

# WATCHMAN™

INTEGRATED LAAC SOLUTIONS

## OPTION Clinical Trial

### Outcomes in Patients with High Stroke Risk

Sub-analysis evaluating the risk of thromboembolic and bleeding events in patients with higher and lower stroke risk.

**Safe and effective alternative to long-term anticoagulation —  
across stroke risk profiles**

#### High Risk

CHA<sub>2</sub>DS<sub>2</sub>-VASc score ≥4  
(N = 738)

#### Lower Risk

CHA<sub>2</sub>DS<sub>2</sub>-VASc score ≤3  
(N = 862)

**WATCHMAN**  
N = 433

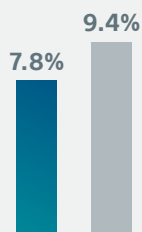
**OAC**  
N = 368

**WATCHMAN**  
N = 433

**OAC**  
N = 429

#### High Risk

(p = 0.37)



### Equivalent stroke protection



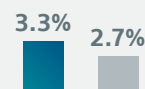
#### Primary Efficacy Endpoint

All-cause mortality, stroke  
and systemic embolism

■ WATCHMAN FLX  
■ OAC

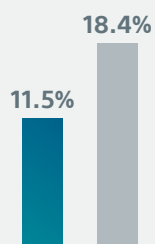
#### Lower Risk

(p = 0.59)



#### High Risk

(p < 0.01)



### Significantly reduced bleeding



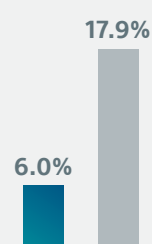
#### Primary Efficacy Endpoint

ISTH Non-procedural bleeding

■ WATCHMAN FLX  
■ OAC

#### Lower Risk

(p < 0.01)



Patient Characteristics

	High Risk CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≥4		Lower Risk CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≤3	
	Ablation + LAAC (n = 370)	Ablation + OAC (n = 368)	Ablation + LAAC (n = 433)	Ablation + OAC (n = 429)
Paroxysmal AF	58.10%	59.00%	60.50%	66.20%
HAS-BLED	1.4 ± 0.8	1.5 ± 0.8	1.0 ± 0.8	1.0 ± 0.7
CHA <sub>2</sub> DS <sub>2</sub> -VASc	4.7 ± 0.9	4.7 ± 0.8	2.6 ± 0.5	2.6 ± 0.5
Female	51.10%	48.40%	21.70%	19.80%
Age 65–74	48.60%	50.00%	59.60%	58.30%
Age 75+	45.90%	41.30%	11.50%	13.30%
CHF	39.20%	39.90%	16.40%	14.90%
Hypertension	94.10%	93.20%	86.10%	83.40%
Prior stroke or TIA	18.90%	23.60%	3.00%	3.00%
Vascular disease	66.50%	67.10%	24.90%	31.00%
Diabetes	36.80%	39.40%	19.90%	17.70%

Outcomes at 36 months

	Higher Stroke Risk Group CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≥4			Lower Stroke Risk Group CHA <sub>2</sub> DS <sub>2</sub> -VASc score ≤3		
	Ablation + LAAC (n = 370)	Ablation + OAC (n = 368)	p-value	Ablation + LAAC (n = 433)	Ablation + OAC (n=429)	p-value
All-cause mortality	6.0% (21)	6.9% (24)	0.61	1.9% (8)	2.5% (10)	0.59
Ischemic stroke or systemic embolism	1.8% (6)	2.9% (10)	0.29	1.2% (5)	0.2% (1)	0.10
TIA	2.3% (8)	2.6% (9)	0.79	1.0% (4)	0.5% (2)	0.43
Hemorrhagic stroke	0.3% (1)	0.9% (3)	0.31	0.5% (2)	0.0% (0)	0.16
Major bleeding	5.1% (18)	6.6% (23)	0.40	2.9% (12)	3.7% (15)	0.51
Composite endpoints:						
Primary efficacy	7.8% ± 1.4%	9.4% ± 1.6%	0.37	3.3% ± 0.9%	2.7% ± 0.8%	0.59
Primary safety	11.5% ± 1.7%	18.4% ± 2.1%	<0.01	6.0% ± 1.2%	17.9% ± 1.9%	<0.01
Secondary safety	5.1% ± 1.2%	6.6% ± 1.3%	0.40	2.9% ± 0.8%	3.7% ± 0.9%	0.51

Event rates are %(n) or % ± SE

Definitions:

Primary efficacy: All-cause death, stroke, or systemic embolism through 3 years

Primary safety: Non-procedural major or clinically-relevant non-major bleeding through 3 years

Secondary safety: Procedural and non-procedural major bleeding through 3 years

