

GORE® CARDIOFORM Septal Occluder and Antiplatelet Medical Management for Reduction of Recurrent Stroke in Patients With Patent Foramen Ovale (PFO): the REDUCE Post Approval Study

NCT03821129

Status	RECRUITING
Phase	Not Applicable
Sponsor	W.L.Gore & Associates
Enrollment	636 participants

Key Eligibility Criteria

Inclusion (3)

- Diagnosed with an ischemic stroke presumed to be an embolic stroke of undetermined source (ESUS) verified by a neurologist within the last 365 days prior to enrollment.
- Presence of Patent Foramen Ovale (PFO), as determined initially by positive bubble study utilizing transesophageal echocardiography (TEE) and/or transcranial Doppler (TCD), demonstrating spontaneous right-to-left shunting or right-to-left shunting during Valsalva maneuver.
- Patient is able to tolerate antiplatelet therapy

Exclusion (12)

- History of or ongoing atrial fibrillation/flutter
- Other co-morbidities including, but not limited to, mural thrombus, dilated cardiomyopathy, cardiac prosthetics (valves), severe native valve disease (including mitral valve stenosis), severe ventricular wall motion abnormalities, aortic dissection, significant atherosclerosis, vasculitis, pre-existing non-vascular neurologic disorders, pulmonary arteriovenous malformations, prior intracranial hemorrhage, severe disability related to prior stroke, autoimmune disorders that would increase the risk of stroke or thromboembolism, or associated with increased risk of infection or procedural complications, in the opinion of the investigator, left ventricular ejection fraction of $<40\%$, coexistent cause or intra-cardiac shunting (e.g. VSD or ASD)
- Previous Myocardial Infarction
- Rankin Scale score greater than or equal to 3 at the time of procedure
- Active infection that cannot be treated successfully prior to enrollment
- ... and 7 more (see full listing online)

Locations (44 total)

St. Mary's Hospital, Tucson, Arizona, United States
Scripps Health La Jolla, La Jolla, California, United States
Loma Linda University Health, Loma Linda, California, United States
... and 41 more locations

<https://clinicaltrials.gov/study/NCT03821129>

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