

PATENT FORAMEN OVALE (PFO) CLOSURE — ECONOMIC VALUE

“Cost-effectiveness of percutaneous closure of a patent foramen ovale (PFO) compared with medical management in patients with a cryptogenic stroke: from the U.S. payer perspective” adapted from *Journal of Medical Economics*

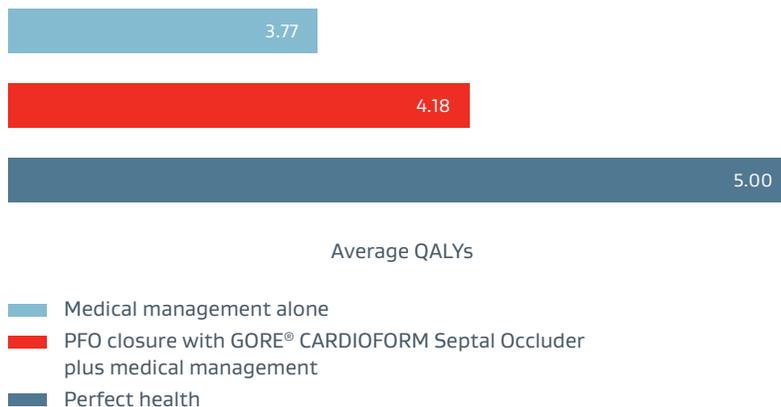
Cost effectiveness

After 2.3 years, closing a PFO with GORE® CARDIOFORM Septal Occluder is cost-effective compared to medical management alone.¹

Quality of life

PFO closure plus medical management improves quality of life compared to medical management alone.¹

Average quality adjusted life years (QALYs) treatment comparison relative to perfect health in a 5 year span



QALYs is commonly used in health economics to quantify the effectiveness of a particular intervention. QALYs combines the impact of gains in quality of life and in quantity of life associated with an intervention. One QALY is equal to 1 year of life in perfect health.^{1,2}

What does the difference in average QALYs between the two treatments mean for the patient?

Within a 5 year span patients treated with PFO closure plus medical management experienced *five more months of improved health related quality of life* relative to patients treated with medical management alone.¹

* Measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance.

1. Volpi JJ, Ridge JR, Nakum M, Rhodes JF, Sondergaard L, Kasner SE. Cost-effectiveness of percutaneous closure of a patent foramen ovale compared with medical management in patients with a cryptogenic stroke: from the US payer perspective. *Journal of Medical Economics* 2019;22(9):883-890.
2. NICE glossary. National Institute for Health and Care Excellence (NICE) Web site. <https://www.nice.org.uk/glossary>. Accessed August 29, 2019.

INDICATIONS FOR USE IN AUSTRALIA, CANADA AND EUROPE: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of atrial septal defects (ASDs), such as ostium secundum and patent foramen ovale. **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take anti-platelet 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. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and contraindications. Rx Only

INDICATIONS FOR USE IN THE U.S.: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs). **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: Unable to take anti-platelet 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. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and contraindications. Rx Only

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