







Watchman (Left Atrial Appendage Occluder Device) Non-Implanter Reference

REFERRAL INFORMATION

Minneapolis Heart Institute Structural Heart Program

Tel: 612-863-3588Fax: 612-863-1300

Minneapolis Heart Institute Cardiac Electrophysiology Program

o Tel: 855-644-4787 (855-MHI-HRTS)

o Fax: 612-775-3230

PATIENT INCLUSION CRITERIA

- Non-valvular atrial fibrillation (excludes patients with any mechanical heart valve, or rheumatic mitral stenosis)
- Patient with an appropriate rationale to seek a non-pharmacologic alternative to warfarin/DOAC (history of bleeding, fall risk, previous trauma, labile INR)
 - o Consult MHI Anticoagulation/Thrombophilia clinic 612-863-6800 for labile INR patient evaluation
- CHAD₂S₂-VASc score ≥ 3
- Suitable for short-term warfarin therapy
 - o Per protocol <u>all patients</u> will be on at least 45 days of warfarin after the Watchman™ implantation before it can be discontinued
- Patient with no alternative indication for long-term warfarin (ex: mechanical AVR/MVR)

RISKS

Risks include but not limited to: infection, bleeding, vessel injury, cardiac perforation at times requiring drainage or surgery, heart failure, migration of the device, emergency surgery, myocardial infarction, stroke and death.

NON-IMPLANTING PROVIDER VISIT

- Use an OAC evidence-based decision tool see education booklet for patients "Atrial Fibrillation and Options to Reduce Your Risk of Blood Clots and Stroke"
 - o Link:http://akn.allina.com/content1/groups/patient-care/@akn-commprgov/documents/patient_care_documents/278707.pdf
 - o Access via AKN, steps to find:
 - Patient Care
 - Patient Education
 - Shared Decision Making folder, click on "Decision Aids"
 - "Atrial Fibrillation and Options to Reduce Your Risk of Blood Clots and Stroke"
 - Copies can be ordered from SMARTworks (ID # 278707)

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- Document a formal discussion between non-implanting provider and patient regarding management options and anticoagulation risks/benefits and options
 - o The MHI EP/structural heart team developed a smart phrase that can be used to document (see below).
 - o Consider consulting with MHI Anticoagulation/Thrombophilia Clinic (612-863-6800)
 - o It does not satisfy CMS requirements if only implanters document discussion with the patient (!).

SMART TEXT PHRASE for Discussion/Decision Making Process (.LAAODICTATION):

• @NAME@ has indication for anticoagulation due to atrial arrhythmias and associated high risk for cardio-embolic stroke. @NAME@ is suitable for short-term warfarin, however, @NAME@ has a relative contraindication for long-term anticoagulation due to ***. I discussed at length the pathophysiology and management strategies of cardio-embolic risk, anticoagulation risks and benefits, and management strategy options with @NAME@. @NAME@ understands that that anticoagulation will be maintained in a variety of forms during the first year.

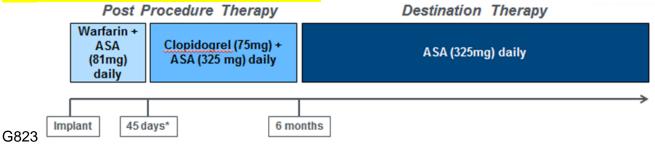
PRE-PROCEDURE ANTITHROMBOTIC THERAPY

- Goal INR for procedure 1.7-2.5
 - o INR < 1.7 day of procedure: move forward with procedure
 - o INR > 2.5 day of procedure: decision is based on patient's risks and benefits
- High risk patients (CHA₂DS₂-VASc score ≥ 5) that need to transition to warfarin
 - o These patients will be given specific recommendations pre-procedure from Watchman implanting team
- ASA 81mg daily, continue uninterrupted
- Plavix (clopidogrel): The implanting provider will give direction for use while on warfarin based on individual patient cardiac interventional history.

PLATELETS

- < 50: EP and Structural Heart nurse clinicians will work with implanting MD for best approach</p>
- > 50: good to go

POST-PROCEDURE ANTITHROMBOTIC THERAPY



Consider aspirin 81 mg rather than 325 mg (45 days to 6 months) in patients with high risk of bleeding.