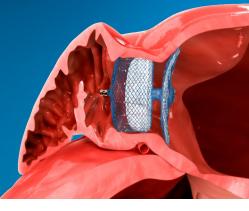
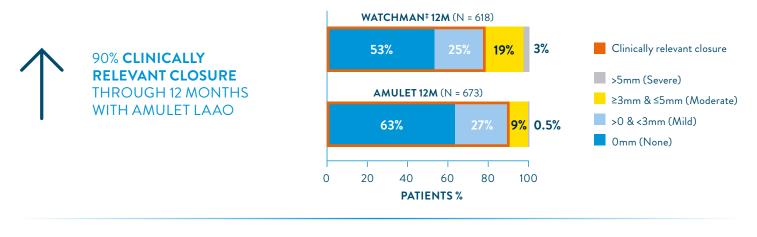
# AMULET IDE FIVE-YEAR RESULTS<sup>1</sup>



# IN THE LARGEST LAAO RANDOMIZED CONTROLLED TRIAL (1878 PATIENTS\*), THE AMPLATZER™ AMULET™ LAA OCCLUDER WITH DUAL-SEAL TECHNOLOGY COMPARED TO THE SINGLE LOBE WATCHMAN<sup>‡</sup> DEVICE DEMONSTRATED:



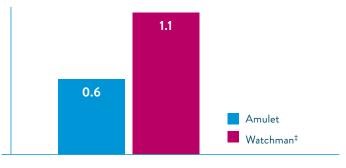
SIGNIFICANTLY **HIGHER** FREEDOM FROM OACs WITH AMULET LAA



DEVICE-RELATED FACTORS (DRT AND PDL) PRECEDED STROKES AND CV DEATHS 2X LESS OFTEN WITH AMULET

**~2X MORE** SEVERE STROKES WITH WATCHMAN'S SINGLE LOBE DEVICE

### SEVERE ISCHEMIC STROKE ANNUALIZED RATE THROUGH 5 YEARS\*\*



AMULET LAAO ENSURES EFFECTIVE CLOSURE IN A BROAD RANGE OF ANATOMIES, REDUCING STROKE RISK AND DRIVING FREEDOM FROM OACS.<sup>1,2,3,4</sup>



## 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.

\*934 randomized to Amulet, 944 randomized to Watchman

\*\*Fatal, disabling, or unknown severity

‡ Third party trademark

#### References

- 1. Lakkireddy, D, Ellis, C, Thaler, D. et al. 5-Year Results From the AMPLATZER Amulet Left Atrial Appendage Occluder Randomized
- Controlled Trial. JACC. 2024.
- Hildick-Smith et al., Left atrial appendage occlusion with the Amplatzer<sup>™</sup> Amulet<sup>™</sup> device: full results of the prospective global observational study. European Heart Journal. 2020.
- observational study. Euro 3. Data on file at Abbott.
- 4. Lakkireddy D, Thaler D, Ellis CR, et al. Amplatzer Amulet Left Atrial Appendage Occluder Versus Watchman Device for Stroke Prophylaxis (Amulet IDE): A Randomized, Controlled Trial. Circulation. 2021;144:1543-1552.

**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.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

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