

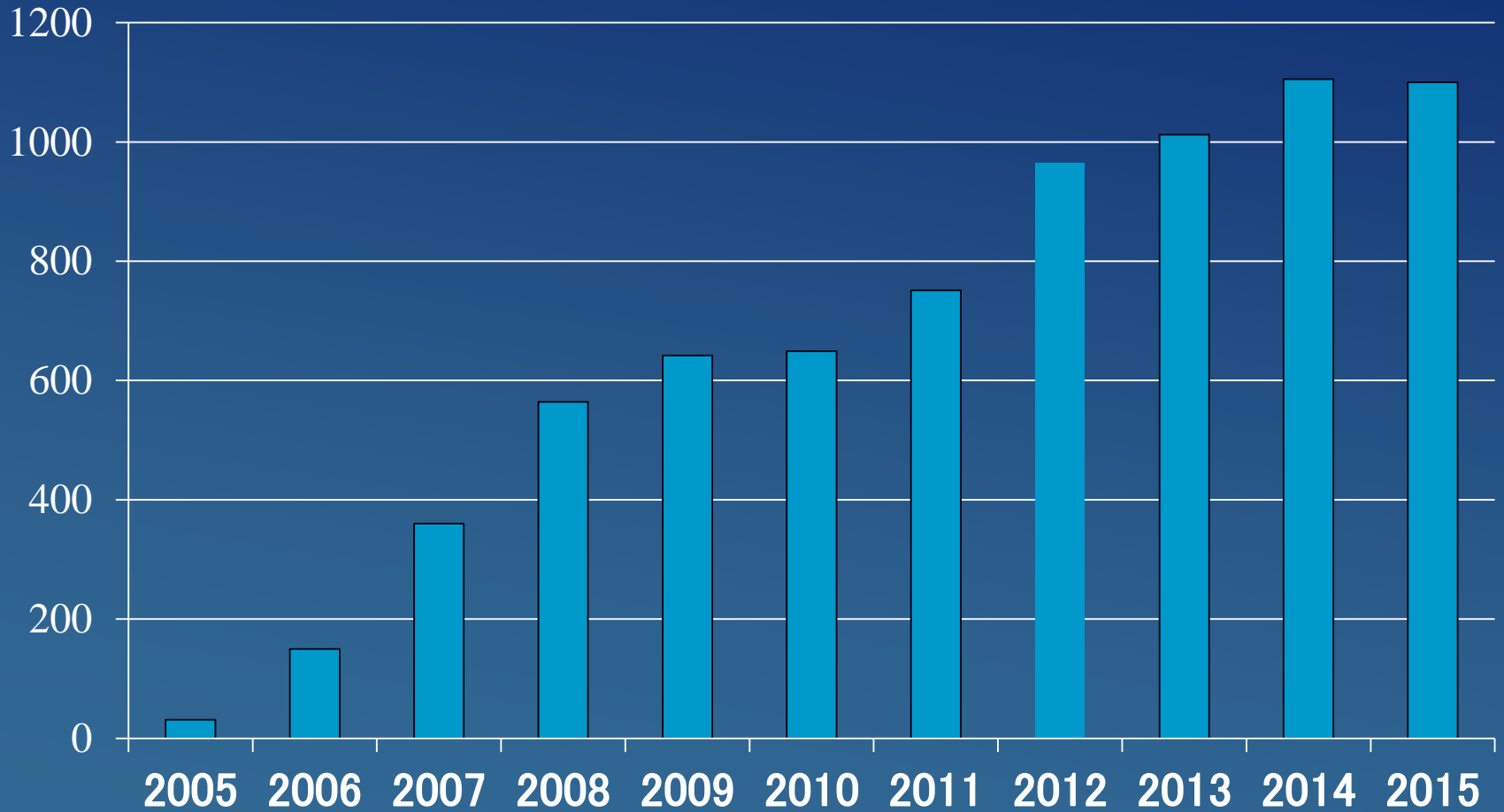
Cardiovascular Complications of ASD

Closure: Japanese Experiences



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ASD Closure in Japan

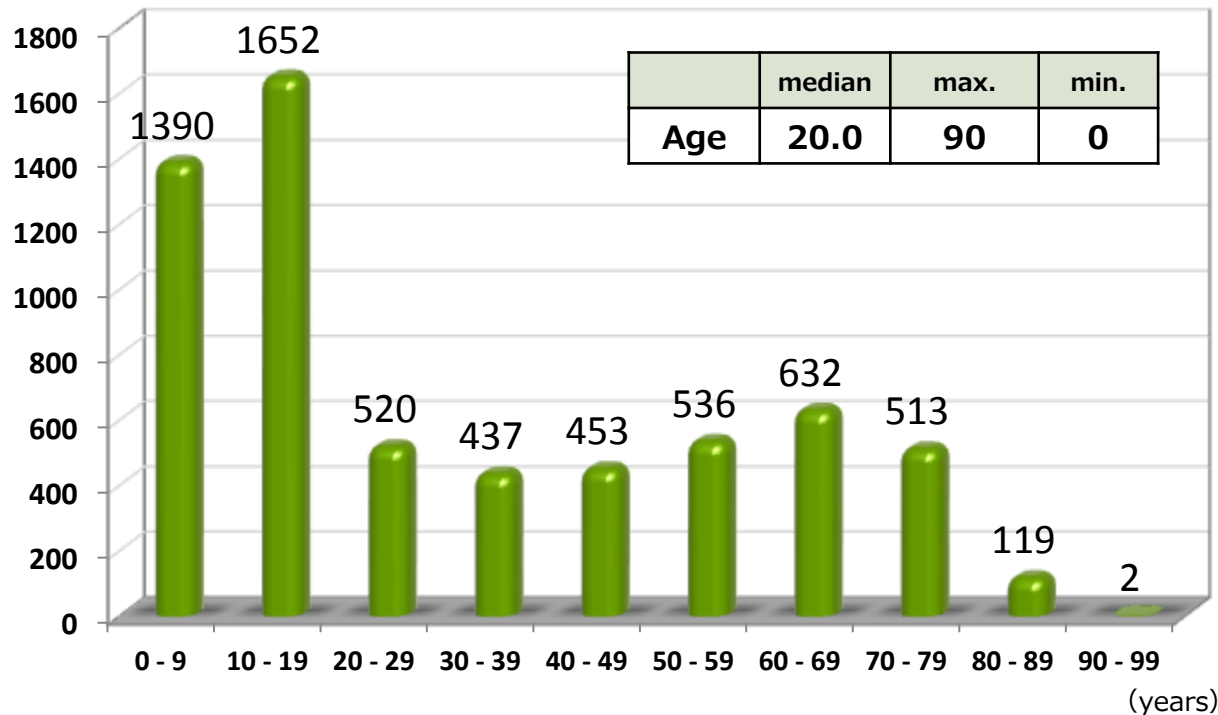


Patient's Profile of ASD Closure

March 2005 ~ December 2015

- Cases : 6,290 patients
- Sex : Male 36 % Female 64 %
- Age distribution

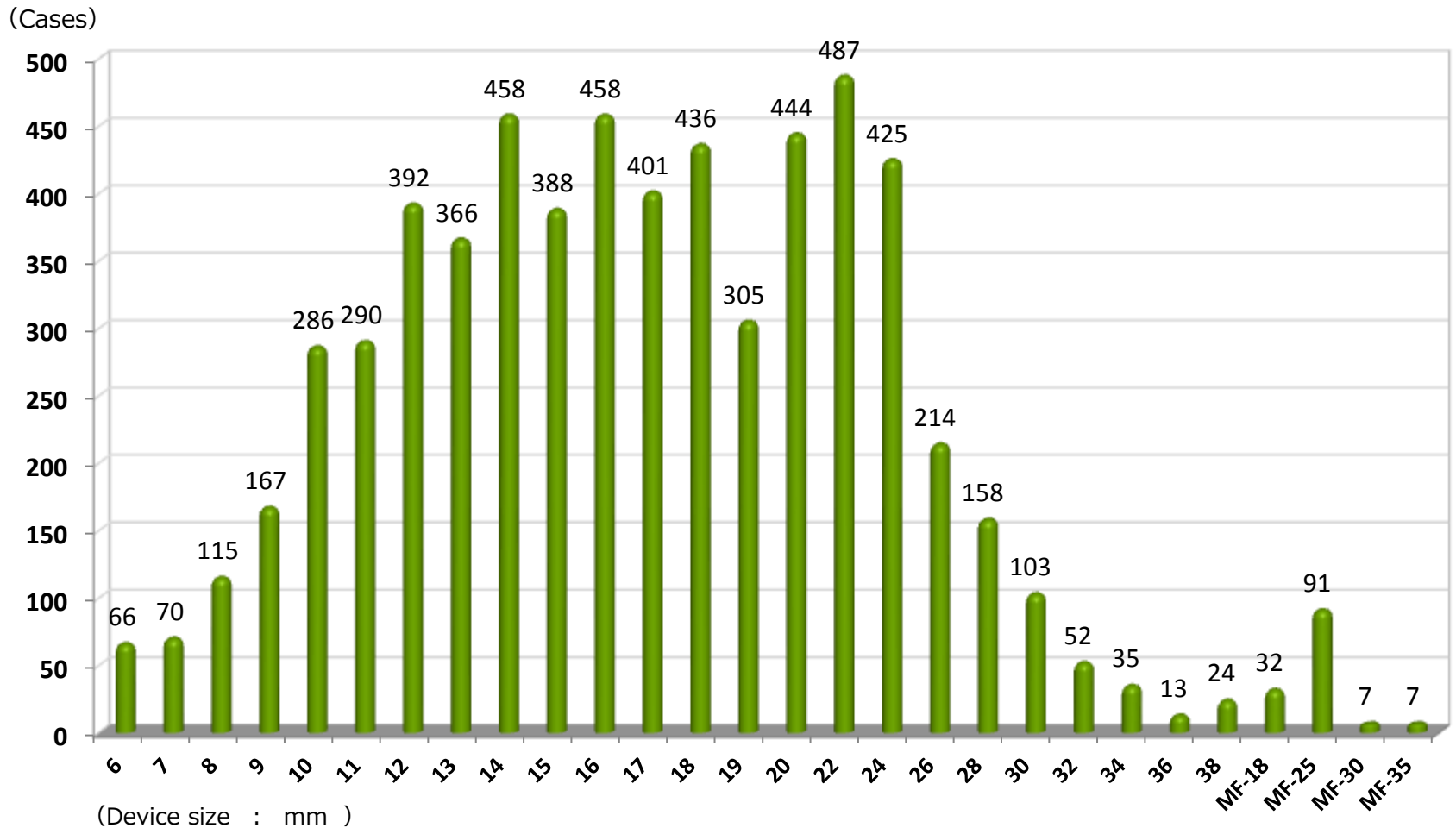
(Cases)



Age	Cases
0~9	1,390
10~19	1,652
20~29	520
30~39	437
40~49	453
50~59	536
60~69	632
70~79	513
80~89	119
90~100	2
合計	6,254

Device size

March 2005 ~ December 2015



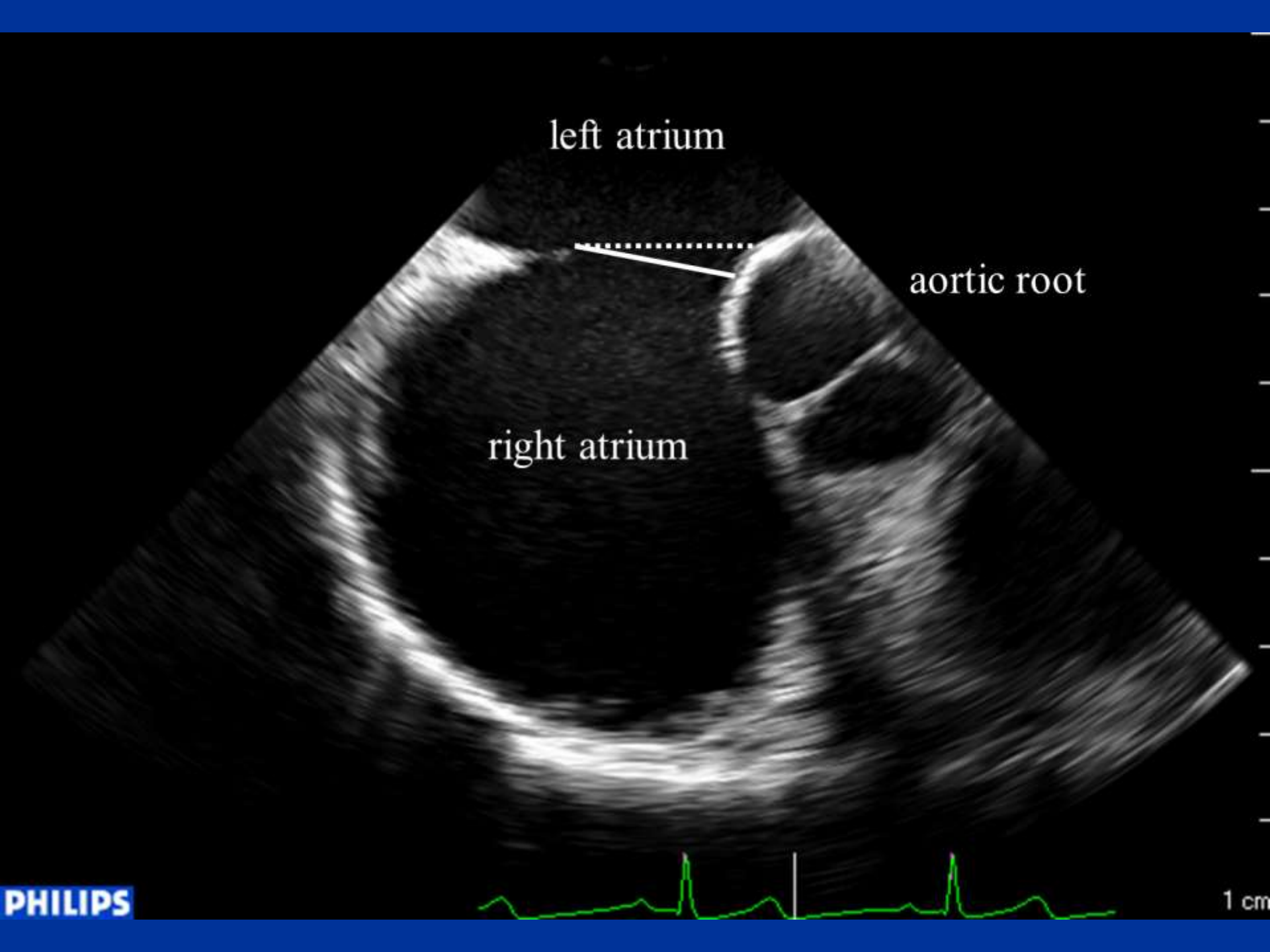
Cardiac Erosion in Japan

- 13/6290 confirmed erosion events (0.21%)

left atrium

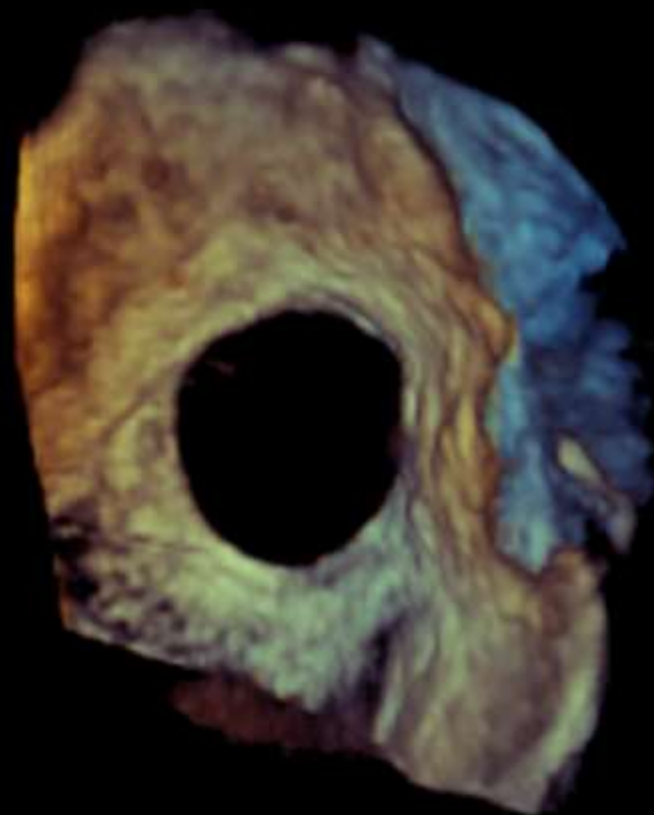
aortic root

right atrium



VR 18Hz 0 180
3cm

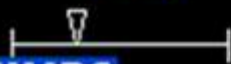
Live 3D
3D 9%
3D 40dB



superior

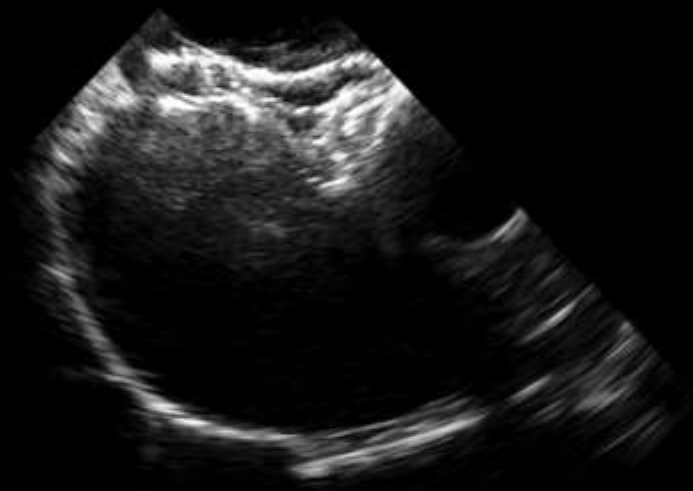


anterior



PHILIPS



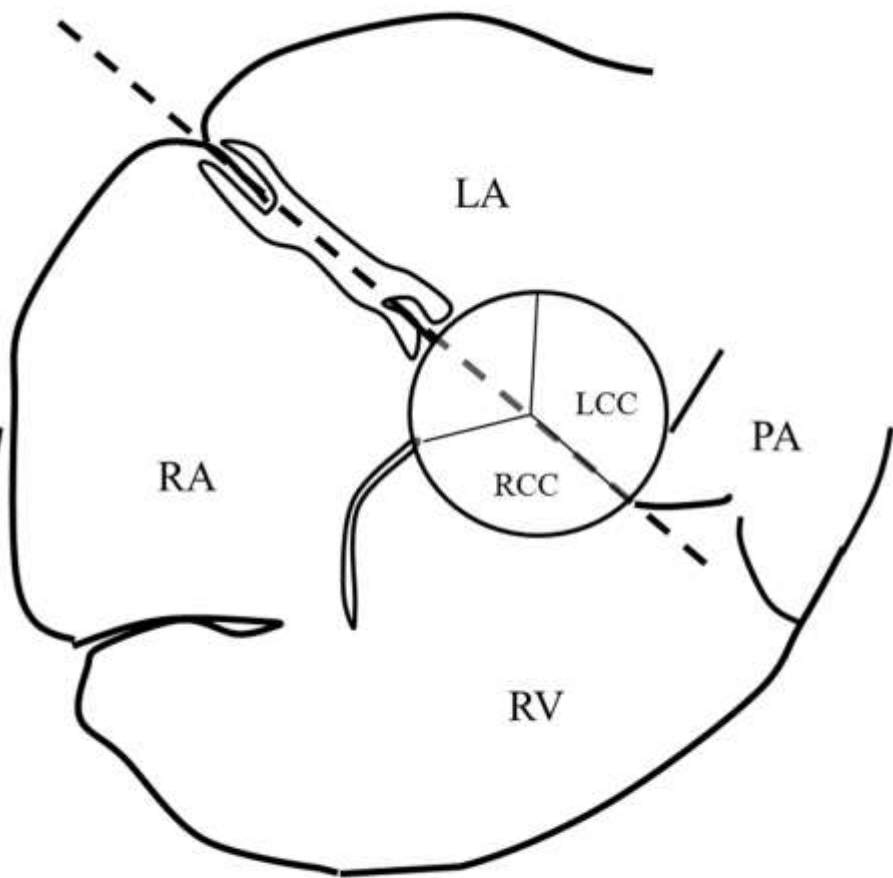
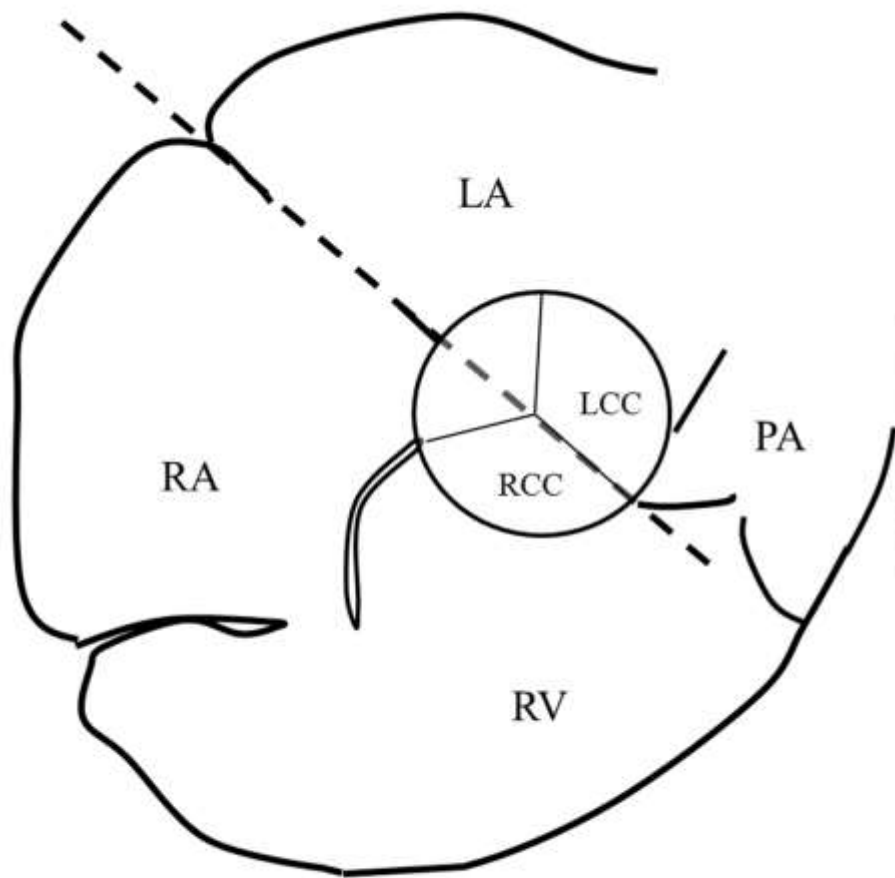


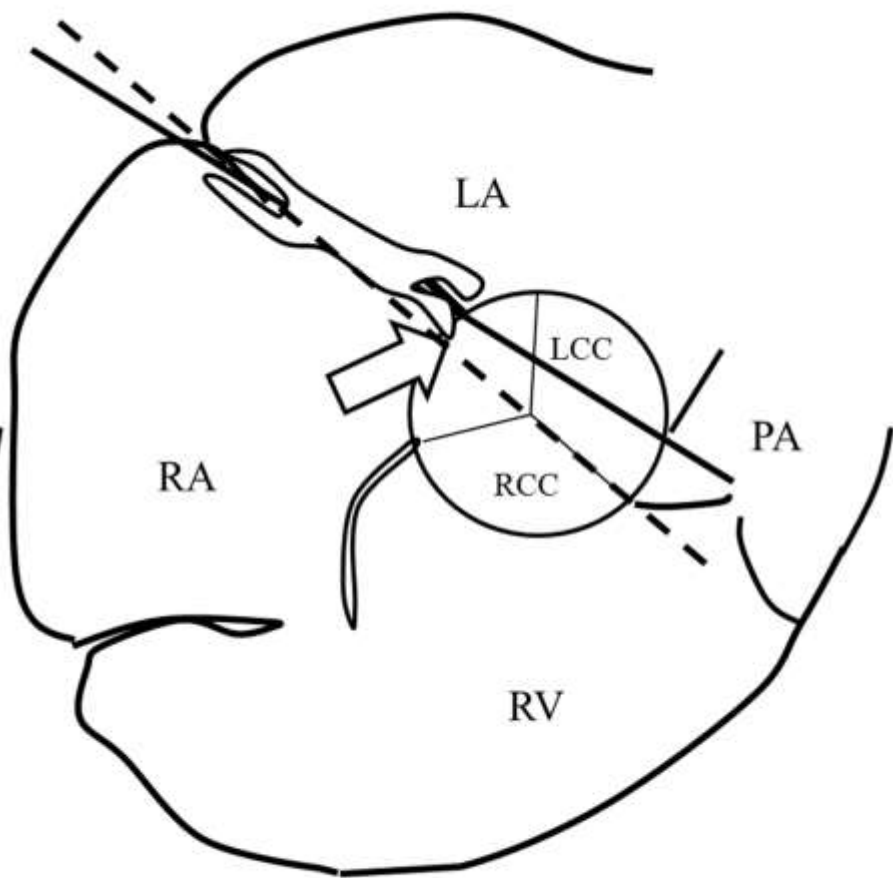
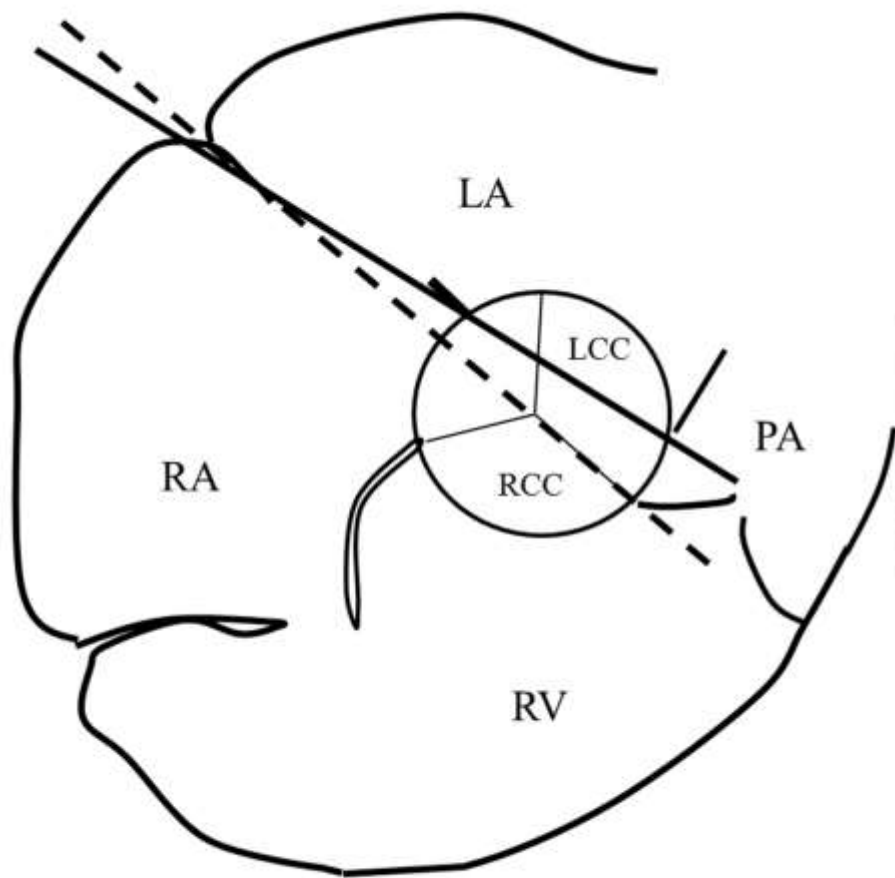
Images of the device before and after releasing from the cable.

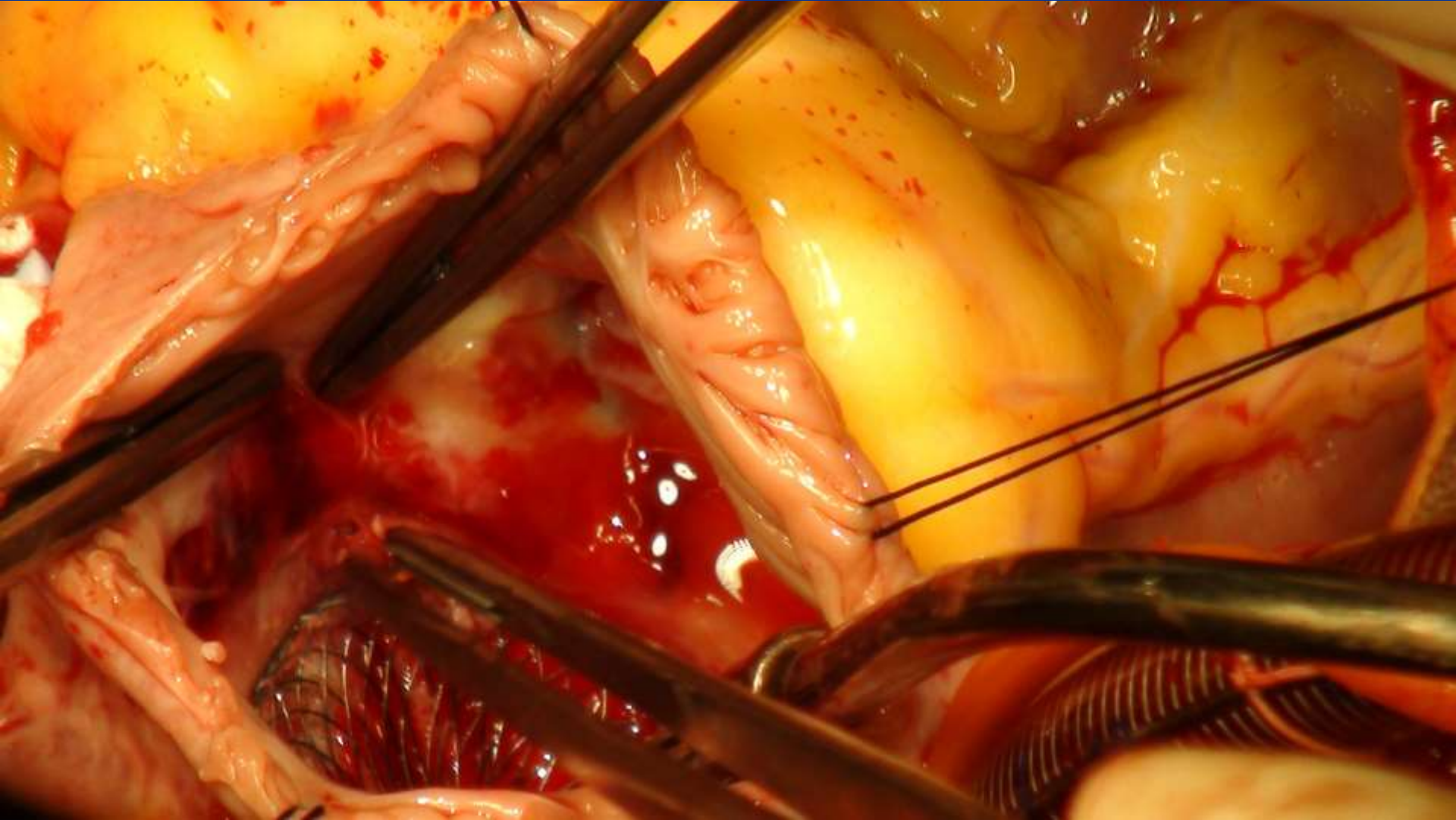
PHILIPS

1 cm PHILIPS

1 cm



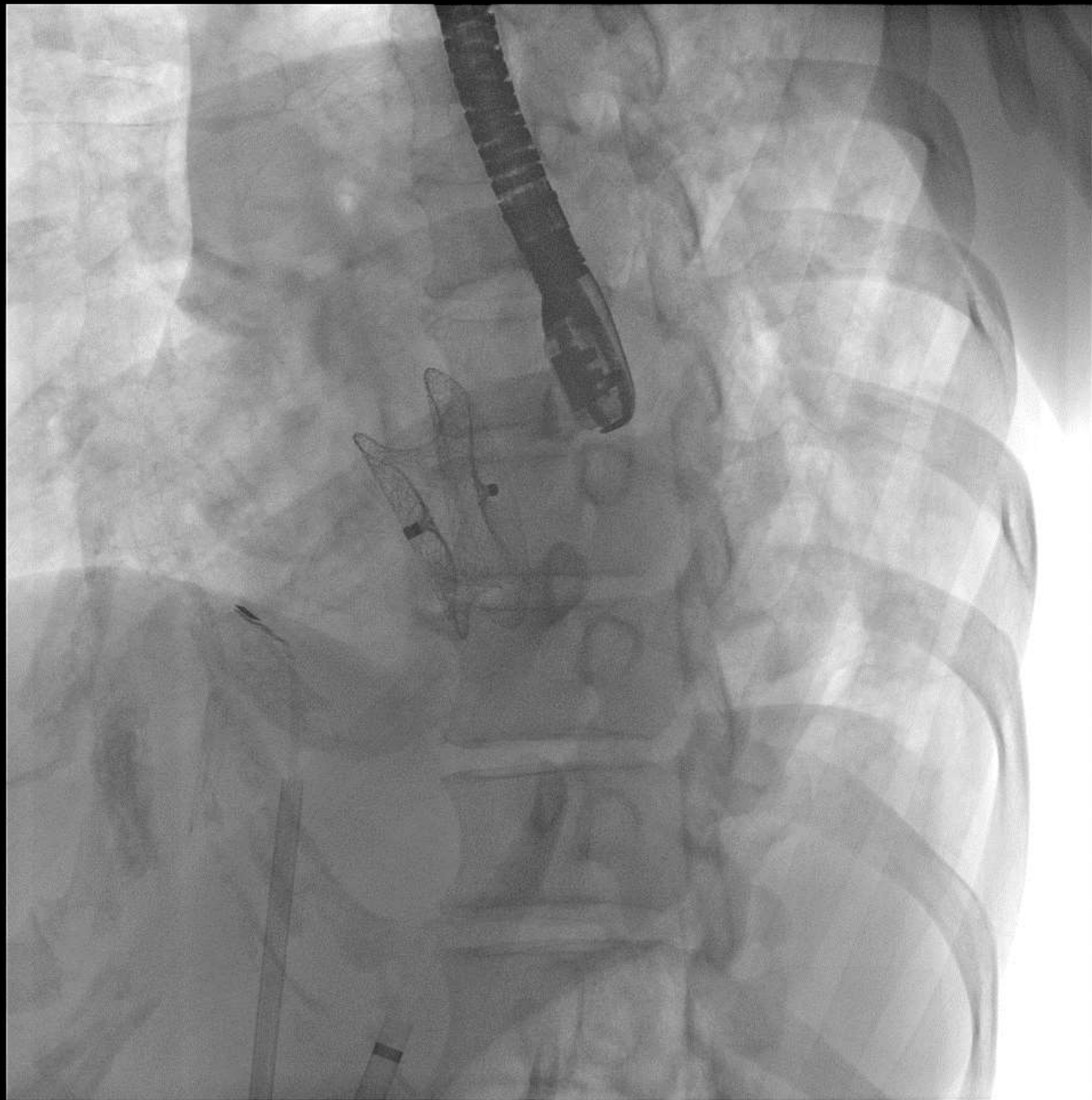


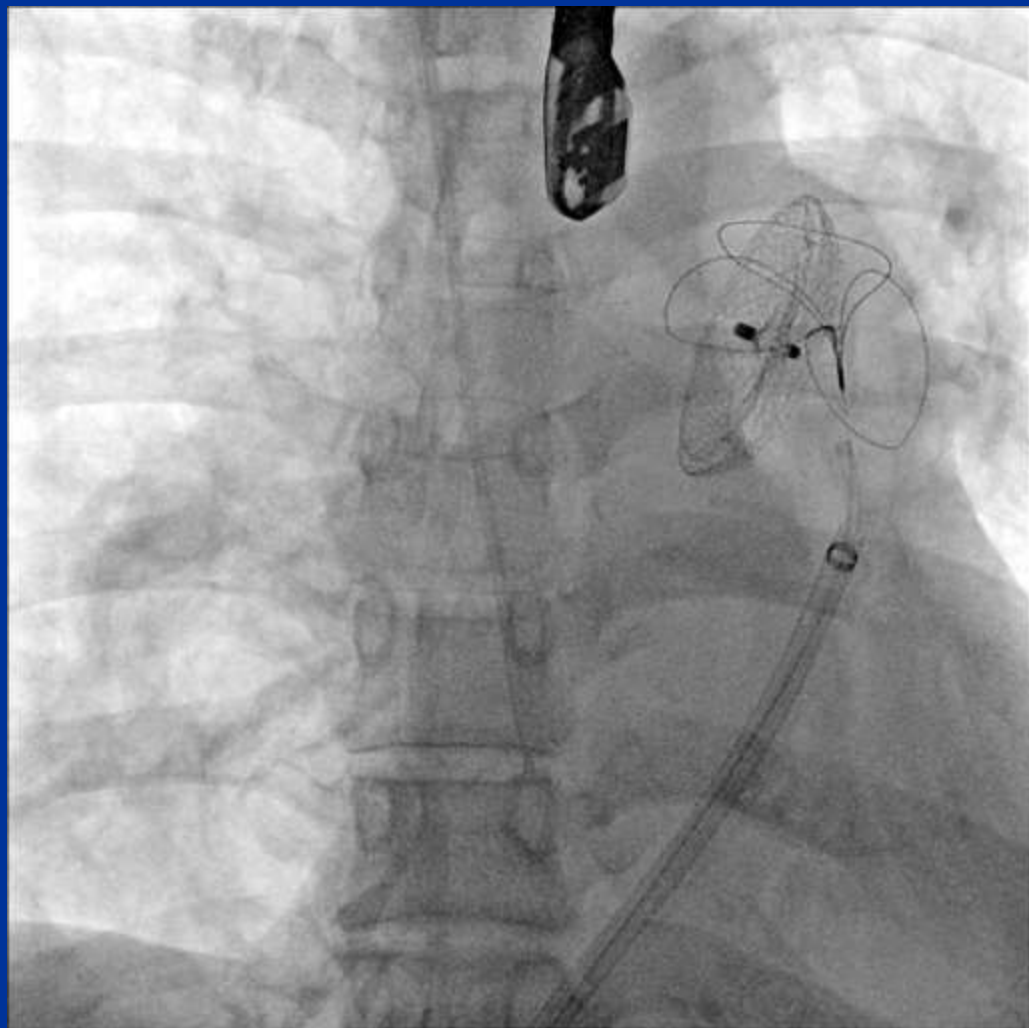


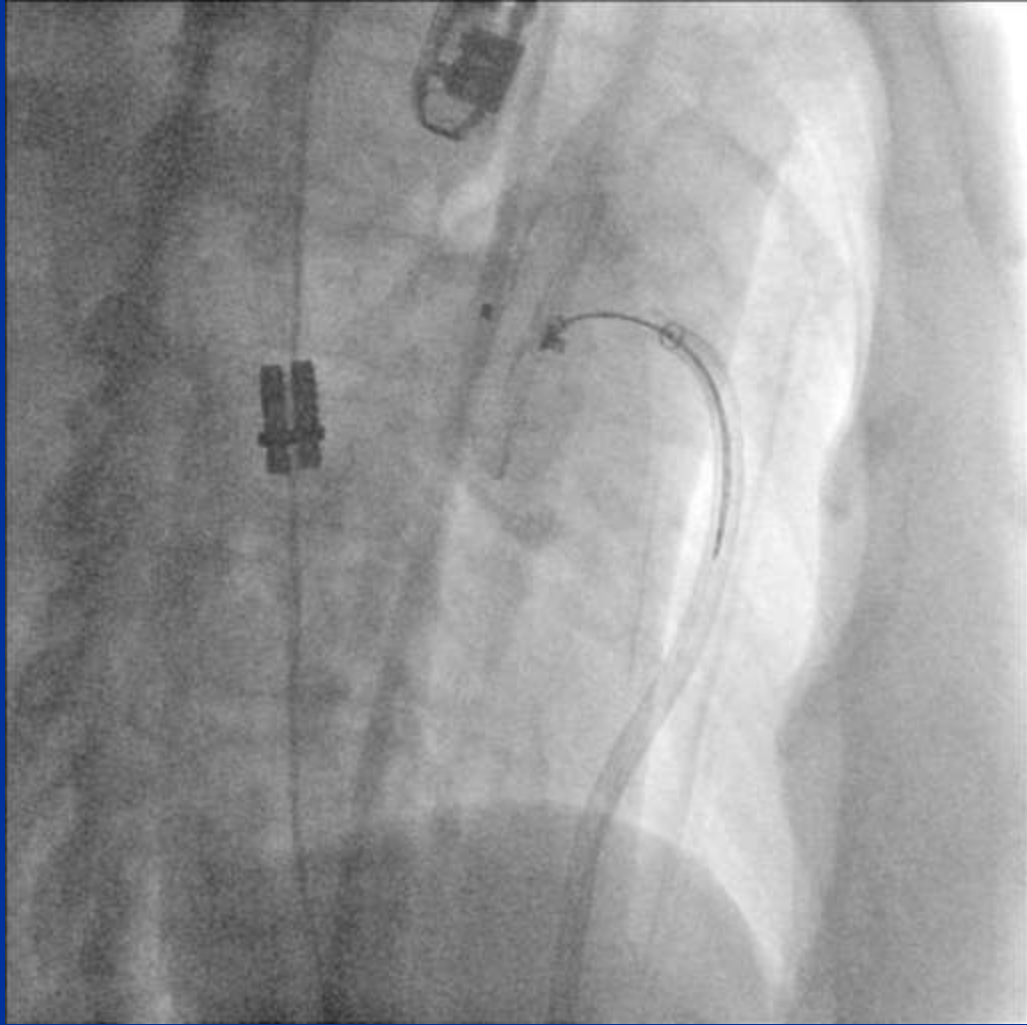
Subject	Site Reported Adverse Event Type	Days from Implant to Event	Age (years)	Device Size (mm)
1	Cardiac Erosion with tamponade	136	13	20
2	Cardiac Erosion	1	33	20
3	Cardiac Erosion	164	11	20
4	Cardiac Erosion	199	9	18
5	Cardiac Erosion	161	38	30
6	Cardiac Erosion	38	7	22
7	Cardiac Erosion with tamponade	3	44	26
8	Cardiac Erosion	17	11	28
9	Cardiac Erosion	98	47	24
10	Cardiac Erosion	83	28	28
11	Cardiac Erosion	2382	12	24
12	Cardiac Erosion	162	30	11
13	Cardiac Erosion	1	63	19

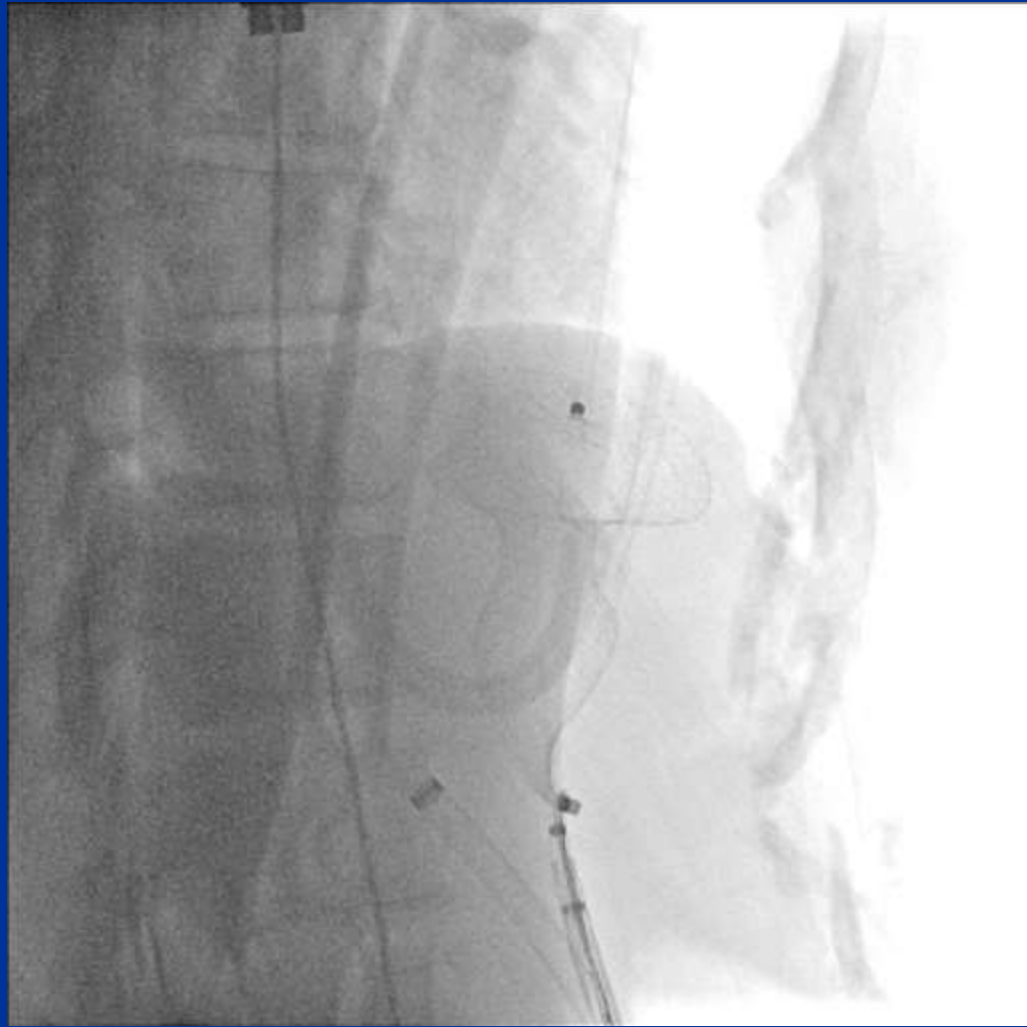
Device Embolization Events in Japan

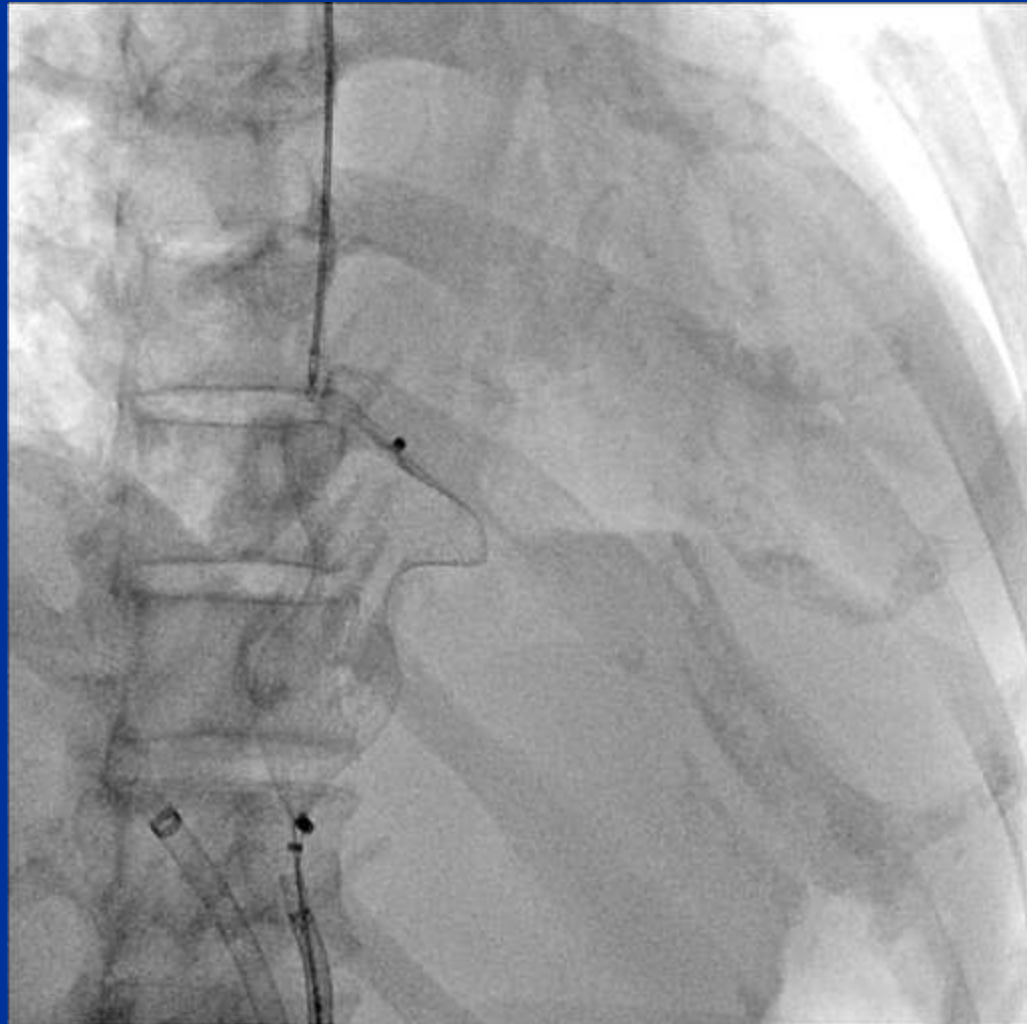
- 30/6290 confirmed embolization events (0.48%)
- Embolization side (transcatheter retrieve)
 - RA: 3 (2), RV: 5 (0), PA: 3 (3)
 - LA: 8 (4). LV: 7 (0), Ao: 4 (4)
 - Largest transcatheter retrieved device: 38 mm











Device related mortality in Japan

- None/6290

Conclusion

- Transcatheter ASD closure using Amplatzer Septal Occluder is safe and effective.
- Serious cardiovascular complications are
 - Cardiac erosion: 0.2%
 - Device embolization: 0.5%
 - Device related mortality: 0.0%

Comparison between device closure and surgical closure

	Surgery	Device
Overall mortality	0.13 %	0.093 %
Need for operation	0.39 %	0.83 %
Mortality per adverse event	1.2 %	7.6 %
Operation per adverse event	3.6 %	68.2%

Major adverse event reported to the US Food and Drug Administration

Estimated implants number from 2002 to 2007 : **18333 cases**

	Number	Percentage
Device embolization	114	0.62 %
Perforation/Erosion/Rupture	51	0.28 %
Thromboembolic complication	11	0.06 %
Residual/recurrent defect	9	0.05 %
Device infection	5	0.03 %