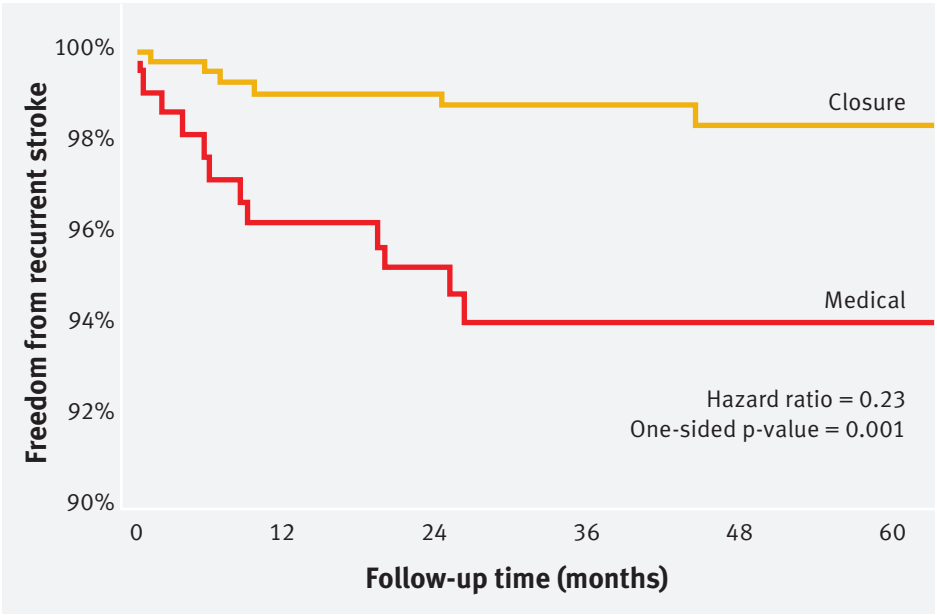
Redefining stroke prevention

Gore REDUCE Clinical Study

The REDUCE Study is the **only** U.S. IDE trial that achieved its primary end point and showed **the largest reduction** in recurrent ischemic stroke*,1 in **all PFO shunt sizes** over medical therapy alone.



77%
Stroke reduction

With PFO closure* plus medical therapy vs. medical therapy alone

No difference in overall SAE rate**	**Low risk†**	**98% Effective closure rate‡,1**
Between closure and medical therapy groups	Of device or procedure-related SAEs	At twelve months

Important Information: This information is intended for education and awareness only. Patients should consult their physician for information on the risks associated with the devices and surgical procedures discussed in this website. All surgical procedures carry potential health risks. Not all patients will be candidates for treatment with these devices, and individual outcomes may vary.

Always follow physician advice on your post-surgery care and recovery.

Refer to the *Instructions for Use* for a complete list of warnings, precautions, contraindications, potential adverse events, and patient-specific information.

Caution: U.S. law restricts use of this device on the order of a physician ℞ Only.

* 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*.

** There was no statistically significant difference in the rate of serious adverse events (SAE) between the closure and medical groups. There was a significantly higher rate of atrial fibrillation or flutter in the closure group (6.6 percent versus 0.4 percent) but the majority was non-serious (66 percent), peri-procedural (69 percent had onset within 30 days of the closure procedure), and had rapid resolution (59 percent with resolution within two weeks of onset). Average of 3.4 years follow-up.

† Device and procedure-related SAEs occurred in 1.4 and 2.5 percent, respectively, of closure patients.

‡ GORE® CARDIOFORM Septal Occluder effective closure rate results. Effective closure defined as freedom from large shunt > 25 bubbles as detected by transthoracic echocardiography adjudicated by echo core lab.

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.

GORE CARDIOFORM SEPTAL OCCLUDER

Redefining stroke prevention

Gore REDUCE Clinical Study

The REDUCE Study is the **only** U.S. IDE trial that achieved its primary end point and showed **the largest reduction** in recurrent ischemic stroke*,1 in **all PFO shunt sizes** over medical therapy alone.

Study design: Prospective, randomized, multinational, open label trial

664
Patients enrolled
Cryptogenic stroke and PFO† / Ages 18–59**

441 Closure group	2:1 Ratio	223 Medical therapy group
GORE® Device* plus antiplatelet therapy		Antiplatelet therapy

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** 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.

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