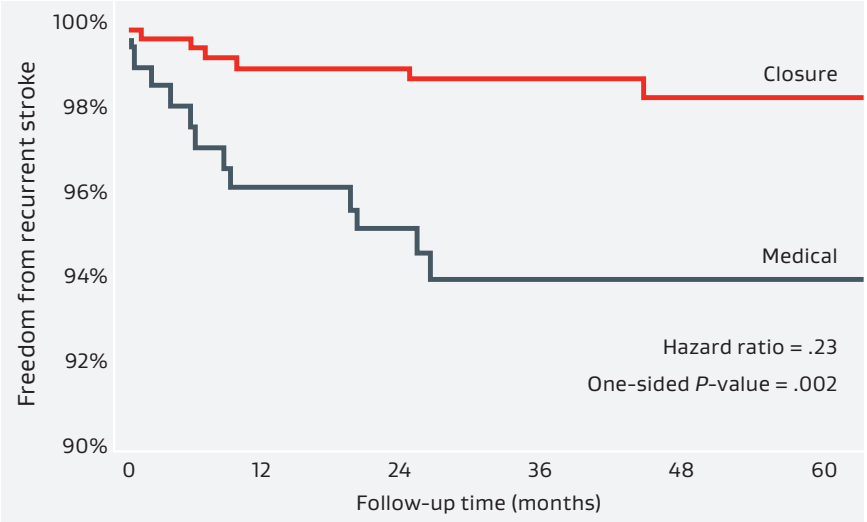
GORE REDUCE CLINICAL STUDY SUB-ANALYSIS SUMMARY

"Characterization of recurrent strokes with and without patent foramen ovale closure (PFO)" as published in the *Journal of American College of Cardiology*

Recurrent ischemic stroke (*P* = .002)

Closure (N = 441)	Medical (N = 223)
Events (Rate*) 6 (.39)	Events (Rate*) 12 (1.71)



77% Relative recurrent stroke reduction with PFO closure plus medical therapy versus medical therapy alone†,[1]

Sub-analysis: Recurrent moderate-to-severe stroke (*P* = .004)

PFO closure plus medical management significantly reduced recurrent moderate-to-severe stroke versus medical management alone.[2]

Closure (N = 441)	Medical (N = 223)
Events (Rate*) 0 (0.00)	Events (Rate*) 4 (0.57)

Moderate-to-severe stroke defined by last-available modified Rankin Scale > 2 or National Institutes of Health Stroke Scale > 5, treatment with intravenous thrombolysis and / or mechanical thrombectomy, or judgment of clinical events committee based on qualitative description of deficits and functional abilities.

Sub-analysis: Recurrent cryptogenic stroke (*P* = .004)

PFO closure plus medical management significantly reduced the risk of recurrent cryptogenic stroke versus medical management alone.‡,[2]

Closure (N = 441)	Antiplatelet (N = 223)
Events (Rate*) 4§ (.26)	Events (Rate*) 9‖ (1.28)

Study design: prospective, randomized, multicenter, multinational, open label trial

664 Patients

- Patients with a cryptogenic¶, ischemic stroke, verified by a neurologist and a PFO**
- Age range: 18-59
- Median follow-up: 3.2 years

441 PFO closure group

- Gore device† plus antiplatelet therapy

223 Medical therapy group

- Antiplatelet therapy

* Rates per 100 person-yrs.

† The REDUCE study determined safety and efficacy of patent foramen ovale (PFO) closure with the GORE® CARDIOFORM Septal Occluder or GORE® HELEX® Septal Occluder plus antiplatelet medical management compared to antiplatelet medical management alone in patients with a PFO and history of cryptogenic stroke. All PFO anatomies were incorporated into this study within indicated sizing parameters of the *Instructions for Use*.

‡ Standard classification systems (TOAST [Trial of ORG 10172 in Acute Stroke Treatment]/ASCOD [Atherosclerosis, Small vessel, Cardioembolism, Other, or Dissection]).

§ Of the 6 recurrent strokes 4 were cryptogenic (3 PFOs completely closed, 1 small residual shunt), 1 was attributed to cardioembolism (atrial fibrillation), and 1 to large artery disease (both completely closed).

II Of the 12 recurrent strokes in the, 9 were cryptogenic, while 3 were attributed to small vessel disease.

¶ Cryptogenic diagnosed as: No stenosis > 50 percent or ulcerated plaque in relevant intra- or extra-cranial vessels, no atrial fibrillation or high-risk source of cardioembolism, non-lacunar (based on neuroimaging), no evidence of hypercoagulable disorder, no other known cause of stroke.

** PFO confirmed by transesophageal echocardiography (TEE / TOE) with bubble study demonstrating right-to-left shunt at rest or during Valsalva maneuver. Patients with PFO eligible regardless of shunt size or presence of atrial septal aneurysm.

1. Søndergaard L, Kasner SE, Rhodes JF, *et al*; Gore REDUCE Study Investigators. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *New England Journal of Medicine* 2017;377(11):1033-1042.

2. Kasner SE, Kase CS, Turan TN, *et al*; REDUCE Study Investigators. Characterization of recurrent strokes with and without patent foramen ovale closure. *Journal of the American College of Cardiology* 2018;72(20):2542-2544.

INDICATIONS FOR USE IN AUSTRALIA, CANADA AND EUROPE: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of atrial septal defects (ASDs), such as ostium secundum and patent foramen ovale. **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take anti-platelet or anticoagulant medications such as aspirin, heparin or warfarin; with anatomy where the GORE® CARDIOFORM Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. ℞ Only

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Products listed may not be available in all markets.

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