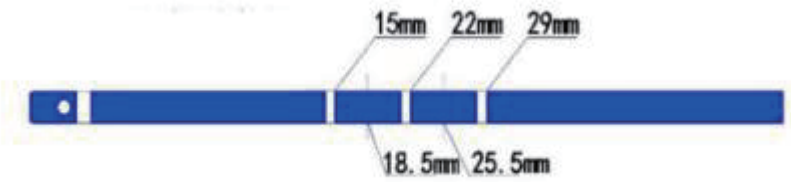

Figure 1 Guiding sheath development marker

8) Prepare Delivery System.

A. Check the temperature exposure indicator on the pouch label to confirm that the product has not been compromised. See Warnings section.

B. Remove Delivery System under sterile conditions.

Note: Inspect sterile package and Delivery System prior to use. If sterile barrier, labeling, packaging, or device have been compromised in any way, DO NOT USE.

Note: Delivery sheath hemostasis valve is packaged closed.

Precaution: Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.

C. Inspect prior to use to ensure there is no damage to hemostasis valve, catheter connections, or Occluder (through Delivery System). Confirm the Occluder is positioned completely inside the Delivery System.

Note: If Occluder extends outside the Delivery System, DO NOT USE.

D. Loosen the hemostasis valve and move the deployment knob away from the hemostasis valve to ensure the Occluder and the core wire assembly move freely. While holding the Delivery System straight, position the distal tip of the Occluder so that it is aligned with the Delivery System distal marker band.

E. Flush the Delivery System and hemostasis valve with saline, to ensure removal of all air. Then close the hemostasis valve to maintain fluid throughout system during handling.

Note: If aspirating the Delivery System during flushing, do so slowly and with limited force, to prevent the formation of air bubbles.

9) With the pigtail in the LAA, the Guiding Sheath tip position and orientation may be carefully adjusted in the LAA as required to engage the target LAA lobe or location for deployment. Slowly remove pigtail catheter.

10) Loosen hemostasis valve of Guiding Sheath , allowing back bleed before inserting the prepped Delivery System. Apply positive pressure saline to the Delivery System flush port during introduction into Guiding Sheath to obtain a wet-to-wet connection.

11) Note: Tightening the Guiding Sheath hemostasis valve onto the WATCHMAN FLX Pro To avoid introduction of air, slowly advance Delivery System into Guiding Sheath under fluoro guidance.

Precaution: Use caution when introducing Delivery System to prevent damage to cardiac structures.

12) Under fluoro guidance, align Delivery System distal marker band with most distal marker band on

Guiding Sheath. Once marker bands are aligned, stabilize Delivery System, retract Guiding Sheath , and

snap together to create the Guiding Sheath /Delivery System Assembly.

Note: To inject contrast, a syringe or a manifold must be attached to the flush port of the Delivery System.

13) Before deploying the occluder, confirm the position of the delivery catheter tip using fluoroscopy and transesophageal echocardiography (TEE).

14) If repositioning is required, loosen the delivery catheter and carefully withdraw it from

the guiding sheath. If needed, reinsert the pig-tail catheter to reposition the guiding sheath. Then, reinsert the delivery catheter as described in steps 11 and 12.

15) Release the Occluder by loosening the valve on the Delivery System, ensuring that the handle remains stable during withdrawal of the Delivery System, and maintaining the connection of the Core Wire.

16) Occluder release criteria: Position, Anchor, Size, and Seal (PASS criteria):

A. Position: Plane of maximum diameter of the Occluder should be at or just distal to the LAA stium, where possible (see Figure 1), while meeting all other PASS criteria.

B. Anchor: Move the tip of the Guiding Sheath back to expose sufficient core wire. Next, gently pull back on the deployment knob to visualize movement of the Occluder and LAA together.

C. Size (compression): Measure plane of maximum diameter of Occluder . Use Table 1 as a guide.

D. Seal: Ensure all lobes are distal to Occluder and sealed (i.e., no leak > 5 mm).

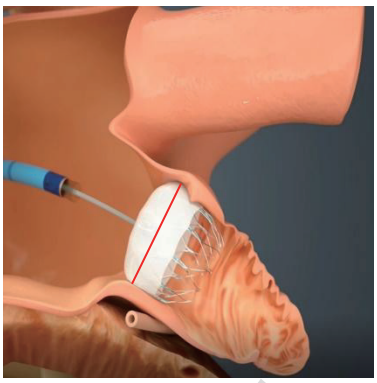

Figure 2 .LeSifter™ Device Position and Size

Note: If repositioning of the Occluder is required, proceed to Step 17 (Occluder repositioning). If removal of the Occluder is required, proceed to Step 18 (Occluder recapture and removal). If the Occluder meets release criteria, proceed to Step 19 (Occluder release).

17) If repositioning of the Occluder is required, recapture the Occluder per the following instructions.

A. Advance tip of Guiding Sheath /Delivery System Assembly up to Occluder and align Guiding Sheath/Delivery System Assembly with Occluder (do not unsnap).

B. Fix deployment knob position with right hand and gently advance Guiding Sheath / Delivery System Assembly over the Occluder by positioning the right thumb against the Delivery System hemostasis valve for stability and push the right thumb forward.

Resistance will be felt as the Occluder is collapsed into the Delivery System.

C. Continue to advance the Guiding Sheath /Delivery System Assembly such that the Occluder anchors are released from the LAA. The Occluder may be fully recaptured into the Guiding Sheath /Delivery System Assembly as needed prior to redeployment. After recapture, the Occluder may be repositioned using the guidance found in Step 13).

18) If removal of the Occluder is required, recapture the Occluder per the following instructions.

A. Advance tip of Guiding Sheath /Delivery System Assembly up to face of Occluder (do not unsnap).

B. Fix deployment knob position with right hand and gently advance Guiding Sheath / Delivery System Assembly over the Occluder by positioning the right thumb against Delivery System hemostasis valve for stability and push the right thumb forward. Resistance will be felt as the Occluder is collapsed into the Delivery System. Continue to advance the Assembly until Occluder is completely collapsed, recaptured, and distal fluoro tip is proximal to the Delivery System Distal Marker Band. Tighten the Delivery System hemostasis valve.

C. Ensure Guiding Sheath hemostasis valve is fully open.Unsnap Delivery System from Guiding Sheath while maintaining Guiding Sheath position.Slowly remove Delivery System.

D. Insert pigtail catheter to reposition Guiding Sheath in LAA,if necessary.

E. Repeat Steps 8-15 with new Delivery System.

19) If the Occluder meets release criteria,release Occluder .

Warning:Do not release the Occluder from the core wire if the Occluder does not meet all release criteria.

A.Confirm proper Occluder release criteria:Positon,Anchor,Size,and Seal(PASS criteria).

B.Advance Guiding Sheath/Delivery System Assembly close to face of Occluder .

C.Rotate deployment knob counterclockwise 3-5 full turns.

D.Confirm core wire is disconnected.

20) Ensure Guiding Sheath is free from anatomical structures prior to removal;adjust Guiding Sheath as necessary.Stop if resistance is felt.

21) Remove Guiding Sheath and Delivery System based on parameters for hemostasis.

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

13. POST-PROCEDURE INFORMATION

Options for post-procedure antithrombotic therapy are shown below. Physicians should exercise clinical judgement based on individual patient characteristics in determining the most appropriate use of antithrombotic drugs for the post-implant medication regimen.

Option A) Short-term OAC

1) Patients should remain on 81 mg - 100 mg of aspirin. OAC therapy should be added post-implant. At 45 days (± 15 days) post-implant, perform WATCHMAN FLX Pro Device assessment with TEE. Cessation of OAC therapy is at physician discretion provided that any leak demonstrated is ≤ 5 mm. If adequate seal is not demonstrated, subsequent OAC therapy cessation decisions are contingent on demonstrating leak is ≤ 5 mm. At the time the patient ceases OAC therapy, the patient should continue aspirin and begin a P2Y12 inhibitor daily. This regimen should continue until 6 months have elapsed after implantation. Patients should then remain on aspirin indefinitely. If a patient remains on OAC therapy and aspirin 81 mg - 100 mg for at least 6 months after implantation and then ceases OAC therapy, the patient should not require a P2Y12 inhibitor but should continue aspirin daily.
2) At 45 days and at 12 months, perform imaging to assess the WATCHMAN FLX Pro Device with TEE.

- Confirm absence of intra-cardiac thrombus.
- Perform color Doppler assessment to include the device/LAA border at the following approximate TEE angles (0°, 45°, 90° and 135°). Measure any residual leak around the device into the LAA. If there is evidence of leak > 5 mm, continuing or restarting antigoagulation therapy is recommended.
- If thrombus is observed on the device, use of anticoagulation is recommended until resolution of thrombus is demonstrated by TEE.

3) Prescribe appropriate endocarditis prophylaxis for 6 months following Closure Device implantation.

The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.

Option B) DAPT-only

1) Patients should remain on 81 mg – 100 mg of aspirin. P2Y12 inhibitor therapy should be added post-implant. At 45 days (± 15 days) post-implant, perform WATCHMAN FLX Pro Device assessment with TEE. P2Y12 inhibitor therapy should continue for 6 months

provided that any leak demonstrated is ≤ 5 mm. If adequate seal is not demonstrated, discontinuation of P2Y12 and starting OAC is recommended. Subsequent OAC therapy cessation decisions are contingent on demonstrating leak is ≤ 5 mm. At the time the patient ceases OAC therapy, the patient should continue aspirin and re-start P2Y12 inhibitor daily. This regimen should continue until 6 months have elapsed after implantation. Patients should then remain on aspirin indefinitely.

2) At 45 days and at 12 months, perform imaging to assess the WATCHMAN FLX Pro Device with TEE.

- Confirm absence of intra-cardiac thrombus.
- Perform color Doppler assessment to include the device/ LAA border at the following approximate TEE angles (0°, 45°, 90° and 135°). Measure any residual leak around the device into the LAA. If there is evidence of leak > 5 mm, discontinuation of P2Y12 and starting OAC is recommended.
- If thrombus is observed on the device, use of anticoagulation is recommended until resolution of thrombus is demonstrated by TEE.

3) Prescribe appropriate endocarditis prophylaxis for 6 months following Closure Device implantation.

The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.

14. Transportation and Storage Conditions

The product should be protected from moisture, direct sunlight, rain, high temperatures, heavy pressure, and impact during transportation. The product should be stored in a cool, dry place, away from direct light.

15. Shelf-Life

Under store requirements conditions, the "Use by" of LeSifter™ Left Atrial Appendage Closure Device is 3 years. The occluder 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 non-biodegradable and are intended to last for the lifetime of the patient.

16. SUPPLEMENTARY INFORMATION

- The Summary of Safety and Clinical Performance (SSCP) of this device is available in the European database on medical devices (Eudamed) by searching the basic UDI-DI "69383701003400UX " at: https://ec.europa.eu/tools/eudamed.
- Basic UDI-DI: 69354847MDP10TX
- The following patients material is available for this product:
  Online patient information guide: http://www.ydbmed.com

17. Warranty

Nanjing YDB Medical Technology Co., Ltd. (YDB) guarantees that the design and manufacture of this product have been thoroughly considered. This warranty supersedes and excludes all other warranties not explicitly stated herein, whether express or implied by law, including but not limited to any implied warranties of merchantability or fitness for a particular purpose. The handling, storage, cleaning, disinfection, and other factors related to the patient, diagnosis, treatment, surgery, and any other issues beyond YDB's control can directly affect the product and its performance. Under this warranty, YDB's obligations are limited to the repair or replacement of the product, and YDB is not liable for any incidental or consequential losses, damages, or costs arising from the direct or indirect use of this product. YDB will not assume or authorize any other person to assume any additional or other responsibilities or obligations in relation to this device. YDB does not bear any responsibility for the reuse, reprocessing, or re-sterilization of this device, nor does it make any express or implied warranties related to the device, including but not limited to warranties of merchantability or fitness for a particular purpose.

18. Symbol Definitions

Symbols	Definition
⚠	Caution
	Manufacturer
REF	Catalog number
SN	Serial number

	Batch code
	Use-by date
	Date of manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Double sterile barrier system
	Consult instructions for use or consult electronicinstructions for use
	Do not resterilize
	Keep dry
	Authorized representative in the European Community/The Netherlands
	Keep away from sunlight
	Translation
	Unique device identifier
	Medical device
	MR Conditional
	Patient identification
	Patient information website
	Health care centre or doctor
	Date

Appendix 1: Supplemental Information

REF of Device	Occluder		Access System			
			Delivery System		Guiding System	
	D（mm）	L（mm）	Core Wire（mm）	Delivery Sheath（mm）	Guiding Sheath(mm)	DIlation Tube(mm)
YFDQ-20-1	20	11	945	800	760	817
YFDQ-20-2					/	/
YFDQ-24-1	24	13			760	817
YFDQ-24-2					/	/
YFDQ-27-1	27	15			760	817
YFDQ-27-2					/	/
YFDQ-31-1	31	17			760	817
YFDQ-31-2					/	/
YFDQ-35-1	35	19.5			760	817
YFDQ-35-2					/	/

NL REP

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In 0032

rev.1.0