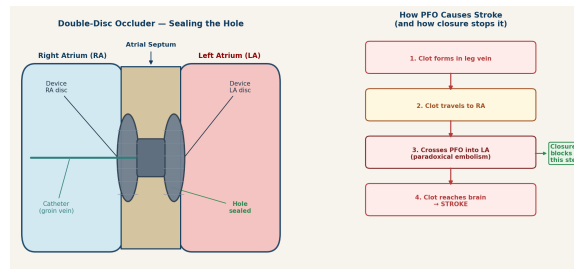


PFO and ASD Closure

Percutaneous (catheter-based) closure of a hole between the heart's upper chambers

Most PFOs need no treatment. When a stroke has no clear cause in a younger patient with a high-risk PFO, closure with a double-disc device — no surgery — can cut the risk of another stroke in half.



Online: <https://go.riasalimd.com/pfo-closure-guide>

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Names & Terms You Will Hear

Term	Meaning
PFO (Patent Foramen Ovale)	A small flap-like opening in the heart wall. Before birth, every baby has this opening. In about 1 in 4 adults, it does not fully close.
ASD (Atrial Septal Defect)	A true hole in the heart wall. It is larger than a PFO. It needs its own workup and may need a different device.
Percutaneous closure	Done through a thin tube called a catheter. The tube goes in through the groin vein. No chest cut and no open-heart surgery.
Double-disc occluder	The sealing device used to close the hole. It has two flat discs joined by a short waist. It grips both sides of the heart wall. Named devices: Amplatzer PFO Occluder, Amplatzer Septal Occluder, GORE Cardioform.
Cryptogenic stroke	A stroke with no clear cause found after a full workup. PFO is a top suspect in patients under age 60.
Right-to-left shunt	Blood, and sometimes clots, crossing from the right side to the left side of the heart through the PFO opening.
Paradoxical embolism	A clot that skips the lungs by crossing the PFO opening. It travels directly to the brain and can cause a stroke.
RoPE Score	A scoring tool that shows how likely a PFO caused a given stroke. A high score means the PFO was the likely cause.
Trans-septal puncture	The step where the catheter crosses the heart wall from the right side to the left side. It is done under echo guidance.
TEE (Transesophageal Echo)	An ultrasound probe placed in the throat. It gives a clear view of the heart wall and the device. See our separate TEE guide.



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PFO and ASD Closure?

- A **PFO** is a small flap-like opening in the wall between the heart's two upper chambers. Every baby has this opening before birth. In about **1 in 4 adults**, the opening does not fully close.
- An **ASD** (atrial septal defect) is a true hole in the wall. It is larger than a PFO and is a different condition. Each is treated differently.
- Both a PFO and an ASD can let a clot cross from the right side to the left side of the heart. That clot can travel to the brain and cause a stroke.
- **Closure** uses a thin tube called a catheter. The tube enters through a small puncture in the groin vein. A **double-disc device** is pushed through the tube. One disc opens on each side of the wall and seals the hole. No chest cut. No open-heart surgery.
- Three devices are FDA-approved: **Amplatzer PFO Occluder** (Abbott), **Amplatzer Septal Occluder** (Abbott), and **GORE Cardioform Septal Occluder**. The doctor picks the best fit for your anatomy.
- Tissue grows over the device in about **6 months**. This seals the opening for good.
- **Most PFOs need no closure.** About 1 in 4 adults has a PFO. Most people never have a stroke or any other problem from it.

PFO vs ASD — Key Differences and Closure Criteria

Feature	PFO (Patent Foramen Ovale)	ASD (Atrial Septal Defect)
What it is	An unfused flap that forms a tunnel. No tissue is missing.	A true hole. Tissue is absent from the wall. Usually larger than a PFO.
How common	About 25% of adults have one. Very common.	About 1 in 700 births. Much less common.
How it causes stroke	A clot crosses from right to left through the PFO during straining. It reaches the brain.	Extra blood flow strains the right heart. This can cause irregular heartbeat and, less often, a stroke.
Closure device	Amplatzer PFO Occluder or GORE Cardioform.	Amplatzer Septal Occluder or GORE Cardioform (for secundum ASD only).



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Feature	PFO (Patent Foramen Ovale)	ASD (Atrial Septal Defect)
When to close	After a cryptogenic stroke in a patient under 60 who has a large shunt or a floppy septum.	When the shunt is causing the right chamber to enlarge or pressures to rise.
Is surgery needed?	Almost never. Device closure works in more than 95% of cases.	Surgery is needed for primum ASD, sinus venosus ASD, or when anatomy does not allow a device.

The most important message: Most PFOs found by accident need NO treatment. About 1 in 4 adults has a PFO. The vast majority never have a stroke or any related problem. Closure is only right after a cryptogenic stroke in the right patient — *not* for a PFO found on an echo done for another reason. Ask your cardiologist and neurologist together whether you meet the criteria.



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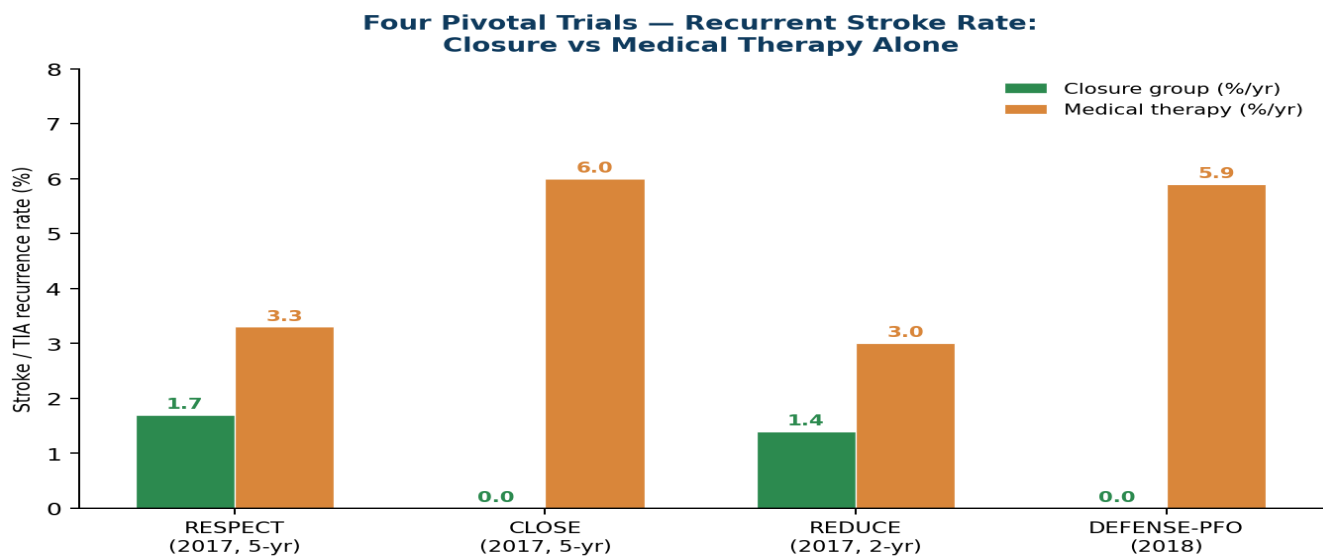
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Why It Matters

- In a younger patient (under age 60) with a stroke that has no clear cause, the PFO is often to blame. A clot from the leg crossed through the PFO and traveled to the brain. This is called a **cryptogenic stroke**.
- Three large studies — **RESPECT, CLOSE, and REDUCE** (all 2017) — showed that closure cut the chance of another stroke by roughly 40 to 100% compared to medicine alone.
- The **CLOSE trial** found zero strokes in the closure group over 5 years. The medicine-only group had a 6% stroke rate in the same period.
- The **DEFENSE-PFO trial** (2018) confirmed the same benefit. It focused on patients with a large PFO or a floppy heart wall.
- Not every PFO needs to be closed. The **RoPE score** helps show how likely the PFO caused the stroke. A low score means another cause may have been missed.
- For an **ASD with right-heart strain** (enlarged right chamber), closure can help prevent heart failure, abnormal heart rhythm, and high pressure in the lung arteries.
- The decision to close a PFO should involve **both a cardiologist and a neurologist** working together.



Recurrent stroke or TIA rates across four pivotal PFO closure trials. The CLOSE trial found zero strokes in the closure arm at 5 years. RESPECT and REDUCE confirmed about 50% relative risk reduction. DEFENSE-PFO confirmed benefit in patients with high-risk PFO anatomy.



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PFO After Cryptogenic Stroke — What the Trials Proved

- **RESPECT (2017)** — 980 patients followed for 5 years. Closure with the Amplatzer device cut the recurrent stroke risk by 45% compared to aspirin alone. The hazard ratio was 0.55.
- **CLOSE (2017)** — 663 patients followed for 5 years. Zero strokes occurred in the closure group. The aspirin-only group had a 6.0% stroke rate. Only patients with high-risk PFO anatomy were enrolled.
- **REDUCE (2017)** — 664 patients. Closure cut the rate of new stroke and brain lesions. A key trade-off: new irregular heartbeat in 6.6% of the closure group vs 0.4% with medicine alone. This usually resolved on its own.
- **DEFENSE-PFO (2018)** — An Asian-population study. It confirmed that closure helps patients with high-risk PFO features such as a large shunt or a floppy septum.
- All four trials agree: the benefit is greatest in patients with **high-risk PFO anatomy, age under 60, and no other stroke cause found.**



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Risk Factors

Some patients are more likely to develop this condition. Knowing your risk helps your care team take extra precautions.

Risk Factor	Why It Increases Risk
Cryptogenic stroke, age under 60	This is the best-proven reason for PFO closure. Most trial patients were in this group. Benefit is greatest when the PFO has high-risk features.
Large right-to-left shunt	More bubbles on the bubble study means a higher chance the PFO caused the stroke. A large shunt is a high-risk PFO feature in the trials.
Atrial septal aneurysm (ASA)	A floppy, bulging wall between the chambers. It raises the shunt risk. It is closely linked to cryptogenic stroke and is a high-risk feature in CLOSE and DEFENSE-PFO.
Prior blood clot in leg or lung	A clot that forms in the leg vein can travel to the right side of the heart. It may then cross the PFO to the brain instead of going to the lungs.
ASD with right-heart strain	The right chamber grows too large due to extra blood from the ASD. This is an indication for ASD closure to prevent heart failure and high lung pressure.
Platypnea-orthodeoxia syndrome	This is a rare condition. Oxygen drops when the patient sits upright. PFO closure is often curative.
Occupational or recreational diving	Divers with a PFO have a higher risk of neurologic injury from decompression. Some divers choose closure for safety on the job or at sport.



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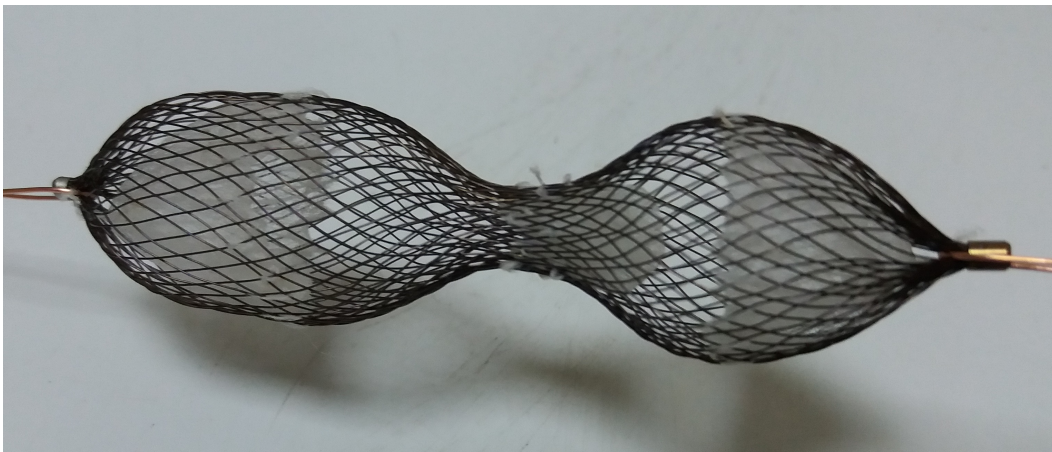
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Treatment Options

- **PFO closure is the treatment described in this guide.** It is used after a cryptogenic stroke in patients who meet the criteria. It is NOT used for a PFO found by chance.
- **Alternatives to closure** for PFO after a stroke: aspirin or clopidogrel alone; blood thinners (DOAC or warfarin) if a venous clot source is confirmed.
- **ASD alternatives:** surgery for non-secundum ASDs such as primum ASD or sinus venosus ASD. Device closure is used for secundum ASD when anatomy allows.
- **Shared decision-making:** the cardiologist and neurologist review the case together. They weigh patient age, RoPE score, PFO size, prior stroke severity, and patient preference.
- **After the procedure:** take aspirin plus clopidogrel for 1 to 6 months as directed, then aspirin alone long-term.
- **Infection prevention:** take antibiotics before dental work or surgery for the first 6 months after device placement, before tissue grows over the device.
- **Follow-up:** a heart echo at 6 to 12 months confirms the device has sealed. Ongoing visits with cardiology and neurology are needed.



A real Amplatzer-style double-disc occluder device, unfolded. The self-expanding nitinol mesh forms two flat discs joined by a short waist. One disc opens on each side of the septum and pinches the hole or flap closed from both sides.



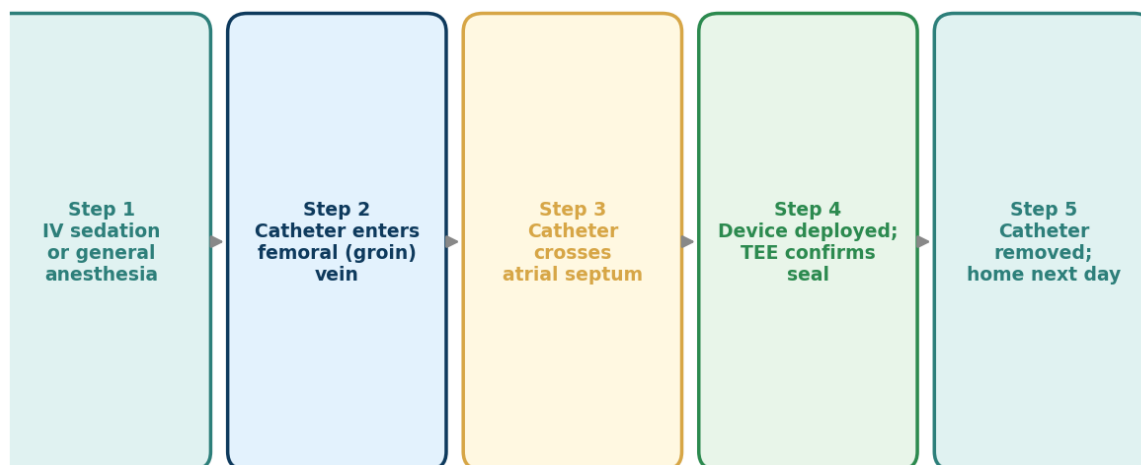
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The Procedure — Five Steps (About 1 Hour, Usually Outpatient)



The five-step procedure. The catheter enters the groin vein, crosses the septum under echo guidance, and deploys the double-disc device. The team confirms the seal with echo before removing the catheter. Most patients go home the next morning.



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Who Is (and Is Not) a Candidate for PFO Closure

Patient Profile	Closure Recommended?	Rationale
Cryptogenic stroke, age under 60, high-risk PFO (large shunt or floppy septum)	YES — strong indication	CLOSE, RESPECT, and REDUCE all show a clear benefit. Supported by joint ACC/AHA/AAN guidelines.
Cryptogenic stroke, age under 60, low RoPE score (PFO likely not the cause)	Discuss carefully — may not benefit	A low RoPE score suggests another undetected cause. The risk and benefit must be weighed together with your doctors.
Cryptogenic stroke, age over 60	Not routinely used	Most trial patients were under age 60. Each case needs individual evaluation.
Incidental PFO, no stroke or symptoms	NO — do not close	25% of adults have a PFO. Most never have a related problem. The risk of the procedure is greater than the benefit.
PFO plus migraine with aura only	Not routinely used	Trials testing closure for migraine (PRIMA trial) were negative. Migraine alone is not an indication.
ASD with right-heart strain	YES — if anatomy allows device	Closure prevents heart failure, irregular heartbeat, and high lung pressure. Device is used for secundum ASD; surgery for primum or sinus venosus types.



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ASD Device Closure — Who Qualifies and Which Device

- **Secundum ASD** is the most common type. It sits in the middle of the wall between the chambers. If it is causing right-heart strain and the anatomy allows it, device closure is the first choice. The **Amplatzer Septal Occluder** and **GORE Cardioform** are the main devices used.
- **Primum ASD** sits low in the wall near the mitral valve. Device closure is not possible. Surgery is required.
- **Sinus venosus ASD** sits near the top or bottom entry veins. Device closure is not possible. Surgery is required.
- Signs that the right heart is overloaded include: enlarged right ventricle on echo, high right-sided pressures, and a septum that moves the wrong way. These signs help drive the decision to close.
- PFO closure is mainly about preventing another stroke. ASD closure is mainly about relieving the burden of extra blood on the right heart. These are different goals.

The New Irregular Heartbeat Risk — What Patients Need to Know

- In the REDUCE trial, new atrial fibrillation after PFO closure occurred in **6.6%** of the closure group. Only 0.4% of the medicine-only group developed it.
- In most cases, the new irregular heartbeat is **short-lived**. Most patients develop it in the first month after the procedure. It usually goes away on its own. Most patients do not need ablation or long-term blood thinners.
- Why it happens: the device causes mild swelling of the septum. As the septum heals over about 6 months, the irregular heartbeat episodes typically stop.
- If the irregular heartbeat does not go away, you may need blood thinners or a procedure to control heart rate or rhythm. Talk to your cardiologist.
- The benefit of closure — a large drop in stroke risk — outweighs this short-term risk in the right patients, as confirmed by all four trial committees.



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Risks, Benefits, and Alternatives

Every choice has trade-offs. Use this table to start the shared decision conversation.

Option	Risks	Benefits	Alternatives
PFO closure — device (Amplatzer, GORE Cardioform)	New irregular heartbeat (atrial fibrillation) in about 3 to 5%. It usually goes away in the first month. Device coming loose: less than 1%. Small gap remaining around the device: 3 to 8% at 6 months, usually minor. Fluid around the heart: rare. Groin-site bleeding or bruising: less than 2%.	Cuts recurrent stroke risk by 50 to 100% in the right patients (RESPECT, CLOSE, REDUCE trials). No need for lifelong blood thinners. The device stays in place and tissue grows over it.	Aspirin or clopidogrel alone; blood thinners; no treatment if RoPE score is low or procedure risk is high.
Aspirin or clopidogrel alone	Stroke may come back at a rate of 3 to 6% per year in high-risk PFO. This is higher than with closure. There is also a risk of stomach bleeding. The hole in the heart is not closed.	No procedure needed. Can be stopped if side effects occur. Supported by guidelines for lower-risk PFO or when the patient does not want closure.	PFO closure; blood thinners; combination antiplatelet therapy.
Blood thinners (DOAC or warfarin)	Major bleeding risk of about 2 to 4% per year. The hole in the heart is not closed. Daily medication is required.	Treats both the venous clot source and the risk of a clot crossing the PFO. Supported by evidence when a leg or lung clot is confirmed as the cause.	PFO closure; aspirin or clopidogrel; watchful waiting for very low-risk PFO.



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Option	Risks	Benefits	Alternatives
Surgery to close ASD (for primum or sinus venosus type)	Open-heart surgery carries risks of infection, bleeding, heart-lung bypass, and a longer recovery of 2 to 6 weeks. It is not needed for most secundum ASDs when device closure works.	Definitive repair. Required for ASDs that cannot be closed with a device, such as primum or sinus venosus types. Long-term outcomes are well studied.	Device closure through a catheter (for secundum ASD only).

Both a cardiologist and a neurologist must be part of this decision. Per ACC/AHA/AAN consensus guidance, the choice to close a PFO after a cryptogenic stroke requires both specialties. The neurologist confirms that no other stroke cause was missed. The cardiologist confirms the PFO anatomy is high-risk and the procedure can be done safely. Neither specialty makes this choice alone.



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Common Misconceptions

Myth	Reality
"My incidental PFO needs to be closed."	No. About 25% of adults have a PFO. The vast majority never have a related problem. A PFO found by chance during a test for another reason almost never needs to be closed.
"Closure guarantees I will never have another stroke."	Closure lowers stroke risk a great deal — but does not remove all risk. Other causes of stroke, such as irregular heartbeat, high blood pressure, high cholesterol, and smoking, still need treatment.
"PFO closure is open-heart surgery."	No. The device goes in through a catheter placed in the groin vein. Most patients go home the next day. There is no chest incision.
"An ASD and a PFO are the same thing."	They are not the same. A PFO is an unfused flap. An ASD is a true hole. The reasons to close them, the devices used, and the anatomy involved are all different.
"After my cardiologist closes the PFO, my neurologist is done."	Neurology stays involved. Both a cardiologist and a neurologist must evaluate the patient. Follow-up for stroke risk factors continues long after the procedure.
"I can stop my blood pressure medicine after closure."	No. Closure stops one specific pathway: a clot crossing the PFO to the brain. All other heart and stroke risk factors, such as blood pressure, still need treatment and medication.
"Closure is experimental."	No. The Amplatzer PFO Occluder was FDA-approved in 2016. GORE Cardioform received FDA approval in 2018. All three pivotal clinical trials were published in 2017 in the New England Journal of Medicine.



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Possible Complications

Knowing what can go wrong helps you spot problems early. Most complications are uncommon, especially with treatment.

Where / What	What Can Happen
New irregular heartbeat (atrial fibrillation) after closure	This is the most common notable complication. It occurs in about 3 to 5% of patients in the first month. It usually goes away on its own without treatment. Monitoring is needed.
Device coming loose (embolization)	The device may slip out of place after it is put in. This is rare, happening in less than 1% of cases. The care team usually catches it right away and retrieves the device through the catheter. Surgery is rarely needed.
Small gap remaining around the device (residual shunt)	A small gap remains around the device in 3 to 8% of patients at 6 months. Most of these gaps are very small and cause no symptoms. Larger gaps may need continued aspirin therapy or another procedure.
Groin-site bleeding or bruising	Bleeding, a bruise, or a pocket of blood (pseudoaneurysm) can form where the catheter entered the vein. This usually heals on its own. It occurs in less than 2% of cases.
Device erosion	This is very rare. The edge of the device slowly erodes into nearby heart tissue. It is more often reported with ASD occluders than with PFO occluders. A yearly follow-up scan is recommended.
Fluid around the heart (pericardial effusion)	This is rare. It can happen if the catheter accidentally injures the heart wall. Treatment with fluid drainage is usually enough. Surgery is very rarely needed.
Stroke after closure	Stroke can still happen from other causes such as irregular heartbeat, other clot sources, or high blood pressure. Closure lowers the risk but does not remove it. All risk factors need ongoing care.



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Points to Know

If you remember nothing else, remember these key points.

- A PFO is present in 1 in 4 adults. Most people with a PFO never need any treatment.
- Closure is used after a cryptogenic stroke in patients under 60 who have a high-risk PFO — such as a large shunt or a floppy septum. It is NOT used for a PFO found by chance.
- The four key closure trials are RESPECT, CLOSE, REDUCE, and DEFENSE-PFO. All four found a clear benefit in the right patients.
- The procedure uses a catheter through the groin vein. There is no chest incision and no open-heart surgery. Most patients go home the next day.
- New irregular heartbeat occurs in about 3 to 5% of patients after PFO closure. It usually goes away on its own but needs monitoring.
- Take aspirin plus clopidogrel as prescribed for 1 to 6 months after the procedure, then aspirin alone.
- For the first 6 months after the device is placed, take antibiotics before dental work or surgery. Tell your dentist and all doctors about your device.
- High blood pressure, high cholesterol, diabetes, and smoking still raise your stroke risk. All of these need treatment even after closure.



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When to Call Us - and When to Call 911

If you are not sure, call. We would rather hear from you twice than miss a real problem.

- **Call 911** for stroke symptoms: sudden face droop, arm or leg weakness, slurred speech, vision loss, or the worst headache of your life.
- **Call 911** for new chest pain, sharp chest pain that worsens lying flat, or sudden shortness of breath after the procedure.
- **Call our office today** if you develop palpitations or rapid irregular heartbeat in the weeks after closure — may be transient AF.
- **Call our office today** if you have groin pain, a growing lump, or bleeding at the catheter access site.
- **Call our office today** if you have fever above 100.4 °F, redness, or drainage from the groin site.
- **Call our office** before any dental procedure, colonoscopy, or surgery in the first 6 months after closure — endocarditis prophylaxis may be needed.
- **Call our office** before you start scuba diving or return to high-altitude activities after closure.
- **Do not skip** your 6- or 12-month follow-up echo — call us if you cannot make the appointment.

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Trusted Resources

The links below are the trusted resources Dr. Ali used to write this guide and that he recommends you visit for more information. Each is a clickable link in the digital version and a Short.io tracked URL on the printed version.

- [American Stroke Association — PFO and Cryptogenic Stroke](#) - Stroke-prevention framing of PFO closure decisions.
- [American Heart Association / AHA-ASA Joint Statement \(2020\)](#) - Joint cardiology and neurology consensus on patient selection for PFO closure.
- [American Academy of Neurology — PFO Practice Advisory](#) - Neurology society guidance on evaluating PFO after cryptogenic stroke.
- [Cleveland Clinic — Atrial Septal Defect](#) - Plain-language overview of ASD, types, and when closure is needed.
- [Mayo Clinic — Patent Foramen Ovale](#) - Clear anatomy, symptoms, diagnosis, and treatment overview.
- [MedlinePlus — Patent Foramen Ovale](#) - NIH/NLM plain-language PFO reference.
- [PFO condition guide \(go.riasalimd.com\)](#) - Our companion guide on PFO as a condition — anatomy, bubble study, and stroke risk.
- [ASD condition guide \(go.riasalimd.com\)](#) - Our companion guide on atrial septal defect — types, right-heart overload, closure criteria.



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Sources Used to Build This Guide

Every recommendation in this guide is grounded in one or more of the studies, guidelines, or trusted resources below. Short links are tracked so Dr. Ali can see which references patients are reading; nothing personally identifying is captured.

- [ACC/AHA 2020 Joint Statement on PFO Closure](#) [Guideline]
AHA/ASA/ACC/HRS/SCAI consensus on PFO closure indication and patient selection.
- [RESPECT Trial — N Engl J Med 2017](#) [Rct]
Primary RCT demonstrating PFO closure superiority over antiplatelet in cryptogenic stroke (HR 0.55); long-term 5-year follow-up.
- [CLOSE Trial — N Engl J Med 2017](#) [Rct]
Showed zero recurrent strokes with PFO closure at 5 years vs 6% with antiplatelet alone; validated high-risk PFO subgroup.
- [REDUCE Trial — N Engl J Med 2017](#) [Rct]
Third pivotal RCT confirming closure benefit; also quantified new AF risk (6.6% vs 0.4%) as a key procedure trade-off.
- [DEFENSE-PFO Trial — JACC 2018](#) [Rct]
Asian-population RCT confirming benefit in high-risk PFO (large shunt + atrial septal aneurysm).
- [RoPE Score — Stroke 2012 \(Kent et al\)](#) [Decision Tool]
Risk of Paradoxical Embolism (RoPE) score: quantifies probability that PFO was causal in a given cryptogenic stroke.
- [Mayo Clinic — PFO Patient Overview](#) [Patient Resource]
Plain-language patient framing of PFO anatomy, indications, and procedure.
- [Cleveland Clinic — Atrial Septal Defect](#) [Patient Resource]
Clear differentiation of ASD vs PFO; indication for ASD closure (right heart volume overload).
- [American Stroke Association — PFO and Cryptogenic Stroke](#) [Patient Resource]
Patient-facing stroke-prevention framing of PFO closure.
- [American Academy of Neurology — PFO Practice Advisory](#) [Guideline]
Neurology consensus on patient selection for PFO closure after cryptogenic stroke.
- [AHA/ACC 2024 Guideline on Structural Heart Disease](#) [Guideline]
Updated ACC/AHA guidance on percutaneous closure of PFO and ASD, including device selection and follow-up protocols.
- [Amplatzer PFO Occluder — FDA Summary of Safety and Effectiveness](#) [Regulatory]
FDA approval data for the Amplatzer PFO Occluder; basis for named-device procedure complication rates cited in this guide.



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About This Guide

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Reviewer note: Reviewed against Mayo Clinic, Cleveland Clinic, AHA/ASA, American Academy of Neurology, and SCAI patient pages. This guide adds: plain-language RoPE score framing, all four pivotal closure trials (RESPECT, CLOSE, REDUCE, DEFENSE-PFO) side-by-side with numbers, a named-device section (Amplatzer PFO Occluder, Amplatzer Septal Occluder, GORE Cardioform), a clear ASD vs PFO comparison, the new irregular heartbeat risk with numbers (a trade-off most pages omit), shared cardiology-neurology decision-making guidance, and the key message that most PFOs found by chance do NOT need closure.

Disclaimer

This guide is for educational purposes only and does not replace medical advice from your physician. Recommendations may not apply to every patient. Always follow the specific instructions of Dr. Ali and your care team. In an emergency call 911 or go to the nearest emergency department.



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