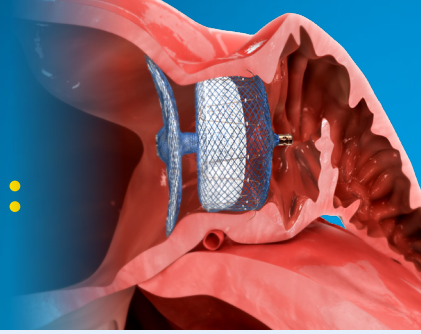
Amplatzer™ Amulet™ Left Atrial Appendage Occluder

LAAO STROKE RISK REDUCTION:
Device-Related Factors Considerations



LAAO THERAPY SHOULD PROVIDE A SOLUTION FOR ALL STAKEHOLDERS WITH LIMITED COMPLICATIONS

DEVICE-RELATED THROMBUS (DRT)

DRT is a complication that occurs when a thrombus, or clot, develops on a medical device.

INCREASED RISK

Increased risk of stroke and systemic embolism in the presence of a DRT.[1]

62% **LOWER DRT RATE WITH AMULET LAAO** AS COMPARED TO WATCHMAN FLX[2]

- High-Risk DRTs result in increased thromboembolic events and mortality.[3]
- Amulet LAAO had significantly fewer High-risk DRTs compared to Watchman LAAC.[3]

PERI-DEVICE LEAK (PDL)

PDL results from incomplete closure of the left atrial appendage following LAAO device implantation when flow is allowed past the device.

GREATER RISK

Greater risk of ischemic stroke or embolism at 5 years with **PDL ≤5 mm**.[4]

39% **INCIDENCE OF DELAYED PDL** AMONG PATIENTS UNDERGOING CLOSURE WITH WATCHMAN FLX[5]

- 2x higher risk of PDL-associated negative outcomes with Watchman LAAC, as compared to Amulet LAAO, in landmark head-to-head study.[6]
- SWISS-APERO Randomized Clinical Trial demonstrated superior complete closure at 45 days with Amulet compared to Watchman FLX.[2]

"The presence of DRT or PDL can significantly worsen patient outcomes and must be avoided in LAAO therapy. Both conditions can lead to severe complications such as increased thromboembolic risk."
Dr. Xavier Freixa Rofastes, Hospital Clínic de Barcelona, Spain

AMULET LAAO'S DUAL-SEAL TECHNOLOGY IS DESIGNED TO REDUCE DEVICE-RELATED FACTORS

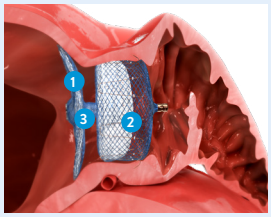
DEVICE-RELATED FACTORS

PRECEDED STROKES AND CV DEATH ~2X MORE OFTEN
with Watchman LAAC vs. Amulet LAAO[2]

See Important Safety Information referenced within.

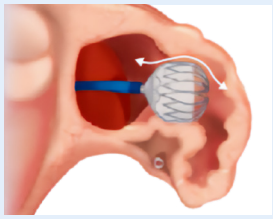
"The design of Amulet allows for successful LAAO even in challenging anatomical scenarios unable to be closed by WATCHMAN FLX." Dr. Akash Makkar, Arizona Heart Arrhythmia Associates, U.S.

Dual seal devicedesign specifics



1. **DISC -** Delivers a complete ostial seal which prevents leaks in more patients and seals off area more prone to thrombus formation.
2. **LOBE -** Requires minimal depth and accommodates different shapes of LAA anatomy.[8]
3. **WAIST -** Provides flexibility to accommodate all morphologies.

Single lobe devicedesign specifics



- **Single lobe mechanism requires positioning more deeply inside appendage**
  - This may predispose patent to higher clot formation compared to Amulet LAAO.
  - Deeper device implantation and larger uncovered LAA areas were associated with a higher incidence of DRT.[9]
- LAA closure often fails with single lobe LAAO devices in appendages that have shallow depth, multiple lobes, many trabeculations, wide orifice, shallow vertical take-off, or chicken wing anatomy.[10]

AMULET LAAO ENSURES EFFECTIVE CLOSURE IN A BROAD RANGE OF ANATOMIES, REDUCING STROKE RISK AND DRIVING FREEDOM FROM OACS [7,8,11,12]

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 $CHADS_2$ 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.

REFERENCES

1. Dukkipati S, et al. Device-Related Thrombus After Left Atrial Appendage Closure. Circulation, 2018. **2.** Galea et al. Amulet or Watchman Device for Percutaneous Left Atrial Appendage Closure: Primary Results of the SWISSAPERO Randomized Clinical Trial. Circulation 2022 145:724-738. **3.** Nielsen-Kudsk, JE et al. Characterization and Clinical Outcomes of Device-Related Thrombus in the Amulet IDE Trial. EuroPCR 2024. **4.** Dukkipati SR et al. Impact of Peridevice Leak on 5-Year Outcomes After Left Atrial Appendage Closure. JACC 2022. **5.** Bhuta S, Carlen A, Savona SJ, Augostini RS, Kalbfleisch SJ, Houmsse M, Daoud EG, Hummel JD, Afzal MR. Incidence and temporal evolution of delayed peridevice leak after left atrial appendage closure. Heart Rhythm. 2024 May 24:S1547-5271(24)02629-8. doi: 10.1016/j.hrthm.2024.05.035. Epub ahead of print. PMID: 38797310. **6.** Ellis C et al. Incidence and clinical outcomes of peri-device leak after transcatheter left atrial appendage occlusion: An analysis of the Amulet IDE Trial. HRS 2022. **7.** Lakkireddy, D, Ellis, C, Thaler, D. et al. 5-Year Results From the AMPLATZER Amulet Left Atrial Appendage Occluder Randomized Controlled Trial. JACC. 2024 Nov. https://doi.org/10.1016/j.jacc.2024.10.101Data on file at Abbott. **8.** Data on file at Abbott. **9.** Cepas-Guillen, et al. Impact of Device Implant Depth After Left Atrial Appendage Occlusion. JACC 2023 Sep, 16 (17) 2139–2149. **10.** Makkar et al. Heart Rhythm 2023;20 **11.** Hildick-Smith et al., Left atrial appendage occlusion with the Amplatzer Amulet device: full results of the prospective global observationalstudy. European Heart Journal. 2020. **12.** 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.

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