First Patient Enrolled In Study For Atrial Septal Defect

(BUSINESS WIRE)--W. L. Gore & Associates (Gore) has reported the first patient enrolled in the GORE® Septal Occluder Clinical Study evaluating the safety and efficacy of the new GORE Septal Occluder in the treatment of percutaneous, trancatheter closure of ostium secundum atrial septal defect (ASD). The patient was successfully treated at Duke University Medical Center in Durham, North Carolina by John Rhodes, MD, Chief of the Congenital Heart Center; and Mandy Green, FNP-C.

“The first procedure using the GORE Septal Occluder was successful and the patient is doing well, having left the hospital the next day,” said Dr. Rhodes. “The Gore device has an exceptional design that makes it easy to deploy, and the innovative ePTFE material conforms to the heart for optimal patient outcomes. It is critical for physicians to help complete studies like this in an effort to get new and novel technologies into the hands of doctors to aid patient needs.”

The GORE Septal Occluder received CE Mark approval in June 2011 for the indication of ASD and patent foramen ovale (PFO). Globally, more than 1,500 devices have been implanted successfully. The US prospective, multicenter, single-arm, clinical study will compare the GORE Septal Occluder to outcomes from previous GORE® HELEX® Septal Occluder clinical studies. The Gore Study will collect patient data six months post-procedure and will continue to monitor patients for three years from 50 patients at 11 investigational sites.

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.

Designed for physician’s ease of use, the GORE Septal Occluder delivery system allows for one hand control. This gives the physician an intuitive, reliable and consistent delivery experience. Enabling precise positioning and repositioning creates optimal occluder placement in even the most challenging anatomies.

“Gore is committed to bringing patients viable and beneficial treatment options that improve their quality of life,” said Stuart Broyles, PhD, Associate with the Gore Medical Division Stroke Cardiac Business. “The GORE Septal Occluder Clinical Study for the indication of ASD closure moves us one step closer to bringing this innovative device to the physicians and improving patient outcomes.”

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