WATCHMANFLX™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

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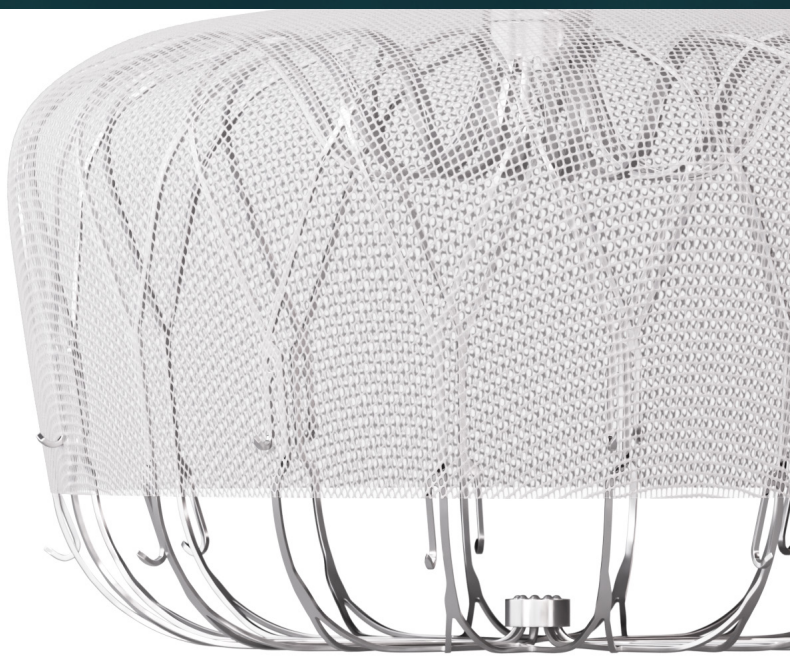
THE WATCHMAN FLX™ LEFT ATRIAL APPENDAGE CLOSURE DEVICE



What is the WATCHMAN FLX Device?

The **WATCHMAN FLX Left Atrial Appendage (LAAC) Device** serves as a one-time alternative to blood thinners for stroke risk reduction in people with non-valvular atrial fibrillation (AF). Built on the WATCHMAN technology – the most studied and implanted LAAC device in the world – the next-generation WATCHMAN FLX device was designed to **advance procedural performance and safety** while **expanding the treatable patient population.**

How the WATCHMAN FLX Device Works

AF affects the heart's ability to pump blood normally, which can cause blood to pool in the heart's left atrial appendage (LAA). There, blood cells can form a clot, and when a blood clot escapes and travels to another part of the body, it can cut off the blood supply to the brain – causing a stroke.[1,2] In people with non-valvular AF, more than **90%** of stroke-causing clots that come from the heart are formed in the LAA[1], so closing off this part of the heart is an effective way to reduce stroke risk.

Implanted via a minimally invasive procedure, the WATCHMAN FLX device is designed to permanently close off the LAA, while allowing many patients to discontinue blood thinners and avoid the bleeding and lifestyle challenges associated with them. Key benefits of the new device include:

- **Advanced Safety:** New frame allows for optimal device engagement with the tissue for long-term stability and a faster, complete seal of the LAA
- **Enhanced Procedural Performance:** Fully rounded design offers physicians the ability to safely enter, and maneuver within, the LAA and to fully recapture, reposition and redeploy the device during the procedure
- **Expanded Treatable Patient Population:** Broader size range allows treatment of widest range of patient anatomies

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Demonstrated Safety and Closure Efficacy

The pivotal clinical trial[3] evaluating the procedural safety and closure efficacy of the WATCHMAN FLX device met its primary safety and efficacy endpoints with a low major complication rate and high rate of effective LAA

Primary Safety Endpoint -
0.5%
event rate

Primary Efficacy Endpoint -
100%
effective LAA closure

96.2%
of patients able to discontinue blood thinner at **45-day follow-up**

98.8%
patients successfully implanted

No hemorrhagic strokes
through **12 months**
of follow-up

For more information on the WATCHMAN FLX device,
visit **watchman.com/implanter**.

[1] Price MJ, Reddy VY, Valderrábano M, et al. Bleeding outcomes after left atrial appendage closure compared with long-term warfarin. JACC Cardiovasc Interv. 2015;8(15):1925-1932.
[2] Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. Ann Thorac Surg. 1996;61:755-759.
[3] Doshi S. Primary Outcome Evaluation of a Next Generation LAAC Device: The PINNACLE FLX Trial. Presented at HRS 2020 Science.

* LAA closure at 12 months is defined as any peri-device flow with jet size ≤ 5mm per core laboratory-assessed TEE
** Defined as occurrence of a major procedure-related complication within 7 days following the procedure or time of hospital discharge, whichever was later

Illustrations for information purposes—not indicative of actual size or clinical outcome.

All photographs taken by Boston Scientific.

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