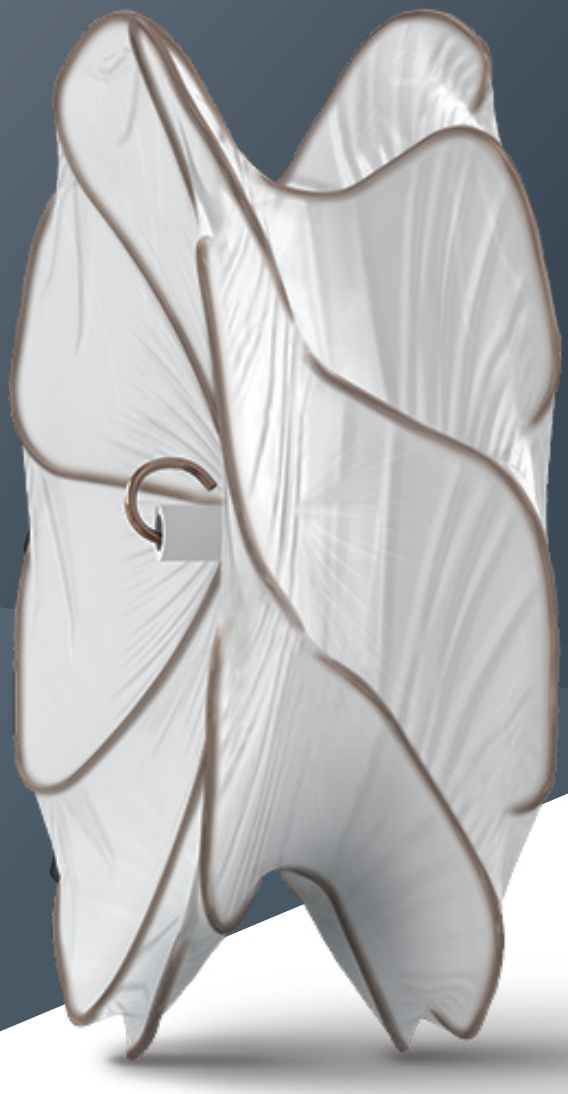
Together, improving life

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

More than
8 YEARS
of clinical use

13,000
devices sold globally

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.

* 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.

Learn more

SEE FULL STUDY

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 reported due to wire frame fracture[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.).

Learn more about the GORE® CARDIOFORM ASD Occluder

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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

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 applicable indications, warnings, precautions and contraindications for the markets where this product is available. $\mathrm{R}_{\mathrm{X}\ \mathrm{Only}}$

Products listed may not be available in all markets.

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