EMERGE LAA POST-APPROVAL STUDY: REAL-WORLD EXPERIENCE WITH THE AMPLATZER™ AMULET™ LAA OCCLUDER IN THE UNITED STATES

AF SYMPOSIUM: LATE BREAKING CLINICAL TRIAL

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The first analysis of the EMERGE LAA study demonstrate strong safety and efficacy in 5,499 patients undergoing LAA closure with the Amulet occluder in the "real-world". 96% of patients received an Amulet occluder successfully, 97% had clinically relevant closure at 45 days, >90% of patients were immediately off OACs at discharge, and a safety endpoint of less than 1% (.76%). Pericardial effusion showed a significant improvement with operator experience and the rate declined compared to the US IDE (1.9% vs. 2.4% in the US IDE).

SAFETY

0.76%
Safety endpoint composite

0.3%
All-stroke at 45 days

EFFICACY

97.3% clinically relevant closure (PDL ≤3mm) at 45 days

>90%
patients free from OACs at discharge

STUDY DESIGN

Objective	EMERGE LAA was designed to assess clinical outcomes with the Amulet occluder in a real-world setting
Analysis Population	Includes patients with an Amulet occluder implant attempt between August 14, 2021 and December 31, 2022 and enrolled in the National Cardiovascular Data Registry (NCDR) LAAO Registry™
Follow-up	Procedural, discharge, and 45 day

PATIENT CHARACTERISTICS

- Age: 76.9 ± 7.9
- CHA2DS2-VASc: 4.7 ± 1.5
- HAS-BLED: 2.7 ± 1.1

- Prior Bleeding: 67.1%
- Prior stroke: 20.8%
- Female: 40.3%

See Important Safety Information referenced within.

SAFETY ENDPOINT COMPOSITE

Composite 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).[1, 2, 3]

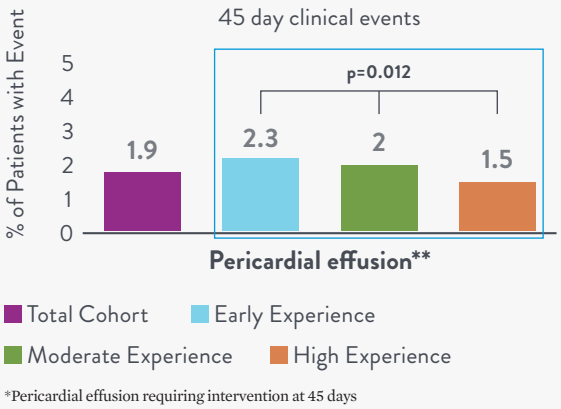
SAFETY

LOW RATES OF ADVERSE EVENTS

0.76%	**0.3%**	**0.2%**
Safety endpoint composite	All-stroke	Ischemic stroke

The 0.76% safety endpoint rate at implant and 7 days or hospital discharge supports the safety of the Amulet occluder and the 0.3% all-stroke rate demonstrates its capability to reduce the rate of stroke.

SIGNIFICANTLY IMPROVED SAFETY WITH OPERATOR EXPERIENCE



*Pericardial effusion requiring intervention at 45 days

PE requiring intervention at 45 days

1.9%
EMERGE LAA

VS

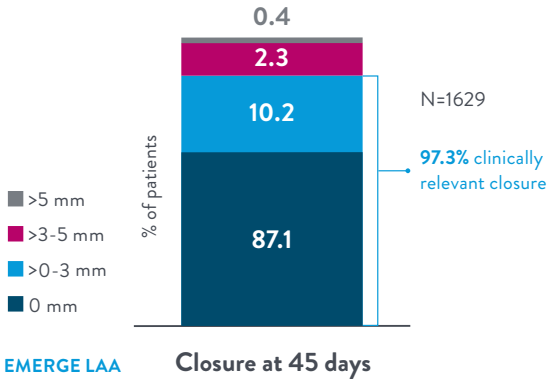
2.4%
AMULET IDE

Pericardial effusion rates in EMERGE LAA significantly improved with increased operator experience and were lower compared to the Amulet IDE trial.

EFFICACY

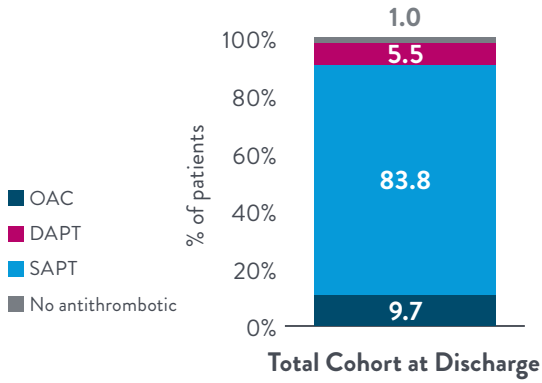
HIGH RATES OF CLOSURE AND FREEDOM FROM OACS

87.1% COMPLETE CLOSURE AT 45 DAYS



EMERGE LAA

Closure at 45 days



Total Cohort at Discharge

>90%
Free from OACs at discharge

The high closure rates demonstrate the value of the Amulet occluder's dual seal design with a lobe that closes the appendage and a disc that seals at the ostium providing two mechanisms of closure.

See Important Safety Information referenced within.

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 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.

1. Holmes DR, Jr., Kar S, Price MJ et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. J Am Coll Cardiol 2014;64:1-12.
2. Kar S, Doshi SK, Sadhu A et al. Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device: Results From the PINNACLE FLX Trial Circulation 2021;143:1754-1762.
3. Enrico G. Ferro, MD,a,b Mohamad Alkhouli, MD, et al. Real-world outcomes with Watchman FLX: early results from SURPASS. J Am Coll Cardiol 2023;15.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference to 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.

See Important Safety Information referenced within.

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