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# REDEFINING STROKE PREVENTION

Data demonstrate the connection between closing a patent foramen ovale (PFO) and recurrent stroke reduction in select patients.

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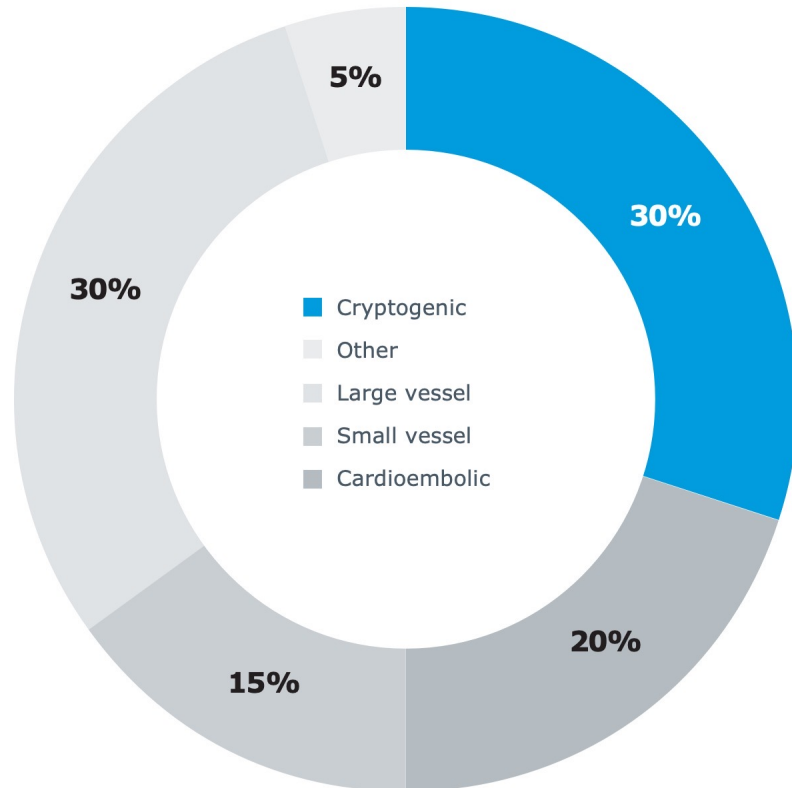
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# Agenda

1. Prevalence of cryptogenic stroke and PFO
2. PFO closure efficacy data
3. PFO closure safety data
4. PFO closure long-term follow-up
5. Patient selection
6. PFO closure procedure basics
7. Post-procedure care
8. Health economics for PFO closure
9. Practice advisory updates

# Cryptogenic stroke: A stroke without consistently transparent causes

How many ischemic strokes are cryptogenic?



~ 1/3

of ischemic strokes are cryptogenic<sup>1</sup>

~ 200K

cryptogenic strokes occur annually in the U.S.<sup>1</sup>

~ 4.5M

cryptogenic strokes occur annually worldwide<sup>1,2</sup>

1. Cryptogenic Stroke Initiative. American Heart Association/American Stroke Association, Inc. website. Accessed July 10, 2020. <https://www.stroke.org/en/professionals/stroke-resource-library/post-stroke-care/cryptogenic-stroke-initiative>

2. World Health Organization. The World Health Report 2002 – reducing risks, promoting healthy life. Published 2002. Accessed October 5, 2018. <https://www.who.int/publications/i/item/9241562072>

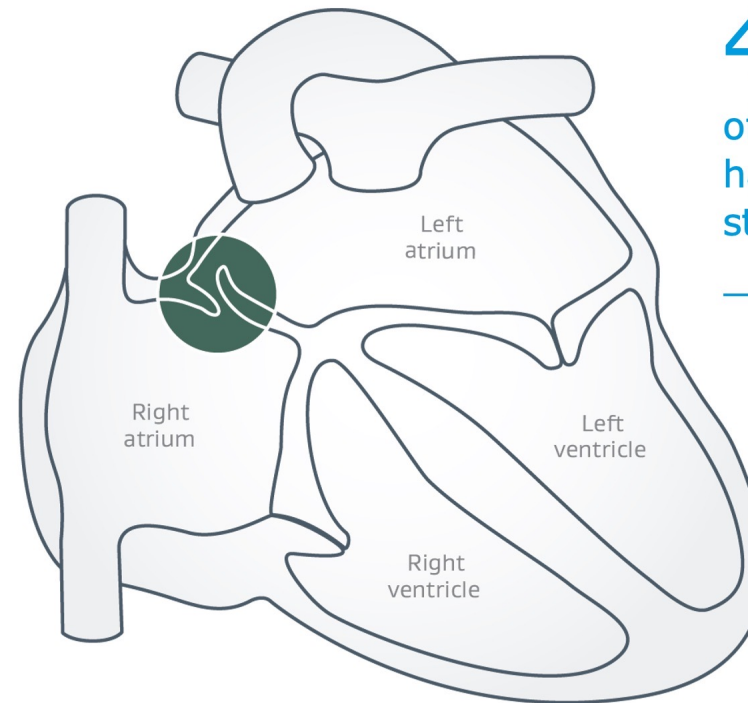


# Cryptogenic stroke: The connection to patent foramen ovale (PFO)

The American Heart Association states that certain conditions should be considered if standard post-stroke workup has not determined probable causation for the cryptogenic stroke, including but not limited to<sup>1</sup>:

- Occult paroxysmal atrial fibrillation
- PFO
- Inherited thrombophilia
- Aortic arch atheroma

A PFO may permit emboli to travel from the right to the left atria, possibly leading to a stroke.



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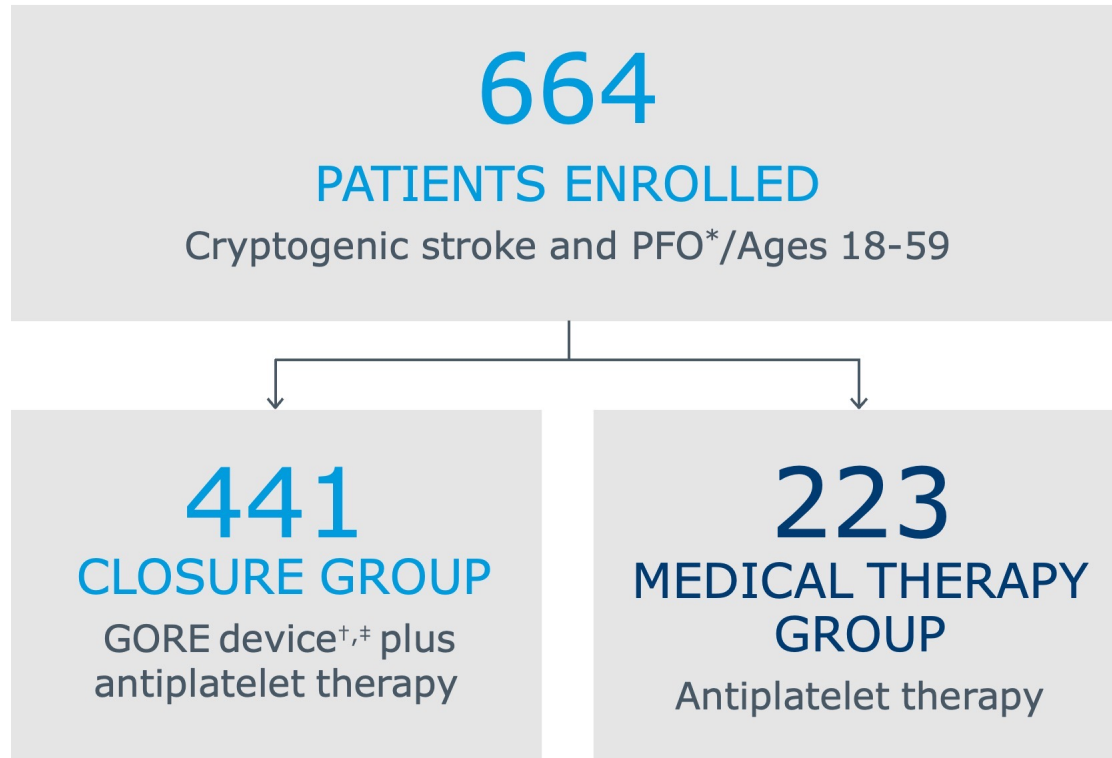
**40–50%**  
of patients who have  
had a cryptogenic  
stroke have a PFO<sup>2</sup>

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1. Cryptogenic Stroke Initiative. American Heart Association/American Stroke Association, Inc. website. Accessed July 10, 2020. <https://www.stroke.org/en/professionals/stroke-resource-library/post-stroke-care/cryptogenic-stroke-initiative>  
2. Caswell J. Holes in the heart. Stroke Connection. 2011:16-17.

# Gore REDUCE Clinical Study

Prospective, randomized, multicenter, multinational, controlled, open-label trial



## Endpoints

- Freedom from recurrent clinical ischemic stroke through at least 24 months
- Incidence of new brain infarct (defined as clinical ischemic stroke or silent brain infarct) through 24 months

## Patient selection

- Cryptogenic ischemic stroke within 180 days
  - Ischemic stroke = clinical symptoms  $\geq$  24 hours or with MRI evidence of infarction
  - Cryptogenic
    - No stenosis > 50% or ulcerated plaque in relevant intra- or extra-cranial vessels
    - No atrial fibrillation or high-risk source of cardioembolism
    - Non-lacunar (based on syndrome and/or size)
    - No evidence of hypercoagulable disorder
    - No other known cause of stroke
- PFO\*
- No indication for anticoagulation
- No uncontrolled diabetes mellitus, hypertension, autoimmune disease, alcohol or drug abuse

## Image confirmation

- MRI at baseline and at 2 years or at time of event

\* PFO confirmed by transesophageal echocardiography (TEE) with bubble study demonstrating right-to-left shunt at rest or during Valsalva maneuver. Patients with PFO eligible regardless of shunt size within sizing parameters of the IFU or presence of atrial septal aneurysm.

† 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*.

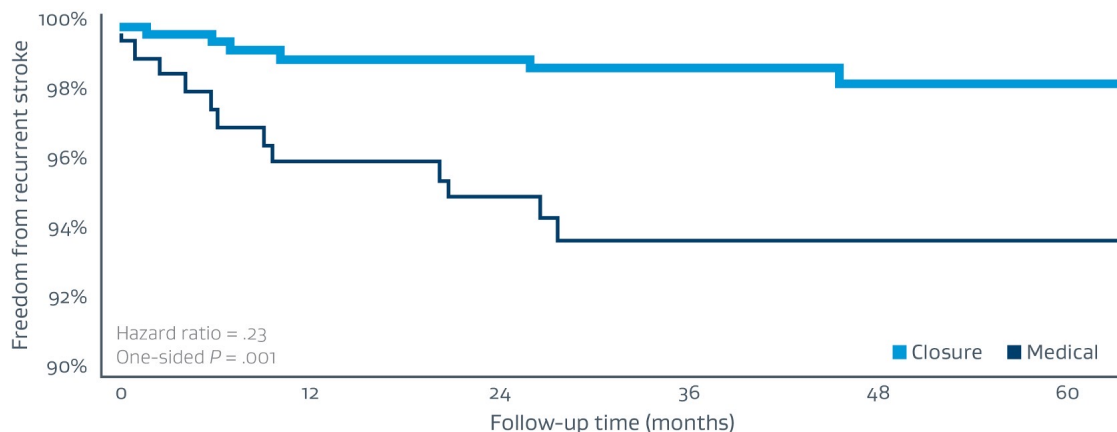
‡ GORE® CARDIOFORM Septal Occluder and GORE® HELEX® Septal Occluder family of devices.

# PFO closure through original follow-up (median 3.2 years)

REDUCE Study: As published in *New England Journal of Medicine*<sup>1</sup>

## REDUCE Study sub-analysis

- As effective for patients 18–45 as patients 46–59 years<sup>\*,1</sup>
- All PFO shunt sizes and anatomies benefited from PFO closure<sup>\*,1</sup>



**77%** RELATIVE STROKE REDUCTION  
with PFO CLOSURE + medical therapy  
versus medical therapy alone<sup>\*,1</sup>

**4X THE PROTECTION** against recurrent stroke than  
medical therapy alone<sup>\*,1</sup>

### Stroke risk<sup>\*,1</sup>

Closure group	Medical therapy group	Absolute stroke reduction <sup>†</sup>
1.4% (6/441)	5.4% (12/223)	4%

\* 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*.

† The 4% represents the difference between 5.4% and 1.4% respectively.

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.



# REDUCE clinical study: Original follow-up safety profile

PFO closure plus medical therapy. Proven to be as safe as medical management alone<sup>\*,1</sup>

There was no significant difference in the overall serious adverse event (SAE) rate between the PFO closure and medical management group in the REDUCE Study.<sup>\*,1</sup>

## REDUCE Study: any SAE

Closure (N = 441)	Medical (N = 223)	P value <sup>†</sup>
102 (23.1%)	62 (27.8%)	.22

## REDUCE Study: SAEs related to the procedure or device<sup>‡</sup>

**6 (1.4%)**  
device-related

**11 (2.5%)**  
procedure-related

No statistical difference in risk of serious atrial fibrillation, bleeding, deep vein thrombosis or pulmonary embolism with PFO closure.<sup>\*,1</sup>

## REDUCE Study: SAEs of interest

	Closure (N = 441)	Medical (N = 223)	P value <sup>†</sup>
Any serious adverse event	102 (23.1%)	62 (27.8%)	.22
Atrial fibrillation	10 (2.3%)	1 (0.4%)	.11
Bleeding	8 (1.6%)	6 (2.7%)	.57
Deep vein thrombosis	0	2 (0.9%)	.11
Pulmonary embolism	2 (0.5%)	1 (0.4%)	1.00
Migraine	2 (0.5%)	1 (0.4%)	1.00

Low risk of device or procedure-related SAEs.<sup>\*,1</sup>

\* 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*.

† P-value were calculated with the use of Fisher's exact test.

‡ Subjects may have experienced both device- and procedure-related SAEs.

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.

# Safety profile

Understanding the risk of atrial fibrillation following PFO closure.

## REDUCE Study: atrial fibrillation or flutter events<sup>\*,1</sup>

	Closure (N = 441)	Medical (N = 223)	P value <sup>†</sup>
Any atrial fibrillation or flutter	29 (6.6%)	1 (0.4%)	< .001
Serious atrial fibrillation or flutter	10 (2.3%)	1 (0.4%)	.11
Serious device-related atrial fibrillation or flutter	2 (0.5%)	-	-
Serious procedure-related atrial fibrillation or flutter	0	-	-

The REDUCE Study found post-implant atrial fibrillation generally does not result in long-term arrhythmia complications or require lifetime use of anticoagulation.<sup>\*,1,2</sup>

1.4% of all closure subjects in the REDUCE Study had ongoing non-serious atrial fibrillation or atrial flutter at the time of data analysis<sup>\*,1</sup>

# 66%

AFIB or flutter cases considered non-serious (19/29)

AFIB detected within 45 days post-procedure <sup>1</sup>	24/29 (83%)
Cases that resolved within 2 weeks of onset <sup>1</sup>	17/29 (59%)

- The majority of atrial fibrillation and flutter events were non-serious.<sup>1</sup>
- Most of the atrial fibrillation and flutter events were resolved in 2 weeks.<sup>1</sup>

\* 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*.

† P-value 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. Volpi JJ, Ridge JR, Nakum M, Rhodes JF, Søndergaard L, Kasner SE. Cost-effectiveness of percutaneous closure of a patent foramen oval compared with medical management in patients with a cryptogenic stroke: from the US payer perspective. *Journal of Medical Economics*. 2019;22(9):883-890.

# REDUCE clinical study: Long-term outcomes

## Groundbreaking stroke risk reduction

The REDUCE Study continues to show the largest reduction in recurrent ischemic stroke in all PFO shunt sizes over medical management alone.<sup>\*,1,2</sup>

69%

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

25

number needed to treat (NNT) to prevent 1 stroke at 5 years<sup>2</sup>

Closure (N = 441) Medical (N = 223)	Original follow-up (Median 3.2 years) <sup>1</sup>	Extended follow-up (Median 5.0 years) <sup>2</sup>
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 across anatomies.<sup>\*,†,1,2</sup>

	12-month assessment <sup>3</sup>	24-month assessment <sup>†</sup>
GORE® CARDIOFORM Septal Occluder effective closure rate <sup>†</sup>	98%	99%

\* 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*.

† Effective closure for the GORE® CARDIOFORM Septal Occluder defined as freedom from large shunt > 25 bubbles as detected by transthoracic echocardiography adjudicated by Echo Core Lab.

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

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. 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; 2021. MD184733.



# Continued legacy of patient safety

Long-term results continue to demonstrate a legacy of patient safety with 2,069 patient years of data.<sup>1,2</sup>

## Device and procedure serious adverse events (SAEs)

0

new device- or procedure-related SAEs at 5 years<sup>2</sup>

Closure (N = 441)	Original follow-up (Median 3.2 years) <sup>1</sup>	Extended follow-up (Median 5.0 years) <sup>2</sup>
Device SAE	6 (1.4%)	No change
Procedure SAE	11 (2.5%)	No change

## Atrial fibrillation<sup>2</sup>

1

additional non-serious atrial fibrillation case after device implant found during extended follow-up and it resolved<sup>2</sup>

Closure (N = 441)	Original follow-up (Median 3.2 years) <sup>1</sup>	Extended follow-up (Median 5.0 years) <sup>2</sup>
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

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. 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.



# Continued legacy of patient safety *(continued)*

## Other safety information<sup>1,2</sup>

Consistently demonstrating no significant difference in risk of bleeding, deep vein thrombosis or pulmonary embolism in 5-year follow-up versus medical management alone.<sup>1,2</sup>

	Closure (N = 441)	Original follow-up (Median 3.2 years) <sup>1</sup>	Extended follow-up (Median 5.0 years) <sup>2</sup>
0 clinical sequelae associated with wire frame fractures at original follow-up or during extended follow-up <sup>1,2</sup>	Clinical sequelae associated with wire frame fractures	0 (0%)	No change
0 reported erosions at original follow-up or during extended follow-up <sup>1,2</sup>	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

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. 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.

# Patient selection algorithm

The following three-step algorithm can help identify patients most likely to benefit from PFO closure.

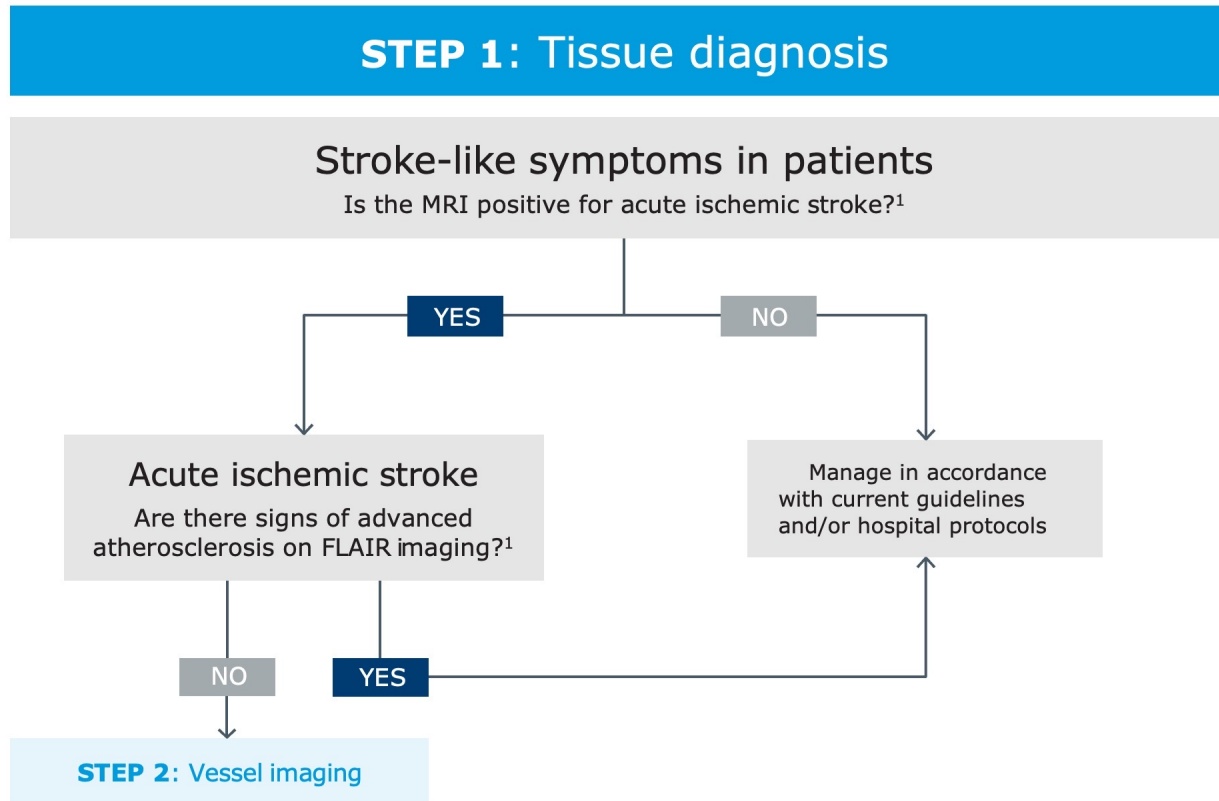


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# Patient selection algorithm

## Step 1



FLAIR, Fluid-attenuated inversion recovery.

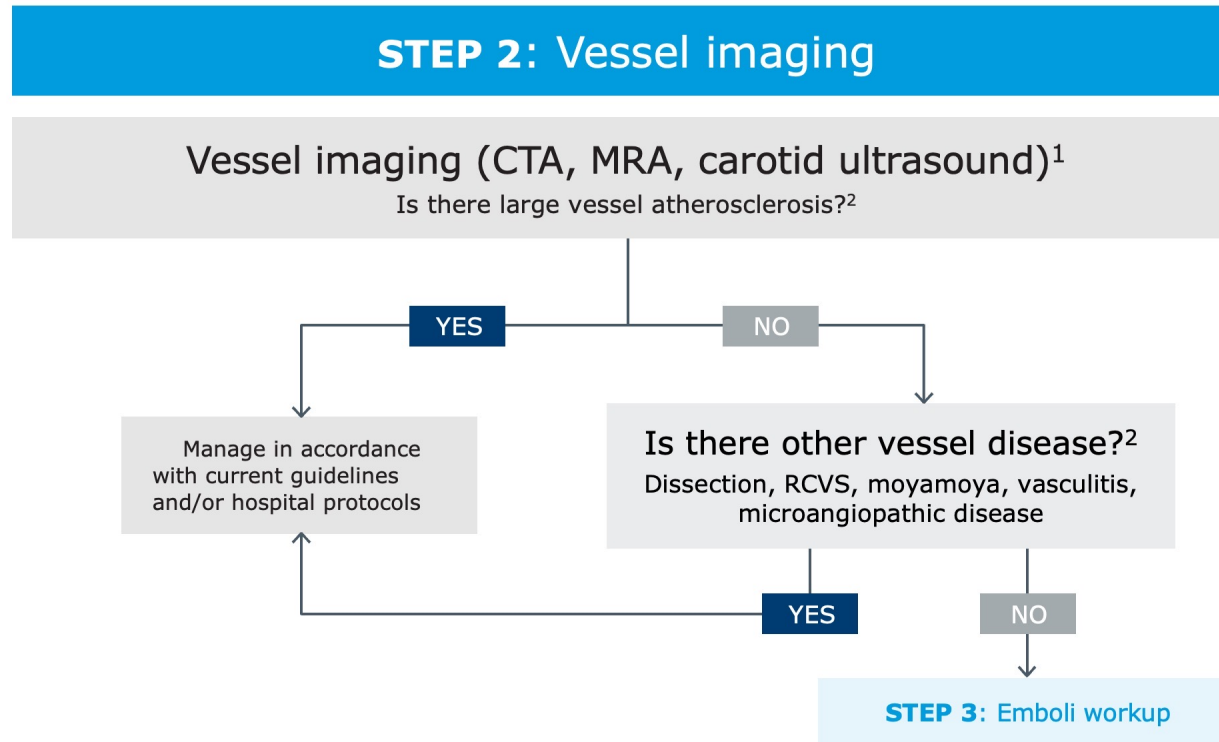
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1. Messé SR, Gronseth GS, Kent DM, *et al.* Practice advisory update summary: patent foramen ovale and secondary stroke prevention: Report of the Guideline Subcommittee of the American Academy of Neurology. *Neurology* 2020;94(20):876-885. <https://n.neurology.org/content/neurology/94/20/876.full.pdf>

# Patient selection algorithm

## Step 2



CTA, Computed tomography angiography; MRA, Magnetic resonance angiography; RCVS, Reversible cerebral vasoconstriction syndrome.

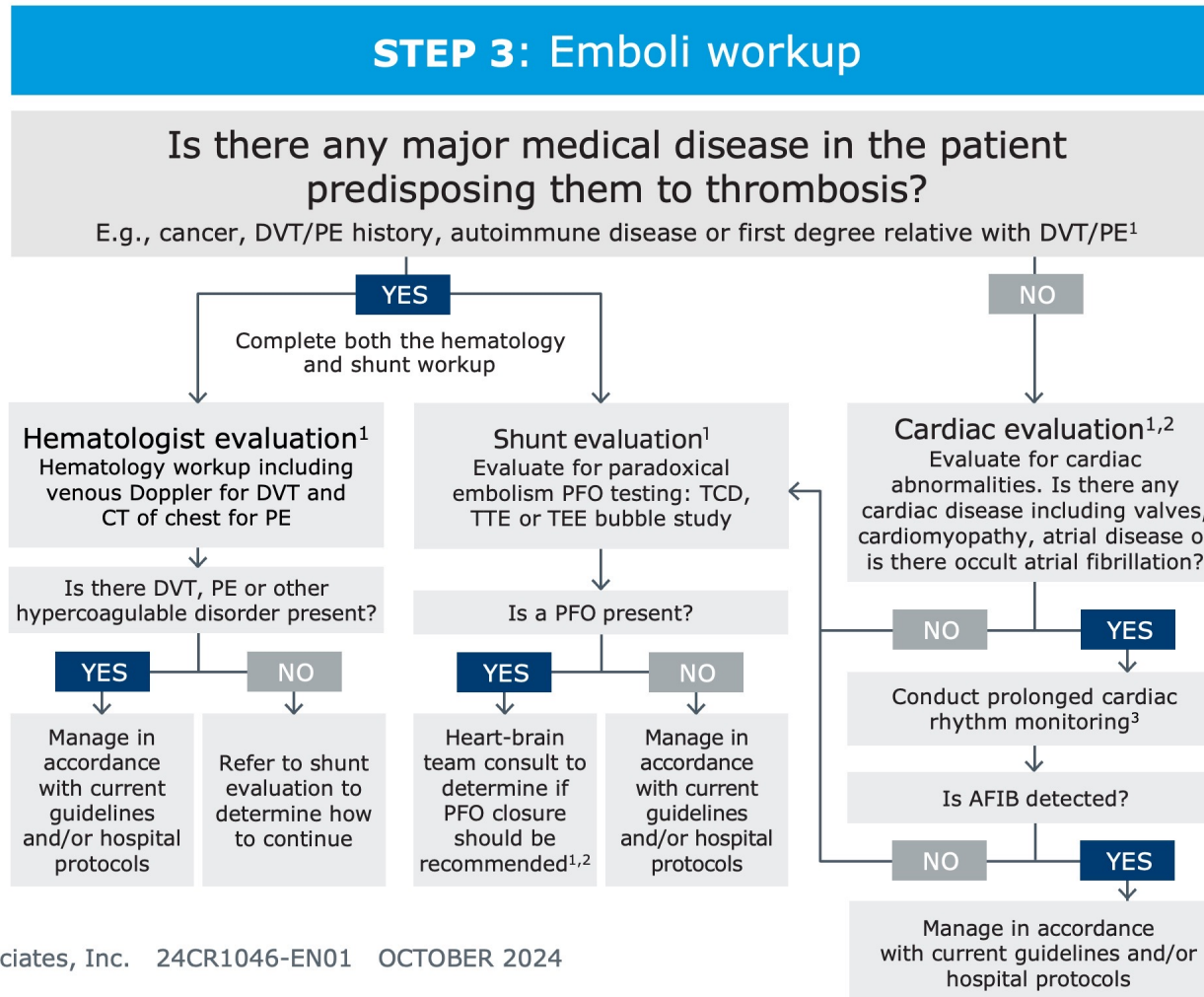
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1. Kleindorfer DO, Towfighi A, Chaturvedi S, *et al.* 2021 Guideline for the prevention of stroke in patients with stroke and transient ischemic attack: a guideline from the American Heart Association/American Stroke Association. *Stroke* 2021;52(7):e364-e467. <https://www.ahajournals.org/doi/10.1161/STR.0000000000000375>
2. Messé SR, Gronseth GS, Kent DM, *et al.* Practice advisory update summary: patent foramen ovale and secondary stroke prevention: Report of the Guideline Subcommittee of the American Academy of Neurology. *Neurology* 2020;94(20):876-885. <https://n.neurology.org/content/neurology/94/20/876.full.pdf>

# Patient selection algorithm

## Step 3



Duration of anticoagulant use varies by case, and the decision to maintain its use in conjunction with PFO closure should be at the physician's discretion.

AFIB, Atrial fibrillation; CT, Computed tomography; DVT, Deep vein thrombosis; MRI, Magnetic resonance imaging; PE, Pulmonary embolism; TCD, Transcranial doppler; TEE, Transthoracic echocardiography; TTE, Transthoracic echocardiogram.

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2. Kleindorfer DO, Towfighi A, Chaturvedi S, *et al.* 2021 Guideline for the prevention of stroke in patients with stroke and transient ischemic attack: a guideline from the American Heart Association/American Stroke Association. *Stroke* 2021;52(7):e364-e467.
3. GORE® CARDIOFORM Septal Occluder [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates Inc; 2021. MD184733.



# PFO closure procedure

## Procedure basics

PFO closure is a minimally invasive transcatheter procedure, usually performed under general anesthesia or conscious sedation in a catheterization laboratory.

Expected procedural timeframes\*

**1-2 hours<sup>†</sup>**

Total length of procedure

**1 day<sup>†</sup>**

Time from admit to discharge

## Permanent implant for PFO closure

The GORE® CARDIOFORM Septal Occluder is a permanent implant that prevents emboli from traveling from the right to the left atrium.

FDA approved, the implant conforms to the anatomy of the heart and creates a framework on which the patient's own tissue will eventually grow over and through, thus closing the PFO.



**99%**

Effective closure  
across PFO  
anatomies  
at 24 months<sup>‡,§</sup>

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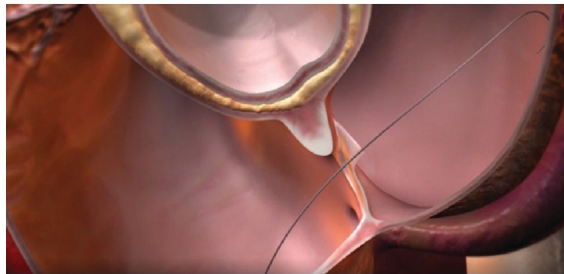
\* Individual outcomes may vary. Individual patients present a range of variables that may impact procedural timeframes. Licensed health care professionals (HCP) are responsible for making decisions about patient care.

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

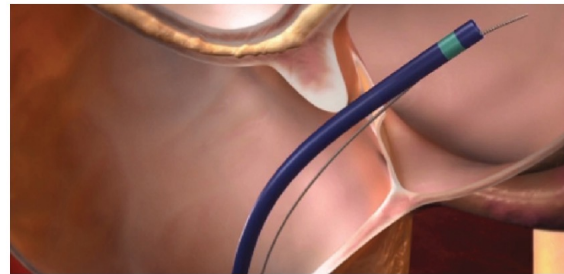
‡ Effective closure for the GORE® CARDIOFORM Septal Occluder defined as freedom from large shunt > 25 bubbles as detected by transthoracic echocardiography adjudicated by Echo Core Lab.

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

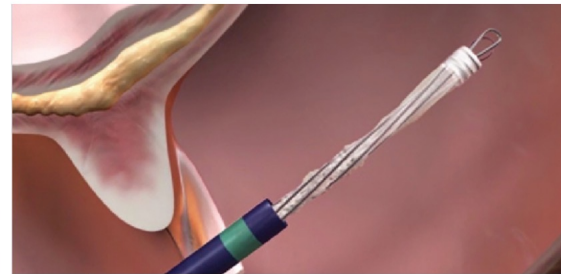
# The procedure, step by step\*



**1** A small incision is made in the right groin. A catheter is threaded via guidewire through the vein and up to the heart. The guidewire is threaded through the PFO from the right to left atrium.



**2** The device is navigated over the guidewire via the catheter and through the PFO.



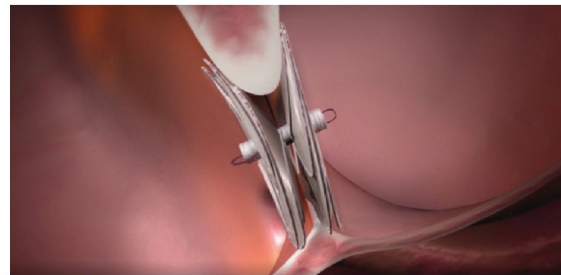
**3** The physician opens the first disc of the PFO closure device inside the left atrium.



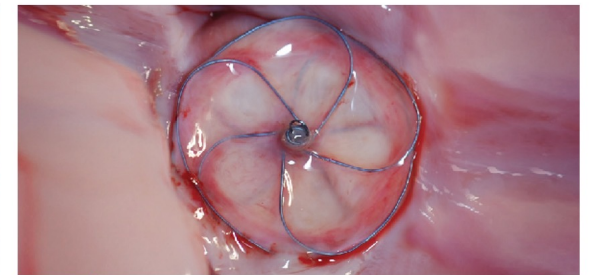
**4** The first disc is positioned to appose the left side of the septum.



**5** The device's second disc is opened and positioned to appose the right side of the septum, closing the PFO.



**6** The two discs are locked together in their final position, and the device is released from the catheter.



**7** The device serves as a scaffold onto which the patient's own cells grow into new tissue.

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\* Refer to *Instructions for Use* (IFU)

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# Post-procedure therapy and care<sup>\*,†</sup>

## Post-procedural follow-up visit protocol

### DISCHARGE

Physical exam, TTE

### 1 MONTH

Physical exam, TTE

### 6 MONTHS

Physical exam, TTE

### 12 MONTHS

Physical exam, TTE<sup>‡</sup>

## Post-procedure care medical therapy protocol

- One of the following antiplatelet options:
  - ASPIRIN Acetylsalicylic Acid (81-325 mg daily)
  - Combination: ASPIRIN Acetylsalicylic Acid (50-100 mg daily)/dipyridamole (225-400 mg daily)
  - Clopidogrel (alone) (75 mg daily)
- Antiplatelet therapy should be used indefinitely

Physicians should evaluate patient need for antibiotic therapy following device implantation.

Following implant, most patients can return to their prior lifestyle after 2 weeks.

## Post-procedural patient activity level

### Day 1

Hospital rest for up to 1 day

### Day 14+

Strenuous physical routine

\* The information provided is intended to be general guidance based on current medical practices in the field. The steps described here may not be complete, and are not intended to be a replacement for the *Instructions for Use (IFU)* or the education, training and professional judgment of health care providers (HCP). Licensed HCP remain responsible for making decisions about patient care and the use of medical technologies. Refer to the IFU for complete safety information.

† Recovery and follow-up based on REDUCE Study protocols.

‡ In instances where device stability is in question, fluoroscopic examination without contrast is recommended.

# PFO closure health economics

PFO closure demonstrates economic and quality of life benefits

In select patients, PFO closure plus medical therapy reduces stroke burden costs and improves quality of life compared to medical management alone.<sup>1,2</sup>

## Cost-effective

After 2.3 years, closing a PFO is more cost-effective than medical management alone.<sup>1</sup>

## Improves quality of life

Patients who underwent PFO closure reported significantly higher physical vitality, general health, mental health and social functioning than non-closure patients.<sup>2</sup>

1. Volpi JJ, Ridge JR, Nakum M, Rhodes JF, Sondergaard L, Kasner SE. Cost-effectiveness of percutaneous closure of a patent foramen oval compared with medical management in patients with a cryptogenic stroke: from the US payer perspective. *Journal of Medical Economics*. 2019;22(9):883-890.
2. Mirzada N, Ladenvall P, Hansson PO, Eriksson P, Taft C, Dellborg M. Quality of life after percutaneous closure of patent foramen ovale in patients after cryptogenic stroke compared to a normative sample. *International Journal of Cardiology*. 2018;257:46-49.

# Practice advisory update: PFO and secondary stroke prevention

Current guidance from the American Academy of Neurology (AAN), the American Heart Association/American Stroke Association (AHA/ASA) and the Society for Cardiovascular Angiography & Interventions (SCAI) concludes that closure of a PFO may be recommended for some people that have had a PFO-associated stroke.<sup>1,2,3</sup>

2020 AAN Practice Advisory <sup>1</sup> :	2021 AHA/ASA Guidelines <sup>2</sup> :	2022 SCAI Guidelines <sup>3</sup> :
<ul style="list-style-type: none"><li>▪ In patients younger than 60 years with a PFO and embolic-appearing infarct and no other mechanism of stroke identified, clinicians may recommend closure following a discussion of potential benefits and risks.</li><li>▪ In patients who opt to receive medical therapy alone without PFO closure, clinicians may recommend an antiplatelet medication such as ASPIRIN (Acetylsalicylic Acid) or anticoagulation.</li></ul>	<ul style="list-style-type: none"><li>▪ In patients 18 to 60 years of age with a non-lacunar ischemic stroke of undetermined cause despite a thorough evaluation and a PFO with high-risk anatomic features*, it is reasonable to choose closure with a transcatheter device and long-term antiplatelet therapy over antiplatelet therapy alone for preventing recurrent stroke.</li></ul>	<ul style="list-style-type: none"><li>▪ In patients between the ages of 18 and 60 with a prior PFO-associated stroke, the SCAI guideline panel recommends PFO closure rather than antiplatelet therapy alone (strong recommendation, moderate certainty of evidence).</li><li>▪ In patients 60 years or older with a prior PFO-associated stroke, the SCAI guideline panel suggests PFO closure rather than long-term antiplatelet therapy alone (conditional recommendation, very low certainty of evidence).</li></ul>

\* In the evidence, each study defines high-risk anatomic features in a different way.

1. Messé SR, Gronseth GS, Kent DM, *et al.* Practice advisory update summary: patent foramen ovale and secondary stroke prevention: Report of the Guideline Subcommittee of the American Academy of Neurology. *Neurology* 2020;94(20):876-885. <https://n.neurology.org/content/neurology/94/20/876.full.pdf>
2. Kleindorfer DO, Towfighi A, Chaturvedi S, *et al.* 2021 Guideline for the prevention of stroke in patients with stroke and transient ischemic attack: a guideline from the American Heart Association/American Stroke Association. *Stroke* 2021;52(7):e364-e467. <https://www.ahajournals.org/doi/10.1161/STR.0000000000000375>
3. Kavinsky CJ, Szerlip M, Goldsweig AM, *et al.* SCAI guidelines for the management of patent foramen ovale. *Journal of the Society for Cardiovascular Angiography & Interventions*. 2022;1(4):100039.

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**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](http://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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