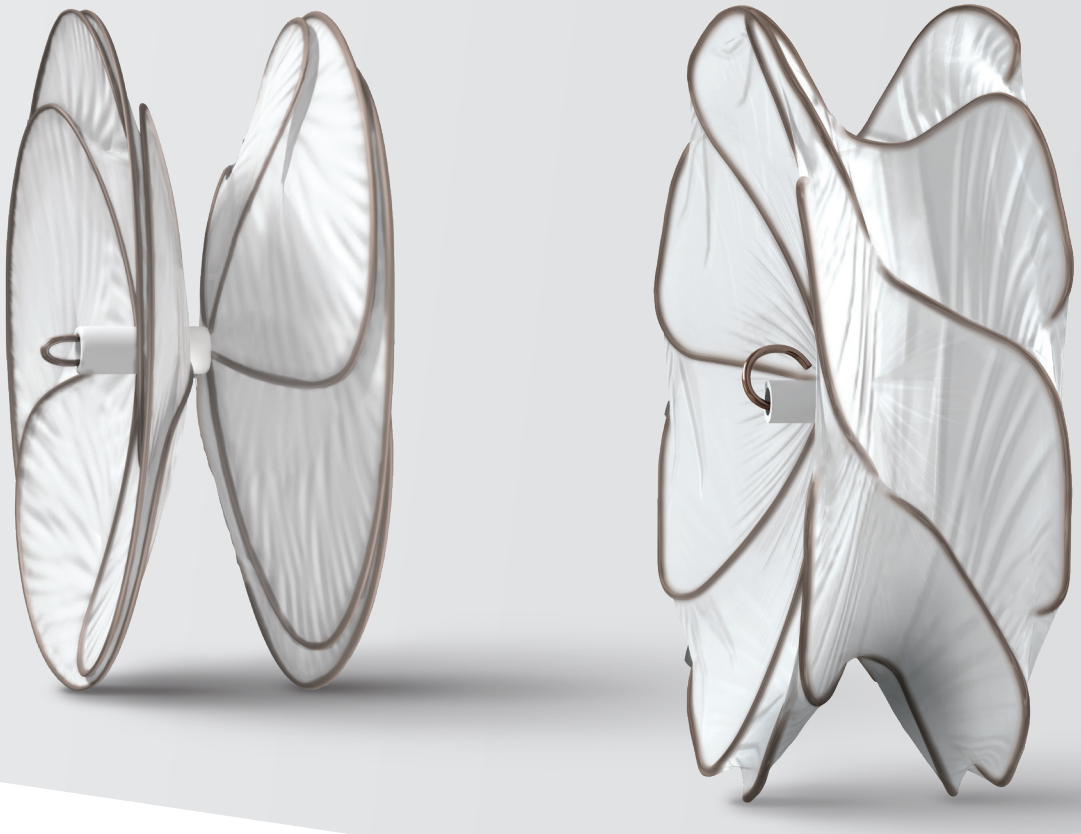
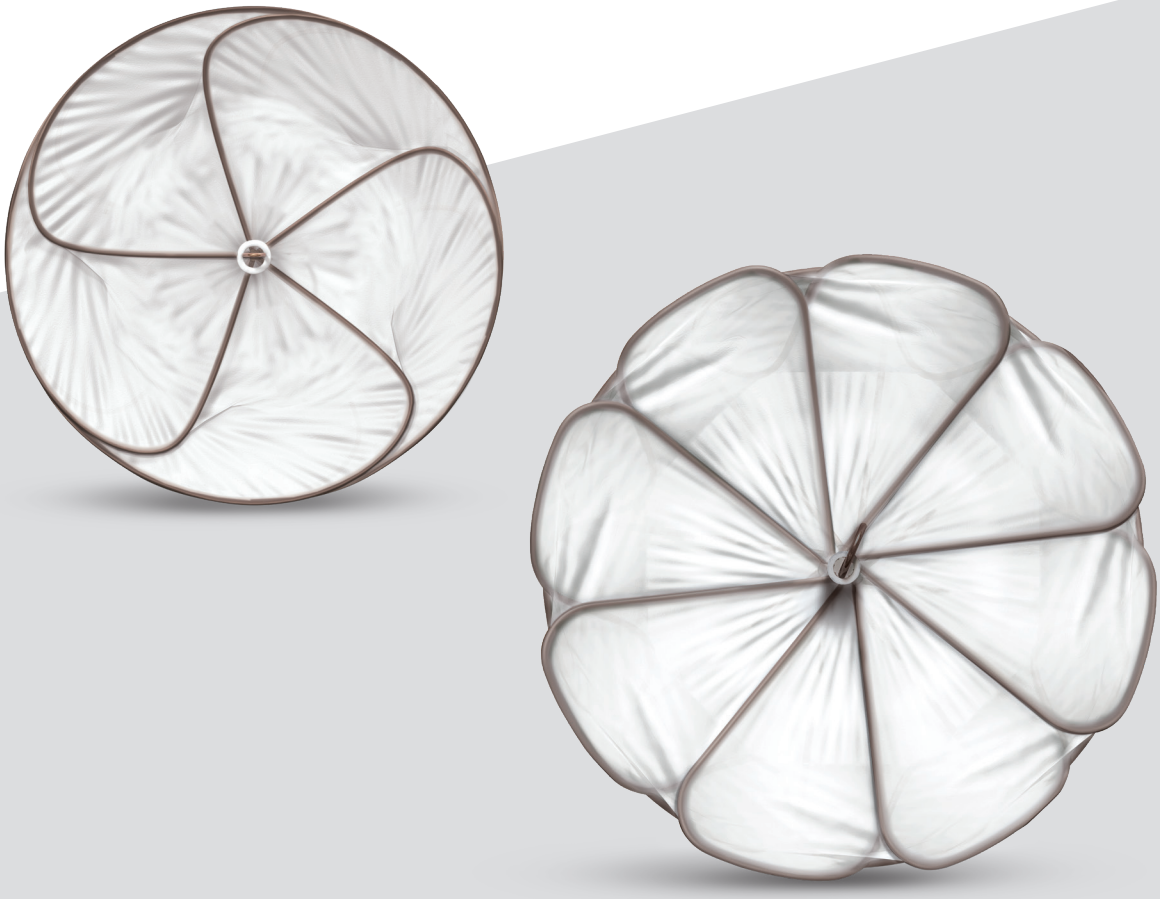
GORE® CARDIOFORM Septal Occluder
GORE® CARDIOFORM ASD Occluder



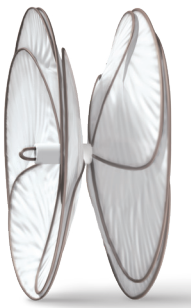
SAFE, EFFECTIVE CLOSURE FOR ATRIAL SEPTAL DEFECTS

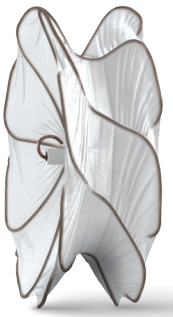
Together, improving life

More than 50,000 GORE® CARDIOFORM Septal Occluders sold globally



Low incidence of clinical sequelae associated with wire frame fracture[1]





GORE® CARDIOFORM Septal Occluder	GORE® CARDIOFORM ASD Occluder
▪ Nine years in clinical use (beginning 2011)	▪ Five years in clinical use (beginning 2015)
▪ > 50,000 devices sold globally	▪ > 2,000 devices sold globally

~0.004%* incidence rate

Only two reported cases of clinical sequelae associated with device wire frame fracture.‡,1,2

0† reported cases

of clinical sequelae associated with device wire frame fracture.†,1

Summary of reported incidence of clinical sequelae associated with wire frame fractures for the GORE® CARDIOFORM Occluders.[1]

Device	First use in humans	Approval year (EU/U.S.)	Devices sold globally	Reported incidence of clinical sequelae associated with wire frame fracture	Incidence rate
GORE® CARDIOFORM Septal Occluder	2011	2011/2015	> 50,000	2‡	~0.004%*
GORE® CARDIOFORM ASD Occluder	2015	2019/2019	> 2,000	0†	0%†

Reported incidence rate of clinical sequelae associated with wire frame fracture for GORE® CARDIOFORM Septal Occluder and GORE® CARDIOFORM ASD Occluder. Calculated using data from CATSWeb Product Surveillance Tracking System (PSTS).

* Data on file. July, 2011 - September, 2020; W. L. Gore & Associates, Inc; Flagstaff, AZ.

† Data on file. March, 2015 - September, 2020; W. L. Gore & Associates, Inc; Flagstaff, AZ.

‡ Clinical experience has reported two cases of clinical sequelae associated with wire frame fracture for GORE® CARDIOFORM Septal Occluder[2] from a total of > 50,000 devices sold globally.[1] In those two events, it was reported that both patients suffered from pericardial tamponade due to perforation of the atrial wall induced by device wire frame fracture. It was reported that urgent medical care and surgical intervention was required with both patients making a full recovery.[2]

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 polytetrafluoroethylene (ePTFE)

Performance
Conforms to the adjacent, native anatomy facilitating high closure rates with rapid tissue ingrowth and stabilization[1,3–8]

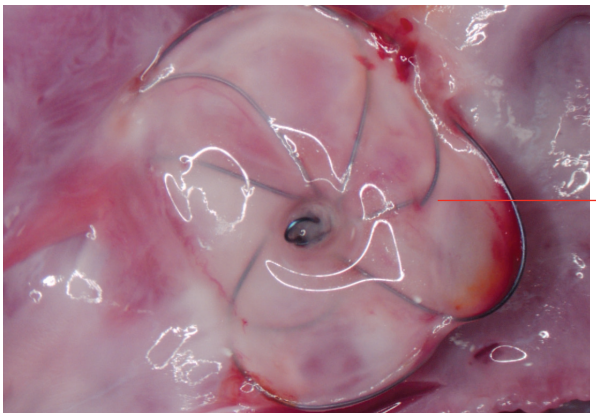
Conformable design may minimize septal wall injury in the presence of wire frame fractures

- Platinum filled nitinol frame is covered with ePTFE, which has been shown to reduce the risk of wire frame protrusion in the presence of fractures in pre-clinical studies.[1]
- ePTFE membrane facilitates rapid tissue ingrowth/endothelialization, covering and stabilizing the device within the septum, even in the presence of wire frame fracture.[1,4–7]
- No reported incidence of wire fragments embolizing away from implanted GORE® CARDIOFORM Occluders.[*,†,1]

Pre-clinical testing and clinical experience

Wire frame fractures can occur in GORE® CARDIOFORM Occluders, but based on pre-clinical testing and clinical experience, the fractures have not resulted in:

- Device instability[1,4–7]
- Partial or full device embolization[1,4–7]
- Residual shunt[1,4–7]



An animal model study showing a typical finding of a GORE® CARDIOFORM ASD Occluder with wire frame fracture. Tissue ingrowth penetrates the ePTFE occlusive membrane and covers the implanted occluder. The fractured wire remains in the ePTFE occlusive membrane.[1]

Clinical experience: GORE® CARDIOFORM Septal Occluder

Clinical experience with the GORE® CARDIOFORM Septal Occluder has reported two cases[2] of clinical sequelae associated with wire frame fracture from a total of > 50,000 devices sold globally.[1]

Of the device-related adverse events reported in prospective clinical trials, none were likely related to wire frame fracture.

GORE® CARDIOFORM Septal Occluder IDE Study for ASD closure: summary of wire frame fracture occurrence through 36-month follow-up.[5,7]

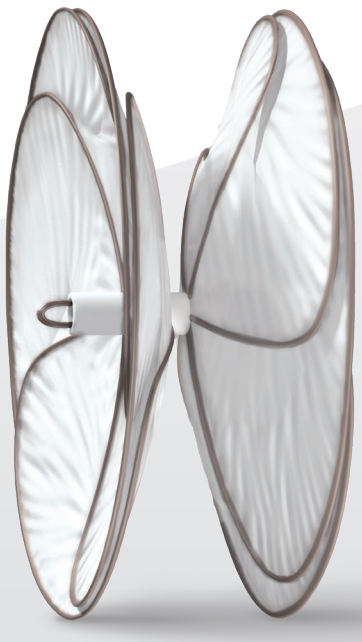
All enrolled subjects (N = 400)*	Overall	15 mm	20 mm	25 mm	30 mm
Fluoroscopy completed	148	4	32	57	55
Wire frame fracture	9 (6.1%)	0 (0.0%)	1 (3.1%)	2 (3.5%)	6 (10.9%)
Clinical sequelae	0	0	0	0	0

* Fluoroscopy was completed in a total of 148 subjects at six months and beyond. A total of 134 subjects completed fluoroscopy at six months and 88 subjects completed fluoroscopy at 36 months from the overall total of 148 subjects that completed fluoroscopic assessments.

Gore REDUCE Clinical Study: summary of wire frame fracture occurrence at 12-month follow-up.[1,8]

PFO closure arm (N = 441)	Overall
Wire frame fracture rate	4.6%
Clinical sequelae	0

The GORE® CARDIOFORM Septal Occluder (61%) and the GORE® HELEX® Occluder (39%) were implanted in the PFO closure arm for the Gore REDUCE Clinical Study.[1,3,8]



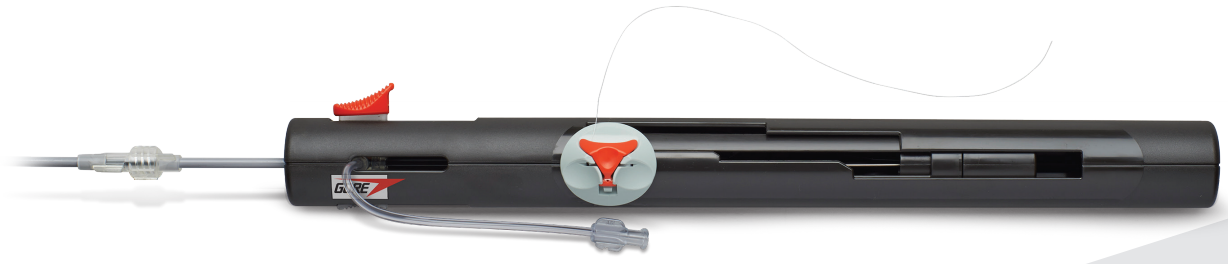
Clinical experience: GORE® CARDIOFORM ASD Occluder

To date there have been no reported adverse events related to device wire frame fractures for GORE® CARDIOFORM ASD Occluder.[1]

Of the device-related adverse events reported in prospective clinical trials, none were likely related to wire frame fracture.

GORE® CARDIOFORM ASD Occluder Pivotal IDE Study for ASD closure: summary of wire frame fracture occurrence at six-month follow-up.[4,9,10]

All enrolled subjects (N = 125)	Overall	27 mm	32 mm	37 mm	44 mm	48 mm
Fluoroscopy completed at 6 months	104	19	38	23	19	5
Wire frame fracture	37 (35.6%)	5 (26.3%)	10 (26.3%)	8 (34.8%)	12 (63.2%)	3 (60.0%)
Clinical sequelae at 6 months	0	0	0	0	0	0



GORE® CARDIOFORM ASD Occluder first-in-man experience.[6]

Subjects with an implanted GORE® CARDIOFORM ASD Occluder device (N = 22)	Overall
Fluoroscopy completed at median follow-up of 186 days	20
Wire frame fracture	5 (25%)
Clinical sequelae	0

Recommended follow-up assessments for GORE® CARDIOFORM Occluders

Follow-up recommendations as listed in the current *Instructions for Use* (IFU) for both GORE® CARDIOFORM Septal Occluder[8,11] and GORE® CARDIOFORM ASD Occluder[10,12] continue to be appropriate.

- Due to the low rate of clinical sequelae over a large number of patients and many years of follow-up, the current recommendations as listed in the IFU continue to be appropriate and focus on ongoing standard of care echocardiography.[1,8,10–12]
- In instances where device stability is questionable, fluoroscopic examination without contrast is recommended.[8,10–12]

GORE® CARDIOFORM Septal Occluder

GORE® CARDIOFORM ASD Occluder

GORE® CARDIOFORM Occluders: devices that can be trusted for safety and performance

GORE® CARDIOFORM Septal Occluder IDE Study for PFO closure (Gore REDUCE Clinical Study)

77%	98%	1.4%	0
Relative recurrent stroke reductions with PFO closure + medical management vs. medical management alone[*,3]	Effective closure rate at 12 months[†,3]	Device related serious adverse events at 12 months[‡,3]	Reported clinical sequelae associated with wire frame fracture[1,8]

GORE® CARDIOFORM Septal Occluder IDE Study for ASD closure (GSO 10-09 Clinical Study)

98.8%	0	0
Clinical closure success at 6 months[§,5,7]	Device events at 6 months[II,5,7]	Reported clinical sequelae associated with wire frame fracture at 6 and 36 months[1,5,7]

GORE® CARDIOFORM ASD Occluder IDE Study for ASD closure (Gore ASSURED Clinical Study)

100%	2.4%	0
Closure success at 6 months[§,4]	Device events at 6 months[¶,4]	Reported clinical sequelae associated with wire frame fracture at 6 months[1,4,9,10]

* The Gore REDUCE Clinical 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.

‡ Serious device events reported in the Gore REDUCE Clinical Study were defined as any adverse event that involved or was related to the device, with the exclusion of arrhythmia.

§ Closure success defined as completely occluded or clinically insignificant shunt as determined by the Echo Core Lab at the six-month evaluation among subjects with technical success.

II Device events reported in the GORE® CARDIOFORM Septal Occluder IDE Study for ASD closure (GSO 10-09 Clinical Study) were defined as any post-procedure device embolizations, erosions or reinterventions.

¶ Device events reported in the GORE® CARDIOFORM ASD Occluder Pivotal IDE Study for ASD closure (Gore ASSURED Clinical Study) were defined as post-procedure embolization, device removal or other reintervention from completion of the implant procedure through six months (180 days) post-procedure.

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.
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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.
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12. GORE® CARDIOFORM ASD Occluder [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2020. MD179707.

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

INDICATIONS FOR USE IN THE U.S.: 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

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 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 IN EUROPE: 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 applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

This information is intended for education and awareness only. Patients should consult their physician for information on the risks associated with the devices and surgical procedures discussed in this document. All surgical procedures carry potential health risks. Not all patients will be candidates for treatment with these devices, and individual outcomes may vary.

Products listed may not be available in all markets.

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