CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECT WITH THE AMPLATZER™ ASO: RESULTS OF A 1000 PATIENT STUDY

Objectives: To evaluate the safety and efficacy of the St. Jude Medical™ AMPLATZER™ Septal Occluder (ASO) for percutaneous closure of secundum atrial septal defects (ASD).

Background: The ASO is a self-expanding, double-disc nitinol wire mesh occluder for percutaneous closure of ASD. Concern has been raised about the potential for cardiac injury with the ASO, although the reported incidence is rare. This prospective study was developed as the first of a two-part study to evaluate safety and efficacy.

Methods: Subjects prospectively enrolled in a 1000 patient single arm study at 50 U.S. sites and followed for 2 years post-procedure. The primary objective of the study was to evaluate the risk of hemodynamic compromise in those receiving the ASO device. Additional safety objectives were to determine the incidence of device and delivery system-related adverse events. Efficacy was measured as the percentage of subjects for whom closure of the defect was achieved through 2 year follow-up.

Results: Between March, 2008 and May, 2012, 1000 patients (age range 0.3 - 83.6 years, mean 21 ± 22 years) underwent attempted ASD closure with the ASO. Closure was successful during the procedure in 97.9% of subjects. The percentage of subjects with complete closure was 98.5% and 97.9% at 1 month and 2 years respectively. Hemodynamic compromise related to the device occurred in 6 subjects by 2 years (0.65% of 928 evaluable subjects), due to dysrhythmia in 2, device embolization in 1, and cardiac erosion in 3. The rate of cardiac erosion was 0.3% at an average of 83 days from implant (range 12-171 days). The level of physician experience implanting the ASO device in this study showed no statistical significant difference in the rate of hemodynamic compromise (p = 0.4 by Fisher’s Exact test). An additional 31 subjects were noted to have pericardial effusions that were treated with observation or pharmacologic therapy. These events of pericardial effusion were adjudicated by an independent committee as not being caused by cardiac erosion.

Conclusions: Closure of ASD with the ASO is safe and effective regardless of physician experience. The incidence of hemodynamic compromise related to cardiac erosion is extremely rare and consistent with previous study results and reports in the literature.