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MEMORIAL HERMANN Heart & Vascular Institute

Device Sizing for the Amplatzer PFO Occluder: Forget the IFU!

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Disclosure Statement of Financial Interest Related to This Presentation

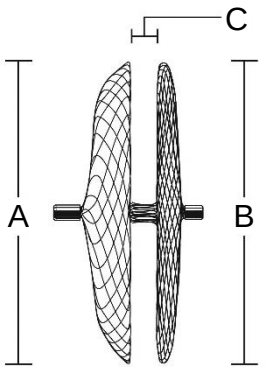
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• St Jude Medical/Abbott
• Consulting Fees/Honoraria	• St Jude Medical/Abbott
• Major Stock Shareholder/Equity	• None
• Royalty Income	• None
• Ownership/Founder	• None
• Intellectual Property Rights	• None
• Other Financial Benefit	• None

RESPECT Final Analysis Results: Procedure or Device Related SAEs

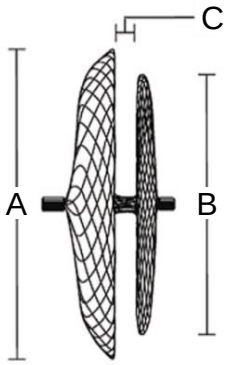
- No intra-procedure strokes
- No device embolization
- No device thrombosis
- No device erosion
- Very low rate of major vascular complications (0.9%) and device explants (0.4%)
- Very low incidence of atrial fibrillation

AMPLATZER™ PFO OCCLUDER



Equal size right & left discs: 18 mm

Device Size (Disc = A)	18 mm
Right Atrial Disc (A)	18
Left Atrial Disc (B)	18
Length of Waist (C)	3
Delivery System	8 FR

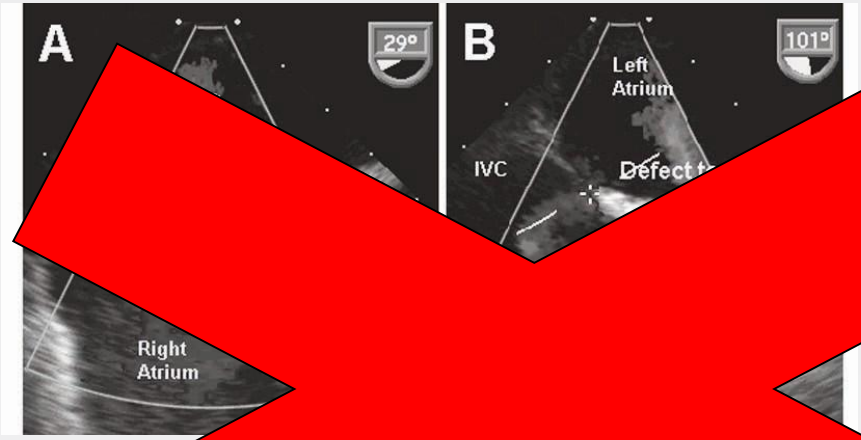


Unequal size right & left discs: 25 mm & 35 mm

Device Size (Disc = A)	25 mm	35 mm
Right Atrial Disc (A)	25	35
Left Atrial Disc (B)	18	25
Length of Waist (C)	3	3
Delivery System	8 FR	9 FR

DEVICE SIZE SELECTION

- Obtain two linear measurements by TEE or intra-cardiac echocardiography (ICE) as shown below:



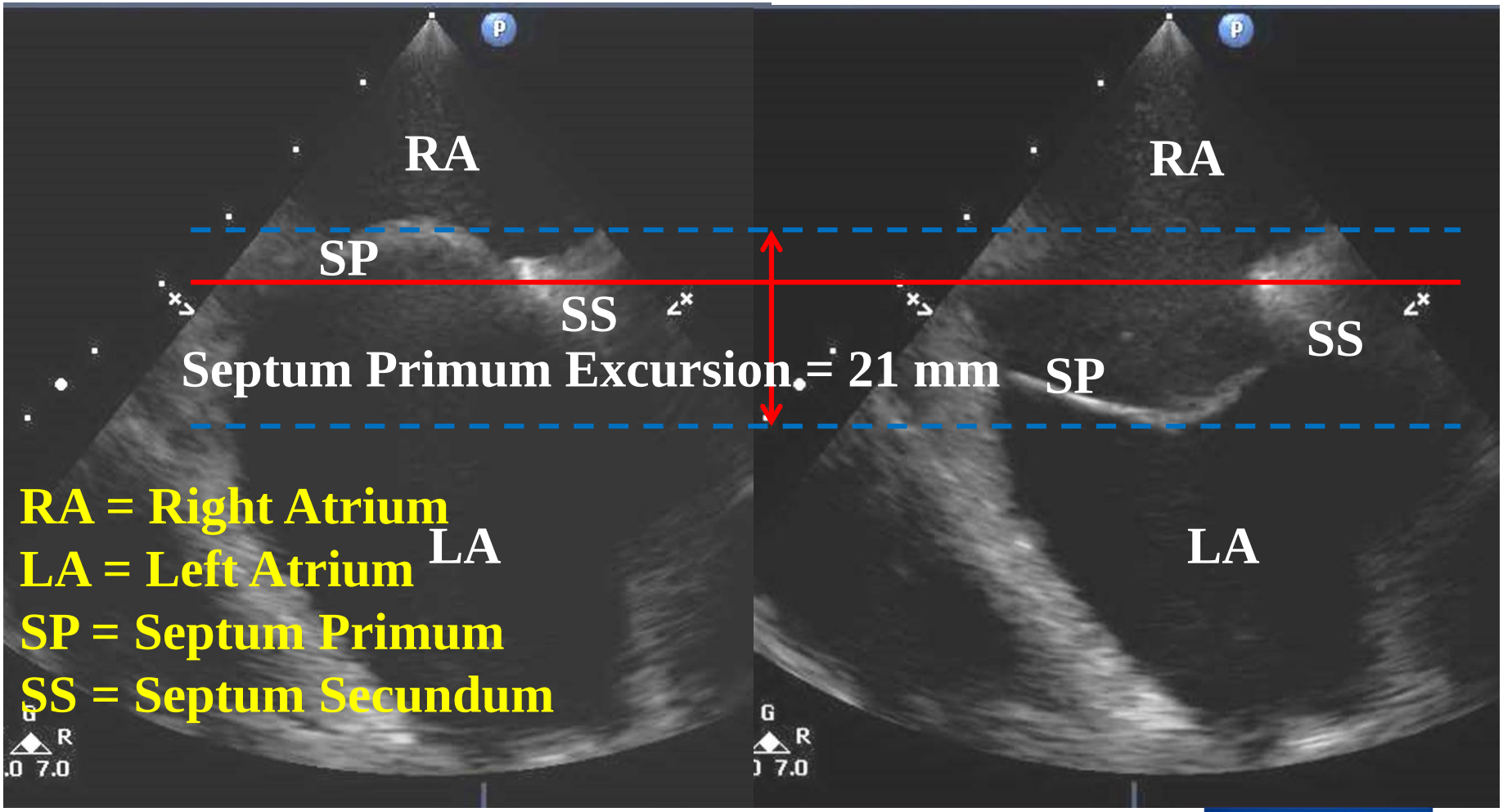
A: Distance from the PFO to … to visualize the aortic root en face)

B: Distance from the PFO … the superior vena cava (SVC) … degree view (range 80 to 125 degrees to … foreshortening of the SVC).

Note: In current practice, TEE measurements are not used for device size selection

The anatomic features of the PFO should be used instead

Atrial Septal Aneurysm in Patient With 2 Prior Cryptogenic Strokes

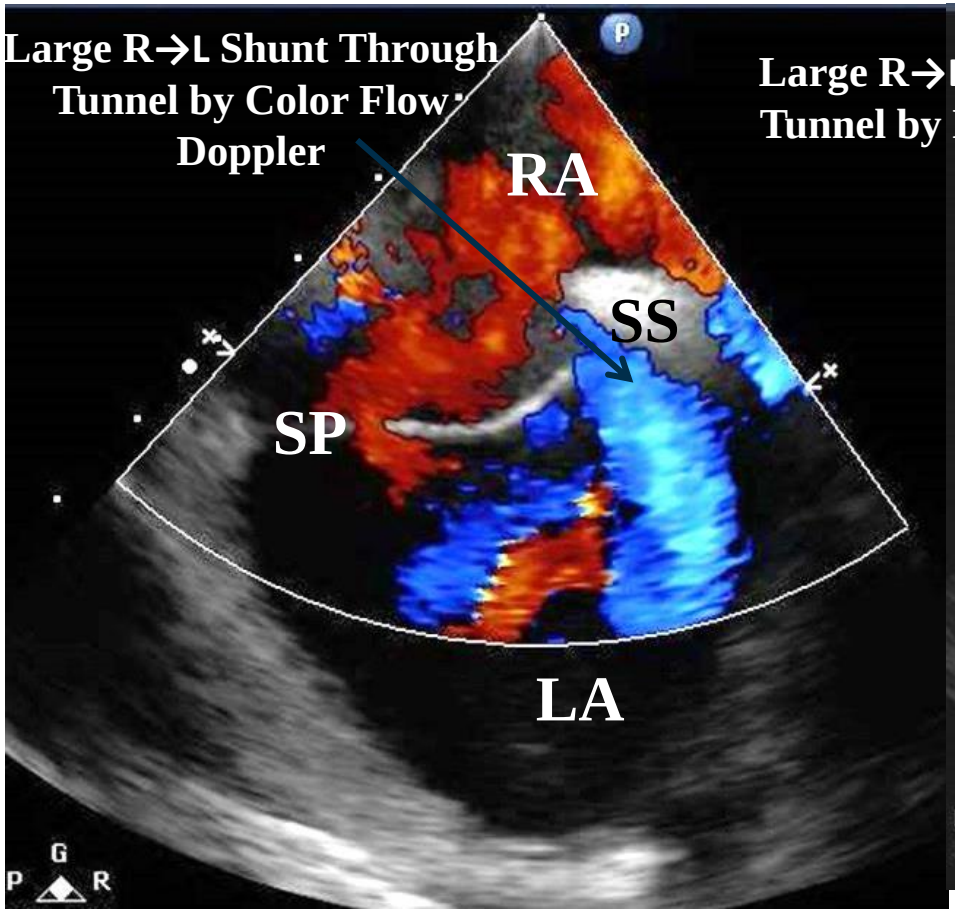


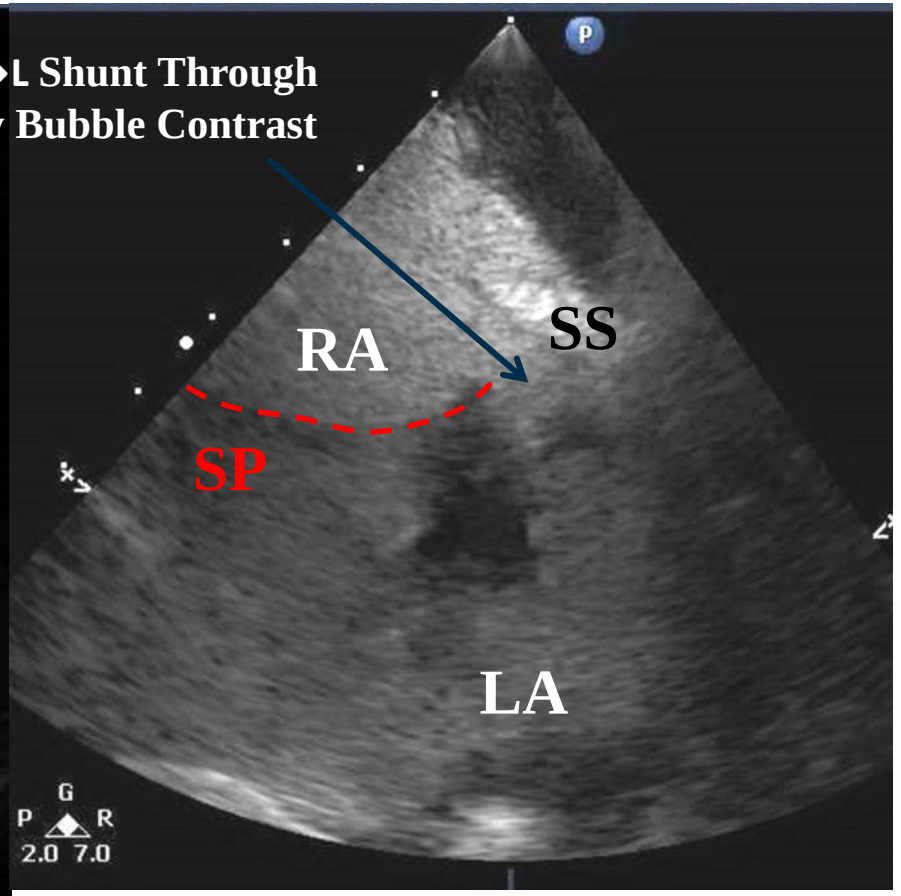
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Large Right to Left Shunt in Patient With 2 Prior Cryptogenic Strokes





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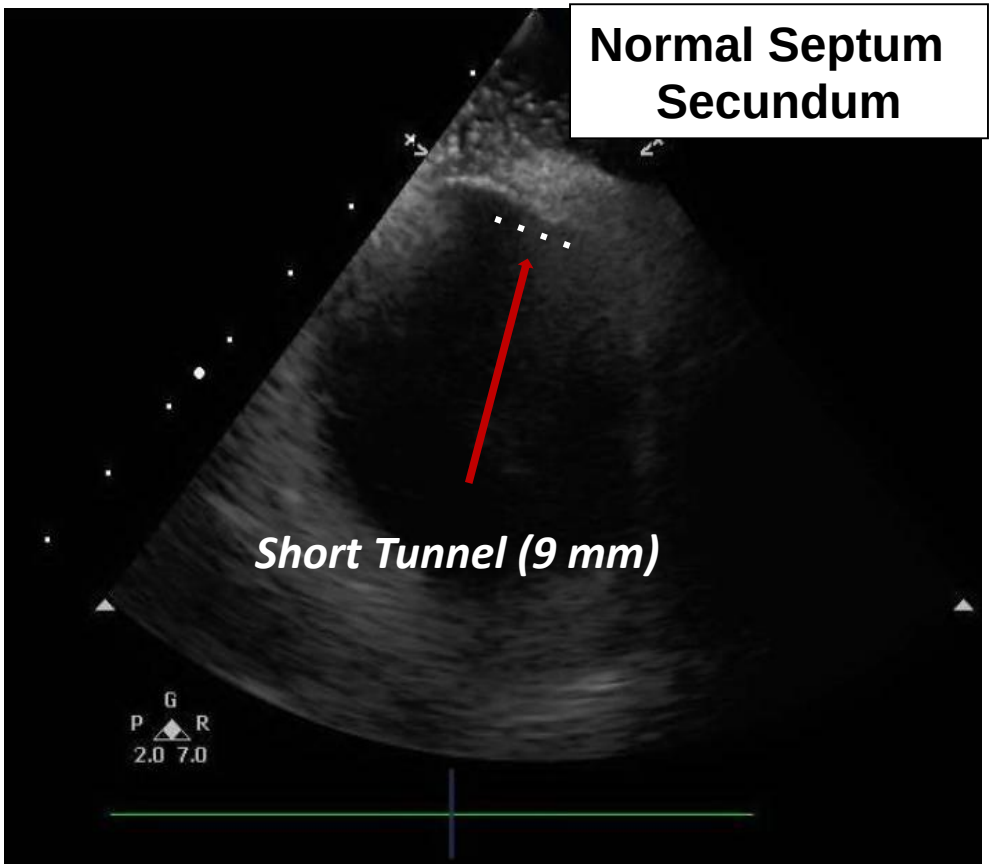


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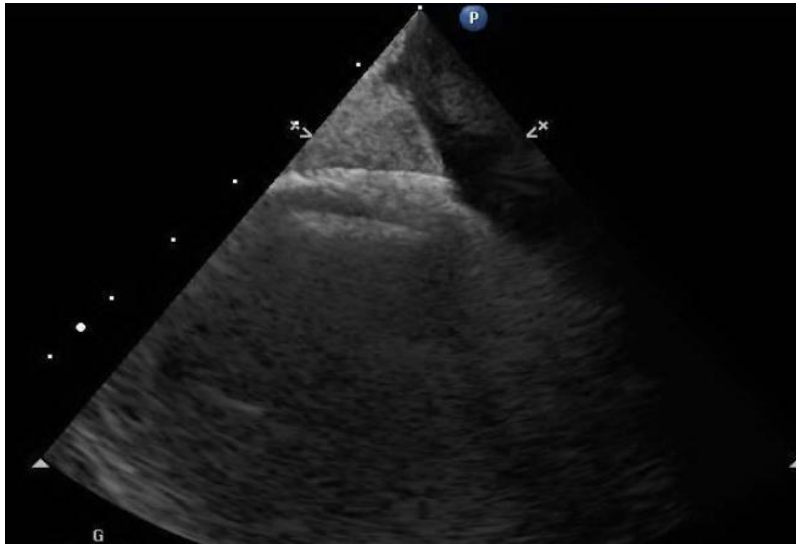
Patient with Atrial Septal Aneurysm, Lipomatous Septum and Large Shunt



PFO Closure with 25 mm Amplatzer PFO Occluder



Tunnel and Septum Well Opposed with 25mm Device

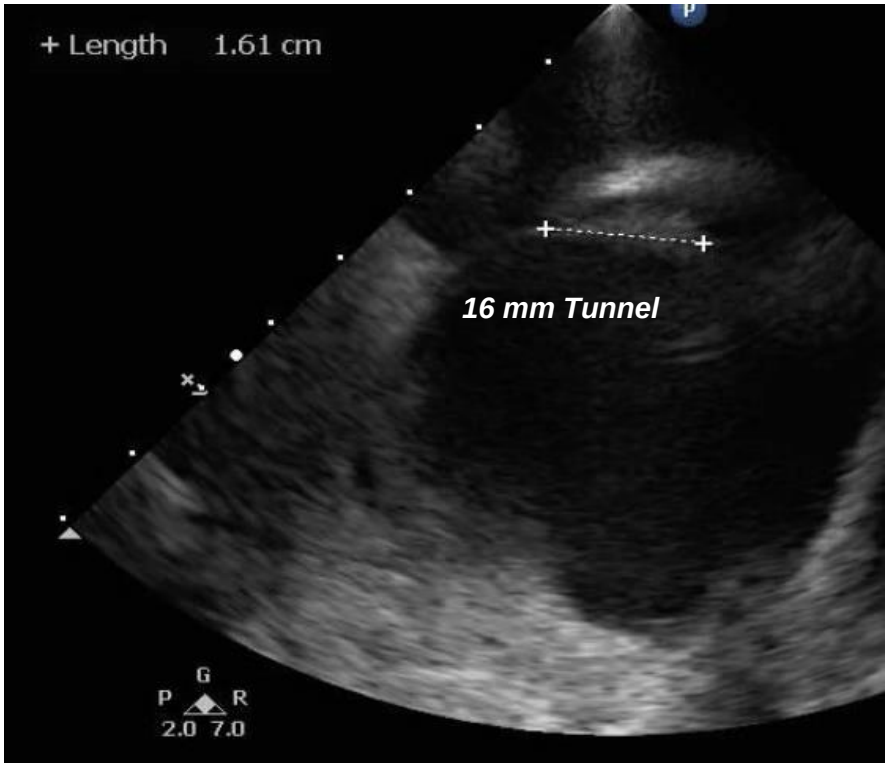


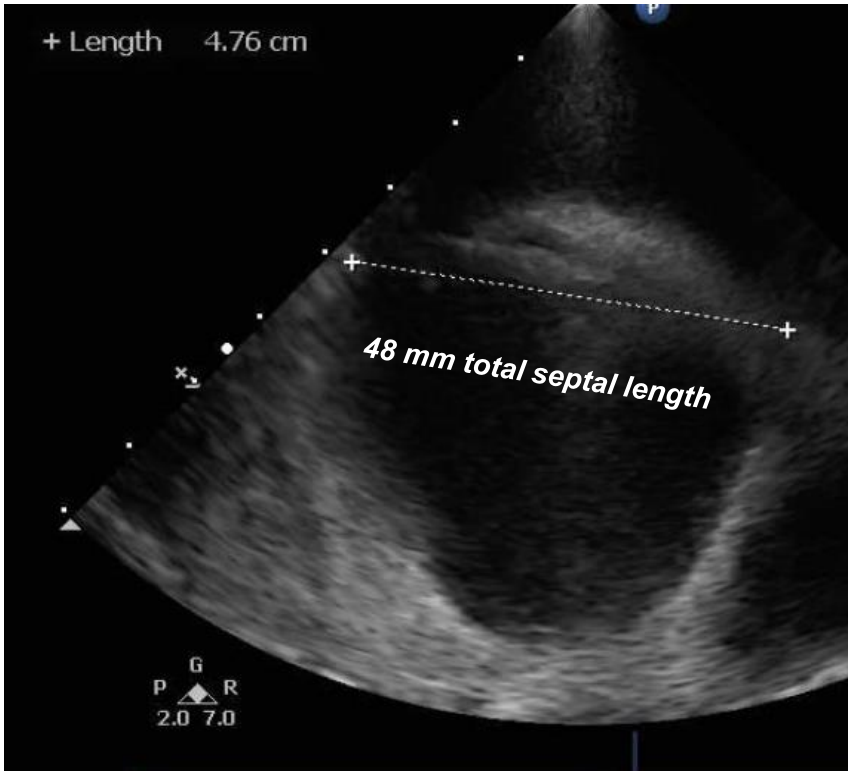
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PFO Closure with 35 mm Amplatzer PFO Occluder





Long Tunnel (16mm)

Total Septal Length (48 mm) Will Accommodate 35 mm Device

(25 mm LA disk)

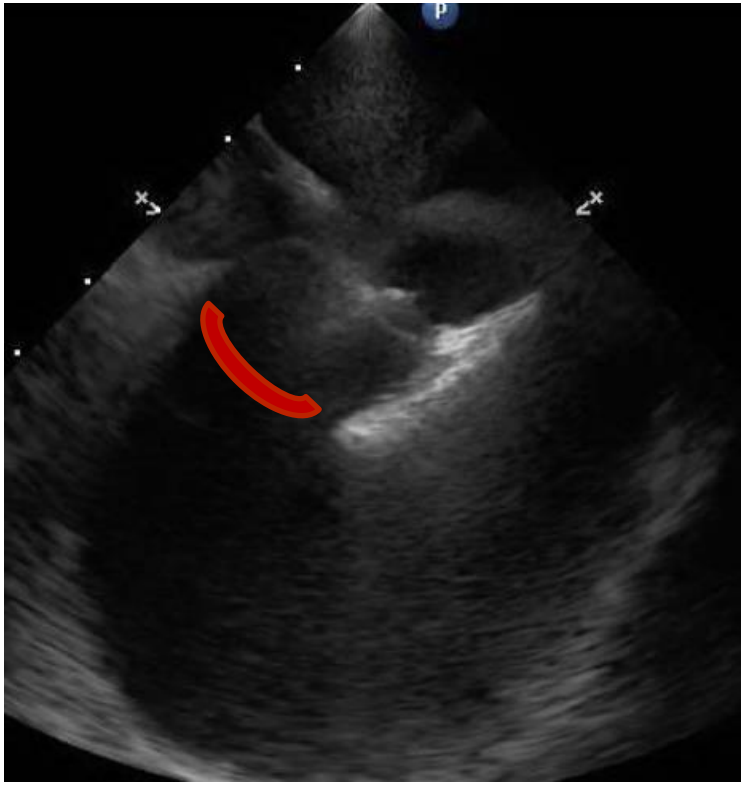
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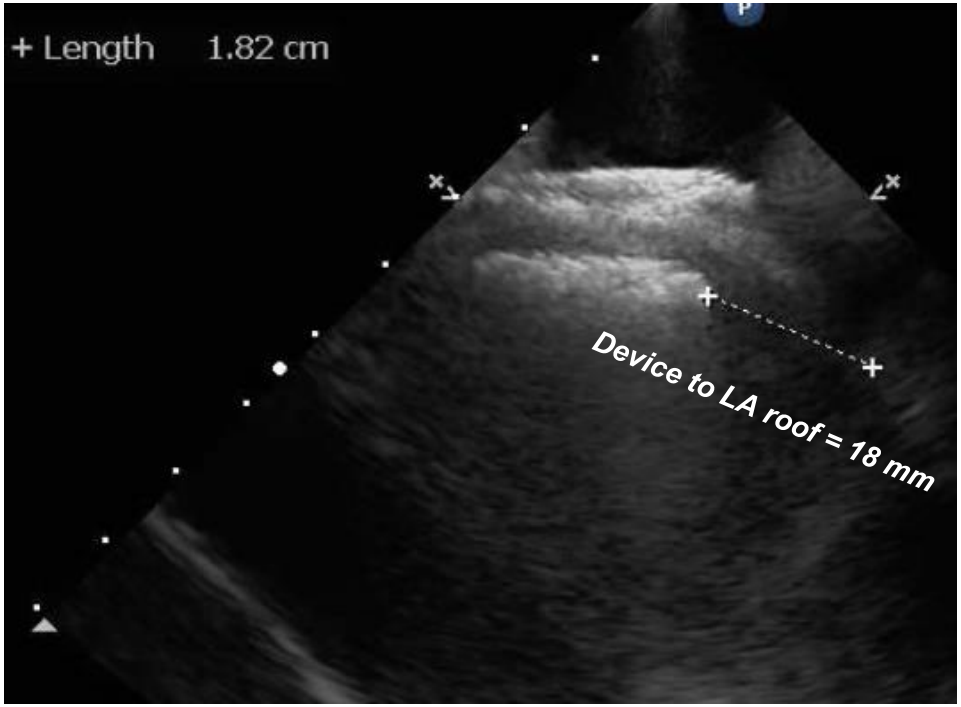
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PFO Closure with 35 mm Amplatzer PFO Occluder

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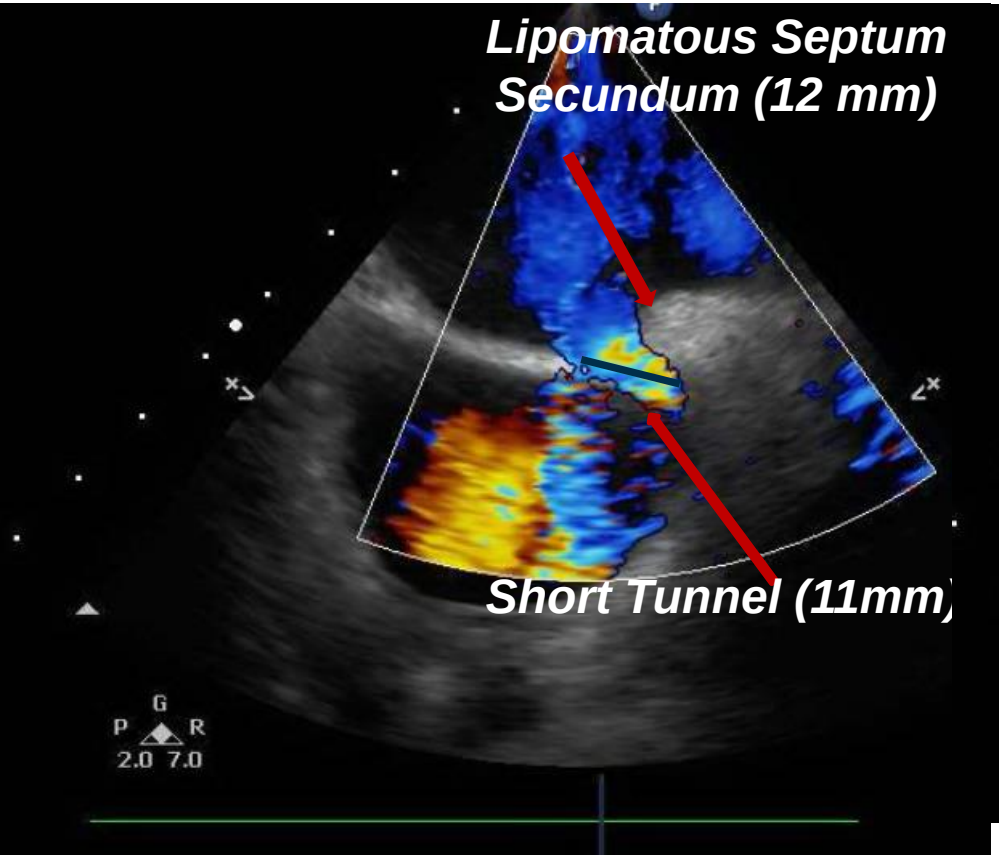


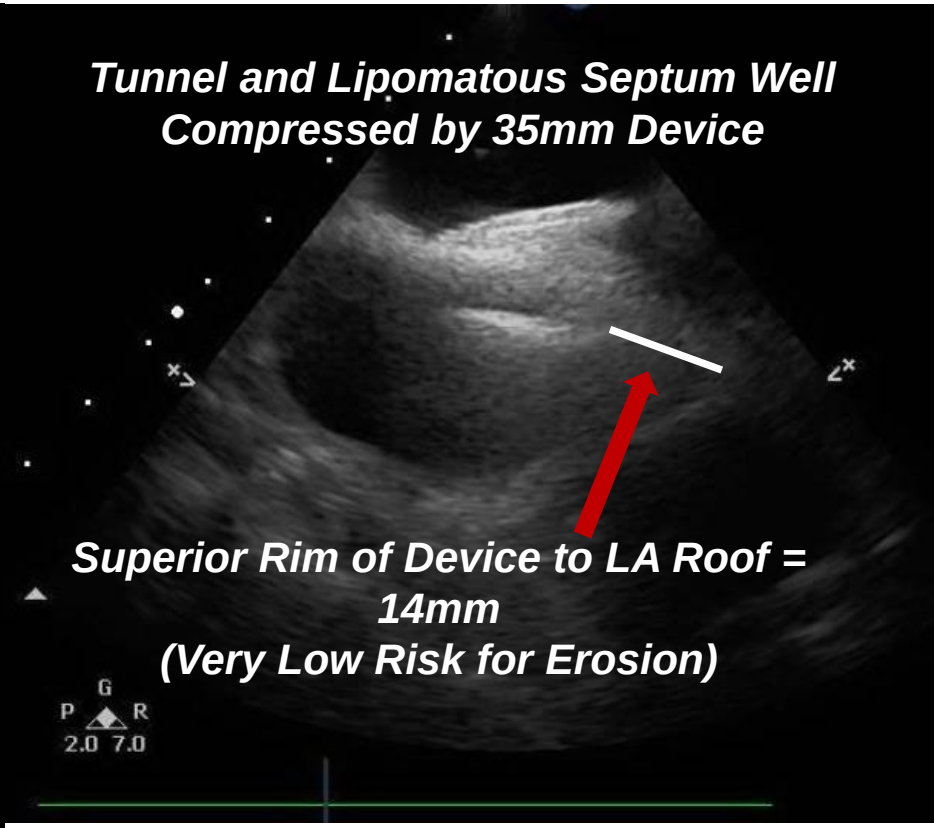
Tunnel Tissue of Septum Primum Being Compressed by 25mm LA Disk



Superior Rim of Device to LA Roof = 18mm (Very Low Risk for Erosion)

PFO Closure with 35 mm Amplatzer PFO Occluder





Summary

- **The PFO anatomy features a persistent septum secundum which insures that the center of the Amplatzer PFO occluder will be positioned away from the roof of the LA and minimizes the risk of device erosion**
- **The goal of device selection is to optimize the probability of complete closure**
- **ICE imaging is important for device selection, delivery and insuring adequate distance from the superior margin of the device to the left atrial roof.**

Amplatzer PFO Occluder Sizing Considerations

1. The majority of PFOs will be well sealed with 25mm devices which have an 18 mm diameter LA disk
2. PFO features which may favor 35 mm devices with a 25 mm LA disk include:
   a. Long (>15mm) tunnel
   b. Lipomatous hypertrophy of septum secundum
   c. Prominent, very mobile, atrial septal aneurysm
   d. Presence of very large R to L shunt which implies a large tunnel effective diameter
3. Smaller PFO occluders (18 mm) may have an increased risk of partial PFO closure/dislodgement but might be considered in patients with very short tunnels and very immobile septum primums.