STUDY SUMMARY

Study Title	GORE® CARDIOFORM ASD Occluder Clinical Study: A Study to evaluate safety and efficacy in the treatment of transcatheter closure of *ostium secundum* atrial septal defects (ASDs) – The Gore ASSURED Clinical Study
Protocol Number	ASD 15-04 - Revision 6 (06 Jan 2021)
IDE Number	G160218
Study Device	GORE® CARDIOFORM ASD Occluder
Sponsor	W. L. Gore & Associates, Inc. Medical Products Division [redacted] Telephone: 800-437-8181 [redacted]
Study Design	Prospective, multicenter, single-arm comparison to performance goals derived from clinical study outcomes for devices indicated for ASD closure
Study Objective	Evaluate the safety and efficacy of the GORE® CARDIOFORM ASD Occluder in the percutaneous closure of *ostium secundum* atrial septal defects (ASDs)
Study Endpoints	<u>Primary Endpoints</u> Co-Primary Endpoint 1: 6-Month Closure Success is 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. Co-Primary Endpoint 2: Composite Clinical Success is evaluated at 6 months after index procedure among subjects with attempted study device closure and is defined as satisfying all of the following criteria: 1. Technical Success: Successful deployment and retention (at conclusion of index procedure) of a GORE® CARDIOFORM® ASD Occluder 2. Safety Success: • Freedom from any Serious Adverse Event (SAE) related to the device or procedure (as adjudicated by the Independent Data Review Board (IDRB)) through 30 days post-procedure • Freedom from device events (post-procedure embolization, device removal, or other device reintervention) from completion of the implant procedure through 6 months (180 days) post-procedure 3. Closure Success: A clinical residual defect status of occluded or clinically insignificant as determined by the Echocardiography Core Lab at the 6-month evaluation <u>Secondary Endpoints</u> • Technical Success • Procedure Success

	• Long-term Composite Clinical Success • Long-term Closure Success • Safety Outcomes • Clinically Significant New Arrhythmia
Subject Population	• No age limitations • Patients with *ostium secundum* ASD measuring 8-35 mm by stop-balloon sizing • Inter-atrial shunting with evidence of right heart volume overload, demonstrating the need for septal defect closure • Absence of concurrent cardiac conditions that could elevate morbidity/mortality beyond what is common for ASD
Number of Subjects	• Training Cases: First 2 subjects per site • Pivotal Phase: 125 subjects (non-training) • Continued Access Phase: up to 535 subjects (non-training) • Total Study Enrollment: up to 704 subjects
Number of Sites	Up to 22 sites in the U.S.
Coordination Principal Investigator	[redacted] National Principal Investigator, Pediatric [redacted] National Principal Investigator, Adult
Significant Inclusion Criteria	• Patient has an *ostium secundum* ASD with evidence of left-to-right shunt and right ventricular volume overload. • Patient has a defect size 8-35 mm as measured directly by stop-flow balloon sizing. • Patient vasculature can accommodate the delivery system and procedural accessories. • Patient can accommodate TEE or intracardiac echocardiography (ICE) probe for implant procedure. • Patient is judged by the implanting physician to have adequate septal rims to retain the study device. [redacted]

	• [redacted]
Significant Exclusion Criteria	• Patient has significant known pre-existing electrophysiologic or structural cardiovascular defect, or other comorbidities that could elevate morbidity or mortality beyond what is common for ASD or would require surgical treatment within three (3) years of device placement. Examples include, but are not limited to, large ventricular septal defect, hypoplastic left heart syndrome, coarctation, univentricular heart or tricuspid atresia, pulmonary hypertension, coronary artery disease, valvular or myocardial dysfunction, and other congenital heart disease requiring surgical repair. • Patient has systemic or inherited conditions that would significantly increase risk of major morbidity and mortality during the term of the study. Examples include endocarditis, cancer, degenerative neuromuscular disorder, cardiomyopathy, and any condition expected to result in significant deterioration of health within three (3) years of the index procedure. • Patient has anatomy where the size or position of the occluder would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins. • Patient has active endocarditis, other infections producing bacteremia, or has known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement. • Patient has known intracardiac thrombi. • Patient has an uncontrolled arrhythmia with evidence of arrhythmia • Control failure within the past 90 days (e.g., supraventricular tachycardia while under rate control or atrial fibrillation while under rhythm control) or requires electrophysiology study or concomitant intervention with device placement. [redacted] • Patient has a history of stroke resulting in a significant morbidity or disability. [redacted] • Patient has elevated pulmonary vascular resistance (PVR) which in the opinion of the implanting physician precludes safe defect closure. • Patient has multiple defects based on screening imaging and stop-flow balloon sizing that would require placement of more than one device.
Expected Time to Complete Enrollment	Pivotal Phase: Enrollment Completion: 12 months Continued Access: Enrollment Completion: 18-24 months

Expected Time of each Study Subject to Complete the Study	36 months
Study Duration	Total Study Duration: 5.5 years
Schedule of Events	Screening Assessments (within 6 months of procedure) • Physical exam • Electrocardiogram (ECG) • Echocardiogram (TTE or TEE) Pre-Study Procedure (within 90 days of procedure) • Echocardiogram (TTE) Procedure • Physical exam • Stop-flow balloon sizing of defect • Echocardiogram (TEE, TTE or ICE) • Fluoroscopy Pre-Discharge • Electrocardiogram (ECG) • Echocardiogram (TTE) 30 days and 6 months: • Physical exam • Electrocardiogram (ECG) • Echocardiogram (TTE) • Fluoroscopy (6 months for all Subjects) Long-term follow-up at 12 months and 36 months included: • Physical exam • Electrocardiogram (ECG) • Echocardiogram (TTE) • Fluoroscopy (36 months for all Subjects) A telephone follow-up occurred at 24 months
Additional Information	Echocardiography Core Lab, Independent Data Review Board (IDRB)