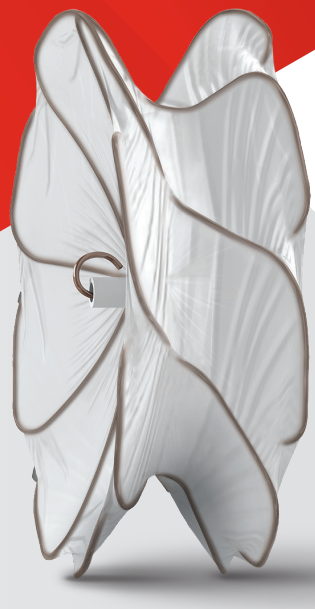
GORE® CARDIOFORM
ASD Occluder

GORE ASSURED CLINICAL STUDY

Wire frame fracture analysis



Together, improving life

GORE® CARDIOFORM ASD Occluder

Gore ASSURED Clinical Study 6-month data

100% closure success rate at 6 months*,[1]

Wire frame fracture was shown to have had *no effect* on the *safety* or *efficacy* of the device through 6-month follow-up.[1]

Subjects (N = 125)	Overall
Technical success rate†,[1]	96% (120 / 125)
Closure success rate*,[1]	100% (112 / 112)
6-month fluoroscopy completed[1]	86.7% (104 / 120)
Wire frame fracture[1]	35.6% (37 / 104)

- 35.6% of device implants were found to have a wire frame fracture at the 6-month fluoroscopy evaluation[1]
- There were *no adverse events related to wire frame fracture* as reported by the sites at the 6-month fluoroscopy evaluation[1]

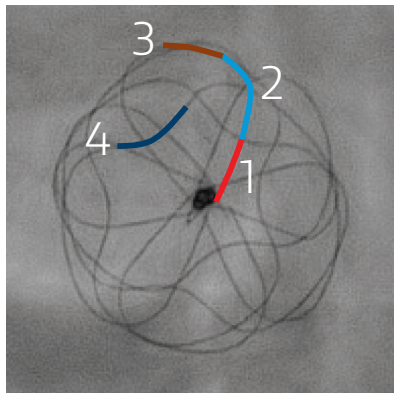
Wire frame fractures resulted in no clinical sequelae through 6-month follow-up including but not limited to:

- Embolization
- Perforations to cardiac structures
- Cardiac tissue erosion
- Device fragmentation
- Residual shunting[1]

Wire frame fracture by location[‡,2]

Location on device	Percent of fractures
1 Spoke	68%
2 Turn	26%
3 Perimeter	6%
4 Waist	0%

Disc	Percent of fractures
Left disc	33%
Right disc	17%
Indeterminable	50%



Frame location identification

Wire frame fracture subject demographics and device size information[§,2]

Significant differences seen in wire frame fracture rates between subgroups had no effect on safety and efficacy outcomes through 6-month follow-up.[1,2]

Subgroup analysis[2]	Wire frame fractures	Subgroups *P* value
Overall	35.6% (37 / 104)	N / A
Age at procedure (yrs)	< 18 = 28.4% (21 / 74) ≥ 18 = 53.3% (16 / 30)	0.023
Weight group (kg)	< 40 = 23.5% (12 / 51) ≥ 40 = 47.2% (25 / 53)	0.014
Device size group	27, 32, 37 mm = 27.5% (22 / 80) 44, 48 mm = 62.5% (15 / 24)	0.003
Device oversized[‖]	Yes = 58.3% (14 / 24) No = 28.8% (23 / 80)	0.014

Significant differences in wire frame fracture rates were seen between age, weight, device size and device oversized.

Subjects who were pediatric, of lower weight and with smaller device size had a lower risk of wire frame fracture and a higher risk for those oversized.

Wire frame fracture by device size

Wire frame fractures had no effect on safety and efficacy on any device size through 6-month follow-up.[1]

All pivotal subjects (N = 125) 6-month fluoroscopy completed N = 104	Overall	27 mm	32 mm	37 mm	44 mm	48 mm
Wire frame fracture[2]	37 (35.6%)	5 (26.3%)	9 (23.7%)	8 (34.8%)	12 (63.2%)	3 (60.0%)

* 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.
‡ Five devices that Case Report Forms stated fractures existed, do not have the 6-month fluoro's uploaded to the database for the evaluation.
§ 104 patients were evaluated with 6-month fluoro, and 37 devices exhibited one or more wire frame fractures. The quantities listed may represent multiple fractures per device.
ll Oversized device was defined as an implanted device whose recommended defect size range was larger than the balloon measured defect at the index procedure.

1. GORE® CARDIOFORM ASD Occluder [*Instructions for Use*]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2019.
2. Hua K. *ASSURED (15-04) Clinical Study – Pivotal 6 Month Fluoroscopic Evaluations Characterization.* Flagstaff, AZ: W. L. Gore & Associates, Inc; 2019. [Work plan]. WP111463.

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 goremedical.com for a complete description of all warnings, precautions and contraindications. ℞ Only

Products listed may not be available in all markets.

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004
+65 67332882 (Asia Pacific) 800 437 8181 (United States)
00800 6334 4673 (Europe) 928 779 2771 (United States) goremedical.com

AY0109-EN1