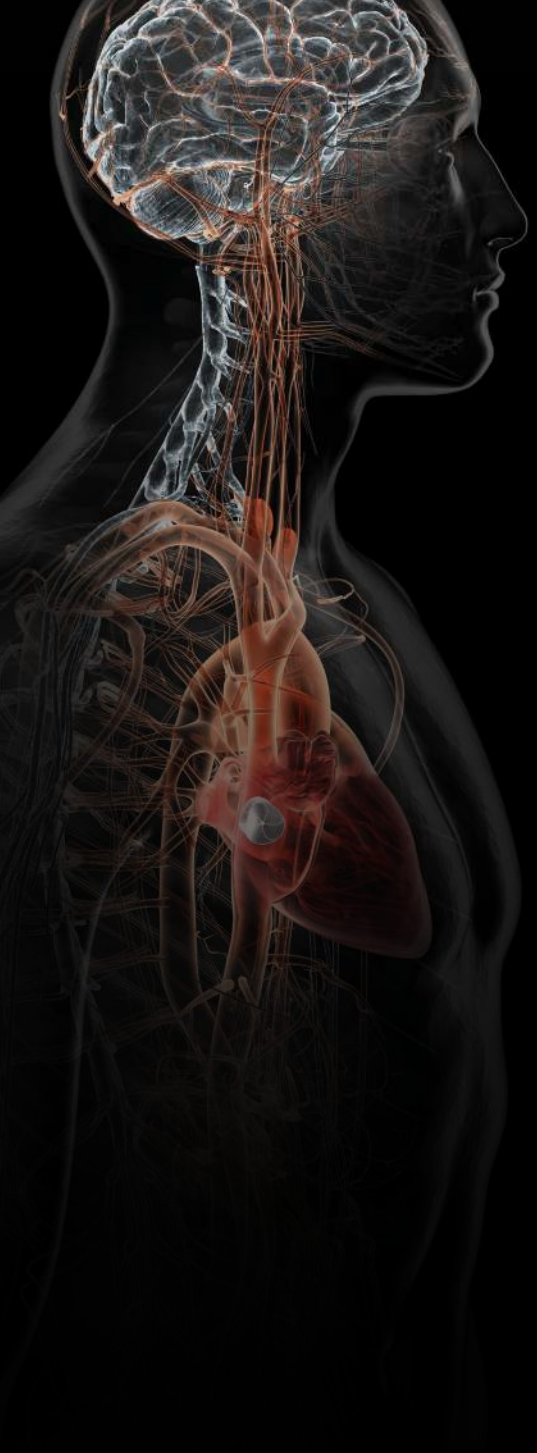

CLEAR DATA.
Confident stroke prevention.

GORE® CARDIOFORM Septal Occluder

An advanced occluder designed in partnership with global leading interventional cardiologists.

The GORE® CARDIOFORM Septal Occluder is approved for atrial septal defects (ASD) and now FDA approved for patent foramen ovale (PFO) closure to reduce the risk of recurrent ischemic stroke in select patients.*

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Gore REDUCE Clinical Study result highlights

Groundbreaking stroke reduction

- 77 percent relative reduction in stroke with PFO closure plus medical therapy versus medical therapy alone[†,1]

Continued legacy of safety

- No significant difference in overall serious adverse events (SAE) rate between closure and medical therapy groups[‡,1]
- Low device and procedure-related SAEs[§,1]

High procedural success

- 98.8 percent successful implant and retention of device[‖]
- 98 percent effective closure at 12 months[¶,1]
- Simplified delivery

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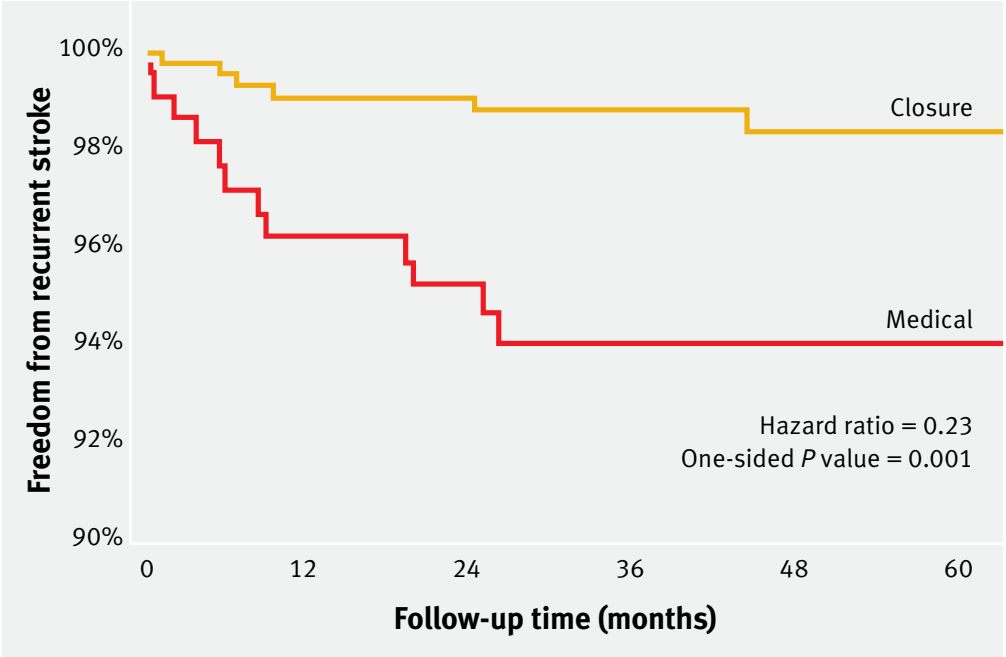
Groundbreaking stroke reduction

As published in the New England Journal of Medicine

The Gore REDUCE Clinical 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% **Relative Stroke Reduction**

With **PFO CLOSURE** plus medical therapy vs. medical therapy alone.[†,1]



Four times the protection against recurrent stroke than medical therapy alone.[†,1]

Protects against potentially **disabling strokes.**[†,2]

Number needed to treat: **Only 28 patients treated** to prevent one stroke at 24 months.[1]

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Continued legacy of safety

No significant difference in overall SAE rate between closure and medical management group.[†,‡,1]

Any serious adverse event

Closure (N = 441)	Medical (N = 223)	*P* value**
102 (23.1%)	62 (27.8%)	0.22

No significant difference in risk of serious atrial fibrillation, bleeding, deep vein thrombosis or pulmonary embolism with PFO closure.[†,1]

Serious adverse events of interest

	Closure (N = 441)	Medical (N = 223)	*P* value**
Serious atrial fibrillation / Atrial flutter	10 (2.3%)	1 (0.4%)	0.11
Bleeding	8 (1.8 %)	6 (2.7%)	0.57
Deep vein thrombosis	0	2 (0.9%)	1.00
Pulmonary embolism	2 (0.5%)	1 (0.4%)	1.00

Low device and procedure-related SAEs[§,1]

Related to device	Related to the procedure
6 (1.4%)	11 (2.5%)

Low risk of serious device or procedure-related atrial fibrillation or flutter[*,†,1]

Related to device	Related to the procedure
2 (0.5%)	0

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High global procedural success

Clinicians in seven countries experienced high technical success and high effective closure rates.

98.8% **technical success** ‖,1

98.0% **effective closure rate** ¶,1 at 12 months

Preassembled with minimal prep steps for simplified delivery.*

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Catalogue number	Device sizes (mm)
United States	
GSX0020A	20
GSX0025A	25
GSX0030A	30
Europe	
GSXE0020	20
GSXE0025	25
GSXE0030	30
Australia / Canada	
GSXE0020B	20
GSXE0025B	25
GSXE0030B	30

Contact your Gore field sales associate for more information.

* Refer to *Instructions For Use* for complete indication.

† 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.

II Technical success defined as: proportion of test arm subjects with successful implantation and retention of a study device where study device implant was attempted.

¶ GORE® CARDIOFORM Septal Occluder effective closure rate results in device group subjects who received a study device. Effective closure defined as freedom from large shunt > 25 bubbles as detected by transthoracic echocardiography adjudicated by echo core lab.

** P values were calculated with the use of Fisher's exact test.

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. Scott E. Kasner, Tanya N. Turan, Carlos Kase, Howard Rowley, Grethe Andersen, Helle Iversen, John Volpi, Steven R. Messe, Lars Sondergaard, John Rhodes, Christina Sjostrand, on behalf of the REDUCE Investigators. ESCO 2018 Conference.

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eifu.goremedical.com

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 eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. $R_{x\ Only}$

INDICATIONS FOR USE IN THE U.S.: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: Ostium secundum atrial septal defects (ASDs); patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: Unable to take antiplatelet 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 eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. $R_{x\ Only}$

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