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WATCHMAN™
INTEGRATED LAAC SOLUTIONS

Shared Decision Making:
An Evidence-Based Cornerstone of LAAC Therapy

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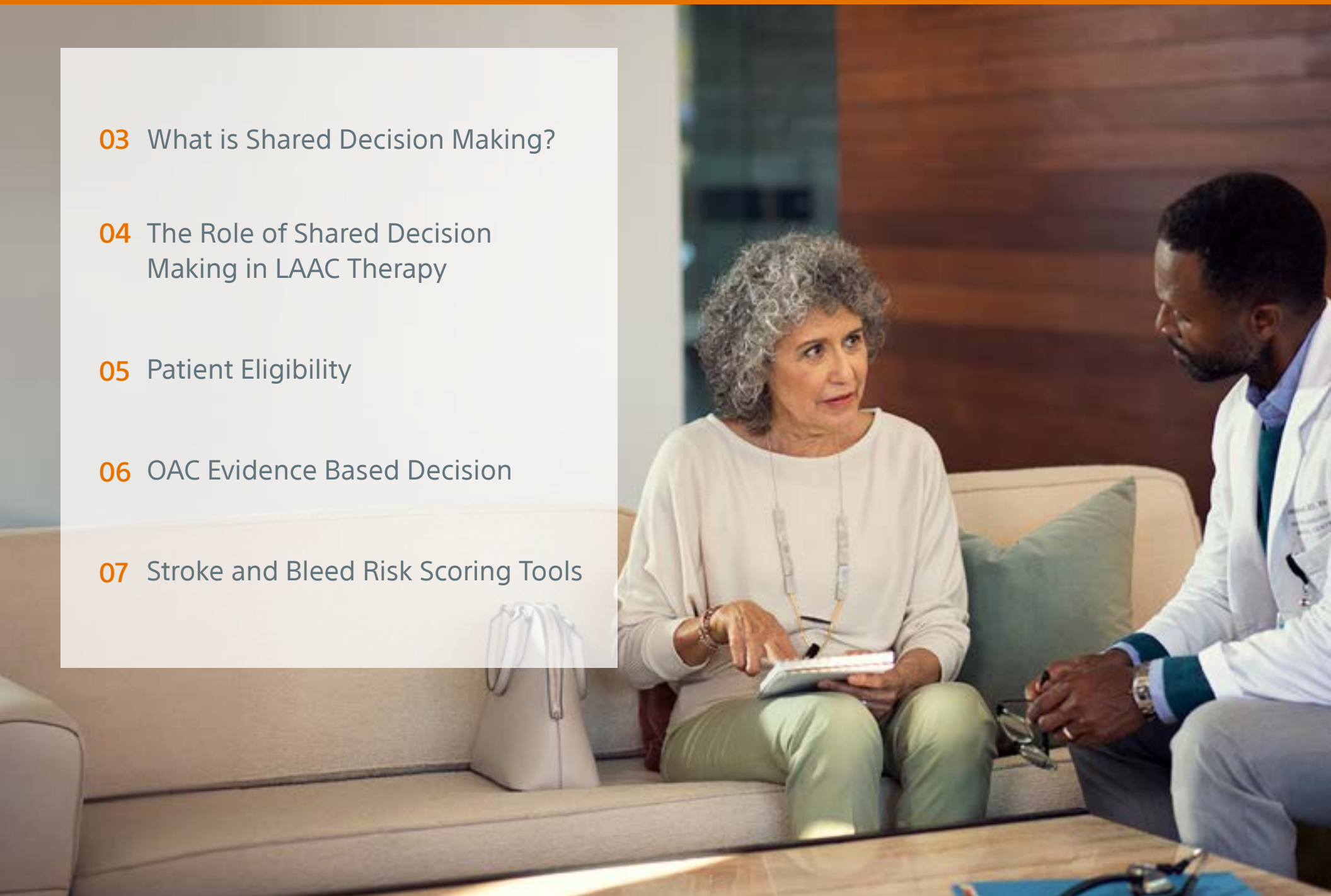


What is Shared Decision Making?

Shared Decision Making: An Evidence Based Cornerstone of LAAC Therapy

Shared decision making is a collaborative process that allows patients and their providers to make health care treatment decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.[1]

How Shared Decision Making Works[2]

In clinical scenarios characterized by more than one viable treatment or screening option, providers facilitate shared decision making by:

- Encouraging patients to communicate what they care about
- Providing decision aids that raise the patient's awareness and understanding of treatment options and possible outcomes

Implementing Shared Decision Making In Clinical Practice

S	H	A	R	E
Start the Conversation with your patient	**Help** your patient explore and compare treatment options	**Assess** your patient's values and preferences	**Reach** a decision with your patient	**Evaluate** your patient's decision

The Role of Shared Decision Making in LAAC Therapy

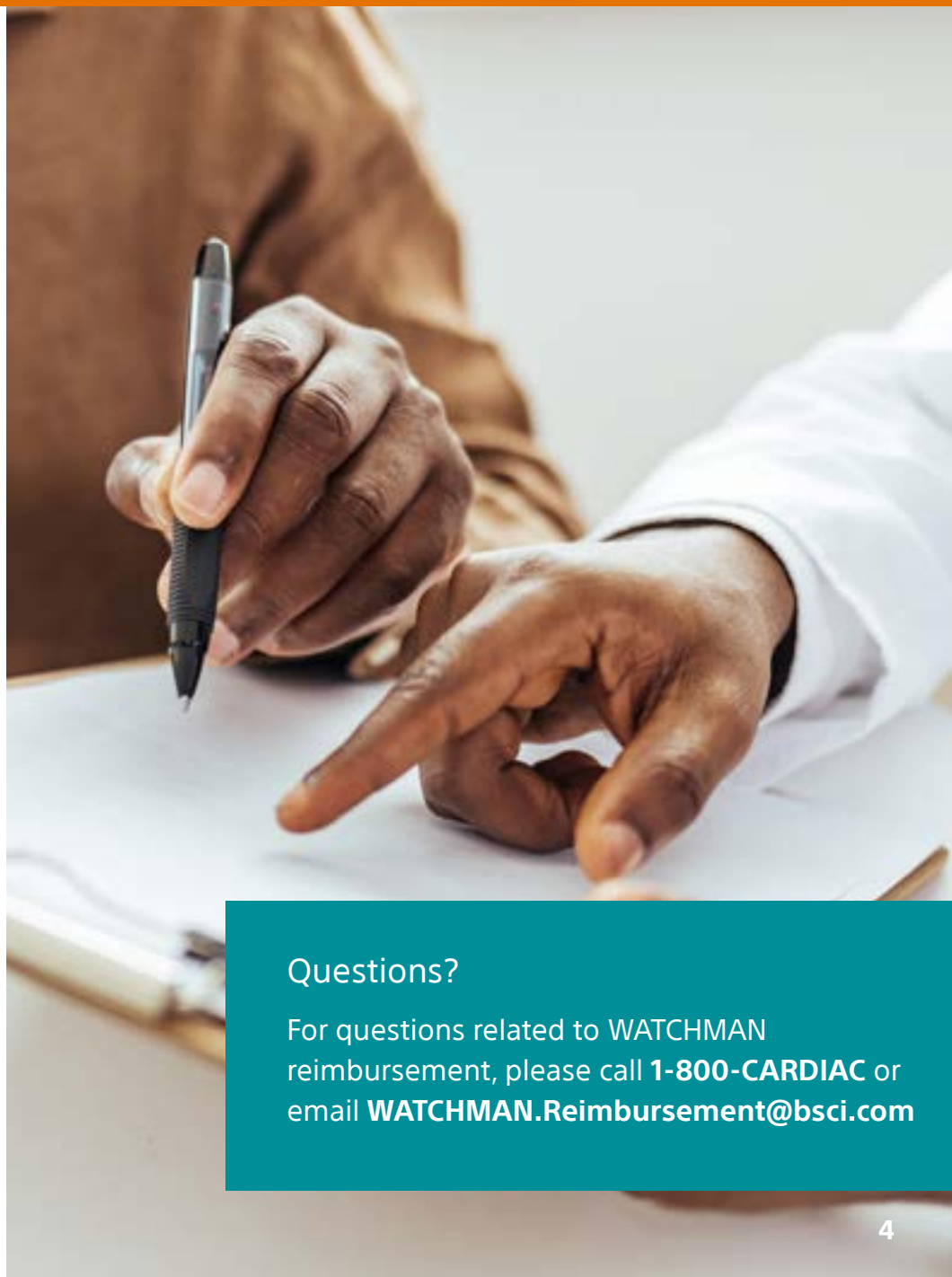
Now covered nationally by CMS and an expanding number of commercial insurers

National Coverage Determination (NCD) for percutaneous LAAC Therapy*

- The Centers for Medicare and Medicaid Services (CMS) issued a final decision memo supporting the NCD for percutaneous LAAC therapy (NCD 20.34) when specific conditions are met[4]
- This major milestone provides appropriate and uniform coverage for Medicare beneficiaries that is largely consistent with the WATCHMAN FDA label

The conditions of this NCD place the treatment decision in the hands of physicians and patients who have reason to seek an alternative to long-term anticoagulation.

**Effective Feb 8, 2016.*



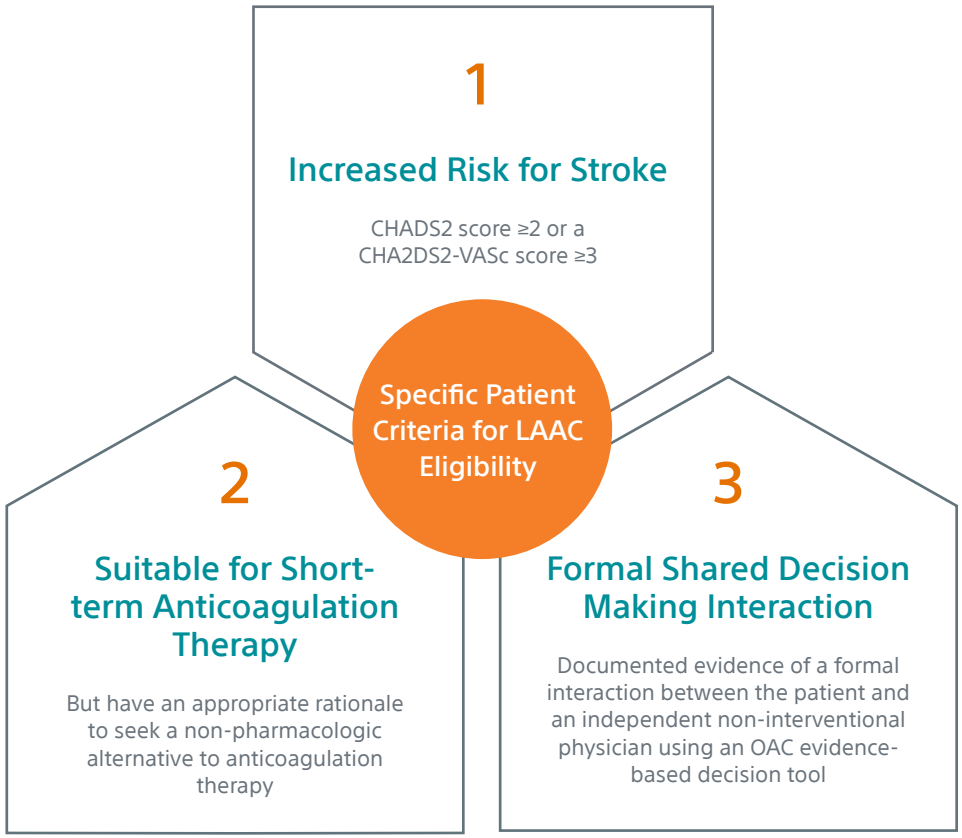
Questions?

For questions related to WATCHMAN reimbursement, please call **1-800-CARDIAC** or email **WATCHMAN.Reimbursement@bsci.com**

Patient Eligibility

Specific patient criteria for LAAC eligibilty include the following and must be documented in patient's medical record:

Patients must also be enrolled in a prospective national registry



What does deemed unable to take long-term oral anticoagulation mean?

Specific factors may include (but not limited to) 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
- 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

Who is an independent non-interventional physician?

A physician other than the implanter who is qualified to have a meaningful discussion with the patient regarding atrial fibrillation and stroke treatment options. Please consult your program's legal counsel to agree on which physicians meet that criteria. Examples of specialists that may be suitable, pending your legal counsel approval are:

- Primary Care Provider
- Non-Interventional Cardiologist
- Neurologists or those who have experience caring for stroke patients

OAC Evidence Based Decision

OAC Evidence Based Decision Tools

CMS encourages the use of an evidence-based tool in any physician and patient discussions to help document the appropriateness of LAAC as a non-pharmacological treatment option in comparing the risk-benefit to anticoagulants

- Patient-provider discussions may uncover barriers to change that include physical pain, emotional difficulties, financial concerns, and lack of confidence in one's ability to change
- These and other barriers can then be addressed so that a realistic personal prevention plan is formulated with specific and achievable outcomes

Shared Decision Making Resources

NICE
National Institute for Health and Care Excellence

nice.org.uk/guidance/ng196

CardioSmart
American College of Cardiology

cardiosmart.org/topics/atrial-fibrillation/preventing-stroke/choosing-blood-thinners-or-left-atrial-appendage-closure

ACP
American College of Physicians
Leading Internal Medicine, Improving Lives

acponline.org/practice-resources/patient-and-interprofessional-education

Stroke and Bleed Risk Scoring Tools

Calculate Your NVAF Patient's Stroke and Bleeding Risk

$CHADS_2$ Score

Use the $CHADS_2$ and CHA_2DS_2VASc calculator to determine your patients AF stroke risk based on specific criteria

$CHADS_2$ Score (Stroke Risk)

	Condition	Points
C	Congestive Heart Failure	1
H	Hypertension (SBP > 160)	1
A	Age ≥ 75 Years	1
D	Diabetes mellitus	1
S_2	Prior stroke/TIA	2
	Total Points	

Score	Yearly Stroke Risk (%)
0	1.9
1	2.8
2	4.0
3	5.9
4	8.5
5	12.5
6	18.2

Stroke and Bleed Risk Scoring Tools

Calculate Your NVAF Patient's Stroke and Bleeding Risk

CHA_2DS_2VASc Score

Use the $CHADS_2$ and CHA_2DS_2VASc calculator to determine your patients AF stroke risk based on specific criteria

CHA_2DS_2VASc Score (Stroke Risk)

	Condition	Points
C	Congestive Heart Failure	1
H	Hypertension (SBP > 160)	1
A	Age ≥ 75 Years	1
D	Diabetes mellitus	1
S_2	Prior stroke/TIA	2
V	Vascular disease (PAD,MI)	1
A	Age 65-74 years	1
S_c	Sex category (Female)	1
	Total Points	

Score	Yearly Stroke Risk (%)
0	0
1	1.3
2	2.2
3	3.2
4	4.0
5	6.7
6	9.8
7	9.6
8	6.7
9	15.2

Stroke and Bleed Risk Scoring Tools

Calculate Your NVAF Patient's Stroke and Bleeding Risk

HAS-BLED Score

Use the HAS-BLED calculator to determine your patient's bleeding risk based on specific criteria

HAS-BLED SCORE (Bleeding risk with WARFARIN)

	Condition	Points
H	Hypertension	1
A	Abnormal renal/liver function (1pt each)	1 or 2
S	Hemorrhagic Stroke	1
B	Bleeding history or disposition	1
L	Labile	1
E	Elderly	1
D	Current drugs (medication) or alcohol use (1pt each)	1 or 2

Total Points

Score	Yearly Stroke Risk (%)
0	1.13
1	1.02
2	1.88
3	3.74
4	8.7
5+	Not well validated

WATCHMAN FLX™ Device Brief Summary

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The WATCHMAN FLX™ 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 anticoagulation therapy;
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

CONTRAINDICATIONS

Do not use the WATCHMAN FLX Device if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a Closure Device (see Table 62 of the eIFU).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section of the eIFU) such that the use of the WATCHMAN FLX Device is contraindicated.
- Any of the customary contraindications for other percutaneous catheterization procedure (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 anticoagulation therapy, aspirin, or P2Y12 inhibitor.

WARNINGS

Implantation of the WATCHMAN FLX Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Physician Training program.

- This device has not been studied in pregnant or breastfeeding women. 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.
- Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]); For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.
- Do not release (i.e., unscrew) the WATCHMAN FLX Device from the core wire unless all release criteria are satisfied to avoid suboptimal results.
- Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section (of the eIFU) for further detail.

PRECAUTIONS

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX 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, recapturing, and repositioning the Closure Device.
- Use caution when introducing a 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 Closure Device, do not allow the WATCHMAN FLX 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 690 kPa (100 psi).

PATIENT SELECTION FOR TREATMENT

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

- 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).
- Details regarding the indications, contraindications, warnings, and precautions for oral anticoagulants approved for patients with non-valvular atrial fibrillation are provided in their respective Instructions for Use. Of note:
- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.
- Factors that need to be considered for the WATCHMAN FLX Device and implantation procedure include the following:

- Overall medical status, including conditions which might preclude the safety of a percutaneous, transcatheter procedure.
- Suitability for percutaneous, transseptal procedures, including considerations of:
- Cardiac anatomy relating to the LAA size and shape.
- Vascular access anatomy (e.g., femoral vein size, thrombus, or tortuosity).
- Ability of the patient to tolerate general or local anesthesia.
- Ability of the patient to undergo required imaging.
- Ability to comply with the recommended post-WATCHMAN FLX Device implant pharmacologic regimen (see Post-Procedure Information section) especially for patients at high risk for bleeding.

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 the contrast media, anesthetic, WATCHMAN Implant material, or medications
- Altered mental status
- Anemia requiring transfusion
- Anesthesia risks
- Angina
- Anoxic encephalopathy
- Arrhythmias
- Atrial septal defect
- Bruising, hematoma, or seroma near the catheter insertion site
- Cardiac perforation
- Chest pain/discomfort
- Confusion post procedure
- Congestive heart failure
- Contrast related nephropathy
- Cranial bleed
- Death
- Decreased hemoglobin
- Deep vein thrombosis
- Device embolism
- Device fracture
- Device thrombosis
- Edema
- Embolism
- Excessive bleeding
- Fever
- Fistula
- Groin pain
- Groin puncture bleed
- Hematuria
- Hemoptysis
- Hypotension
- Hypoxia
- Improper wound healing
- Inability to reposition, recapture, or retrieve the device
- Infection/pneumonia
- Interatrial septum thrombus
- Intratracheal bleeding
- Major bleeding requiring transfusion
- Misplacement of the device/improper seal of the appendage/movement of device from appendage wall
- Myocardial erosion
- Myocardial infarction
- Nausea
- Oral bleeding
- Pericardial effusion/tamponade
- Pleural effusion
- Prolonged bleeding from a laceration
- Pseudoaneurysm
- Pulmonary edema
- Radiation injury
- Renal failure
- Respiratory insufficiency/failure
- Stroke - Hemorrhagic
- Stroke - Ischemic
- Surgical removal of the device
- TEE complications (e.g., throat pain, bleeding, esophageal trauma)
- Thrombocytopenia
- Thrombosis
- Transient ischemic attack (TIA)
- Valvular or vascular damage
- Vasovagal reactions

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

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WATCHMAN™
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Learn more about the WATCHMAN Device and to find the nearest implanting center www.watchman.com/hcp