

WATCHMAN™ and WATCHMAN FLX™ LEFT ATRIAL APPENDAGE CLOSURE Approval/Coverage Status & Clinical Evidence Summary

The FDA Approved the WATCHMAN™ on March 13, 2015 and on July 21, 2020 they approved WATCHMAN FLX™

The WATCHMAN™ Left Atrial Appendage Closure (LAAC) implant procedure received FDA approval on March 13, 2015 and has been established as safe and effective for treating patients within its approved indication. WATCHMAN FLX™ is the second generation, it is designed to improve safety during implantation and Left Atrial Appendage sealing. The WATCHMAN FLX™ device received FDA approval on July 21, 2020. The devices (WATCHMAN™ and WATCHMAN FLX™) are 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-VASc¹ scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- 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.

To access the percutaneous LAAC (WATCHMAN™ and WATCHMAN FLX™) approval document, visit the FDA website at:

https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130013S035A.pdf

“ The professional societies (HRS,ACC,SAI), recommended a [list to CMS](#), during the initial public comment period for LAAC, to describe the populations they view as contraindications to long-term anticoagulation. “

CMS National Coverage Determination established February 8, 2016

CMS finalized a National Coverage Determination for percutaneous LAAC (20.34) on February 8, 2016. The NCD establishes uniform coverage and access to the WATCHMAN Device for Medicare beneficiaries who meet specific patient criteria, including:

- A CHADS₂ score ≥ 2 or CHA₂DS₂-VASc score ≥ 3
- A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation
- Documented evidence of a formal shared decision-making interaction between the patient and an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation.

To access the NCD for percutaneous LAAC therapy in its entirety, visit the CMS website at:

<https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAid=281>

2019 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation

The 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation recommends Percutaneous LAAC therapy as a Class IIb therapy and LOE B-NR.

The guidelines state that Percutaneous LAAC may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation. The updated guidelines specifically note that the Watchman device provides an alternative for patients who are poor candidates for long-term oral anticoagulation (because of the propensity for bleeding or poor drug tolerance or adherence). The guidelines are consistent with and reinforce WATCHMAN's labeling and the CMS coverage decision which support the use of WATCHMAN as an option for AF patients at an increased risk of stroke who have relative contraindications to long-term anticoagulation.¹

2020 NCDR Left Atrial Appendage Occlusion Review

The LAAO Registry is the largest registry of patients undergoing percutaneous LAAO procedures in the world. Centers for Medicare and Medicaid Services (CMS), under the Coverage with Evidence Development (CED) policy, requires mandatory participation in the LAAO Registry. To date, the 38,000 patients who have been enrolled in the LAAO Registry are at higher risk of both stroke and bleeding than those who participated in the clinical trials that led to FDA approval of the Watchman device. Despite this more complex patient population, implant success rates in contemporary practice were higher (98.3%) and in-hospital major adverse event rates (2.16%) were lower compared with those reported in the pivotal randomized trials. The registry also noted that the complications rates were very low, and death (.19%) was rare.”²

WATCHMAN™ and WATCHMAN FLX™ CLINICAL OVERVIEW

Clinical Condition and Treatment Options

Atrial fibrillation (AF) is the most common cardiac arrhythmia, currently affecting more than 5 million Americans.³ In AF, the left atrium does not beat, but it fibrillates and barely moves. Because of this, AF patients have a five-fold increased risk of stroke due to blood pooling in the left atrium and left atrial appendage (LAA). The pooled blood can form blood clots (i.e., thrombus formation), which can break off and go into the systemic circulation and lodge somewhere else in the body. Most commonly, these clots will lodge in the brain causing a stroke. Ninety-one percent of left atrial thrombi in non-valvular atrial fibrillation have been shown to be isolated to, or originate in, the LAA.⁴ The most common treatment for reducing the risk of these strokes from forming is using oral anticoagulants. Warfarin has been used for many years and works by interfering with the body’s clot forming mechanisms. Despite its proven efficacy, long-term warfarin therapy is not well-tolerated by some patients, has a very narrow therapeutic range, and carries a high risk for bleeding complications.

WATCHMAN™ and WATCHMAN FLX™ Left Atrial Appendage Closure

The WATCHMAN™ and WATCHMAN FLX™ Left Atrial Appendage Closure Devices are the first-of-their-kind, a proven alternative to long-term oral anticoagulation for stroke risk reduction in patients with non-valvular atrial fibrillation. WATCHMAN™ is the most studied LAAC device in the world and is the only one with long-term data from randomized trials and prospective, multi-center registries. The results of PINNACLE FLX clinical trial support that WATCHMAN FLX™ is a safe and effective device.

The WATCHMAN™ and WATCHMAN FLX™ Devices are 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-VASc¹ scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- 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.

The WATCHMAN™ and WATCHMAN FLX™ Left Atrial Appendage is an implant that acts as a physical barrier, sealing the LAA to prevent thromboembolic from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for OAC therapy in those patients with non-valvular AF who are eligible for OAC. Implant of the WATCHMAN™ or WATCHMAN FLX™ Device is performed under local or general anesthesia in a cardiac catheterization or electrophysiology laboratory. The WATCHMAN™ or WATCHMAN FLX™ Device is implanted percutaneously via a transcatheter approach, using a standard transseptal technique.

Clinical Evidence for WATCHMAN™ and WATCHMAN FLX™

The WATCHMAN™ clinical program consists of eight prospective investigational studies (PILOT, PROTECT AF, CAP, PREVAIL, CAP2, EWOLUTION, and WASP) which include more than 3,300 patients implanted and >10,000 patient-years of follow-up regarding WATCHMAN™ Device performance. Final, five-year results from the PROTECT AF, CAP and PREVAIL studies have been published and/or presented. These long-term data continue to demonstrate the WATCHMAN™ Device is a safe alternative to long-term warfarin therapy which offers comparable stroke risk reduction and enables patients to stop taking warfarin.

The PILOT study⁵ enrolled the first clinical study patient in 2002 and proved the safety and feasibility of WATCHMAN™ implant. The prospective randomized trial PROTECT AF⁶ enrolled the first clinical study patient in 2005 and was published in the *Lancet* in August 2009 with a mean follow-up of 18 months. The efficacy results were very compelling in that 87% of patients were successfully implanted with the device and able to discontinue warfarin therapy 45 days post-implant. Patients in the device group also had a 38% lower risk of stroke, systemic embolism, and cardiovascular or unexplained death when compared to patients treated with warfarin alone. Several subsequent analyses have been performed over the course of follow-up and continue to demonstrate a durable benefit in primary efficacy event reduction.^{7,8,9}

The cadence and growing body of clinical evidence continues to support the medical value and safety of the WATCHMAN™ implant therapy. The second randomized control trial, PREVAIL, enrolled its first patient in 2012, all patients have completed the required follow-up (mean 4.0 years). First results were published in 2014 in *JACC* and support that WATCHMAN™ was successfully implanted with low complication rates and no differences in procedure-related events between new and experienced operators.⁹ Since the device was approved by the FDA in March of 2015, procedural safety data for both new and experience operators continue to show consistent results between 1.5% and 2% for major serious adverse events.^{12,13} Furthermore, PREVAIL also showed that 92% of patients were able to discontinue warfarin therapy 45 days post implant, and >99% were able to discontinue warfarin therapy after 12 months.

The FDA mandated prospective, multi-center Continued Access to PROTECT AF (CAP) and Continued Access to PREVAIL (CAP2) registries enrolled the first trial patient in 2009 and enrolled 566 and 578 patients using the same inclusion and exclusion criteria as the PROTECT AF and PREVAIL study. These 2 registries included 1,144 patients, respectively, representing more device patients in each study than were in the RCTs, and they have the longest follow-up reported to date. These patients have completed all study follow-up (mean 4.2 years) with final results published in *JACC*.¹⁰ Ninety-four percent (94%) of patients in the study (CAP and CAP2) were successfully implanted and procedure complications were significantly reduced when compared to the PROTECT AF experience.¹¹ In addition, 96.9% of patients discontinued warfarin by 12 months post-implant. While there was not a warfarin control arm as a comparator in the study, the rate of hemorrhagic stroke is the lowest reported, with a rate of 0.17 per 100 patient-years in CAP and 0.09 per 100 patient-years in CAP2. The rate of ischemic stroke was also low at 1.30 per 100 patient-years and 2.20 per 100 patient-years, respectively. Compared with the predicted ischemic stroke rate based on CHA2DS2-VASc scores, LAAC patients had relative reductions of 78% (4.56 per 100 patient years) and 69% (4.90 per 100 patient-years) in CAP and CAP2, respectively.

The efficacy endpoint of the PREVAIL trial used a Bayesian statistical model that incorporated a portion of the PROTECT AF results, efficacy results for PREVAIL are presented in conjunction with PROTECT AF in order to fully describe the effect of LAAC therapy compared to warfarin. As a result, a patient-level meta-analysis using the results of both randomized trials and were published in 2017 in *JACC*.¹³ The 5-Year Patient-Level Meta-Analysis of PROTECT AF and PREVAIL (2:1 Randomization) provided the totality of the evidence from both randomized trials for the WATCHMAN™ therapy after study required follow-up was completed for both randomized trials. This analysis demonstrated that LAAC with WATCHMAN™ provided stroke reduction in non-valvular atrial fibrillation patients that was comparable to warfarin with additional, statistically significant reductions in disabling or fatal stroke, hemorrhagic stroke, cardiovascular and all-cause mortality, as well as major non-procedure related bleeding.

The totality of the clinical evidence on WATCHMAN™ reinforces the following clinical outcomes^{12,14,9,15}

Reference	Parameter	Measurement	Outcome
JACC 2018 ¹² Peer-Reviewed J. Am. Coll. Cardiol 2020 ² Peer-Reviewed	Safety	Procedure is Safe	1.5% complication rate ¹² 0.19% complication rate ²
J. Am. Coll. Cardiol 2017 ¹⁴ Peer-Reviewed	Primary Efficacy	Comparable to Warfarin	18% reduction in events (p = 0.27) Non-inferior ¹⁴ **All-cause stroke, systemic embolism, and cardiovascular/unexplained mortality
J. Am. Coll. Cardiol 2014 ⁹ Peer-Reviewed	OAC Cessation	Allows 9 out of 10 patients to Discontinue Warfarin	92% of patients discontinue after 45-days ⁹ 99% of patients discontinue after 1 year ⁹
J. Am. Coll. Cardiol 2017 ¹⁴ Peer-Reviewed	Stroke	Comparable to Warfarin with Statistically Significant Reductions	55% reduction in disabling/fatal stroke (p=0.03), largely driven by reduction in hemorrhagic strokes (p=0.002) ¹⁴
J. Am. Coll. Cardiol 2017 ¹⁴ Peer-Reviewed	Mortality	Statistically Significant Reductions	27% reduction in all-cause mortality (p=0.04) ¹⁴ 41% reduction in CV/unexplained mortality (p=0.03) ¹⁴
JACC 2015 ¹⁵ Peer-Reviewed	Major Bleeding	Statistically Significant Reductions vs. Warfarin Post-Procedure	72% reduction vs. warfarin after 6-months (p=0,001) ¹⁵

PINNACLE FLX:¹⁶ The US IDE trial designed to evaluate the procedural safety and closure efficacy with the WATCHMAN FLX™ device. In this clinical trial 400 patient, 29 US site, single arm, non-randomized trial evaluated WATCHMAN FLX™ for non-inferiority to safety and efficacy performance goals based on the WATCHMAN device.

- Primary Safety Endpoint: All-cause death, ischemic stroke, systemic embolism, or device- or procedure related adverse events requiring surgery or major endovascular intervention within 7 days following the procedure or by hospital discharge, whichever is later.
- Primary Efficacy Endpoint: The rate of effective LAA closure defined as any peri-device flow ≤5mm demonstrated by TEE at 12 months.
- Secondary Efficacy Endpoint: The occurrence of ischemic stroke or systemic embolism at 24 months from the time of enrollment.

Of 400 main cohort patients (age 73.38±8.6; CHA₂DS₂VASc 4.2±1.5; HAS-BLED 2.0±1.0), implantation was successful in 395 (98.8%). All patient completed 45-day visit, and 95.4% completed the 1-year visit (mean follow-up 12.8±3.5 months). Most patients (95.4%) discontinued OAC after 45-days. Both primary safety (0.5% 95% upper confidence bound = 1.6%, p<0.0001) and primary efficacy (100% effective seal at 12-months, 95% lower confidence bound = 98.9%, p<0.0001) endpoints met the performance goals. There were no device embolizations, pericardial effusions requiring surgery, or procedural deaths. There were 2 ischemic strokes within 7 days of the

procedure and 9 ischemic strokes not associated with the procedure. Device-related thrombus occurred in 7 patients, though none of these subjects experienced an ischemic stroke over the course of follow-up. The results of this study support the safety and efficacy of the WATCHMAN FLX™ device.¹⁶

The PINNACLE FLX clinical trial results reinforces the following clinical outcomes.¹⁶

Parameter	Measurement	Outcome
Safety endpoint	The occurrence on one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later: <ul style="list-style-type: none"> • Ischemic stroke, • All-cause death, • Pericardial effusion requiring open cardiac surgery • Device embolization 	Ischemic stroke: 0.5% All-cause death: 0% Pericardial effusion requiring open cardiac surgery: 0% Device embolization: 0%
Efficacy endpoint	The rate of effective LAAC defined as: <ul style="list-style-type: none"> • Any peri-device flow ≤ 5mm demonstrated by TEE at 12 months 	Effective LAAC: 100%
Procedural success	Defined as successful and release of a WATCHMAN FLX™ device into the LAA	Procedural success: 98.8%
Novel Oral Anticoagulants (NOAC) discontinuation	Defined as NOAC discontinued at 45 day follow-up	NOAC discontinued: 96.2%

Technology Assessments

The summary of evidence notes that WATCHMAN™ is efficacious in preventing stroke in the subset of patients with Atrial Fibrillation who are at increased risk for embolic stroke. The evidence also indicates that among patients in which long term risk of systemic anticoagulation exceeds the procedural risk of device implantation, the net health outcome will be improved. “The evidence is sufficient to determine that the technology results in meaningful improvement in the net health outcome.”¹⁷

The WATCHMAN™ and WATCHMAN FLX™ Devices are the only FDA approved devices for percutaneous left atrial appendage closure and are the most studied LAAC devices in the world. WATCHMAN™ is the only LAAC device with long-term clinical data from both randomized clinical trial and prospective, multi-center registries, with five-year follow-up data on many patients. The data demonstrates that the WATCHMAN™ and WATCHMAN FLX™ Devices are safe alternative to long-term warfarin therapy which offers comparable stroke risk reduction and enables patients to stop taking oral anticoagulation therapy.

There is enough research to show that the WATCHMAN™ and WATCHMAN FLX™ devices for left atrial appendage closure results in improved health outcomes for the prevention of stroke in patients with atrial fibrillation. The majority of payers now cover Watchman for their Medicare and Commercial populations.

References

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Brief Summary Statement (BSS)

Overview

Product: Watchman LAA Closure Dev w Del Sys – DFU 90746221

Rx Statement: Include the following with every Brief Summary Statement:

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.

Content

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 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, taking into account the safety and effectiveness of the device compared to warfarin.

CONTRAINDICATIONS

Do not use the WATCHMAN 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 device. See Table 47 (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 echocardiographic imaging guidance in multiple views (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.

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 view of the concerns 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
 - Anesthesia risks
 - Angina
 - Anoxic encephalopathy
 - Arrhythmias
 - Atrial septal defect
 - AV fistula
 - Bruising, hematoma 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
 - Groin pain
 - Groin puncture bleed
 - Hematuria
 - Hemoptysis
 - Hypotension
 - Hypoxia
 - Improper wound healing
 - Inability to reposition, recapture, or retrieve the device
- (cont'd)
- 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
 - Nausea
 - Oral bleeding
 - Pericardial effusion / tamponade
 - Pleural effusion
 - Prolonged bleeding from a laceration
 - Pseudoaneurysm
 - Pulmonary edema
 - Renal failure
 - Respiratory insufficiency / failure
 - Surgical removal of the device
 - Stroke – Ischemic
 - Stroke – Hemorrhagic
 - Systemic embolism

- TEE complications (throat pain, bleeding, esophageal trauma)
- Thrombocytopenia
- Thrombosis
- Transient ischemic attack (TIA)
- Valvular damage
- Vasovagal reactions

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

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