SUPPLEMENTAL MATERIAL

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1. TABLE SI: TRIAL ORGANIZATION AND PARTICIPATING SITES

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Europe (203 Randomized) – *Cardioangiologisches Centrum am Bethanien Krankenhaus (26)*: Schmidt, Boris; *Skejby University Hospital (26)*: Nielsen-Kudsk, Jens Erik; *Hospital Universitario Virgen Macarena (17)*: Ruiz Salmeron, Rafael; *Herzzentrum Leipzig GmbH (16)*: Sandri, Marcus; *Nemocnice Na Homolce (14)*: Neuzil, Petr; *Rigshospitalet (12)*: Soendergaard, Lars; *Universitatsmedizin Berlin - Campus Benjamin Franklin (CBF) (11)*: Landmesser, Ulf; *Clinica Universidad de Navarra (11)*: Garcia Bolao, Ignacio; *Medizinische Einrichtungen der Universitat Dusseldorf (10)*: Zeus, Tobias; *Center Inselspital Bern (9)*: Windecker, Stephan; *Elisabeth-Krankenhaus Essen GmbH (8)*: Schmitz, Thomas; *Asklepios Klinik St. Georg (7)*: Meincke, Felix; *Hospital de la Santa Creu I Sant Pau (6)*: Arzamendi, Dabit; *Evangelisches Krankenhaus Bielefeld (5)*: Israel, Carsten; *Internistisches Klinikum Munchen SUD (4)*: Lewalter, Thorsten; *St. Antonius Ziekenhuis (4)*: Boersma, Lucas; *Hospital Universitario de Salamanca (4)*: Cruz Gonzalez, Ignacio; *Klinikum Coburg GmbH (3)*: Brachmann, Johannes; *Hospital General Juan Ramon Jimenez (3)*: Diaz, Jose; *Kliniken Villingen-Schwenningen (3)*: Jung, Werner; *UNIVERSITATSMEDIZIN der Johannes Gutenberg-Universitat Mainz (1)*: Gori, Tommaso; *Santa Maria Hospital (1)*: Oliveira, Eduardo; *CardioVaskulares Centrum St. Katharinen (1)*: Sievert, Horst; *Ospedale San Raffaele – Aritmologia (1)*: Mazzone, Patrizio

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Canada (7 Randomized) – *Institut de Cardiologie de Montreal (Montreal Heart Inst.) (4)*: Ibrahim, Reda; *Vancouver General Hospital (U of BC) (3)*: Saw, Jacqueline

2. TABLE SII. PATIENT ENTRY CRITERIA

Inclusion Criteria
1. 18 years of age or older 2. Documented paroxysmal, persistent, or permanent non-valvular atrial fibrillation and the patient has not been diagnosed with rheumatic mitral valvular heart disease 3. At high risk of stroke or systemic embolism defined as $CHADS_2$ score $\geq$ 2 or a CHA_2DS_2-VASc score of $\geq$ 3 4. Has an appropriate rationale to seek an alternative to warfarin or other anticoagulant medication 5. Deemed by investigator to be suitable for short term warfarin therapy but deemed unable to take long term anticoagulation, following the conclusion of shared decision making (see inclusion criteria #6) 6. Deemed suitable for LAA closure by a multidisciplinary team of medical professionals (including an independent non-interventional physician) involved in the formal and shared decision-making process, and by use of an evidence-based decision tool on oral anticoagulation (final determination must be documented in the subject's medical record) 7. Able to comply with the required medication regimen post-device implant 8. Able to understand and is willing to provide written informed consent to participate in the trial 9. Able and willing to return for required follow-up visits and examinations
Exclusion Criteria
1. Requires long-term oral anticoagulation therapy for a condition other than atrial fibrillation 2. Contraindicated for or allergic to aspirin, clopidogrel, or warfarin use 3. Indicated for chronic P2Y12 platelet therapy inhibitor 4. Is considered at high risk for general anesthesia, in the opinion of the investigator, and/or based on past adverse reaction(s) requiring medical intervention or which resulted in prolongation of hospital stay (criterion is only applicable where general anesthesia is planned for the study procedure). 5. Has undergone atrial septal defect (ASD) repair or has an ASD closure device present 6. Has undergone patent foramen ovale (PFO) repair or has a PFO closure device implanted 7. Implanted with a mechanical valve prosthesis 8. Has any of the customary contraindications for a percutaneous catheterization procedure (e.g. subject is too small to accommodate the TEE/TOE probe or required catheters, or subject has active infection or bleeding disorder) 9. Stroke or transient ischemic attack (TIA) within 90 days prior to randomization or implant procedure (as applicable) 10. Underwent any cardiac or non-cardiac intervention or surgery within 30 days prior to randomization, or intervention or surgery is planned within 60 days after implant procedure (e.g. cardioversion, ablation, cataract surgery, etc.) 11. Myocardial infarction (MI) within 90 days prior to randomization 12. New York Heart Association Class IV Congestive Heart Failure 13. Left ventricular ejection Fraction (LVEF) $\leq$30% 14. Symptomatic carotid disease (defined as >50% stenosis with symptoms of ipsilateral transient or visual TIA evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral stroke); if subject has a history of carotid stent or endarterectomy the subject is eligible if there is <50% stenosis 15. Reversible cause of AF (i.e. secondary to thyroid disorders, acute alcohol intoxication, trauma, recent major surgical procedures) 16. History of idiopathic or recurrent venous thromboembolism

17. Left atrial appendage is obliterated or surgically ligated
18. Thrombocytopenia or anemia requiring transfusions
19. Hypersensitivity to any portion of the device material or individual components of either the Amulet or Boston Scientific LAA closure device (e.g. nickel allergy)
20. Actively enrolled or plans to enroll in a concurrent clinical study in which the active treatment arm may confound the results of this trial
21. Subject is pregnant or pregnancy is planned during the course of the investigation
22. Active endocarditis or other infection producing bacteremia
23. Subject has had a transient case of AF (i.e. never previously detected, provoked/induced by surgical or catheter manipulations, etc.)
24. Subjects with severe renal failure (estimated glomerular filtration rate <30 ml/min/1.73m^2)
25. Subject whose life expectancy is less than 2 years
26. Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical trial or to comply with follow up requirements, or impact the scientific soundness of the clinical trial results.

The following were echocardiographic exclusion criteria:

1. Intracardiac thrombus visualized by echocardiographic imaging
2. Existing circumferential pericardial effusion >2mm
3. Significant mitral valve stenosis (i.e. mitral valve area <1.5 cm^2)
4. High risk patent foramen ovale (PFO), defined as an atrial septal aneurysm (excursion > 15mm or length $\geq$ 15mm; excursion defined as maximal protrusion of the ASA beyond the plane of the atrial septum) or large shunt (early, within 3 beats and/or substantial passage of bubbles i.e. $\geq$ 20)
5. Complex atheroma with mobile plaque of the descending aorta and/or aortic arch
6. Cardiac tumor
7. LAA anatomy cannot accommodate either a Boston Scientific LAA closure device or Amulet device, as per manufacturer's IFU. (i.e. the LAA anatomy and sizing must be appropriate for both devices in order to be enrolled in the trial. This is applicable to all roll-in and randomized subjects).
8. Placement of the device would interfere with any intracardiac or intravascular structure

3. TABLE SIII: STUDY ASSESSMENTS

Study Evaluation	Baseline	Procedure[2]	Discharge	45-day visit (± 5 days)	3-month visit (± 30 days) Phone Contact	6-month visit (± 30 days)	9-month visit (± 30 days) Phone Contact	12-month visit (±30 days)	**18-month visit	24-month visit (±30 days)	Annual visits 3, 4 and 5 years (±60 days) Phone Contact	Stroke Assessment Visit
Informed Consent Process	X											
History & Physical	X											
Cardiovascular & Medical Exam	X											
Neurological exam	X											
$CHADS_2$ and CHA_2DS_2-VASc scores	X											
HAS-BLED score	X											
Reason for seeking an alternative to Warfarin/OAC therapy	X											
INR assessment (as applicable while on warfarin/oral anticoagulants requiring INR assessments)	X			X		X		X	X	X		X
12-lead ECG	X											
Pregnancy Test[1]	X											
Medication Assessment	X		X	X	X	X	X	X	X	X	X	X
MRI (CT if contraindicated)	X[3]											X
Modified Rankin Scale, NIHSS & Barthel Index[4]	X											X
QVSFS	X			X	X	X	X	X	X	X	X	
EQ-5D-5L	X			X		X		X	X			
Angiography		X										
TTE			X									
TEE/TOE	X*	X		X		X[5]		X[6]				X[7]
Adverse Event Assessment	X	X	X	X	X	X	X	X	X	X	X	X

*Echoes performed within 90 days prior to consent will be accepted; otherwise TEE/TOE must be conducted after consent; [1]Pregnancy test for women of childbearing potential; [2] Procedure must occur within 14 days from the date of randomization. Follow-up visit windows for implanted patients will be calculated based on the date of procedure; [3]MRI (CT if contraindicated) is required for patients with a documented history of TIA or stroke. Previous imaging done post-neurological event is acceptable; otherwise must be repeated; [4] Perform additional Neurological assessments after a confirmed stroke or TIA and repeat within 90 days of stroke confirmation. [5] TEE/TOE is not required if closure was confirmed at 45 days (defined as residual jet <5mm); [6] TEE/TOE is required for all patients at 12 months; [7] TEE/TOE is required at stroke visit only if stroke is confirmed by MRI/CT **As an endpoint visit, the 18-month visit window is -7/ +45 days based on the date of implant procedure. Note: Patients that are randomized but do not have a procedure or do not receive a device will be followed according to Table 3; however, medication requirements and follow-up TEE/TOEs are not required

4. TABLE SIV: TRIAL ENDPOINTS

Primary Endpoints
Mechanism of Action: Device closure (defined as residual jet around the device ≤ 5 mm) at the 45-day visit documented by transesophageal echocardiogram (TEE/TOE) defined by Doppler flow. **Safety:** A composite of procedure-related complications, or all-cause death, or major bleeding (Type 3 or greater per Bleeding Academic Research Consortium) at 12 months. **Effectiveness:** A composite of ischemic stroke or systemic embolism at 18 months
Secondary Endpoints
• A composite of ischemic stroke or systemic embolism at 18 months (superiority analysis) • A composite of procedure-related complications, or all-cause death, or major bleeding at 12 months (superiority analysis) • Major bleeding rate at 18 months, defined as Type 3 or greater based on BARC definition (superiority analysis) • Device closure (defined as residual jet around the device ≤5 mm) at the 45-day visit documented by TEE/TOE, defined by Doppler flow (superiority analysis) • A composite of all stroke, systemic embolism, or cardiovascular/unexplained death at 18 months (non-inferiority analysis)
Descriptive Endpoints
• Technical success rate • Procedural success rate • Device success rate • Number of patients on oral anticoagulant at each follow-up visit • Procedure duration • Procedural complications by operator • Device thrombosis • Transient ischemic attack • Hemorrhagic stroke • Systemic embolism • All-cause mortality • Cardiovascular mortality • Major bleeding, by site and severity (defined as Type 3 or greater based on BARC definition) • Minor bleeding, by site and severity (defined as Type 1 or Type 2 based on BARC definition)

5. TABLE SV: DEFINITIONS OF OUTCOME EVENTS

Term	Definition
Cardiovascular Mortality	• Death due to proximate cardiac cause, e.g. myocardial infarction, cardiac tamponade, worsening heart failure, endocarditis. • Death caused by non-coronary, non-CNS vascular conditions such as pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular disease. • Death from vascular CNS causes ▪ From hemorrhagic stroke ▪ From ischemic stroke • All procedure-related deaths, including those related to a complication of the procedure or treatment for a complication of the procedure. • Sudden or unwitnessed death defined as non-traumatic, unexpected fatal event occurring within 1 hour of the onset of symptoms in an apparently healthy patient. If death is not witnessed, the definition applies when the victim was in good health 24 hours before the event. • Death of unknown cause
Stroke	Stroke: Stroke is an acute episode of focal or global neurological dysfunction caused by the brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction. Sub classifications of stroke: i. Ischemic Stroke is defined as an acute symptomatic episode of focal cerebral, spinal, or retinal dysfunction caused by an infarction of central nervous system tissue. ii. Hemorrhagic Stroke is defined as an acute symptomatic episode of focal or global cerebral or spinal dysfunction caused by a nontraumatic intraparenchymal, intraventricular, or subarachnoid hemorrhage.
Transient Ischemic Attack (TIA)	A transient (less than (<) 24 hrs) episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia, without acute infarction. No evidence of infarction if imaging performed.
Systemic Embolism	Acute vascular insufficiency or occlusion of the extremities or any non-CNS organ associated with clinical, imaging, surgical/autopsy evidence of arterial occlusion in the absence of other likely mechanism (e.g. trauma, atherosclerosis, or instrumentation). When there is presence of prior peripheral artery disease, angiographic or surgical or autopsy evidence is required to show abrupt arterial occlusion.
Success Definitions	• **Device success:** Device deployed and implanted in correct position • **Technical success:** Exclusion of the LAA with no device-related complications and no residual jet >5mm on color Doppler TEE • **Procedural success:** Technical success with no procedure-related complications, except for uncomplicated (minor) device embolization

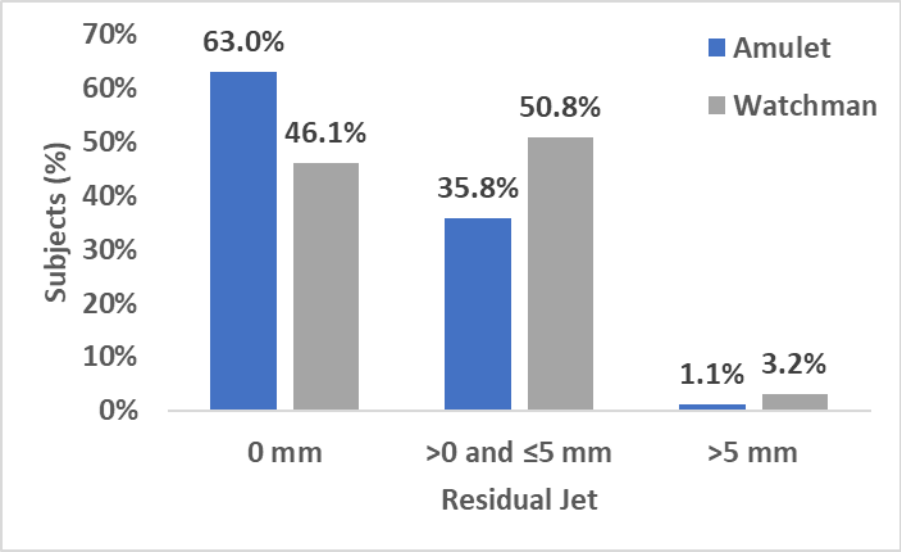
Device Related Complication	Adverse events which are adjudicated as device-related and require either an invasive surgical or percutaneous intervention. Examples of device-related complications may include embolization requiring percutaneous/surgical intervention, pericardial effusion or cardiac tamponade requiring pericardiocentesis or surgery, device-related infection, etc.
Procedure Related Complication	Adverse events which are adjudicated as procedure-related and require either an invasive surgical or percutaneous intervention. Examples of procedural complications may include embolization requiring percutaneous/surgical intervention, pericardial effusion or cardiac tamponade requiring pericardiocentesis or surgery, etc.
Major Bleeding (BARC)	• **Type 3a:** Any transfusion with overt bleeding. Overt bleeding plus a hemoglobin drop of ≥ 3 to < 5 g/dL (provided hemoglobin drop is related to bleeding) • **Type 3b:** Overt bleeding plus hemoglobin drop ≥ 5 g/dL (provided hemoglobin drop is related to bleed), cardiac tamponade, bleeding requiring surgical intervention or intravenous vasoactive drugs • **Type 3c:** Intracranial hemorrhage including subdural hemorrhages (does not include microbleeds or hemorrhagic transformation, does include intraspinal), intraocular bleed compromising vision • **Type 5a:** Probably fatal bleeding: bleeding that is clinically suspicious as the cause of death, but the bleeding is not directly observed and there is no autopsy or confirmatory imaging • **Type 5b:** Definite fatal bleeding: bleeding that is directly observed (by either clinical specimen [blood, emesis, stool, etc.] or imaging) or confirmed on autopsy

6. TABLE SVI: PRESPECIFIED ANALYSIS POPULATIONS

Study Population	Definition	Amulet	Watchman	Endpoints
Intention-to-Treat (ITT)	All randomized patients	934	944	Primary Effectiveness
As Attempted (AT)	ITT patients who underwent an implant attempt regardless of the device attempted or implanted.	917	916	Secondary: Major Bleeding at 18 months
Attempt as Randomized	Patients who underwent an implant attempt with the device as randomized	915	916	Secondary: Stroke/Systemic Embolism/CV Death at 18 months
Per Protocol (PP)	ITT patients who met all inclusion criteria and none of the exclusion criteria, who underwent an implant attempt with the device as randomized	903	896	Primary Safety
Success as Randomized	Patients who received a device as randomized (including reattempt procedures, based on last procedure)	903	885	Primary Mechanism of Action *(Patients who had closure status at 45 days determined by the echo core lab)*

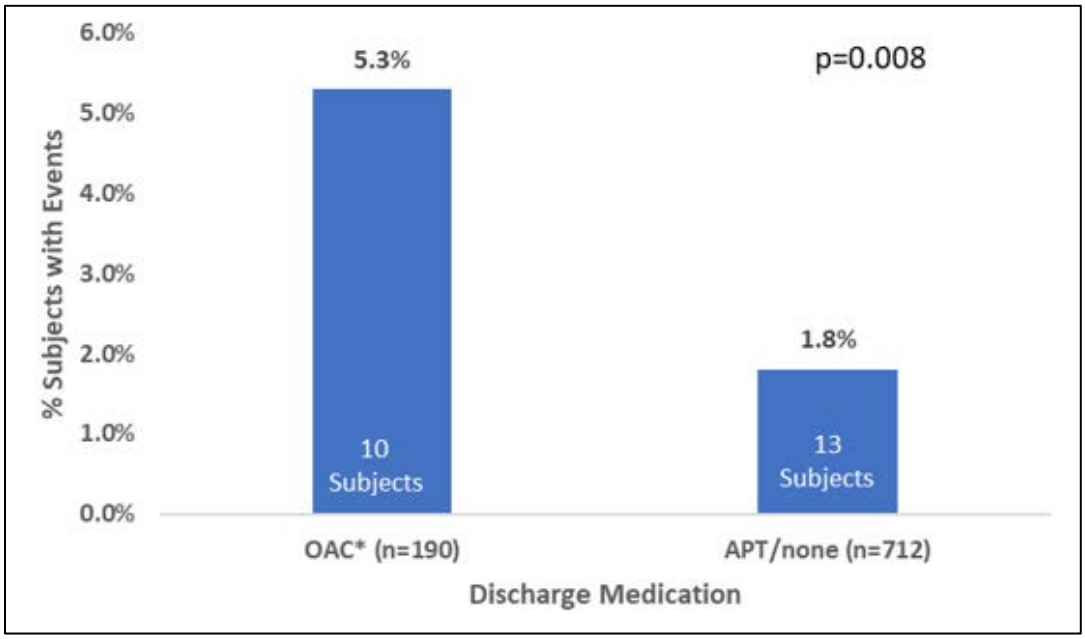
7. FIGURE SI: RESIDUAL JET AT 45 DAYS

Shows the distribution of residual jet at 45 days. No residual jet around the device was observed in 63.0% of Amulet patients and 46.1% of Watchman patients. Flow >0 mm and ≤ 5 mm was observed in 35.8% of Amulet patients and 50.8% of Watchman patients. A small percentage of patients (1.1% Amulet and 3.2% Watchman) had residual jet > 5 mm.



8. FIGURE SII: LATE PERICARDIAL EFFUSION BY DISCHARGE ANTITHROMBOTIC MEDICATION IN AMULET PATIENTS

A total of 23 Amulet patients experienced late pericardial effusion in the Amulet IDE trial. A review of discharge medication for these 23 Amulet patients who experienced late pericardial effusion (>2 days post implant) indicates that patients discharged on anticoagulation therapy had a higher event rate (5.3%) than those discharged on antiplatelet therapy alone or on no antithrombotic medication (1.8%, p=0.008 by chi-square test).

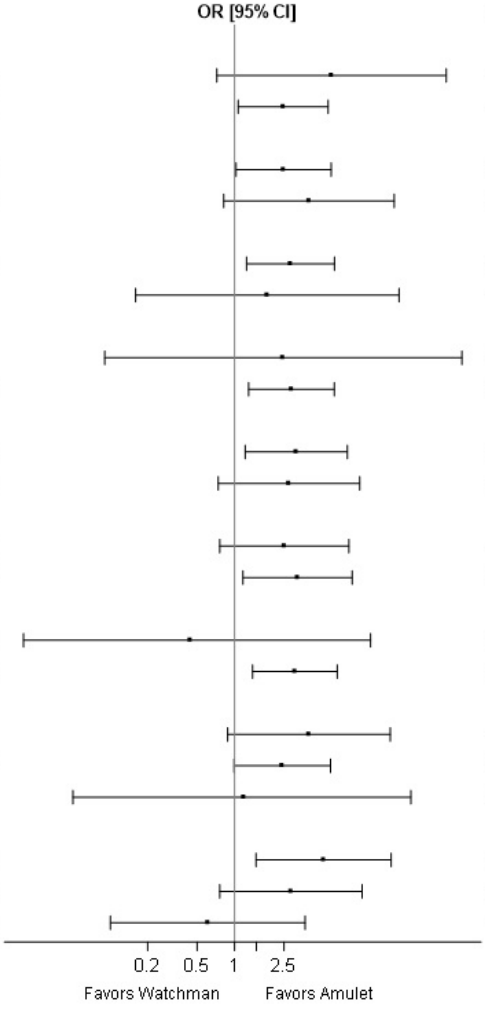


*Oral anticoagulation. One patient was discharged on low molecular weight heparin and is counted in this category

9. FIGURE SIII: SUBGROUP ANALYSIS FOR THE PRIMARY MECHANISM OF ACTION ENDPOINT

Subgroup analyses were conducted on the primary mechanism of action endpoint for age, gender, race, ethnicity, stroke risk, bleeding risk, device size, and AF pattern via an interaction test between treatment group and subgroup stratum in a logistic regression model. No significant interaction effects were observed (interaction p-value > 0.15 for all subgroups), indicating there is no evidence that the difference in device closure rates between Amulet and Watchman is different across the subgroup strata.

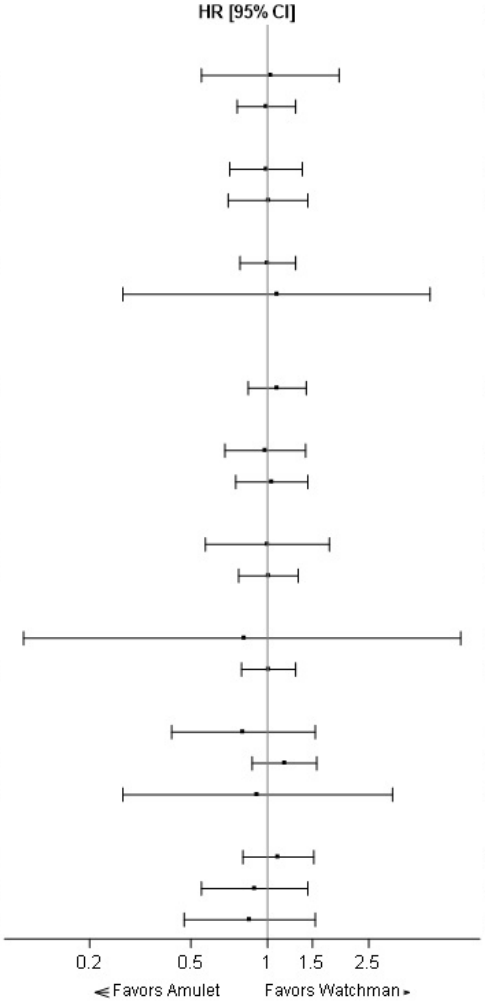
Subgroup	Amulet	Watchman	OR [95% CI]	P-value
Age				
< 70 years	99.4% (0.6%) [n=169]	96.5% (1.4%) [n=173]	6.04 [0.72, 50.68]	0.44
≥ 70 years	98.7% (0.4%) [n=632]	96.9% (0.7%) [n=619]	2.47 [1.07, 5.68]	
Gender				
Male	98.5% (0.6%) [n=462]	96.3% (0.9%) [n=489]	2.48 [1.03, 6.00]	0.60
Female	99.4% (0.4%) [n=339]	97.7% (0.9%) [n=303]	3.98 [0.82, 19.33]	
Race				
White	98.9% (0.4%) [n=719]	96.9% (0.6%) [n=714]	2.83 [1.25, 6.39]	0.74
Others	97.1% (2.9%) [n=34]	94.7% (3.6%) [n=38]	1.83 [0.16, 21.17]	
Ethnicity*				
Hispanic or Latino	100.0% (0.0%) [n=22]	96.4% (3.5%) [n=28]	2.45 [0.09, 67.75]	0.92
Non-Hispanic or non-Latino	98.8% (0.4%) [n=693]	96.6% (0.7%) [n=681]	2.88 [1.30, 6.36]	
CHADS2 Score				
< 3	98.5% (0.6%) [n=411]	95.6% (1.1%) [n=360]	3.14 [1.22, 8.11]	0.86
≥ 3	99.2% (0.4%) [n=389]	97.9% (0.7%) [n=432]	2.74 [0.74, 10.18]	
CHA2DS2-VASc Score				
< 4	98.0% (1.0%) [n=200]	95.1% (1.6%) [n=184]	2.52 [0.76, 8.33]	0.75
≥ 4	99.2% (0.4%) [n=601]	97.4% (0.6%) [n=608]	3.22 [1.17, 8.85]	
HAS-BLED Score*				
< 2	96.0% (3.9%) [n=25]	100.0% (0.0%) [n=18]	0.44 [0.02, 12.46]	0.26
≥ 2	99.0% (0.4%) [n=775]	96.8% (0.6%) [n=774]	3.07 [1.40, 6.72]	
Device Size*				
Small	99.0% (0.6%) [n=290]	96.0% (2.3%) [n=75]	3.97 [0.88, 17.95]	0.75
Medium	98.8% (0.5%) [n=493]	96.9% (0.7%) [n=622]	2.42 [0.99, 5.94]	
Large	100.0% (0.0%) [n=15]	96.8% (1.8%) [n=94]	1.19 [0.05, 26.33]	
AF Pattern				
Paroxysmal	99.3% (0.4%) [n=458]	96.7% (0.9%) [n=421]	5.22 [1.49, 18.28]	0.15
Persistent	98.6% (0.8%) [n=213]	96.1% (1.3%) [n=230]	2.85 [0.76, 10.67]	
Permanent	97.7% (1.3%) [n=130]	98.6% (1.0%) [n=141]	0.61 [0.10, 3.70]	



10. FIGURE SIV: SUBGROUP ANALYSIS FOR THE PRIMARY SAFETY ENDPOINT (PP)

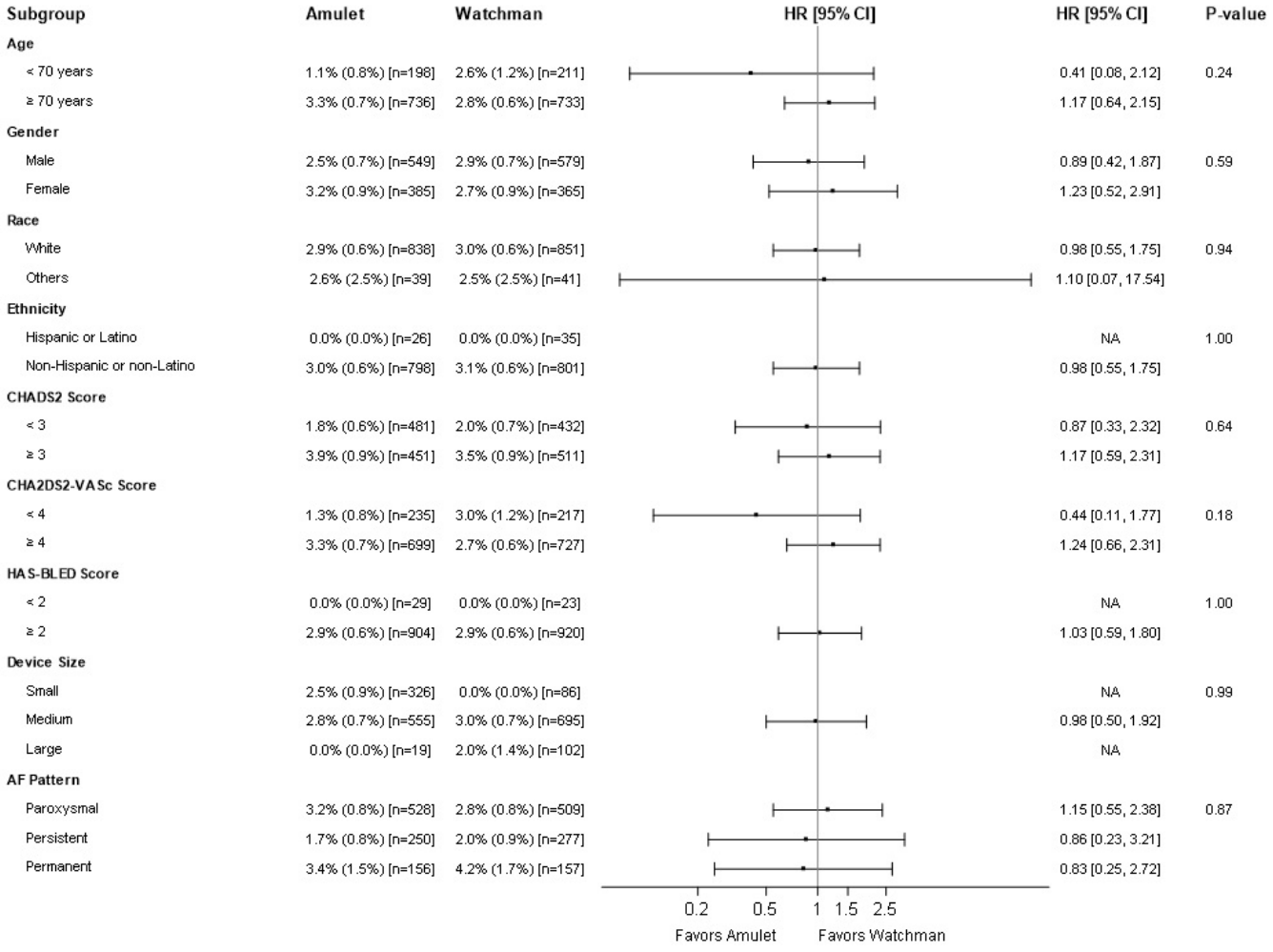
Subgroup analyses were conducted on the primary safety endpoint for age, gender, race, ethnicity, stroke risk, bleeding risk, device size, and AF pattern via a Cox regression model. No significant interaction effects were observed (interaction p-value >0.15 for all subgroups), indicating that there is no evidence that the difference in event rates between the Amulet and Watchman groups is different across the subgroup strata.

Subgroup	Amulet	Watchman	HR [95% CI]	P-value
Age				
< 70 years	10.6% (2.2%) [n=189]	10.4% (2.2%) [n=195]	1.03 [0.55, 1.91]	0.92
≥ 70 years	15.6% (1.4%) [n=714]	15.9% (1.4%) [n=701]	0.99 [0.76, 1.29]	
Gender				
Male	13.1% (1.5%) [n=528]	13.3% (1.5%) [n=548]	0.99 [0.71, 1.37]	0.93
Female	16.6% (1.9%) [n=375]	16.8% (2.0%) [n=348]	1.01 [0.70, 1.44]	
Race				
White	14.8% (1.2%) [n=812]	14.9% (1.3%) [n=813]	1.00 [0.78, 1.29]	0.90
Others	10.8% (5.1%) [n=37]	10.3% (4.9%) [n=39]	1.09 [0.27, 4.35]	
Ethnicity				
Hispanic or Latino	0.0% (0.0%) [n=26]	12.0% (5.6%) [n=34]	NA	0.96
Non-Hispanic or non-Latino	15.2% (1.3%) [n=771]	14.1% (1.3%) [n=764]	1.09 [0.84, 1.42]	
CHADS2 Score				
< 3	13.2% (1.6%) [n=463]	13.6% (1.7%) [n=414]	0.98 [0.68, 1.41]	0.82
≥ 3	16.0% (1.8%) [n=438]	15.6% (1.7%) [n=481]	1.04 [0.75, 1.44]	
CHA2DS2-VASc Score				
< 4	11.2% (2.1%) [n=224]	11.2% (2.2%) [n=207]	1.00 [0.57, 1.75]	0.97
≥ 4	15.6% (1.4%) [n=679]	15.7% (1.4%) [n=689]	1.01 [0.77, 1.32]	
HAS-BLED Score				
< 2	7.7% (5.2%) [n=27]	9.1% (6.1%) [n=22]	0.81 [0.11, 5.74]	0.83
≥ 2	14.8% (1.2%) [n=875]	14.8% (1.2%) [n=873]	1.01 [0.79, 1.29]	
Device Size				
Small	11.6% (1.8%) [n=320]	14.3% (3.8%) [n=84]	0.80 [0.42, 1.54]	0.55
Medium	16.0% (1.6%) [n=549]	14.1% (1.3%) [n=678]	1.17 [0.87, 1.56]	
Large	15.8% (8.4%) [n=19]	17.9% (3.8%) [n=101]	0.91 [0.27, 3.10]	
AF Pattern				
Paroxysmal	15.6% (1.6%) [n=513]	14.5% (1.6%) [n=480]	1.10 [0.80, 1.52]	0.65
Persistent	12.8% (2.2%) [n=242]	14.2% (2.2%) [n=264]	0.89 [0.55, 1.44]	
Permanent	13.5% (2.8%) [n=148]	16.0% (3.0%) [n=152]	0.85 [0.47, 1.54]	



11. FIGURE SV: SUBGROUP ANALYSIS FOR THE PRIMARY EFFECTIVENESS ENDPOINT (ITT)

Subgroup analyses were conducted on the primary effectiveness endpoint for age, gender, race, ethnicity, stroke risk, bleeding risk, device size, and AF pattern via a Cox regression model. No significant interaction effects were observed (interaction p-value >0.15 for all subgroups), indicating that there is no evidence that the difference in event rates between the Amulet and Watchman groups is different across the subgroup strata.



12. TABLE SVII: ADDITIONAL ANALYSES OF PRIMARY ENDPOINTS

Endpoint	Amulet Occluder	Watchman Device	P-value for non-inferiority
	No. of patients (%)		
Primary Mechanism of Action Endpoint including unsuccessful implants	792 (86.6)	767 (83.7)	<0.001
Primary Safety Endpoint after multiple imputation to account for missing data[1]	14.7% (1.2%)	15.3% (1.2%)	<0.001
Primary Safety Endpoint (AT)	134 (14.6)	133 (14.7)	<0.001
Procedure Related Complications	41 (4.5)	23 (2.5)	
Major Bleeding (Type 3 or greater)	98 (10.8)	89 (9.9)	
Non-Procedure Related Major Bleeding	73 (8.1)	70 (7.8)	
All-Cause Death	35 (3.8)	47 (5.2)	
Primary Effectiveness Endpoint after multiple imputation to account for missing data[1]	2.9% (0.6%)	3.1% (0.6%)	<0.001
Primary Effectiveness Endpoint (PP)	23 (2.6)	23 (2.8)	<0.001
Ischemic Stroke	20 (2.3)	22 (2.6)	
Systemic Embolism	3 (0.3)	2 (0.2)	
Primary Effectiveness Endpoint excluding the first 45 days post procedure[1]	19 (2.2)	21 (2.5)	<0.001
Cox Regression with OAC use as a time varying covariate	0.65 [0.42, 1.00][2]		

[1] Kaplan-Meir event rate (std. error) [2] Hazard ratio of Amulet vs. Watchman and 95% confidence interval

13. TABLE SVIII: PROCEDURE-RELATED COMPLICATIONS AT 12 MONTHS (PP POPULATION, FIRST EVENT)

Event Description	Amulet Occluder (N=903)	Watchman Device (N=896)
Pericardial Effusion/Tamponade 0-2 days post procedure	12	10
Pericardial Effusion/Tamponade >2 days post procedure	10	1
Device Embolization	6	2
Vascular Access-Related Complications	3	3
Air Embolus	0	2
Cardiac Perforation	1	1
Esophageal Laceration and Rupture	1	1
Hematoma	1	1
Pleural Effusion	2	0
Third Degree Heart Block/Asystole	1	1
Acute Peritonitis	1	0
Gastrointestinal Bleeding	1	0
Hematuria	1	0
Inferior Myocardial Infarction	1	0
Ischemic Stroke	0	1
Peripheral Arterial Occlusion	1	0
Total Number of Patients*	**41**	**22**

*One Amulet patient experienced both pericardial effusion and pleural effusion on POD 20. One Watchman patient experienced both air embolism and ischemic stroke on POD 0. Therefore, these totals are not equal to the sum of the numbers in the rows above.