RANDOMIZED CONTROLLED PATENT FORAMEN OVALE (PFO) CLOSURE TRIALS

Atrial fibrillation (AFib) and
atrial flutter clinical outcomes

Together, improving life

GORE

PFO closure and AFib: A clinical outcome review

As published in the *New England Journal of Medicine*.[1-3]

Randomized controlled PFO closure trials: AFib and atrial flutter clinical outcomes

The data presented below are from separate and independent clinical studies with different patient populations and interventions and thus not a direct head-to-head comparison.

	Gore REDUCE Clinical Study[2] Closure (N = 441) (median 5 years)
Any AFib	30 (6.8%)
Any atrial flutter	2 (0.5%)[a,4]
Serious AFib	10 (2.3%)
Serious atrial flutter	1 (0.2%)[4]
Serious device- or procedure-related AFib	2 (0.5%)[4]
Serious device- or procedure-related atrial flutter	0 (0%)[4]

	RESPECT Clinical Study[3] Closure (N = 499) (median 5.9 years)
Any AFib	22 (4.4%)[5]
Any atrial flutter	2 (0.4%)[5]
Serious AFib	6 (1.2%)
Serious atrial flutter	1 (0.2%)
Serious device or procedure related AFib	2 (0.4%)
Serious device or procedure related atrial flutter	1 (0.2%)

Both studies only had 1 patient with recurrent stroke and AFib

The data presented below are from separate and independent clinical studies with different patient populations and interventions and thus not a direct head-to-head comparison.

	Gore REDUCE Clinical Study[2] Closure (N = 441) (median 5 years)
Subjects with post-implant AFib or atrial flutter who had a recurrent stroke	1 (0.2%)

	RESPECT Clinical Study[3] Closure (N = 499) (median 5.9 years)
Subjects with post-implant AFib or atrial flutter who had a recurrent stroke	1 (0.2%)

a. Two subjects who experienced AFib also experienced atrial flutter.[4]

Understanding AFib and atrial flutter data in the REDUCE Study

The majority of the AFib and atrial flutter cases in the REDUCE Study were nonserious, early onset, and resolved.[1,2,b]

67% of AFib or atrial flutter cases were considered nonserious (20/30)[2,4]

AFib detected within 45 days after procedure[4]	24/30 (80%)
Cases that resolved within 2 weeks of onset[4]	18/30 (60%)

The REDUCE Study continues to show the largest reduction in recurrent ischemic stroke in all PFO shunt sizes over medical management alone.[1,2,b]

Randomized controlled PFO closure trials: Relative stroke reduction

The data presented below are from separate and independent clinical studies with different patient populations and interventions and thus not a direct head-to-head comparison.

	REDUCE Study[2]
Ischemic stroke reduction relative to medical management intention to treat	69%
Number needed to treat to prevent 1 recurrent stroke at 5 years	25

	RESPECT Study[3]
Ischemic stroke reduction relative to medical management intention to treat	45%[3]
Number needed to treat to prevent 1 recurrent stroke at 5 years	42[5]

b. The REDUCE Study determined the safety and efficacy of 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 the indicated sizing parameters of the *Instructions for Use*.

GORE® CARDIOFORM Septal Occluder

100,000+
devices sold globally[c]

14+
years of clinical use[c]

For more information on GORE® CARDIOFORM Septal Occluder, contact your Field Sales Associate.

c. Beginning in June 2011.

References

1. Søndergaard L, Kasner SE, Rhodes JF, et al; Gore REDUCE Clinical Study Investigators. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *N Engl J Med*. 2017;377(11):1033-1042. doi:10.1056/NEJMoa1707404
2. Kasner SE, Rhodes JF, Andersen G, et al; Gore REDUCE Clinical Study Investigators. Five-year outcomes of PFO closure or antiplatelet therapy for cryptogenic stroke. *N Engl J Med*. 2021;384(10):970-971. doi:10.1056/NEJMc2033779
3. Saver JL, Carroll JD, Thaler DE, et al; RESPECT Investigators. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. *N Engl J Med*. 2017;377(11):1022-1032. doi:10.1056/NEJMoa1610057
4. Data on file. W. L. Gore & Associates; 2026. FSR data export L_AE_CEC_XLS_CLSD_12_PT.
5. *Abbott. Amplatzer™ PFO Occluder Instructions for Use*. Abbott; 2022. ARTEN600197057_B.

Consult Instructions for Use
eifu.goremedical.com

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. $\mathrm{Rx}_{\text{Only}}$

INDICATIONS FOR USE IN THE US: 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.

Products listed may not be available in all markets.

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