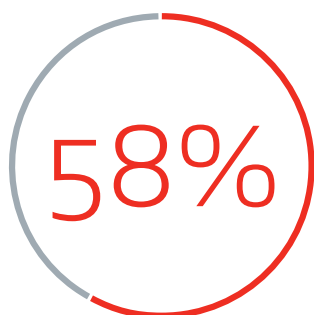


PFO CLOSURE META-ANALYSIS

"Meta-analysis comparing patent foramen ovale (PFO) closure versus medical therapy to prevent recurrent cryptogenic stroke" as published in the *American Journal of Cardiology*

Meta-analysis of five randomized controlled trials (RCTs) found PFO closure plus medical management significantly reduces the risk of recurrent stroke compared to medical management alone.¹



Relative recurrent stroke risk reduction with PFO closure plus medical therapy versus medical therapy alone¹

Stroke events

(p = .03)

Closure	Medical
(N = 1829)	(N = 1611)
37 (2%)	72 (4.5%)

Major bleeding

(p = .93)

No increased risk of major bleeding with PFO closure¹

Closure	Medical
(N = 1760)	(N = 1523)
24 (1.4%)	19 (1.2%)

Atrial fibrillation (AF)

(p = .0001)

Increased risk of AF with PFO closure¹

Closure	Medical
(N = 1784)	(N = 1607)
76 (4.3%)*	12 (.7%)*

71% (54 / 76) of AF events were considered transient¹

* Newly detected AF.

3,440 Patients

- Cryptogenic stroke† and PFO‡
- Mean age range: 43–50
- Mean follow-up: 4.1 years

1,829 PFO closure group

- Devices varied
- Medical therapy regimen: Varied per study — Antiplatelet, anticoagulation or both

1,611 Medical therapy group

- Medical therapy regimen: Varied per study — Antiplatelet, anticoagulation or both

RCTs: Closure 1-2012²,
PC Trial-2013³,
REDUCE-2017⁴,
RESPECT-2017⁵
and CLOSE-2017⁶

† Variable rates of cardiovascular risk factors.

‡ Variable rates of high-risk PFO features.

1. Ando T, Holmes AA, Pahuja M, et al. Meta-analysis comparing patent foramen ovale closure versus medical therapy to prevent recurrent cryptogenic stroke. *American Journal of Cardiology* 2018;121(5):649-655.
2. Furlan AJ, Reisman M, Massaro J, Mauri L, Adams H, Albers GW, Felberg R, Herrmann H, Kar S, Landzberg M, Raizner A, Wechsler L, CLOSURE I Investigators. Closure or medical therapy for cryptogenic stroke with patent foramen ovale. *N Engl J Med* 2012;366:991-999.
3. Meier B, Kalesan B, Mattle HP, Khattab AA, Hildick-Smith D, Dudek D, Andersen G, Ibrahim R, Schuler G, Walton AS, Wahl A, Windecker S, Juni P, PC Trial Investigators. Percutaneous closure of patent foramen ovale in cryptogenic embolism. *N Engl J Med* 2013;368:1083-1091.
4. Sondergaard L, Kasner SE, Rhodes JF, Andersen G, Iversen HK, Nielsen-Kudsk JE, Settergren M, Sjostrand C, Roine RO, Hildick-Smith D, Spence JD, Thomassen L, Gore REDUCE Clinical Study Investigators. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *N Engl J Med* 2017;377:1033-1042.
5. Saver JL, Carroll JD, Thaler DE, Smalling RW, MacDonald LA, Marks DS, Tirschwell DL, RESPECT Investigators. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. *N Engl J Med* 2017;377:1022-1032.
6. Mas JL, Derumeaux G, Guillon B, Massardier E, Hosseini H, Mechtouff L, Arquizan C, Bejot Y, Vuillier F, Detante O, Guidoux C, Canaple S, Vaduva C, Dequatre-Ponchelle N, Sibon I, Garnier P, Ferrier A, Timsit S, Robinet-Borgomano E, Sablot D, Lacour JC, Zuber M, Favrole P, Pinel JF, Apoil M, Reiner P, Lefebvre C, Guerin P, Piot C, Rossi R, Dubois-Rande JL, Eicher JC, Meneveau N, Lussion JR, Bertrand B, Schleich JM, Godart F, Thambo JB, Leborgne L, Michel P, Pierard L, Turc G, Barthelet M, Charles-Nelson A, Weimar C, Moulin T, Juliard JM, Chatellier G, CLOSE Investigators. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. *N Engl J Med* 2017;377:1011-1021.

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. Rx 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 ostium secundum atrial septal defects (ASDs). **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 contraindications, warnings, precautions and adverse events. Rx only

Products listed may not be available in all markets.

GORE and designs are trademarks of W. L. Gore & Associates, Inc.
© 2019 W. L. Gore & Associates, Inc. OCTOBER 2019

