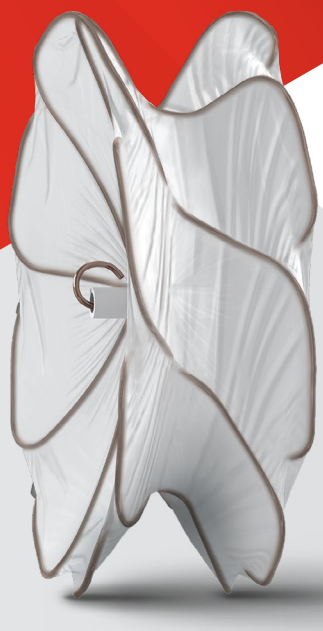
Together, improving life

GORE® CARDIOFORM
ASD Occluder

YOUR ASD TOOLKIT JUST GOT BIGGER



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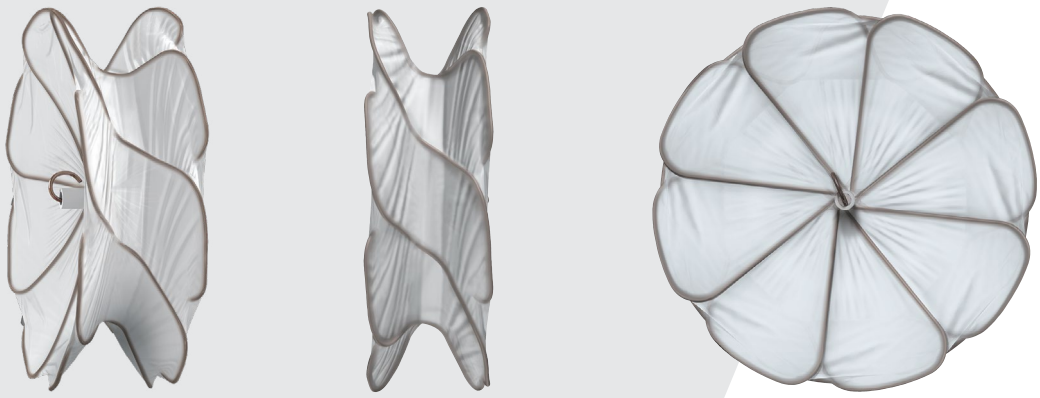
The new GORE® CARDIOFORM ASD Occluder lets you extend confident closure to more patients than ever

Anatomically adaptable waist

- Fills and conforms to the defect for atrial septal defects (ASDs) from 8 to 35 mm[1]
- Soft and conformable construction designed to integrate with the natural structure of the atrial septum
- Device design and material properties combine to optimize septal conformability and tissue ingrowth for short and long term performance



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Confident closure

Gore ASSURED Clinical Study six-month data

Clinicians at 20 sites enrolled 125 patients and experienced high technical success and 100 percent closure success rate at six months[*,†,2]

Technical success rate[†,2]	96% (120 / 125)
Closure success rate[*,2]	100% (112 / 112)

- No retro-aortic rim required — closure success with retro-aortic rim lengths of 0 to 27 mm (median of four mm)[2]
- 57 percent of patients had a deficient retro-aortic rim (< five mm)[4]
- Repositionable and retrievable technology helps ensure proper device positioning

100% closure success rate at six months[*,2]

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Proven safety

Designed in partnership with leading interventional cardiologists across the globe, the GORE® CARDIOFORM ASD Occluder builds on a legacy of safety.

Low rate of 30-day SAEs[2]

Attempted closure	Subjects (N = 125)
30-day SAEs[2]	6 (4.8%)
Supraventricular tachycardia	1 (0.8%)
Cerebrovascular accident	1 (0.8%)
Device embolization	1 (0.8%)
Fever	1 (0.8%)
Atrial fibrillation	1 (0.8%)
Migraine with aura	1 (0.8%)

The GORE® CARDIOFORM ASD Occluder is an extension of a family of occluders that has demonstrated no history of erosion.[2,3]

Low rate of clinically significant new arrhythmia[‡,2]

Low rate of device events[§,2]

Attempted closure	Subjects (N = 125)
Clinically significant new arrhythmia[‡,2]	6 (4.8%)
Device events[§,2]	3 (2.4%)

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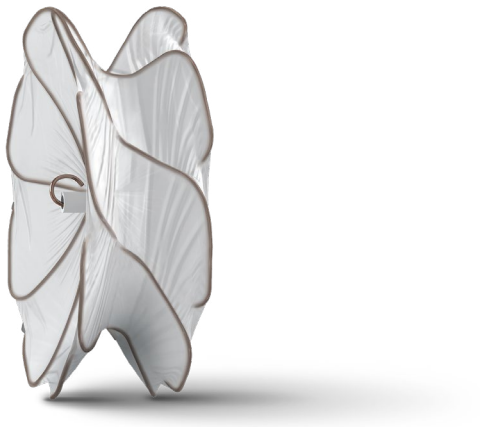
Extending what you can achieve with the GORE® CARDIOFORM Occluder family

With the conformable design of the GORE® CARDIOFORM family, eight catalogue numbers cover ASDs up to 35 mm.‡

GORE® CARDIOFORM ASD Occluder

Catalogue number	Treatment range measured with stop flow balloon sizing	Catheter size‖
ASD27A	8–15 mm	10 Fr
ASD32A	13–20 mm	10 Fr
ASD37A	18–25 mm	11 Fr
ASD44A	23–30 mm	12 Fr
ASD48A	28–35 mm	14 Fr



GORE® CARDIOFORM Septal Occluder

Catalogue number	Maximum recommended defect size (Stop flow balloon sizing)	Catheter size
GSX0020A	11 mm	10 Fr
GSX0025A	14 mm	10 Fr
GSX0030A	17 mm	10 Fr

Ask your Gore field sales associate about opportunities to train on the GORE® CARDIOFORM ASD Occluder.

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References

1. GORE® CARDIOFORM ASD Occluder Imaging Training Tool. Flagstaff, AZ. W. L. Gore & Associates; 2017. [Digital training tool]. AW0214-EN1.
2. GORE® CARDIOFORM ASD Occluder [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2019.
3. Søndergaard 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.
4. Gore ASSURED Clinical Study.

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

† Successful deployment and retention (at conclusion of index procedure) of a GORE® CARDIOFORM ASD Occluder.

‡ The GORE® CARDIOFORM ASD Occluder is only indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs).

§ Defined as post-procedure embolization, device removal, or other device reintervention from completion of the implant procedure through 6 months (180 days) post-procedure.

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

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS / INTENDED 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.

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