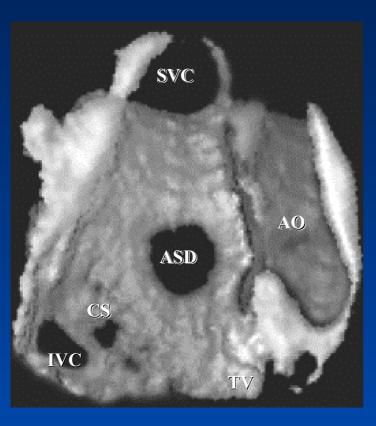
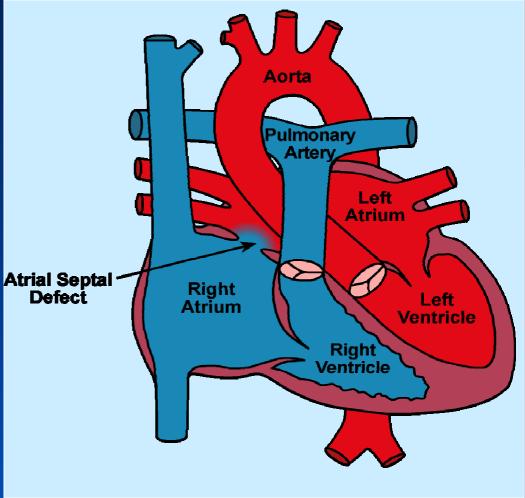
Percutaneous Closure of Atrial Septal Defect

Atrial Septal Defect





Percutaneous ASD Closure Indications

Ostium secundum ASD with

- Clinical symptoms
- Qp/Qs > 1.5:1

Percutaneous ASD Closure Contraindications

- Resting pulmonary hypertension
- Non-secundum type ASD
- Insufficient septal rims
- Pregnancy
- Extensive congenital cardiac anomaly
- Recent infection or sepsis
- Contraindication to antiplatelets
- Intracardiac thrombi



Surgery vs. Percutaenous

	Device	Surgical	P-value
	(N=442)	(N=154)	T-vuine
Technical success	96%	100%	NS
Procedure time, min	106 ± 43	160 ± 54	< 0.001
Hospital stay, day	1.0 ± 0.3	3.4 ± 1.2	< 0.001
Complications			
Major	7 (1.6%)	8 (5.2%)	0.03
Minor	27 (6.1%)	29 (18.8%)	< 0.001
Overall	32 (7.2%)	37 (24.0%)	< 0.001
1-year success rate	98.5%	100%	0.33

Kramer P, TCT 2003



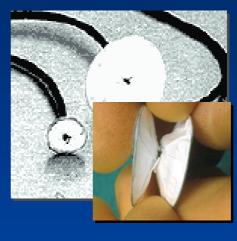
ASD Closure Devices The Big Four



Amplatzer



CardioSEAL / Starflex



HELEX



PFOStar

ASD Closure Devices "Ideal" ASD Repair

- Minimally invasive
- Procedural safety
- Simplicity
- Efficacy
- Low profile "patch"
- Conforms to variable anatomy
- Long term biocompatibility

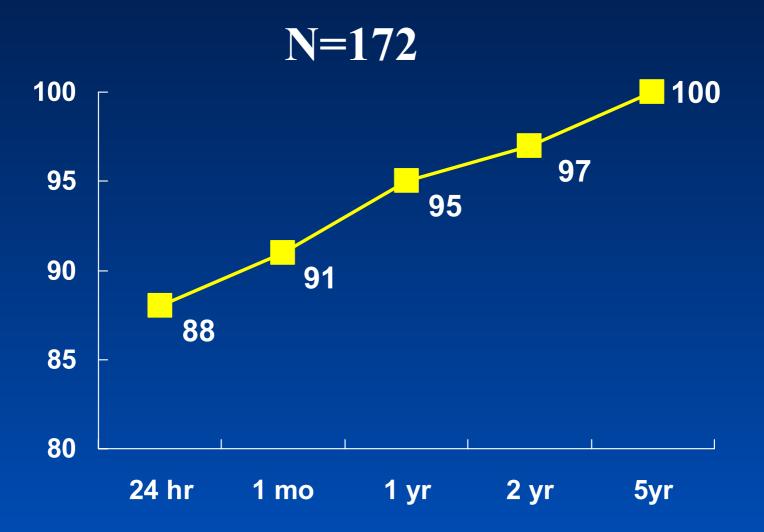


Procedural Results

- Procedural success rate; 95%-98%
- Very rare complication (<0.5%)
 - Entrapment in RA structures
 - Inability to release, withdraw
 - Twisting of device
 - Dislodgment
 - Thrombosis

Cardiovascular Research Foundation **ANGIOPLASTY SUMMIT**

Occlusion Rate with Time



Bialkowski J, Rev Esp Cardiol. 2003;56:383



Thrombosis

- Very rare: 0.05~0.2%
- Related to
 - Poor implant apposition
 - Poor device endothelialization
 - Underlying prothrombotic states

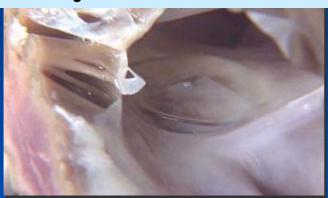
Krumsdorf U et al. J Am Coll Cardiol 2004;43:302

Thrombosis

Poor apposition



Delayed endothelization





Conclusion

Percutaneous closure of the secundum ASD is a safe, effective, and less invasive treatment than surgical closure

ASD Closure With Amplatzer Device

Amplatzer® Septal Occluder

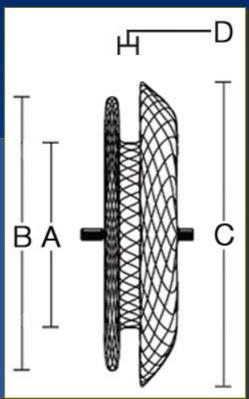
- •Self-Expandable
- Short-connecting Waist
- •Nitinol Wire .004" .008"
- •Sizes: 4-38 mm

Device Size (Waist = A)

RA Disc (B)

LA Disc (C)

Length of Waist = (D)







Amplatzer® Sheath Selection Guide

6F: 60 cm, Device Size 4-10mm

7F: 60 or 80 cm, Device Size 11-17mm

8F: 60 or 80 cm, Device Size 18-20

9F: 80cm, Device Size 22-24

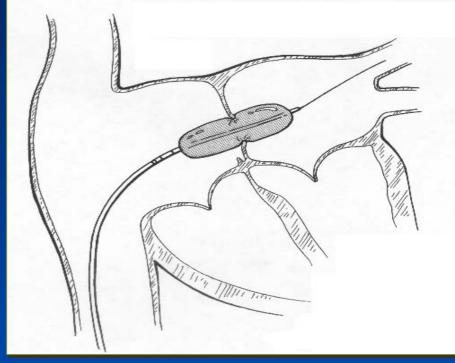
10F: 80 cm, Device Size 26-30

12F: 80 cm, Device Size 32-38



Amplatzer® Sizing Balloon

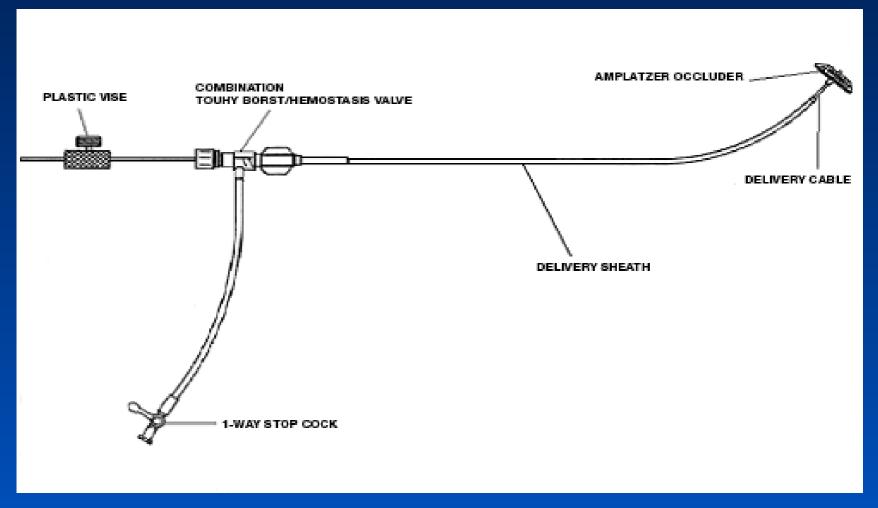




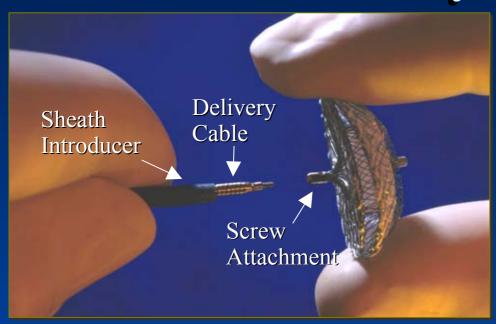
Amplatzer® Device Size

- Connecting waist ≤2mm greater than stretched diameter of defect
- Defects up to ≤36 mm in diameter
- Rim of ≥5mm on all sides

Amplatzer® Delivery System



Amplatzer® Delivery System



Attach the loading device to the delivery sheath. Advance the device into the sheath by pushing (not rotating) the delivery cable.



Attachment



Transfer



Deployment

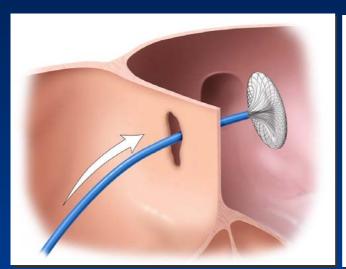


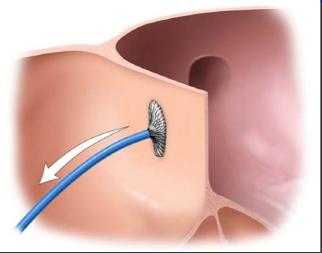
Loading

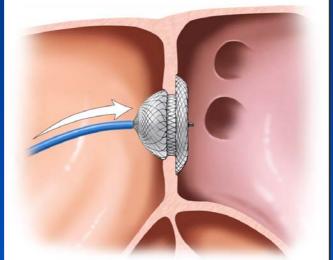


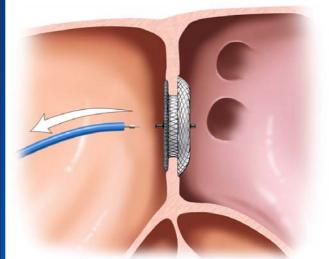
Advancement

Amplatzer® Deployment









Endothelization Amplatzer



Amplatzer

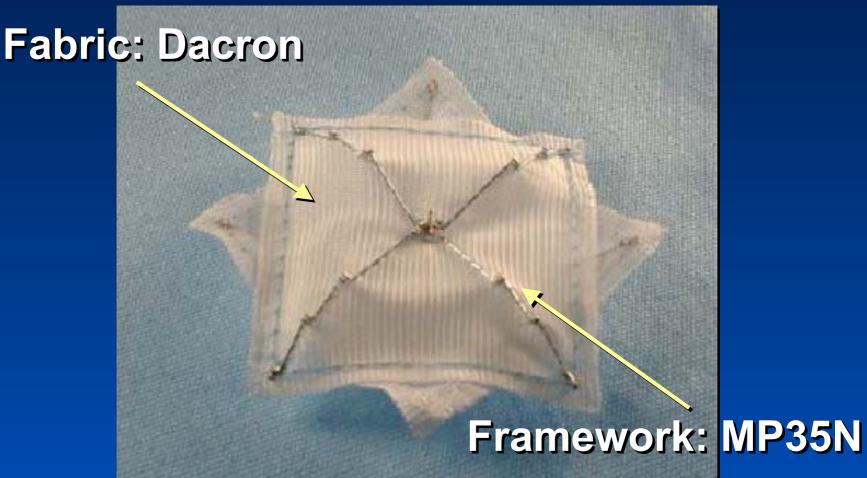


Endothelialization

ASD Closure With CardioSEAL / Starflex



CardioSEAL: Device

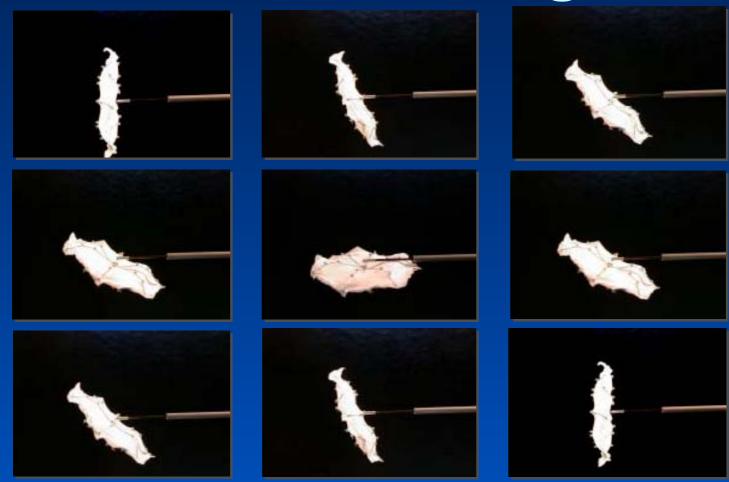


Novel Delivery System

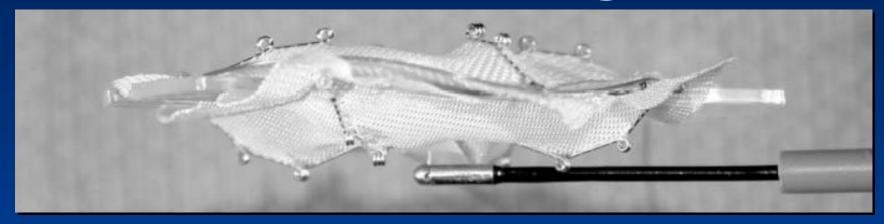


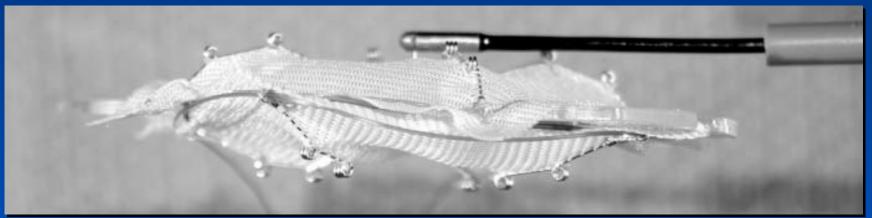
NMT Medical Single operator Minimal septal distortion d/t 180° pivoting

CardioSEAL 180° Pivoting

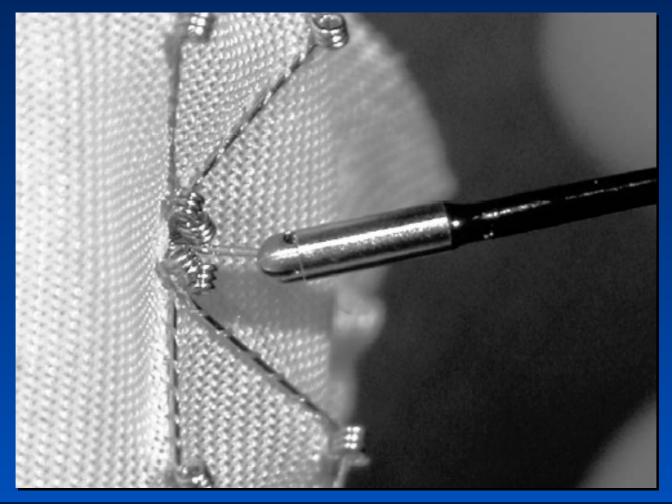


CardioSEAL 180° Pivoting





CardioSEAL Attachment



CardioSEAL Flushing



CardioSEAL: Device Suitable For

- ASDs up to 25 mm
- Fenetrated Fontan
- Muscular VSDs
- Window-type PDAs