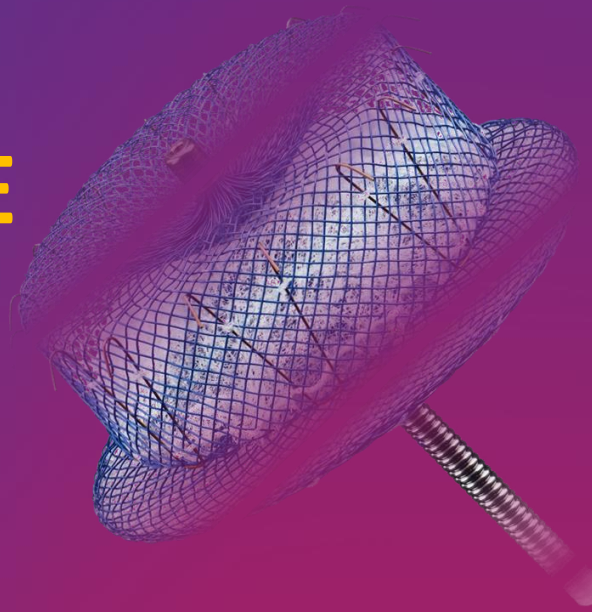
IDE TRIAL SUMMARY

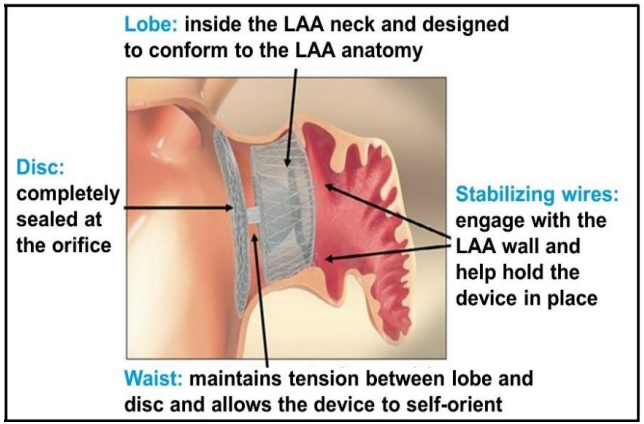
AMPLATZER™ AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER

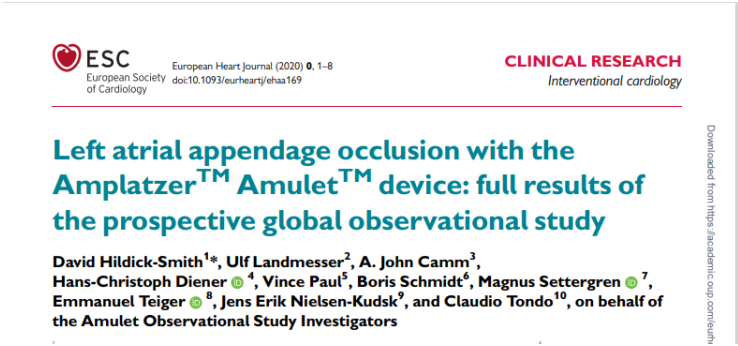


MAT-2111203 v1.0 | Item approved for Global OUS use only.

AMULET IDE TRIAL BACKGROUND

- The Amulet IDE trial was initiated in 2016 to establish safety and effectiveness of the Amplatzer™ Amulet™ LAA occluder to reduce the risk of thrombus embolization from the LAA in patients with non-valvular atrial fibrillation
- The Amplatzer Amulet LAA occluder received CE Mark in January 2013 and is a 2nd generation device
  - Final two-year results of the prospective real-world post market Amulet Observational Study including 1088 patients were published in 2020
- During enrollment of the trial, Watchman‡ was the only FDA approved transcatheter percutaneous LAAO device.
- Key differentiating features of the Amulet LAA occluder:
  - Dual-seal mechanism consisting of a lobe and a disc connected by a central waist with polyester patches sewn into both the lobe and disc to facilitate effective occlusion
  - No need for oral anticoagulant therapy (OAC) following the implant procedure




ESC European Society of Cardiology

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CLINICAL RESEARCH
Interventional cardiology

Left atrial appendage occlusion with the Amplatzer™ Amulet™ device: full results of the prospective global observational study

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AMULET IDE TRIAL[1]

KEY INCLUSION CRITERIA

- Documented paroxysmal, persistent, or permanent non-valvular atrial fibrillation
- At high risk of stroke or systemic embolism defined as CHADS2 score of ≥2 or CHA2DS2-VASc score of ≥3
- Deemed by investigator to be suitable for short term warfarin therapy but deemed unable to take long term oral anticoagulation

KEY EXCLUSION CRITERIA

- LAA anatomy cannot accommodate either a Watchman‡ device or Amulet LAA occluder, as per manufacturer's IFU based on pre-enrollment screening with imaging studies

1. Amulet IDE Trial: Head-to-head Amulet IDE trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

AMULET IDE ENDPOINTS[1]

PRIMARY ENDPOINTS (NON-INFERIORITY TESTS)

- **Mechanism of action (45 days):** Residual jet around the device ≤5mm
- **Safety (12 months):** Composite of procedure-related complications, or all cause death, or major bleeding
- **Effectiveness (18 months):** Composite of ischemic stroke or systemic embolism

SECONDARY ENDPOINTS

- **Mechanism of action (45 days):** superiority test
- **Primary safety endpoint (12 months):** superiority test
- **Primary effectiveness endpoint (18 months):** superiority test
- **Composite of stroke/systemic embolism/cardiovascular death (18 months):** non-inferiority test
- **Major bleeding (18 months):** superiority test

1. Amulet IDE Trial: Head-to-head Amulet IDE trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

FIRST LARGE SCALE RANDOMIZED
HEAD-TO-HEAD STUDY AMULET VS WATCHMAN‡[1]

Amulet showed **superior effective closure** and **> 60%** of subjects had **complete closure**

Amulet showed **non-inferior** rates of **effective endpoint (stroke, systemic embolism)**

Amulet showed **non-inferior** rates of **safety endpoint (procedure-related complications, all-cause death or major bleeding)**

OAC = Oral anticoagulant
CV = Cardiovascular
DRT = Device Related Thrombosis

1. Amulet IDE Trial: Results from a head-to-head IDE trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

IDE TRIAL SHOWS STRONG PERFORMANCE[1]

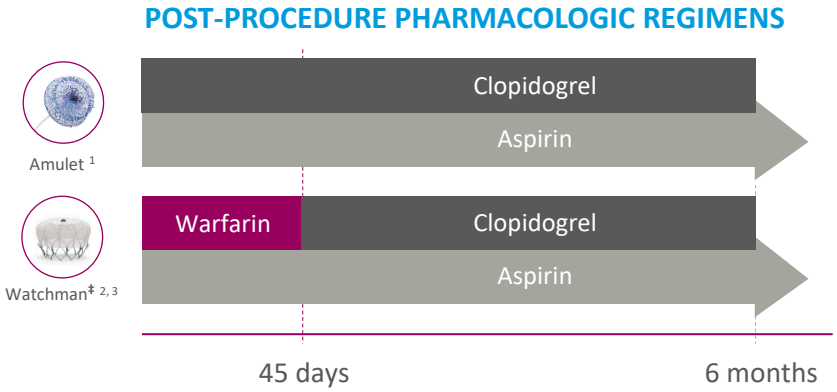
	AMULET CLAIMS	SUPPORTING DATA[1]
Post Implant Therapies	Amulet patients may be discharged on DAPT pharmacological regimen only	79% of Amulet patients discharged from hospital without the use of oral anticoagulant (OAC) medication
Effective Closure	Superior effective closure at ≤5 mm residual jet flow vs. Watchman‡	Effective closure at ≤5 mm residual jet flow - Amulet 99% of subjects - Watchman‡ at 97% of subjects
Complete Closure	Higher complete closure at 0 mm residual jet flow vs. Watchman‡	Complete closure at 0 mm residual jet flow - Amulet 63% of subjects - Watchman‡ 46% of subjects
Stroke / CV Death	Non-inferiority rates at 18 months for all strokes, systemic embolism and CV death vs. Watchman‡	At 18 months - All Stroke: Amulet 2.7% vs. Watchman‡ 3.4% - Systemic Embolism: Amulet 0.3% vs. Watchman‡ 0.2% - CV Death: Amulet 3.1% vs. Watchman‡ 4.8%
Device Related Thrombosis	Low DRT at 18 months vs. Watchman‡	DRT at 18 months - Amulet 3.3% (n=30 patients) - Watchman‡ 4.5% (n=40 patients)

DAPT= Dual antiplatelet therapy CV = Cardiovascular DRT = Device Related Thrombosis

1. Amulet IDE Trial: Results from a head-to-head IDE trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

OACs NOT REQUIRED AT DISCHARGE

THE FIRST AND ONLY LAA OCCLUDER



Amulet n=903 **79%**

vs

Watchman n=885 **4%**

Patients leaving the hospital without using OACs*

Unlike Watchman‡, Amulet patients may be discharged with DAPT only

DAPT = Dual antiplatelet therapy.

* Amulet IDE Trial: Results from a head-to-head trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

1. Amplatzer Amulet LAA Occluder IFU. 2021. 2. Watchman LAA Closure Device DFU. 2015. 3. Watchman 2.5 website

CLOSURE SUPERIORITY DEMONSTRATED IN THE FIRST LARGE SCALE RANDOMIZED HEAD-TO-HEAD STUDY VS WATCHMAN‡[1]

EFFECTIVE CLOSURE WITH ≤5 MM RESIDUAL JET AROUND THE DEVICE

98.9%
Amulet LAA Occluder

vs

96.8%
Watchman‡
(*P* = 0.0025)

COMPLETE CLOSURE WITH NO RESIDUAL JET (0 MM) AROUND THE DEVICE

63.0%
Amulet LAA Occluder

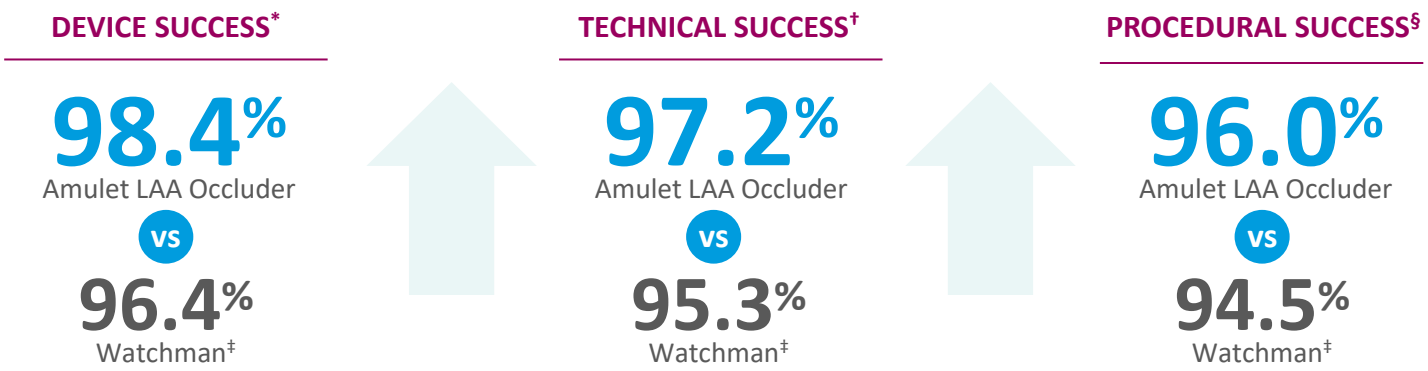
vs

46.1%
Watchman‡

SUPERIOR CLOSURE FOR RESIDUAL PERI-DEVICE FLOW

1. Amulet IDE Trial: Results from a head-to-head trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

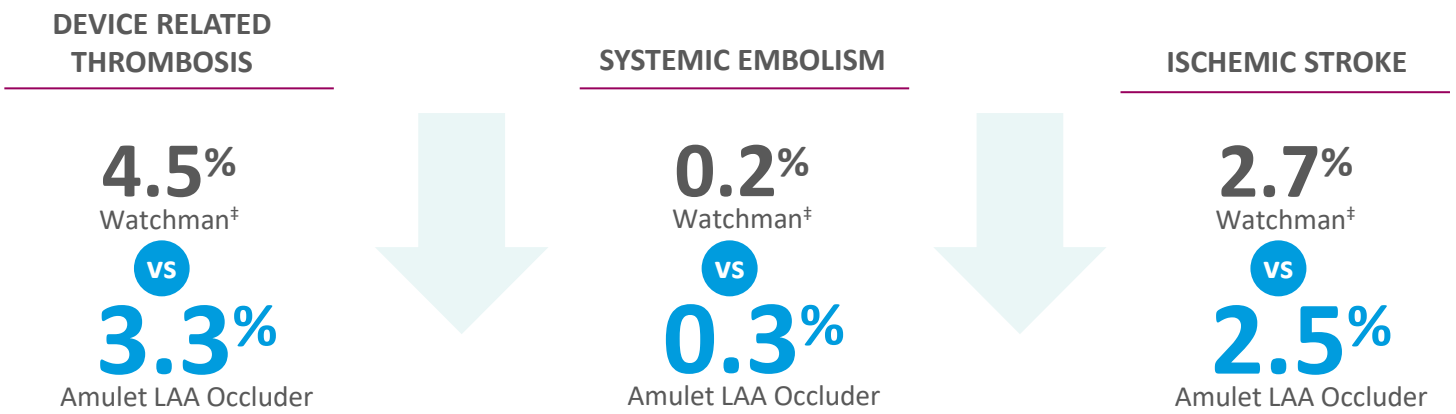
DEMONSTRATED SUCCESS
BY EVERY MEASURE[1]



The most common reason for unsuccessful implant was unsuitable subject anatomy, which was less common in the Amulet group than in the Watchman‡ group (9 Amulet and 30 Watchman).

* Device was deployed and implanted in the correct position
† Device success with site reported residual jet ≤5 mm and no device-related complications through discharge or 7 days whichever is earlier
§ Technical success with no procedure-related complications
1. Amulet IDE Trial: Results from a head-to-head trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

PROVEN NON-INFERIOR
ACROSS PRIMARY ENDPOINTS[1]



LOW RATES of device related thrombosis, embolism and stroke at 18 months.

1. Amulet IDE Trial: Results from a head-to-head trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

IDE DATA POSITIONS AMULET WELL AGAINST WATCHMAN‡ IN HEAD-TO-HEAD STUDY[1]

79% of Amulet subjects discharged **without OAC medication**

Amulet showed **superior effective closure** and **> 60%** of subjects had **complete closure**

Amulet showed **non-inferior** rates of **stroke, systemic embolism or CV death** and **low DRT rates**

OAC = Oral anticoagulant
CV = Cardiovascular
DRT = Device Related Thrombosis

1. Amulet IDE Trial: Results from a head-to-head IDE trial comparing the efficacy and safety of Amulet and Watchman (N=1878).

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