# FDA Approves GORE® Septal Occluder for Use in Gore REDUCE Clinical Study

The Associated Press

FLAGSTAFF, Ariz. & MIAMI--(BUSINESS WIRE)--Oct 22, 2012--W. L. Gore & Associates (Gore) today announced that the FDA has approved the use of the new GORE® Septal Occluder for inclusion in the Gore REDUCE Clinical Study. Gore is introducing this latest technology in its Gore REDUCE Clinical Study for prevention of recurrent stroke in patent foramen ovale (PFO) patients. The study is designed to demonstrate that PFO closure with the Gore device plus antiplatelet medical management reduces the risk of recurrent stroke or imaging-confirmed Transient Ischemic Attack (TIA) when compared to antiplatelet medical management alone. The prospective, randomized, multi-center, multi-national trial includes up to eighty investigational sites in the US, Europe and Canada.

GORE Septal Occluder (Photo: Business Wire) The new Gore device received CE Mark in June of 2011 for the indication of PFO and atrial septal defect (ASD) closure. Dr. Lars Sondergaard, Nordic Region Cardiology Principal Investigator for the Gore REDUCE Clinical Study, performed the first European procedures using the Gore device. “We have seen great success with the GORE Septal Occluder since we completed the first implant. The device provides ease of deployment and confidence through design for the patient’s well being,” said Sondergaard.

Leveraging more than 13 years of clinical experience with septal occluders, the GORE Septal Occluder is a next generation device that successfully integrates innovative material and design to yield a treatment option whose discs are intended to conform to the anatomy of the individual patient. The Gore device is comprised of a five-wire support frame covered with a thin ePTFE, patch-like material. The soft, strong and conformable membrane is intended to improve closure performance, providing an open microstructure to encourage fast controlled tissue ingrowth. This structure is designed to help enhance the safety of the procedure, one of several characteristics that will be investigated in the Gore REDUCE Clinical Study.

“Our commitment is to patients and bringing them viable and beneficial treatment options to reduce recurrent stroke and improve their quality of life. With today’s announcement we ensure that the latest technology is applied to the Gore REDUCE Clinical Study,” said Stuart Broyles, PhD, Associate with the Gore Medical Division Stroke Business. “By integrating innovative design and material, the GORE Septal Occluder is truly a next generation device that underscores Gore’s ongoing commitment to clinical and product performance.” 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. www.goremedical.com.

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