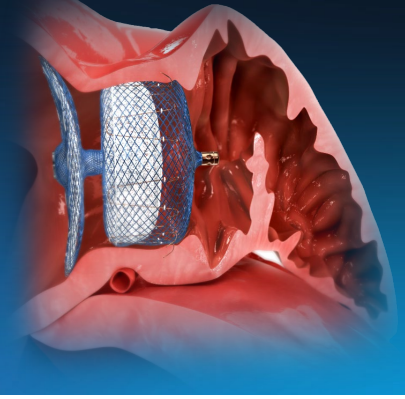
SHAH A ET AL. TCT CONFERENCE 2024

EMERGE LAA Post-Approval Study[1]:

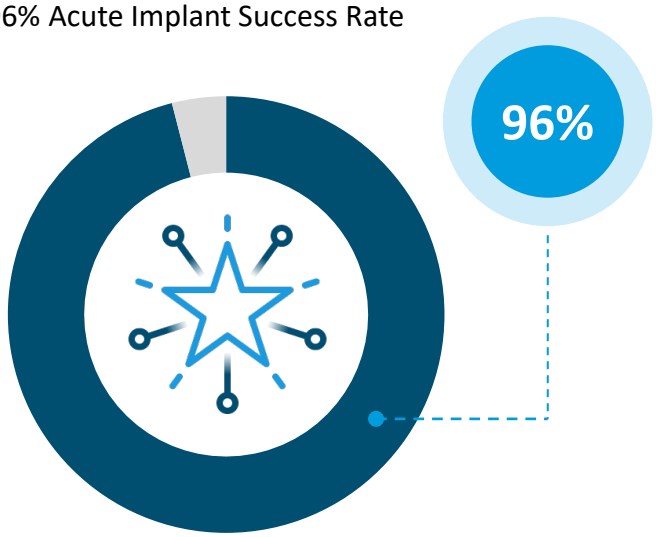
One-year real-world outcomes with the Amplatzer™ Amulet™ LAA Occluder in the U.S.



EMERGE LAA one-year outcomes for the first 5600 patients demonstrate the safety and effectiveness of the Amulet LAA Occluder in the real-world setting, consistent with the randomized controlled Amulet IDE Trial.

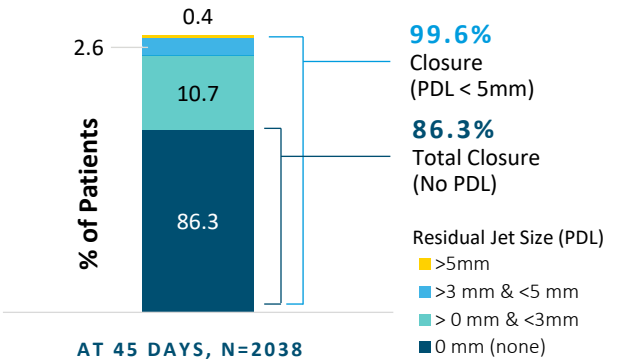
HIGH IMPLANT SUCCESS RATE

96% Acute Implant Success Rate



HIGH DEGREE OF CLOSURE

97% Clinically Relevant Closure*



Closure rates are improved compared to those with single lobe device

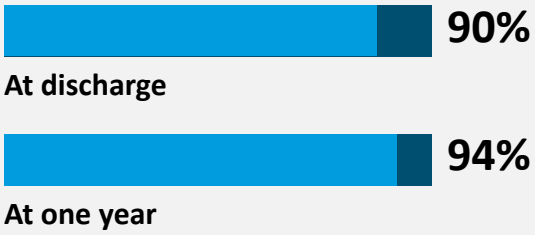
*PDL <3mm

LOW RATE OF ADVERSE CLINICAL OUTCOMES AT ONE YEAR

1-year clinical outcomes comparable with competitor device real-world US data

HIGH DEGREE OF FREEDOM FROM OACS

90% freedom at discharge and
94% freedom at one year



Key Callout

Data demonstrated that, regardless of discharge medication regimen, Amulet LAAO delivers a positive safety profile with <1% late pericardial effusion rate (>2 day through 1 year).

Increased operator experience with Amulet LAAO drives significant improvement in:

Implant Success
Significantly Higher
Procedural Success Rate

Procedure Time
Significantly Shorter
Procedure Time

Safety
Significantly Lower
Short-term Safety
Event Rates

AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER

1. Shah et al. One-Year Real-World Outcomes With the Amulet Occluder From the EMERGE LAA Post-Approval Study. TCT 2024

Rx Only

IMPORTANT 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 $CHADS_2$ or CHA_2DS_2-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.

CAUTION:

Product(s) 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 eLabeling | Abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Abbott
3200 Lakeside Dr., Santa Clara, CA. 95054 USA, Tel: 1.800.227.9902
www.structuralheartsolutions.com