NEW RECOMMENDATION FOR STROKE SURVIVORS

"...closing the PFO may reduce the risk of having another stroke better than medication alone."[1]

—Steven R. Messé, M.D.

2020 Practice Advisory Update from the American Academy of Neurology (AAN) supports percutaneous closure of a patent foramen ovale (PFO) to prevent stroke recurrence in select patients[2]

See Important Safety Information referenced within.

Abbott

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 PFO[3]
- **80%** of cryptogenic strokes in patients with a Risk of Paradoxical Embolism **(RoPE) score of 7** or greater are due to a PFO[3]

AAN NOW SUPPORTS PFO CLOSURE FOR MORE PATIENTS[2]

For **people less than 60 years of age,** PFO closure may be recommended:

- When thought to be the cause of stroke and no other mechanism has been identified
- After discussing the potential benefits and risks

For **people 60-65 years of age,** PFO closure may be offered:

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

"Having no control is scary. Walking around in fear of having another stroke or being on thinners forever. I just wanted to live a normal life without constant worry."

– Heidi, stroke at age 37

See Important Safety Information referenced within.

HOW TO KNOW IF A PFO IS THE LIKELY CAUSE

HIGHER RoPE SCORES POINT TO PFO AS A CAUSATIVE MECHANISM FOR STROKE[4]

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

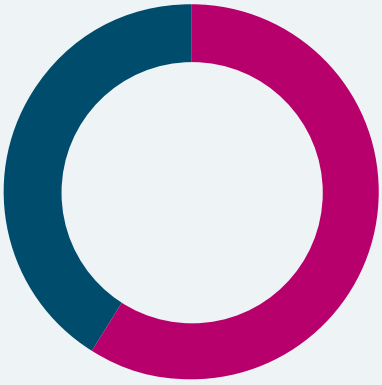
TOTAL RoPE SCORE	PREVALENCE OF PFO (%)	PFO-ATTRIBUTED FRACTION (%)
7	54	72
8	67	84
9-10	73	88

See Important Safety Information referenced within.

WHY PFO CLOSURE? WHY NOW?

An expanded body of evidence prompted the AAN to support percutaneous PFO closure to reduce the risk of recurrent stroke.

LESS RISK OF STROKE RECURRENCE[2]



Relative risk reduction for recurrent stroke compared to medical management:
59%

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

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.[2]

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%).[2]

See Important Safety Information referenced within.

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.

See Important Safety Information referenced within.

AMPLATZER™ PFO OCCLUDER IS THE #1 DEVICE SELECTED FOR PFO CLOSURE

EXTENSIVE EXPERIENCE

130,000 PATIENTS TREATED GLOBALLY[5]

An unmatched track record with over two decades of experience

#1 device selected for PFO closure

EFFECTIVE CLOSURE[6]

94% CLOSURE RATE*
at 6 months in RESPECT trial[6]

LONG-TERM PATIENT FOLLOW-UP[6]

5,810
patient-years of data

5.9
years average patient follow up

EXCELLENT SAFETY[6]*

0
device-related events

< 1% AF
low risk of atrial fibrillation

OVER 700

INTERVENTIONAL CARDIOLOGISTS IN THE US ARE CERTIFIED AND TRAINED ON THE PFO CLOSURE PROCEDURE.[5]

*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.

See Important Safety Information referenced within.

HOW TO OFFER PFO CLOSURE FOR STROKE SURVIVORS

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

IDENTIFY APPROPRIATE PATIENTS

Perform a detailed workup using the updated AAN practice advisory for specific recommendations

COLLABORATE WITH AN INTERVENTIONAL CARDIOLOGIST TO SELECT APPROPRIATE PATIENTS

Find an interventional cardiologist near you at https://cryptogenicstroke.com/us-centers

PRESENT PFO CLOSURE AS AN OPTION TO YOUR PATIENTS

Access and share information for patients at cryptogenicstroke.com

1. Press release. AAN Updates Recommendation on Closure of Common Heart Defect After Stroke. April 29, 2020. 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. 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. 4. 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. 5. Internal data. Data on-file at Abbott. 6. 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.

IMPORTANT SAFETY INFORMATION

℞ ONLY

AMPLATZER™ PFO OCCLUDER

INDICATIONS AND USAGE

The AMPLATZER™ PFO Occluder is indicated for percutaneous transcatheter closure of a 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

- Patients with intra-cardiac mass, vegetation, tumor or thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the PFO is gained.
- Patients whose vasculature, through which access to the PFO is gained, is inadequate to accommodate the appropriate sheath size.
- Patients with anatomy in which the AMPLATZER™ PFO device size required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins.
- Patients with other source of right-to-left shunts, including an atrial septal defect and/or fenestrated septum.
- Patients with active endocarditis or other untreated infections.

WARNINGS

- Patients who are at increased risk for venous thromboembolic events should be managed with thromboembolic risk reduction regimen after the PFO Closure following standard of care.
- Do not use this device if the sterile package is open or damaged.
- Prepare for situations that require percutaneous or surgical removal of this device. This includes availability of a surgeon.
- Embolized devices must be removed as they may disrupt critical cardiac functions. Do not remove an embolized occluder through intracardiac structures unless the occluder is fully recaptured inside a catheter or sheath.
- Patients who are allergic to nickel can have an allergic reaction to this device.
- This device should be used only by physicians who are trained in standard transcatheter techniques.
- Transient hemodynamic compromise may be encountered during device placement, which may require fluid replacement or other medications as determined by the physician.
- Do not release the device from the delivery cable if the device does not conform to its original configuration, or if the device position is unstable or if the device interferes with any adjacent cardiac structure (such as Superior Vena Cava (SVC), Pulmonary Vein (PV), Mitral Valve (MV), Coronary Sinus (CS), Aorta (AO)). If the device interferes with an adjacent cardiac structure, recapture the device and redeploy. If still unsatisfactory, recapture the device and either replace with a new device or refer the patient for alternative treatment.

PRECAUTIONS

- The safety and effectiveness of the AMPLATZER™ PFO Occluder has not been established in patients (with):
  - Age less than 18 years or greater than 60 years because enrollment in the pivotal study (the RESPECT trial) was limited to patients 18 to 60 years old
  - A hypercoagulable state including those with a positive test for a anticardiolipin antibody (IgG or IgM), Lupus anticoagulant, beta-2 glycoprotein-1 antibodies, or persistently elevated fasting plasma homocysteine despite medical therapy
  - Unable to take antiplatelet therapy
  - Atherosclerosis or other arteriopathy of the intracranial and extracranial vessels associated with a ≥50% luminal stenosis
  - Acute or recent (within 6 months) myocardial infarction or unstable angina
  - Left ventricular aneurysm or akinesis
  - Mitral valve stenosis or severe mitral regurgitation irrespective of etiology
  - Aortic valve stenosis (mean gradient greater than 40 mmHg) or severe aortic valve regurgitation
  - Mitral or aortic valve vegetation or prosthesis
  - Aortic arch plaques protruding greater than 4 mm into the aortic lumen
  - Left ventricular dilated cardiomyopathy with left ventricular ejection fraction (LVEF) less than 35%
  - Chronic, persistent, or paroxysmal atrial fibrillation or atrial flutter
  - Uncontrolled hypertension or uncontrolled diabetes mellitus
  - Diagnosis of lacunar infarct probably due to intrinsic small vessel as qualifying stroke event
  - Arterial dissection as cause of stroke
  - Index stroke of poor outcome (modified Rankin score greater than 3)
  - Pregnancy at the time of implant
  - Multi-organ failure
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or re-sterilize this device. Attempts to re-sterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- The AMPLATZER™ PFO Occluder device consists of a nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted.
- Store in a dry place.
- Pregnancy – Minimize radiation exposure to the fetus and the mother.
- Nursing mothers – There has been no quantitative assessment for the presence of leachables in breast milk.

ADVERSE EVENTS

Potential adverse events that may occur during or after a procedure using this device may include, but are not limited to:

• Air embolus • Allergic drug reaction • Allergic dye reaction • Allergic metal reaction: Nitinol (nickel, titanium), platinum/iridium, stainless steel (chromium, iron, manganese, molybdenum, nickel) • Anesthesia reactions • Apnea • Arrhythmia • Bacterial endocarditis • Bleeding

Brachial plexus injury • Cardiac perforation

Cardiac tamponade • Cardiac thrombus • Chest pain • Device embolization • Device erosion • Deep vein thrombosis • Death • Endocarditis

• Esophagus injury • Fever • Headache/migraine

Hypertension/hypotension • Myocardial infarction • Pacemaker placement secondary to PFO device closure • Palpitations • Pericardial effusion • Pericardial tamponade • Pericarditis

Peripheral embolism • Pleural effusion

Pulmonary embolism •Reintervention for residual shunt/device removal • Sepsis

Stroke •Transient ischemic attack • Thrombus

Valvular regurgitation • Vascular access site injury • Vessel perforation

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 *www.vascular.eifu.abbott* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

www.cardiovascular.abbott

Abbott