

NEW RECOMMENDATIONS FOR STROKE SURVIVORS

Physician societies around the world have updated their guidelines to support percutaneous closure of a patent foramen ovale (PFO) to prevent stroke recurrence in select patients ¹⁻⁶



LESS RISK FOR STROKE SURVIVORS LIVING WITH PFO

PFO IS THE LIKELY CAUSE OF MORE STROKES THAN PREVIOUSLY RECOGNIZED

- Approximately **5%** of all ischemic strokes and **10%** of those occurring in young and middle-aged adults are associated with a PFO⁷.
- **80%** of strokes of unknown cause in patients with a Risk of Paradoxical Embolism (**RoPE**) **score of 7** or greater are due to a PFO⁷.

CLINICAL IMPLICATIONS FROM RECENT GUIDELINES UPDATES^{1,2}

PFO closure may be recommended for people < 60 years of age¹:

- When stroke is thought to be caused by a PFO and no other mechanism has been identified.
- After discussing the potential benefits and risks.

PFO closure may be offered for people 60-65 years of age¹:

- After a thorough evaluation, including monitoring for atrial fibrillation.
- With very limited degree of traditional vascular risk factors (hypertension, diabetes, hyperlipidemia, smoking).
- In whom no other mechanism of stroke has been detected.

PFO closure may be recommended in patients 18-60 years of age²:

- When stroke is thought to be caused by a PFO with high-risk anatomic features, such as atrial septal aneurysm and/or large shunt.
- If PFO is considered low risk anatomically and RoPE Score has been factored into clinical decision.

HOW TO KNOW IF A PFO IS THE LIKELY CAUSE

HIGHER ROPE SCORES POINT TO PFO AS A CAUSATIVE MECHANISM FOR STROKE⁸

RoPE SCORE CALCULATOR	POINTS	SCORE
CHARACTERISTIC	Select all that apply	
No history of hypertension	1	
No history of diabetes	1	
No history of stroke or TIA	1	
Non-smoker	1	
Cortical infarct on imaging	1	
AGE (YEARS)	Select the one that applies	
18-29	5	
30-39	4	
40-49	3	
50-59	2	
60-69	1	
≥70	0	
TOTAL SCORE	POINTS	SCORE
SUM OF INDIVIDUAL POINTS	Add up your total score from above	
Maximum score (patient <30 y.o. without vascular risk factors, no history of stroke or TIA, and cortical infarct)		10
Minimum score (patient >70 y.o. with vascular risk factors, prior stroke, and no cortical infarct)		0

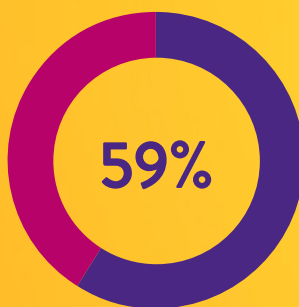
TOTAL RoPE SCORE	PREVALENCE OF PFO (%)	PFO-ATTRIBUTED FRACTION (%)
7	54	72
8	67	84
9-10	73	88

WHY PFO CLOSURE? WHY NOW?

An expanded body of evidence and a review of existing clinical evidence prompted physician societies around the globe to support percutaneous PFO closure to reduce the risk of recurrent stroke. The most recent societies to recommend PFO closure are the American Academy of Neurology and the American Heart Association/American Stroke Association. Here's closure look at their recommendations.

AAN RECOMMENDATIONS

LESS RISK
OF STROKE
RECURRENCE¹



Relative risk reduction for recurrent stroke compared to medical management

- ▶ Absolute risk reduction of stroke at 5 years: **3.4%**
- ▶ Periprocedural complication risk: **3.9%**

AHA/ASA RECOMMENDATIONS²

- Closure recommended for patients 18-60 with nonlacunar stroke and PFO with high risk anatomical characteristics over anti-platelet medication alone.
- Joint decision making between patient, neurologist and cardiologist is recommended to determine if PFO closure is appropriate for recurrent stroke prevention.

WHAT'S THE OUTLOOK POST-PFO CLOSURE?

Events including non-periprocedural atrial fibrillation (summary rate difference 0.33% per year [95% CI 0.04% to 0.65%]), were self-limited and of uncertain long-term clinical consequence given the lower rate of stroke in patients whose PFO was closed.¹

After a median of 5.9 years follow up, data show no difference in the rate of new-onset non-periprocedural atrial fibrillation between participants receiving closure and those receiving medical treatment (difference 0.14% [95% CI, -0.9% to -0.4%]).¹

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Always check the regulatory status of the device in your region.

PFO CLOSURE: A SAFE, SAME-DAY PROCEDURE WITH LIFE CHANGING OUTCOMES

- ✓ MINIMALLY INVASIVE, CATHETER-BASED PROCEDURE
- ✓ SHORT PROCEDURE TIME
- ✓ PROCEDURE DOES NOT REQUIRE GENERAL ANESTHESIA
- ✓ USUALLY AN OUTPATIENT PROCEDURE
- ✓ CAN REDUCE THE NUMBER OF ONGOING ANTITHROMBOTIC MEDICATIONS AS SOON AS ONE MONTH AFTER CLOSURE

“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, stroke at age 33**



WORK WITH AN INTERVENTIONAL CARDIOLOGIST TO DETERMINE IF PFO CLOSURE IS RIGHT FOR YOUR PATIENTS.

EFFECTIVE PFO CLOSURE MADE EASIER⁹, WITH THE AMPLATZER™ TALISMAN™ PFO OCCLUDER

EXTENSIVE EXPERIENCE



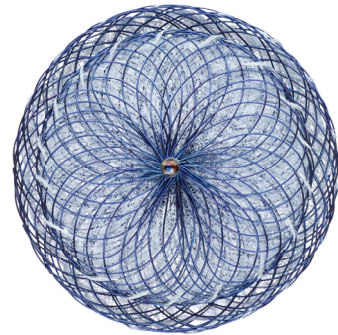
OVER 180,000 PATIENTS TREATED GLOBALLY¹⁰

#1 device selected
for PFO closure

An unmatched
track record
with over two decades
of experience

Offering a wide
range of device sizes
Optimized for most
patient anatomies

CONFIDENCE IN CLOSURE



>94% CLOSURE RATE[†]
at 6 months in RESPECT trial¹¹

LONG-TERM PATIENT FOLLOW-UP^{11*}

5,810

patient-years of data

5.9

years average patient follow up

EXCELLENT SAFETY^{11*}

0

device-related events

< 1% AF

Low risk of atrial fibrillation

PARTNER WITH AN INTERVENTIONAL
CARDIOLOGIST TO INCORPORATE
PFO CLOSURE INTO YOUR PRACTICE.

HOW TO OFFER PFO CLOSURE FOR STROKE SURVIVORS

INTEGRATE PFO CLOSURE INTO YOUR NEUROLOGY PRACTICE WITH THIS THREE-STEP PROCESS:



IDENTIFY POSSIBLE CANDIDATES FOR CLOSURE



COLLABORATE WITH AN INTERVENTIONAL CARDIOLOGIST TO SELECT APPROPRIATE PATIENTS



PRESENT PFO CLOSURE AS AN OPTION TO YOUR PATIENTS

* Rates calculated based on data in final publication. CLOSE Trial data not included as follow-up patient-years was not reported. In RESPECT, serious AF was adjudicated by an independent board of physicians.

† Effective Closure

REFERENCES: **1.** Messé SR, Gronseth GS, Kent DM, et al. Practice advisory update summary: Patent foramen ovale and secondary stroke prevention. *Neurology* 2020;94:1-10. **2.** Sharrief et al, 2021 Guideline for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack. A Guideline from the American Heart Association/American Stroke Association, *Stroke*, 2021;52:e364– e467. DOI: 10.1161/STR.0000000000000375. **3.** Japan Stroke Society Stroke Guidelines Committee “Stroke Treatment Guidelines 2021” (issued July 15, 2021) **4.** Stroke Foundation. Clinical Guidelines for Stroke Management 2019. Melbourne Australia. **5.** Liu L, et al. *Stroke & Vascular Neurology* 2020;5:e000378. doi:10.1136/svn-2020-000378. **6.** Diener et al. *Neurological Research and Practice* <https://doi.org/10.1186/s42466-019-0008-2>. **7.** Elgendy AY, Saver JL, Amin Z, et al. Proposal for Updated Nomenclature and Classification of Potential Causative Mechanism in Patent Foramen Ovale -Associated Stroke. *JAMA Neurology* April 2020. **8.** Kent DM, Ruthazer R, Weimar C, et al. An index to identify stroke-related vs incidental patent foramen ovale in cryptogenic stroke. *Neurology*® 2013;81:619 -625. **9.** Tests performed by and data on file at Abbott. **10.** Abbott Internal Sales Data 1998-2021. **11.** Saver JL, Carroll JD, Thaler DE, et al. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. *N Engl J Med* 2017; 377: 1022-32.

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3200 Lakeside Dr., Santa Clara, CA. 95054 USA

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