

ONE STROKE IS ONE TOO MANY

If you've had a stroke due to an unknown cause, learn how you may be able to prevent another.



**PFO CLOSURE NOW RECOMMENDED BY
THE AMERICAN ACADEMY OF NEUROLOGY
GUIDELINE SUBCOMMITTEE FOR
SECONDARY STROKE PREVENTION**

CRYPTOGENICSTROKE.COM



UNDERSTANDING PFO CLOSURE AND THE AMPLATZER™ PFO OCCLUDER



WHAT IS A STROKE?

Strokes are caused by a sudden interruption in blood flow to a part of the brain or bleeding within the brain tissue. When this happens, brain cells are deprived of oxygen and begin to die, causing brain damage. When brain cells die during a stroke, the function controlled by that part of the brain, like speech or movement, may be impaired.

There are two major types of stroke: **hemorrhagic stroke** and **ischemic stroke**. A hemorrhagic stroke occurs when damaged blood vessels in the brain allow bleeding into the brain tissue, resulting in swelling and pressure that damages the brain. An ischemic stroke occurs when a blockage develops in a blood vessel carrying blood to the brain.

WHAT IS A CRYPTOGENIC STROKE?

An ischemic stroke—for which no definite cause is found—is known as a **cryptogenic stroke**. It is estimated that 25% to 30% of ischemic strokes are cryptogenic.

One possible factor that may have contributed to your cryptogenic stroke is the presence of a patent foramen ovale (PFO).

This brochure is not intended to explain everything you need to know about your treatment options for PFO and cryptogenic stroke. Please discuss any questions you have with your doctor to determine which treatment option is right for you.

WHAT IS A PATENT FORAMEN OVALE?

During development, prior to birth, a channel between the right and left sides of the heart, called the foramen ovale, allows blood from veins to bypass the lungs. In about 33%¹ of people, the foramen ovale does not close completely after birth. When the foramen ovale remains open, it is called a “patent foramen ovale,” or a PFO. Typically, a PFO causes no problems. However, in some cases, it can allow a small amount of blood to pass from the right side of the heart to the left side of the heart.

The diagram below shows an open foramen ovale before birth, a closed foramen ovale after birth, and a patent foramen ovale after birth.

FIGURE 1:

Prior to birth

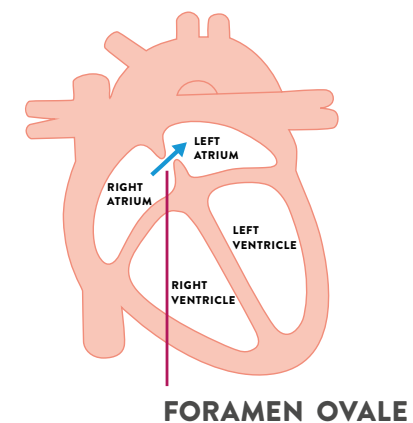


FIGURE 2:

Post-birth, natural sealing of the foramen ovale

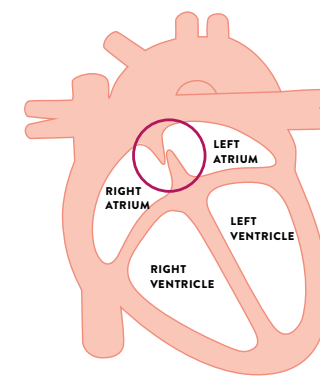
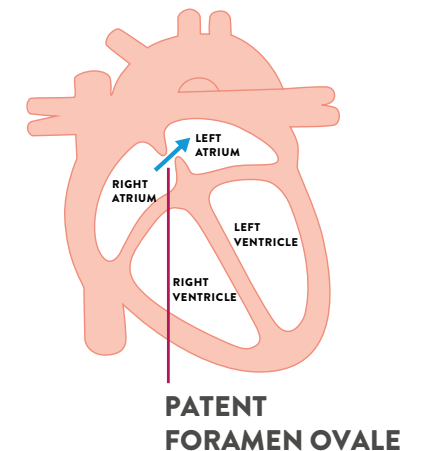


FIGURE 3:

Foramen ovale remains open, creating a PFO



HOW DOES A PFO AFFECT STROKE RISK?

Blood clots can develop in your veins for various reasons and travel to the right side of the heart. Normally, they are then pumped to the lungs, which act as a filter. However, a PFO can allow those clots to bypass the lungs and cross to the left side of the heart. From there, they can be pumped to the brain, causing a stroke.

Patients who have a PFO and have had a cryptogenic stroke may be at an increased risk for having a second stroke. In some patients, a second stroke can be prevented by having the PFO closed.

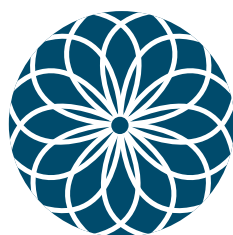
ABOUT THE PROCEDURE

PFO closure is a same-day, outpatient procedure that should last between one and two hours. It involves making a tiny skin incision, typically in the right groin area. A small medical device designed to close the PFO is guided through a small tube called a catheter. Once this device, the Amplatzer™ PFO Occluder, is in place, the cardiologist will carefully study its position using cardiac imaging tools. When the cardiologist is satisfied with the position of the occluder, it will be set to remain in the heart to help prevent another stroke.



RECOMMENDED BY THE AMERICAN ACADEMY OF NEUROLOGY (AAN)

Experts from the AAN reviewed the available evidence regarding secondary stroke prevention in patients with a PFO. They concluded that PFO closure significantly reduced the risk of future strokes in patients younger than 60 years of age who have had a cryptogenic stroke and have a PFO.



PFO CLOSURE WITH THE AMPLATZER™ PFO OCCLUDER

The Amplatzer™ PFO Occluder is a device that can be placed in your heart to close the PFO through a minimally invasive, catheter-based technique, and is designed to stop blood flow through the PFO.

“I’ve gotten a lot of tools from it. And just felt incredibly freed. This little device has completely been life changing for me. The doctors who recommended it and put it in my body...I’m forever grateful.”

CHRISTINE, PATIENT

This testimonial relates an account of an individual’s response to the treatment. This patient’s account is genuine, typical and documented. However, it does not provide any indication, guide, warranty or guarantee as to the response other persons may have to the treatment. Responses to the treatment discussed can and do vary and are specific to the individual patient.

PREVENTING RECURRING ISCHEMIC STROKE WITH THE AMPLATZER™ PFO OCCLUDER

The fear of having another stroke can be overwhelming. With the Amplatzer™ PFO Occluder, your doctor may be able to significantly reduce the risk of stroke reoccurrence. Researched extensively in clinical trials, PFO occlusion therapy has shown up to a **97%² relative risk reduction** for recurrent ischemic stroke when compared to medical therapy.

With a proven track record of more than 130,000³ patients treated globally over 25 years, the Amplatzer™ PFO Occluder is relied upon by thousands of physicians around the world.



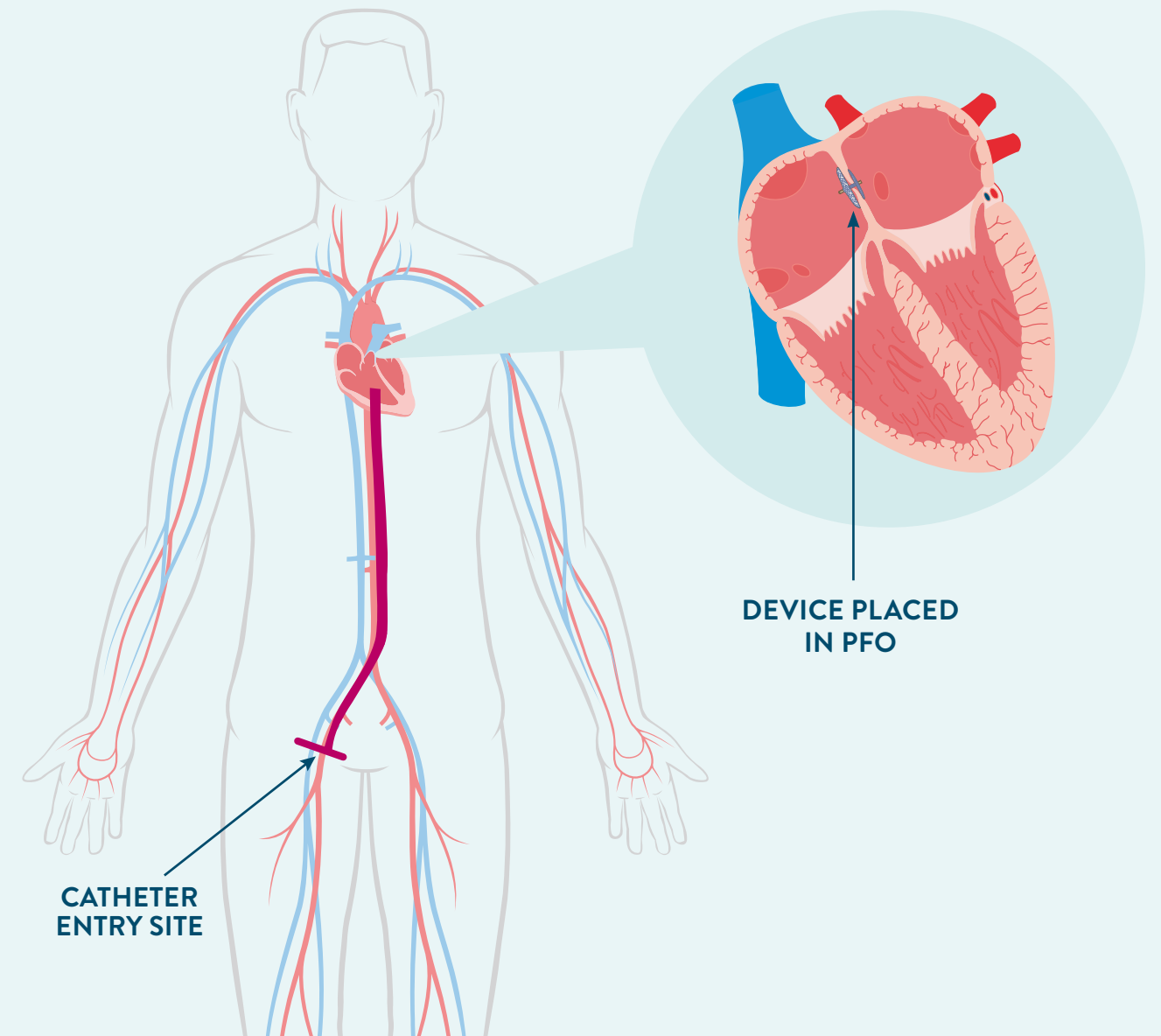
AMPLATZER™ PFO OCCLUDER DEVICE DESCRIPTION



The Amplatzer™ PFO Occluder consists of two nitinol wire mesh discs that can be placed in your heart to close the PFO through a minimally invasive, catheter-based technique.

The PFO occluder is designed to stop the blood flow and potential clots through the PFO.

Visit cryptogenicstroke.com to learn more.



PHYSICIAN PERSPECTIVE ON PFO CLOSURE

“The PFO closure procedure is one of the safest and most effective cardiac interventional procedures I perform. With proper patient selection, procedure planning, and an experienced team, it should be possible to complete the procedure in one hour. Often patients can be discharged the same day or the next morning.”

—Dr. John D. Carroll

Professor of Medicine, University of Colorado Denver

PATIENTS WHO HAVE HAD THE PFO CLOSURE PROCEDURE HAVE EXPERIENCED UP TO



97% REDUCTION

in their risk of a recurring stroke²

For more information about the Amplatzer™ PFO Occluder and recurrent stroke prevention, talk to your doctor or visit

[CRYPTOGENICSTROKE.COM](https://cryptogenicstroke.com)

WHAT ARE THE RISKS?

As with any medical procedure, there is a possibility of complications. The most serious risks of the procedure include:

- Death
- Stroke (major or minor)
- Blood or fluid build-up between the heart muscle and the sac that covers the heart requiring a drainage procedure
- Blood clot in the heart, leg or lung requiring long-term anticoagulation therapy
- Irregular and/or rapid heart rate (particularly atrial fibrillation)
- Perforation of the heart muscle or vessels

ADDITIONAL POTENTIAL RISKS ASSOCIATED WITH THE PROCEDURE OR THE DEVICE INCLUDE:

- Blood vessel blockage due to blood clots or air
- Allergic reaction to a drug used during the procedure
- Allergic reaction to contrast dye used to visualize heart during the implant procedure
- Allergic reaction to anesthesia
- Allergic metal reaction: Nitinol (nickel, titanium), platinum/ iridium, stainless steel (chromium, iron, manganese, molybdenum, nickel)
- Trouble or inability to breathe
- Infection
- Bleeding
- Injury to the nerves in the arm or lower neck
- Injury to the heart or vessels
- Chest pain
- Movement of the device from its position within the PFO or to other parts of the body
- Fever
- Headache or migraine
- High or low blood pressure
- Heart attack
- Pacemaker implant
- Hard or fast heart beat
- Sudden interruption of blood flow to an organ or body part
- Fluid buildup around lungs
- Incomplete closure of PFO
- Infection
- Blood clot on device
- Heart valve damage that interferes with valve closure
- Surgery or intervention to remove the device

WARNINGS

- If you are prone to venous blood clots, your doctor may prescribe a blood thinning medication (usually an anticoagulant) for at least 6 months.
- Talk to your doctor if you are allergic to nickel. The Amplatzer™ PFO Occluder is made of a metal called nitinol containing nickel and titanium.

PRECAUTIONS

Talk to your doctor if you are:

- Pregnant
- Have a history of multi-organ failure
- Unable to take blood thinning medication

WHO SHOULD NOT HAVE THE PROCEDURE?

The Amplatzer™ PFO Occluder should not be implanted in patients who:

- Have a tumor or history of blood clots at the implantation site of the device or in the vessels through which the device is advanced to reach the heart

REFERENCES:

1. Preventive Cardiology What Proportion of Stroke Is Not Explained by Classic Risk Factors? Catalina C. Ionita, MD; Andrew R. Xavier, MD; Jawad F. Kirmani, MD; Subasini Dash, MD; Afshin A. Divani, PhD; Adnan I. Qureshi, MD *Disclosures Prev Cardiol.* 2005;8(1):41-46. 2. Mas JL, Derumeaux G, Guillon B, et al. Patent foramen ovale closure or anticoagulation vs. antiplatelets after stroke. *N Engl J Med.* 2017;377:1011-21 and supplementary appendix. 3. Abbott (2018). Internal Sales Data 1996-2018.

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