Contents
Instructions
Module 1: WATCHMAN™ LAA Closure Technology
Module 2: WATCHMAN™ Imaging Guidelines
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.
Learning Objectives
After completing this lesson, you should be able to:
• Identify suitable candidates for a WATCHMAN™ Device.
• Identify and describe WATCHMAN™ components.
• List basic device implant steps.
• Describe device release criteria (DRC).
• Describe the repositioning requirements for a device placed too distal or too proximal.
• Discuss the post-procedure guidelines for patients implanted with a WATCHMAN™ Device.

Learning Module
Module 1: WATCHMAN™ LAA Closure Technology
Application

1. The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with _________________ atrial fibrillation who:
   a. Are at increased risk for ________________ or systemic embolism based on CHADS$_2$ or CHA$_2$DS-VASc scores and are recommended for anticoagulation therapy
   b. Are deemed by their physicians suitable for warfarin
      Have an appropriate rationale to seek a non-pharmacologic alternative to ________________:
      __________________________________________________________
      __________________________________________________________
      __________________________________________________________

2. Describe the function of the WATCHMAN Device, WATCHMAN Access System (WAS), and WATCHMAN Delivery System (WDS).
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

3. Draw and label the WATCHMAN Device correctly deployed in the LAA.
4. Number the steps to describe the LAA closure procedure.
   _____ Introduce WATCHMAN Access System (WAS)
   _____ Deploy WATCHMAN Device in LAA
   _____ Cross interatrial septum (IAS)
   _____ Introduce WATCHMAN Delivery System (WDS)
   _____ Release device after confirming device release criteria (DRC)

5. Complete each sentence to describe the criteria for releasing the deployed WATCHMAN Device from the core wire.
   The device is stable when ________________________________________________________________
   The device is optimally positioned when____________________________________________________
   The device is properly sized when___________________________________________________________
   The device is adequately sealed when_____________________________________________________

6. Complete the sentences to describe the repositioning requirements for a WATCHMAN Device placed too distal or too proximal.
   A device placed too distal requires __________________________________________________________
   A device placed too proximal requires _______________________________________________________

7. Complete the following paragraph to describe post-procedure guidelines for patients implanted with a WATCHMAN Device.
   At 45 days (+/- 15 days) post-implant, perform WATCHMAN Device assessment with __________ imaging.
   Cessation of warfarin is at physician discretion provided that any peri-procedural flow demonstrated by TEE is less than or equal to __________.
   At the time the patient ceases warfarin, the patient should begin clopidogrel 75 mg daily and increase __________ dosage to 300-325 mg daily.
Learning Objectives  After completing this lesson, you should be able to:

• Describe echo exclusion criteria.
• Describe baseline, intraoperative, and follow-up imaging guidelines.

Learning Module  Module 2: WATCHMAN Imaging Guidelines
Application

1. Place a checkmark (√) beside each condition that makes patients ineligible for a WATCHMAN Device.

   _____ LVEF of 50% on TTE
   _____ MV stenosis with a valve area < 1.5cm²
   _____ Pericardial effusion > 2mm ± 1mm
   _____ Cardiac tumor
   _____ High risk PFO
   _____ Secondary LAA lobes

2. Describe the purpose of baseline TTE imaging.

   _______________________________________________________
   _______________________________________________________
   _______________________________________________________

3. Describe the purpose of baseline TEE imaging.

   _______________________________________________________
   _______________________________________________________
   _______________________________________________________

4. Describe the purpose of intraoperative TEE imaging.

   _______________________________________________________
   _______________________________________________________
   _______________________________________________________

5. Describe the purpose of follow-up TEE imaging.

   _______________________________________________________
   _______________________________________________________
   _______________________________________________________
Indications for use
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 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, taking into account the safety and effectiveness of the device compared to warfarin.

The WATCHMAN Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.

Contraindications
Do not use the WATCHMAN Device if:

- Intracardiac thrombus is visualized by echocardiographic imaging.
- 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 device. See Table 46 in the DFU.
- Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
- There are contraindications to the use of warfarin, aspirin, or clopidogrel.
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN Device is contraindicated.

Warnings
- Device selection should be based on accurate LAA measurements obtained using fluoroscopy and ultrasound guidance (TEE recommended) in multiple angles (e.g., 0°, 45°, 90°, 135°).
- Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria.
- If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE.
- The potential for device embolization exists with cardioversion ≤30 days following device implantation. Verify device position post-cardioversion during this period.
- Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion.

• For single use only. Do not reuse, reprocess, or resterilize.
• The WATCHMAN Access System is intended to provide vascular and transseptal access for all WATCHMAN Left Atrial Appendage Closure Devices with Delivery Systems.

• Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

• Are deemed by their physicians to be suitable for warfarin; and

• 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

• Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for anticoagulation therapy.

Precautions
• The safety and effectiveness (and benefit-risk profile) of the WATCHMAN Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.

• The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying the device.

• Use caution when introducing the WATCHMAN Access System to prevent damage to cardiac structures.

• Use caution when introducing the Delivery System to prevent damage to cardiac structures.

• To prevent damage to the Delivery Catheter or device, do not allow the WATCHMAN Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath.

• If using a power injector, the maximum pressure should not exceed 100 psi.

• In the absence of the considerations that were raised by the RE-ALIGN study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

ADVERSE EVENTS
Potential adverse events (in alphabetical order) which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to:

Air embolism, Airway trauma, Allergic reaction to contrast media/medications or device materials, Altered mental status, Anemia requiring transfusion, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, AV fistula, Bruising, hematomata or seroma, Cardiac perforation, Chest pain/discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cranial bleed, Decreased hemoglobin, Deep vein thrombosis, Death, Device embolism, Device fracture, Device thrombosis, Edema, Excessive bleeding, Fever, Gastrointestinal bleeding, Heart failure, Hematuria, Hemoptysis, Hypotension, Hypoventilation, Hyperthermia, Impaired wound healing, Inability to reposition, recapture, or retrieve the device, Infection / pneumonia, Intestinal ischemia, Ischemia, Ischemic stroke, Intracerebral bleeding, Major bleeding requiring transfusion, Myocardial infarction, Myocardial ischemia, Myocardial reperfusion injury, Nausea, Oral bleeding, Pericardial effusion / tamponade, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency / failure, Surgical removal of the device, Stroke – Ischemic, Stroke – Hemorrhagic, Systemic embolism, TEE complications (thrombus formation), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular damage, Vasoconstriction, Vascular injury.

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

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

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