

Amplatzer™ Amulet™
Left Atrial Appendage Occluder

CLOSURE.
ONCE AND FOR ALL.^{1,2}

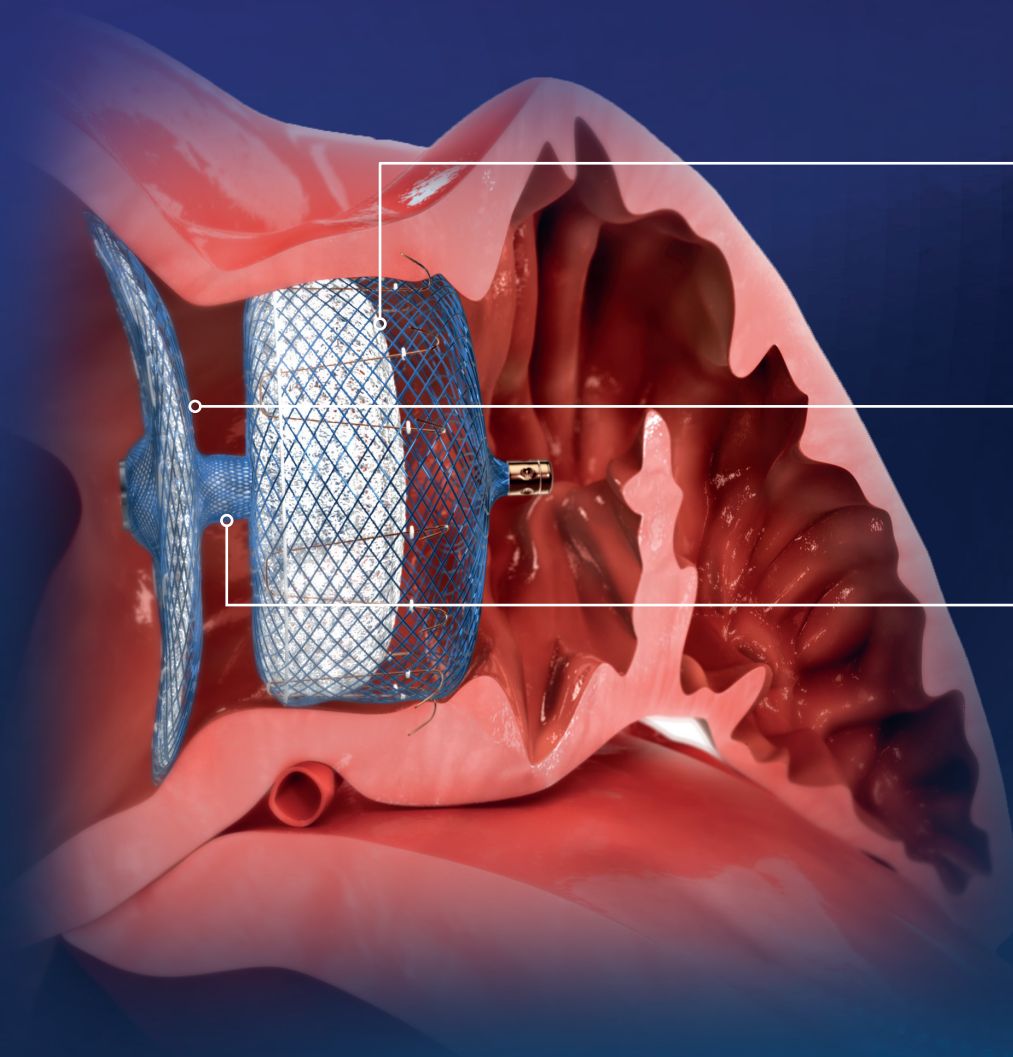


DUAL SEAL TECHNOLOGY

- DESIGNED TO SEAL ALL MORPHOLOGIES
- REDUCES THE RISK OF STROKE
- ELIMINATES THE NEED FOR OACs

TWO MECHANISMS OF CLOSURE

DESIGNED TO ENSURE COMPLETE OCCLUSION OF THE LAA IN ALL TYPES OF MORPHOLOGIES

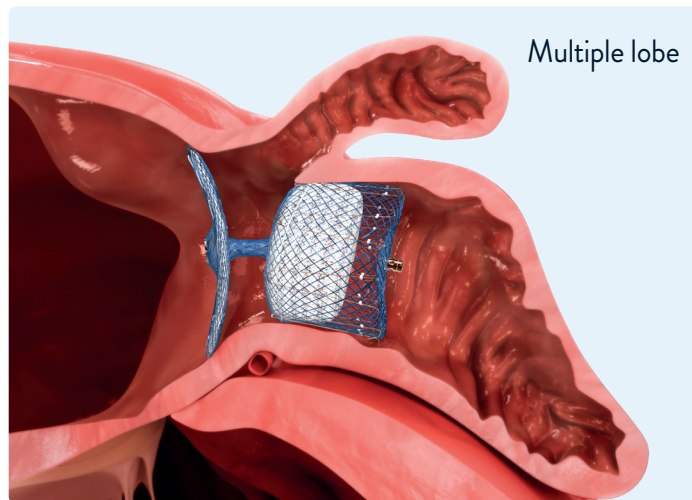
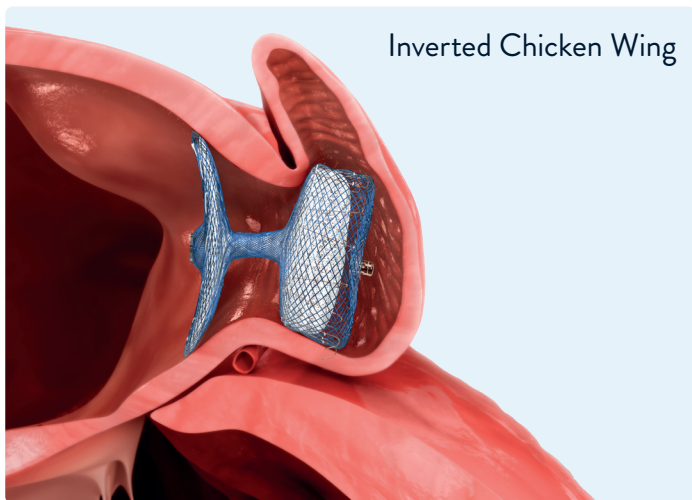
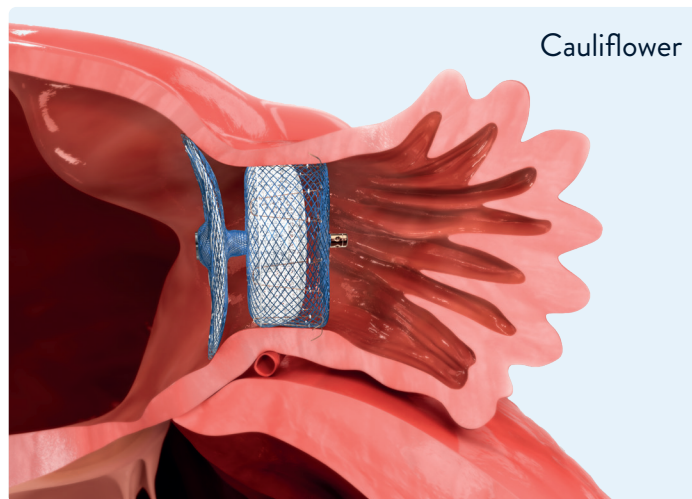
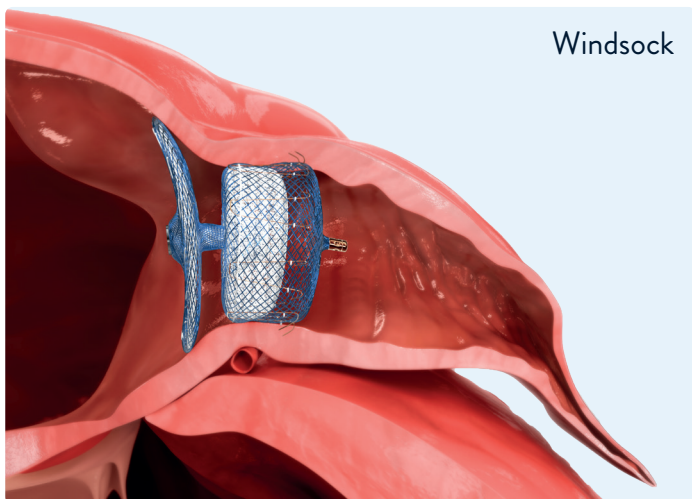


LOBE requires minimal depth and conforms to different LAA shapes

DISC delivers a complete ostial seal

WAIST provides flexibility to accommodate all morphologies

TREATING THE SIMPLEST TO MOST COMPLEX ANATOMIES



80%

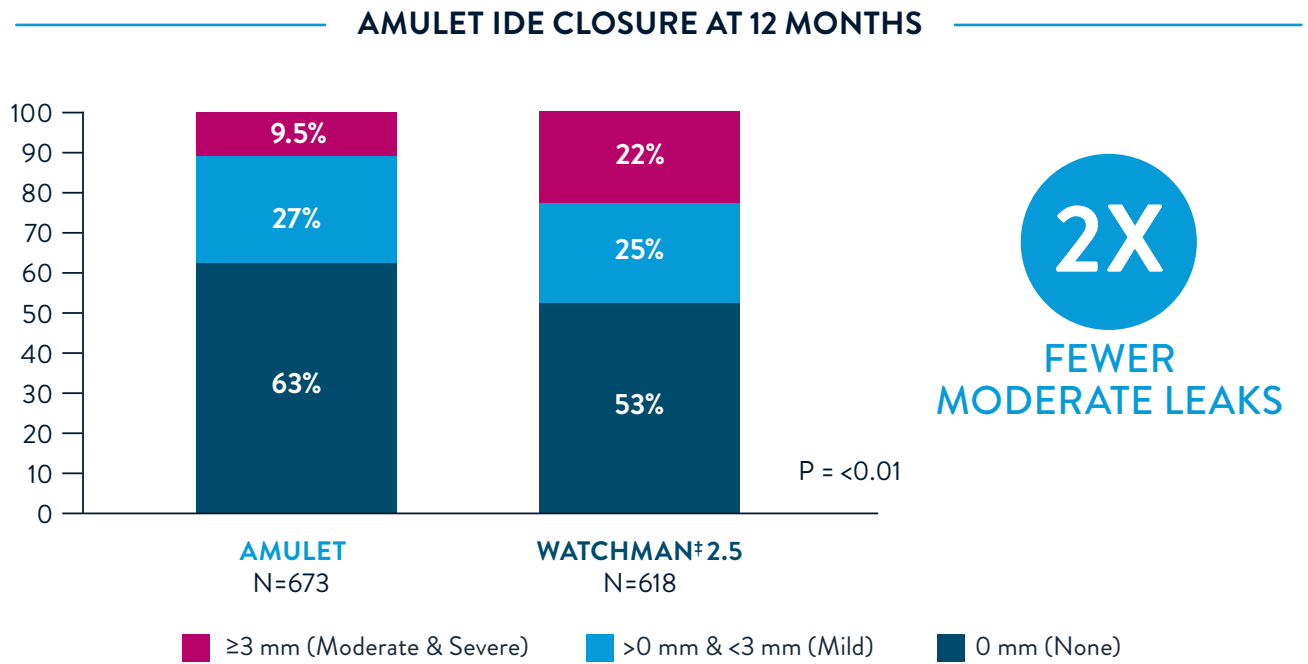
OF APPENDAGES HAVE MORE THAN 1 LOBE⁶

NEARLY
50%

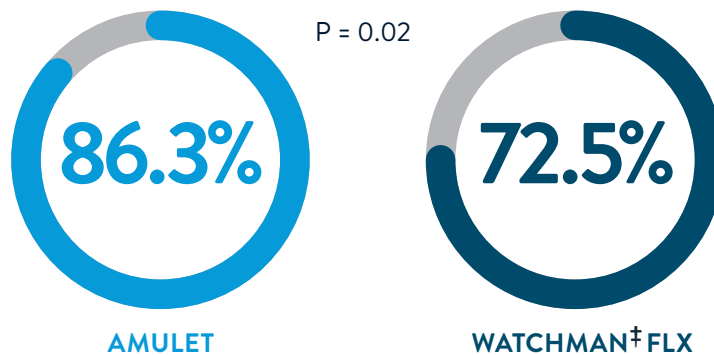
NEARLY 50% OF APPENDAGES ARE CHICKEN WING ANATOMY WHICH PRESENTS CHALLENGES WITH A SHALLOW LANDING ZONE⁷

SUPERIOR CLOSURE

THE AMULET OCCLUDER SHOWED SIGNIFICANTLY BETTER CLOSURE COMPARED TO WATCHMAN[†] 2.5 AND WATCHMAN[†] FLX^{3,4}



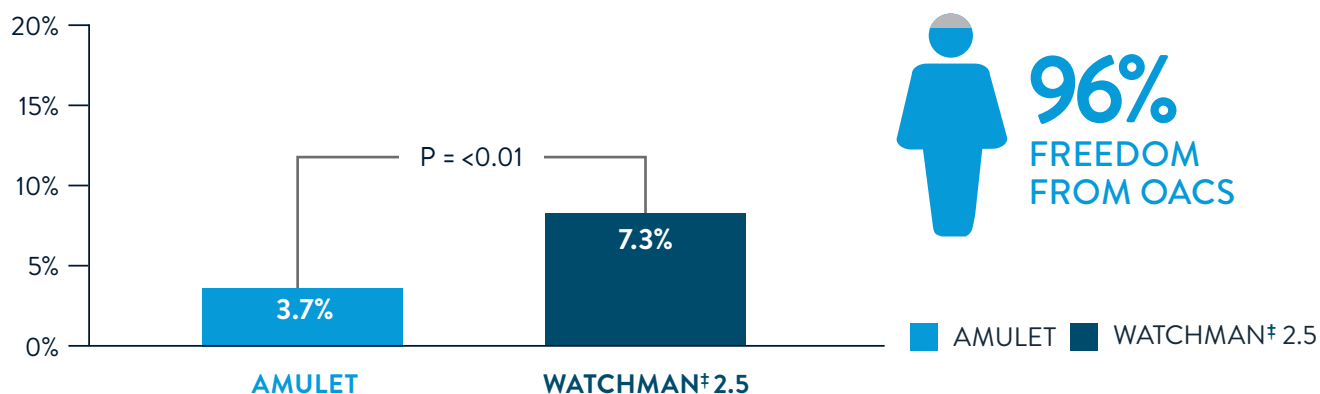
SWISS-APERO COMPLETE CLOSURE AT 45 DAYS BY TEE
SIGNIFICANTLY HIGHER COMPLETE CLOSURE



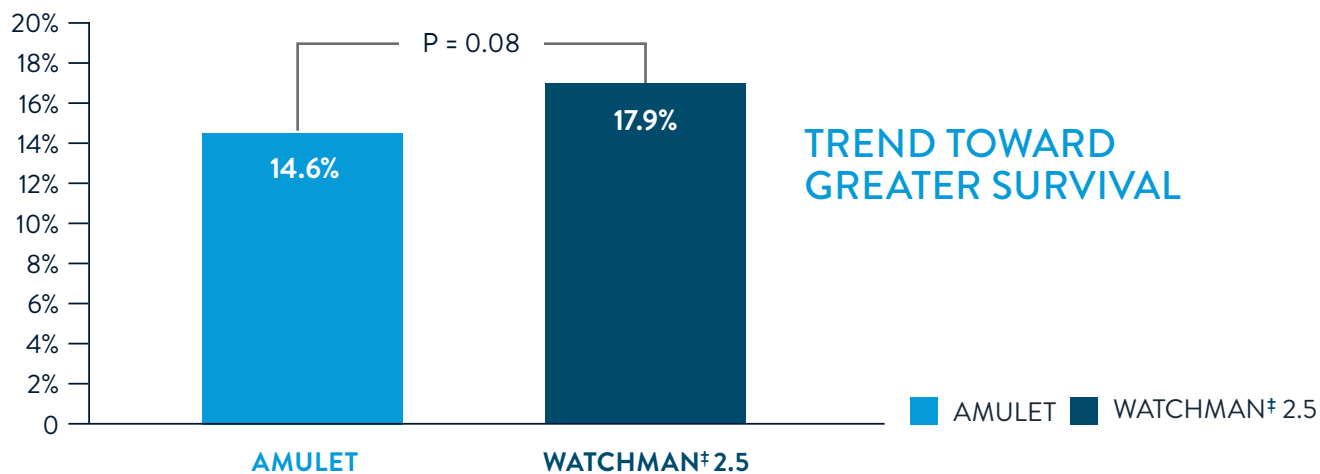
BETTER OUTCOMES

THE AMULET OCCLUDER SHOWED SIGNIFICANTLY HIGHER FREEDOM FROM OACS AND A TREND TOWARD GREATER SURVIVAL⁵

AMULET IDE ORAL ANTICOAGULATION USAGE



AMULET IDE ALL-CAUSE DEATH AT 3 YEARS



AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER

Rx **Important**
ONLY **Safety Information**

INDICATION FOR USE

The Amplatzer™ Amulet™ Left Atrial Appendage Occluder is a percutaneous transcatheter device intended to reduce the risk of thrombus embolization from the left atrial appendage (LAA) in patients who have nonvalvular atrial fibrillation and who are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2D2-VASc scores, are suitable for short term anticoagulation therapy, and have appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation, taking into consideration the safety and effectiveness of the device.

CONTRAINDICATIONS

The Amplatzer™ Amulet™ Left Atrial Appendage (LAA) Occluder is contraindicated for patients:

- With the presence of intracardiac thrombus.
- With active endocarditis or other infections producing bacteremia.
- Where placement of the device would interfere with any intracardiac or intravascular structures.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with the device or implant procedure include, but are not limited to, the following: Air embolism; Airway trauma; Allergic reaction; Anemia; Anesthesia reaction (nausea, vasovagal reaction, confusion/altered mental status or other); Arrhythmia; Atrial septal defect; Bleeding; Cardiac arrest; Cardiac tamponade; Chest pain/discomfort; Congestive heart failure; Death; Device embolization; Device erosion; Device malfunction; Device malposition; Device migration; Device-related thrombus; Fever; Hematuria; Hypertension/hypotension; Infection; Multi-organ failure; Myocardial infarction; Perforation; Pericardial effusion; Pleural effusion; Renal failure/dysfunction; Respiratory failure; Seizure; Significant residual flow; Stroke; Thrombocytopenia; Thromboembolism: peripheral and pulmonary; Thrombus formation; Transient ischemic attack; Valvular regurgitation/insufficiency; Vascular access site injury (hematoma, pseudoaneurysm, arteriovenous fistula, groin pain or other); Vessel trauma/injury.

REFERENCES

1. Charate et al., Evaluation of Multimodality LAA Leak Closure Methods Following Incomplete Occlusion. JACC Cardio Interv 2022. 2. Piayda et al., Safety and feasibility of peri-device leakage closure after LAAO. Eurointervention. 2022. 3. Ellis et al., Incidence and Clinical Outcomes of Peri-Device Leak After Transcatheter LAAO. HRS. 2022. 4. Galea et al. Amulet or Watchman Device for Percutaneous Left Atrial Appendage Closure: Primary Results of the SWISS-APERO Randomized Clinical Trial. Circulation 2022 145:724-738. 5. Lakkireddy et al. 3-year Outcomes from the Amplatzer Amulet Left Atrial Appendage Occluder Randomized Controlled Trial (Amulet IDE) JACC: Cardio Interv 2023 16(15)1902-1913. 6. Veinot, JP, et al. Anatomy of the Normal Left Atrial Appendage. Circulation. 1997; 96: 3112-3115. 7. Beigel et al., The Left Atrial Appendage: Anatomy, Function, and Noninvasive Evaluation. JACC: Cardiovascular Imaging. 2014.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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