Catalyst

INVESTIGATORS	• Dinesh Sharma, MD-Principal Investigator • Robert Cubeddu, MD Sub Investigator • Adam Frank, MD Sub-Investigator • David Axline, MD Sub-Investigator
Trial Objective	• The objective of this trial is to evaluate the safety and effectiveness of the Amulet device compared to NOAC therapy in patients with non-valvular AF at increased risk for ischemic stroke and who are recommended for long-term NOAC therapy.
Randomization	• Subjects will be randomized in a 1:1 ratio between the Amulet LAA occlusion device (Device Group) and a commercially available NOAC medication (Control Group). The choice of NOAC in the Control Group will be left to study physician discretion.
Key Inclusion	• Documented paroxysmal, persistent, or permanent non-valvular AF • High Risk of stroke or systemic embolism, defined as a CHA_2DS_2-VAS_c Score of ≥ 3 • Eligible for long-term NOAC therapy
Key Exclusion	• Requires long-term OAC therapy for a condition other than AF • Has Undergone ASD repair or ASD closure • Has undergone PFO or has a PFO closure device implanted • Is implanted with a mechanical valve prosthesis • Is implanted with an inferior vena cava filter • History of rheumatic or congenital mitral valve heart disease • NYHA Class IV Congestive Heart Failure • LVEF ≤ 30%