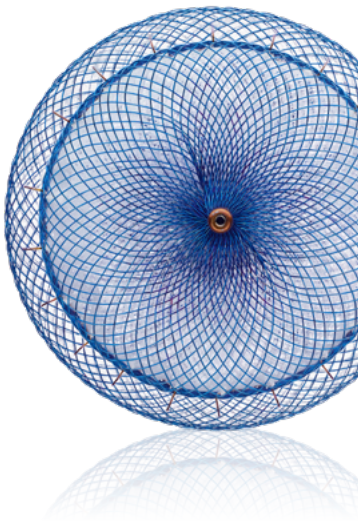
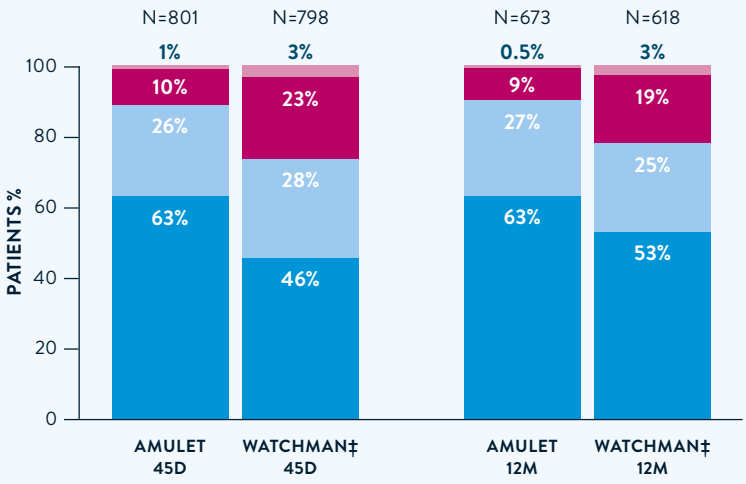
AMULET IDE STUDY
3 YEAR OUTCOMES[1]

In the largest LAAO randomized controlled trial, the Amplatzer™ Amulet™ LAA Occluder compared to Watchman‡ device demonstrated at 3 years follow up:



1. Superior closure and less peri-device leaks (PDL) by TEE
2. Significantly higher freedom from oral anticoagulants (OAC) and less device related thrombus (DRT)
3. Fewer device factors (DRT and PDL) preceding ischemic strokes and cardiovascular deaths
   - Despite a higher usage rate of OACs in the Watchman‡ group, device factors were more frequent in the Watchman‡ device, which led to more ischemic strokes and cardiovascular deaths in these patients
4. A positive trend toward overall survival

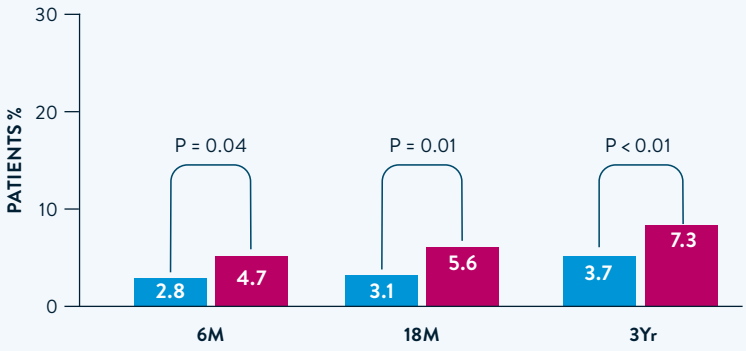
AMULET OCCLUDER HAD HIGHER COMPLETE LAA CLOSURE ON CORE LAB ANALYZED TEES



1. Amulet occluder patients had a significantly higher complete LAA closure rate by TEE compared to Watchman‡ device

- >5mm (Severe)
- ≥3mm & ≤5mm (Moderate)
- >0 & <3mm (Mild)
- 0mm (None)

ORAL ANTICOAGULATION USAGE

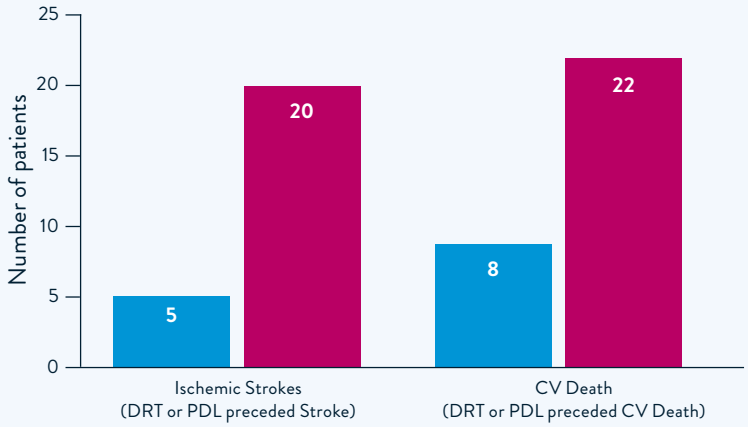


2. Amulet occluder demonstrates continued safety and effectiveness with over 96% free of oral anticoagulation (OAC) usage through 3 years in a high-risk population

- Amulet
- Watchman‡

Abbott

DEVICE-RELATED FACTORS

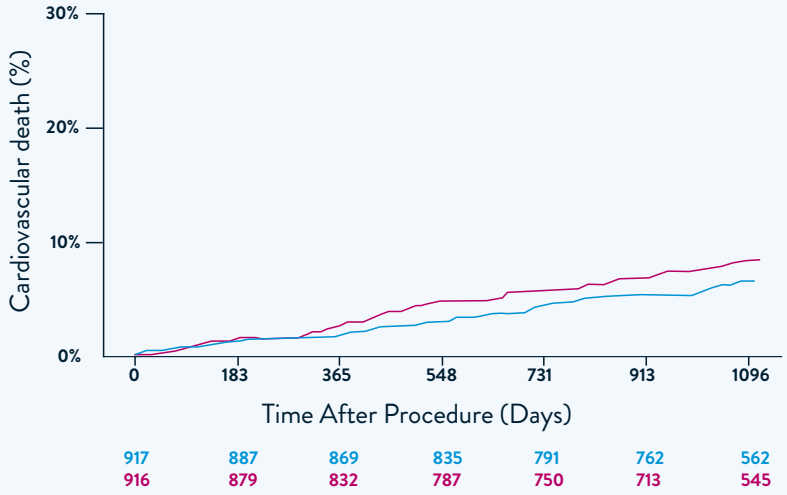


3. Device factors (DRTs and PDLs) corresponded to more ischemic strokes and cardiovascular deaths for the Watchman‡ group after 3 years

Amulet
Watchman‡

BOTH CARDIOVASCULAR DEATH AND ALL-CAUSE DEATH TRENDED LOWER AT 3 YEARS WITH AMULET™ OCCLUDER THAN WATCHMAN‡ DEVICE*

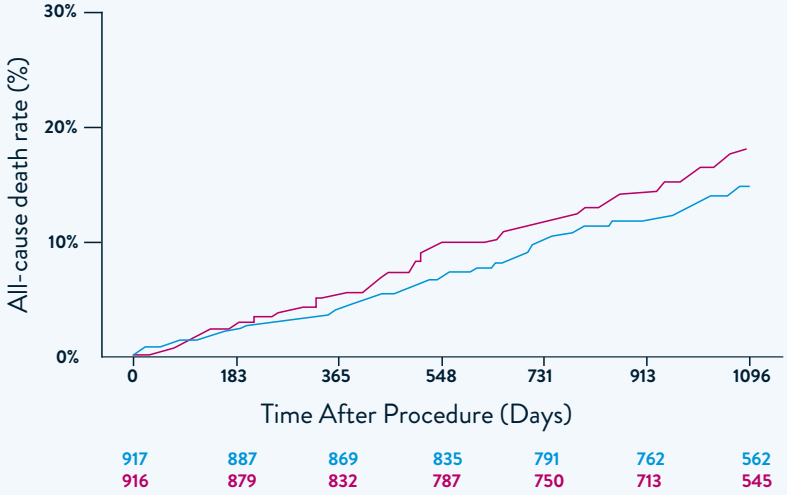
CARDIOVASCULAR DEATH



Amulet: 6.6%
Watchman‡: 8.5%
HR [95%CI] 0.77 [0.54-1.02]
(p= 0.14)

Amulet
Watchman‡

ALL-CAUSE DEATH



Amulet: 14.6%
Watchman‡: 17.9%
HR [95%CI] 0.81 [0.64-1.02]
(p= 0.07)

4. Trend toward longer survival for the Amulet device group 3 years post implantation

Amulet
Watchman‡

Abbott

WHAT DO WE ALSO KNOW?

Amulet IDE study[1] demonstrates that dual seal technology, the disc and a lobe, provides a superior closure rate. Superior closure leads to significantly more patients being free from OACs and suggests a trend toward improved overall survival compared to Watchman‡, a single lobe device.

- Amulet has also demonstrated superior closure compared to Watchman FLX‡ in the randomized SWISS-APERO trial[2]. In this study, closure rates by TEE at 45 days were 86.3% vs 72.5% for Amulet and Watchman FLX respectively (p=0.04).
- All Watchman‡ devices (WM 2.5, WM FLX, and WM FLX PRO) have the same single lobe closure mechanism. A single lobe device cannot seal the appendage at the ostium and leaves the patient at higher risk of peri-device leak, device related thrombus, and continued use of OACs.

There were no pericardial effusion (PE) related deaths in either group at 3 years

- The greater number of PEs in the Amulet group were linked to the operator's learning curve (82% of PEs in the Amulet arm occurred in the first 9 cases of the implanter).
- After the initial learning curve, the rate of PEs requiring intervention in the IDE Study was 1.6%. Watchman's‡ PE intervention rate for the entire study was comparable at 1.2%.
- PINNACLE FLX trial[3] shows 0% rate of PEs with the Watchman FLX‡ device. It is important to notice that this reporting includes only PEs that required open cardiac surgery (not accounting those that need drainage or care).
- Considering all the adverse events in the supplement section of the publication, PE rates were 2.2% across the PINNACLE FLX study. This is even higher than the PE rate for the Watchman‡ 2.5 in the Amulet IDE Trial (1.2%).

Due to the different protocols and study designs, including the definition and reporting of pericardial effusions and peri-device leaks, results from Watchman‡ studies cannot be compared in a straightforward manner with Amulet's data.

REFERENCES:

1. Lakkireddy, Dhanunjaya, et al. "3-year outcomes from the AMPLATZER amulet left atrial appendage occluder randomized controlled trial (Amulet IDE)." JACC: Cardiovascular Interventions, vol. 16, no. 15, 2023, pp. 1902–1913, https://doi.org/10.1016/j.jcin.2023.06.022.
2. Kar, Saibal et al. "Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device: Results from the PINNACLE FLX Trial." Circulation vol. 143,18 (2021): 1754-1762. doi:10.1161/CIRCULATIONAHA.120.050117
3. Galea, Roberto, et al. "Amulet or watchman device for percutaneous left atrial appendage closure: Primary results of the Swiss-apero randomized clinical trial." Circulation, vol. 145, no. 10, 2022, pp. 724–738, https://doi.org/10.1161/circulationaha.121.057859.

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