

WATCHMAN™ is the only Left Atrial Appendage Closure Device with over 2000 patients studied in multiple randomized trials and registries and about 6000 patient-years of follow-up.

PROTECT AF¹

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 RESULTS²

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**
- **85% reduction in Hemorrhagic stroke**
- **63% reduction in Fatal/Disabling stroke**

WATCHMAN™ was non-inferior to Warfarin in All-Stroke demonstrating a relative risk reduction of 32%

PREVAIL³

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

ASAP⁴

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

1 - David R Holmes et al., Lancet 2009; 374: 534-42; Vivek Y. Reddy, et al., Circulation. 2013;127:720-729
2 - Reddy, VY et al. JAMA. 2014; 312(19):1988-1998
3 - Holmes DR et al. Randomized Trial of LAA Occlusion. JACC. Vol. 64: 1-12, 2014
4 - Reddy VY, JACC 2013; 61: 2551-56

CHA₂DS₂-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)].¹

Vascular disease prior myocardial infarction, peripheral artery disease, aortic plaque.²

HAS-BLED DEFINITIONS²

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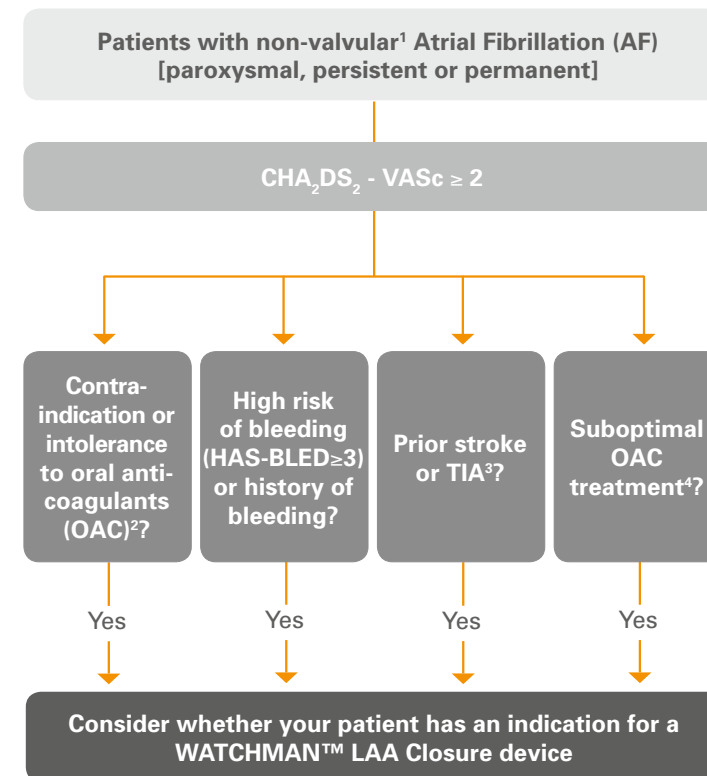
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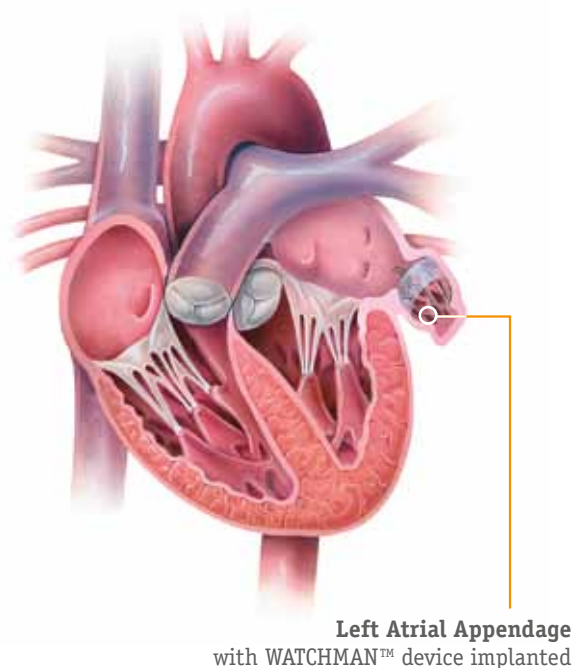
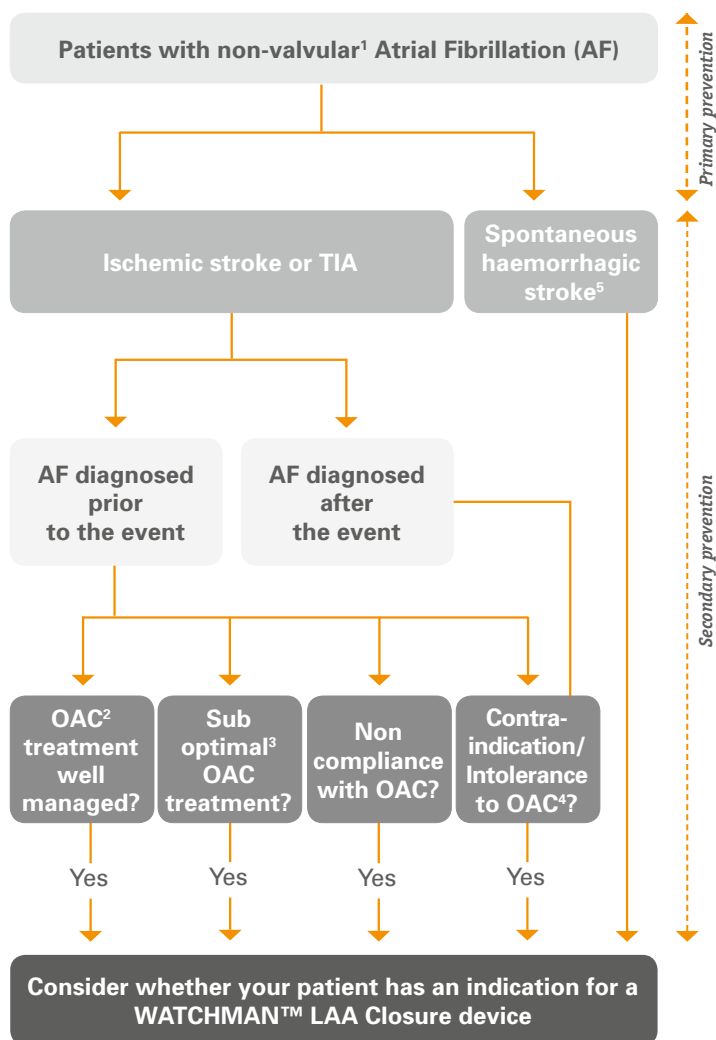
Reducing the risk of stroke in atrial fibrillation with the WATCHMAN™ Left Atrial Appendage (LAA) Closure Device

PATIENT SELECTION



1 - Non-valvular AF: excluding rheumatic valvular disease or prosthetic heart valves
2 - For contraindications, refer to Instructions for use of the anticoagulants drugs. NOACs (dabigatran, rivaroxaban, 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
3 - Transient Ischemic Attack
4 - Examples: difficulties to stabilize INR (International Normalized Ratio) in the therapeutic range, compliance issues, drug discontinuation...

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 ₂	Age ≥ 75	2
D	Diabetes mellitus	1
S ₂	Stroke/TIA/thrombo-embolism	2
V	Vascular disease	1
A	Age 65–74	1
Sc	Sex category (i.e. female sex)	1
TOTAL (maximum 9)		

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
E	Eldery (e.g. age ≥ 65 years)	1
D	Drugs or alcohol (1 point each)	1 or 2
TOTAL (maximum 9)		

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.lat

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, rivaroxaban, 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...