Gore Completes Patient Enrollment in U.S. Pivotal Clinical Study of GORE® CARDIOFORM ASD Occluder

New addition to GORE® CARDIOFORM Occluder family is designed to treat larger atrial septal defects by adapting to the patient's anatomy for a permanent and safe closure

FLAGSTAFF, Ariz. – September 26, 2017 – W. L. Gore & Associates, Inc. (Gore) has completed enrollment for the pivotal phase of the Gore ASSURED Clinical Study. This investigational device exemption (IDE) trial is researching the new GORE® CARDIOFORM ASD Occluder for the interventional closure of Atrial Septal Defects (ASDs), sized 8 to 35 mm. The GORE® CARDIOFORM ASD Occluder is designed with a unique, anatomically adaptable waist to accommodate the natural anatomy of the heart and mitigate the potential for cardiac injury. This new device will complement the existing GORE® CARDIOFORM Septal Occluder to allow the treatment of a broader range of ASDs with a soft, conformable device design.

"The GORE CARDIOFORM ASD Occluder represents an exciting innovation in the endovascular treatment of larger ASDs," said Matthew Gillespie, MD, Children's Hospital of Philadelphia, co-principal investigator of the Gore ASSURED Study. "The larger the defect, the greater the risk for complications, which makes the repair of larger ASDs imperative. As we consider closure of large ASDs today, we must be mindful of the potential risks associated with the long-term interaction of the device with the heart. Completion of enrollment brings us one step closer toward having a unique conformable alternative for the closure of large ASDs, potentially reducing the risk of cardiac injury for these patients."

As part of the GORE CARDIOFORM Occluder family, the GORE CARDIOFORM ASD Occluder is designed with a minimal metal frame covered in Gore's proprietary, ePTFE film technology to facilitate tissue ingrowth that permanently closes ASDs. The GORE CARDIOFORM ASD Occluder has five device size offerings that are able to treat a broad defect range.

"Physicians value the soft, conformable design, and improved safety of our currently available GORE CARDIOFORM Septal Occluder, but were only able to treat ASDs up to 17 mm in diameter," said Jake Goble, MBA, PhD, Gore Structural Heart Pipeline Leader. "Together with insights from leading physicians, we have designed the new GORE CARDIOFORM ASD Occluder featuring an anatomically adaptable waist to permit treatment of a wider range of patients. Uniquely, this new device is also capable of adapting itself to the defect, potentially making the repair of a broader range of heart defects available for patients."

The Gore ASSURED Study is a prospective, 22 site, U.S.-based IDE study designed to evaluate the safety and effectiveness of the GORE CARDIOFORM ASD Occluder in the treatment of *ostium secundum* ASDs. An ASD is a congenital heart defect, or hole in the heart present at birth, that allows blood to flow between the left and right atria of the heart. If left untreated, ASDs can lead to pulmonary hypertension, atrial fibrillation, heart failure, stroke and other complications. The pivotal stage of the study includes 125 patients and 3 years of follow-up, with patients being assessed for technical, safety, and closure success at 6 months. Results are expected in mid-2018, which will allow Gore to submit to the U.S. Food and Drug Administration (FDA) for device approval. Robert

Sommer, MD, Columbia University Medical Center, and Matthew Gillespie, MD, Children's Hospital of Philadelphia serve as co-principal investigators of the study.

The GORE CARDIOFORM Occluder family also includes the GORE CARDIOFORM Septal Occluder, which received U.S. FDA approval in 2015 for the treatment of ASDs up to 17 mm. In May of this year, positive results were announced from the Gore REDUCE Clinical Study, which assessed use of the device in the closure of *patent foramen ovale* (PFO) for the reduction of recurrent ischemic stroke and new brain infarct. Gore intends to leverage the REDUCE data to seek FDA approval for a PFO indication for the GORE CARDIOFORM Septal Occluder.

MEDICAL PRODUCTS DIVISION

Gore Medical Products Division engineers devices that treat a range of cardiovascular and other health conditions. With more than 40 million medical devices implanted over the course of more than 40 years, Gore builds on its legacy of improving patient outcomes through research, education and quality initiatives. Product performance, ease of use, and quality of service provide sustainable cost savings for physicians, hospitals and insurers. Gore is joined in service with clinicians, and through this collaboration, we are improving lives. www.goremedical.com

ABOUT W. L. GORE & ASSOCIATES

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Founded in 1958, Gore has built a reputation for solving complex technical challenges in the most demanding environments — from revolutionizing the outerwear industry with GORE-TEX® fabric to creating medical devices that improve and save lives to enabling new levels of performance in the aerospace, pharmaceutical and mobile electronics markets, among other industries. The company is also known for its strong, team-oriented culture and continued recognition from the Great Place to Work® Institute. Headquartered in Newark, Del., Gore employs approximately 10,000 Associates and generates annual revenues that exceed $3 billion. www.gore.com

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