

## INITIAL EXPERIENCE WITH THE ATRIASEPT: A New Device For Transcatheter Closure Of Secundum Atrial Septal Defect.

### Our thanks to:

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### OBJECTIVE:

To evaluate the safety and efficacy of the new ATRIASEPT device.

### Patients

7 different international centers  
Pediatric and adult patients with secundum ASD  
Prospective, non-randomized data collection

N = 58; 36 (62%) female  
Median age = 25.7 years (range 3.17–68 yrs)  
Median weight = 45 kg (range 13–155 kg)

### Immediate Results

6/58 (10%) pts had small < 2 mm (color Doppler) residual left-to-right shunts  
1 through an additional, partially covered defect  
1/58 (2%) pt developed mild mitral regurgitation  
13 kg pt  
Deficient anterior-superior rim  
1/58 (2%) pt required device retrieval with subsequent placement of a larger device  
1/58 (2%) pt developed a small pericardial effusion  
Did not require drainage

### Procedures TEE or ICE

Balloon stretched diameter by color-flow occlusion (most patients)  
Device size chosen to closely match defect diameter  
Median defect stretched diameter = 16.6 mm (range 8-26 mm)  
Median device centering ring diameter : defect stretched diameter ratio = 1.08 mm (range 0.86–2 mm)  
Median device arm length : defect stretched diameter ratio = 1.88 mm (range 1.62–3.75 mm)  
Follow-up TTE at 1, 3, 6, and 12 months

### Follow-up

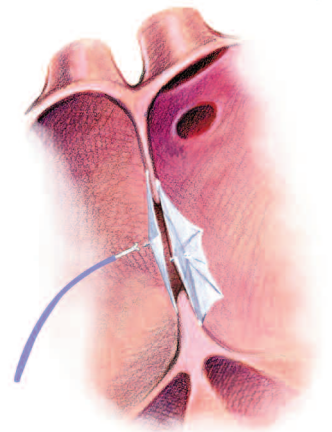
Median F/U = 1 month (range 0–12 mo)  
58/58 (100%) pts with stable device position  
58/58 (100%) pts with sinus rhythm  
2/6 immediate shunts resolved at 1 mo F/U  
1/6 immediate shunts persists at 3 mo F/U  
Pericardial effusion and mitral regurgitation each resolved at 1 and 3 mos, respectively, in the previously mentioned patients

# ATRIASEPT™

Advancing Septal Closure Technology

### BACKGROUND

The ATRIASEPT (Cardia, Eagan, MN) is a low-profile, self-centering, fully retrievable, and repositionable double-umbrella device with a woven Nitinol frame and polyvinyl alcohol sails. It can be used for transcatheter closure of moderate-size secundum atrial septal defects (ASD) up to approximately 24 mm in stretched diameter. The diameter of the inner self-centering ring is designed to closely match the stretched diameter of the ASD, and the total arm length is 14 mm longer than the centering ring diameter. Device endothelialization is excellent.



CARDIA®

The ATRIASEPT is safe and effective for closure of moderate-size secundum. ASD Further study of the ATRIASEPT, including the larger device sizes, is warranted.

Pediatric Cardiology & Adult with Congenital Heart Disease Department IRCCS Policlinico San Donato

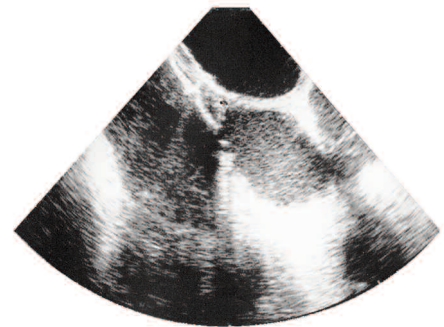
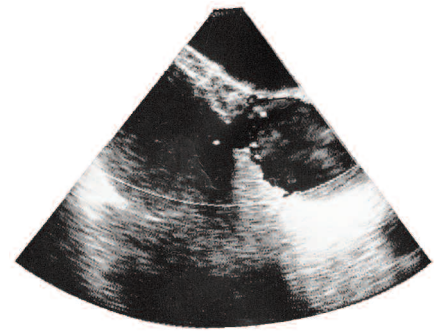
# ATRIASEPT™

*Advancing Septal Closure Technology*

ATRIASEPT™ ASD Device has been developed for the transvenous closure of Atrial Septal Defects. The dual articulating sails along with the patented centering mechanism allows for **easy deployment** of the device as well as a **super low profile** within the atria.

The patented **self-centering mechanism** is incorporated into the device for optimal **positioning and repositioning** of the device within the defect. An integral locking delivery and retrieval mechanism ensures safe and stable deployments.

ATRIASEPT™ is **fully retrievable** before and after release.



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ATRIASEPT™ is available in even sizes with a centering mechanism of 8-32mm.

*For More Information Contact:*

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