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[1,2] Closure (N = 441) (median 5 years)	**RESPECT Clinical Study[3] Closure (N = 499) (median 5.9 years)**
Any AFib	30 (6.8%)	22 (4.4%)[4]
Any atrial flutter	2 (0.5%)	2 (0.4%)[4]
Serious AFib	10 (2.3%)	6 (1.2%)
Serious atrial flutter	1 (0.2%)	1 (0.2%)
Serious device or procedure related AFib	2 (0.5%)	2 (0.4%)
Serious device or procedure related atrial flutter	0 (0%)	1 (0.2%)

Both studies only had one 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.

	REDUCE Study[1,2] Closure (N = 441) (median 5 years)	**RESPECT Study[3] Closure (N = 499) (median 5.9 years)**
Subjects with post-implant AFib or flutter who had a recurrent stroke	1 (0.2%)	1 (0.2%)

Understanding AFib and atrial flutter data in the Gore REDUCE Clinical Study

Majority of the AFib and atrial flutter cases in the REDUCE Study were non-serious, early onset and resolved.*[,1,2]

67% AFib or atrial flutter cases considered non-serious (20/30)[1,2]

AFib detected within 45 days post procedure[1,2]	24/30 (80%)
Cases that resolved within 2 weeks of onset[1,2]	18/30 (60%)

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

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]	RESPECT Study[3]
Ischemic stroke reduction relative to medical management intention to treat	69%	45%[3]
Number needed to treat to prevent one recurrent stroke at 5 years	25	42[4]

* The REDUCE Study determined 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 indicated sizing parameters of the *Instructions for Use*.

GORE® CARDIOFORM Septal Occluder

68,000+ devices sold globally

11+ years of clinical use*

250+ publications[5]

* Beginning in June 2011.

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

References

1. Søndergaard L, Kasner SE, Rhodes JF, *et al*; Gore REDUCE Study Investigators. PFO closure or antiplatelet therapy for cryptogenic stroke. *New England Journal of Medicine* 2017;377(11):1033-1042.
2. Kasner SE, Rhodes JF, Andersen G; Gore REDUCE Clinical Study Investigators. Five-year outcomes of PFO closure or antiplatelet therapy for cryptogenic stroke. *New England Journal of Medicine* 2021;384(10):970-971.
3. Saver JL, Carroll JD, Thaler DE, *et al*, RESPECT Investigators. Long-term outcomes of PFO closure or medical therapy after stroke. *New England Journal of Medicine* 2017;377(11):1022-1032.
4. Amplatzer™ PFO Occluder [Instructions for Use]. Plymouth, MN: Abbott Medical; 2022. ARTEN600197057 A.
5. W. L. Gore & Associates, Inc. *GORE® CARDIOFORM Septal Occluder Complete Bibliography.* Flagstaff, AZ: W. L. Gore & Associates, Inc.; 2020 [Bibliography].

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN AUSTRALIA 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 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. ℞ Only

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