

The annual economic burden of patent foramen ovale-associated stroke in the United States

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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

Stroke is the 2nd leading cause of death worldwide

25%-40%

of ischemic strokes are classified as cryptogenic, with patent foramen ovale (PFO) as a potential underlying cause

44,000-71,000

new and recurrent PFO-associated strokes occur annually

Up to 2,900 PFO-associated strokes are fatal

\$56.5B

In the U.S., the **economic burden of stroke** between 2018 and 2019 was **estimated at \$56.5 billion**, corresponding to 0.26% of the gross domestic product in that year.

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Early intervention and PFO closure could significantly reduce both clinical and economic burden

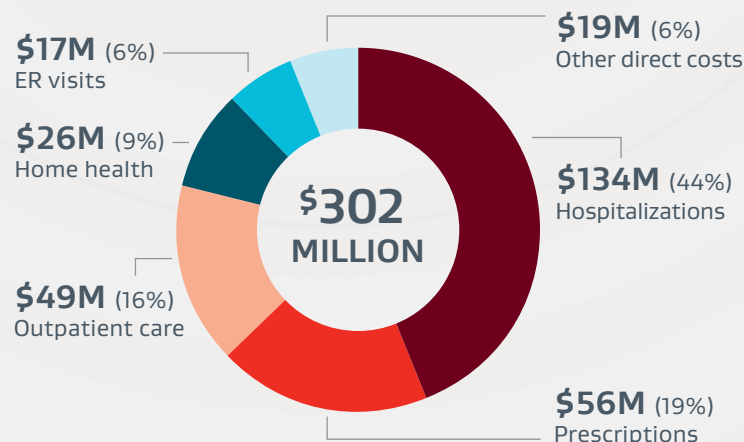
Study results^f

The total direct and indirect costs of PFO-associated strokes in the U.S. were estimated at \$1.3 billion annually, with \$1.0 billion from new strokes and \$302 million from recurrent strokes.

Societal total annual direct and indirect costs



Payer total annual direct medical costs



Conclusions

Recurrent strokes account for 25% of total societal costs, and in-patient hospitalization is the largest driver of direct medical costs.

Recurrent PFO-associated stroke is a costly, preventable condition. These findings provide a powerful case for increased screening and treatment.

By changing the way we look at PFO screening, diagnosis and treatment, we have the opportunity to reduce PFO-associated stroke costs and improve patient outcomes.

Discover the potential impact of PFO diagnosis and treatment. [Access the full publication.](#)

^fThe data presented utilized a top-down, prevalence-based approach. This estimate applies national stroke incidence and cost data to calculate the annual economic burden of PFO-associated stroke. The societal perspective includes both direct and indirect medical costs. The payer perspective focused solely on direct health care costs.

References

1. Volpi JJ, Kasner SE, Neervoort J, et al. The annual economic burden of patent foramen ovale-associated stroke in the United States. *Journal of Stroke & Cerebrovascular Diseases: The Official Journal of National Stroke Association* 2025;34(6):108319.

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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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