ONE STROKE
IS ONE TOO MANY

If you've had a PFO-associated stroke,
learn how you may be able to prevent another.

PFO CLOSURE RECOMMENDED BY THE AMERICAN ACADEMY OF NEUROLOGY AND THE AMERICAN HEART ASSOCIATION/ AMERICAN STROKE ASSOCIATION

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UNDERSTANDING THE CONNECTION **BETWEEN PFO AND STROKE**

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 PFO-ASSOCIATED STROKE?

It is estimated that 25% of ischemic strokes are due to an unknown cause.

One possible factor that may have contributed to your stroke is the presence of a patent foramen ovale (PFO). **This is called a PFO-associated stroke**.

This brochure is not intended to explain everything you need to know about your treatment options for PFO-associated stroke. Please discuss any questions you have with your doctor to determine which treatment option is right for you.
See Important Safety Information referenced within.

WHAT IS A PATENT FORAMEN OVALE?

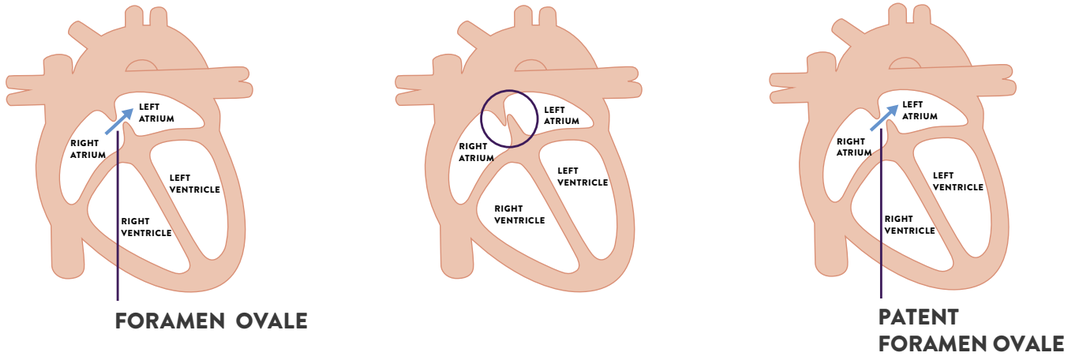
During development, prior to birth, a channel between the right and left sides of the heart, called the foramen ovale, allows blood from veins to bypass the lungs. In about 25%[1] of people, the foramen ovale does not close completely after birth. When the foramen ovale remains open, it is called a "patent 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 had a PFO-associated 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 PFO CLOSURE 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™ Talisman™ 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 MULTIPLE PHYSICIAN SOCIETIES

Experts from the American Academy of Neurology and American Heart Association/American Stroke Association reviewed the available evidence regarding secondary stroke prevention in patients with a PFO. They concluded that for some patients, particularly those younger than 60 years who have had a stroke thought to be caused by a PFO, closure of the PFO reduces the risk of having another stroke better than medical treatment alone.

PFO CLOSURE WITH THE AMPLATZER™ TALISMAN™ PFO OCCLUDER

The Amplatzer™ Talisman™ 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

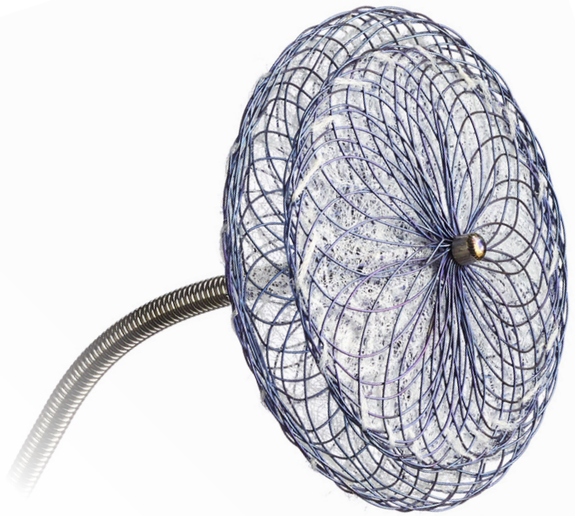
This testimonial relates an account of an individual's response to the treatment. This patient's account is genuine, typical and documented. However, it does not provide any indication, guide, warranty or guarantee as to the response other persons may have to the treatment. Responses to the treatment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

REDUCING RISK OF ANOTHER STROKE WITH THE AMPLATZER™ TALISMAN™ PFO OCCLUDER

The fear of having another stroke can be overwhelming. With the Amplatzer™ Talisman™ PFO Occluder, your doctor may be able to significantly reduce the risk of stroke reoccurrence. A group of experts conducted a meta-analysis of eight clinical studies and found a **59% relative risk reduction** for recurrent stroke compared to medical management[2].

With a proven track record of more than 180,000[3] patients treated globally over 20 years, the Amplatzer™ Talisman™ PFO Occluder is relied upon by thousands of physicians around the world.

AMPLATZER™ TALISMAN™ PFO OCCLUDER
DEVICE DESCRIPTION



The Amplatzer™ Talisman™ 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 Amplatzer™ Talisman™ PFO Occluder is designed to stop the blood flow and potential clots through the PFO.

Visit **PFOstroke.com** to learn more.

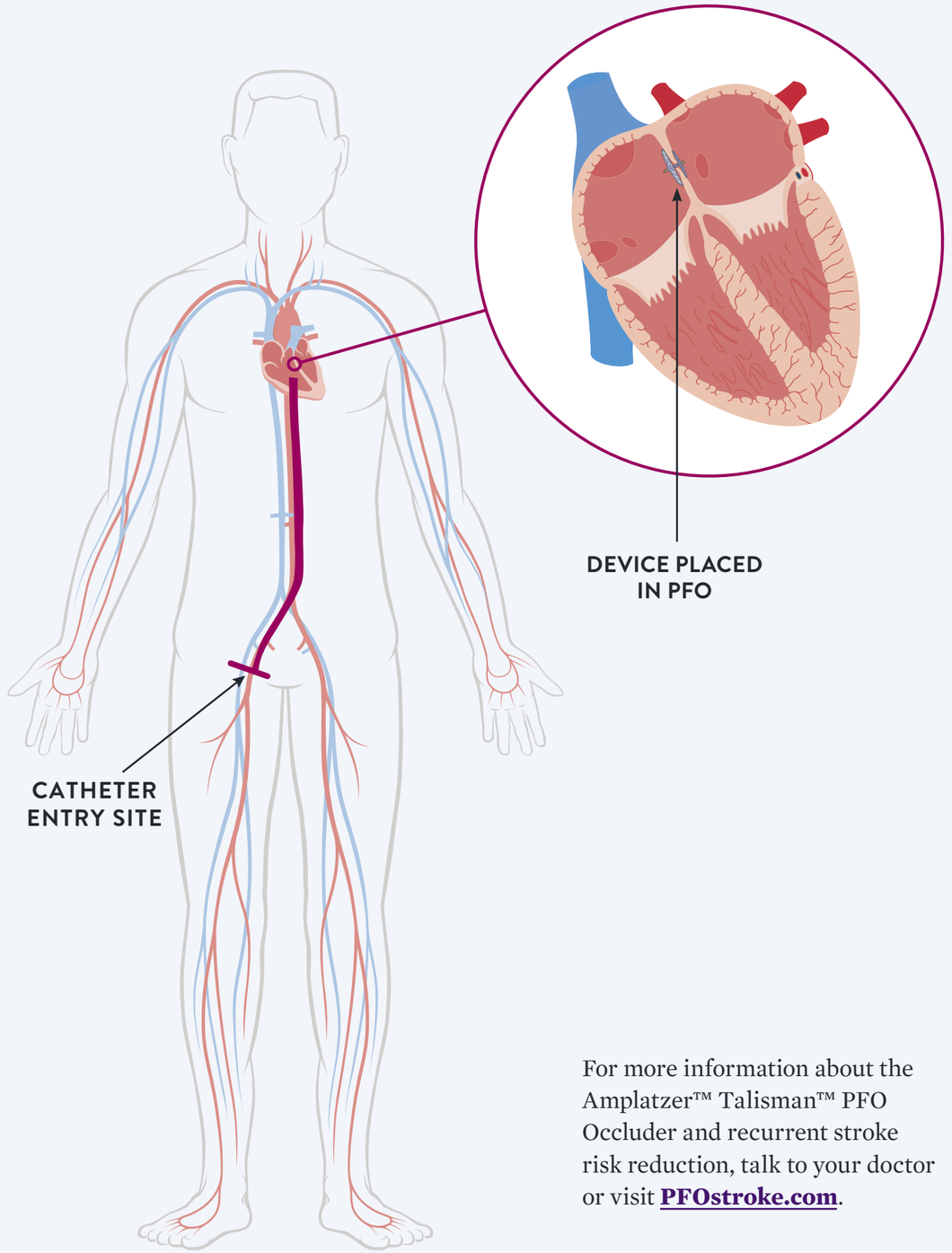
PHYSICIAN PERSPECTIVE ON PFO CLOSURE

"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

See Important Safety Information referenced within.



For more information about the Amplatzer™ Talisman™ PFO Occluder and recurrent stroke risk reduction, talk to your doctor or visit **PFOstroke.com**.

AMPLATZER™ TALISMAN™ PFO OCCLUDER

IMPORTANT SAFETY INFORMATION

℞ ONLY WHAT IS THE AMPLATZER™ TALISMAN™ PFO OCCLUDER APPROVED FOR?

The Amplatzer™ Talisman™ PFO Occluder is a device that is placed in the heart during a minimally invasive, catheter-based procedure to close a patent foramen ovale (PFO) to reduce the risk of another stroke in patients who have already had a stroke that was found to be related to the PFO.

WHO SHOULD NOT RECEIVE THE AMPLATZER™ TALISMAN™ PFO OCCLUDER?

Patients who have any of the following conditions should not receive the Amplatzer™ Talisman™ PFO Occluder: blood clots in the heart or blood vessels; mass, vegetation, or tumor inside the heart; heart or veins that are too small for the appropriate sheath size; anatomy in which the Amplatzer™ Talisman™ PFO Occluder would interfere with other heart structures, such as valves or veins; other sources of right to left shunts, including atrial septal defect; active heart infection or other untreated infections; or inability to take anticoagulant or antiplatelet therapy.

WHAT ARE THE POSSIBLE COMPLICATIONS ASSOCIATED WITH THE AMPLATZER™ TALISMAN™ PFO OCCLUDER?

Potential adverse events that may occur during or after a procedure using this device include, but are not limited to: air bubble that blocks blood flow in a vessel; allergic reaction to anesthesia, contrast dye, medication, or metal; loss of regular heart rhythm; abnormal connection between an artery and a vein; bleeding; perforation of the heart muscle or vessels; blood or fluid build-up around the heart; blood clot formation over the device or in the heart, leg, or lung; chest pain; death; obstruction of a blood vessel by all or part of an implanted device that entered the blood stream; device erosion; infection or inflammation in the heart; injury to the esophagus; fever; headache or migraine; high or low blood pressure; heart attack; pacemaker implant; pain; blood leakage outside a vessel; intervention to remove the device; stroke; temporary lack of oxygen to the brain; abnormal backward flow of blood through a valve; injury to the incision site.

WHAT ARE THE WARNINGS ASSOCIATED WITH THE AMPLATZER™ TALISMAN™ PFO OCCLUDER?

Patients at increased risk for blood clots may be prescribed a blood thinning medication following the procedure. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies.

Talk to your doctor to learn more about the risks associated with the Amplatzer™ Talisman™ PFO Occluder.

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.** Messé SR, Gronseth GS, Kent DM, et al. Practice advisory update summary: Patent foramen ovale and secondary stroke prevention. Neurology® 2020;94:1-10. **3.** Abbott Internal Sales Data 1998-2021.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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