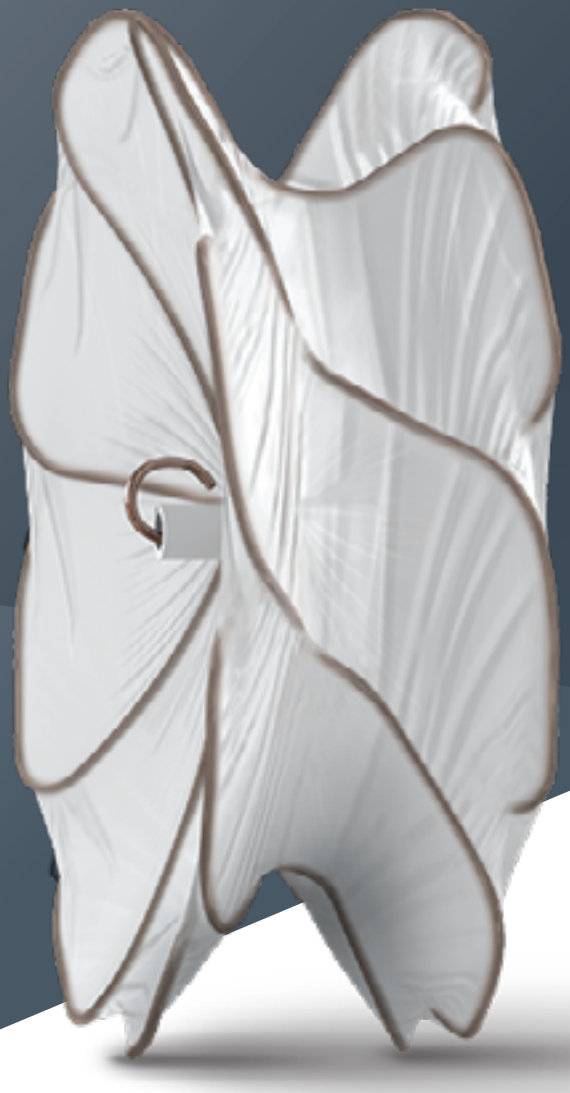
Together, improving life

GORE ASSURED CLINICAL STUDY:

RESULTS THROUGH 36 MONTHS[1]



The GORE® CARDIOFORM ASD Occluder continues to demonstrate a well-established safety profile and clinical performance[1]

"Gore ASSURED 36-month data demonstrated the device continues to be safe and effective across a broad spectrum of patients with no reported clinical sequelae related to frame fractures or erosion. The device expands the capability of interventional cardiologists to close secundum ASDs in a safe and effective way."

– Matthew J. Gillespie, M.D., co-principal investigator of the ASSURED Study

Study design

The Gore ASSURED Clinical Study was a multicenter, prospective, single-arm evaluation of the safety and efficacy of the GORE® CARDIOFORM ASD Occluder for patients with ostium secundum ASDs.[1]

No age limitations

Ostium secundum ASDs measuring 8–35 mm by stop-flow balloon sizing

No retro-aortic rim requirements

22 sites in the U.S.

125
Patients enrolled in the pivotal phase[2]

444
Patients enrolled in the continued access phase

569
Pivotal and continued access patients

Learn more

SEE FULL STUDY

The GORE® CARDIOFORM ASD Occluder results show high closure success rate*,[1] at 36 months

100%

High Closure Success Rate

Inclusive of retro-aortic rim deficiencies across a broad range of ASD anatomies (n = 357/357)*,†,‡,[1,3]

92.4%

High Technical Success Rate

Technical success was achieved in 92.4% of subjects (n = 526/569)[§,1]

"These long-term safety and efficacy outcomes speak directly to the performance and effectiveness of the GORE® CARDIOFORM ASD Occluder."

– Athar M. Qureshi, M.D., site investigator and lead author of the 36-month ASSURED Study manuscript

Learn more about the GORE® CARDIOFORM ASD Occluder

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* Closure success defined as a clinical residual defect status of occluded or clinically insignificant as determined by the Echo Core Lab at the 36-month evaluation among subjects with technical success.
† Deficient retro-aortic rim was defined as a retro-aortic rim measuring less than or equal to 5 mm on any view on echocardiogram.
‡ All ASD anatomies within indicated sizing parameters of the *Instructions for Use*.
§ Technical success defined as successful deployment and retention (at conclusion of index procedure) of a GORE® CARDIOFORM ASD Occluder.

The GORE® CARDIOFORM ASD Occluder shows a continued legacy of patient safety through 36 months[1]

Low rate of 30-day device-/procedure-related serious adverse events (SAEs): 3.7% (n = 21/569)[1]

Low rate of device events: 4.1% (n = 17/418)*,†,[1]

Low rate of clinically significant new arrhythmia: 4.2% (n = 24/569)‡,[1]

0

No reported device erosions[1]

0

No reported device embolizations or thrombus beyond 6 months[1]

0

No reported clinical sequelae due to wire frame fracture in the ASSURED Clinical Study[1]

* Device events defined as post-procedure embolization, device removal or other device reintervention from completion of the implant procedure through 6 months (180 days) and 36 months (1,095 days) post-procedure.

† Device event rate (n = 17/418) among patients evaluated for the clinical composite success endpoint at 36 months.

‡ In subjects without prior history of arrhythmia, any new arrhythmia (documented on ECG) requiring hospitalization, initiation of new long-term medical therapy (persisting > 45 days) or any post-index procedure cardioversion or intervention (pacemaker, ablation, etc.).

GORE® CARDIOFORM ASD Occluder:

MORE THAN 10 YEARS OF CLINICAL USE

15,000 Devices sold globally

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1. Qureshi AM, Sommer RJ, *et al;* GORE ASSURED Clinical Trial Investigators. Long-term results of the Atrial Septal Defect Occluder ASSURED Trial for combined pivotal/continued access cohorts. *JACC: Cardiovascular Interventions.* In press.
2. 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.
3. GORE® CARDIOFORM ASD Occluder [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2024. MD200690.

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

Products listed may not be available in all markets.

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 86004 800 437 8181 928 779 2771