

# PFO CLOSURE: FROM RARE TO ROUTINE

*"...closing the PFO may reduce the risk of having another stroke better than medication alone."* — Steven R. Messé, M.D.

Updated guidance from physician societies around the world supports percutaneous closure of a patent foramen ovale (PFO) to prevent stroke recurrence in select patients.

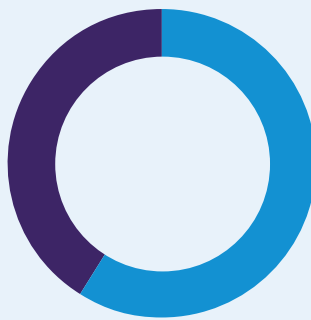


An expanded body of evidence prompted the American Academy of Neurology (AAN) and American Heart Association/American Stroke Association (AHA/ASA) to update their guidances regarding percutaneous PFO closure and risk of recurrent stroke.<sup>2,3</sup>

A multidisciplinary team of neurologists, internists and cardiologists was convened for the AAN practice advisory to review the results from a meta-analysis of eight clinical studies.

In addition to the AAN findings, the updated AHA/ASA guideline also favors PFO closure, recommending it for patients with a PFO that have high-risk anatomical features, such as atrial septal aneurysm and/or large right-to-left shunt.

## AAN SUMMARY OF EFFECTS OF PERCUTANEOUS PFO CLOSURE<sup>2</sup>



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%**
- ▶ Increased absolute rate of non-periprocedural atrial fibrillation:  
**0.33% Per Year**

## AAN CLINICAL IMPLICATIONS<sup>2</sup>

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

- When a PFO is present and no other mechanism of stroke has been identified after a thorough diagnostic evaluation.
- After discussing the potential benefits and risks.

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

- After a thorough evaluation, including prolonged 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.

## AHA/ASA CLINICAL IMPLICATIONS<sup>3</sup>

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

- 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.

For more information about the Amplatzer™ Talisman™ PFO Occluder or updated guidelines, contact your Abbott sales representative.



## RECOMMENDED BY MULTIPLE PHYSICIAN SOCIETIES FROM AROUND THE WORLD

Beyond the U.S., an increasing number of physician societies recommend PFO closure for well selected patients with a PFO-associated stroke, including:

- Japanese Stroke Society<sup>4</sup> - 2021
- Australian Stroke Council<sup>5</sup> - 2019
- Chinese Stroke Association<sup>6</sup> - 2019
- German Society of Neurology/DSG German Stroke Society/ German Cardiology Society<sup>7</sup> - 2018

# EFFECTIVE PFO CLOSURE MADE EASIER<sup>8</sup>, WITH THE AMPLATZER™ TALISMAN™ PFO OCCLUDER

## EXTENSIVE EXPERIENCE



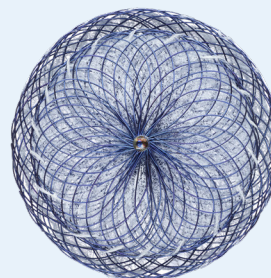
OVER 180,000 PATIENTS TREATED GLOBALLY<sup>9</sup>

#1 device selected for PFO closure

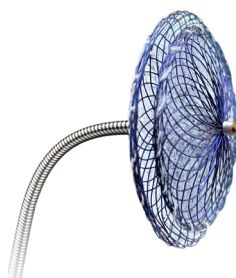
An unmatched track record with over two decades of experience

Wide range of device sizes including a re-engineered 30mm with a smaller left atrial disc

## CONFIDENCE IN CLOSURE



**>94% CLOSURE RATE<sup>+</sup>**  
at 6 months in RESPECT trial<sup>10</sup>



## SIMPLIFIED PREPARATION AND ENHANCED EASE OF USE

- The Amplatzer™ Talisman™ PFO Occluder comes assembled and ready for use, reducing preparation time.
- Fully recapturable and repositionable, ensuring optimal anatomical placement of the device for effective closure.

## LONG-TERM PATIENT FOLLOW-UP<sup>10</sup>

**5,810**  
patient-years of data

**5.9**  
years median patient follow up

## EXCELLENT SAFETY<sup>10</sup>

**ZERO**

- Device erosions
- Device thrombus
- Device embolization events
- Wire frame fractures

**< 1% AF\***  
Low risk of serious atrial fibrillation

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<sup>†</sup>Effective closure

\* Serious AF as defined in RESPECT Trial. In RESPECT, serious AF was adjudicated by an independent board of physicians.

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. 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.

4. Japan Stroke Society Stroke Guidelines Committee “Stroke Treatment Guidelines 2021” (issued July 15, 2021)
5. Stroke Foundation. Clinical Guidelines for Stroke Management 2019. Melbourne Australia.
6. Liu L, et al. *Stroke & Vascular Neurology* 2020;5:e000378. doi:10.1136/svn-2020-000378
7. Diener et al. *Neurological Research and Practice* <https://doi.org/10.1186/s42466-019-0008-2>
8. Tests performed by and data on file at Abbott.
9. Data on-file at Abbott.
10. 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.

Information contained herein for **DISTRIBUTION outside of the U.S. ONLY**.

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

**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](http://eifu.abbottvascular.com) or at [medical.abbott/manuals](http://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. Photo(s) on file at Abbott.

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