

**WATCHMAN™** is the only Left Atrial Appendage Closure Device with over 2000 patients studied in multiple randomized trials and registries and 4800 patient-years of follow-up.

### PROTECT AF<sup>1</sup>

Demonstrated the efficacy of the WATCHMAN™ LAA closure device for stroke risk reduction in AF patients:

- 29% reduction in efficacy events (stroke, cardiovascular/unexplained death or systemic embolism) at 2.3 years when compared to warfarin therapy
- 36% reduction in efficacy events in the secondary prevention population

### PROTECT AF - LONG-TERM RESULTS<sup>2</sup>

Local therapy with WATCHMAN™ was superior to Warfarin (mean follow up 45 months)

- 40% reduction of stroke, systemic embolism, Cardiovascular/unexplained death
- 60% reduction in Cardiovascular Mortality
- 34% reduction in All-Cause Mortality

### PREVAIL<sup>3</sup>

Confirmed the safety of the procedure with the WATCHMAN™ Left Atrial Appendage Closure Device, with additional reductions in vascular complications from previous WATCHMAN™ studies.

### ASAP<sup>4</sup>

Showed a 77% reduction in the risk of stroke in patients with atrial fibrillation contraindicated to oral anti-coagulation therapy.

### CHA<sub>2</sub>DS<sub>2</sub>-VASc DEFINITIONS

**Congestive heart failure/LV dysfunction** refers to documented moderate-to-severe systolic dysfunction [i.e. heart failure with reduced ejection fraction (HF-REF)] or patients with recent de-compensated heart failure requiring hospitalization, irrespective of ejection fraction [i.e. both HF-REF and heart failure with preserved ejection fraction (HF-PEF)].<sup>1</sup>

**Vascular disease** prior myocardial infarction, peripheral artery disease, aortic plaque.<sup>2</sup>

### HAS-BLED DEFINITIONS<sup>2</sup>

**Hypertension** is defined as systolic blood pressure >160 mm/Hg.

**Abnormal kidney function** is defined as the presence of chronic dialysis or renal transplantation or serum creatinine ≥200 µmol/L.

**Abnormal liver function** is defined as chronic hepatic disease (e.g. cirrhosis) or biochemical evidence of significant hepatic derangement (e.g. bilirubin >2x upper limit of normal, in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphatase >3x upper limit normal, etc.).

**Bleeding** refers to previous bleeding history and/or predisposition to bleeding, e.g. bleeding diathesis, anaemia, etc.

**Labile INR** refers to unstable/high INRs or poor time in therapeutic range (e.g. >60%).

**Drugs/alcohol** use refers to concomitant use of drugs, such as anti-platelet agents, non-steroidal anti-inflammatory drugs, or alcohol abuse, etc. INR = international normalized ratio. Adapted from Pisters et al.

1 - 2012 focused update of the ESC Guidelines for the management of atrial fibrillation.  
2 - ESC Guidelines for the management of atrial Fibrillation-European Heart Journal (2010) 31, 2369-2429.

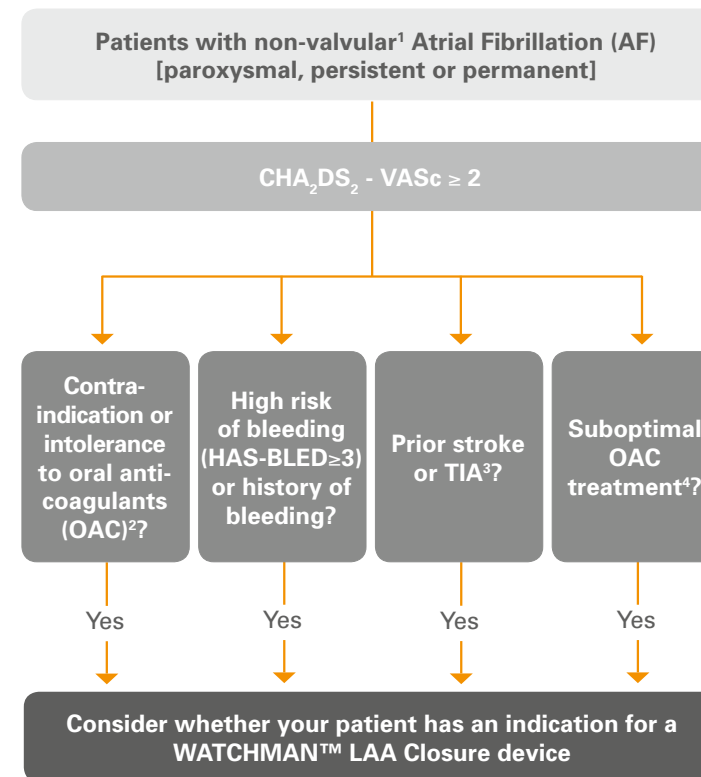


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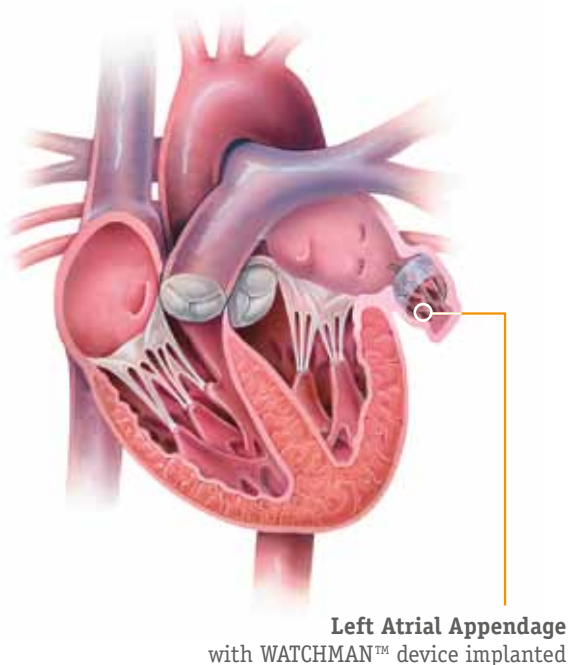
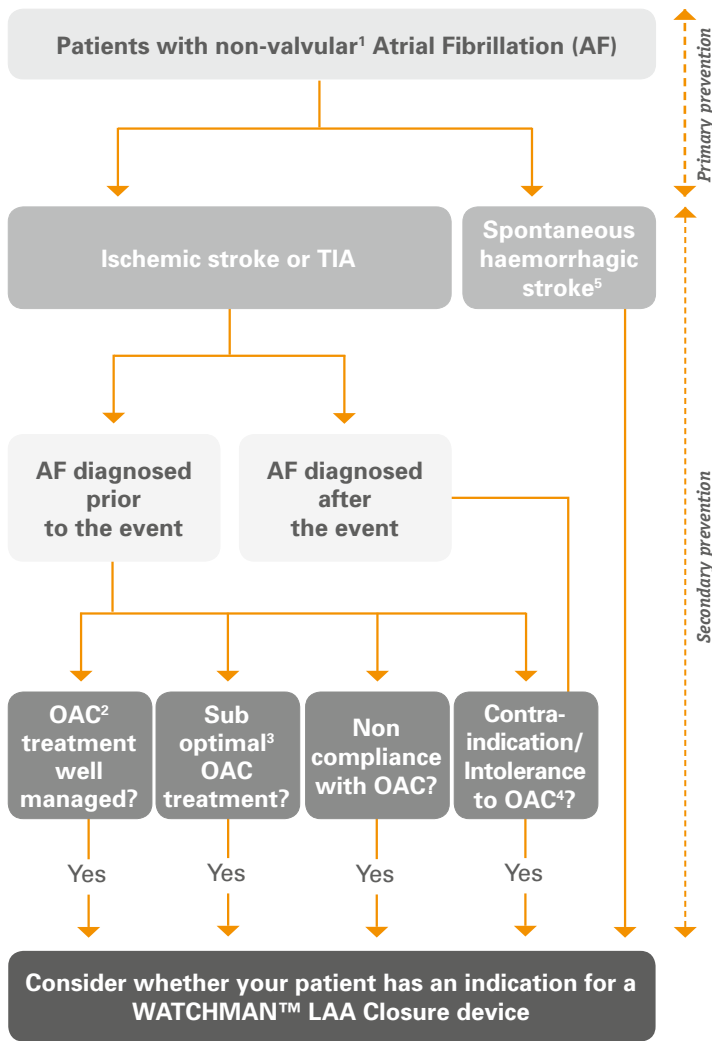
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Reducing the risk of stroke in atrial fibrillation with the WATCHMAN™ Left Atrial Appendage (LAA) Closure Device

## PATIENT SELECTION



## Secondary prevention



## Indications

The WATCHMAN™ Left Atrial Appendage Closure Technology is intended to prevent thrombus embolization from the left atrial appendage and reduce the risk of life-threatening bleeding events in patients with non-valvular atrial fibrillation who are eligible for anti-coagulation therapy or who have a contraindication to anti-coagulation therapy.

## Thrombo-embolic risk

Letter	Risk factor	Score
C	Congestive heart failure/LV dysfunction	1
H	Hypertension	1
A <sub>2</sub>	Age ≥75	2
D	Diabetes mellitus	1
S <sub>2</sub>	Stroke/TIA/thrombo-embolism	2
V	Vascular disease	1
A	Age 65–74	1
Sc	Sex category (i.e. female sex)	1
<b>TOTAL (maximum 9)</b>		

Stroke rate (%/year) by score	0	1	2	3	4	5	6	7	8	9
	0.0	1.3	2.2	3.2	4.0	6.7	9.8	9.6	6.7	15.2

Lip GY et al, Chest 2010; 137(2): 263 - 72  
Camm AJ et al, Eur Heart J 2010; 31, 2369 - 2429

## Bleeding risk

Letter	Clinical characteristic	Points awarded
H	Hypertension	1
A	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
F	Eldery (e.g. age ≥65 years)	1
D	Drugs or alcohol (1 point each)	1 or 2
<b>TOTAL (maximum 9)</b>		

Bleeds per 100 patient-years by score	0	1	2	3	4
	1.13	1.02	1.88	3.74	8.70

Pisters R, et al. Chest 2010; 138:1093-100  
European Heart Journal 2012 - doi:10.1093/eurheartj/ehs253

More information on:  
[www.bostonscientific.com/watchman-eu/](http://www.bostonscientific.com/watchman-eu/)

1 - Non-valvular AF: excluding rheumatic valvular disease or prosthetic heart valves

2 - Oral Anticoagulation

3 - Examples: difficulties to stabilize INR (International Normalized Ratio) in the therapeutic range, compliance issues, drug discontinuation...

4 - For contraindications, refer to Instructions for use of the anticoagulants drugs. NOACs (dabigatran, rivaroxan, and apixaban) are not recommended in patients with severe renal impairment (CrCl <30 mL/min) - 2012 focus update of the ESC Guidelines for the management of atrial fibrillation

5 - Hypertension, amyloid angiopathy, VKA or OAC...