ASD Device Closure: Aortic Rim Deficiency & Erosions

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Disclosure
Consultant: Occlutech

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Atrial Septal defects

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Ideal Device For Catheter Closure

1. User friendly “Simple mechanics”
2. Retrievable or repositionable.
3. Effective/high complete closure rate.
4. Small delivery system.
5. Low profile within the heart.
6. Durability until full endothelialization.
7. Non-thrombogenic.
8. Preservation of flow & function despite embol.
9. Lack of ongoing morbidity.
10. Economical.

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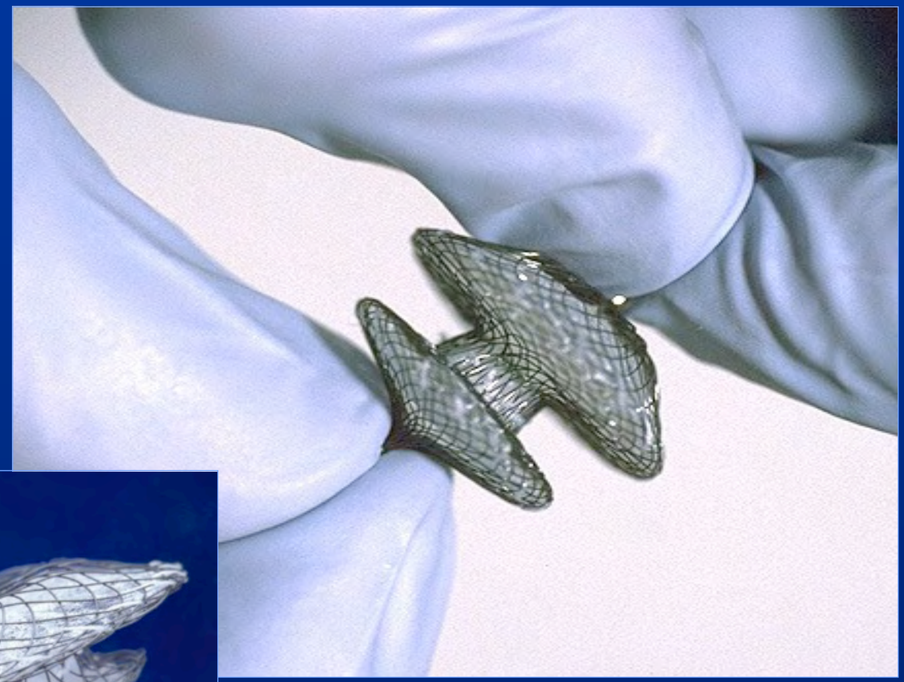
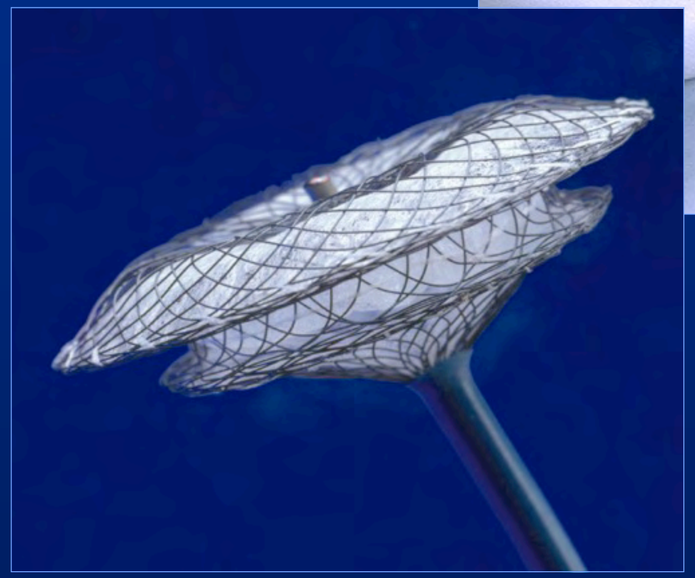
Approved Devices in US

0.004-0.0075” Nitinol
Two Flat Disks
4mm Waist
Dacron Mesh
4-40 mm Sizes
Delivery Cable
7-12F





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The Gore Helex Device

- Low profile, double-disk.
- Expanded polytetrafluoroethylene membrane bonded to a single nitinol wire frame

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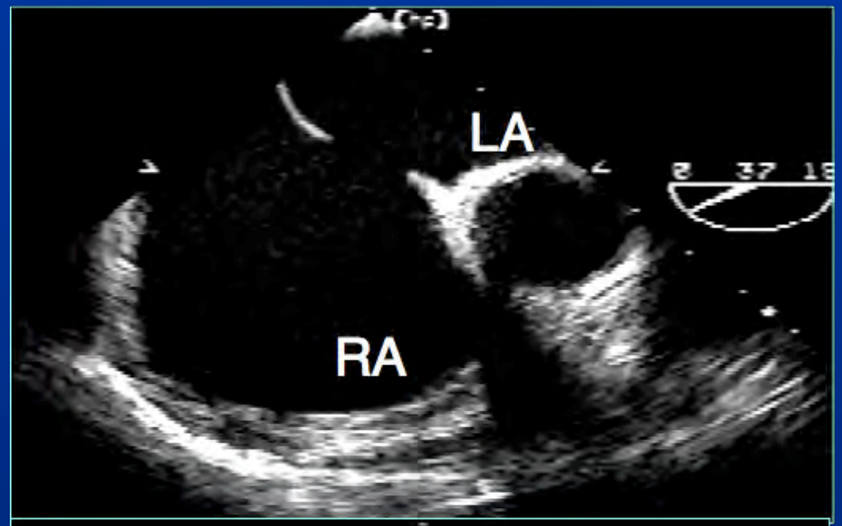

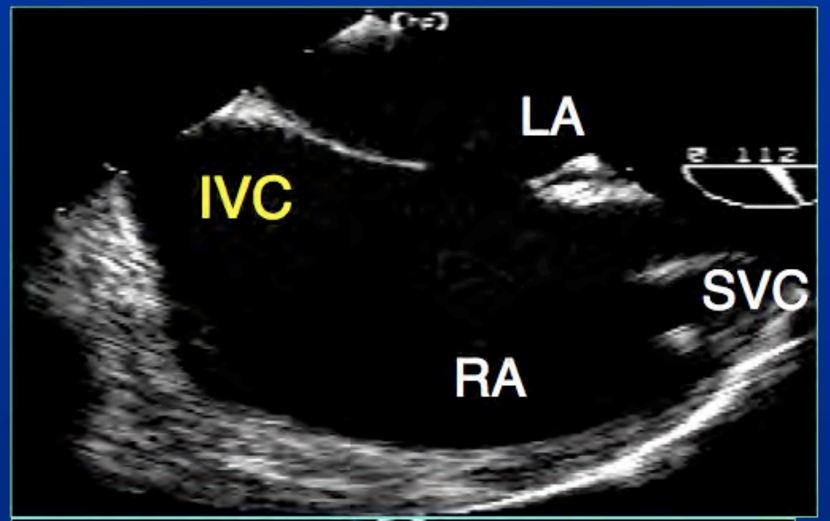

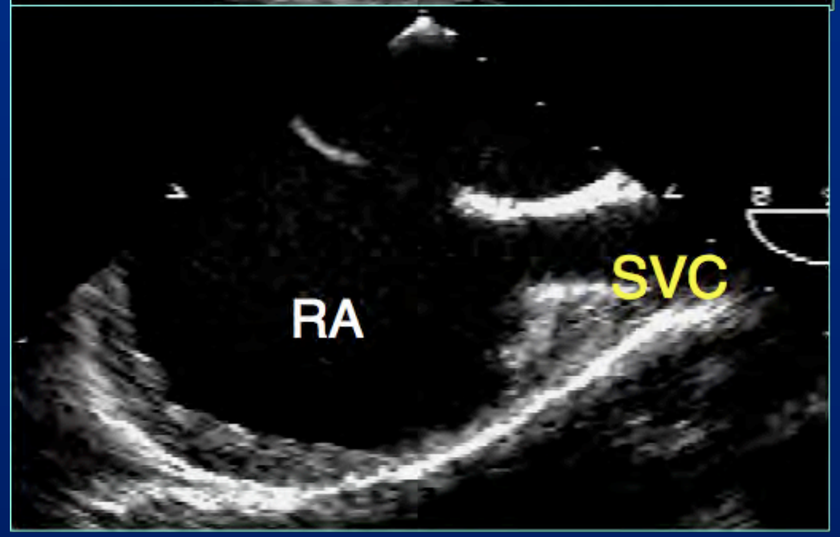

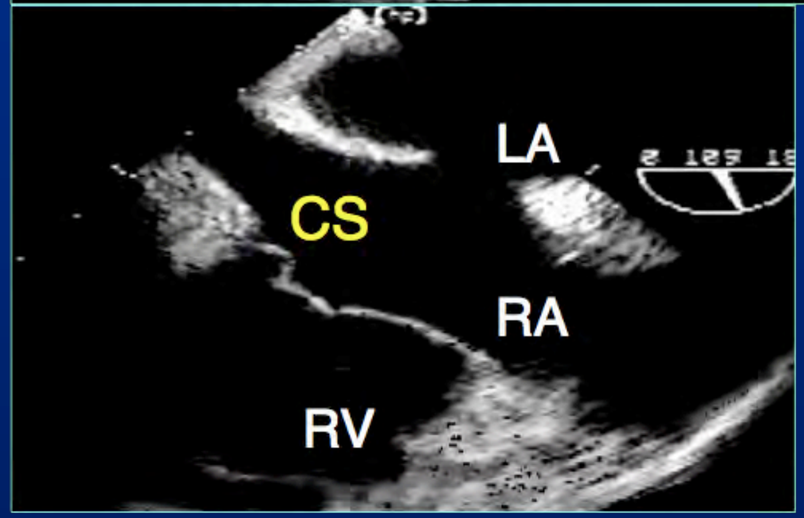

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When To Close ASDs?

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Possible Advantages of Transcatheter vs Surgical Closure

- Minimizes pain and discomfort
- Avoids incisional scar
- No exposure to cardiopulmonary bypass.
- Unlikely to require blood or blood product transfusion
- Reduction in hospital stay
- Rapid return to normal activities
- Results in cost savings

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Possible Complications

- Embolization
- Arrhythmias/CHB
- Thrombus formation
- Air Embolism
- TIA/Stroke
- Erosions/PE/Tamponade/Death
- SBE
- Frame Fracture
- Headaches/Migraines

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Comparison Between Transcatheter and Surgical Closure of Secundum Atrial Septal Defect in Children and Adults

Results of a Multicenter Nonrandomized Trial

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Chicago, Illinois; Orlando, Florida; San Francisco, California; and Minneapolis, Minnesota

OBJECTIVES This study sought to compare the safety, efficacy and clinical utility of the Amplatzer septal occluder (ASO) for closure of secundum atrial septal defect (ASD) with surgical closure.

BACKGROUND The clinical utility of a device such as the ASO can only be judged against the results of contemporaneous surgery.

METHODS A multicenter, nonrandomized concurrent study was performed in 29 pediatric cardiology centers from March 1998 to March 2000. The patients were assigned to either the device or surgical closure group according to the patients' option. Baseline physical exams and echocardiography were performed preprocedure and at follow-up (6 and 12 months for device group, 12 months for surgical group).

RESULTS A total of 442 patients were in the group undergoing device closure, whereas 154 patients were in the surgical group. The median age was 9.8 years for the device group and 4.1 years for the surgical group ($p < 0.001$). In the device group, 395 (89.4%) patients had a single ASD; in the surgical group, 124 (80.5%) ($p = 0.008$) had a single ASD. The size of the primary ASD was 13.3 ± 5.4 mm for the device group and 14.2 ± 6.3 mm for the surgery group ($p = 0.099$). The procedural attempt success rate was 95.7% for the device group and 100% for the surgical group ($p = 0.006$). The early, primary and secondary efficacy success rates were 94.8%, 98.5% and 91.6%, respectively, for the device group, and 96.1%, 100% and 89.6% for the surgical group (all $p > 0.05$). The complication rate was 7.2% for the device group and 24% for the surgical group ($p < 0.001$). The length of hospital stay was 1.0 ± 0.3 day for the device group and 3.4 ± 1.2 days for the surgical group ($p < 0.001$). [illegible] for surgery.

CONCLUSIONS The early, primary and secondary efficacy success rates for surgical versus device closure of ASD were not statistically different; however, the complication rate was lower and the length of hospital stay was shorter for device closure than for surgical repair. Appropriate patient selection is an important factor for successful device closure. Transcatheter closure of secundum ASD using the ASO is a safe and effective alternative to surgical repair. (J Am Coll Cardiol 2002;39:1836–44) © 2002 by the American College of Cardiology Foundation

Complication rate was 7.2% for the device Group and 24% for the surgical group (P<0.001)

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Outcome Comparison with OHS

STS Data

2000-2009, N=365
Mortality: Zero
Complications: 20% (arrhythmias 7.7%, pleural effusions 1.6%, pneumonia 3.3%,
mechanical ventilation >7 days 0.6%; bleeding requiring reoperation i 0.6%.

Mascio CE et al. Outcomes in adult congenital heart surgery: Analysis of the Society of Thoracic Surgeons Database. J Thorac Cardiovasc Surg 2011;142:1090-7

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Outcome Comparison with OHS

Non Congenital adult cardiac surgeons
In-hospital mortality of 2.1% for isolated ASD
5% if combined with another procedure

Mascio CE et al. Outcomes in adult congenital heart surgery: Analysis of the Society of Thoracic Surgeons Database. J Thorac Cardiovasc Surg 2011;142:1090-7

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Outcome Comparison with OHS

13 original non-randomized studies (3,082 patients) of surgery/device.
One death was reported in the surgical group (0.08%.
Complications 31% in surgical patients vs 6.6% for device.
OR for surgery *vs.* catheter-based closure for total complications was 5.4 (95% CI 2.96-9.84; p<0.0001), significantly in favor device.
Major complication 6.8% surgery vs 1.9% device.

Butera G et al. Percutaneous versus surgical closure of secundum atrial septal defects: a systematic review and meta-analysis of currently available clinical evidence. EuroInterven 2011;7:377-85

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Long-term Outcome

1. Dr. King's first patients from 1975
2. Sadiq et al: 1999-2009, N=205 patients. No mortality, no thromboembolic events, no erosions. Afib in 1.5%.
3. Post Surveillance Study: 876 patients, 2 erosions!

Sadiq M, Kazmi T, Rehman AU, et al. Device closure of atrial septal defect: medium-term outcome with special reference to complications. Cardiol in Young 2012;22(1):71-78

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Long-term Outcome

4. Krumsdorf et al. 1000 patients. Clot formation 0% for ASO; 0.8% for Helex. No thromboembolic events.

krumsdorf et al. Incidence and clinical course of thrombus formation on atrial septal defect and patient foramen ovale closure devices in 1,000 consecutive patients. JACC 2004 Jan 21;43(2):302-9

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Long-term Outcome

Kutty et al: Long-term outcome of SC vs PC of ASD.
They concluded both methods are excellent with no significant differences were found between device and surgical closure with regard to survival, functional capacity, atrial arrhythmias, or embolic neurologic events.

Kutty S et al. Long-Term (5- to 20-Year) Outcomes After Transcatheter or Surgical Treatment of Hemodynamically Significant Isolated Secundum Atrial Septal Defect. Am J Cardiol. 2012 Feb 13. [Epub ahead of print].

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Long-term Outcome

Device Fracture

Zero for ASO

0-5.5% for Helex: usually larger devices (30 or 35mm); no significant clinical sequlae.

Smith BG, Wilson N, Richens T, Knight WB. Midterm follow-up of percutaneous closure of secundum atrial septal defect with Helex septal occlude. J Interven Cardiol 2008;21:363-68

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Mechanism of Erosion

Multi-factorial:

- Rim deficiency
- Patient characteristics
- Defect shape
- Device size

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FDA MAUDE

11 & 12/2011 had 27 reports of significant adverse events.
All occurred in 2011 except 4 which occurred in 1998, 2006, 2007 and 2008 all of which were adjudicated as erosions. In all there were 6 erosions but in two of these the device was left in place with limited management. Only one erosion from 2006 was unexplained based on the data presented. The vast majority of the remaining MAUDE reports noted device embolizations primarily related to operator error or efforts to undersize the device to avoid erosion. This limited sample of MAUDE reports suggest:

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FDA MAUDE

1.That erosions are extremely rare when operator error and frank device oversizing are excluded. (Only one erosion from 2006 was unexplained).
2.That operator technical errors and inexperience are frequently the cause of most ASO adverse events.
3.There are more device embolizations and retrieval surgery reported which occur primarily to avoid potential liability by under-sizing the device.

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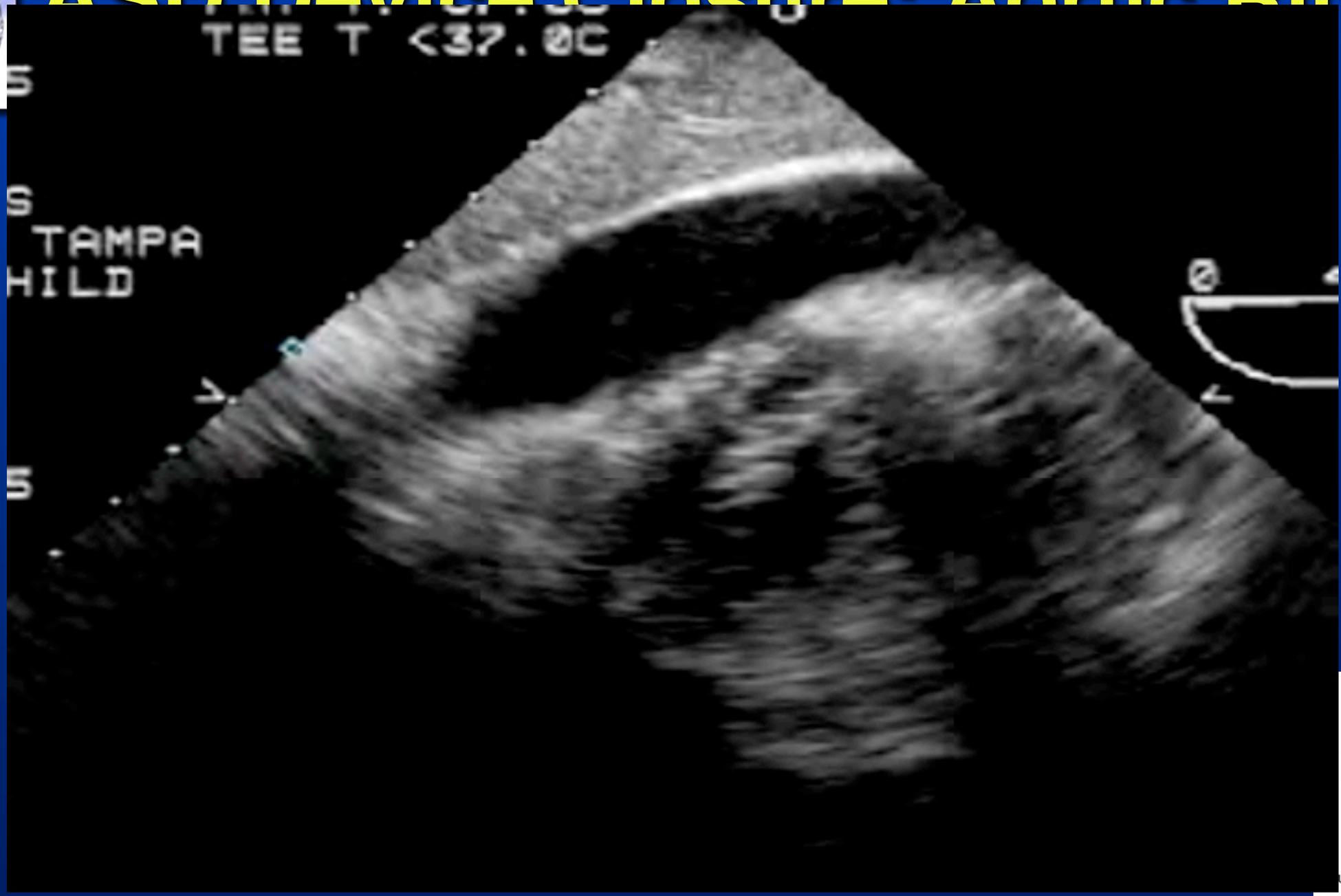

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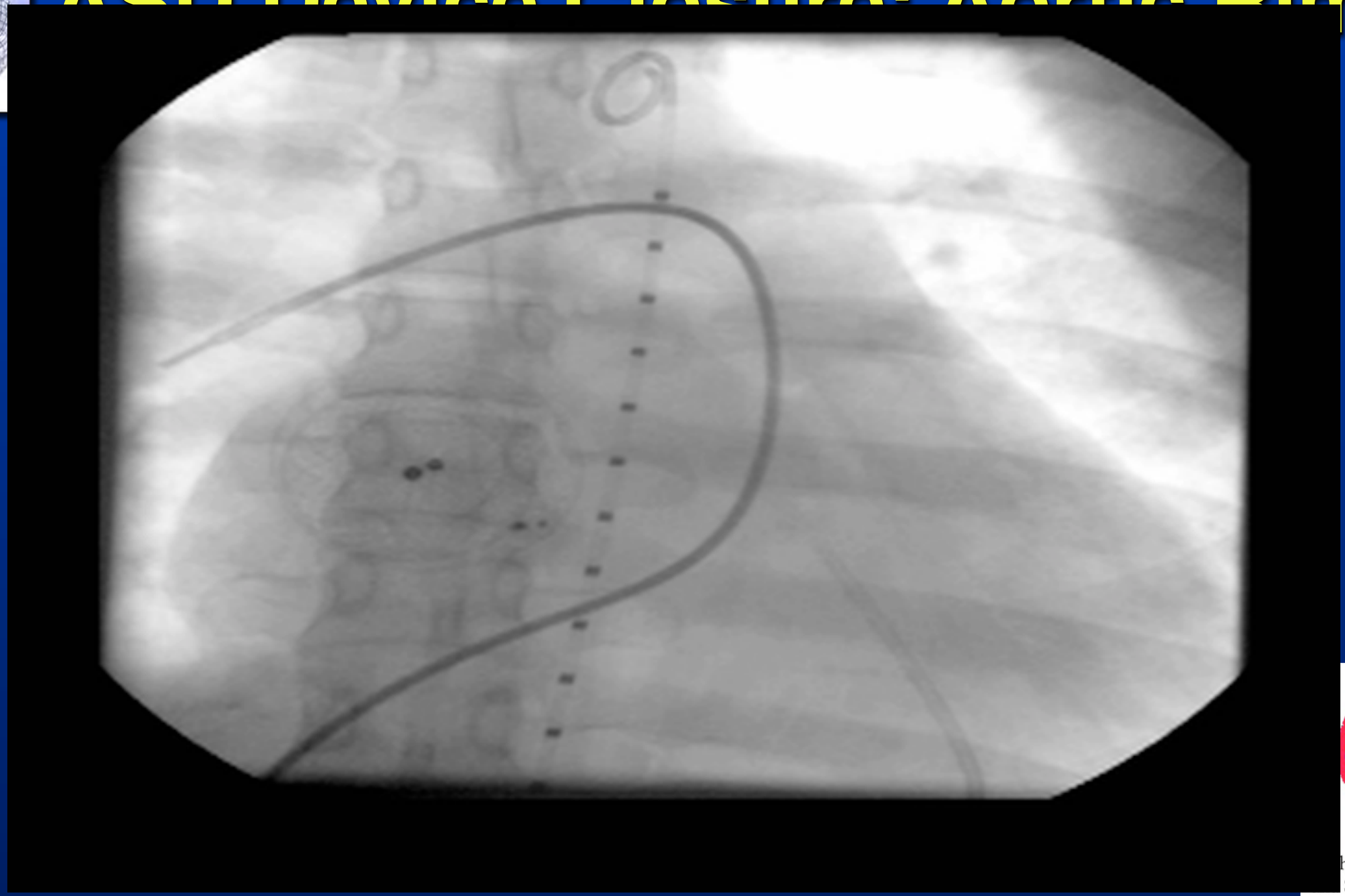

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History of Erosions

First erosion case reported in US 2002

2004: IFU updated for device sizing

2009: IFU updated about sizing with additional warning.

2011: SJM/FDA agreed to change IFU to include contra indications in patients with deficient ant/sup rim.

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Numbers of Erosions as of 3/2012

Source	Potential Erosions (n=202)	Confirmed -- Not Erosion Events (n=105)	Confirmed Erosions (n=97)
Literature	44	28	16
Field Event Report-MAUDE	122	46	76
PAS Investigator Query	10	7	3
PAS	26	24	2

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Confirmed Erosion Events By Year

Year	US	OUS	Total
1998	0	1	1
1999	0	0	0
2000	0	1	1
2001	0	2	2
2002	6	4	10
2003	6	3	9
2004	1	6	7
2005	3	3	6
2006	5	5	10
2007	5	6	11
2008	4	4	8
2009	6	5	11
2010	6	6	12
2011	2	3	5
2012	2	0	2
unknown	2	0	2
total	48	49	97

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EROSION ANALYSIS

- Hemodynamic presentation(n=97)
  - –Aortic atrial fistula – 16 (16.5%)
  - –Tamponade with a hemo PE -68 (70.1%)
  - –PE or Hemo PE or tamponade – 13(13.4%)
- Site of erosion
  - –LA – 47(28 involving the Ao)
  - –RA – 26(22 involving the Ao)
  - –RA & LA – 9
  - –Unknown - 15

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EROSION MORTALITY RATE

	Number of Deaths from Erosion	Mortality Rate
SJM (WW)	8	0.004-0.015%
SJM (US)	6	0.008-0.016%

- No deaths occurred in patients younger than 15 years
- All reported deaths occurred within 16 months of implant
- Each event confirmed presence of device oversizing, defi ient anterior superior rim, or both

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EROSION ANALYSIS

- Management
  - –Explanted 74
  - –Not explanted 21
    - •Repair of the erosion site
    - •Pericardiocentesis alone
  - –Unknown – 2

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ROOT CAUSE ANALYSIS SUMMARY

97 Worldwide erosion cases have been identified in association with the on-label use of the AMPLATZER ASO device from December 1998 to March 2012:

- 48 US/49 OUS
- 40% Pediatric
- 70% Female
- 75% involved device sizes > 18mm
- 87.6% occurred within the first year of implants
- 57% of pediatric erosion events occurred <72 hours
- 35% of adult erosions occurred <72 hours

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ROOT CAUSE ANALYSIS SUMMARY

The most frequently observed relationship to erosion was oversizing and deficient anterior superior rims

- 40% of all erosion events were oversized
  - 31% pediatric
  - 46% adult
  - Declining from earlier reported 50%
- 90% of all erosion cases had anterior-superior rim deficiency
  - 100% pediatric
  - 84% adult
- Every erosion case except 2 had either a deficient anterior superior rim or were oversized

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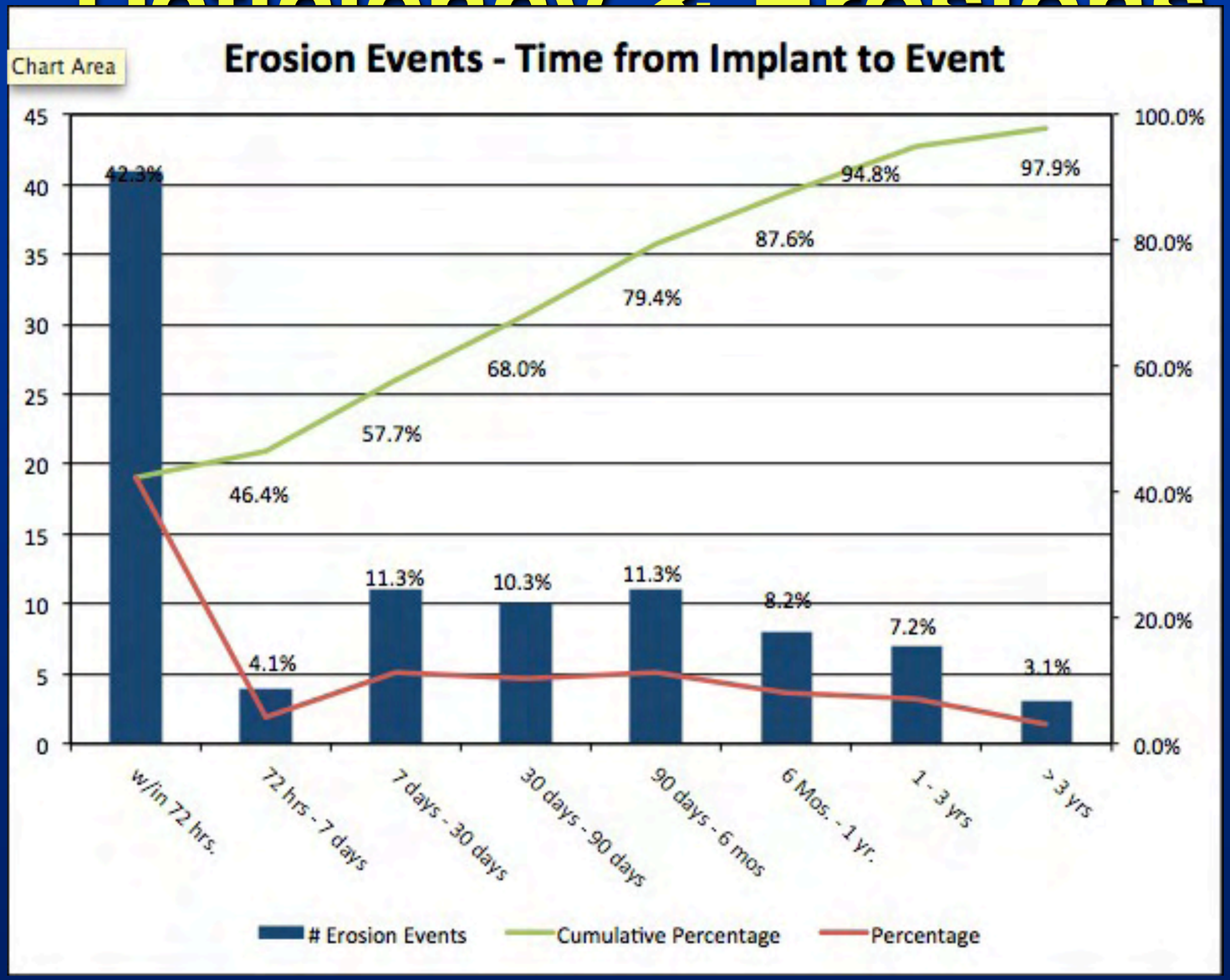

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EROSION INCIDENCE RATE

	# of Erosions	Sales	With Cards	Incidene
SJM (WW)	97	223,965	55,000	0.04-0.17%
SJM (US)	48	72,566	38,000	0.07- 0.11%
	Number of Erosions	Number of Implants	Incidence	
Pivotal Trial	0	452	0%	
PAS	2	970	0.23%	

Note: PAS erosion events are included in the 48 US erosion events

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Recommendations by the FDA

1. Retro aortic rim deficiency-warning vs contra indications
2. Record keeping of any device implanted
3. Work with ASE to come up with guidelines for device implantation and follow up.
4. Notify all patients of potential erosions
5. TTE within a week from implant
6. A letter to all cardiologists

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Conclusions

Most secundum ASDs are amenable for device closure.

The procedure is generally safe, but EROSIONS are fact!!

Appropriate device sizing may eliminate erosions!

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Acknowledgment

William E. Hellenbrand, MD

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