conformal®
THE SHAPE OF STROKE PREVENTION

Instructions for Use

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.

Exclusively for clinical investigation

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THE SHAPE OF STROKE PREVENTION

Table of Contents

1 Symbols Glossary 4
2 Indications for Use 6
3 Device Description 6
4 Contraindications 9
5 Warnings and Precautions 9
6 Adverse Events 9
7 Pre-Procedural Instructions 12
7.1 Accessory / Optional Devices Needed for Implantation Procedure 13
7.2 CLAAS Devices Needed for Implantation Procedure 13
7.3 Implantation Procedure 13
8 Delivery System (Access Sheath & Delivery Catheter) Preparation 14
8.1 Access Sheath and Dilator 14
8.2 Delivery Catheter with Implant 14
9 Intra-Procedure 15
9.1 Device Deployment Optimization 16
9.2 Release Criteria Guideline: Anchoring, Seal, Position 16
9.3 Device Repositioning 17
9.4 Implant Release – Continued from Intra-Procedure 18
9.5 Post-Procedure / Follow-Up - Antiplatelet and oral anticoagulant therapy requirements 18
10 Magnetic Resonance Imaging 19
11 How Supplied 20
11.1 Handling and Storage 20

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THE SHAPE OF STROKE PREVENTION

Table of Tables

Table 1: Symbols for CLAAS® System and Accessories 4
Table 2: CLAAS Implant sizing 13

Table of Figures

Figure 1: CLAAS Implant components of construction. 6
Figure 2: Single curve Access Sheath with Dilator components 7
Figure 3: Delivery Catheter, Pusher, and Implant 8
Figure 4: Loading Cone and Pusher Handle 8
Figure 5: CLAAS Implant (left) with Shoulder delineated which is coincident with internal fluoroscopic marker and CLAAS Implant in optimal position (right), shoulder aligned with LAA ostium. 16
Figure 6: Example of Shoulder-to-ostium engagement. 17
Figure 7: Access Sheath Marker Band (A) and distal Bumper Markers (B) 18

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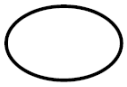
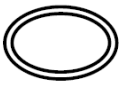
THE SHAPE OF STROKE PREVENTION

1 Symbols Glossary

The symbols in this glossary appear in the labels, packaging, and/or manual for the CLAAS® System.

Table 1: Symbols for CLAAS® System and Accessories

SYMBOL	EXPLANATORY TEXT
	Catalogue number
	Batch code
	Use-by date
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Do not resterilize
	Keep away from sunlight
	Keep dry
	Consult instructions for use or consult electronic instructions for use
	Sterilized using ethylene oxide

SYMBOL	EXPLANATORY TEXT
	Medical device manufacturer
	Number of pieces per package
	MR Conditional
	Medical device
	Inner Diameter
	Outer Diameter
	Date of manufacture
	Single sterile barrier system
	Double sterile barrier system

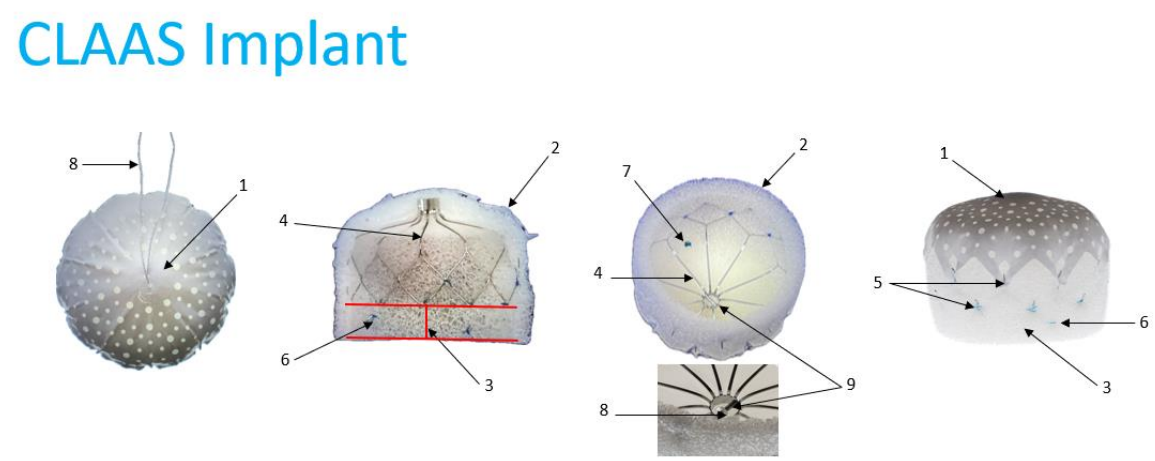
2 Indications for Use

The CLAAS® System is intended to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for oral anticoagulation (OAC) therapy; AND
- Are deemed by their physician to be suitable for OAC; AND
- Have an appropriate rationale to seek a non-pharmacological alternative to OAC, taking into account the safety and effectiveness of the device compared to OAC.

3 Device Description

The CLAAS Implant is a permanent implant designed to occlude the left atrial appendage (LAA) to eliminate blood flow into and clot passage from the LAA. It is a self-expanding occluder consisting of a cylindrical Nitinol endoskeleton (with low-profile anchor barbs around the midpoint) covered with a porous foam cup. The proximal face of the foam cup has an ePTFE cover to enhance re-sheathing, and the distal portion of the foam cup extends beyond the frame to serve as an atraumatic leading edge.



1. ePTFE Outer Cover – thromboresistant surface
2. Foam Body
3. Foam Bumper – 5mm height
4. Endoskeleton
5. Anchors – 2 rows; 10/row for Regular 27mm CLAAS or 12/row for Large 35mm CLAAS
6. Bumper Markers (x4 within the Bumper)
7. Shoulder Marker (for placement reference)
8. Tether
9. Tether Pin

Figure 1: CLAAS Implant components of construction.

The Implant is designed to conform to irregular LAA anatomies while maintaining secure fixation and is partially re-sheathable and re-deployable prior to final release from the Delivery System via a removable, flexible tether. The implant is available in two sizes: Regular (27 mm) and Large (35 mm).

In addition to the Implant, the CLAAS System includes a Delivery System (Access Sheath & Delivery Catheter) that allows percutaneous delivery of the Implant to the LAA via standard femoral venous access and transseptal puncture. The insertable length of the access sheath is 77.5cm. The insertable length of the delivery catheter is 73.0cm.

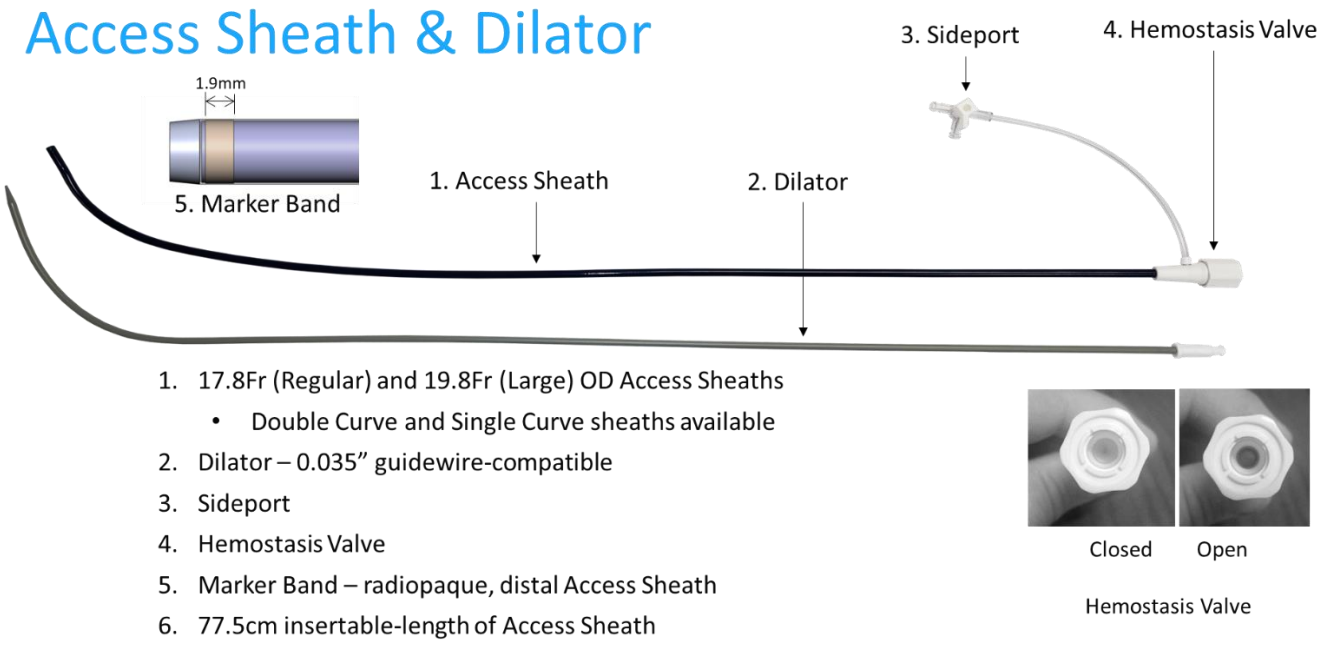


Figure 2: Single curve Access Sheath with Dilator components

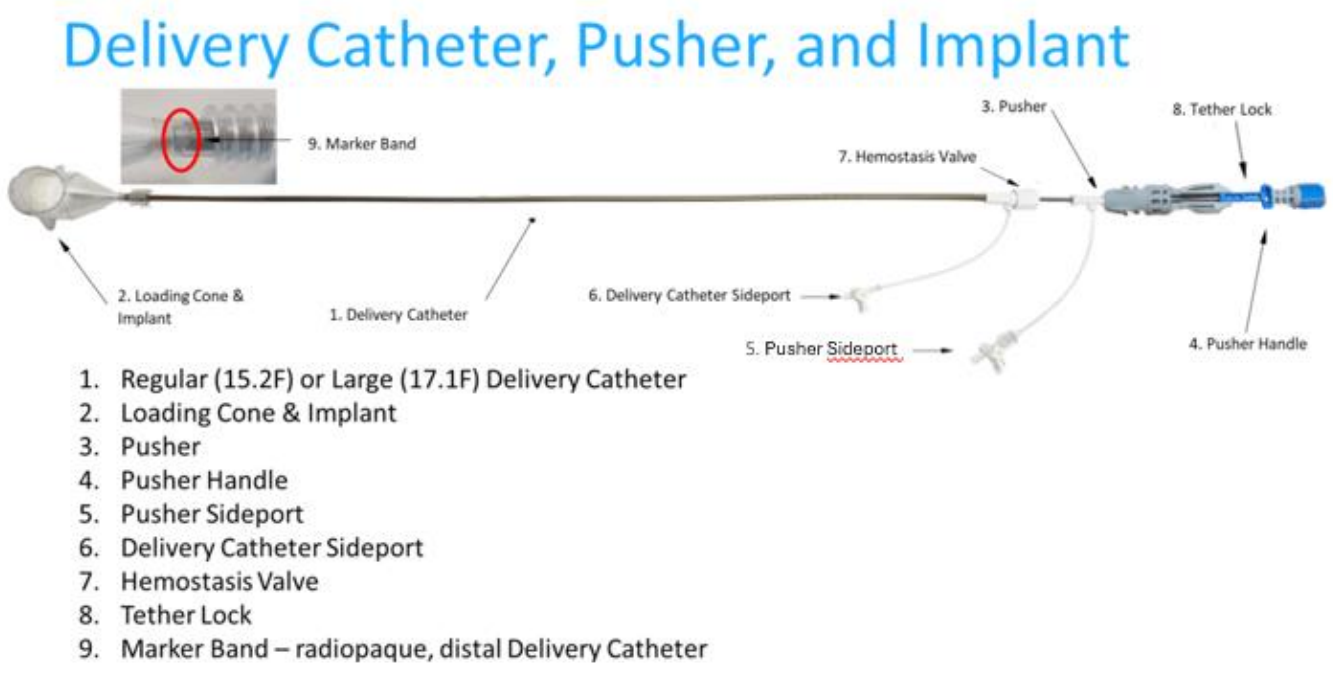


Figure 3: Delivery Catheter, Pusher, and Implant

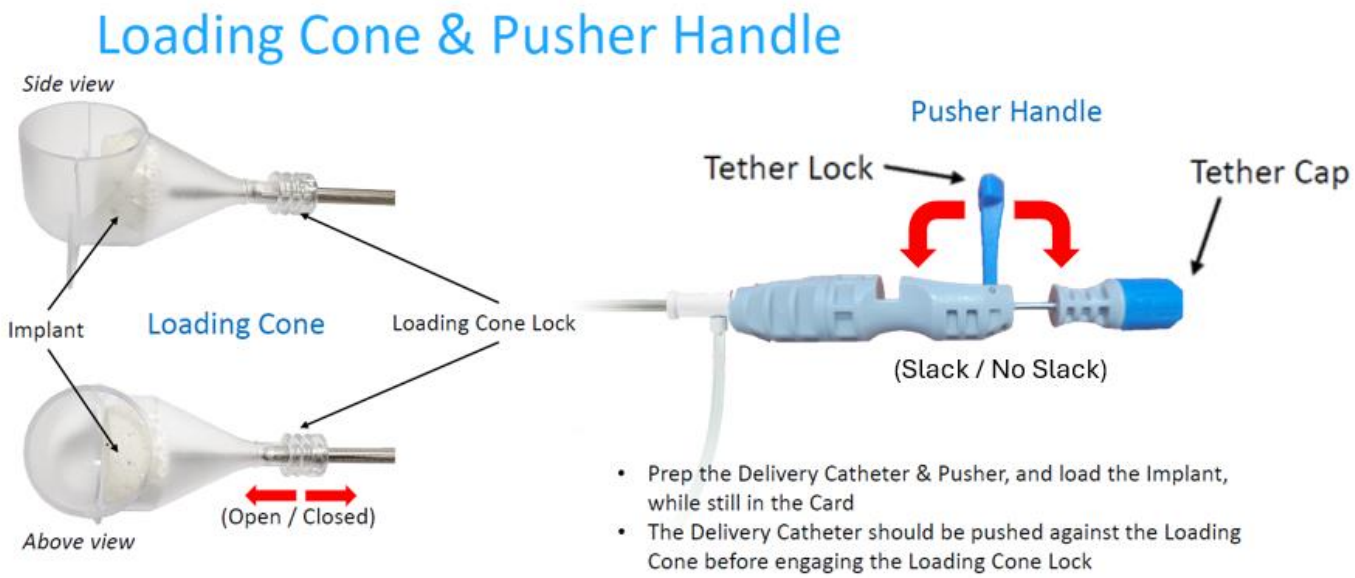


Figure 4: Loading Cone and Pusher Handle

4 Contraindications

Do not use the CLAAS System if:

1. The LAA anatomy will not accommodate the CLAAS device (See Table 2).
2. There is presence of intracardiac thrombus or dense, spontaneous echo contrast consistent with thrombus, as visualized by TEE prior to implant
3. Left Ejection Fraction (LVEF) <30%
4. Moderate or large circumferential pericardial effusion >10 mm or symptomatic pericardial effusion, signs, or symptoms of acute or chronic pericarditis, or evidence of tamponade physiology
5. Atrial septal defect that warrants closure
6. High risk patent foramen ovale (PFO), defined as an atrial septal aneurysm (excursion >15 mm or length > 15 mm) or large shunt (early [within 3 beats] and/or substantial passage of bubbles, e.g., ≥20)
7. Moderate or severe mitral valve stenosis (mitral valve area <1.5 cm^2)
8. Complex atheroma with mobile plaque of the descending aorta and/or aortic arch
9. Evidence of cardiac tumor
10. There are contraindications to the use of OAC, aspirin or P2Y12 inhibitors.
11. The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description).

5 Warnings and Precautions

Implantation of the CLAAS should only be performed by physicians trained in percutaneous and transseptal procedures who have completed Conformal Medical, Inc.'s CLAAS training.

NOTE: The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying the Device.

- The CLAAS Access Sheath and Delivery Catheter with Implant are sterile and intended for single patient use only. Do not reuse or resterilize.
- If the sterile barrier has been compromised in any way or appears damaged DO NOT USE.

Precaution: If using a power injector, connect to the Pusher Side port. Maximum pressure setting is not to exceed 100 PSI.

6 Adverse Events

The device and procedure are both associated with risks. Below is a summary of the risks that may occur. Risks are delineated by events associated with the procedure and those associated with the CLAAS System. There may be additional risks that are unknown at this time.

Procedural Risks: The risks of delivery of the CLAAS Implant are similar to those of other procedures that require a transseptal puncture and transcatheter delivery of an implant through the venous system, across the interatrial septum, and into the left atrium using a large bore catheter (e.g., EP procedures and/or other LAA occlusive devices such as Watchman). These risks are well recognized, and experienced clinicians that are well versed in the use of large bore catheters have mitigated these risks to the extent possible in their standard of care.

The recognized procedural risks observed in CLAAS clinical studies and observed with other LAAO products include, but are not limited to (in alphabetical order):

- Acute Kidney Injury/Renal Failure potentially requiring need for dialysis
- Air embolus
- Allergic reaction to contrast media necessary for imaging during procedure
- Altered Mental Status
- Anesthesia risks (e.g., nausea/vomiting, aspiration pneumonia)
- Anoxic encephalopathy
- Arrhythmia
- Bleeding/anemia requiring transfusion
- Cardiac perforation
- Chest pain/angina
- Contrast related nephropathy
- Damage to vasculature or cardiac structure (e.g., valve, chordae)
- Death
- Deep Vein Thrombosis or Pulmonary Embolism
- Dyspnea
- Edema
- Electrolyte imbalance
- Fever
- Heart Failure
- Hematuria

- Hemodynamic Instability (hypotension/hypertension)
- Hemoptysis
- Hemothorax
- Iatrogenic ASD requiring treatment
- Improper wound healing
- Interatrial septum thrombus
- MI including ST segment elevation
- Pericardial Effusion/tamponade
- Pleural Effusion
- Pulmonary Edema
- Pulmonary Vein/Pulmonary Artery perforation
- Radiation Injury
- Respiratory failure/Hypoxia
- Stroke/TIA related to embolic, thromboembolic, or hemorrhagic event
- Systemic Infection including pneumonia
- TEE/intubation risks including throat pain, trauma to airway or esophagus with or without bleeding
- Thrombocytopenia
- Vasovagal reactions
- Venous access site complications including pain, AV fistula, pseudoaneurysm, infection, hematoma, bleeding requiring transfusion and/or the need for surgical repair

Device Risks: In addition to the risks of undergoing an interventional procedure, there should be consideration to the risks which are specific to the CLAAS Implant and CLAAS Delivery System. Conformal Medical has identified a set of risks, the rates of which may be different due to the design of the CLAAS System as outlined below. A number of the risks have been determined to be present with other interventional (e.g., Watchman) as well as surgical implants designed to occlude the LAA. These risks include but are not limited to (in alphabetical order):

- Arrhythmias
- Cardiac perforation, puncture, tamponade, and/or effusion caused by device

- Chest pain/angina
- Death
- Deep Vein Thrombosis or Pulmonary Embolism
- Device embolization or thrombosis
- Device fracture
- Device malfunction/breakage resulting in the inability to reposition, resheath or retrieve requiring further intervention.
- Device manipulation resulting in the inability to reposition, resheath or retrieve requiring further intervention.
- Device migration requiring intervention
- Edema
- Heart Failure
- Infection
- Major bleed requiring transfusion
- Myocardial Erosion
- Prolonged procedure time risk/Radiation injury
- Pulmonary Vein/Pulmonary Artery perforation
- Re-intervention due to incomplete seal
- Re-intervention to remove device
- Residual leak in LAA
- Stroke/TIA or Systemic embolization
- Thrombus formation

7 Pre-Procedural Instructions

Oral anticoagulation (Warfarin or DOAC) should be discontinued prior to the procedure. DOAC's should be managed according to the drug specific Prescribing Information. Warfarin should be discontinued as per site protocol with confirmation of appropriate INR on the day of the procedure.

The following loading doses should be administered prior to the index procedure:

- ASA 81-100 mg (administered 1 day prior to procedure)

or

- ASA 325 mg (chewed 1 hour prior to procedure)

A baseline TEE or Cardiac CT should be performed to verify LAA anatomy meets CLAAS implant sizing criteria and the absence of contraindications 1-9.

- For ICE guided implant procedures, reference the current ICE Imaging Protocol
- For TEE guided implant procedures, reference the current TEE Imaging Protocol

1. Assess the following through multiple imaging planes (e.g., 0°, 45°, 90°, 135°).
    a. LAA size/shape, number of lobes in the LAA and location of lobes relative to ostium
    b. Confirm the absence of thrombus (use Color Doppler and echo contrast as necessary)
    c. Record the largest (D_{max}) and smallest (D_{min}) LAA ostium diameters and LAA depth (0°, 45°, 90° and 135° sweep).
2. Confirm LAA anatomy is appropriate for CLAAS Implant based on sizing criteria (Table 2).

Table 2: CLAAS Implant sizing

CLAAS Size	Mean LAA Ostium Diameter (D_{min} + D_{max}) / 2	LAA Ostium Diameter Ranges (D_{min} & D_{max} must be within range)	Minimum Landing Zone (Depth)
Regular	≤ 25 mm	10 – 33 mm	10 mm
Large	≤ 32 mm	20 – 40 mm	10 mm

7.1 Accessory / Optional Devices Needed for Implantation Procedure

- (Optional) 18F or 20F Venous Introducer
- Transseptal access system
- 0.035” guidewire (exchange length, e.g., extra support)
- Angiographic Pigtail Catheter
- 50cc syringe with luer connection
- (Optional) VizaraMed Multiflex Steerable Sheath (**15.5F only**) used in compliance with the product’s instructions for use for Regular CLAAS Implant

7.2 CLAAS Devices Needed for Implantation Procedure

- CLAAS Access Sheath (Single or Double Curve) with Dilator
- CLAAS Delivery Catheter with Implant

7.3 Implantation Procedure

NOTE: **DO NOT USE** if the sterile barrier, labeling, packaging, or any component of the Delivery System (Access Sheath, Dilator, Delivery Catheter, Pusher, and Implant) have been compromised or appear damaged.

8 Delivery System (Access Sheath & Delivery Catheter) Preparation

8.1 Access Sheath and Dilator

- Remove the CLAAS Access Sheath and Dilator from its sterile packaging, using sterile technique
    - Inspect both for any damage and check that the stopcock is securely connected to the Sideport
- Flush and de-air the CLAAS Access Sheath with Dilator. Advance the Dilator through the Access Sheath; secure this combination by snapping the Dilator Hub to the Access Sheath Hemostasis Valve.

8.2 Delivery Catheter with Implant

Prepare the CLAAS Implant and Delivery Catheter:

- Remove the Delivery Catheter with Implant from the sterile packaging using sterile technique
- Leave the Delivery Catheter Secured to the Backer Card in which it is packaged
- Inspect prior to use to ensure there is no damage to the handle, catheter, connections, and Implant
- Unfasten the Pusher Handle and Sideports
- Make sure all luer connections are secure; this includes stopcocks, the connection between the Pusher & Pusher Handle, and Tether Cap
- Ensure Tether Lock is snapped securely in the locked position
- Ensure Delivery Catheter Hemostasis Valve is closed
- Ensure the Delivery Catheter Marker Band can be seen in the distal neck of the Loading Cone and the Loading Cone Lock is closed
- Flush the Pusher, while gently tapping the length of the Pusher and Delivery Catheter, until de-aired
- Flush the Delivery Catheter, while gently tapping the length of the Delivery Catheter, until de-aired
    i. The Loading Cone should fill with flush and submerge the Implant
- Ensure the Loading Cone, Delivery Catheter, and Support Tube are secured together, before loading the Implant
    i. The Support Tube is pre-packaged around the Delivery Catheter to provide support during the loading of the Implant
- Pull the Pusher to load the Implant into Delivery Catheter, while ensuring the Loading Cone, Delivery Catheter, and Support Tube do NOT separate from each other during loading of the Implant
- Unlock and remove the Loading Cone from the Delivery Catheter
- Confirm the distal foam bumper of the loaded Implant is within the range of the radiopaque marker of the Delivery Catheter
- Inspect for air bubbles

i. If air bubbles are present, slightly elevate the Delivery Catheter while flushing the Delivery Catheter sideport

The system is ready for use and may be removed from the Support Tube and Card.

9 Intra-Procedure

Intraprocedural anticoagulation should be maintained according to physician standard practice in accordance with published guidelines and local standards of care, with a goal of maintaining an activated clotting time (ACT) of 250-350 sec (or equivalent) throughout the procedure.

1. Once the presence of intracardiac thrombus and exclusion criteria are ruled out and LAA anatomy is confirmed to meet CLAAS Implant sizing criteria (Table 2), prepare the patient for standard transcatheter procedure via femoral venous access
2. Use a standard, commercially available transseptal access system to cross the inter-atrial septum
3. Position an appropriate 0.035’ guidewire in the left upper pulmonary vein (LUPV) or loop it in the left atrium (LA). Remove the transseptal access sheath while maintaining wire position
4. Advance the prepared CLAAS Access Sheath and Dilator over the guidewire into the LA
    - Once sufficiently across the septum, separate the Dilator from the Access Sheath and remove the Dilator and guidewire, leaving the Access Sheath in the LA or LUPV
    - Aspirate from the side port to minimize the potential of introducing air into the system, then flush the Access Sheath

NOTE: Use caution when introducing the CLAAS Access Sheath to prevent damage to cardiac structures.

NOTE: The Access Sheath’s Hemostasis Valve can be opened/loosened or closed/tightened. After introduction or removal of equipment, ensure the Access Sheath’s Hemostasis Valve is sufficiently closed/tightened to prevent unnecessary bleeding from the hub.

5. Advance an angiographic pigtail catheter through the Access Sheath, into the distal portion of the LAA, under fluoroscopic guidance. Obtain an angiogram of the left atrial appendage in the optimal projection
6. Slowly remove the pigtail catheter while maintaining Access Sheath position
7. Advance the prepared Delivery Catheter into the Access Sheath
    - Advance the Delivery Catheter until the hubs meet, and snap together
    - Fluoroscopy may be used to visualize the movement of the Delivery Catheter, but the Delivery Catheter should not extend beyond the Access Sheath
8. Using fluoroscopy and/or ultrasound imaging, confirm the position of the Access Sheath tip (distal to the ostium) before initiating deployment of the Implant
9. While using fluoroscopy, hold the Access Sheath / Delivery Catheter assembly in one hand and the Pusher in the other hand, slowly advance the Pusher until 3-5 mm of the Implant is exposed beyond the Access Sheath Marker Band

- Under fluoroscopy, the 4 distal Bumper Markers will be slightly separated and need to be at least 2.5 millimeters beyond the Access Sheath Marker Band
- Do not advance the Pusher any farther

10. Position the Delivery System (Access Sheath and Delivery Catheter) so the Implant Shoulder Marker is at the LAA ostium
11. Prior to full deployment, ensure the Implant Shoulder Marker is correctly positioned
    - Adjust placement as necessary and desheath the Implant until the Implant is fully deployed
    - Desheathing/Unsheathing: Fix the Pusher in place with slight forward pressure, then slowly pull back on the Access Sheath/Delivery Catheter Assembly to expose and deploy the Implant
12. Upon deployment, provide Tether slack
    - Unsnap the Tether Lock and secure in the unlocked position
        i. Advance the Tether Cap until it abuts the Pusher Handle
        ii. Slowly retract the Delivery System from the Implant to ensure there is no contact

9.1 Device Deployment Optimization

1. Evaluate the Implant position with fluoroscopy /angiography and/or ultrasound, and adjust as needed to align the CLAAS device with the LAA ostium (See Release Criteria Guidelines below).
2. NOTE: The Pusher should be close to, but not touching, the Implant for contrast injections through the Pusher Sideport

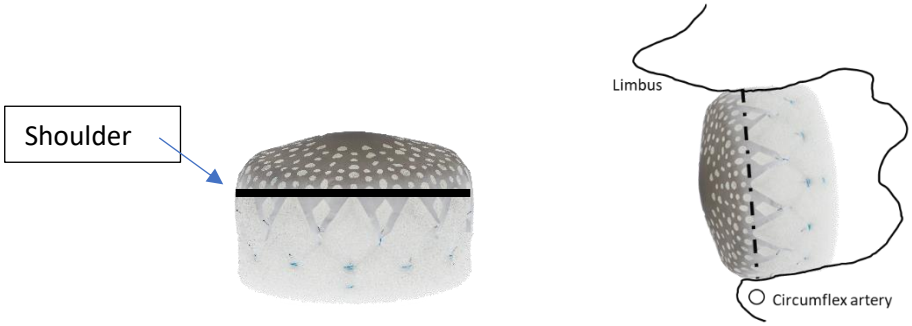


Figure 5: CLAAS Implant (left) with Shoulder delineated which is coincident with internal fluoroscopic marker and CLAAS Implant in optimal position (right), shoulder aligned with LAA ostium.

3. Evaluate Implant Anchoring with a Tug Test
    - Retract the Pusher approximately 2 cm from the surface of the Implant
        i. Unscrew the Tether Cap and gently pull Tether while observing motion of the Implant and LAA tissue
    - Evaluate the seal with angiography and ultrasound

9.2 Release Criteria Guideline: Anchoring, Seal, Position

Verify **ASP Guideline Criteria** before releasing the Implant:

1. **A**nchoring – With the Tug Test
    a. Observe tissue movement with the Implant, with ultrasound imaging
    b. Repeat if it is observed that the Implant moved from its original position
2. **S**eal – Using ultrasound imaging
    a. Target ≤ 3mm leak in all ultrasound views (0°, 45°, 90°, 135°)
        i. For ICE guided procedures, reference the current ICE Imaging Protocol
        ii. For TEE guided procedures, reference the current TEE Imaging Protocol
3. **P**osition – The plane of the Shoulder Line of the CLAAS device should be at or just proximal to the LAA ostium. CLAAS Implant position in relation to the LAA ostium may vary based on individual patient anatomy and the imaging views.
    a. CLAAS position should be evaluated in all FOUR ultrasound views (0°, 45°, 90°, 135°)
    b. Target deployment is for the Shoulder Line to be <5mm proximal to the LAA ostium and not to exceed 8mm.

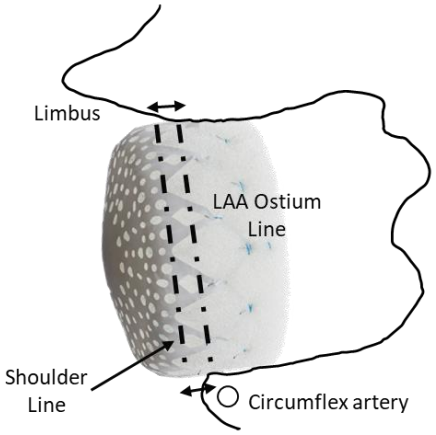


Figure 6: Example of Shoulder-to-ostium engagement.

If the Implant Anchoring, Seal, or Position are not acceptable, the Implant should be repositioned. The Implant will need to be partially resheathed before repositioning and may be partially resheathed into the Access Sheath, up to three times.

9.3 Device Repositioning

1. Remove Tether slack by retracting the Tether Cap and securing the Tether Lock in the closed position cradle
    - Resheath under fluoroscopy
    - Hold the Access Sheath/Delivery Catheter assembly in one hand and the Pusher in the other, then advance the Sheath/Catheter assembly over the Implant until the Implant Shoulder Marker is at the proximal edge of the Access Sheath Marker Band
    - The distal Bumper Markers should still be several millimeters beyond the Access Sheath Marker Band

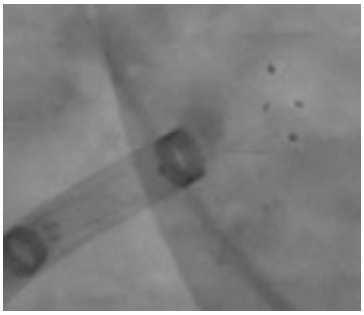


Figure 7: Access Sheath Marker Band (A) and distal Bumper Markers (B) positioned during partial resheath

2. Reposition the Implant, by adjusting the position of the Delivery System, using the Shoulder Marker as a guide
    - With light forward pressure on the Pusher, retract the Access Sheath/Delivery catheter assembly (desheath) to redeploy

NOTE: The Implant can be removed from the patient by fully resheathing the implant into the Access Sheath and then into the Delivery Catheter, which can then be removed from the Access Sheath. Do not reuse a device that has been fully resheathed.

9.4 Implant Release – Continued from Intra-Procedure

Note: the Implant has been deployed and tether slack has been provided

1. Remove the Tether Cap and apply slight tension
2. Advance the Pusher near the face of the Implant, while keeping the Tether Cap & Delivery Catheter/Access Sheath assembly stationary
3. Cut **one** of the exposed strands of the Tether
4. Slowly withdraw the Tether until it is fully removed from the Delivery Catheter
5. Retract the Pusher so its entirety is within the Access Sheath and slowly disconnect and remove the Delivery Catheter with Pusher from the Access Sheath
6. Re-confirm Implant Position and Seal with imaging
7. Slowly remove the Access Sheath
8. Confirm absence of pericardial effusions
9. Remove the femoral access sheath and close as per routine

Note: It is important to cut only one strand of the Tether when releasing the implant.

9.5 Post-Procedure / Follow-Up - Antiplatelet and oral anticoagulant therapy requirements

- Details of the post-procedure follow-up requirements are detailed in the CONFORM trial protocol.

10 Magnetic Resonance Imaging

Non-clinical testing demonstrated that the CLAAS Implant is MR Conditional. A patient with this implant can be scanned safely in an MR system under the following conditions:

MRI Safety Information

The Conformal Left Atrial Appendage Seal (CLAAS) Implant is MR Conditional. A patient with the Conformal Left Atrial Appendage Seal (CLAAS) Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MR Conditional

Parameter	*Condition*
Nominal Values of Static Magnetic Field (T)	1.5-T and 3.0-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back to back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

11 How Supplied

The CLAAS Implant is provided with the Delivery Catheter.
The CLAAS products are supplied STERILE using an ethylene oxide (EO) process.
Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.

NOTE: Contents of inner package are STERILE.

11.1 Handling and Storage

Store in a cool, dry, dark place

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