Progress starts with *ONE PATIENT*

Health Economics Article Series | Summary 2 of 6

# Evaluating cost-effectiveness of PFO management strategies

## Closure with GORE® CARDIOFORM Septal Occluder vs ABBOTT® AMPLATZER® PFO Occluder, and treatment with medical therapy alone, for secondary stroke prevention

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An in-depth analysis of stroke data reveals the significant patient- and budget-related impacts around the treatment of cryptogenic stroke (which occurs without a clear underlying cause), including screening, diagnosis and device selection.

### Current challenge

Patent foramen ovale (PFO) associated stroke management consists of treatment with medication and/or transcatheter closure with an implantable medical device, but there is uncertainty about which approach is cost-effective and offers value.

This study addresses that uncertainty by evaluating the economic and clinical outcomes of the leading PFO closure devices compared to medical therapy alone, helping inform smarter, more cost-effective health care decisions.
**See *About the methods* on page 3.**

### The growing burden of stroke


**Ischemic strokes account for 87% of strokes worldwide,** affecting over 7.6 million people annually and resulting in approximately 3.3 million deaths.

Cryptogenic strokes **comprise 25%–40% of ischemic strokes.**


**PFO is present in around 40% of cryptogenic stroke patients** and is thought to be a contributing factor in approximately two-thirds of these cases.

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# Value analysis of PFO treatment options

## Study results

Results are drawn from a published health economic model simulating a 1,000-patient cohort structure over a 5-year period. Results depend on specific assumptions and inputs that may not reflect all practice patterns. This analysis is intended to provide general economic context only; it should not be relied on as a predictor of individual clinical outcomes.

The safety and efficacy were informed from 2 randomized controlled trials (RCTs), REDUCE Clinical Study and RESPECT Clinical Study, and outcomes were derived from a match adjusted indirect treatment comparison (MAIC) study from the 2 RCTs. **See *About the methods* on page 3.**

### CARDIOFORM Device vs medical therapy alone

Based on the model's assumptions and available published clinical data, PFO closure with CARDIOFORM Device + medical therapy compared to medical management alone was projected to result in:

**$3 MILLION MODELED COST SAVINGS**[f]

**$15.7 MILLION MODELED NET MONETARY BENEFIT**
under the cost and utility inputs described

**CARDIOFORM Device was cost-effective vs medical therapy alone**
and well below the willingness-to-pay threshold (WTP) of $75,000 per QALY in 92.5% of simulation.[g]

### PFO closure with CARDIOFORM Device

Based on the model's assumptions and available published clinical data, PFO closure with CARDIOFORM Device was projected to result in:

**$1.3 MILLION MODELED COST SAVINGS**

**$3.2 MILLION MODELED NET MONETARY BENEFIT**
under the cost and utility inputs described

**PFO closure using CARDIOFORM Device was economically beneficial,**
providing both cost savings and improved effectiveness.

[f]The PFO closure procedure led to higher costs than medical therapy alone.
[g]The WTP reflects a commonly accepted benchmark in U.S. health economics for determining whether an intervention provides good value for money. The $75,000 threshold is recommended by the Institute for Clinical and Economic Review and falls within the broader range of $50,000-$150,000 per QALY frequently cited in cost-effectiveness literature.

## CARDIOFORM Device vs medical therapy alone

Reduce the occurrence of ischemic strokes over the modeled time horizon

**ESTIMATED 67 FEWER STROKES IN THE MODELED COHORT**

Increase average life expectancy

**BY APPROXIMATELY 1.2 YEARS**

Increase modeled QALY

**BY 408.7**

across the cohort studied

Corresponds to

**1 MODELED STROKE AVOIDED**

for every 15 patients treated over the time horizon

## PFO closure with CARDIOFORM Device

Reduce the occurrence of ischemic strokes over the modeled time horizon

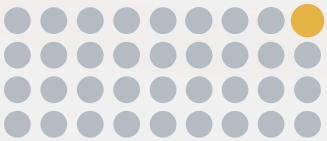
**ESTIMATED 28 FEWER STROKES IN THE MODELED COHORT**

Increase average life expectancy

**BY APPROXIMATELY 0.49 YEARS**

Increase modeled quality-adjusted life years (QALY) **BY 24.8**

across the cohort studied



Corresponds to

**1 MODELED STROKE AVOIDED**

for every 36 patients treated over the time horizon

**Analysis results suggest closing PFOs with the CARDIOFORM Device is more cost-effective than medical therapy alone and offers clinical benefits in preventing recurrent ischemic strokes.** Additionally, PFO closure using CARDIOFORM Device was a cost-effective strategy in the modeled cohort for patients with PFO-associated stroke.

**Discover the potential impact of PFO diagnosis and treatment. Access the full publication.**

## About the methods

This study relied on a matched adjusted indirect treatment comparison (MAIC), which compared treatments from different trials by adjusting for patient differences using recognized methods. MAIC analyses have limitations, including potential unmeasured confounding factors and impact of sample size. Please refer to the full publication for a complete description of study methods, findings and associated limitations.[2]

This analysis is intended to provide health care decision-makers with exploratory information on potential economic and health outcomes. It is not a substitute for clinical judgment and does not establish comparative clinical superiority or cost-effectivness in all settings. Refer to the full publication for complete details on methodology and limitations. Institutions should consult their formulary or payer representatives for guidance on local applicability.


**References**

**1.** Volpi JJ, Wolters LF, Louwsma T, *et al.* Evaluating cost-effectiveness of PFO management strategies: closure with Cardioform vs. AMPLATZER, and treatment with medical therapy alone, for secondary stroke prevention. *Journal of Medical Economics* 2024;27(1):1398-1409. **2.** Kasner SE, Sondergaard L, Nakum M, *et al.* A matching-adjusted indirect comparison of results from REDUCE and RESPECT—two randomized trials on patent foramen ovale closure devices to prevent recurrent cryptogenic stroke. *Journal of Medical Economics* 2024;27(1):337-343.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**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.

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