

Cardiology in the Young

Transcatheter treatment of Congenital Heart Defect in Adults

K.C. Chan MBBS, FRCP, FACC, FSCAI
Director

Pediatric Cardiology Inpatient Services & Interventional Catheter
Joe DiMaggio Children's Hospital
Hollywood, Florida



Disclosure

- ❖ Dr. Chan participated in the Amplatzer extended Phase II clinical trial for Amplatzer Septal Occluder, Amplatzer Ductal Occluder, Amplatzer Muscular VSD occluder
- ❖ Dr. Chan is a proctor for the Amplatzer Septal Occluder
- ❖ Dr. Chan participated in phase II clinical trial for the Helex Septal occluder
- ❖ Off label use of devices will be discussed



Interventional Cardiac Catheter in the Young



Rubio Alvarez - 1954
Pulmonary Valvotomy

Creation of an Atrial Septal Defect Without Thoracotomy

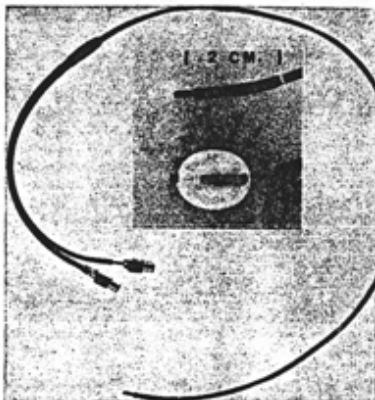
A Palliative Approach to Complete Transposition of the Great Arteries

William J. Rashkind, MD, and William W. Miller, MD

Transposition of the great vessels (TGV) occurs in approximately 20% of children who die with congenital heart disease.¹ With rare exceptions, patients with this lesion die in the first 6 months of life (50% within the first month). Approximately 40% of patients with TGV have an otherwise normal heart. In recent years, various types of complete corrections for this lesion have been attempted. Mustard et al² has simplified these procedures and has reduced mortality to reasonable levels. Best results are obtained in children well beyond 6 months of age. Therefore, it is imperative to provide early palliation that is effective until the optimal age for complete correction and that does not interfere significantly with subsequent surgery. Creation of an interatrial communication seems the best available choice to suit these requirements. The Blalock-Hanlon technique,³ or some modified version, is commonly used to remove a portion of the atrial septum surgically. The purpose of this report is to present a technique for producing an atrial septal defect without thoracotomy and without anesthesia, using a cardiac catheter introduced into a femoral vein.

Method and Material

The femoral vein is exposed as for routine cardiac catheterization in infancy. The device is a double-lumen cardiac catheter. One lumen continues the entire length of the catheter, the other ends in the balloon. It is passed via the femoral vein into the right atrium and is then manipulated through the foramen ovale into the left atrium. Location in the left atrium is verified by passing the catheter tip into a pulmonary vein, by sampling highly saturated blood, or by selective angiography. The balloon is inflated in the left atrium with 2 to 6 ml of dilute radiopaque solution. It is then withdrawn rapidly (one to two seconds) into the right atrium tearing the atrial septum. The balloon is then deflated rapidly (two to four seconds) and

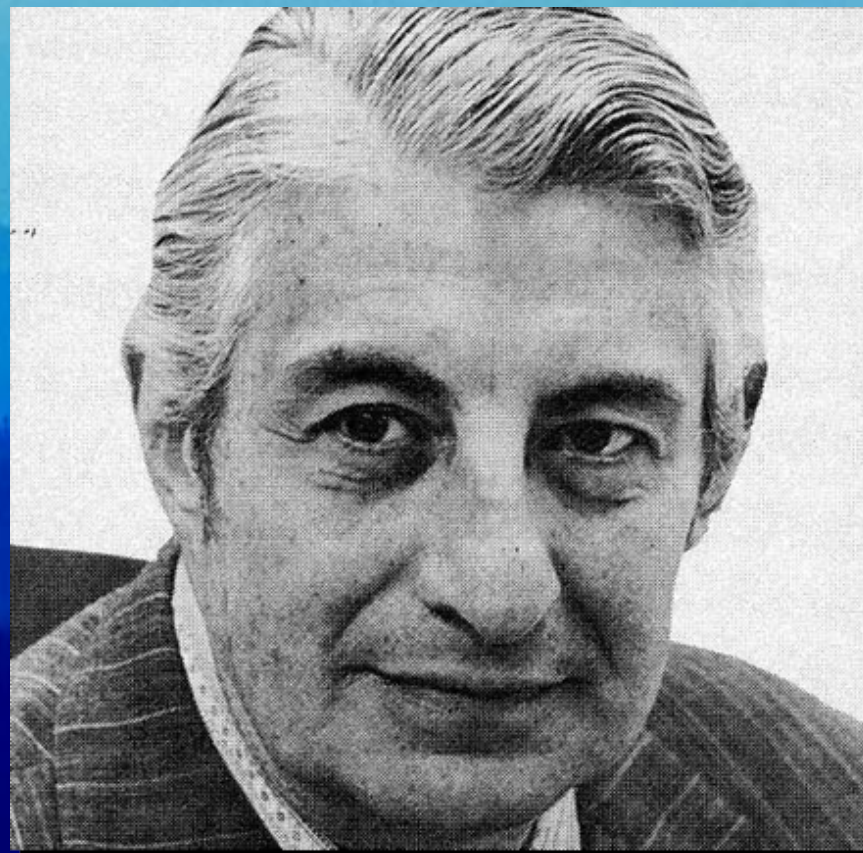


1. Illustration of the special balloon-tipped catheter (6.5 F). Insert shows the tip magnified in both deflated and inflated positions.

the procedure repeated until the filled balloon be withdrawn from the left to the right atrium without resistance. Figure 1 illustrates the special catheter. The insert is a magnified view of the catheter tip with the balloon deflated and inflated.

Seven littermate puppies weighing between and 8 lb (2.7 to 3.6 kg) were studied. Six had atrial septal defects created by the technique described. The seventh served as a normal control. Five the puppies have been sacrificed at intervals of hour to two months after the procedure. The maining puppy is being kept for one year of follow up study. Figure 2 compares the atrial septal defect and the tricuspid valve in the animal sacrificed two months after septotomy.

Three infants with TGV, age 15 hours, 5 weeks and 6 weeks, have been treated successfully with this technique. None of them showed ventricular or ductal shunting on angiography. They are:



William Rashkind MD

JAMA 1966;196:991

From the Cardiovascular Laboratories, The Children's Hospital of Philadelphia.
Reprint requests to Children's Hospital of Philadelphia, 18th and Bainbridge Streets, Philadelphia 19146 (Dr. Rashkind).



Case study - H.G.

- ❖ 47 y man
- ❖ Hypertension & subarachnoid bleed
- ❖ Emergent neuro-intervention
- ❖ Cardiac cath and coronary angiography
 - ❖ Significant coronary artery disease
 - ❖ Coarctation of aorta
- ❖ What next?



Case study - H.G.

Lossy Compression - not intended for diagnosis ...

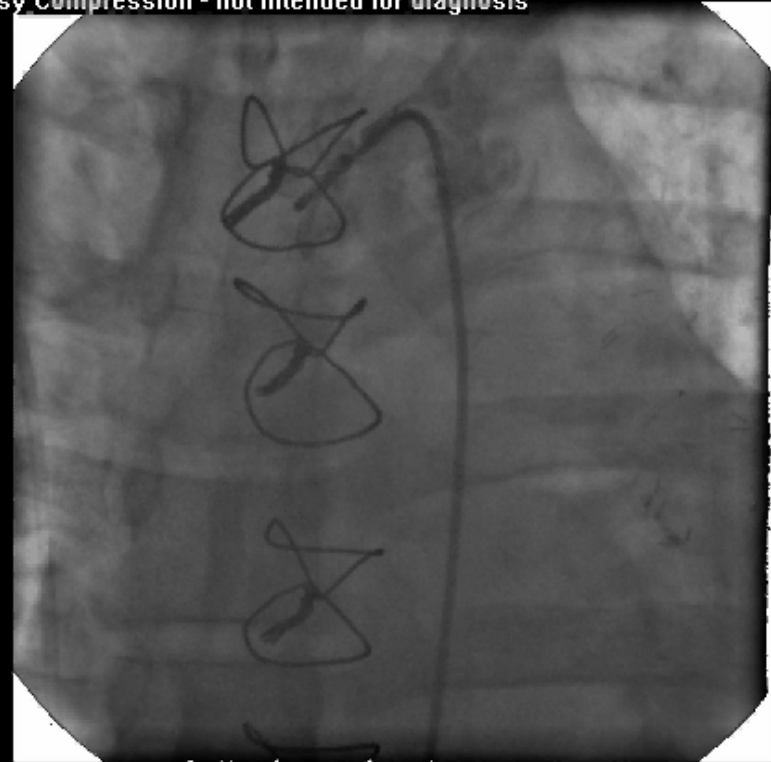


Case study - H.G.

Lossy Compression - not intended for diagnosis



Lossy Compression - not intended for diagnosis



Case study - H.G.

Lossy Compression - not intended for diagnosis

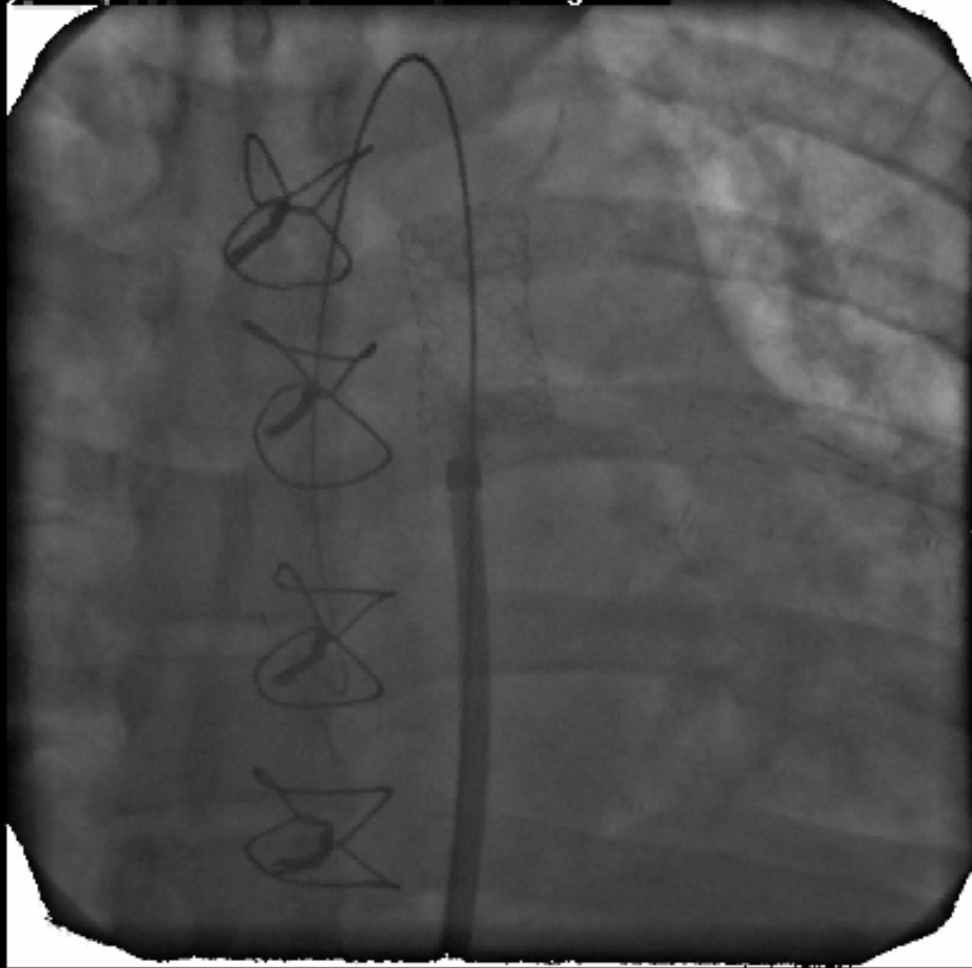


After 3 months



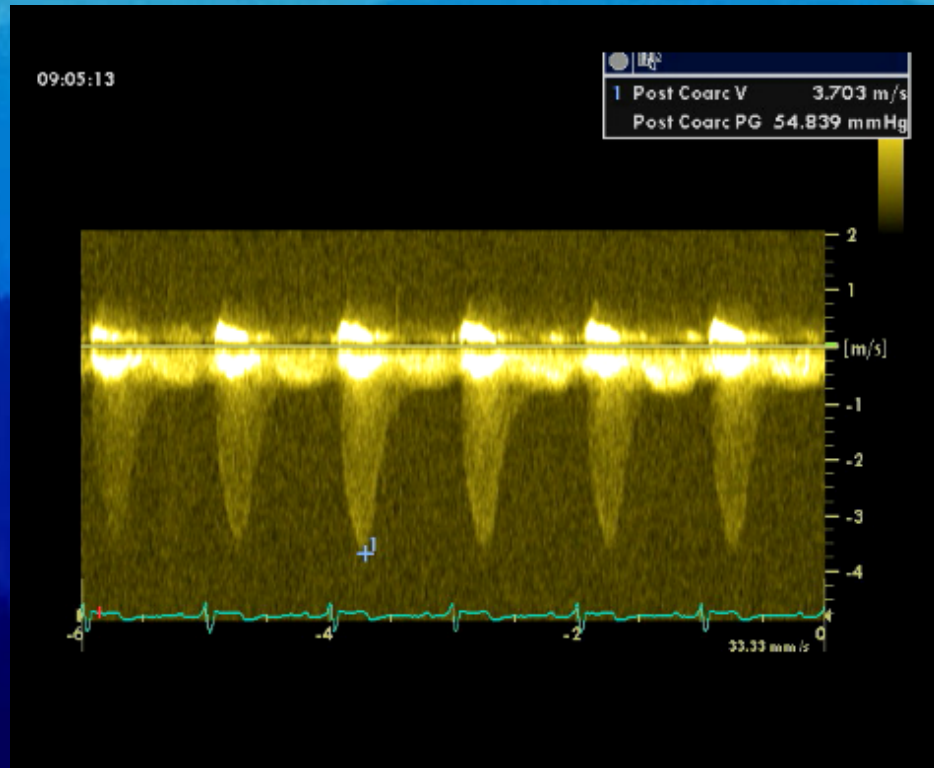
Case study - H.G.

Lossy Compression - not intended for diagnosis

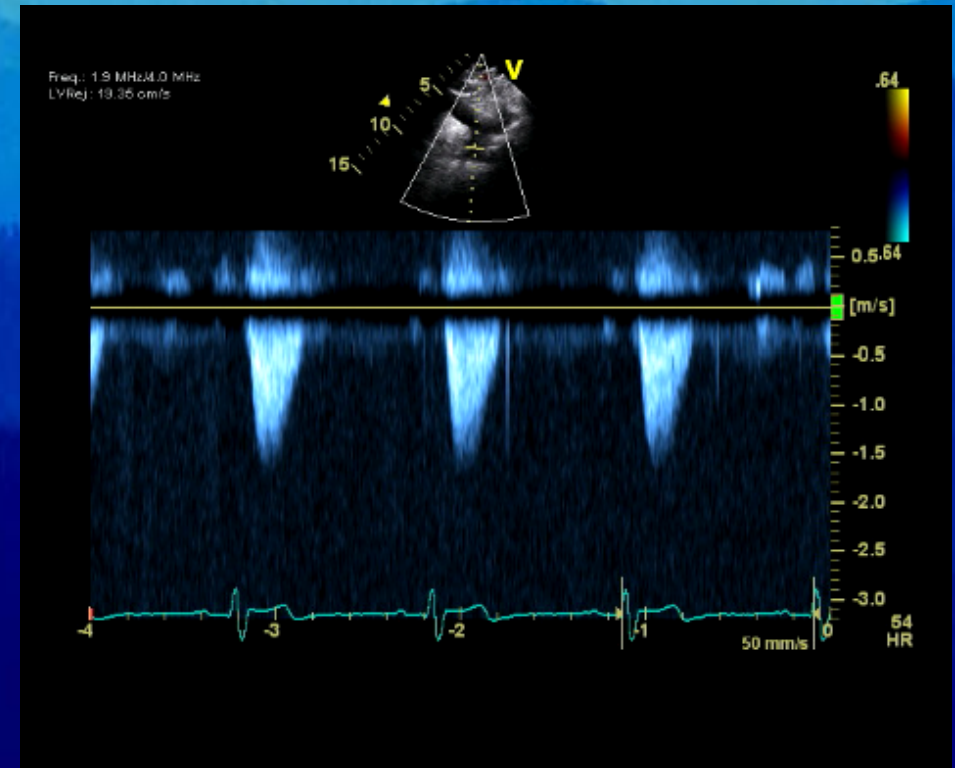


After 3 months

Case study - H.G.



Before



After

After 6 months

ACHD

Care of the Adult With Congenital Heart Disease.
Presented at the 32nd Bethesda Conference,
Bethesda, Maryland, October 2—3, 2000.

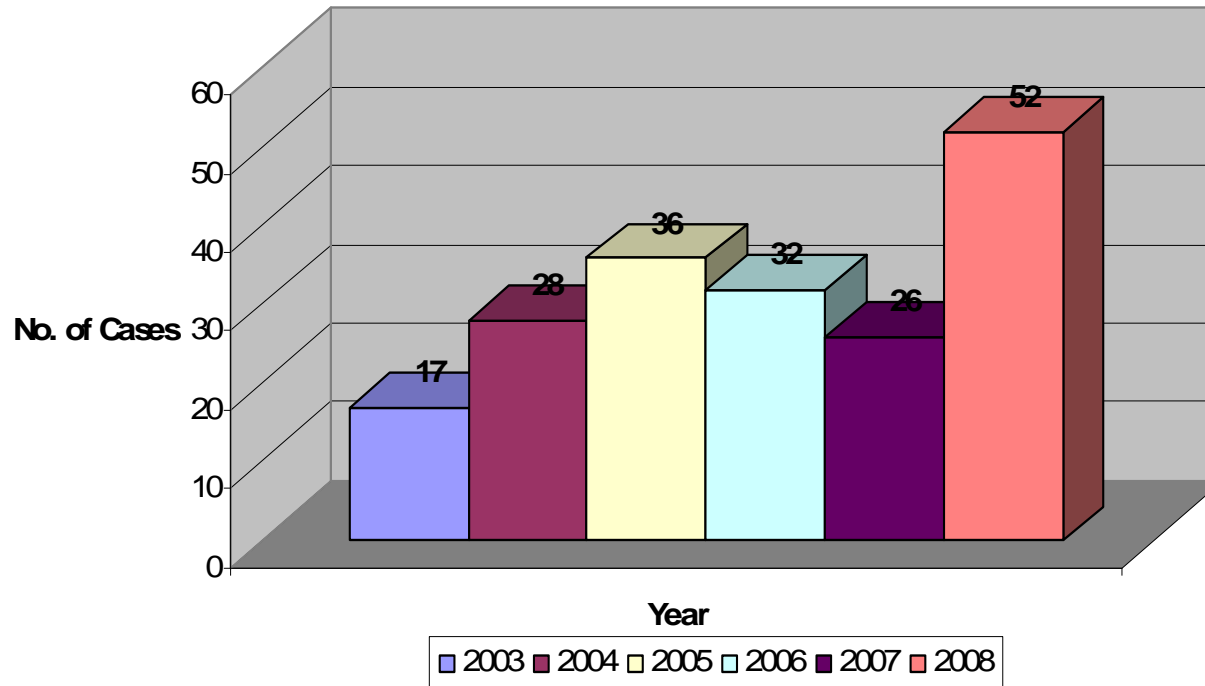
“All adults born with complex congenital heart defects should be seen at specialized ACHD care centers.”

J Am Coll Cardiol 2001;37:1161—98



ACHD - Memorial Regional

Adult Congenital Interventional Procedures - Memorial Regional



- ❖ Better survival
- ❖ Better diagnosis
- ❖ Newer techniques
- ❖ Newer devices
- ❖ Better trained cardiologist?



What can be done?

- ❖ Coarctation of aorta
- ❖ Pulmonary valve stenosis
- ❖ Aortic valve stenosis
- ❖ Atrial septal defect/PFO
- ❖ Persistent ductus arteriosus
- ❖ Muscular ventricular septal defect
- ❖ Post infarct "VSD"
- ❖ Intervention on post-op CHD
 - ❖ Conduit stenosis
 - ❖ Vessel stenosis
 - ❖ Implantable pulmonary valve



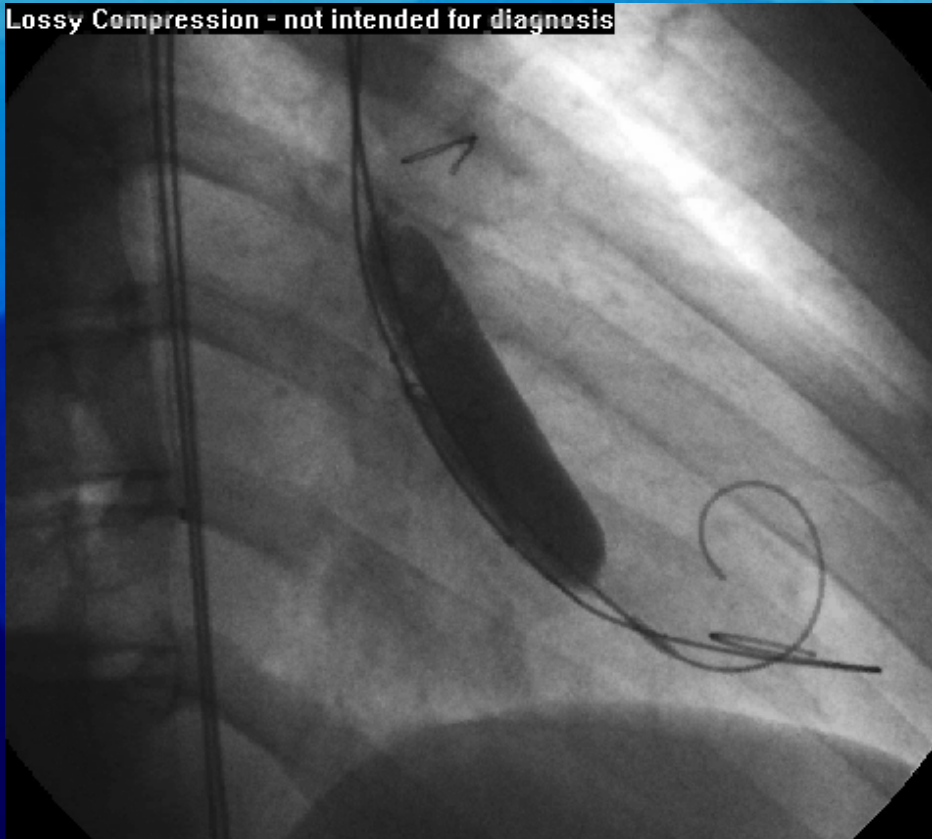
Pulmonary & aortic valve angioplasty

- ❖ Non compliant balloon
- ❖ Balloon selection
 - ❖ PS - 120 to 150% "annular" size
 - ❖ AS - up to 100% "annular" size
- ❖ Problems
 - ❖ Large "annular size"
 - ❖ >20 mm balloon
 - ❖ Low pressure
 - ❖ Unstable position - "melon seed phenomenon"
- ❖ Solutions
 - ❖ Kevlar balloon
 - ❖ Longer balloon
 - ❖ Double balloon technique
 - ❖ Procedures to decrease cardiac output
 - ❖ Adenosine
 - ❖ Rapid pacing



Pulmonary & aortic valve angioplasty

Lossy Compression - not intended for diagnosis



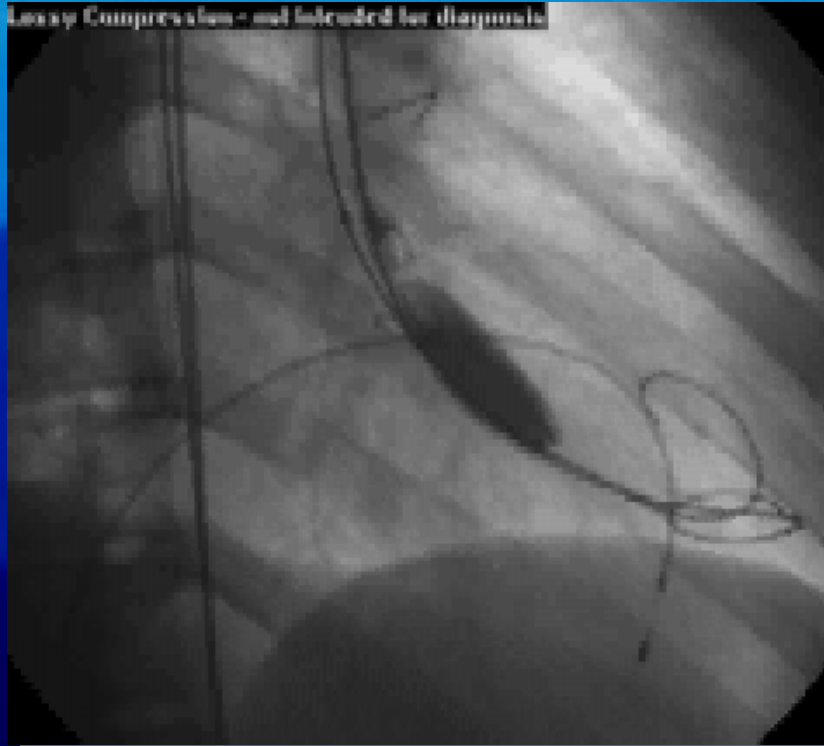
Effective balloon diameter

$$\frac{D1 + D2 + \pi (D1/2 + D2/2)}{\pi}$$

$$"0.82 (D1 + D2)"$$



Pulmonary & aortic valve angioplasty



Rapid ventricular pacing

Cardiology in the Young

Transcatheter Closure of ASD

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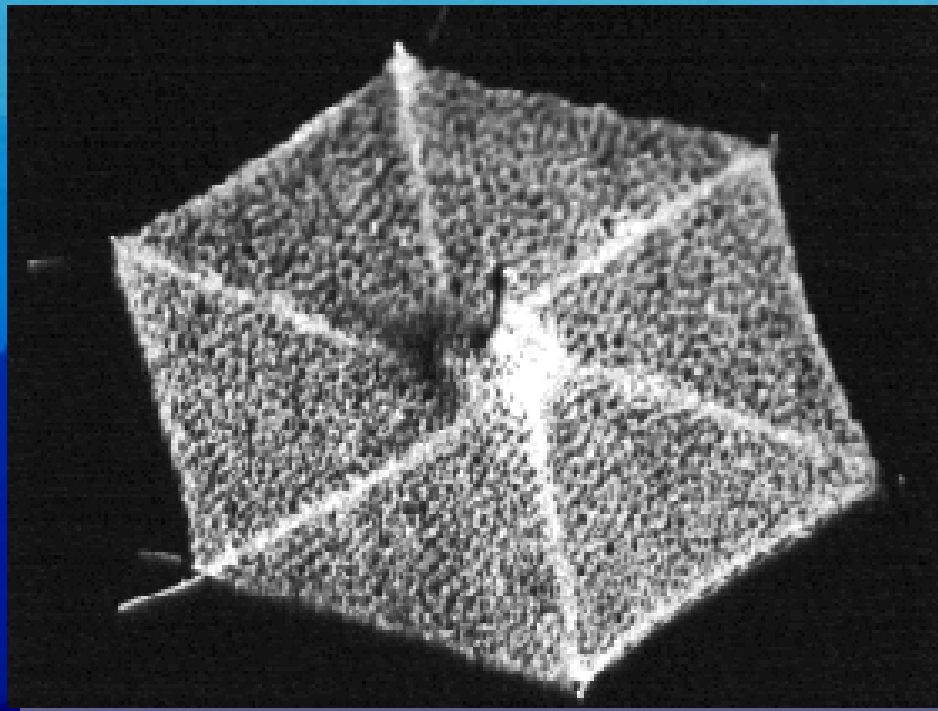


ASD Closure Devices - Historical

- ❖ King & Mills - 1974 (Double disk)
- ❖ Rashkind - 1975 (Single disk)
- ❖ Clam-Shell - 1983 (Double Umbrella)
- ❖ Sideris Button Device - 1988 (Double disk)
- ❖ Das Angel-Wings - 1994 (Double disk, self centering)
- ❖ Babic ASDOS - 1995 (Double disk, A-V circuit)
- ❖ Amplatzer Septal Occluder - 1995 (Double disk, self centering)
- ❖ CardioSeal - 1998 (Double umbrella)
- ❖ Star-Flex - 1999 (Double umbrella, self centering)
- ❖ Helex - 1999 (Helical disks)
- ❖ "Others"



Historical - Rashkind Hook device



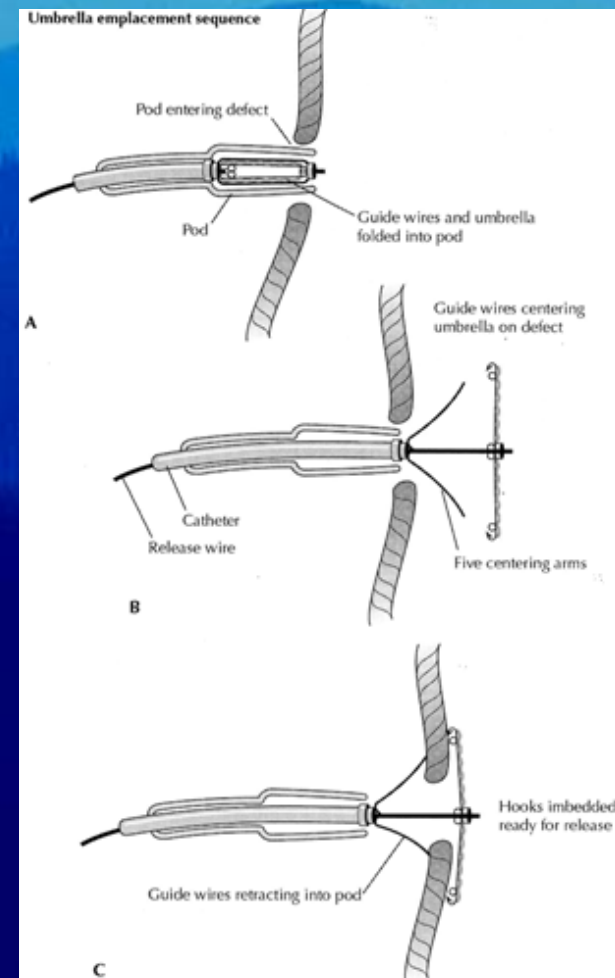
Rashkind 1985

33 patients

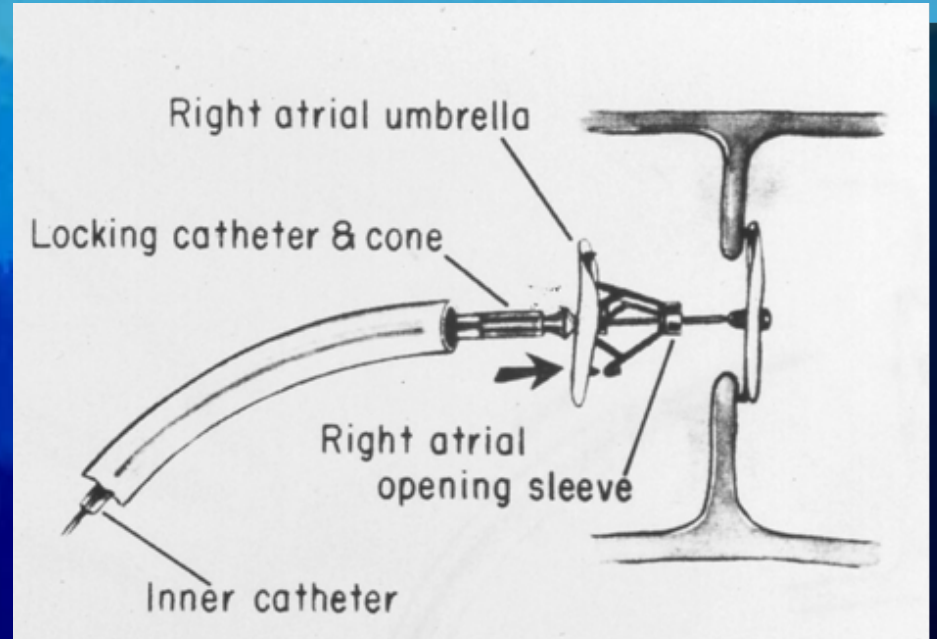
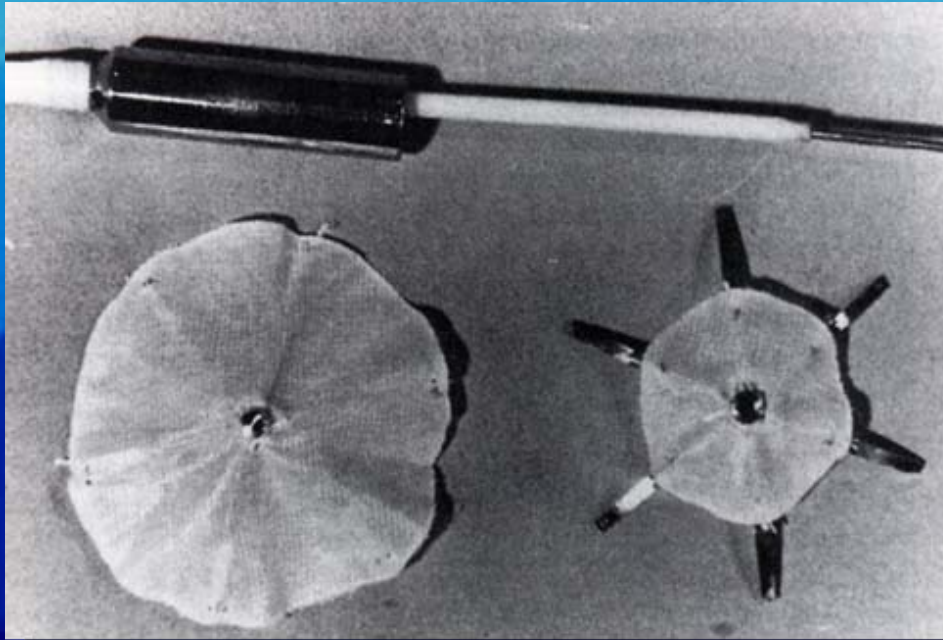
70% implant

17% complications

61% effective



Historical - King & Mills



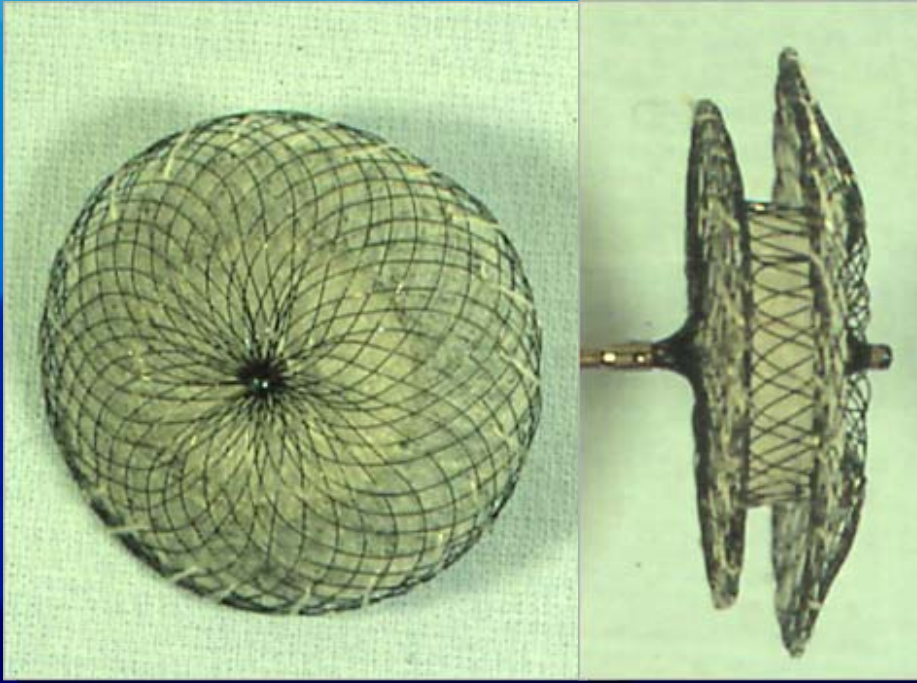
King & Mills 1976

- ❖ dacron & stainless steel
- ❖ 23F sheath
- ❖ 5/10 patient
- ❖ 4 effective closure

Terry King



Transcatheter Closure of ASD



Amplatzer Septal Occluder

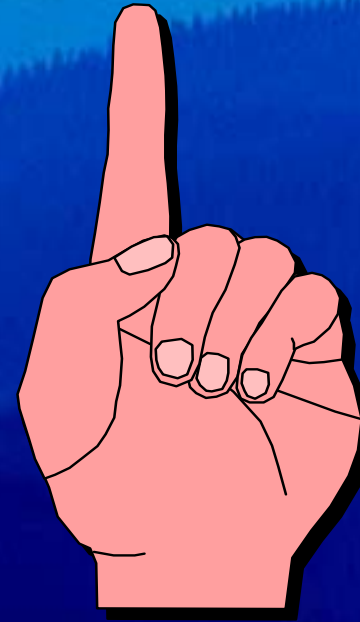


Helex Septal Occluder

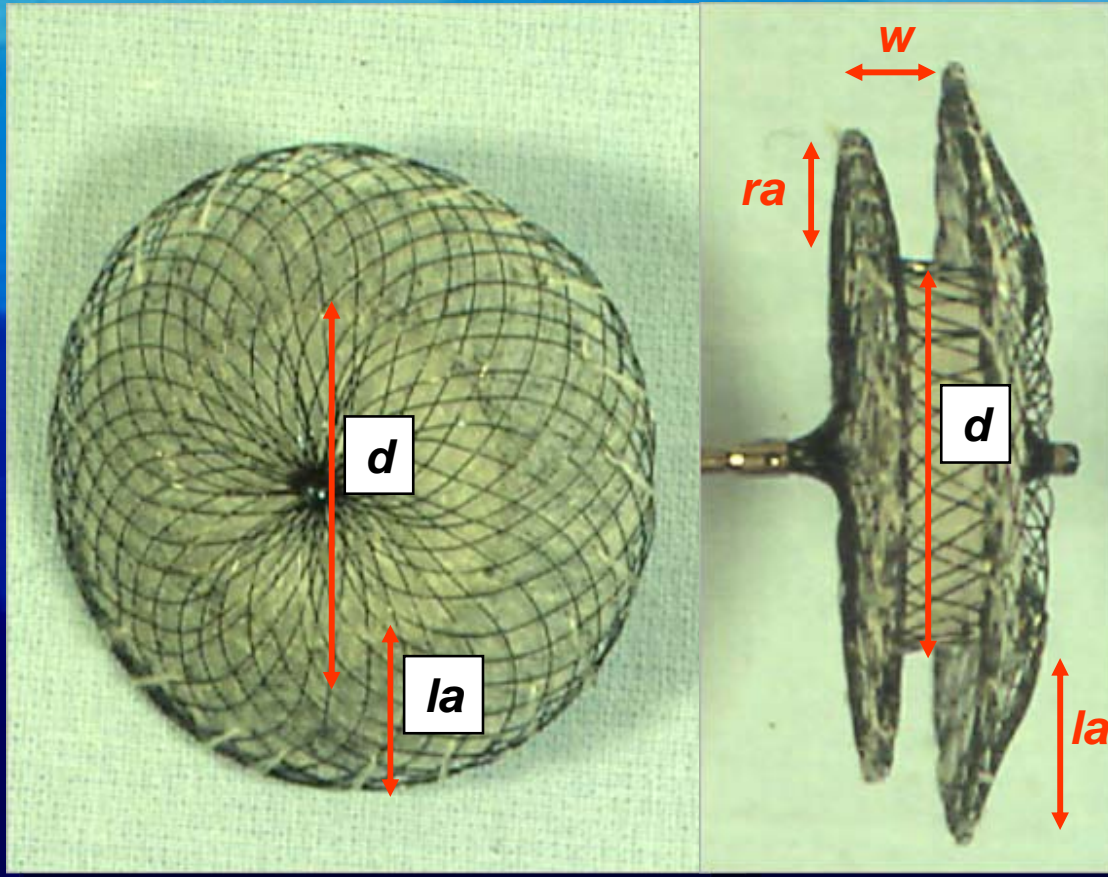
FDA approved ASD occluder devices in USA

Wish list!!

- ❖ Small delivery system
- ❖ Self centering
- ❖ Simple
 - ❖ least "technical steps"
 - ❖ easy positioning
 - ❖ short procedural time
 - ❖ short learning curve
- ❖ Safe
 - ❖ easily retrievable
 - ❖ stable
 - ❖ low or no complications
- ❖ Successful
 - ❖ high rate of complete closure

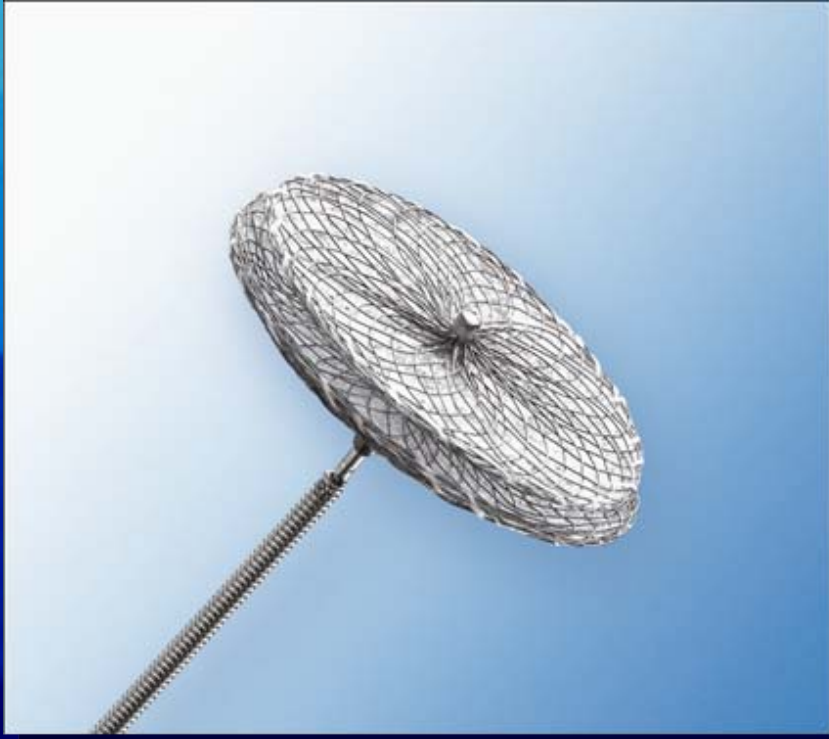


Amplatzer Septal Occluder



- ❖ d = diameter of waist
 - ❖ "size" of device
 - ❖ 4 to 20 mm (1 mm incr.)
 - ❖ 20 to 40 mm (2 mm incr.)
- ❖ w = width (4 mm)
- ❖ la = LA rim (5 - 7 mm)
- ❖ ra = RA rim (3 mm)

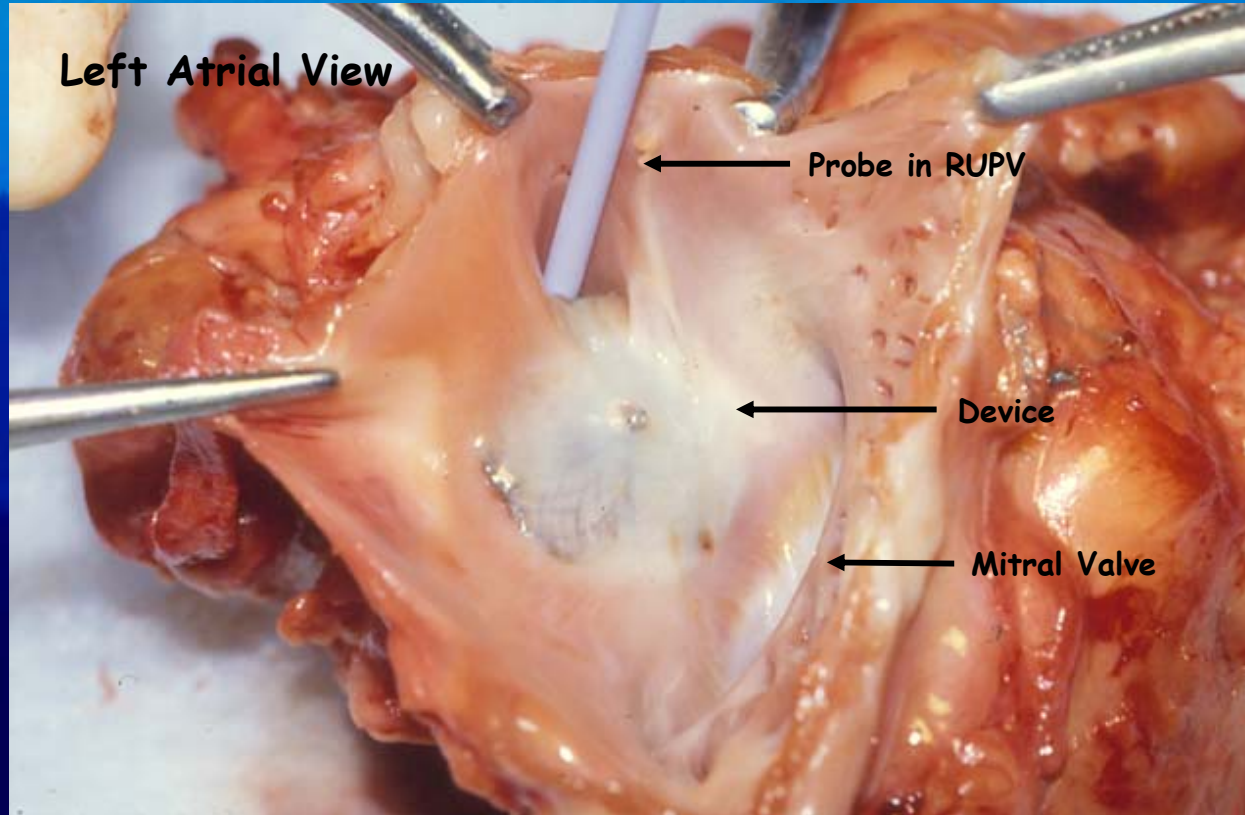
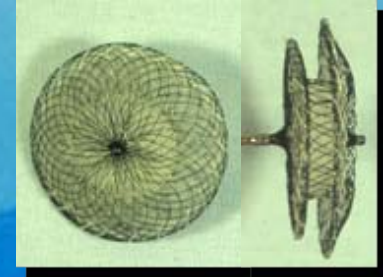
Amplatzer Cribiform Septal Occluder



- ❖ Nitinol wire frame
- ❖ No waist
- ❖ RA disk = LA disk
- ❖ 18mm, 25mm, 30mm, 35mm
- ❖ 7 to 9 F delivery sheath

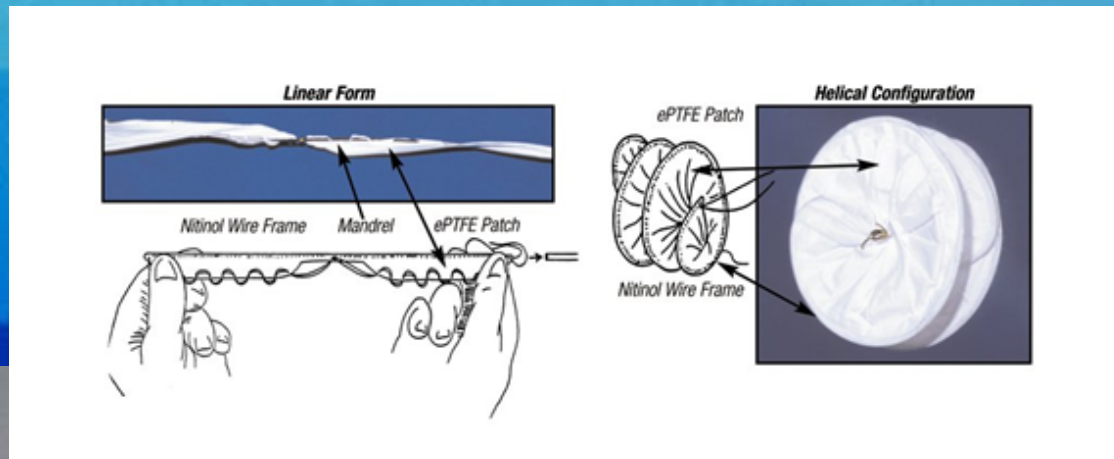


Amplatzer Septal Occluder



3 months post implant

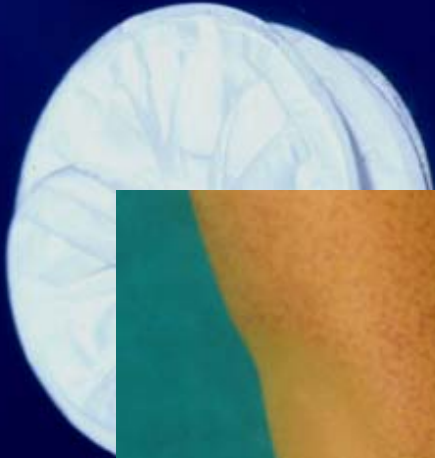
Helex Septal Occluder



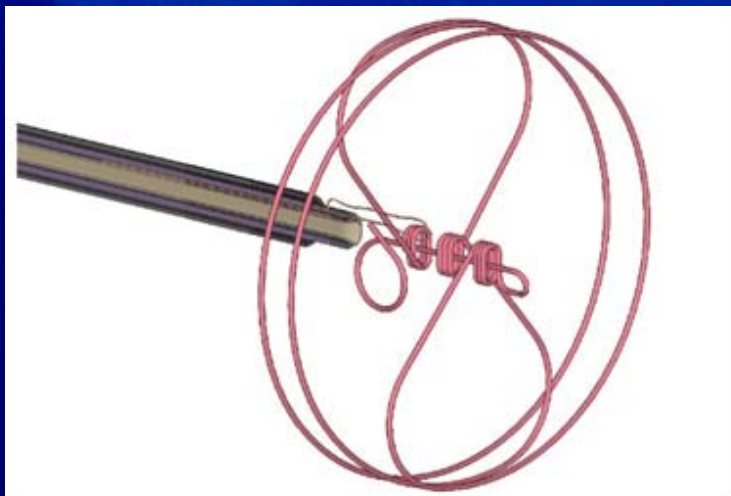
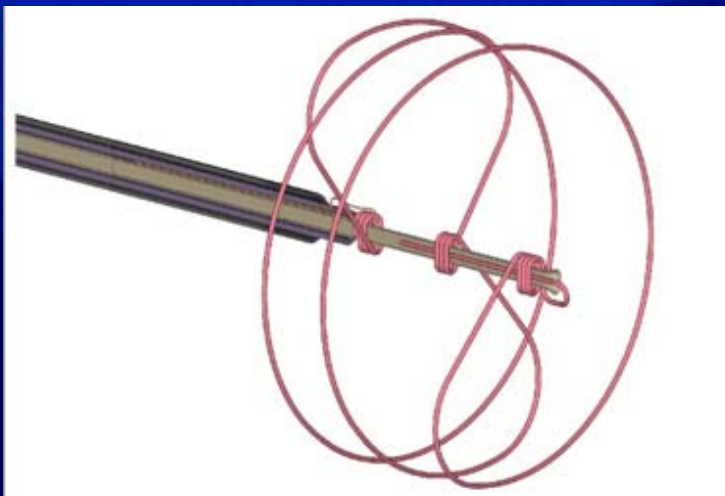
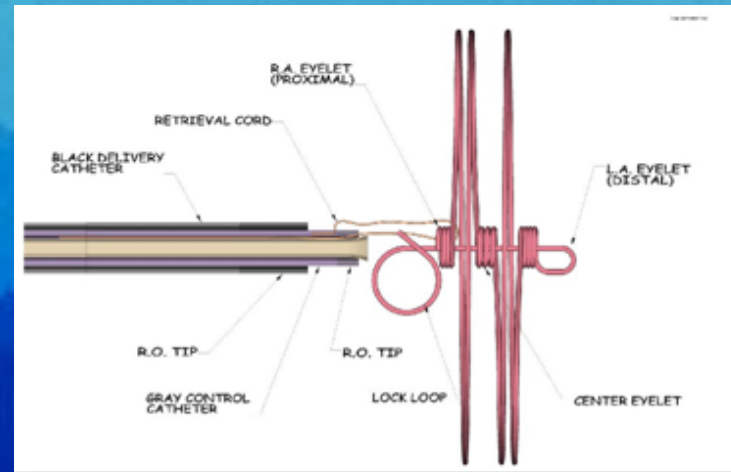
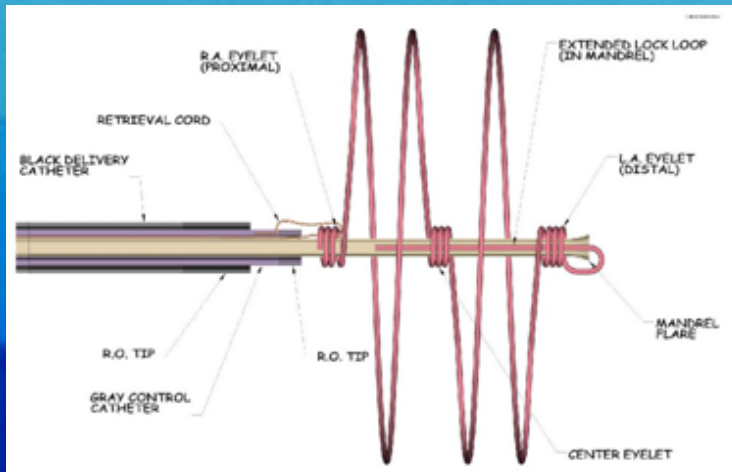
Helex Septal Occluder

- ❖ Nitinol wire frame (hoop)
- ❖ ePTFE membrane
- ❖ 15 mm to 40 mm
- ❖ 10 F delivery sheath

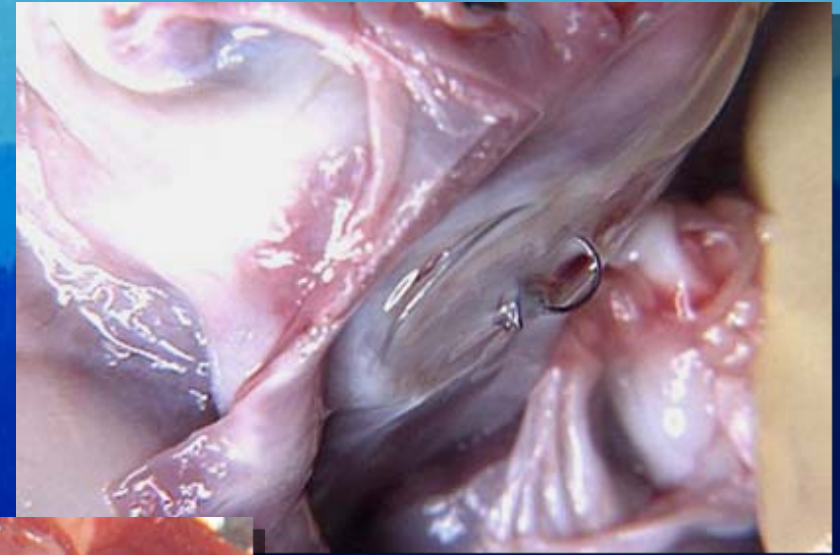
Helex Septal Occluder



Helex Septal Occluder



Helex Septal Occluder

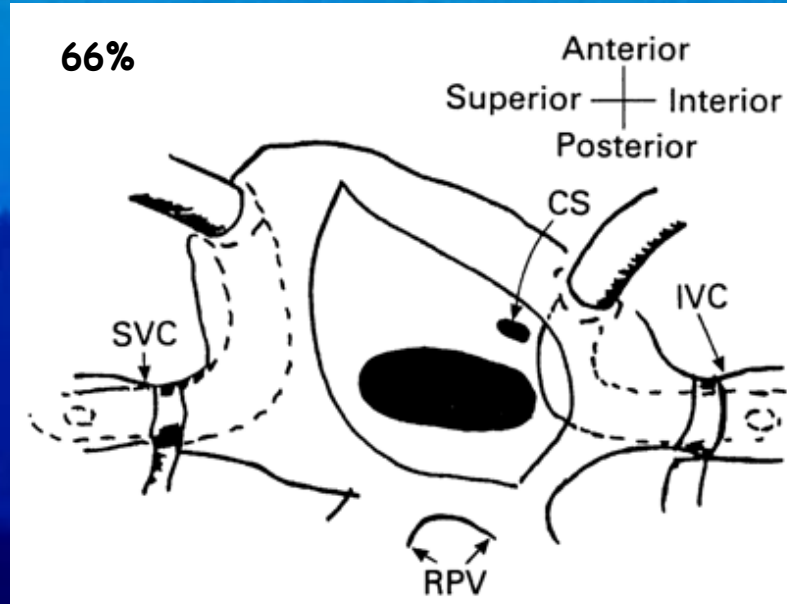


Transcatheter Closure of ASD

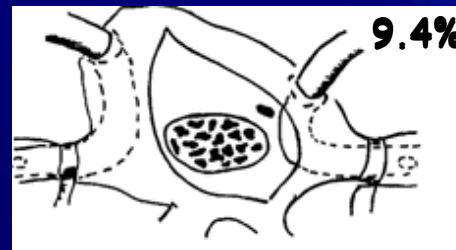
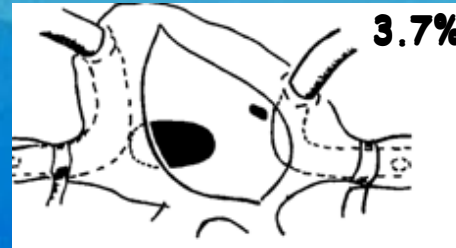
- ❖ Clarification of anatomy of ASD
- ❖ Imaging modality
 - ❖ TEE
 - ❖ ICE
- ❖ Sizing
 - ❖ “stop flow” balloon sizing
- ❖ Device selection
- ❖ Device deployment



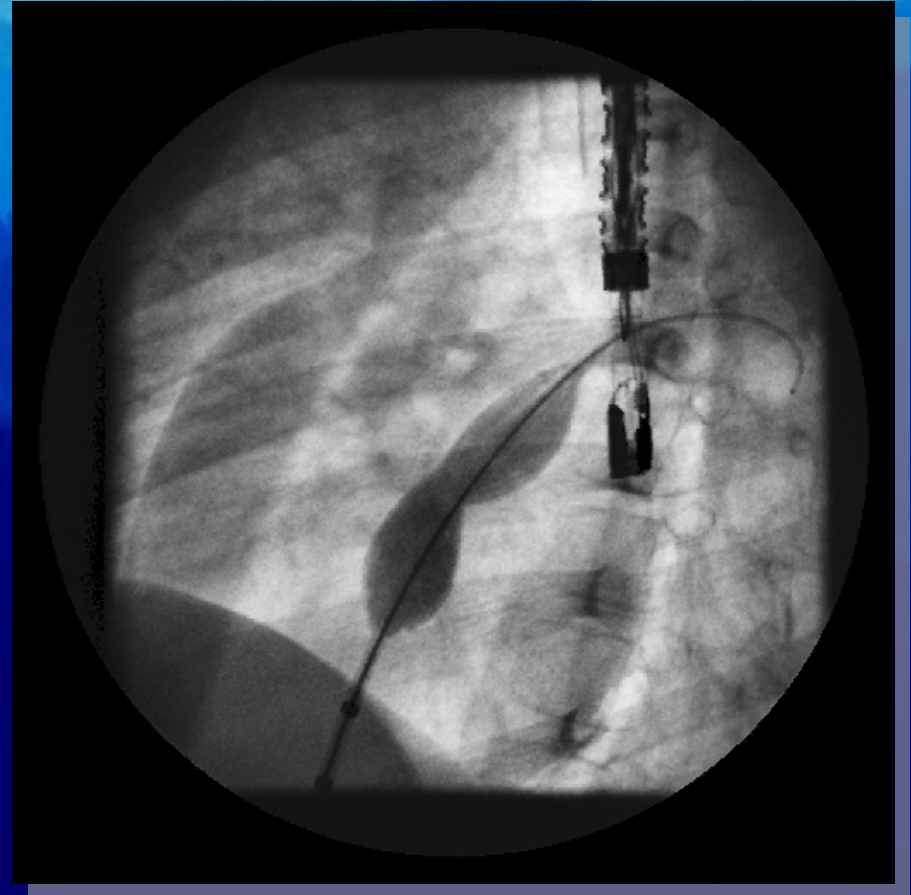
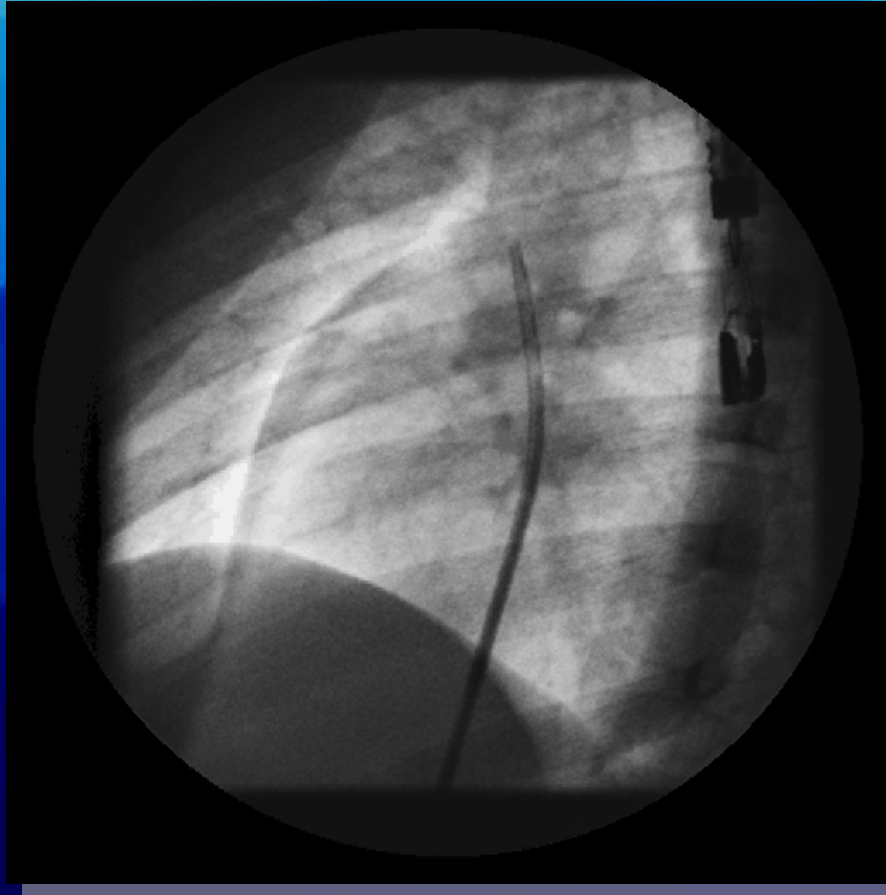
Anatomic variations of Fossa Ovalis ASD



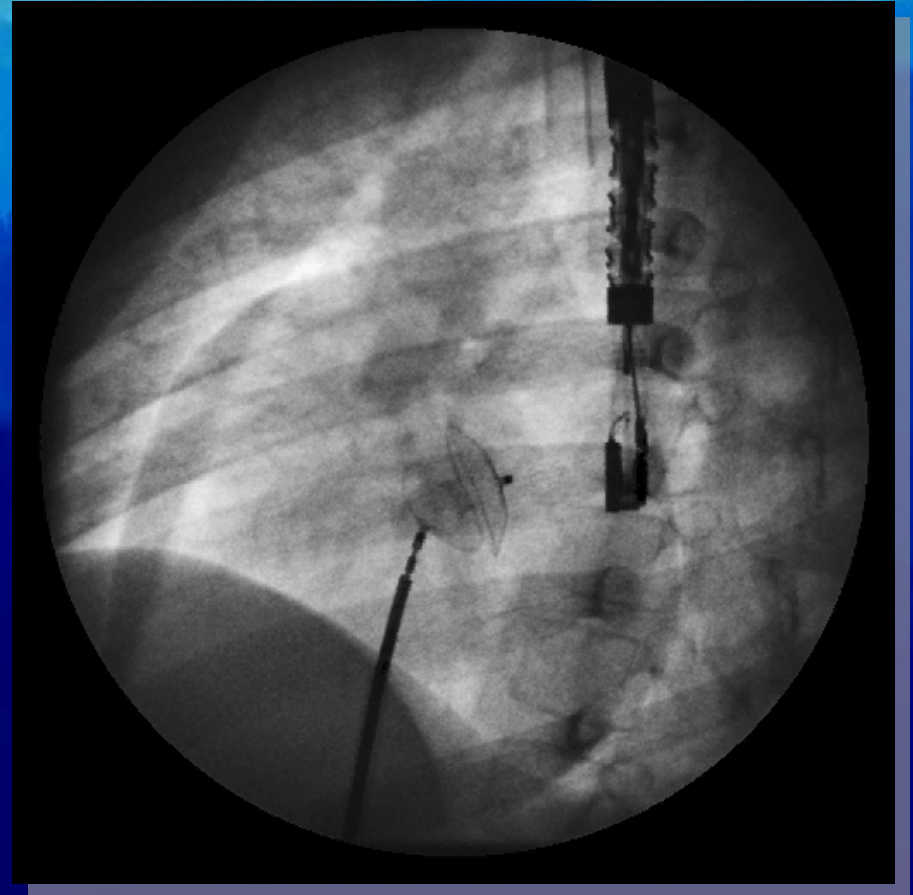
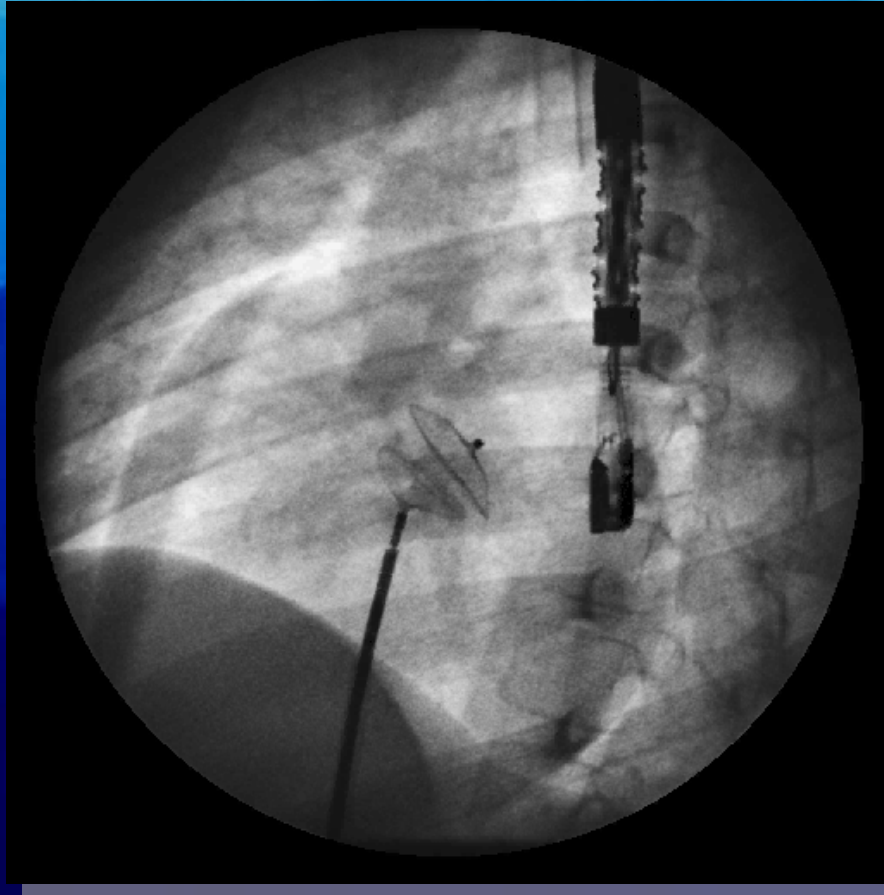
n = 106



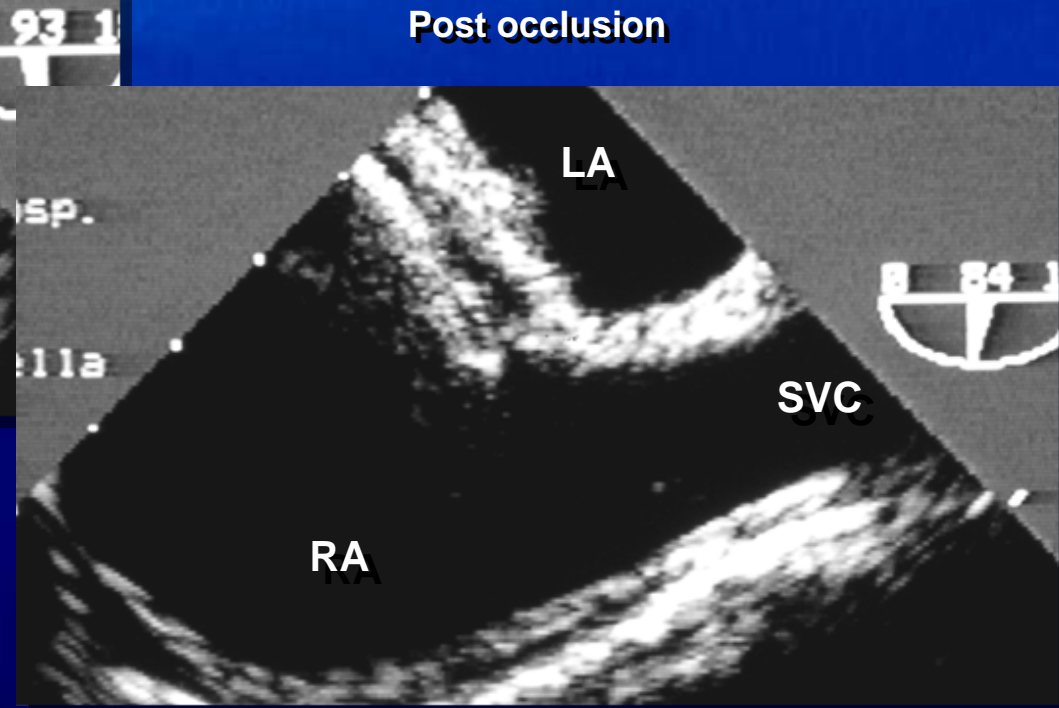
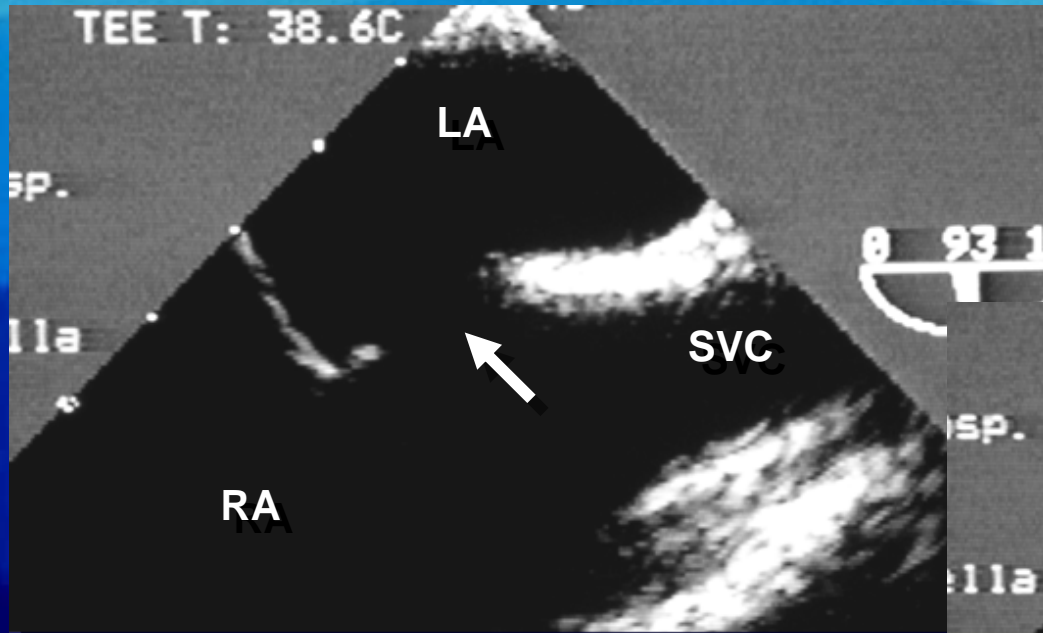
Transcatheter Closure of ASD



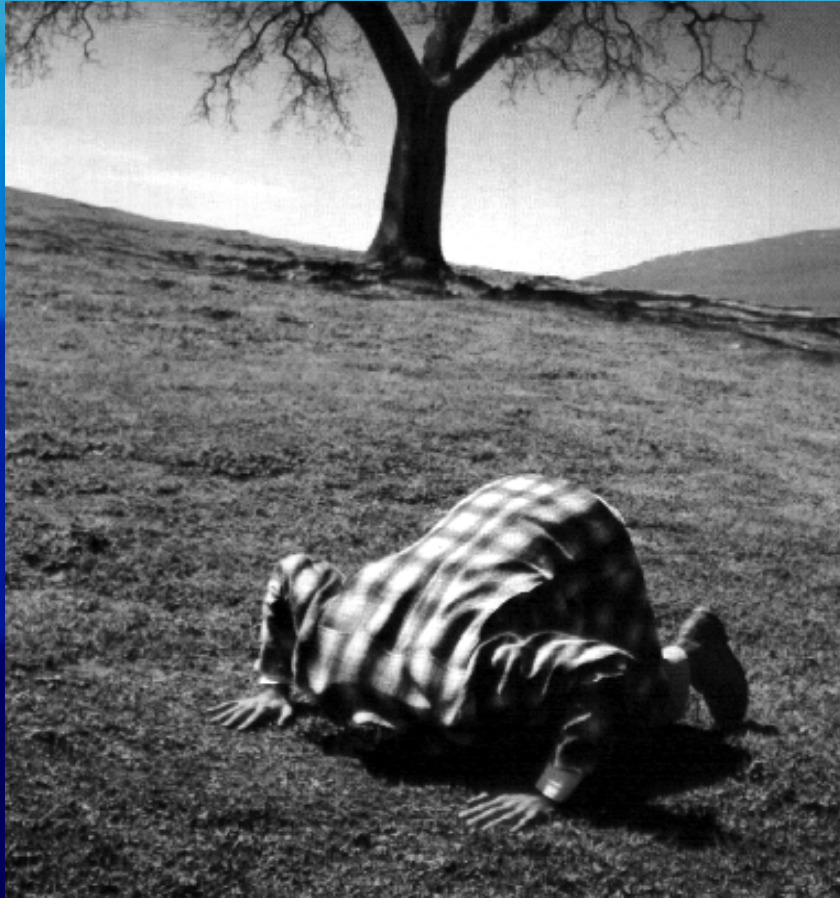
Transcatheter Closure of ASD



Transcatheter Closure of ASD



Transcatheter Closure of PFO



- ❖ Controversial
- ❖ Cryptogenic strokes & classical migraine
- ❖ No devices approved by FDA in USA



Cardiology in the Young

Transcatheter Closure of VSD

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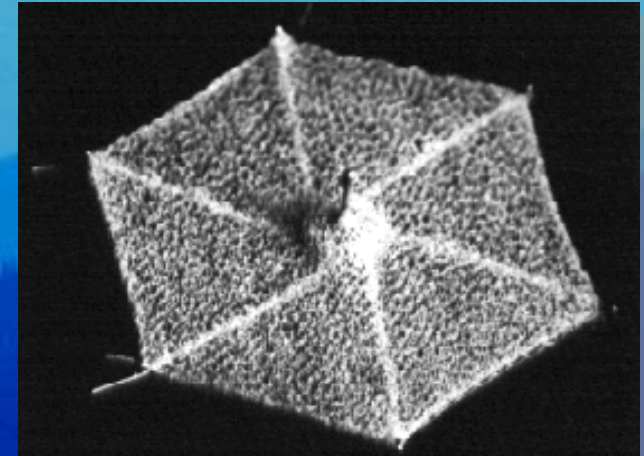
Pediatric Cardiology Inpatient Services & Interventional Catheter
Joe DiMaggio Children's Hospital
Hollywood, Florida



Historical

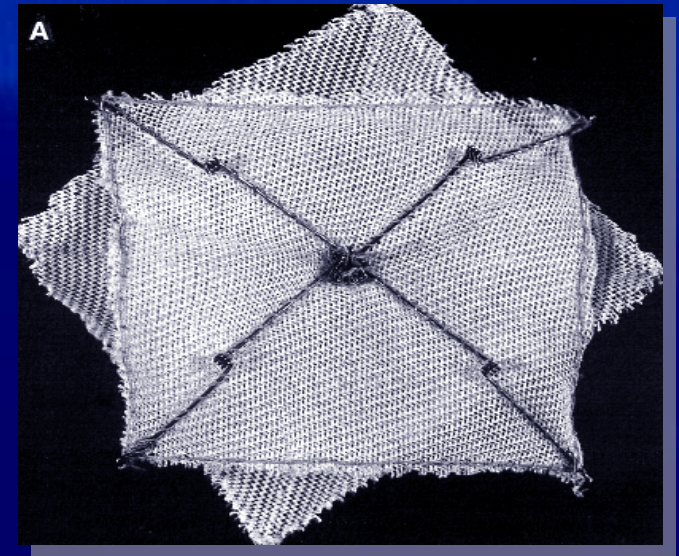
❖ Early animal models

- ❖ Rashkind, W.J.
- ❖ *Circulation* 1975;52:11
- ❖ Hooked single disk device



❖ Early human experience

- ❖ Lock, J. E.
- ❖ *Circulation* 1988;78:361
- ❖ Clamshell double disk device
- ❖ Redington, A.
- ❖ *Brit Heart J* 1993;69:47
- ❖ Rashkind double disk PDA occluder device

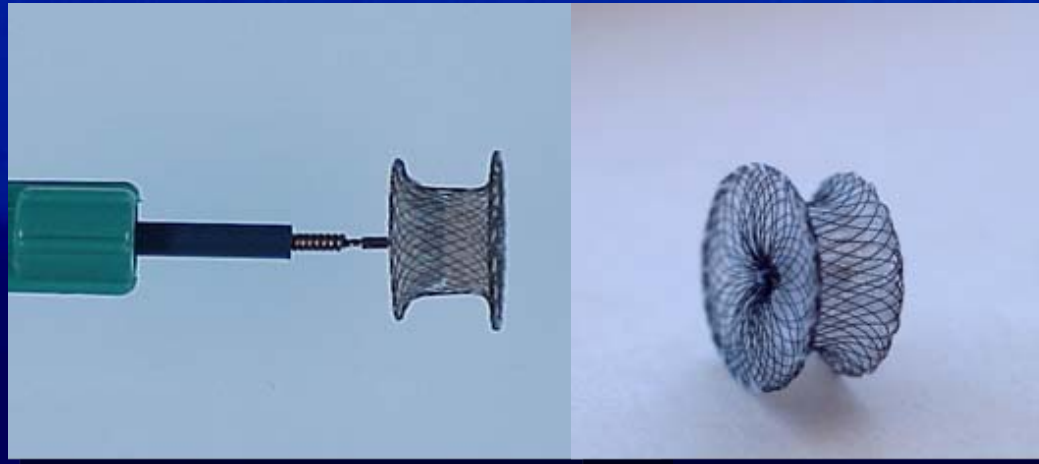


Current approved devices

CardioSeal Septal Occluder



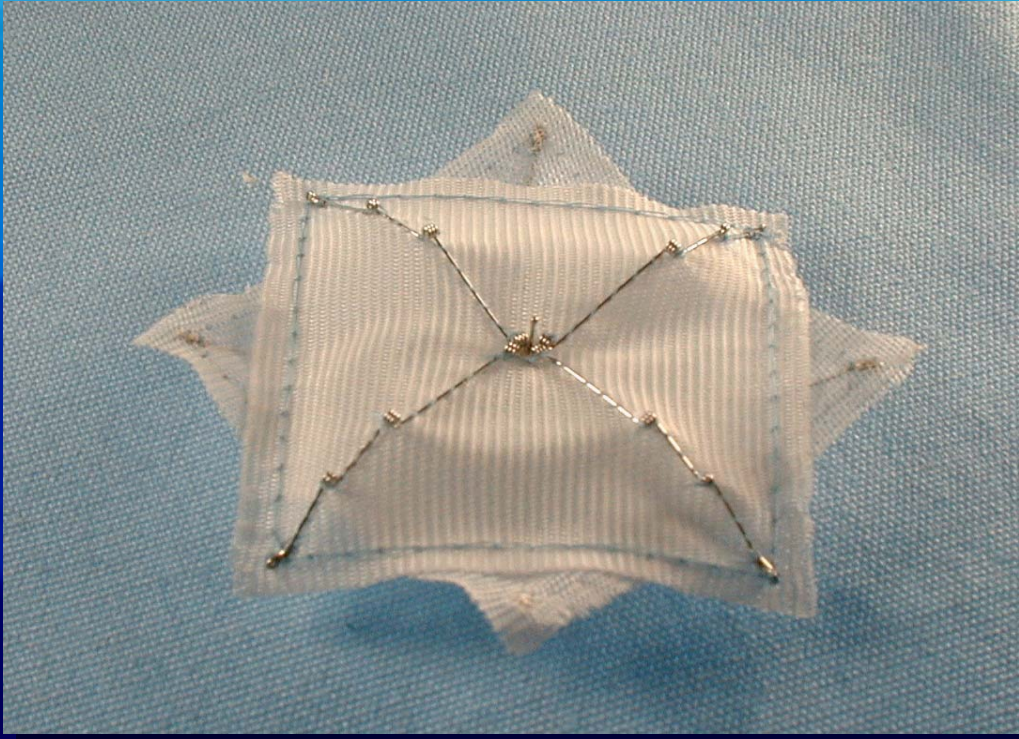
PFM Nit-Occlud



Amplatzer mVSD Occluder



CardioSeal Occluder

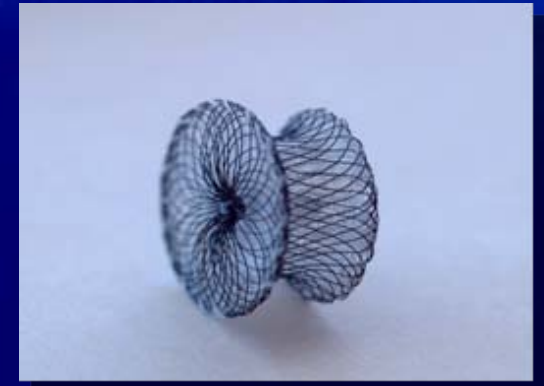
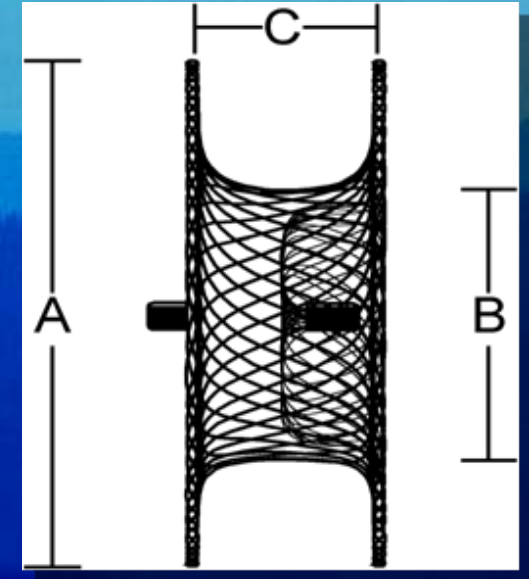


- ❖ Double Umbrella implant
- ❖ Framework is MP35n
- ❖ Fabric is Polyester
- ❖ 10F/11F sheath
- ❖ Significant clinical history.
- ❖ > 10,000 pt yrs.

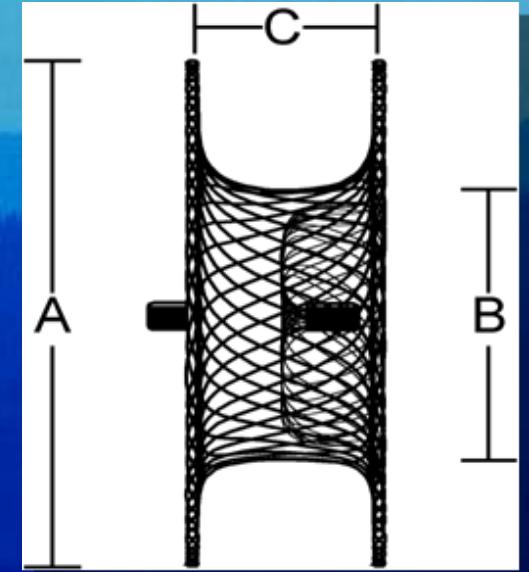
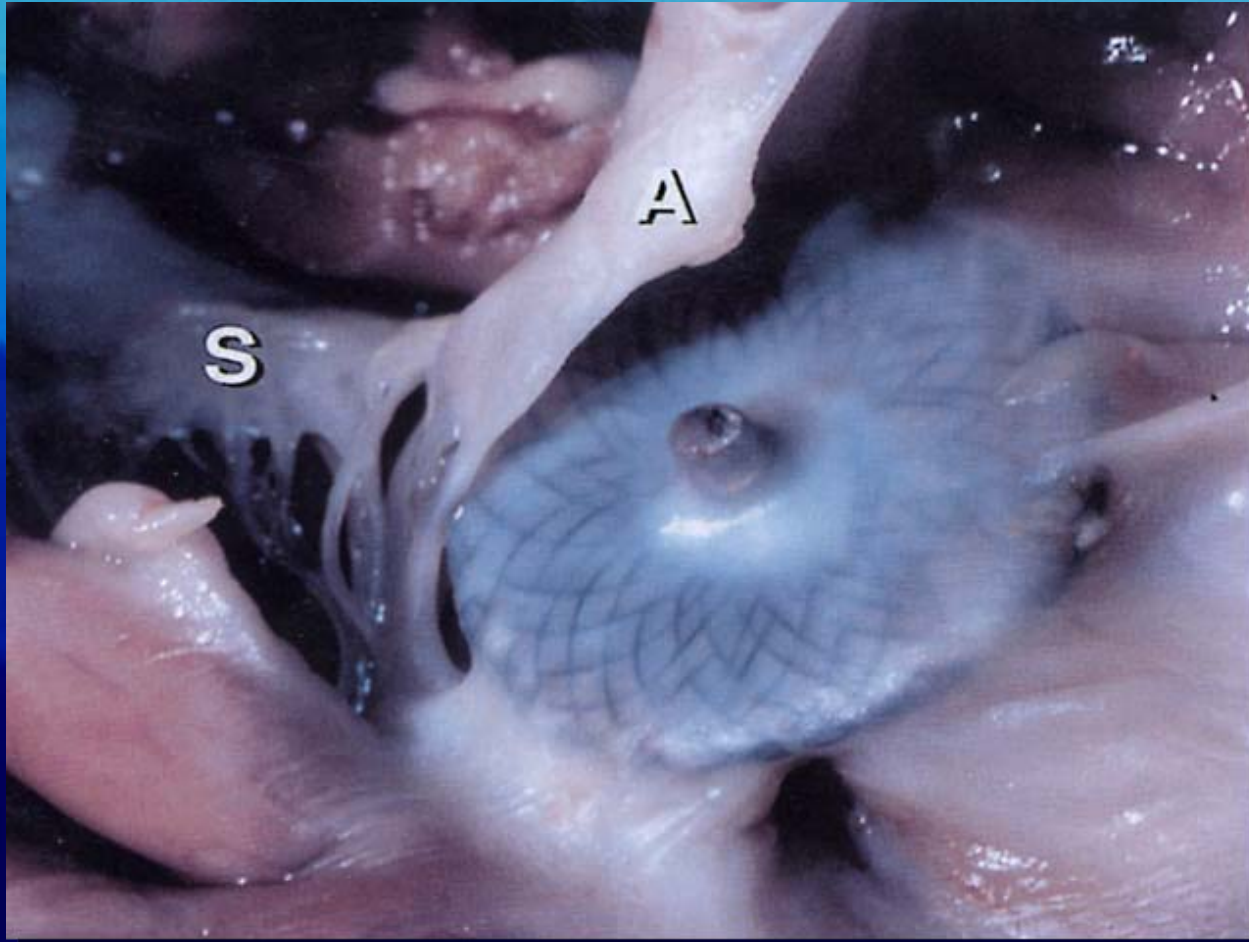
The first FDA approved VSD occluder device in USA

Amplatzer mVSD Occluder

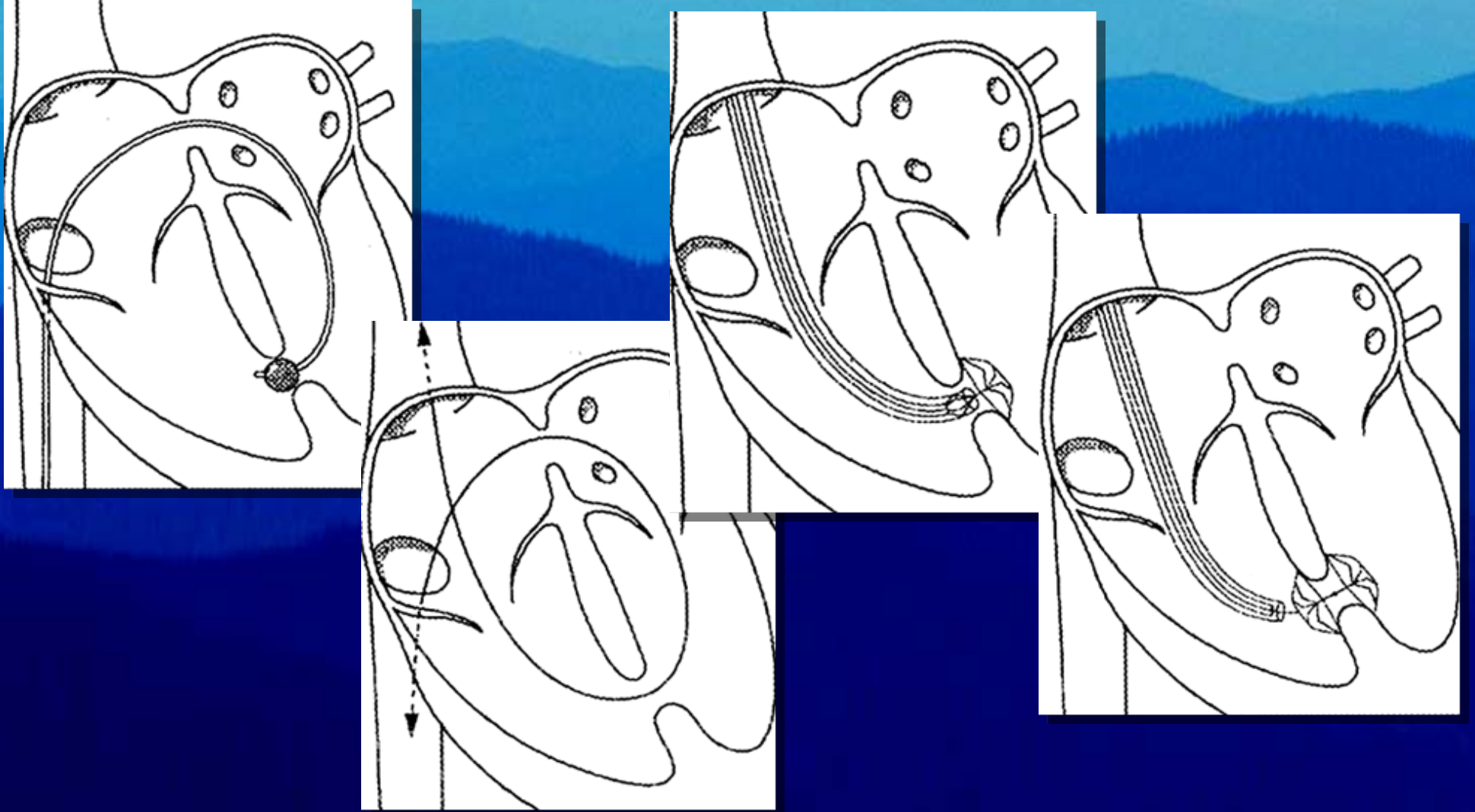
- ❖ Self expanding double disk with a connecting waist
 - ❖ Nitinol wire mesh (0.004-0.005 in)
 - ❖ Polyester fiber inserts
 - ❖ Left and right disk "A" = B + 4 mm
 - ❖ Connecting waist "C" = 7 mm
- ❖ 4 mm to 18 mm ("B") in 2 mm increments
- ❖ 6F to 8F delivery system



Amplatzer mVSD Occluder

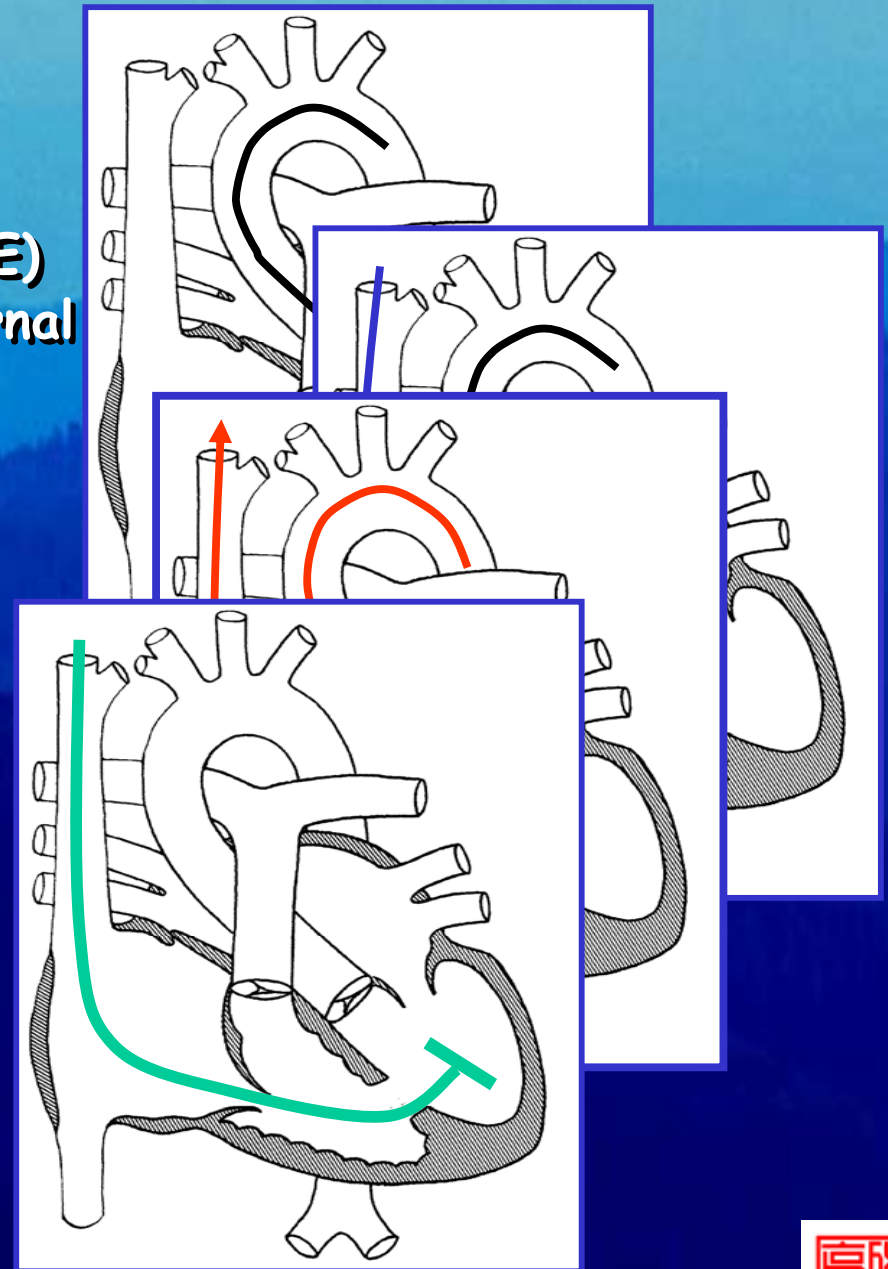


Transcatheter Closure of VSD

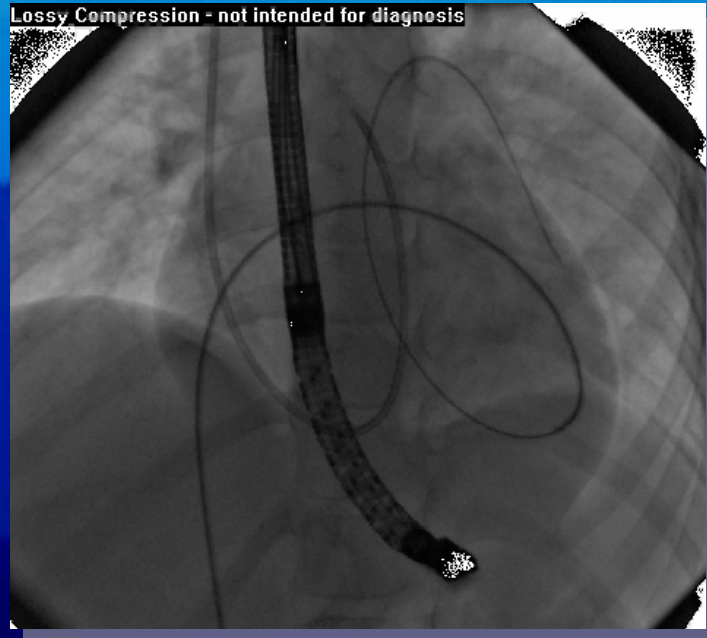


Technique

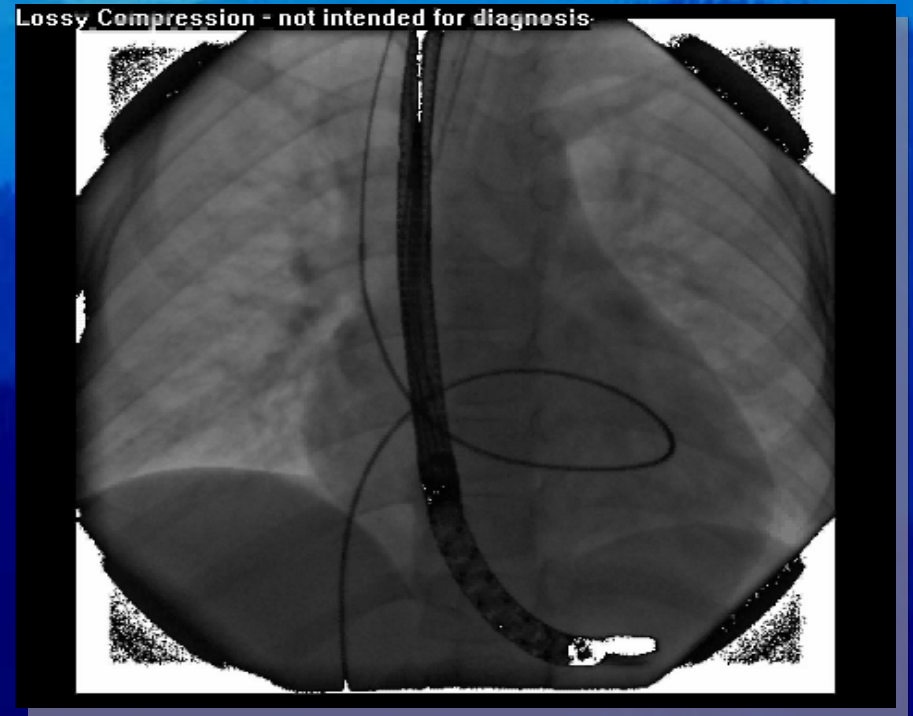
- ❖ General anesthesia
- ❖ Echocardiographic imaging (TEE/ICE)
- ❖ Femoral artery, femoral vein, internal vein
- ❖ Hemodynamic study
- ❖ LV angiogram
- ❖ Heparinize (ACT > 250s)
- ❖ Size VSD
- ❖ Cross VSD
 - ❖ Trans-arterial
 - ❖ Trans-septal
 - ❖ Trans-venous
- ❖ Establish A-V / V-V circuit
 - ❖ Snare guide wire in PA or SVC
- ❖ Introduce long delivery sheath
- ❖ Deploy device



Transcatheter Closure of mVSD



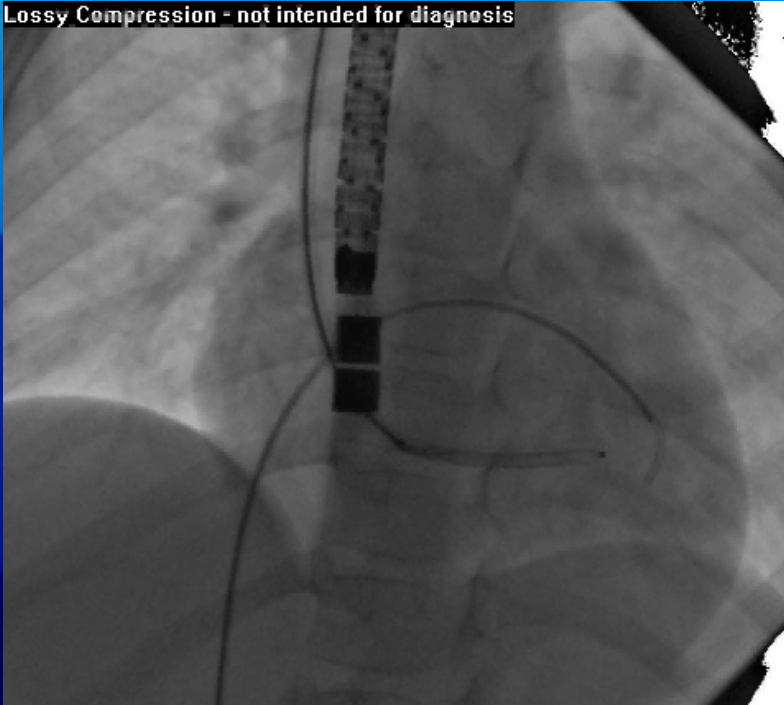
Cross VSD



Establish A-V circuit

Transcatheter Closure of mVSD

Lossy Compression - not intended for diagnosis



Deploy left disk

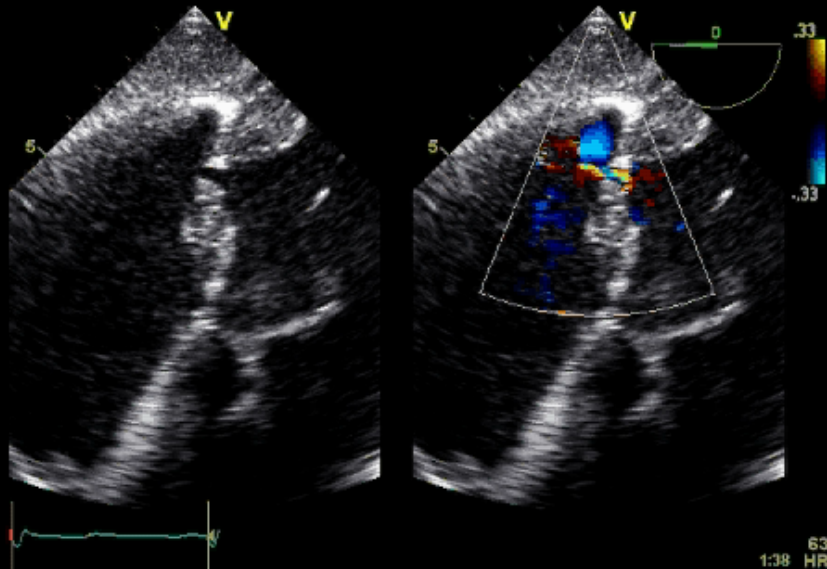
Lossy Compression - not intended for diagnosis



Deploy right disk

Transcatheter Closure of mVSD

Lossy Compression - not intended for diagnosis

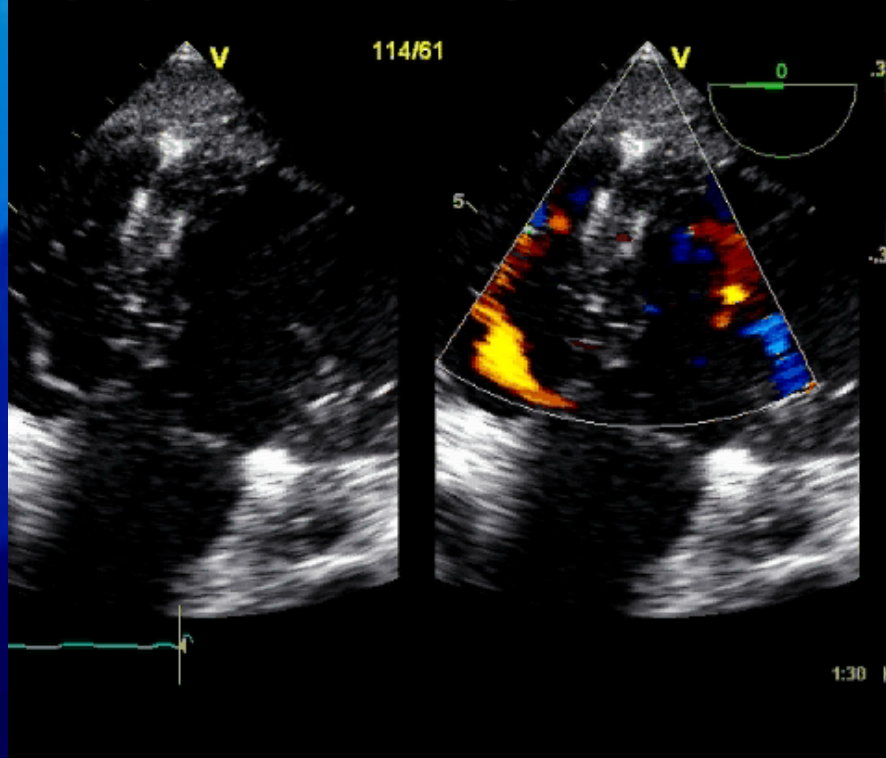


Lossy Compression - not intended for diagnosis

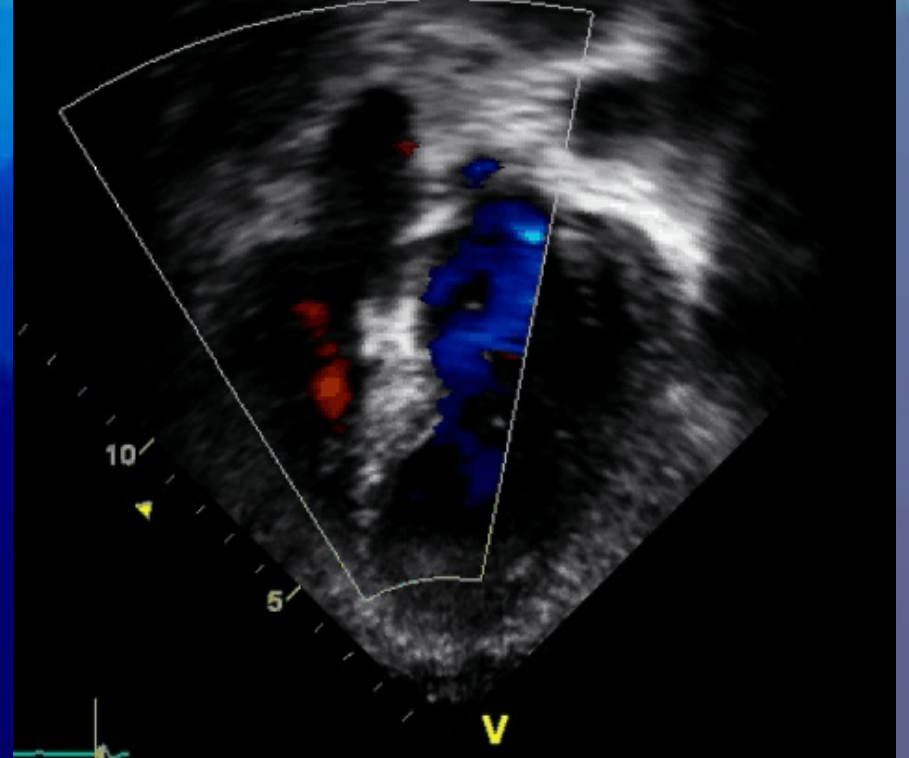


Transcatheter Closure of mVSD

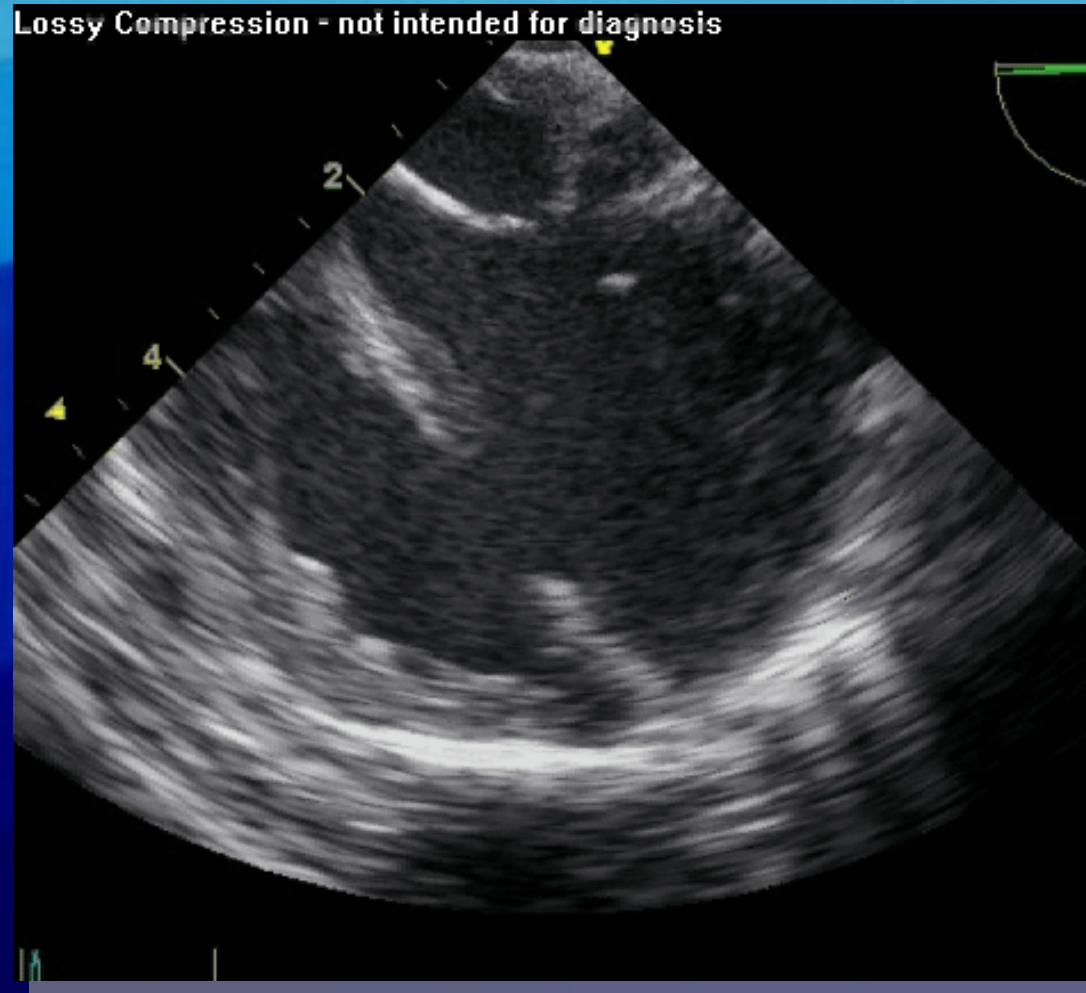
Lossy Compression - not intended for diagnosis



Lossy Compression - not intended for diagnosis



Periventricular Closure of mVSD

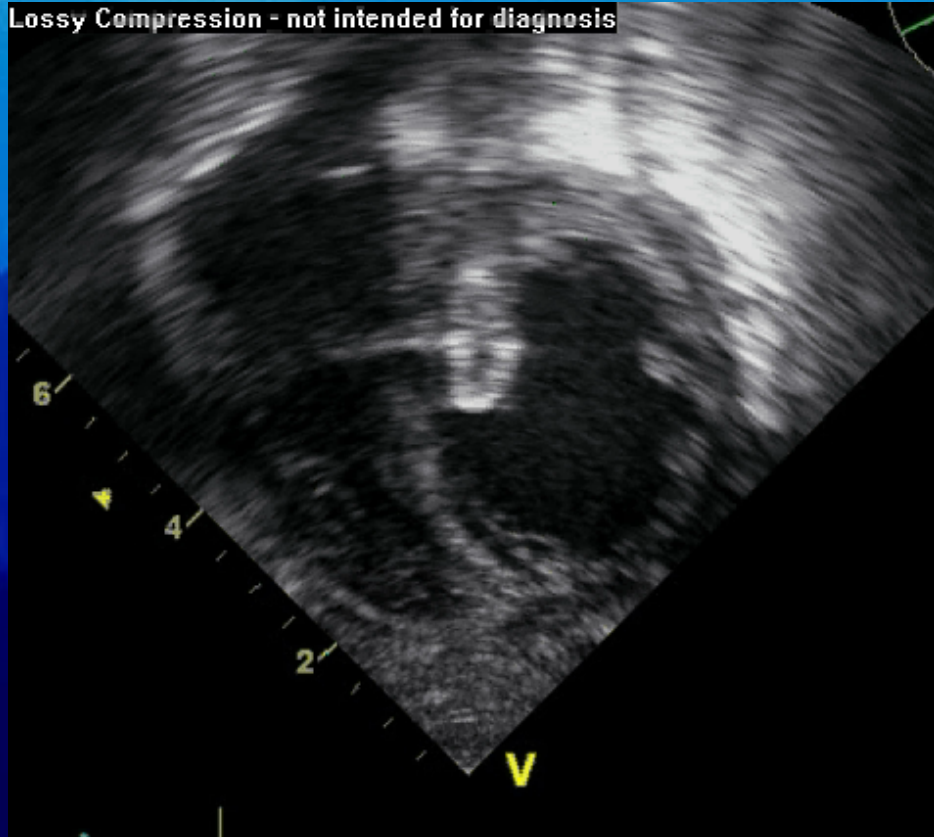


Periventricular Closure of mVSD



Periventricular Closure of mVSD

Lossy Compression - not intended for diagnosis



Lossy Compression - not intended for diagnosis



Why Transcatheter Closure?

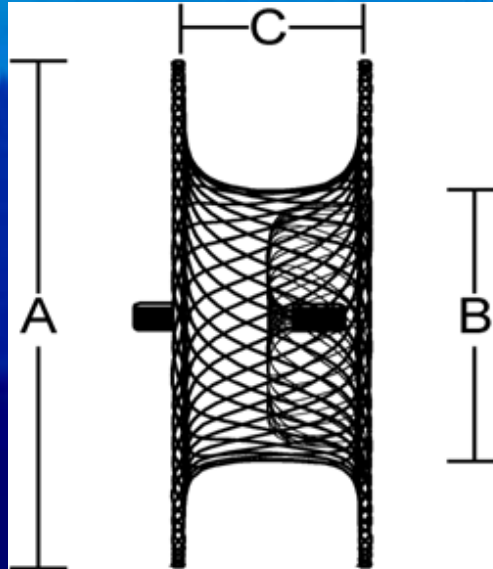
- ❖ Post infarct VSD / Ventricular Septal Dehiscence
 - ❖ High mortality
 - ❖ 14% - 46% with surgery
 - ❖ 7% - 10% alive after 1yr
 - ❖ High risk surgery
 - ❖ Acute poor CVS status
 - ❖ Ongoing ischemia
 - ❖ "sewing wet toilet tissue"
 - ❖ Variable anatomy
 - ❖ Serpingous track
 - ❖ Evolving necrosis
 - ❖ Residuals & recurrences



Post-Infarct VSD Occluder

Muscular VSD Occluder

- ❖ Left and right disk "A" = B + 4 mm
- ❖ Connecting waist "C" = 7 mm
- ❖ 4 mm to 18 mm ("B") in 2 mm increments
- ❖ 6F to 8F delivery system

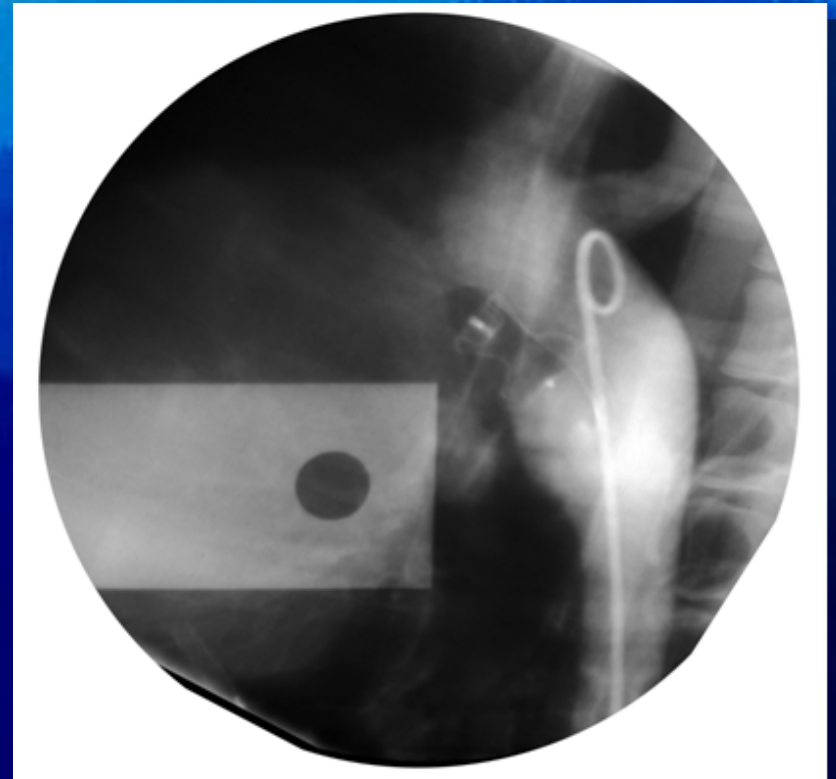


Post-Infarct VSD Occluder

- ❖ Left and right disk "A" = B + 5 mm
- ❖ Connecting waist "C" = 10 mm
- ❖ 16 mm to 24 mm ("B") in 2 mm increments
- ❖ 8F to 12F delivery system

Not FDA approved for human use in USA

Tanscatheter closure of large PDA with Amplatzer Ductal Occluder



Transcatheter closure of large PDA with Amplatzer Ductal Occluder



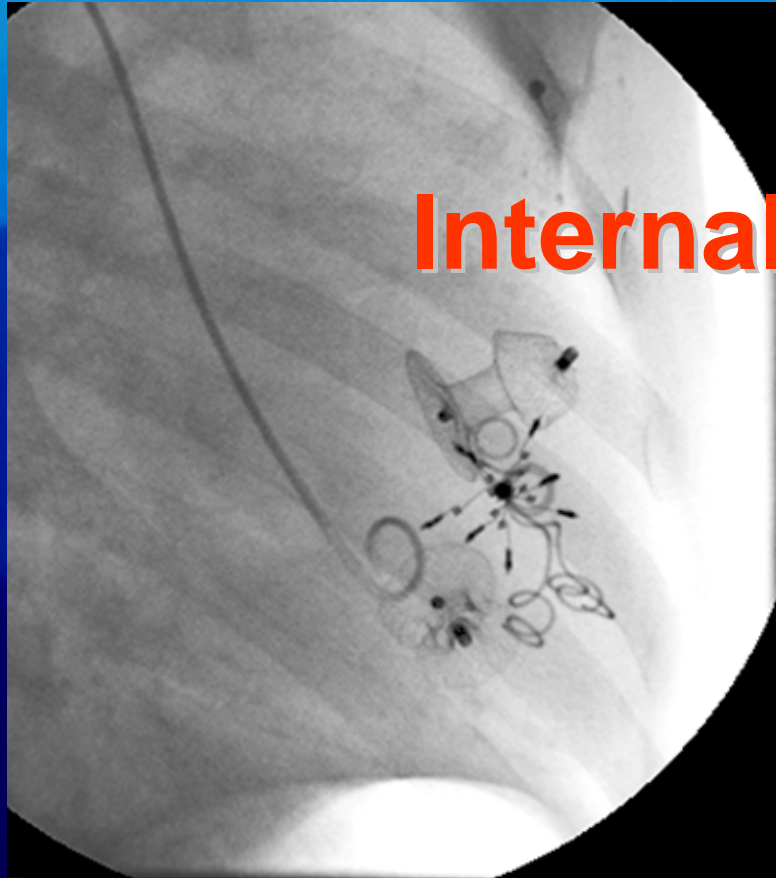
**“Woof woof!”
Thank You**





Transcatheter Closure of VSD

Amplatzer mVSD Occluder, CardioSeal, Gianturco coil

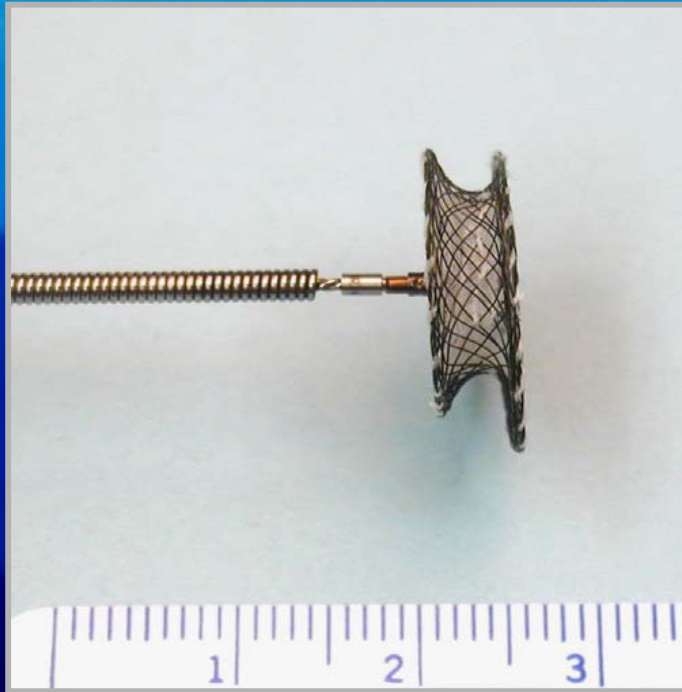


Internal jewelry!!



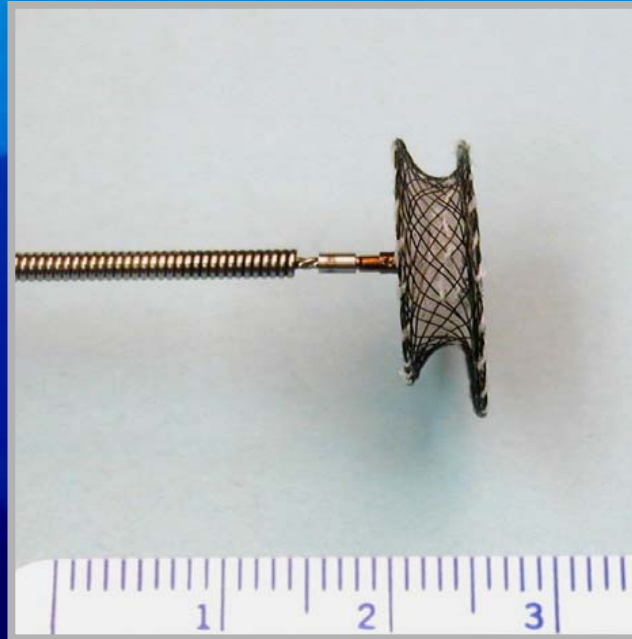
Transcatheter Closure of VSD

Amplatzer pVSD Occluder



Transcatheter Closure of VSD

Amplatzer pVSD Occluder



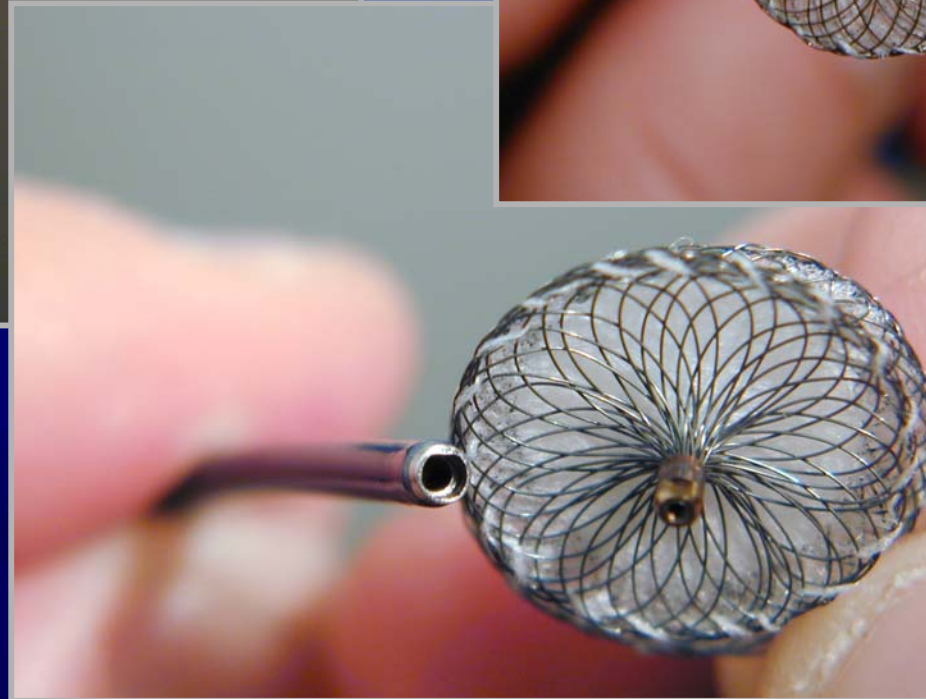
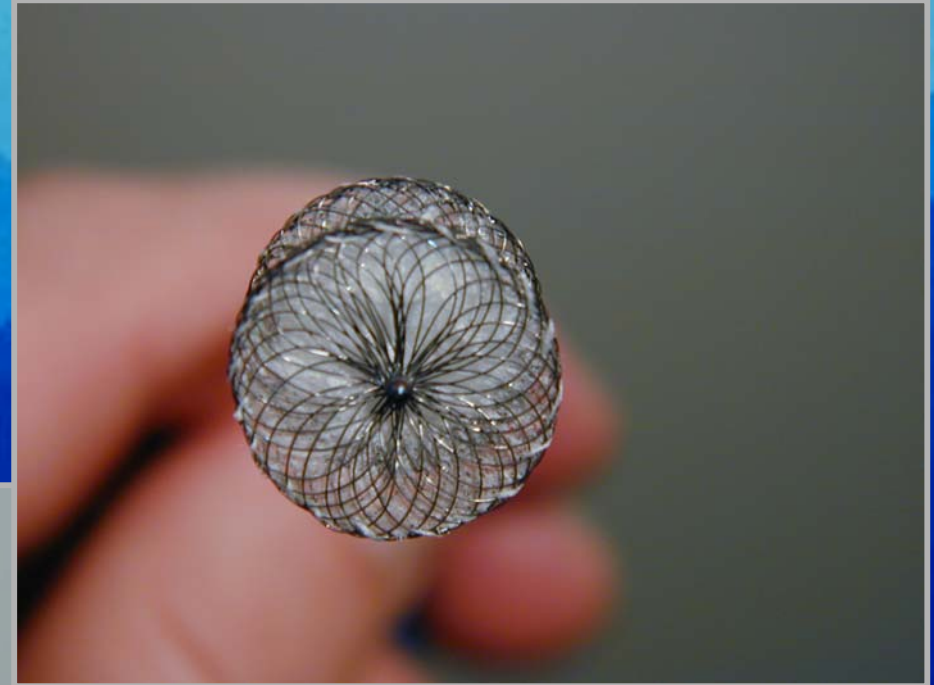
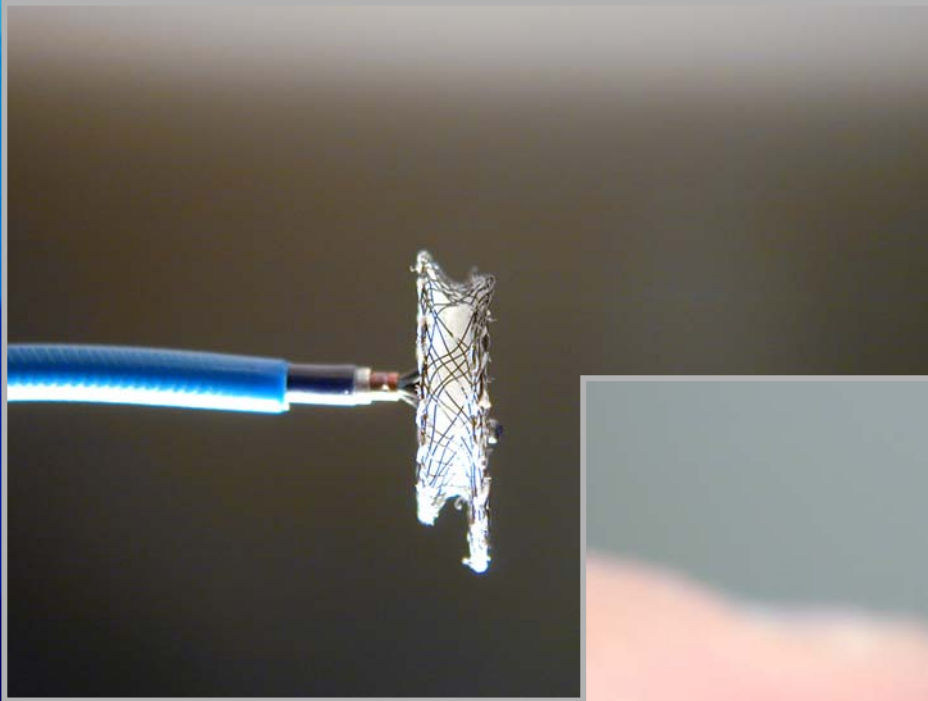
- ❖ 12 Yucatan mini pigs
 - ◆ Natural perimembranous VSD
 - ◆ Concentric & eccentric left disk
 - ◆ 6 or 7F delivery sheath
- ❖ Outcome
 - ◆ 11/12 successful implant
 - ◆ 58.3% occlusion at implant
 - ◆ 100% at 6mths
 - ◆ AR
 - ◆ in 2/3 with concentric LA disk
 - ◆ in 1/8 with eccentric LA disk
 - ◆ TR in 5/11
 - ◆ Endothelialized at 3mths

* Gu X et al
Catheter Cardiovasc Interv 2000;50:502



Transcatheter Closure of VSD

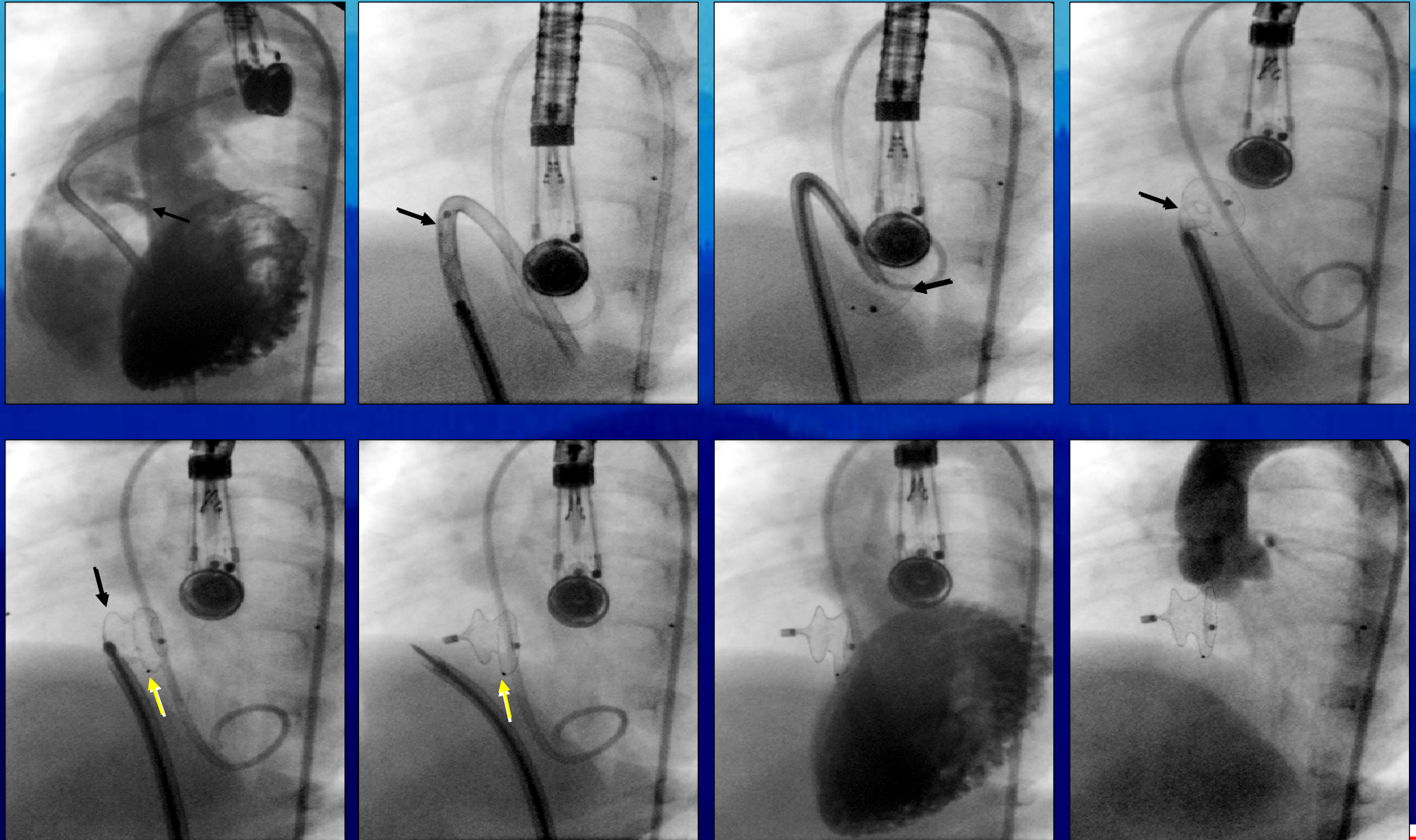
Amplatzer pVSD Occluder



Courtesy of Dr. Hijazi

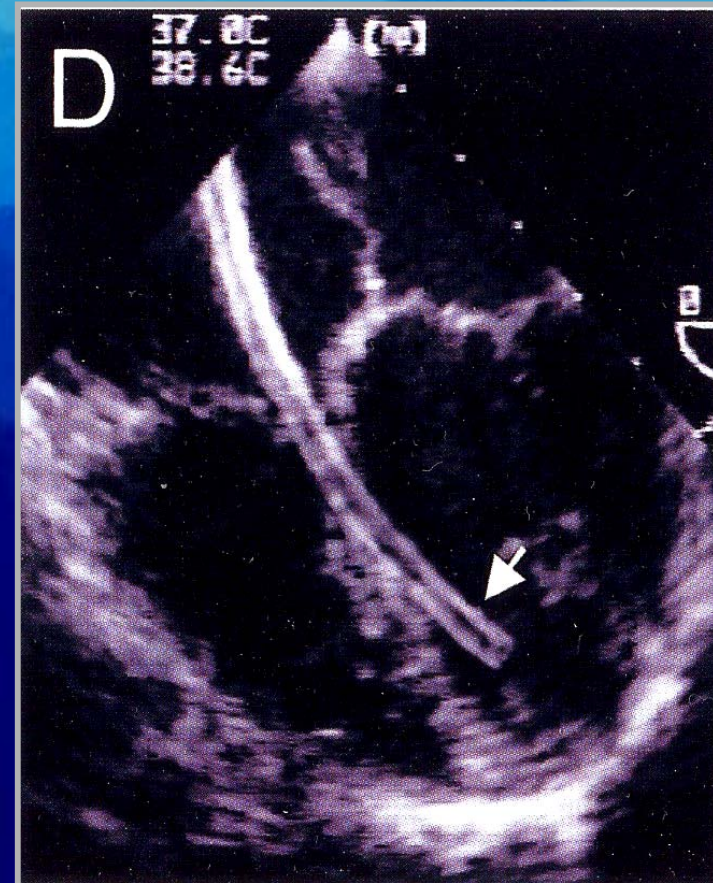
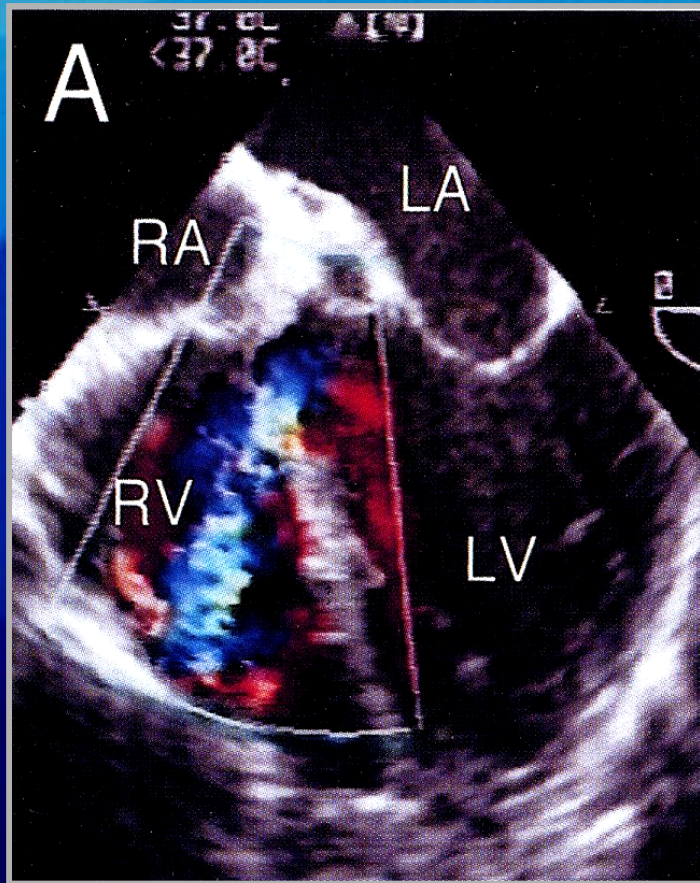
Transcatheter Closure of VSD

Amplatzer pVSD Occluder



Transcatheter Closure of VSD

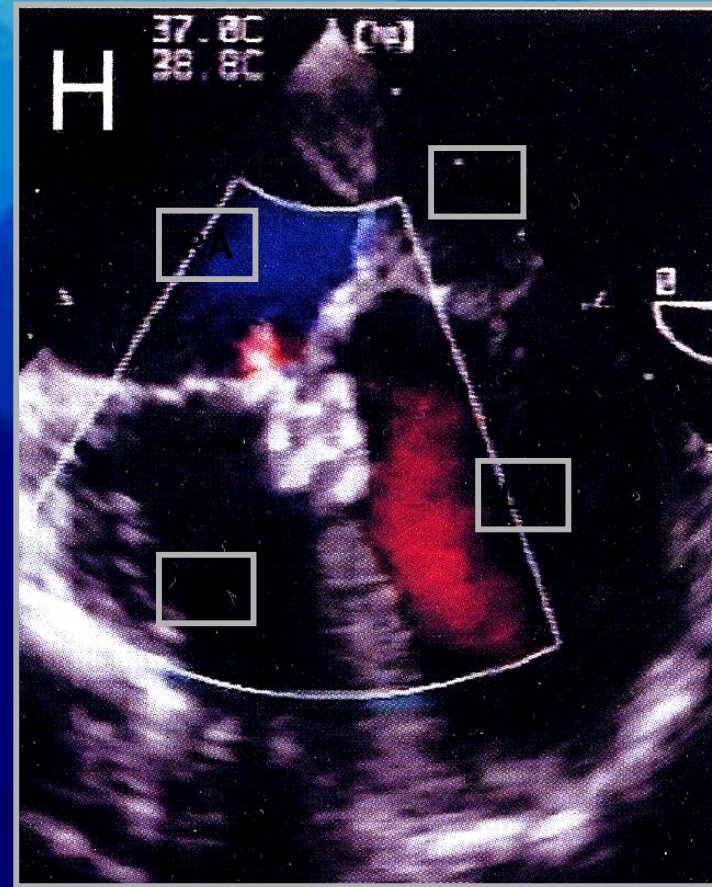
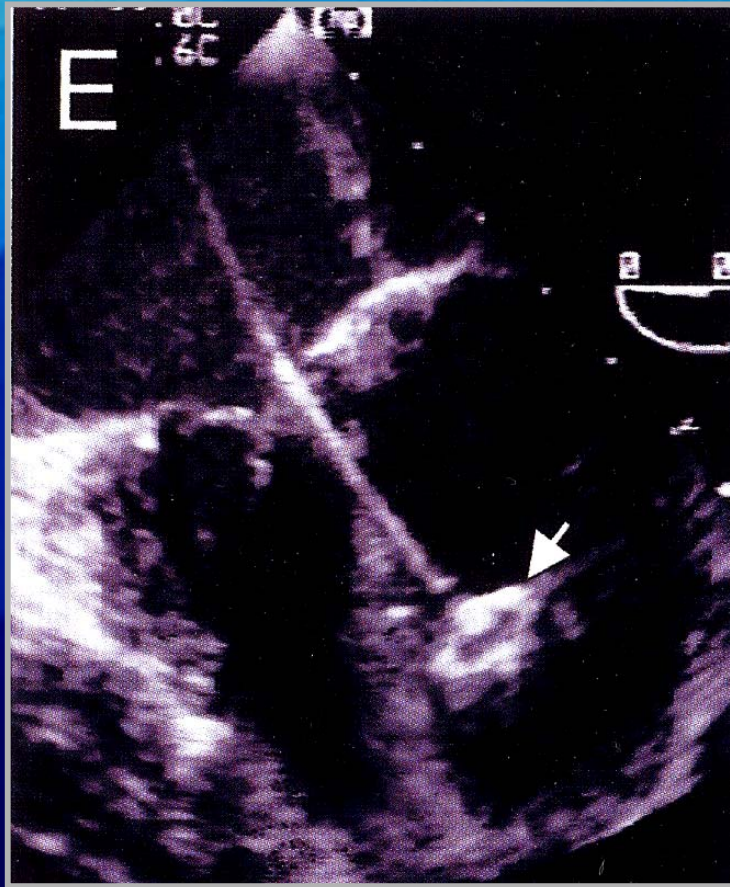
Amplatzer pVSD Occluder



Hijazi et al Cath & Cardiovasc Inter; 2002;56:508

Transcatheter Closure of VSD

Amplatzer pVSD Occluder



Hijazi *et al* Cath & Cardiovasc Inter; 2002;56:508

Transcatheter Closure of Shunts

Experience at TCH

❖ Persistent Ductus Arteriosus

- ❖ 1997 - 2003
- ❖ Procedures = 168
- ❖ Age - 1m - 384m (mean 39.1)
- ❖ Wt. - 3.9 - 146kg (mean 15.2)
- ❖ Fl. Time - <1 - 185mins (mean 24.4)

❖ Atrial Septal Defect

- ❖ 1998 - 2003
- ❖ Procedures = 153
- ❖ Age - 3m - 69.2yrs (mean 6.7)
- ❖ Wt. - 4.3 - 167kg (mean 23)
- ❖ Fl. Time - <1 - 335mins (mean 19)

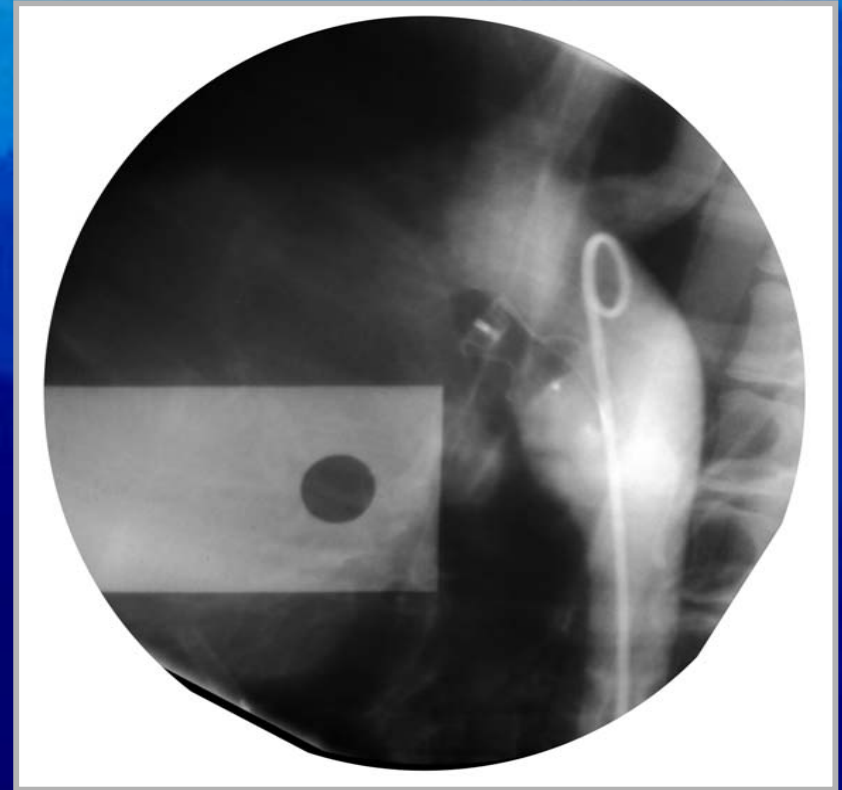
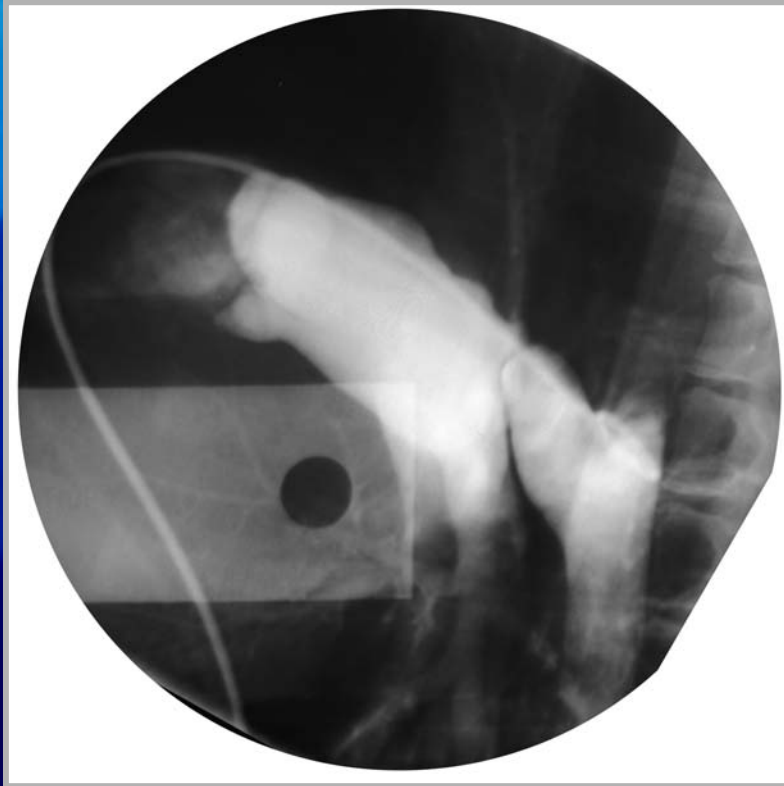
❖ Ventricular Septal Defect

- ❖ 1999 - 2003
- ❖ Procedures = 18
- ❖ Age - 3m - 166.8m (mean 14.4)
- ❖ Wt. - 5.1 - 65.6kg (mean 8.5)
- ❖ Fl. Time - <8 - 165mins (mean 72.5)



Transcatheter Closure of Shunts

Transcatheter closure of large PDA with Amplatzer Ductal Occluder



Transcatheter Closure of Shunts

Transcatheter closure of large PDA with Amplatzer Ductal Occluder



“Woof!”



Interventional Cardiac Catheter in the Young

Finale

Thank you

The child first and always

The child first and always

The child first and always

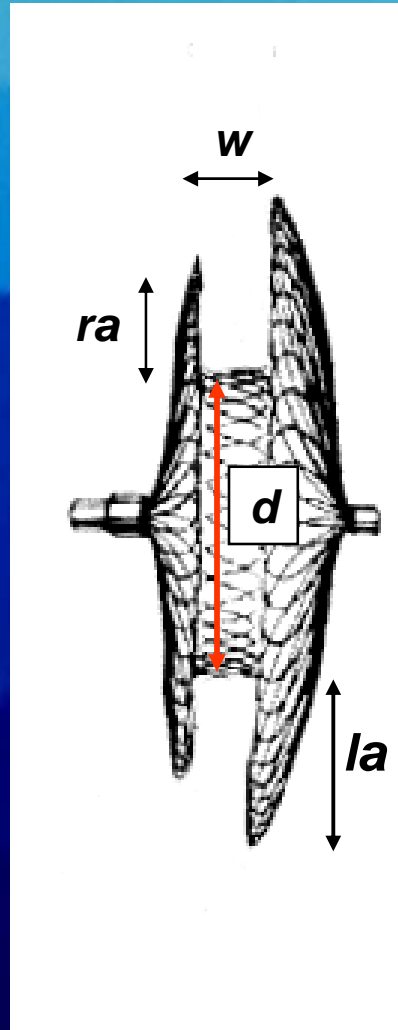
The child first and always

The child first and always

The child first and always

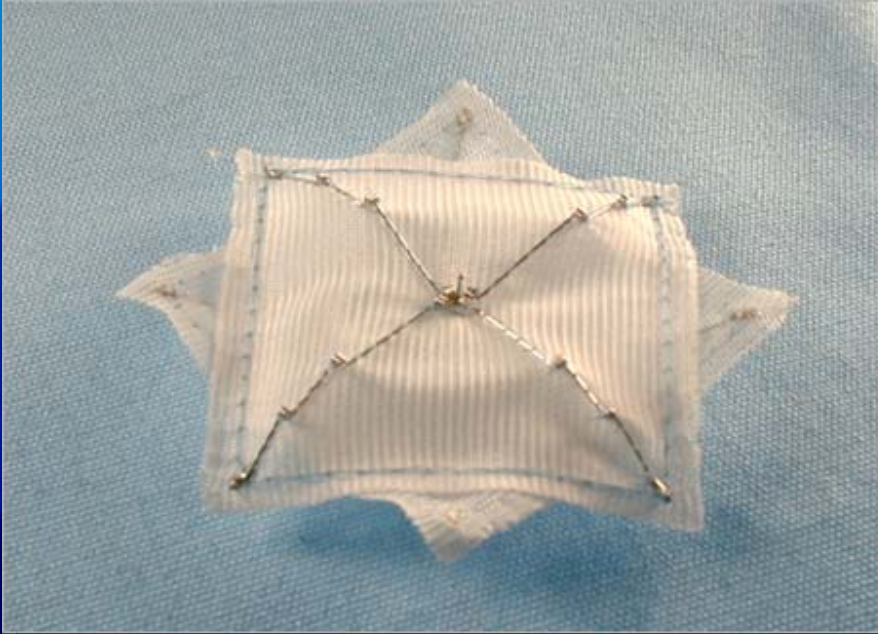


Amplatzer Septal Occluder

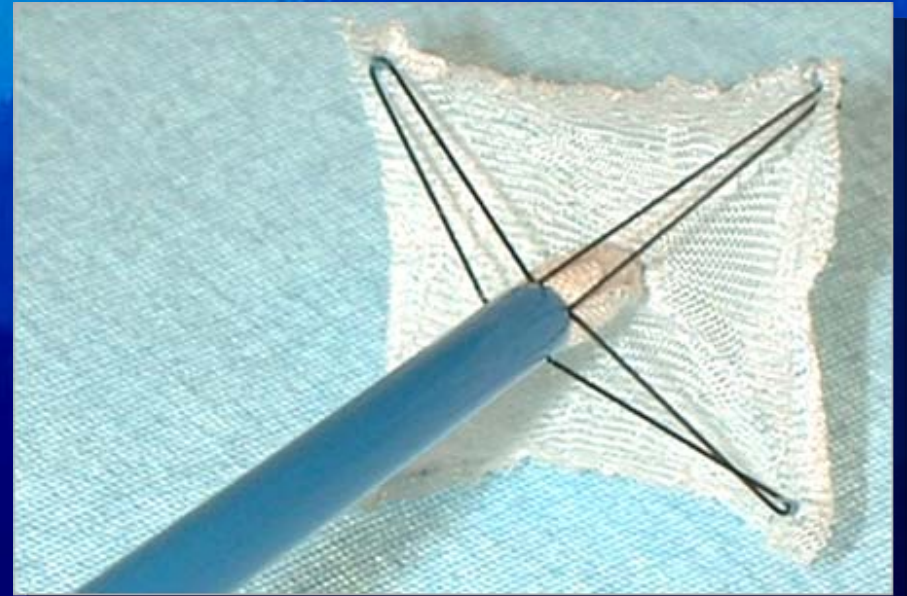


- ❖ d = diameter of waist
 - ❖ "size" of device
 - ❖ 4 to 20 mm (1 mm incr.)
 - ❖ 20 to 40 mm (2 mm incr.)
- ❖ w = width (4 mm)
- ❖ la = LA rim (5 - 7 mm)
- ❖ ra = RA rim (3 mm)

Transcatheter Closure of ASD



CardioSeal Septal Occluder



StarFlex Septal Occluder

Amplatzer Septal Occluder

- ❖ Self expandable double disk
 - ❖ connecting waist
 - ❖ 4 to 40mm
- ❖ Circular
 - ❖ self centering
 - ❖ "stenting" the ASD
- ❖ Nitinol wire mesh (0.004" - 0.006")
 - ❖ nickel, titanium alloy (48-52%)
 - ❖ corrosion resistant
 - ❖ super-elastic & thermal memory
- ❖ Polyester inserts
 - ❖ patches
 - ❖ fibres
- ❖ Stainless steel screw attachment
 - ❖ laser welded
 - ❖ female thread
 - ❖ controlled release
- ❖ 7 - 12F delivery sheath

