

Reduce PAS

<u>INVESTIGATORS</u>	<ul style="list-style-type: none">• Robert Cubeddu, MD- Primary investigator• Mazen Albaghdadi, MD- Sub-Investigator• Adam Frank, MD- Sub Investigator• Michael Vickers, MD – Sub-Investigator
<u>Trial Objective</u>	<ul style="list-style-type: none">• The purpose of the GORE® CARDIOFORM Septal Occluder (GSO device) post-approval study is to assess the safety and effectiveness of GSO device as observed in the REDUCE pivotal IDE study, and to evaluate the quality of operator education and training and transferability of trial experience to a post-market setting.
<u>Randomization</u>	<ul style="list-style-type: none">• All patient meeting Inclusion/Exclusion Criteria Received Study device
<u>Key Inclusion</u>	<ul style="list-style-type: none">• Patient is age 18-70 at the time of informed consent signature• Embolic stroke within last 455 days• Patient has presence of PFO• Patient is able to tolerate antiplatelet therapy
<u>Key Exclusion</u>	<ul style="list-style-type: none">• Patient has ongoing history of AFIB-Aflutter• Patients has comorbidities including but not limited to, cardiac prosthetics, severe native valve disease, aortic dissection, prior intracranial hemorrhage, LVEF of <40%• Patient has previously myocardial infraction