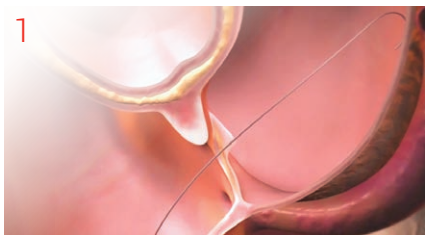
PATENT FORAMEN OVALE (PFO) CLOSURE

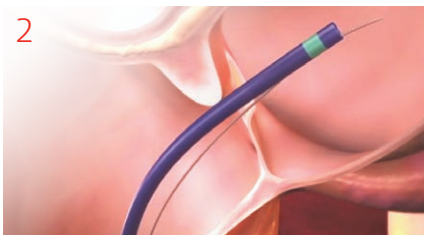
Understanding the PFO closure procedure can help you and your doctor determine if PFO closure is right for you.

How Does a Device Close My PFO?

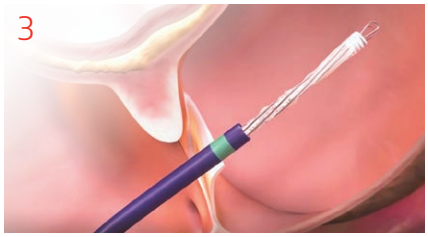
Catheter-based PFO closure puts a permanent implant inside your heart without open-heart surgery. The PFO closure device is placed inside the heart using a minimally invasive procedure.[1]

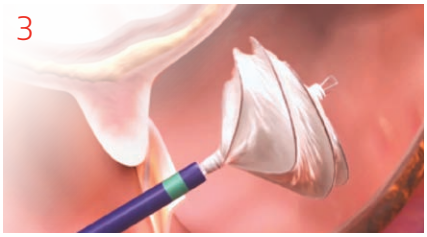


A doctor makes a small cut, or incision, typically in your right groin to access a vein. A catheter is threaded through the vein and up to the heart.

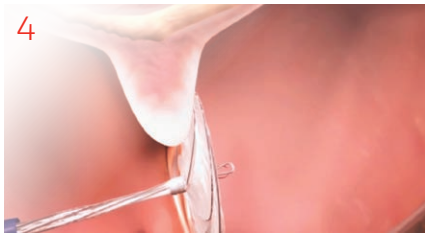


The PFO closure device is contained within the catheter. Your physician controls the placement and deployment of the device using a hand-held mechanism, guided by live ultrasound or X-ray images of your body and the device inside it.

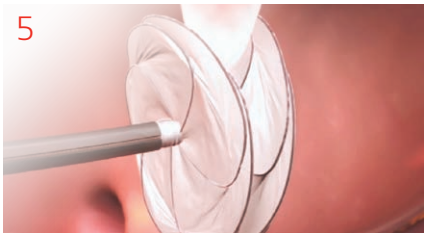




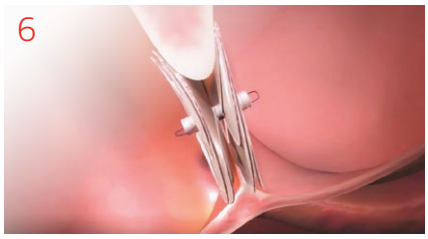
Your physician opens the left disc of the PFO closure device inside the left atrium.



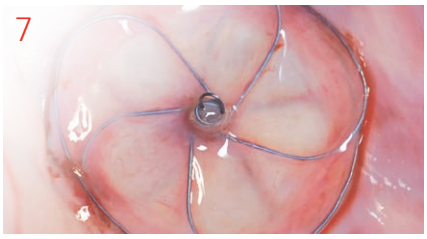
The left disc is positioned against the left side of the septum and conforms to the anatomy.



The device's right disc is deployed and positioned against the right side of the septum, closing the PFO.



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



The soft, conformable device allows for your cells to grow new tissue in and around the device.

What Else Should I Know About PFO Closure?

PFO closure procedure basics and duration

PFO closure is usually performed under general anesthesia or conscious sedation in the hospital.

PFO closure safety

PFO closure has been proven to be safe and has a low rate of serious adverse events related to the device or procedure. While PFO closure has been shown to increase your risk of rapid or irregular heartbeat, this is typically non-serious and resolves within a few weeks of onset.*,[2]

PFO closure effectiveness

Overall, the Gore REDUCE Clinical Study showed that PFO closure in combination with antiplatelet drugs was a better option for preventing another ischemic stroke than antiplatelet drugs alone.*,[2]

1-2 Hrs
Total length of procedure

1 Day
Time from admit to discharge

77%
Relative stroke reduction
with PFO closure plus antiplatelet drugs and/or blood thinners vs. medication alone.*,[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*.

1. GORE® CARDIOFORM Septal Occluder *Instructions for Use*. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2018. MD167065.

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. Rx_{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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