

## **Focus on Safety and Effectiveness of GORE@ HELEX@ Septal Occluder for Closure of Atrial Septal Defect (ASD)**

The Associated Press

FLAGSTAFF, Ariz.--(BUSINESS WIRE)--Jun 7, 2012-- W. L. Gore & Associates (Gore) today announced participation details for the May 24th FDA Circulatory System Devices Advisory Panel Meeting, where worldwide data was reviewed for the GORE HELEX Septal Occluder, indicated for closure of Atrial Septal Defects (ASD). The FDA convened the meeting to discuss current knowledge about the safety and effectiveness of devices approved for transcatheter ASD closure.

Satisfied with meeting outcomes, Gore valued the opportunity to participate and have the FDA and Advisory Panel review more than a decade of clinical experience with the GORE HELEX device.

Approved by the FDA in August 2006, the GORE HELEX Septal Occluder was one of two devices discussed. The Advisory Panel did not recommend additional data analysis or new studies for the GORE HELEX device. The Panel was satisfied that Gore's five year Post-Approval Study, slated for completion in 2014, will provide useful information to physicians and patients. The Panel did make a number of recommendations for more robust patient communications regarding the risks / benefits of transcatheter ASD closure. To view the FDA's presentations and official meeting summary visit: Meeting Materials.

John Rhodes, MD, Chief of The Congenital Heart Center, Duke University Medical Center presented a detailed analysis of the clinical performance in the application of ASD closure using the Gore device.

This review spanned the experience from the initial clinical studies, initiated in Spring 2000, to the device's post-approval experience through December 31, 2011. The presentation concluded that the GORE HELEX Septal Occluder is an effective treatment option for patients with ASDs less than 18 mm in diameter and is associated with a low risk of adverse events.

"I am confident in recommending closure with the GORE HELEX Septal Occluder to my patients because of its solid record of performance earned over a decade of clinical use, and my confidence in its long term safety profile," said Dr. Rhodes.

Howard Rosenfeld, MD, Chief of the Division of Pediatric Cardiology at Children's Hospital and Research Center Oakland, served as the chair of Gore's Data Safety Monitoring Board (DSMB) through the Feasibility, Pivotal and Continued Access Studies of the GORE HELEX Septal Occluder. Speaking during the public forum section of the Panel's deliberations, Dr. Rosenfeld stated, "Throughout my DSMB involvement the Gore team has been aggressive in evaluating adverse events and

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testing theories regarding possible device or procedural flaws." "The GORE HELEX Septal Occluder has an excellent safety profile for its indicated use, the closure of ASDs. In a thorough review of data, from more than a decade of implants worldwide, Gore has not received any reports of heart wall erosion or late emergent surgical intervention," said Stuart Broyles, PhD, Associate with the Gore Medical Division Stroke Business. "We are reviewing feedback from the Circulatory System Devices Panel and will continue to work with the FDA to ensure patient safety. We intend to complete our five-year post-approval study, as the data generated from this study will provide pertinent information for the FDA, physicians and patients. We remain committed to maintaining this level of excellence and commend the FDA for convening this timely discussion." ABOUT W. L. GORE & ASSOCIATES The Gore Medical Products Division has provided creative therapeutic solutions to complex medical problems for more than 35 years. During that time, more than 30 million innovative Gore Medical Devices have been implanted, saving and improving the quality of lives worldwide.

The extensive Gore Medical family of products includes vascular grafts, endovascular and interventional devices, surgical meshes for hernia repair, soft tissue reconstruction, staple line reinforcement and sutures for use in vascular, cardiac and general surgery. Gore was recently named one of the best companies to work for by Fortune magazine for the 15th consecutive year. For more information, visit [www.goremedical.com](http://www.goremedical.com).

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CONTACT: Chempetitive Group for W. L. Gore & Associates Kena Hudson or Erik Clausen 858-457-2437 [GoreMedical@Chempetitive.com](mailto:GoreMedical@Chempetitive.com) KEYWORD: UNITED STATES EUROPE NORTH AMERICA ARIZONA INDUSTRY KEYWORD: SURGERY HEALTH CARDIOLOGY CLINICAL TRIALS MEDICAL DEVICES FDA SOURCE: W. L. Gore & Associates Copyright Business Wire 2012 PUB: 06/07/2012 09:00 AM/DISC: 06/07/2012 09:00 AM <http://www.businesswire.com/news/home/20120607005276/>

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