GORE STRUCTURAL HEART FELLOWS PROGRAM

Training, support and certification
for the next stage of your career

Together, improving life

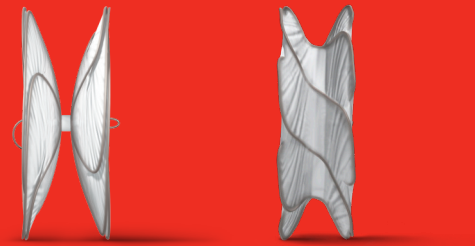
Welcome to the Gore Structural Heart Fellows Program

Gore offers hands-on training and a library of self-study materials to help improve your skills to confidently perform patent foramen ovale (PFO) and/or atrial septal defect (ASD) closures.

Your training will focus on anatomy, disease states and imaging of the atrial septum, with a focus on PFO and/or ASD treatment with the GORE® CARDIOFORM family of products.*,†

A Gore representative will be your main point of contact throughout the year, taking you through the curriculum and facilitating live virtual and in-person events, including hands-on training.

Throughout this program, you can train and become certified on Gore occluder devices: the GORE® CARDIOFORM Septal Occluder and the GORE® CARDIOFORM ASD Occluder.



Program overview

Gore has developed a curriculum focused on the understanding of PFO and ASD disease states, anatomy, imaging, case planning and procedural steps, delivered through both on- and off-site training. This curriculum includes the opportunity to certify academic fellows on these devices:

- GORE® CARDIOFORM Septal Occluder
- GORE® CARDIOFORM ASD Occluder

In-person, virtual or self-guided offerings will cover foundational principles and best practices in the clinical use of the GORE® CARDIOFORM portfolio.

Available Training:

- Overview of disease state
- Simulation-based device training
- TEE and ICE simulator training
- Porcine heart dissection
- Training letter and certification

Experience live training events

Your Gore representative will also work with you to schedule a variety of training events throughout the year. These can include:

Virtual live procedures

When traveling is not an option, the education can come to you. Observe and ask questions in real time as a healthcare expert performs live PFO and ASD closures.

Simulator sessions

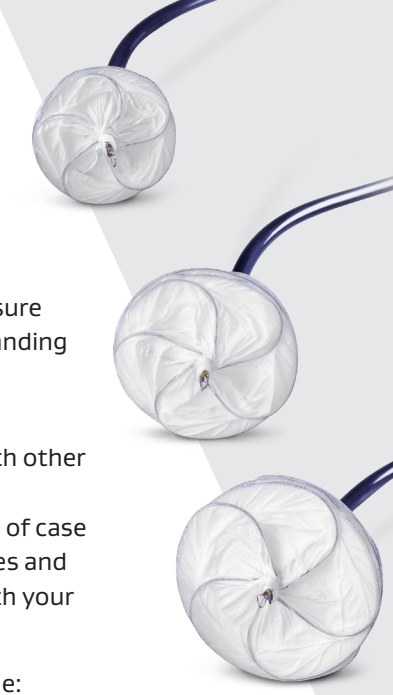
Working in-person with a Gore representative, get hands-on procedural skill simulation practice, understand procedural steps and practice positioning of Gore devices to optimize outcomes.

Live webinars

Learn about clinical aspects of PFO and ASD closure from experienced ICs and get a deeper understanding of Gore structural heart products.

Hands-on workshop

Train alongside leading experts and network with other fellows. This workshop is focused on the clinical application of Gore devices using a combination of case planning discussions, simulated case experiences and model deployment. Spots are limited. Speak with your Gore representative to learn more.



The organizations and congresses that Gore supports for the education of fellows and early career physicians include:

- Pediatric and Congenital Interventional Cardiovascular Society
- SCAI Fellows

Explore your training library

As part of the program, you have access to the Gore Medical Fellows Program Virtual Platform. A digital library of training materials to help you review and expand your knowledge of PFO and ASD closure.

The virtual platform includes:

- PFO & ASD anatomy
- Imaging modalities
- Case studies
- Clinical data
- Didactic
- Patient education resources
- Science behind Gore
- Webinar and training registrations

Register for the Gore Medical Fellows Program Virtual Platform online at **www.goreevents.com/StructuralHeartFellowsProgram**

Safety by design

GORE® CARDIOFORM Occluders combine unique materials and design to provide a soft and conformable device for effective repair of the septum.

Materials and design

5-8 independent, helically wound, platinum filled nitinol wire frame structures covered with expanded polyetrafluoroethylene (ePTFE)

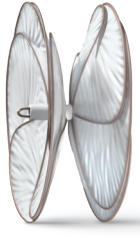
Performance

Conforms to the adjacent, native anatomy facilitating high closure rates with rapid tissue ingrowth and stabilization [1-7]

Scan to register for the Gore Medical Fellows Program Virtual Platform and learn more about the GORE® Cardioform products.

The GORE® CARDIOFORM Occluder family

With the conformable design of the GORE® CARDIOFORM family, a small number of devices can cover PFOs up to 17 mm and ASDs up to 35 mm.*,†



GORE® CARDIOFORM Septal Occluder

For ASDs and PFOs up to 17 mm*

- 77% relative stroke reduction with PFO closure and medical management vs. medical management alone ‡,2
- 98% effective closure rate at 12 months‖,2

Labeled Occluder diameter	Maximum recommended defect size measured with stop flow balloon sizing	Catheter size§
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.

GORE® CARDIOFORM ASD Occluder

For ASDs 8-35 mm*,†

- 100% closure success rate at 6 months¶,**
- No retro-aortic rim required – effective closure with retro-aortic rim lengths of 0-27 mm (median of 4 mm)**

Device size (Disc diameter)	Treatment range measured with stop flow balloon sizing	Catheter size††
27 mm	8–15 mm	10 Fr
32 mm	13–20 mm	10 Fr
37 mm	18–25 mm	11 Fr
44 mm	25–30 mm	12 Fr
48 mm	28–35 mm	14 Fr

††If a 0.035" guidewire is used it is recommended to increase the introducer sheath size by 2 Fr.

INDICATIONS FOR USE: 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

INDICATIONS FOR USE: The GORE® CARDIOFORM ASD Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs).

CONTRAINDICATIONS: The GORE® CARDIOFORM ASD 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 ASD 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 warnings, precautions and adverse events. ℞ Only

Products listed may not be available in all markets.

References

1. *Safe and Effective Closure for Atrial Septal Defects with GORE® CARDIOFORM Septal Occluder and GORE® CARDIOFORM ASD Occluder.* Flagstaff, AZ: W. L. Gore & Associates, Inc; 2020. [Wire frame fracture evaluation]. AZ1882-EN1.
2. Sondergaard L, Kasner SE, Rhodes JF, et al.; Gore REDUCE Study Investigators. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. *New England Journal of Medicine.* 2017;377(11):1033-1042.
3. Sommer RJ, Love BA, Paolillo JA, et al; ASSURED Investigators. ASSURED clinical study: new GORE® CARDIOFORM ASD occluder for transcatheter closure of atrial septal defect. *Catheterization & Cardiovascular Interventions.* 2020;95(7):1285-1295.
4. Gillespie MJ, Javois AJ, Moore P, Forbes T, Paolillo JA; GSO Investigator Group. Use of the GORE® CARDIOFORM Septal Occluder for percutaneous closure of secundum atrial septal defects: results of the multicenter U.S. IDE trial. *Catheterization & Cardiovascular Interventions*. 2020;95(7):1296-1304.
5. de Hemptinne Q, Horlick EM, Osten MD, et al. Initial clinical experience with the GORE® CARDIOFORM ASD Occluder for transcatheter atrial septal defect closure. *Catheterization & Cardiovascular Interventions.* 2017;90(3):495-503.
6. W. L. Gore & Associates. *GORE® Septal Occluder Clinical Study: A Study to Evaluate Safety and Efficacy in the Treatment of Transcatheter Closure of Ostium Secundum Atrial Septal Defects (ASDs).* Flagstaff, AZ: W. L. Gore & Associates, Inc; 2019. [Clinical study report]. MD171724.
7. GORE® CARDIOFORM Septal Occluder [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2018.

If you have any questions, please contact your Gore representative.

Scan to register and access valuable Gore Structural Heart content.

* 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.

† The GORE® CARDIOFORM ASD Occluder is only indicated for the percutaneous, transcatheter closure of ostium secundum ASDs and is not FDA-approved for the closure of PFOs.

‡ The REDUCE study determined safety and efficacy of patent foramen ovale (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 incorporated into this study within indicated sizing parameters of the Instructions for Use.

|| GORE® CARDIOFORM Septal Occluder effective closure rate results in device group subjects who received a study device. Effective closure defined as freedom from large shunt (> 25 bubbles) as determined by the Echo Core Lab at 12 months.

¶ Defined as a clinical residual defect status of occluded or clinical insignificant, as determined by the Echo Core Lab at the 6-month evaluation among subjects with technical success.

** GORE® CARDIOFORM ASD Occluder [Instructions for Use]. Flagstaff, AZ: W.L. Gore & Associates, Inc.; 2021.

Consult Instructions for Use
eifu.goremedical.com

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

W. L. Gore & Associates, Inc.
goremedical.com

Asia Pacific +65 6733 2882 **Australia/New Zealand** 1800 680 424 **Europe** 00800 6334 4673 **United States** Flagstaff, AZ 86003 800 437 8181 928 779 2771