

## **Initial Experience with the Cardia Ultrasept PFO and ASD Occluder**

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### **Background**

The Ultrasept septal occluder (Cardia, Eagan, MN, USA) is a circular, low profile, fully retrievable and repositionable device. It employs hands-free loading and produces an extremely flat profile with minimal use of metal and materials. It is available in models used for transcatheter closure of the patent foramen ovale (PFO) and atrial septal defect (ASD). The accompanying delivery system includes a braided wire reinforced sheath for better positioning and directional control.

### **Methods and Results**

Transcatheter closure of septal defects was undertaken at our institution using the Ultrasept septal closure device in 8 patients. Patent Foramen Ovale with known right-to-left atrial shunting and presumed paradoxical emboli was closed in 5 patients and Atrial Septal Defects ranging in size from 14mm to 21mm before balloon sizing were closed in 3 patients. First implant date was October 2010.

Four PFO patients received a 25 mm device and 1 PFO patient received a 30 mm device. ASD device sizes used varied between 18 mm and 26 mm. During all procedures we employed general anesthesia and trans-esophageal echocardiography. The total duration time of all procedures was less than 30 minutes. Fluoroscopy times averaged approximately 4 minutes per procedure. Implantation of the Ultrasept device was easily achieved in all patients without procedural complications.

At 24 hour follow-up, an echocardiogram and chest x-ray showed all devices in correct position with no residual shunt and all patients were then discharged from the hospital. Each patient received a double Anti-Platelet therapy (6 months ASA – 4 weeks Clopidogrel) together with a subacute bacterial endocarditis prophylaxis for 6 weeks.

No immediate or late complications have occurred in any patient. Total follow-up time of this patient cohort is 49 months.