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Study Guide: WATCHMAN™ LAA Closure Technology

IMPORTANT INFORMATION: These materials are intended to describe typical considerations and procedural steps that reflect current standards of care. Patients and their medical circumstances vary and the information and procedural steps described may not be appropriate for every patient or case. As always, decisions surrounding procedural care must be made at the physician’s discretion in light of all available information and the patient’s best interests. Similarly, BSC product considerations are based solely on the author’s experience and may not be interpreted or relied upon to support clinical or competitive product claims. The experiences of other users may vary.

Note: All images have been sourced from the PROTECT AF trial.
This workbook describes the WATCHMAN™ LAA closure technology and imaging guidelines at baseline, during the closure procedure, and at follow-up.

To use this workbook:

• Study the illustration as you read the description written here.

• Fill in the blanks to review the Key Concept listed in the righthand column.

• Refer to More information in the righthand column to learn more about the topic.

• Complete the Applications in the Study Guide that accompanies this workbook.

**Key Concept**: This workbook describes WATCHMAN ____________ and related imaging.

LAA closure technology

**More information...**

• Read this information to find out more about the topic.
Module 1: WATCHMAN™ LAA Closure Technology

LAA Closure Components
- Patient Indications
- WATCHMAN™ Device
- WATCHMAN™ Access System (WAS)
- WATCHMAN™ Delivery System (WDS)

LAA Closure Procedure
- Basic Steps
- Cross Interatrial Septum (IAS)
- Introduce WAS
- Introduce Pigtail Catheter
- Introduce WDS
- Deploy WATCHMAN Device
- Confirm Device Release Criteria (DRC)
- Release Device

Device Modifications
- Partial Device Recapture
- Full Device Recapture

Patient Management
- Guidelines

Reference
- Summary of LAA Closure
WATCHMAN LAA closure technology is designed to prevent the embolization of thrombi that may form in the left atrial appendage (LAA). It may protect patients from ischemic stroke or systemic embolism and eliminate the need for long-term anticoagulation therapy.*

- The WATCHMAN Device is indicated 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 CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy;
  - Are deemed by their physicians to be suitable for warfarin; and
  - Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin.

In considering the use of the WATCHMAN Device, the rationale for seeking an alternative to long-term warfarin therapy and the safety and effectiveness of the device compared to warfarin should be taken into account.

- Clinical study data show that patients with AF are at significantly higher risk for ischemic stroke or systemic embolism than patients who do not have AF. Studies also show that 91% of NVAF-related LA thrombi were isolated to, or originated in, the LAA (SPAF III).

Key Concept: WATCHMAN LAA closure may eliminate the need for ________________therapy in patients with non-valvular ___________________.

anticoagulation, atrial fibrillation

More information...

- Chronic anticoagulation presents problems of safety and tolerability, especially in patients older than 75, an age group that includes about half of AF-associated stroke patients.

*Note: A thrombus is a blood clot. An embolus is a thrombus that breaks free from the site of formation and circulates in the bloodstream until it becomes lodged in a blood vessel. A stroke – also called cerebrovascular accident (CVA) – occurs when the vessels of the brain are occluded (plugged) by an embolus.
The **WATCHMAN Device** is a self-expanding nitinol structure with a polyethylene terephthalate (PET) porous membrane on the proximal face.

- The device is constrained within the Delivery System until deployment in LAA.
- Appropriate device sizing is determined by using fluoroscopy (fluoro) and transesophageal echocardiography (TEE).
- Available sizes are listed in the following table:

<table>
<thead>
<tr>
<th>WATCHMAN Size Options</th>
<th>Access sheath Marker band</th>
<th>Loaded device length</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>21mm</strong></td>
<td><strong>20.2mm</strong></td>
<td></td>
</tr>
<tr>
<td><strong>24mm</strong></td>
<td><strong>22.9mm</strong></td>
<td></td>
</tr>
<tr>
<td><strong>27mm</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>30mm</strong></td>
<td><strong>29.4mm</strong></td>
<td></td>
</tr>
<tr>
<td><strong>33mm</strong></td>
<td><strong>31.5mm</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Key Concept:** The device is constrained within the Delivery System until deployment in ______. thrombi, LAA
The **WATCHMAN Access System (WAS)** consists of an access sheath (AS) and vessel dilator. The AS provides a conduit for catheter delivery of the WATCHMAN Device.

- The **access sheath (AS)** has a 12 French inner diameter, 14 French outer diameter, 75cm working length, and sideport for flushing the system. Other AS features are as follows:
  - **Radiopaque marker bands** to position the AS in the LAA. The *distal marker band* is used to guide the AS into the distal LAA. The *proximal marker bands* correspond to device size (maximum device diameter) and are positioned at or just distal to the LAA ostium.
  - **Vent holes** to reduce pressure at the AS tip when injecting contrast
  - **Soft radial tip** to reduce tissue trauma
- The access sheath (AS) is available in three curve configurations. The **single curve** accommodates an LAA curved in an anterior direction. The **double curve** accommodates an LAA curved in an anterior then superior direction. The **anterior curve** accommodates an LAA curved in a more extreme anterior then superior direction.

**Key Concept:** The access sheath (AS) is a conduit for ___________ of the WATCHMAN Device. It is available in single, anterior and ___________ curve configurations.

catheter delivery, double

**More information...**

- Selection of an access sheath (AS) curve is based on LAA assessment using fluoro and TEE images.
- The double curve AS is used most often.
The **WATCHMAN Delivery System (WDS)** consists of a delivery catheter (DC) and the preloaded WATCHMAN Device. The DC constrains the WATCHMAN Device until it is deployed.

- The delivery catheter has a 12 French outer diameter, **sideport**, and **deployment knob** attached to a **core wire**. The **control handle** is used to deploy and release the device.

- In addition to the WDS and WAS, the following implant equipment is recommended, **but not included**.
  - Venous introducer
  - Standard transseptal access system (TAS)
  - 0.35”guidewire (exchange length / extrasupport)
  - 4 to 6 French pigtail catheter
  - Intravascular radiocontrast agent
  - 60cc syringe and 3-way stopcock to flush system
  - Pressurized saline bag with a drip chamber and sterile line to prevent the introduction of air
  - Pericardiocentesis tray
  - 14 to 16 French sheath for device retrieval (loop, bioptome)

**Key Concept**: The WDS constrains the **______________** until it is deployed in the **__________**.

**WATCHMAN Device, LAA**

**More information...**

- If using a power contrast injector, ensure the maximum pressure does not exceed 100 psi.
Transseptal catheterization is used to place the WATCHMAN Device at or distal to the LAA ostium. **Basic steps** are listed below and described in detail on the next several pages.*

1. Cross interatrial septum (IAS)
2. Introduce WATCHMAN Access System (WAS)
3. Introduce pigtail catheter (PC)
4. Introduce WATCHMAN Delivery System (WDS)
5. Deploy WATCHMAN Device in LAA
6. Confirm device release criteria (DRC); then release device

* **Note:** Module 2 of this workbook provides image acquisition guidelines.

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**Key Concept:** The WATCHMAN Device is placed at or distal to the ____________.

LAA ostium

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**More information...**

- Use fluoro and multiple TEE views (0°, 45°, 90°, 135°) to visualize procedural maneuvers.
To cross the interatrial septum (IAS):

1. Access the heart:
   - Puncture femoral vein using standard percutaneous technique.
   - Insert standard transseptal access system (TAS), 0.032 to 0.035” guidewire, and vessel dilator.

Some experienced implanters suggest a posterior transseptal puncture for LAA occlusion. Too anterior a puncture can result in failure to insert the AS in the LAA.

**Key Concept:** Some implanters suggest a ________ transseptal puncture for LAA occlusion.

posterior

**More information...**

- Provide systemic heparin to ensure the activated clotting time (ACT) is maintained between 200 to 300 seconds for the duration of the LAA closure procedure.
To cross the interatrial septum (IAS):

2. **Cross IAS**
   - Use standard transseptal technique to cross the IAS.
   - Exchange the crossing sheath with an exchange length extra support guidewire.
   - Advance guidewire into left upper pulmonary vein (LUPV) or loop in the left atrium.
   - Remove TAS and dilator.
   - Use standard techniques to confirm entry into LA.

It may be helpful to acquire mid-esophageal (ME) bicaval and AV short axis (ME AV SAX) TEE views to guide the IAS puncture location and obtain a coaxial trajectory into the LAA.

**Key Concept:** Use standard transseptal technique to cross the interatrial septum (IAS).
To introduce the WATCHMAN Access System (WAS):

1. **Prepare access sheath (AS) and dilator**
   - Confirm patient’s LAA angle and select AS curve (single or double).
   - Inspect the WAS and its packaging to ensure neither is damaged. Remove packaging under sterile conditions.
   - Flush sheath and dilator with saline.
   - Insert dilator into AS via hemostasis valve (Touhy).

2. **Advance access sheath (AS) to initial position**
   - Insert the AS and dilator over guidewire, then carefully advance toward the center of left atrium (LA).
   - Hold dilator and guidewire in place and continue advancing AS to its initial position in the LA or LUPV ostium. *Avoid advancing the dilator as doing so could damage cardiac structures.*
   - Remove dilator and guidewire, leaving AS at initial position.*

*Note: Most implanters prefer to retain the guidewire for pigtail catheter placement.

**Key Concept:** Advance the access sheath to its initial position in the _____ or ostium of the ________.

LA, LUPV

**More information...**
- Avoid using any WATCHMAN component if the sterile packaging has been compromised.
- Use standard air management techniques.
To introduce the pigtail catheter (PC):

1. **Prepare PC**
   - Inspect and flush PC.

2. **Advance PC**
   - Carefully advance PC through AS to distal LAA, using cine with contrast for visualization. Rotate to desired orientation.

2. **Advance access sheath (AS) into LAA**
   - Use TEE and two orthogonal fluoro views to confirm the **LAA dimensions** acquired during baseline imaging.
   - Use distal marker band to guide AS over PC to distal LAA. Continue advancing AS until the proximal marker band that corresponds to the maximum device diameter is **at or just distal** to the LAA ostium.
   - Carefully remove PC.

**Key Concept:** When the AS is at the LAA ostium, confirm baseline LAA dimensions, then guide the AS into the distal LAA.

**More information...**

- Use orthogonal fluoro and multiple TEE views to observe the distal tip of the access sheath when advancing.
  **Stop advancing if resistance is felt.**
- Avoid manipulating the access sheath in the LAA without a pigtail catheter.
To introduce the WATCHMAN Delivery System (WDS):

1. **Confirm device integrity**
   - Inspect WDS / packaging to ensure neither is damaged.
   - Loosen **proximal valve** to displace **deployment knob**.
   - Hold delivery catheter (DC) body and pull deployment knob back a few centimeters to confirm the preloaded device is securely attached to the **core wire**.
   - Slowly push forward on DC control handle until the device is aligned with **distal marker band** of DC.

2. **Flush delivery catheter (DC)**
   - Flush DC in antegrade and retrograde directions.
   - Use 60cc syringe to remove air and thoroughly flush the DC, maintaining fluid throughout its length. *If desired, submerge DC in saline and tap gently to remove air bubbles.*
   - Ensure valve is tightly closed to prevent device movement.

3. **Advance delivery catheter (DC)**
   - Loosen proximal valve of AS. *To avoid introducing air, connect pressurized, controlled saline drip to sideport or use standard air management techniques.*
   - Slowly advance DC into AS, using fluoro to observe distal tip. Stop advancing when **marker bands** of the DC and AS are aligned with one another.

**Key Concept:** Ensure the preloaded device is securely attached to the __________ and aligned with the distal __________.

**core wire, marker band**

**More information...**

- Avoid twisting deployment knob of delivery catheter during pre-implant inspection.
- After flushing catheter, ensure the preloaded device is still aligned with the marker band and **does not protrude** past the distal marker band.
LAA Closure Procedure

Deploy WATCHMAN™ Device

To deploy the WATCHMAN Device in LAA:

1. **Snap access sheath (AS) to delivery catheter (DC)**
   - Retract AS until it *snaps* onto DC and forms a single AS/DC assembly.
   - Use fluoro and TEE images to confirm that the AS/DC assembly is still correctly positioned within the LAA.

2. **Deploy (unsheath) device slowly**
   - Loosen hemostasis valve on DC.
   - Hold deployment knob in place; then *slowly* retract AS/DC assembly until the WATCHMAN Device is completely deployed (unsheathed). It should take about *five seconds* to deploy the device.
   - Withdraw AS/DC assembly about **1 cm** from proximal face of device, leaving the core wire attached. *This position permits assessment of device release criteria.*

**Key Concept:** Device deployment takes about _______ seconds. After deployment, withdraw AS/DC assembly about _______ from device face.

- **five, 1 cm**

**More information...**

- Some implanters find it helpful to remember the acronym, **SAFE:**
  - **S**top when AS/DC snap together
  - **A**gree on position of the AS/DC
  - **F**luoro the deployment
  - **E**ngage AS/DC and unsheath device slowly in LAA

**Notes:**

- Use contrast in AS to visualize any trapped air ahead of the delivery catheter. To remove trapped air, it may be necessary to remove the assembly and refill.

- **Avoid advancing AS with the delivery catheter in place.** If the AS requires further advancement, unsnap DC from AS hub; then carefully remove DC. Insert optional pigtail catheter (PC) to reposition the AS in distal LAA if necessary.
To confirm device release criteria (DRC):

1. **Perform a stability tug**
   - While injecting contrast, gently retract and release the DC control handle. Observe the proximal movement of device and LAA. *The device is stable when it moves in unison with the LAA on both TEE and fluoro.*

2. **Check device position**
   - Use fluoro and all TEE views (0°, 45°, 90°, 135°) to measure the device depth relative to the ostial plane of the LAA. *When optimally positioned, the device spans the entire LAA ostium, the maximum device diameter is at or distal to the LAA ostium, and the device does not protrude too far into the left atrium (LA).*

The following table lists the acceptable amount of protrusion into the LA for either shoulder of the device.

<table>
<thead>
<tr>
<th>Original size</th>
<th>Acceptable protrusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>21mm</td>
<td>≤ 4.2mm</td>
</tr>
<tr>
<td>24mm</td>
<td>≤ 4.8mm</td>
</tr>
<tr>
<td>27mm</td>
<td>≤ 5.4mm</td>
</tr>
<tr>
<td>30mm</td>
<td>≤ 6.0mm</td>
</tr>
<tr>
<td>33mm</td>
<td>≤ 6.6mm</td>
</tr>
</tbody>
</table>

**Key Concept:** When optimally positioned, the device moves in unison with the ________, is positioned at or distal to the ________, and protrudes only slightly into the _____.

LAA, LAA ostium, LA

**More information...**

- Double-check all images to confirm device release criteria (DRC) have been met.
- Proper positioning prevents dislodgement and potential embolization of the device.
3. **Confirm device size**
   - Use fluoro and TEE views to measure the maximum device diameter. On TEE, measure the device at the widest diameter with the threaded insert visible. *When properly sized, the maximum device diameter is 80% to 92% of its original size.*

   The table lists the appropriate compressed diameters.

<table>
<thead>
<tr>
<th>Original diameter</th>
<th>Compressed diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>21mm</td>
<td>16.8 to 19.3mm</td>
</tr>
<tr>
<td>24mm</td>
<td>19.2 to 22.1mm</td>
</tr>
<tr>
<td>27mm</td>
<td>21.6 to 24.8mm</td>
</tr>
<tr>
<td>30mm</td>
<td>24.0 to 27.6mm</td>
</tr>
<tr>
<td>33mm</td>
<td>26.4 to 30.4mm</td>
</tr>
</tbody>
</table>

4. **Confirm device seal**
   - Use fluoro and all TEE views (0°, 45°, 90°, 135°) to ensure all LAA lobes are **distal** to the proximal face of the device.
   - Use TEE with contrast and color Doppler to measure residual jet flow around the margins of the device. *When the device is adequately sealed, jet measurements are 3mm ± 2mm or less.*

**Key Concept:** The compressed device should be _______ of its original size. Residual jet flow should be ______ or less.
80 to 92%, 3mm ± 2mm.

**More information...**
- Compression ensures the device exerts enough radial force to keep it stable against opposing LAA walls.
- One indicator of appropriate device compression is a 3mm to 5mm protrusion of the threaded insert.
To release the WATCHMAN Device:

1. **Confirm device position**
   - Use fluoro and TEE images to ensure the AS/DC assembly is advanced to the face of the device.

2. **Release device from core wire**
   - Rotate DC control handle *counterclockwise* three to five full turns to unscrew the *core wire* from device.
   - Remove and inspect the access sheath and delivery catheter.
   - Obtain fluoro and TEE images of the implanted device.

**Key Concept:** Once device release criteria are met, turn the DC control handle ________ to disconnect the ________ from the device.

counterclockwise, core wire

**More information...**

- Visualize the device post-release to ensure it is positioned as expected.
A WATCHMAN Device placed **too distal** (too deep within the LAA) requires **partial recapture** and **repositioning** before release. *A device placed too distal may not meet all device release criteria and may leave thrombogenic areas exposed.*

**To partially recapture and reposition the device:**

1. **Advance AS/DC assembly**
   - Loosen hemostasis valve on DC.
   - Fix deployment knob with right hand to stabilize device.
     Use thumb to stabilize the DC hub.
   - Slowly advance AS/DC assembly while maintaining backward pressure on deployment knob. *Resistance is felt as the device collapses.*

2. **Withdraw AS/DC assembly**
   - Advance DC up to, **but not beyond**, the level of the fixation anchors.
   - Tighten hemostasis valve; then withdraw the entire AS/DC to the desired position.

3. **Reposition, redeploy, and release device**
   - Reposition AS/DC assembly in the LAA.
   - Open hemostasis valve. Hold DC deployment knob in place; then slowly retract AS/DC assembly until device is completely deployed.
   - Withdraw AS/DC assembly 1cm, leaving core wire attached.
   - Reconfirm device release criteria; then release the device by disconnecting it from the core wire.

**Key Concept:** If the closure device is placed too deep in the LAA and repositioning is necessary.

**Partial recapture**

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**More information...**

- If the device is inadvertently captured beyond the fixation anchors, it is necessary to fully recapture the device and start again with a new delivery catheter. *See Full Device Recapture on the next page.*
A WATCHMAN Device placed too proximal (protrudes too far into the left atrium) requires full recapture and placement of a new device. A device placed too proximal does not meet device release criteria.

To fully recapture the device:

1. **Advance AS/DC assembly**
   - Loosen hemostasis valve on DC.
   - Fix DC deployment knob with right hand to stabilize device. Use thumb to stabilize DC hub.
   - Slowly advance AS/DC assembly while maintaining backward pressure on deployment knob. **Resistance is felt as the device collapses.**
   - Advance DC past the fixation anchors. **Resistance is felt again when the anchors enter the DC.**
   - Withdraw device until its distal tines are proximal to the marker band.
   - Tighten hemostasis valve.

2. **Remove device and replace WDS**
   - Unsnap DC from AS hub; then carefully remove the DC.
   - Insert pigtail catheter to reposition the AS in distal LAA if necessary.
   - Introduce a new WDS and continue.

**Key Concept:** If the closure device protrudes too far into the left atrium, ________ and device replacement is necessary.

**full recapture**

**More information...**

- When replacing the WDS, double-check all device release criteria and visualize the device post-release to ensure it is properly positioned.
Post Procedure Information:
Post-procedure warfarin therapy is required in ALL patients receiving a WATCHMAN Device.

- Patients should remain on 81-100 mg of aspirin and warfarin for a minimum of 45 days post-implant (INR 2.0-3.0).

- At 45 days (±15 days) post-implant perform WATCHMAN Device assessment with TEE. Cessation of warfarin is at physician discretion provided that any peri-device flow demonstrated by TEE is ≤ 5mm. Subsequent warfarin cessation decisions are contingent on demonstrating adequate seal (flow ≤ 5mm).

- At the time patients cease warfarin, patients should begin clopidogrel 75 mg daily and increase aspirin dosage to 300-325 mg daily. This regimen should continue until 6 months have elapsed after implantation. Patients should then remain on aspirin 300-325 mg indefinitely. If a patient remains on warfarin and aspirin 81-100mg for at least 6 months after implantation, and then ceases warfarin, the patient should not require clopidogrel, but should increase to aspirin 300-325mg indefinitely.

Key Concept: Patients remain on warfarin until TEE measurement of residual jet flow is less than or equal to 3mm ± 2mm.

3mm ± 2mm

More information....

The WATCHMAN Device typically endothelializes within 45 to 60 days of implant, as shown in this canine heart.
### Pre-procedure
- Obtain baseline TEE/TTE images
- Start 81mg ASA 1 day before (continue through 45 day follow-up)

### 1. Cross interatrial septum (IAS)
- Access heart via femoral vein
- Use standard technique to cross IAS: Advance GW into LUPV or loop in LA
- Remove TAS and dilator

Maintain ACT of 200 to 300 seconds throughout procedure.

### 2. Introduce WATCHMAN Access System (WAS)
- Select AS curve (double or single), inspect and flush WAS
- Advance AS to initial position in LA or LUPV ostium
- Remove dilator and guidewire, leaving AS in place

### 3. Introduce pigtail catheter (PC)
- Inspect and flush PC
- Advance PC to distal LAA
- Confirm LAA dimensions (TEE, fluoro)
- Use **distal marker band** to guide AS over PC to distal LAA. Continue advancing until proximal marker band corresponding to maximum device diameter is at or distal to LAA ostium.

- Remove PC

For air management, attach pressurized saline drip to AS sideport.

### 4. Introduce WATCHMAN Delivery System (WDS)
- Inspect, loosen valve, pull knob back to confirm device is attached
- Align device with distal marker band of DC, flush throughout
- Loosen AS valve, advance DC into AS observing distal tip
- Stop advancing when distal DC and AS marker bands meet

### 5. Deploy WATCHMAN Device
- Snap AS onto DC, confirm AS/DC is centered in LAA
- Loosen DC valve, fix knob, slowly unsheath device (5-7 seconds)
- Withdraw AS/DC 1 cm from device face, leave core wire attached

SAFE: Stop, Agree, Fluoro, Engage

### 6. Confirm device release criteria (DRC); release device
- Perform stability tug to confirm device moves with LAA
- Check device position to confirm max diameter is at or distal to LAA
- Check device size to confirm proper compression (80%-92%)
- Check device seal to confirm jet flow is 3mm ± 2mm or less
- Release device: advance AS/DC to face, rotate DC control handle counterclockwise 3-5 turns to unscrew core wire, remove/inspect AS/DC
- Obtain final images

A device placed too distal requires partial recapture and repositioning
A device placed too proximal requires full recapture and replacement
Module 2: WATCHMAN™ Imaging Guidelines

Overview
   Imaging Guidelines
   Echo Exclusion Criteria

TTE Imaging
   TTE Acquisition Guidelines

TEE Imaging
   TEE Acquisition Guidelines
   Baseline TEE
   Intraoperative TEE

Typical TEE Work-up
   LAA Perspective

Follow-up Imaging
   TEE Guidelines
The following **imaging guidelines** were developed by the echo corelab (Duke Clinical Research Institute) to ensure the acquisition of consistent patient data.

- **Baseline TTE images** are used to:
  - Measure the left ventricular ejection fraction (LVEF)
  - Measure left atrial dimensions (Echo Core lab)
  - Document the presence and size of pericardial effusion

- **Baseline TEE images** are used to:
  - Assess LAA anatomy to determine if the patient is a suitable candidate for WATCHMAN® therapy
  - Guide interatrial septal (IAS) crossing
  - Obtain LAA measurements to determine the proper device size
  - Rule out pericardial effusion

- **Intra-operative TEE images** are used to:
  - Reconfirm LAA measurements obtained at baseline.
  - Evaluate device release criteria

- **Follow-up TEE images** are used to:
  - Confirm the LAA seal by assessing residual blood flow through and around the device
  - Confirm the absence of intracardiac thrombus
  - Assess residual interatrial shunt
  - Determine if warfarin therapy can be discontinued

**Key Concept:** TEE exams are required at __________, ____________, and at __________.

 baseline, intra-operatively, follow-up

**More information:**

- When possible, the same equipment and settings should be used for the baseline, intra-operative, and follow-up imaging.
Patients who meet any one of the following **echo exclusion criteria**, assessed with **TEE and TTE**, or any one of the other criteria listed, are ineligible for a WATCHMAN Device.

Do not use the WATCHMAN Device if:

- Intracardiac thrombus is visualized by echocardiographic imaging.
- An atrial septal repair or closure device is present.
- The LAA anatomy will not accommodate a device. See Table 41 in the DFU.
- Any of the customary contraindications for other percutaneous catheterization interventions (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder, untreated ulcer) are present.
- There are contraindications to the use of warfarin, aspirin, or clopidogrel.
- Use of the WATCHMAN Device is contraindicated in patients with known hypersensitivity to any device material or their individual components (see Device Description section in the DFU).

**Key Concept:** Echo exclusion criteria for a WATCHMAN Device are assessed with _______ and ________.

TEE, TTE

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**More information:**

- If pericardial effusion or cardiac perforation should occur intra-operatively, the procedure should be discontinued and the complication promptly and aggressively managed.
To assess the LAA anatomy:

- Use standard **four chamber** TEE views to visualize and assess the LAA anatomy and determine if it is **single-lobed, bi-lobed, or multi-lobed**. A full 180° sweep is needed to ensure all lobes are fully visualized.

- Definitively rule out **LAA thrombus**, using LAA contrast material if necessary. Patients who have an LAA thrombus may be eligible for a WATCHMAN Device after anticoagulation, if re-evaluation by TEE shows the thrombus is resolved.

Spontaneous echo contrast (left), large pectinate muscles (right), or secondary lobes may be mistaken for LAA thrombus.

**Key Concept:** To assess the LAA anatomy, use a full 180° sweep to fully visualize all LAA lobes.
To obtain baseline LAA measurements:

- Perform a slow 180° sweep, stopping at 0°, 45°, 90°, and 135° to record measurements of the maximum LAA ostium diameter and length of the primary LAA lobe.
- At 0°, measure in a plane from the left coronary artery to about 1 to 2 cm from the tip of the left upper pulmonary vein (LUPV) limbus. See Figure.
- At other angles, measure in a plane from the top of the mitral valve annulus to about 1 to 2 cm from the tip of the LUPV limbus.* See Figure.

*Note: The location of the LUPV limbus varies from one LAA anatomy to another.

Key Concept: Record baseline LAA measurements at angles of _____, _____, _____, and _______.

0°, 45°, 90°, 135°

More information:

- The maximum LAA ostium width is often obtained at 135°. However, a full 180° sweep is recommended to determine the number of LAA lobes and fully assess LAA dimensions.
To confirm LAA measurements taken at baseline:

- Just as for baseline measurements, perform a slow 180° sweep, stopping at 0°, 45°, 90°, and 135° to record measurements of the maximum LAA ostium diameter and length of the primary LAA lobe.

- At 0°, measure in a plane from the left coronary artery to about 1 to 2cm from the tip of the LUPV limbus. See Figure.

- At other angles, measure in a plane from the top of the mitral valve annulus to about 1 to 2cm from the tip of the LUPV limbus. See Figure.

**Key Concept:** Record LAA measurements at angles of 0°, 45°, 90°, and 135°
To assess device stability and position:

- **Stability:** Gently pull back; then release the deployment knob. Observe the proximal movement of the deployed device and LAA. The device is stable if it moves in **unison** with the LAA and returns to its original position.
  - Ensure the access sheath is at least 1cm from the face of the device before performing the stability tug.
  - Inject contrast into LAA to better visualize movement.

- **Position:** Visualize the device from all angles to ensure that its maximum diameter is at or distal to the LAA ostial plane in the majority of views. Measure and record how distal the maximum diameter is from the LAA ostium.

**Note:** Avoid pushing the deployment knob when assessing device stability.

**Key Concept:** The device is stable if it moves in **________** with the LAA. It is optimally positioned if the maximum diameter is **________** the ostial plane in the majority of views.

**More information:**

- Use echo landmarks to ensure the device is optimally placed.
To assess the device size and seal:

- **Size:** Measure the **maximum diameter** of the device in multiple planes to ensure the device is compressed **8% to 20%** (80% to 92% of original diameter). Obtain at least two TEE views and a biplane fluoro view if possible. When measuring device compression, ensure the device profile with threaded insert is visible.

- **Seal:** Use color Doppler with contrast to check residual blood flow around the margins of the device. The seal is adequate if all lobes are **at or distal to** the face of the device and jet flow measurements do not exceed **3mm ± 2mm**.

To obtain accurate jet measurements, measure the narrowest cross section of the jet in the plane at which the device connects most closely to the LAA wall (vena contracta). Avoid measuring the narrowest jet or the gap between the implanted device and LAA wall.

**Key Concept:** The device is properly sized if it is compressed **___**. It is adequately sealed if all lobes are **at or distal to** the device face and residual jet flow does not exceed **______**.

**8% to 20%, distal, 3mm ± 2mm.**

**More information:**

- Record jet measurements in multiple planes and identify the most reproducible jet, the view that:
  - Shows clear evidence of a leak through the plane of the device to the LA along the device side.
  - Appears in multiple consecutive frames with the least aliasing and bleed onto implanted device or LAA wall.
LAA Perspective 0 Degree View Longitudinal Plane

LAA Perspective 40 to 60 Degree View Longitudinal Plane
Typical TEE Work-up

LAA Perspective 90 Degree View Longitudinal Plane

Baseline Implant 45 days

Fluoro View

Echo View

Implant

LAA Perspective 110 to 140 Degree View Longitudinal Plane

Baseline Implant 45 days

Implant

Fluoro View

Echo View

AP AP
At 45 days and 12 months: assess WATCHMAN 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 if necessary.

If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE.