

AMPLATZER® AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER

Consider occluding the left atrial appendage to reduce stroke risk in Atrial Fibrillation (AFib) patients who have suffered an intracerebral hemorrhage (ICH) and have been on anticoagulant medication.



A CHALLENGING DILEMMA

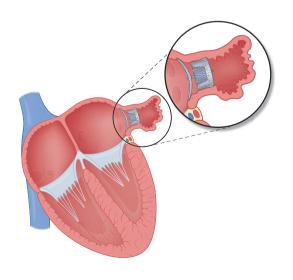
Neurologists are presented with a challenge when an Atrial Fibrillation (AFib) patient on oral anticoagulants (OAC) suffers an intracerebral hemorrhage (ICH). While OAC drugs can be effective in mitigating stroke caused by thrombus build-up and embolism from the left atrial appendage (LAA)¹, OAC drugs can increase the risk of a recurrent ICH event².

Faced with these alternatives, physicians most often decide to discontinue OAC therapy, thus leaving patients exposed to ischemic stroke.



THE OCCLUSION ANSWER

Left atrial appendage occluders are designed to reduce the risk of thrombus embolization from the left atrial appendage (LAA)—the most common source of thrombus-causing stroke in Atrial Fibrillation (AFib) patients. By sealing off the LAA, ICH patients with AFib who are unable to take oral anticoagulation are protected from LAA-related thromboembolism.



THE AMPLATZER® AMULET™ LEFT ATRIAL APPENDAGE OCCLUDER:

Complete Closure—Designed to completely seal the LAA at the ostium, reducing the risk of thrombus embolization from the LAA.

Minimally Invasive—Deployed in a catheter-based procedure using the transfemoral vein.

Straightforward Procedure—Performed by an interventional cardiologist or electrophysiologist under general anaesthesia or sedation in approximately 1 hour, with a 1-2 day hospital stay.

AMPLATZER AMULET: SUPPORTED BY GUIDELINES, PROVEN BY REAL WORLD EXPERIENCE



AUTHORIZED BY ESC AF GUIDELINES

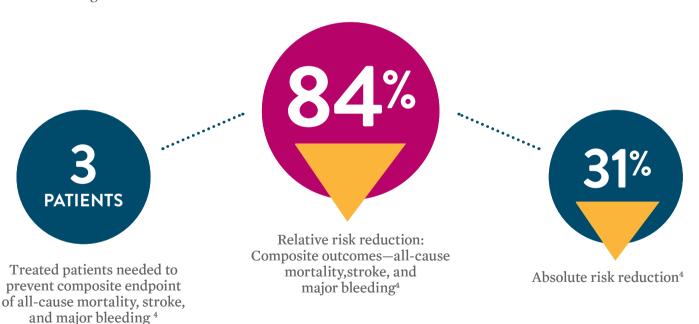
"LAA occlusion may be considered for stroke prevention in patients with AF and contra-indications for long-term oral anticoagulation treatment"—IIb, level of evidence B³.

PROVEN SUPERIOR TO MEDICAL MANAGEMENT

For Afib patients with a prior ICH, AMPLATZER Amulet is proven superior to medical management⁴ for the reduction of ischemic stroke, all-cause mortality, and major bleeding.

RELATIVE RISK REDUCTION: AMPLATZER AMULET VS. MEDICAL MANAGEMENT

In a study of 302 patients, 151 were treated with Left Atrial Appendage Occlusion and 151 were treated with medical management.⁴





Relative risk reduction: Ischemic stroke⁴



Relative risk reduction: Mortality⁴



Relative risk reduction: Major bleeding⁴



Relative risk reduction: Recurrent ICH⁴



AMPLATZER® AMULET™

For ICH patients with AFib, the AMPLATZER AMULET Left Atrial Appendage Occlusion device is a proven, reliable, minimally-invasive way to reduce the risk of LAA-related thromboembolism and ischemic stroke when anticoagulant medication is discontinued.

CONNECT WITH AN INTERVENTIONAL CARDIOLOGIST OR ELECTROPHYSIOLOGIST TO DISCUSS THE OPTION OF LEFT ATRIAL APPENDAGE OCCLUSION FOR YOUR ICH PATIENTS WITH AFIB.

REFERENCES

- $\textbf{1.} \text{Lip 2015 Stroke Prevention (v1.0) GYH, Lane DA. Stroke Prevention in Atrial Fibrillation: A Systematic Review. \textit{JAMA}. 2015; 313(19):1950-1962. \\ \text{doi:} 10.1001/\text{jama.} 2015.4369 \\ \text{$
- 2. Angelozzi A, Renda G, et al. The Risk of Intracranial Hemorrhage with Anticoagulation in the Elderly Estimates of Prevalence (v1.0) and Therapeutic Strategies. American College of Cardiology, 2015; Available from: http://www.acc.org/latest-in-cardiology/articles/2015/12/21/12/59/the-risk-of-intracranial-hemorrhage-with-anticoagulation-in-the-elderly; Accessed June 6, 2018.
- 3. Kirchhof 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration (vl.0) with EACTS. European Heart Journal. 2016;37(38):2893-2962.
 4. Nielsen-Kudsk, 2017 Left atrial appendage occlusion (vl.0) versus standard medical care in patients with atrial fibrillation and intracerebral hemorrhage: A propensity score matched follow-up study. EuroIntervention. doi:10.4244/EIJ-D-17-00201.

CAUTION: This product is 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://manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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