REDEFINING STROKE PREVENTION

Gore REDUCE Clinical Study
long-term outcomes

Together, improving life

The extended follow-up results from the REDUCE Study highlight that GORE® CARDIOFORM Septal Occluder* can be trusted for long-term safety and performance

Groundbreaking stroke risk reduction

The REDUCE Study continues to show the largest reduction in recurrent ischemic stroke in all Patent Foramen Ovale (PFO) shunt sizes over medical management alone.*,1,2

69%

relative stroke risk reduction with PFO closure plus medical management versus medical management alone at extended follow-up*,2

25

number needed to treat (NNT) to prevent one stroke at five years[2]

Closure (N = 441) Medical (N = 223)	**Original follow-up (median 3.2 years)[1]**	**Extended follow-up (median 5.0 years)[2]**
Ischemic stroke reduction relative to medical management alone	77% (*P* = .002)	69% (*P* = .007)
Closure group ischemic strokes	6 (1.4%)	8 (1.8%)
Medical therapy group ischemic strokes	12 (5.4%)	12 (5.4%)
NNT	28	25

High closure performance

Enduring effective closure for all patient types.*,1,2

	12-month assessment[3]	**24-month assessment**
GORE® CARDIOFORM Septal Occulder effective closure rate†	98%	99%

Data on file 2020;
W. L. Gore & Associates, Inc.;
Flagstaff, AZ.

Continued legacy of patient safety

Long-term results continue to demonstrate a legacy of patient safety with 2,069 patient years of data.[1,2]

Device and procedure serious adverse events (SAEs)

0

new device- or procedure-related SAEs at 5 years[2]

Closure (N = 441)	**Original follow-up (median 3.2 years)[1]**	**Extended follow-up (median 5.0 years)[2]**
Device SAE	6 (1.4%)	No change
Procedure SAE	11 (2.5%)	No change

Atrial fibrillation[1,2]

1

additional non-serious atrial fibrillation case after device implant found during extended follow-up and it resolved[2]

Closure (N = 441)	**Original follow-up (median 3.2 years)[1]**	**Extended follow-up (median 5.0 years)[2]**
Any atrial fibrillation	29 (6.6%)	30 (6.8%)
Serious atrial fibrillation	10 (2.3%)	No change
Serious device-related or procedure-related atrial fibrillation	2 (0.5%)	No change

Other safety information[1,2]

Consistently demonstrating no significant difference in risk of bleeding, deep vein thrombosis or pulmonary embolism in five-year follow-up versus medical management alone.[1,2]

0

clinical sequelae associated with wire frame fractures at original follow-up or during extended follow-up[2]

0

reported erosions at original follow-up or during extended follow-up[1,2]

Closure (N = 441)	**Original follow-up (median 3.2 years)[1]**	**Extended follow-up (median 5.0 years)[2]**
Clinical sequelae associated with wire frame fractures	0 (0%)	No change
Any deep vein thrombosis/ pulmonary embolism	3 (0.7%)	5 (1.1%)
Serious bleeding	8 (1.8%)	12 (2.7%)
Cardiac erosion	0 (0%)	No change

GORE® CARDIOFORM Septal Occluder:

45,000+ devices sold globally

9 years of clinical use§

250+ publications‖

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

References

* 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*.

† Effective closure defined as freedom from large shunt > 25 bubbles as detected by transthoracic echocardiography adjudicated by Echo Core Lab.

‡ One stroke occurred at approximately 25 months after PFO closure and one stroke occurred at approximately 28 months after PFO closure.

§ Beginning in June 2011.

‖ W. L. Gore & Associates, Inc. GORE® CARDIOFORM Septal Occluder Complete Bibliography. Flagstaff, AZ: W. L. Gore & Associates, Inc.; 2020. [Bibliography].

1. Sondergaard 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. GORE® CARDIOFORM Septal Occluder [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc.; 2018. MD157448.

Consult Instructions for Use
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. ℞ 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. ℞ Only

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