

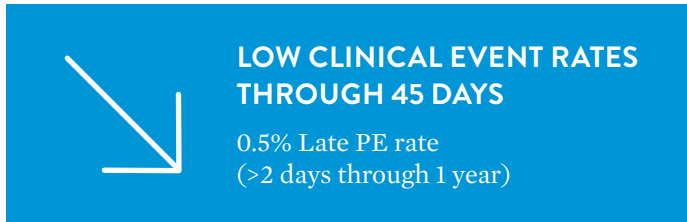
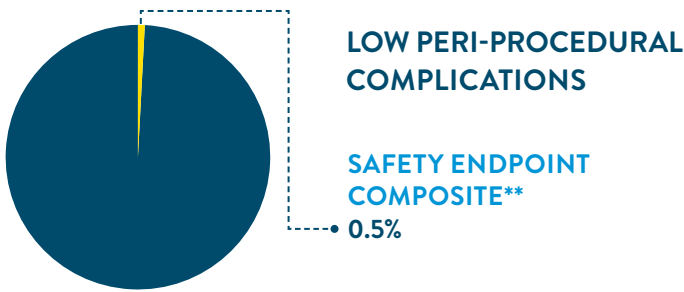
EMERGE LAA POST-APPROVAL STUDY¹:

Concomitant Catheter Ablation and LAA Occlusion with the Amplatzer™ Amulet™ LAA Occluder in the U.S.*

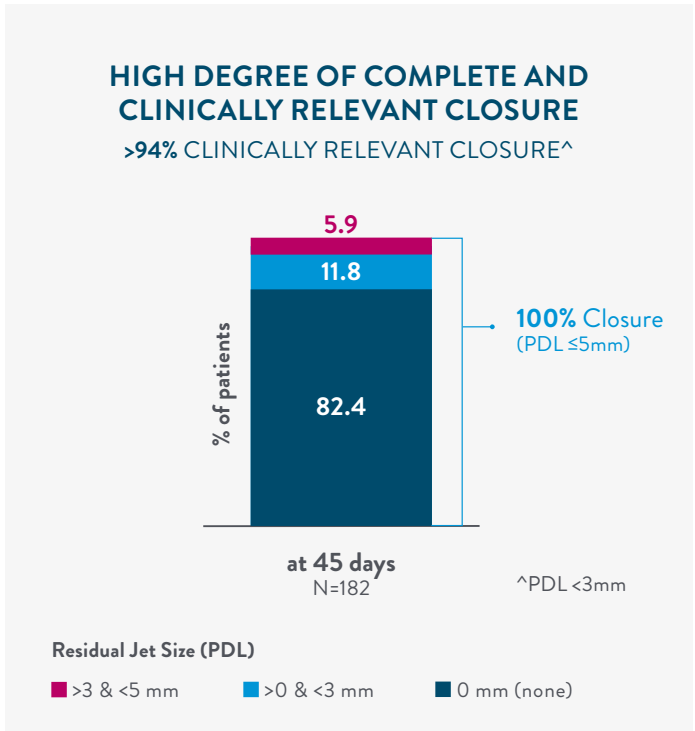
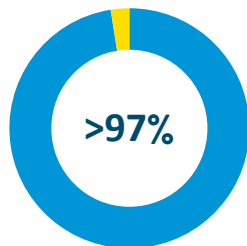


EMERGE LAA DATA DEMONSTRATES THAT COMBINING AF ABLATION WITH THE DUAL-SEAL AMULET OCCLUDER IMPLANT IS FEASIBLE AND SAFE, PROVIDING AN EFFICIENT AND EFFECTIVE MEANS TO MANAGE AF AND STROKE RISK.

SIMILAR TO AMULET LAAO ALONE, AMULET LAAO IMPLANTATION COMBINED WITH AF ABLATION PROVIDES:



HIGH IMPLANT SUCCESS RATE
97.3% IMPLANT SUCCESS RATE



KEY CALLOUT
Data demonstrated that, regardless of discharge medication regimen, Amulet LAAO implantation in combination with AF ablation delivers a positive safety profile.

See Important Safety Information referenced within.



AMULET LAAO IMPLANTATION COMBINED WITH AF ABLATION PROVIDES:



IMPLANT SUCCESS
97.3% IMPLANT SUCCESS RATE¹



SAFETY
LOW PERI-PROCEDURAL
COMPLICATIONS & CLINICAL
EVENT RATES¹



HIGH CLOSURE
BOTH COMPLETE AND
CLINICALLY RELEVANT¹

Rx Only
Important Safety Information

AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER

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 CHA₂DS₂-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. Ellis, C, et al. Concomitant Catheter Ablation and Left Atrial Appendage Occlusion with the Amulet Occluder from the EMERGE LAA Post-Approval Study. J Cardiovasc Electro. AF Symposium 2025.

*182 patients (1.5%) had concomitant ablation with Amulet (Concomitant) performed by 55 operators at 31 sites compared to 11,935 patients with Amulet alone (Amulet Only).

**Safety composite endpoint of all-cause death, ischemic stroke, systemic embolism, or device/procedure-related events requiring open cardiac surgery or major endovascular intervention between device implantation and 7 days or hospital discharge (whichever is later).

CAUTION: Product(s) 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 <https://www.eifu.abbott/> for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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