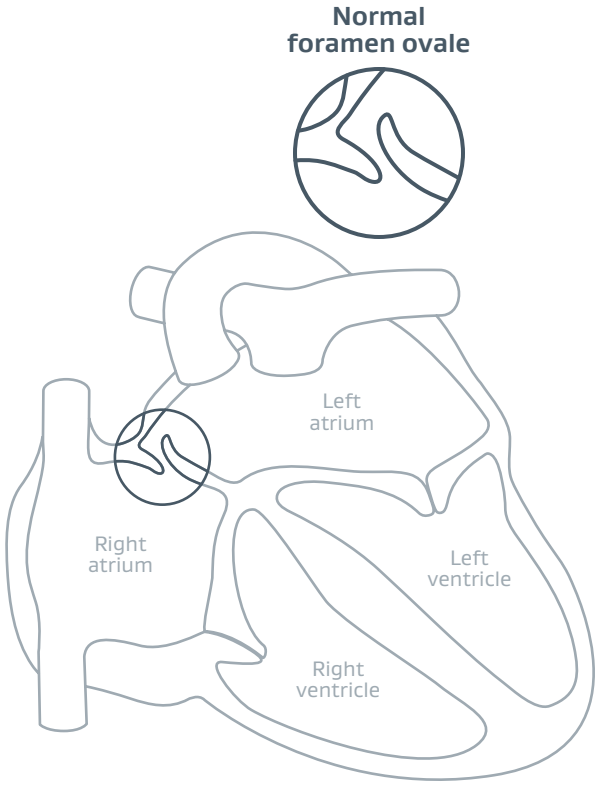
PATENT FORAMEN OVALE (PFO)

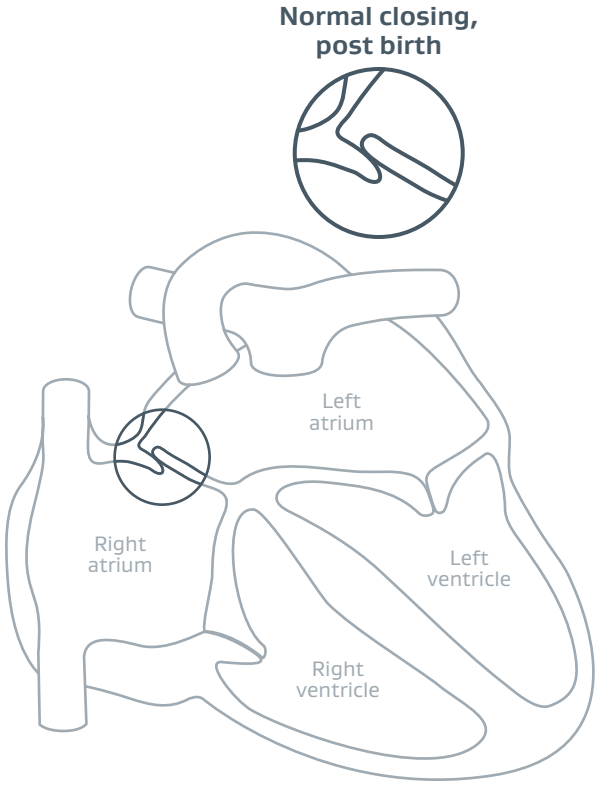
Understanding the role a PFO can play in cryptogenic stroke

What is a Foramen Ovale?

Before birth

Before birth, a baby's heart will have a hole with a flap-like covering between the upper two chambers of the heart. This opening (the foramen ovale) allows blood rich in oxygen from the mother to bypass the baby's lungs which do not function until the baby is born.





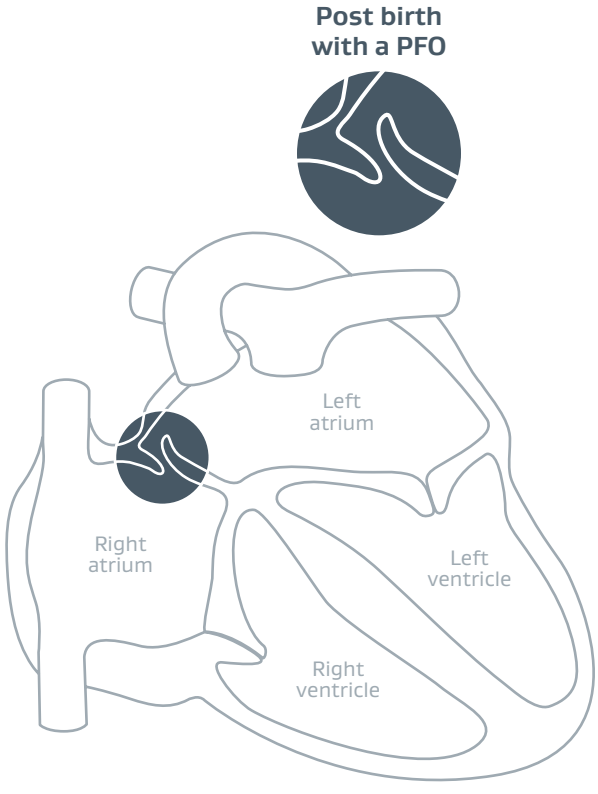
After birth

After birth, the flap-like covering will typically close the hole permanently.

What is a PFO?

25%

In approximately *one out of every four* individuals, the hole in the heart will remain open after birth. This is called a patent foramen ovale, or PFO.[1]



How Can a PFO Contribute to a Stroke?

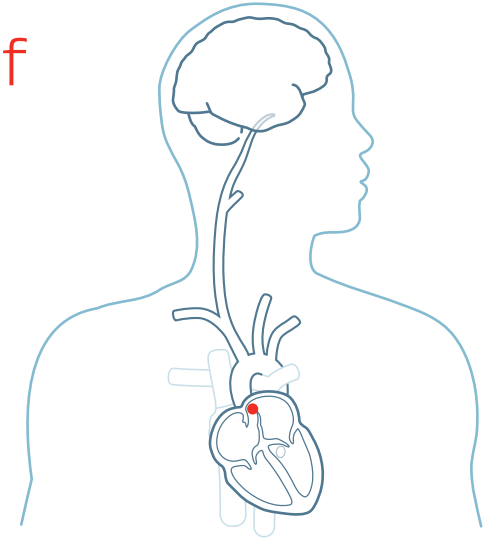
In most people, a PFO creates no symptoms and requires no treatment. However, in a small minority, a PFO may permit blood clots to pass from the right side of the heart to the left side, possibly leading to a stroke.

PFOs have been found to be more prevalent in cryptogenic stroke patients.[1]

Prevalence increases to between 40–50% in cryptogenic stroke patients.[1]

Could a PFO Be the Cause of My Cryptogenic Stroke?

If no other identifiable cause of your stroke can be found, your doctors may conclude that your PFO may have contributed to your stroke.



The opening in the PFO allows a blood clot to pass from the right side of the heart to the left side. This may cause a stroke.

How Can I Reduce My Chance of Having Another Stroke Related to My PFO?

There are FDA approved devices that can close the PFO. PFO closure together with antiplatelet drugs and/or anticoagulants, may reduce your risk of having another stroke by preventing future clots from blocking a blood vessel that supplies blood to the brain.*,†,[2]

It is important to speak with your doctor about the potential benefits and risks of PFO closure.

Learn more at AboutPFO.com and ask your doctor if PFO closure is right for you.

References

* 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*.

† Only RESPECT (Amplatzer PFO Occluder) allowed anticoagulants to be used in their study. REDUCE only allowed antiplatelets.

1. American Heart Association, Inc. Web site. Patent Foramen Ovale (PFO). http://www.heart.org/HEARTORG/Conditions/More/CardiovascularConditionsofChildhood/Patent-Foramen-Ovale-PFO_UCM_469590_Article.jsp#.Wp7sFWr4-pp. Published March 2017. Accessed August 20, 2019.

2. 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.

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 goremedical.com for a complete description of all warnings, precautions and adverse events. ℞ Only

This information is intended for education and awareness only. Patients should consult their physician for information on the risks associated with the devices and surgical procedures discussed in this document. All surgical procedures carry potential health risks. Not all patients will be candidates for treatment with these devices, and individual outcomes may vary.

Always follow physician advice on your post-surgery care and recovery.

Caution: U.S. law restricts use of this device on the order of a physician (Rx).

Products listed may not be available in all markets.

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