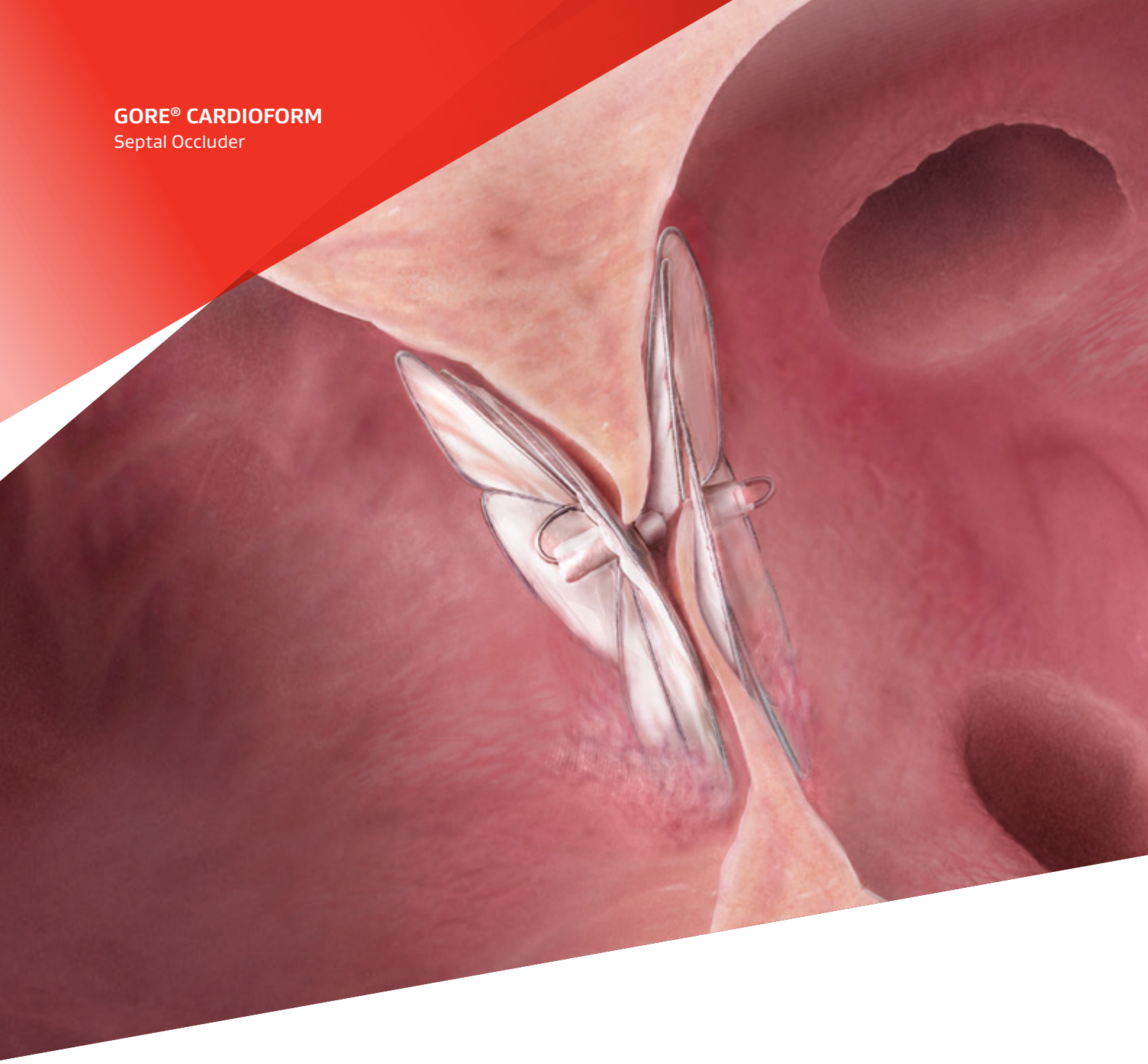
GORE® CARDIOFORM
Septal Occluder



DESIGNED TO CONFORM.
SO THE HEART DOESN'T HAVE TO.

The advanced conformable solution for patent foramen ovale (PFO) and ostium secundum atrial septal defect (ASD) closure.

Together, improving life

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DESIGNED TO CONFORM. SO THE HEART DOESN'T HAVE TO.

The GORE® CARDIOFORM Septal Occluder advances PFO closure with a solution designed to naturally conform to a patient's unique PFO anatomy* — delivering on long-term safety and performance.[3]

A leader in safety	0	reported cardiac erosions†
Trusted closure performance	99%	effective closure across anatomies‡,§
Clinically proven secondary stroke prevention‖,¶,**,1,3	69%	relative reduction in recurrent stroke versus medical management alone at 5-year median follow-up¶,3
Reliable and safe delivery	1-2-3	straightforward procedural steps with the ability to reposition and retrieve

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

† Reported incidence rate of device-related cardiac erosions for GORE® CARDIOFORM Septal Occluder. Data from CATSWeb Product Surveillance Tracking System (PSTS). June, 2011–January, 2023.

‡ 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*.

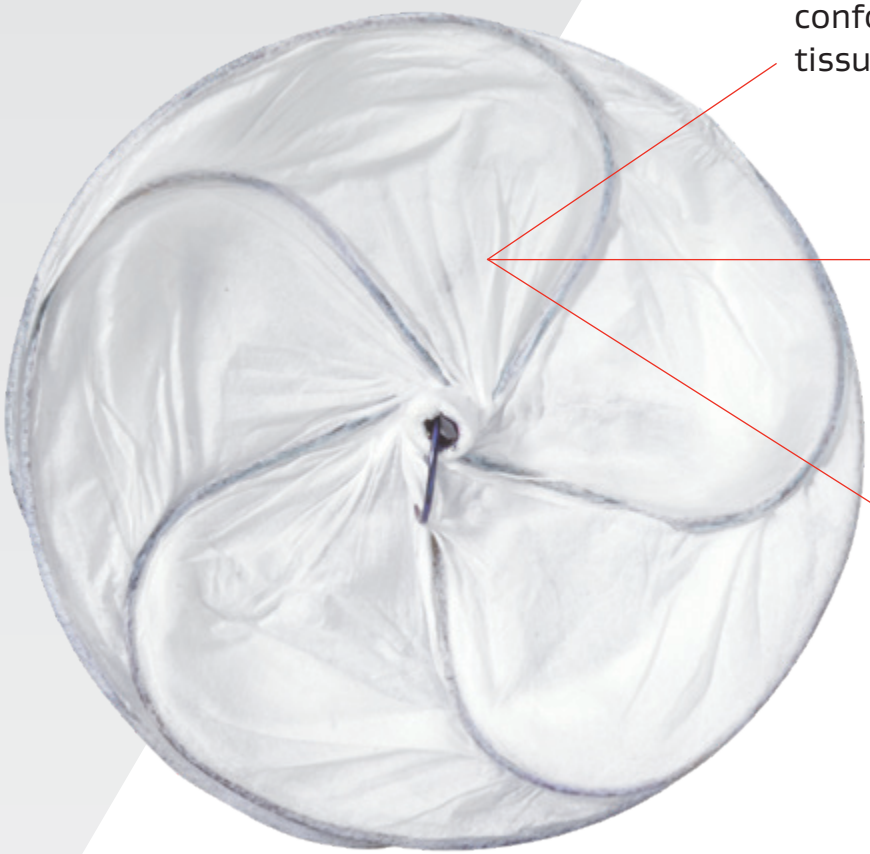
** REDUCE is the only U.S. IDE trial that achieved its primary endpoint, and over five years showed a significant reduction in recurrent ischemic stroke across PFO anatomies over medical therapy alone.

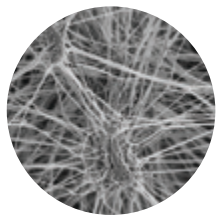
ADVANCED MATERIALS DELIVERING EXCEPTIONAL CONFORMABILITY*,†,‡,§,1-3

- More than 60 years of materials science expertise
- Engineered to conform to a broad range of PFO anatomies§,1-3
- No minimum retro-aortic rim requirementsII

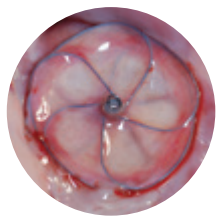
ePTFE

Biocompatible, compliant material enables exceptional conformability and rapid tissue ingrowth





ePTFE 250x magnification



30 days post implant in canine model

* 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.

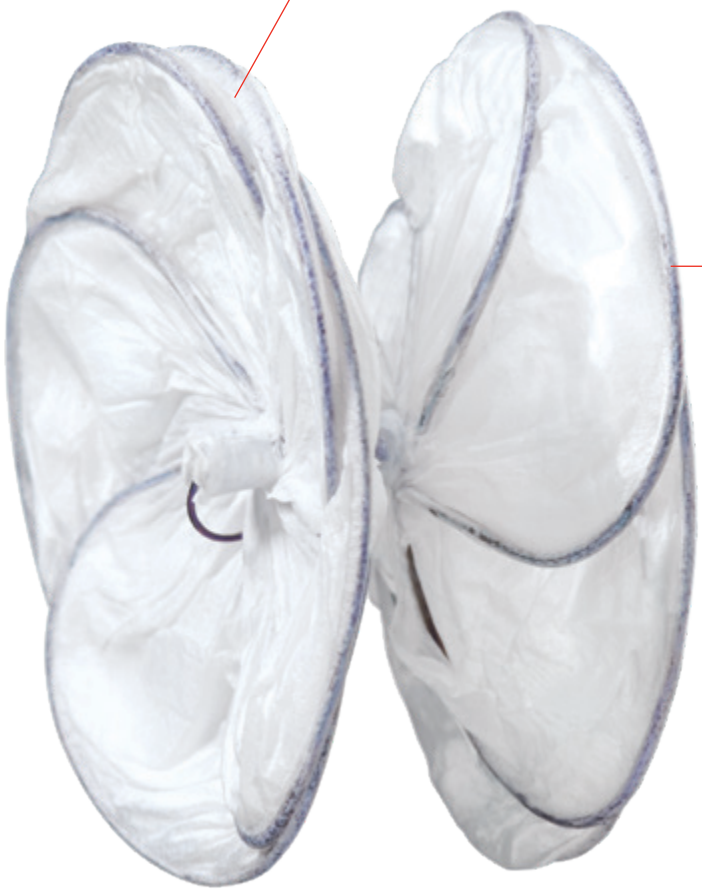
‡ Data on file 2020; W. L. Gore & Associates, Inc.; Flagstaff, AZ.

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

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

2 independent discs
5 independent petals

Allow the device to conform to the anatomy to treat simple to complex defects



Minimal metal
(5 platinum-filled nitinol* wires)

Low metal mass solution for defect closure

Designed to reduce the risk of tissue damage

Minimal nickel elution and exposure relative to other competitive nitinol-framed devices[†,‡,4]

* Nickel titanium

† 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.

A LEADER IN SAFETY

11+
years of clinical use

68,000+
devices sold globally

250+
publications*

2,069
patient years of data for PFO closure[1,3]

* W. L. Gore & Associates, Inc. GORE® CARDIOFORM Septal Occluder Complete Bibliography. Flagstaff, AZ: W. L. Gore & Associates, Inc.; 2020. [Bibliography].

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

The data presented below are from separate and independent clinical studies with different patient populations and interventions and thus are not a direct head-to-head comparison.

Low risk of device- or procedure-related serious adverse events (SAEs)

	REDUCE (median 5 years)	RESPECT (median 5.9 years)[5]
Device-related SAE	6 (1.4%)	13 (2.6%)
Procedure-related SAE	11 (2.5%)	12 (2.4%)

Low risk of atrial fibrillation (AF)[1,3]

	REDUCE (median 5 years)[3]	RESPECT (median 5.9 years)[5]
Serious device- or procedure-related AF	2 (0.5%)	2 (0.4%)
Subjects with post-implant AF or flutter who had a recurrent stroke	1 (0.2%)	1 (0.2%)

No reports of erosion

	REDUCE (median 5 years)[3]
Cardiac Erosion	0

	GORE® CARDIOFORM Septal Occluder (reported between July 2011 and January 2023)*	ABBOTT® AMPLATZER PFO OCCLUDER (reported between October 2000 and December 2006)[6]
Reported Cardiac Erosion	0	2

* Data on file. July, 2011–January 2023; W. L. Gore & Associates, Inc.; Flagstaff, AZ.

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TRUSTED CLOSURE PERFORMANCE

99%

Effective closure across PFO anatomies at 24 months*,†

Characteristics of simple and complex PFOs

PFO Category	Anatomical Characteristics
Simple:	Should not have characteristics such as: aneurysmal septum, large eustachian valve, thick septum secundum or any other defects within the fossa ovalis[7]
Complex:	▪ Long Tunnel > 10 mm[8] ▪ Atrial Septal Aneurysm (ASA): Redundant or excessive tissue that flaps into either atrium 10 mm or total excursion of 15 mm[9] ▪ Thick septum secundum > 10 mm[7] ▪ Hybrid defects, multiple fenestrations[9] ▪ Eustachian valve or Chiari network[9]

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

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Long Tunnel

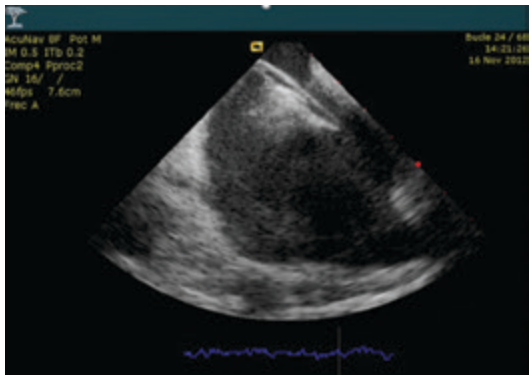


Image 1a: ICE demonstrating interrogation of PFO with a long tunnel.

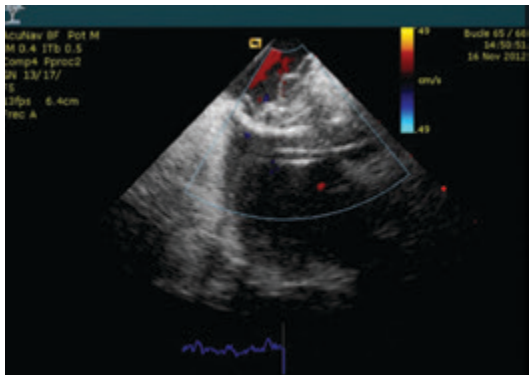


Image 1b: Closure of PFO with 25 mm GORE® CARDIOFORM Septal Occluder.

ASA

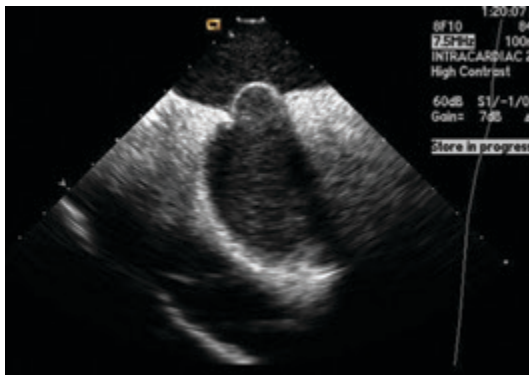


Image 2a: ICE demonstrating PFO with ASA.

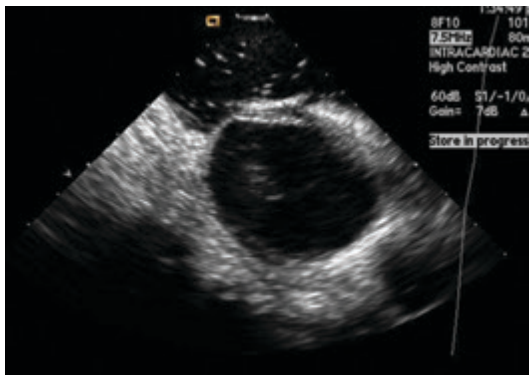


Image 2b: Closure of PFO with 30 mm GORE® CARDIOFORM Septal Occluder.

Thick Secundum

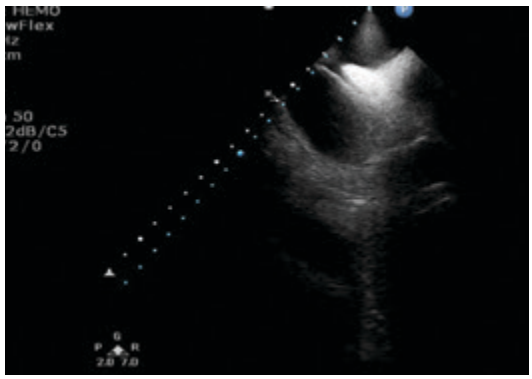


Image 3a: ICE demonstrating PFO with thick septum secundum measuring 10.3 mm.

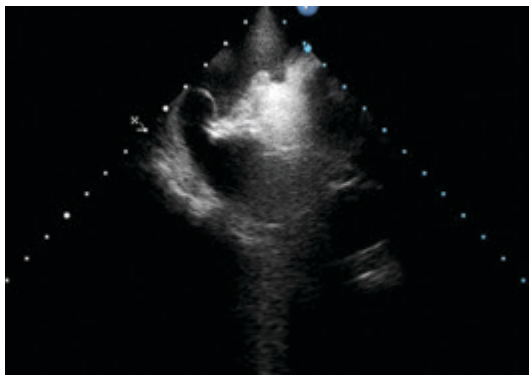


Image 3b: Closure of PFO with 30 mm GORE® CARDIOFORM Septal Occluder.

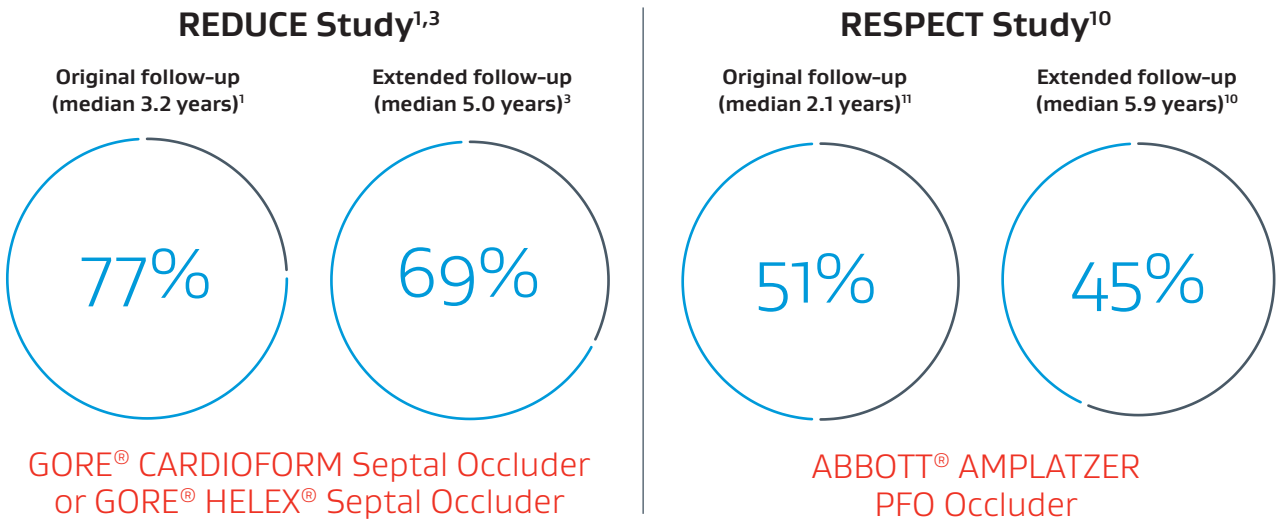
CLINICALLY PROVEN SECONDARY STROKE PREVENTION[*,†,‡,1,3]

The GORE® CARDIOFORM Septal Occluder is 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.[*,†,‡]

Stroke reduction data

The data presented below are from separate and independent clinical studies with different patient populations and interventions and thus are not a direct head-to-head comparison.

Ischemic stroke reduction relative to medical management



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* 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*.

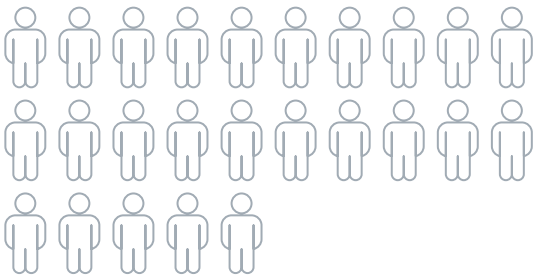
‡ REDUCE is the only U.S. IDE trial that achieved its primary endpoint, and over five years showed a significant reduction in recurrent ischemic stroke across PFO anatomies over medical therapy alone.

Compelling real-world results

The data presented below are from separate and independent clinical studies with different patient populations and interventions and thus are not a direct head-to-head comparison.

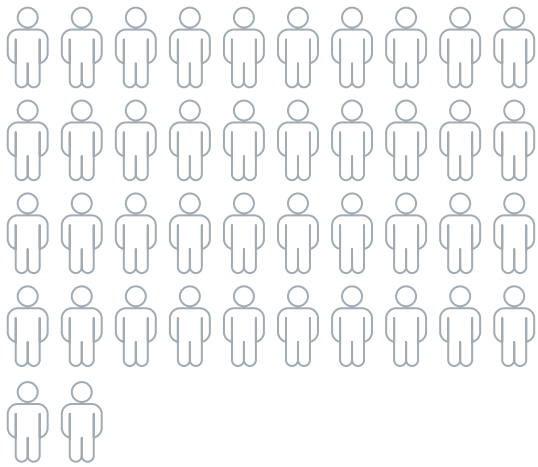
Number of patients needed to treat to prevent one recurrent ischemic stroke at five years.

25 **REDUCE Study**
Extended follow-up
(median 5.0 years)[3]



GORE® CARDIOFORM Septal Occluder
or GORE® HELEX® Septal Occluder

42 **RESPECT Study**
Extended follow-up
(median 5.9 years)[5]



ABBOTT® AMPLATZER
PFO Occluder

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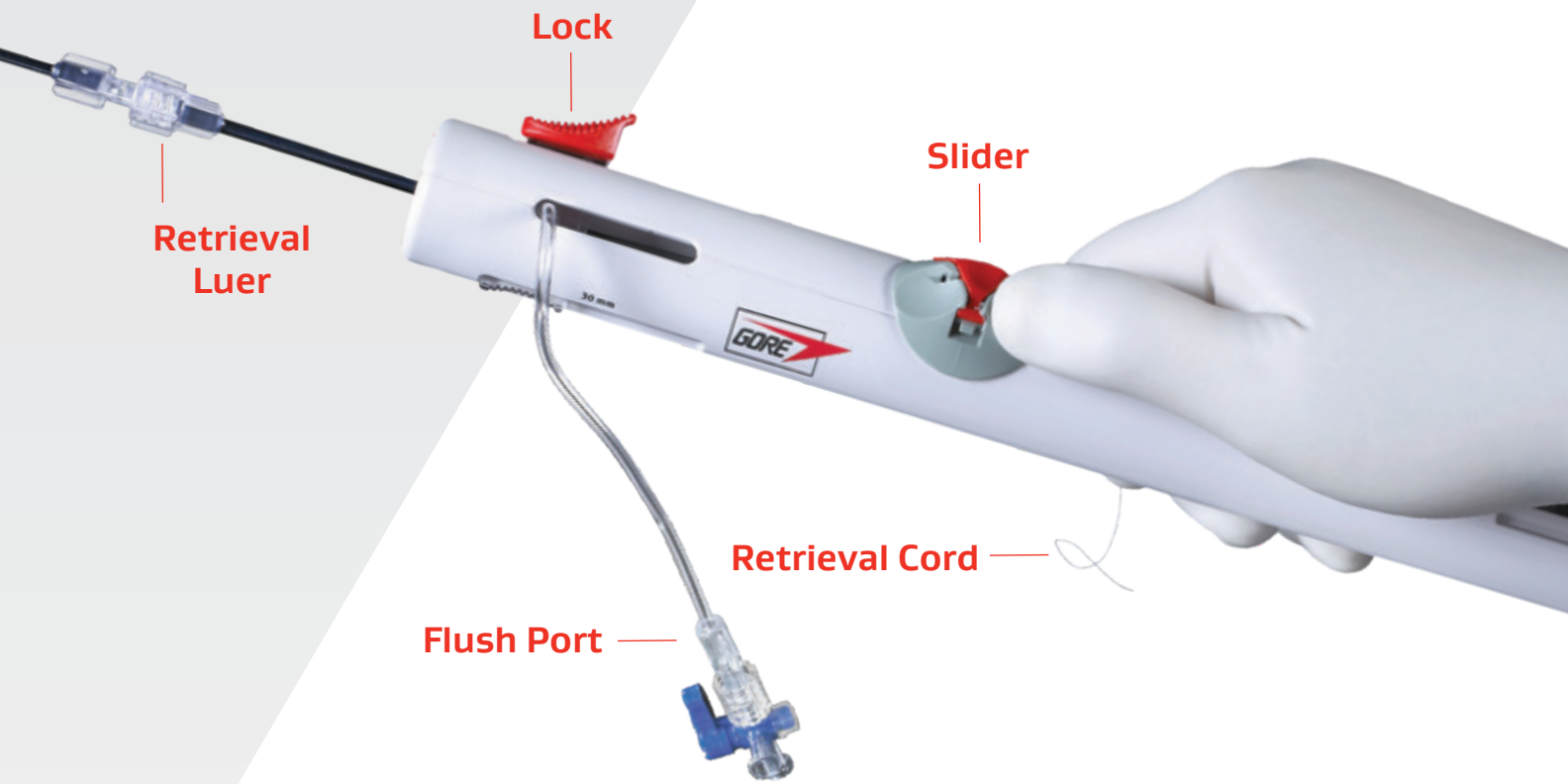
RELIABLE AND SAFE DELIVERY

- Straightforward delivery with the ability to reposition and retrieve*
- Pre-assembled occluder and delivery system designed to reduce device preparation time

The built-in retrieval cord allows for tension-free assessment and retrieval post-lock, if needed.

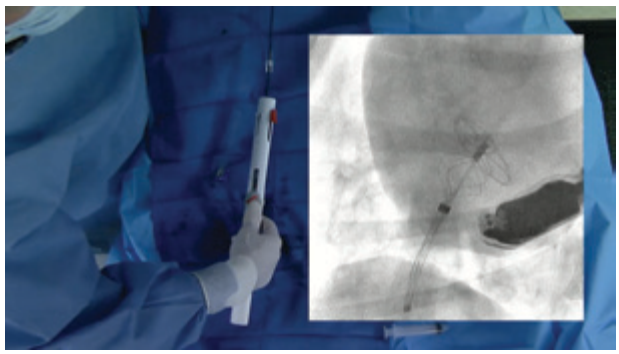


* Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

1-2-3 Deployment Sequence

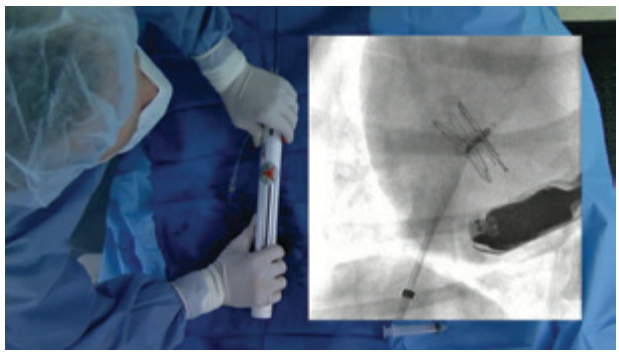
1 Deploy

Handle design with slider enables accurate deployment with the ability to reposition.



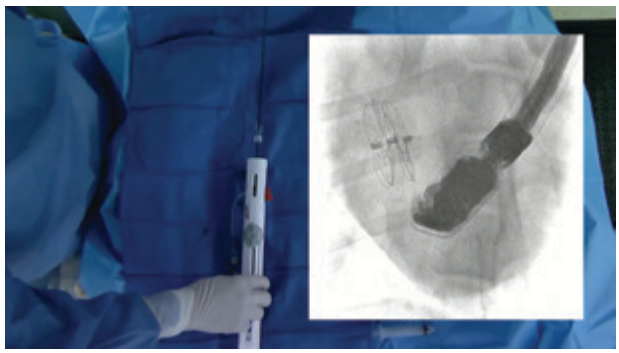
2 Lock

Simple-to-use locking mechanism. Occluder is partially released and remains tethered to delivery system.



3 Release

Pull the Retrieval Cord until completely removed to release the device from the delivery system.



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DEVICE SPECIFICATIONS

With the conformable design of the GORE® CARDIOFORM Septal Occluder, three devices cover PFOs and ASDs up to 17 mm.*

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.

20 mm

25 mm

30 mm

Catalogue number	Device sizes (mm)
United States	
GSX0020A	20
GSX0025A	25
GSX0030A	30
Europe	
GSXE0020	20
GSXE0025	25
GSXE0030	30
Australia/Canada	
GSXE0020B	20
GSXE0025B	25
GSXE0030B	30

To learn more about the GORE® CARDIOFORM Septal Occluder, contact your Gore Representative.

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Consult Instructions for Use

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