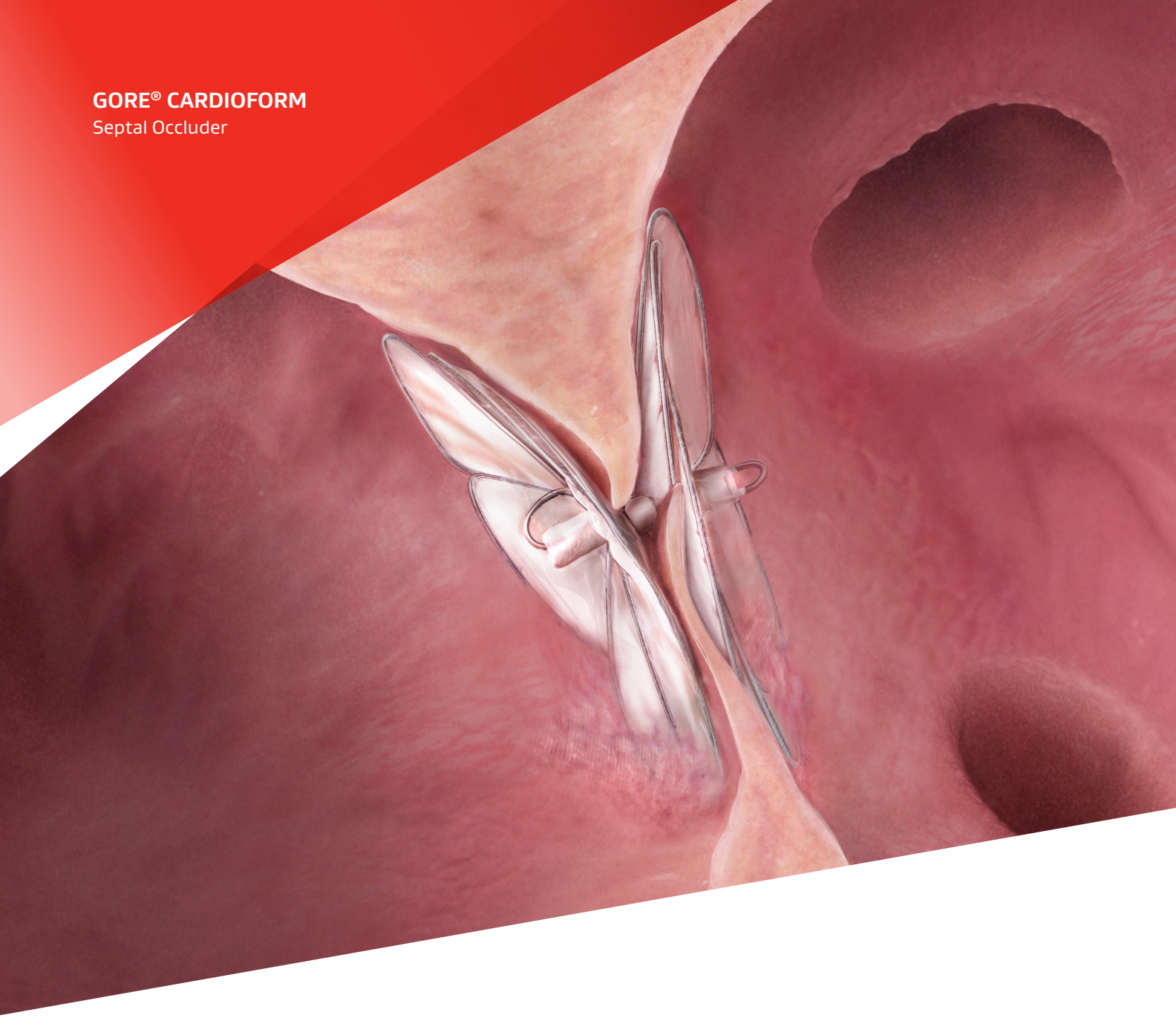
GORE® CARDIOFORM
Septal Occluder



TOP 5 REASONS TO CHOOSE **GORE® CARDIOFORM** SEPTAL OCCLUDER

The GORE® CARDIOFORM Septal Occluder advances patent foramen ovale (PFO) closure with a solution designed to naturally conform to a patient's unique PFO anatomy — delivering on long-term safety and performance.*,[1]

*All PFO anatomies within indicated sizing parameters of the *Instructions for Use* (IFU).

Together, improving life

1

Advanced Materials Delivering Exceptional Conformability[*,†,‡,§,1-3]

Engineered to conform to a broad range of PFO anatomies.[§,1-3]

- **ePTFE** – Biocompatible, compliant material enables exceptional conformability and rapid tissue ingrowth.
- **Two independent discs and five independent petals** – Allow the device to conform to the anatomy to treat simple to complex defects.
- **Minimal metal** – Designed to reduce the risk of tissue damage. Minimal nickel elution and exposure relative to other competitive nitinol-framed devices.[II,¶,4]

2

A Leader in Safety

Long-term results continue to demonstrate a legacy of patient safety.

68,000+

devices sold globally

0

reported cardiac erosions[**]

* 99% effective closure rate across PFO anatomies at 24 months.

† Effective closure defined as freedom from large shunt > 25 bubbles as detected by transthoracic echocardiography adjudicated by Echo Core Lab.

‡ Data on file 2020; W. L. Gore & Associates, Inc.; Flagstaff, AZ.

§ All PFO anatomies were eligible for inclusion into this study within indicated sizing parameters of the *Instructions for Use*.

II Patients allergic to nickel may suffer an allergic reaction to the GORE® CARDIOFORM Septal Occluder device. 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 in breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted. Refer to the *Instructions for Use* for complete device information, including contraindications, warnings and cautions.

¶ As characterized by an in vitro assessment.

** Reported incidence rate of device-related cardiac erosions for GORE® CARDIOFORM Septal Occluder and GORE® CARDIOFORM ASD Occluder. Data from CATSWeb Product Surveillance Tracking System (PSTS).

Trusted Closure Performance

Conforms to fit a broad range of PFO anatomies — simple to complex.

99% effective closure across PFO anatomies at 24 months[*,†]

3

Complex PFO: Atrial Septal Aneurysm (ASA)

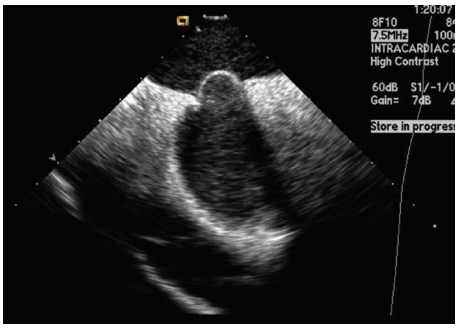


Image A: ICE demonstrating PFO with ASA.

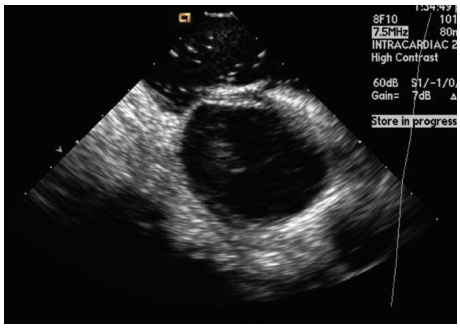


Image B: Closure of PFO with 30mm GORE® CARDIOFORM Septal Occluder.

4

Unmatched Secondary Stroke Prevention[‡,§,ll,1,2]

Backed by the only U.S. IDE trial that achieved its primary endpoint, and over five years showed a significant reduction in recurrent stroke across PFO anatomies over medical therapy alone.[‡,§,ll]

69% relative reduction in recurrent stroke versus medical management alone at 5-year median follow-up[§,1]

5

Reliable and Safe Delivery

Straightforward delivery with the ability to reposition and retrieve.[¶]

- Pre-assembled Occluder and delivery system designed to reduce device preparation time.

* Effective closure defined as freedom from large shunt > 25 bubbles as detected by transthoracic echocardiography adjudicated by Echo Core Lab.

† Data on file 2020; W. L. Gore & Associates, Inc.; Flagstaff, AZ.

‡ In patients with a PFO and history of cryptogenic stroke.

§ The REDUCE Study determined safety and efficacy of PFO closure with the GORE® CARDIOFORM Septal Occluder or GORE® HELEX® Septal Occluder plus antiplatelet medical management compared to antiplatelet medical management alone in patients with a PFO and history of cryptogenic stroke. All PFO anatomies were eligible for inclusion into this study within indicated sizing parameters of the *Instructions for Use*.

ll REDUCE is the only U.S. IDE trial that achieved its primary endpoint, and over five years showed a significant reduction in recurrent ischemic stroke across PFO anatomies over medical therapy alone.

¶ Refer to *Instructions for Use* at eifu.goremedical.com for all applicable indications, warnings, precautions and contraindications for the markets where this product is available.

Device Specifications

Labeled Occluder diameter	Maximum recommended defect size measured with stop flow balloon sizing	Catheter size without guidewire*
20 mm	11 mm	10 Fr
25 mm	14 mm	10 Fr
30 mm	17 mm	10 Fr

* Recommendation for sheath size is 2 Fr larger when used with a wire.

To learn more about the device that naturally conforms to a patient's unique PFO anatomy, contact your Gore Representative or call 928 864 2927.

References

1. Kasner SE, Rhodes JF, Andersen G; Gore REDUCE Clinical Study Investigators. Five-year outcomes of PFO closure or antiplatelet therapy for cryptogenic stroke. *New England Journal of Medicine* 2021;384(10):970-971.
2. Søndergaard L, Kasner SE, Rhodes JF, *et al.*; Gore REDUCE Study Investigators. PFO closure or antiplatelet therapy for cryptogenic stroke. *New England Journal of Medicine* 2017;377(11):1033-1042.
3. Lefebvre B, Naidu S, Nathan AS, *et al.* Impact of echocardiographic parameters on recurrent stroke in the randomized REDUCE PFO cryptogenic stroke trial. *Structural Heart* 2021;5(4):367-375.
4. Verma DR, Khan MF, Tandar A, *et al.* Nickel elution properties of contemporary interatrial shunt closure devices. *Hours of Invasive Cardiology* 2015;27: 99-104.

Consult Instructions for Use
eifu.goremedical.com

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. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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