Left Atrial Appendage Closure

Technique, Risk, and Benefit

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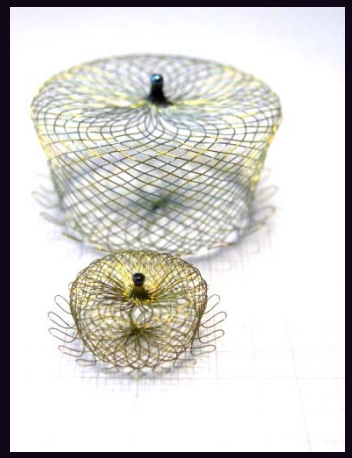
Percutaneous LAA Closure Devices

PLAATO
(no longer developed)

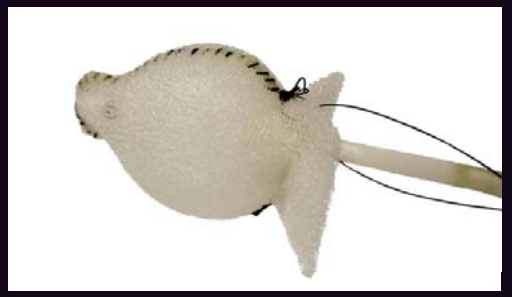
Watchman®
Cardiac Plug

Amplatzer®
Cardiac Plug

Coherex
WaveCrest



Occlutech LAA

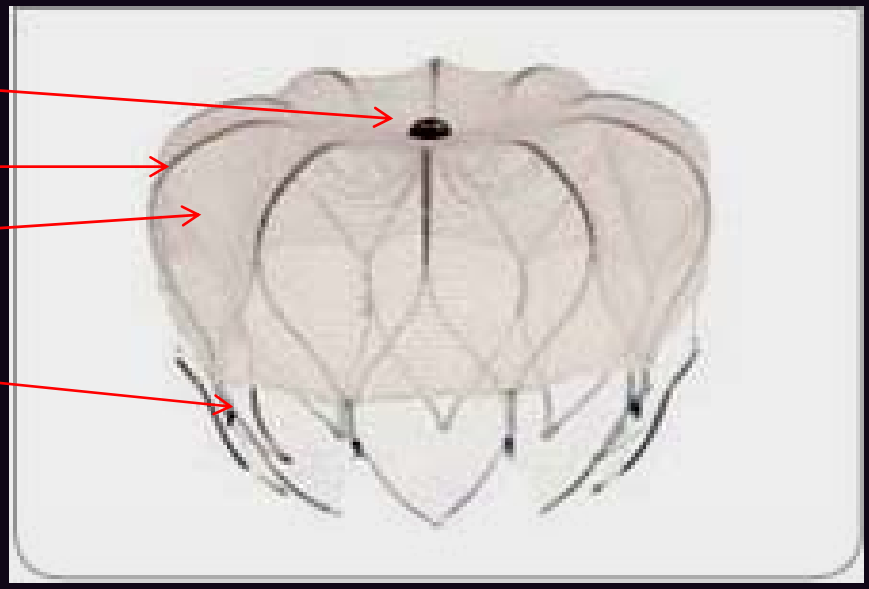


Sideris patch

Other - Gore

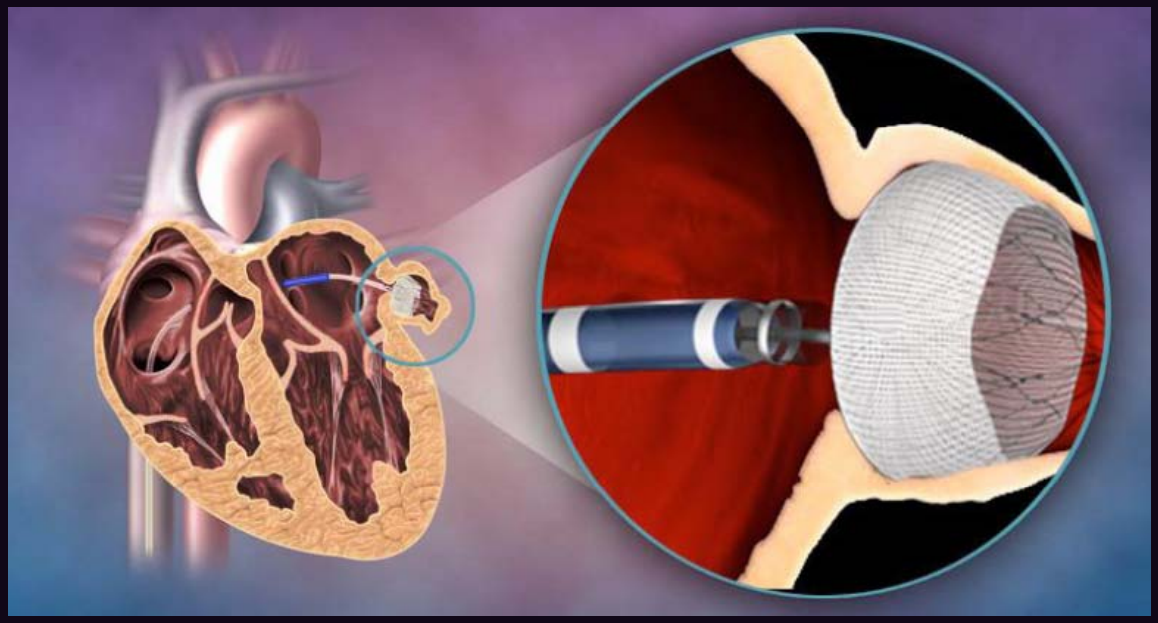
Watchman LAA Closure System
(Atritech/Boston Scientific)

- Threaded insert
- Nitinol frame
- 160 µ PET fabric
- Barbs
- Various sizes (21, 24, 27, 30, 33 mm)



The barbs & radial force ensure fixation in the LAA wall

LAA Closure



Purpose:

- To prevent ischemic stroke or systemic embolism caused by *embolization of LAA thrombi in pts with AF**
- To eliminate the need for *long-term anticoagulation* therapy.

*91% of all thrombi in patients with NVAF is found in the LAA (SPAF III study).

Exclusions: TTE/TEE ± Contrast CT Scan

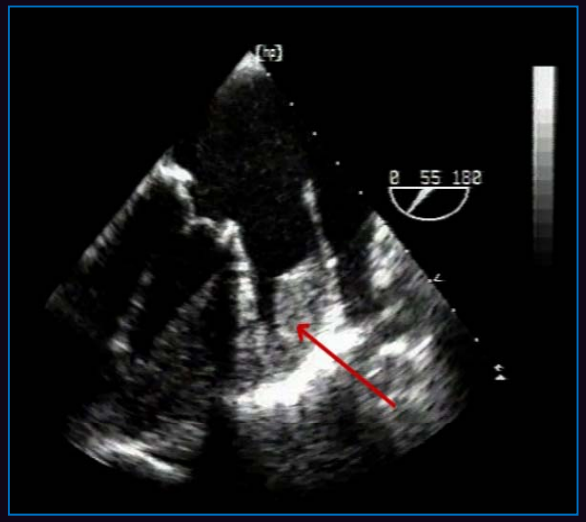
Watchman exclusion criteria:

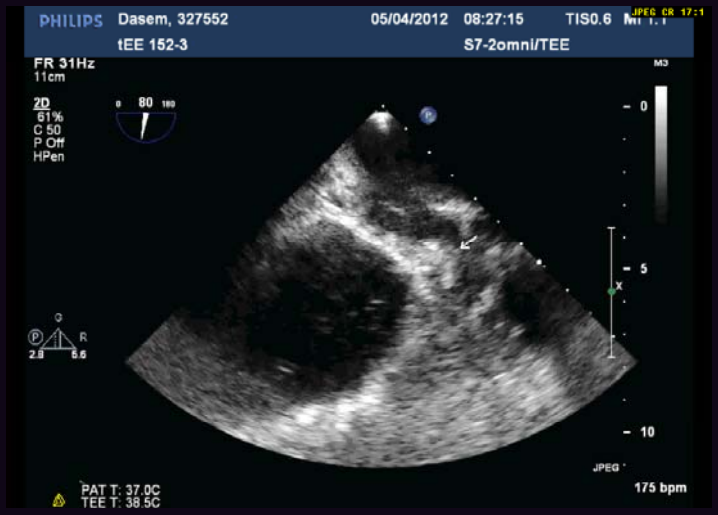
1. Intracardiac thrombus or spontaneous echo-contrast (SPEC) on TEE
2. Cardiac tumor
3. Endocarditis
4. Situs inversus abdominalis/thoracalis
5. Maximum LAA ostium width > 32 mm or < 17 mm in at least 3 consecutive views
6. Maximum LAA length insufficient to accommodate the device
7. Significant mitral stenosis (MVA < 1.5 mm^2)
8. Existing pericardial effusion > 2 mm ± 1 mm
9. LVEF < 30% on TTE
10. High risk PFO that presents with either one of the following:
    1. atrial septal aneurysm with a total excursion > 15 mm & total length > 15 mm
    2. large shunt detected within 3 cardiac cycles
11. Complex atheroma of the aortic arch or descending aorta with a mobile plaque (thickness ≥ 4 mm)

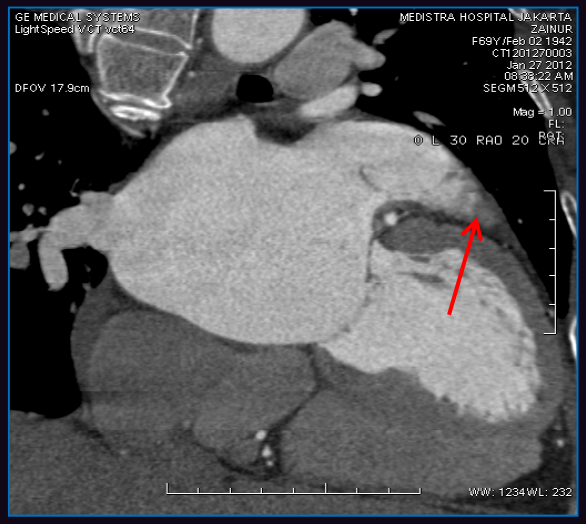
Steps Of The Procedure

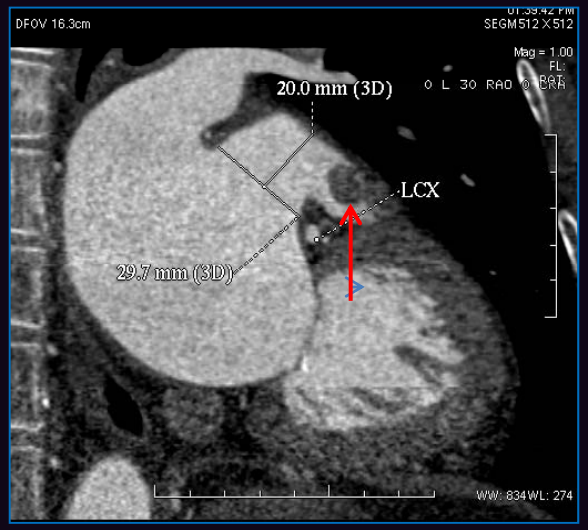
- Baseline TTE/TEE and/or contrast CT scan
- Choosing the Watchman Device (WD)
- Transseptal puncture (Fluoro/TEE guided)
- Access to LAA (Watchman Access System [AS])
- Delivery, positioning & deployment of Watchman Device
- Checking Watchman Device prior to final deployment
- Final TEE assessment
- Management of venous access site

LAA Thrombus: One of the most important contraindication !!







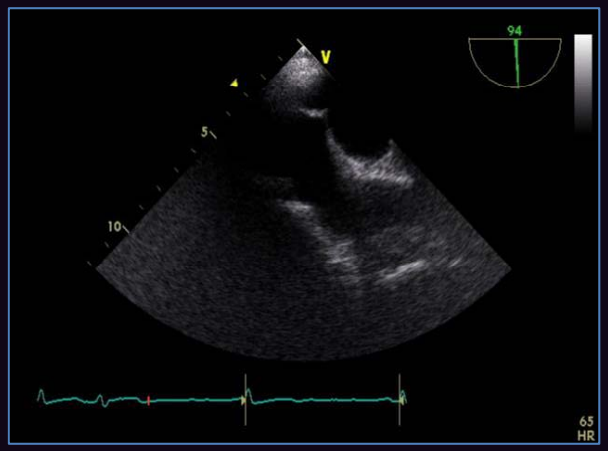


Appropriate Location During Transseptal Puncture
Will Ease The Procedure & Prevent Tamponade

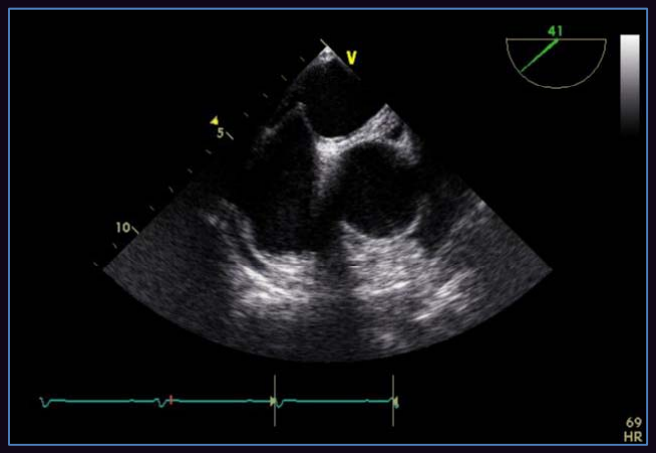
Fluoroscopy : AP or RAO 20^0 & LAO 90^0

TEE : essential !! *(midfossa & posterior)*

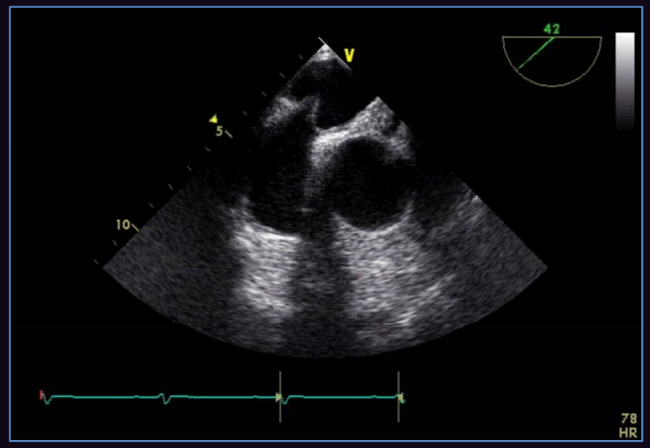
Bicaval view, 90-100^0



Short axis view, 35-50^0



The sheath/needle tip is indicated by *IAS tenting*.



Avoid excessive tenting.
Use of *stylet or back end of a coronary guide wire* may help penetration. If the IAS is very thick & resistant, *electrocoagulation* may also help

TEE & Angio Corelations

Following successful transseptal puncture, before doing the measurements:

- Check LAA pressure. *Infuse fluids if < 10 mmHg*.
- Re-check until it is > 10 mmHg

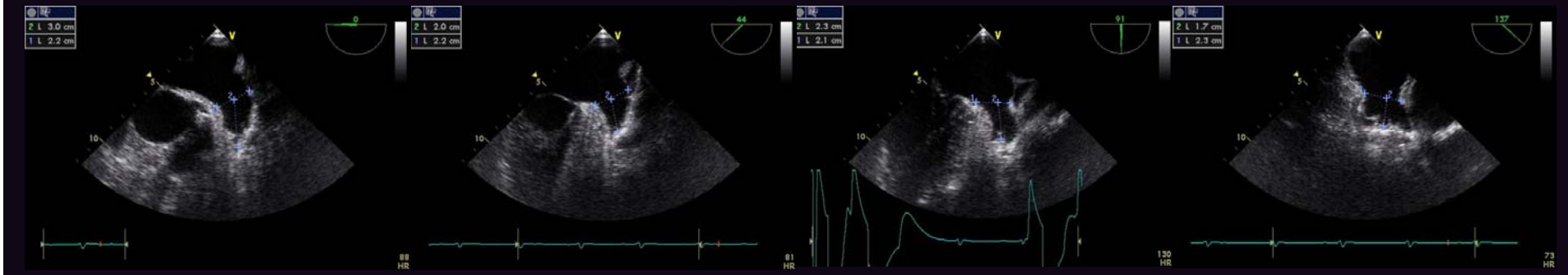
TEE View	Angio view
0^0	AP cranial
45^0	RAO 30^0 cranial 20^0
90^0	RAO 30^0
135^0	RAO 30^{00} caudal 20^0

Maximal diameter measured usually in 0^0 & 135^0

Working view:

- *TEE: 135^0*
- *Angio: RAO 30^0 caudal 20^0* (maximal angio diameter)

Choose Device Size Based On Measurements By TEE

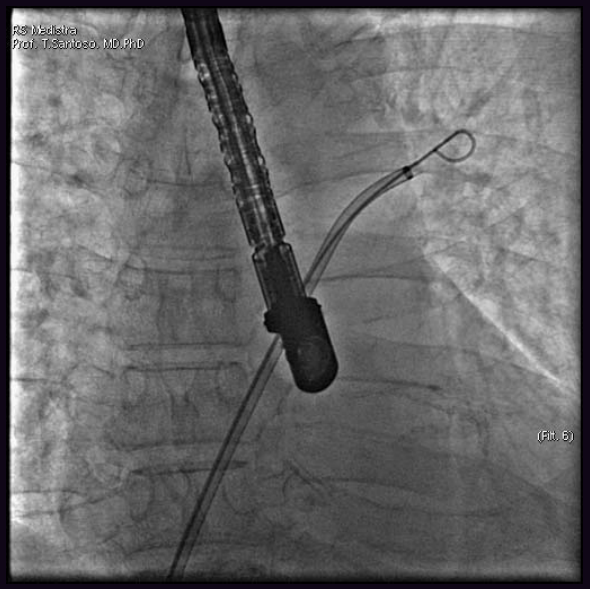


Record the measurements of the *maximum LAA ostium diameter & length* or the primary LAA lobe at 0^0, 45^0, 90^0 and 135^0

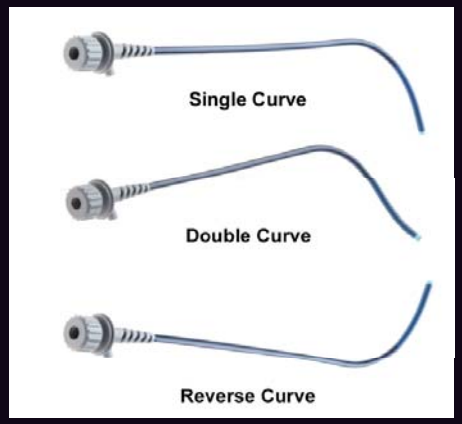
WATCHMAN Device (WD) Size Options	
Diameter	Standard profile length
21 mm	23.5 mm
24 mm	27.5 mm
27 mm	30.5 mm
30 mm	33.9 mm
33 mm	36.0 mm

Choose a device *20% bigger* than the maximum measurement

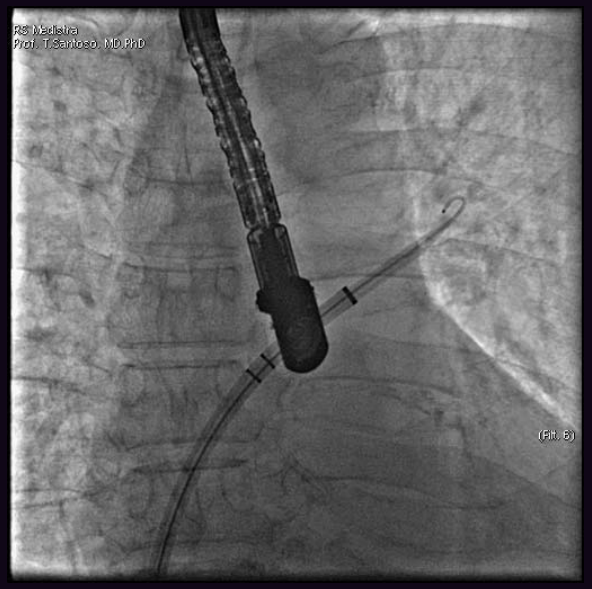
Access To The LAA



Pull out the needle & dilator, then advance *extra length support GW into the LUPV*. Remove the crossing sheath.

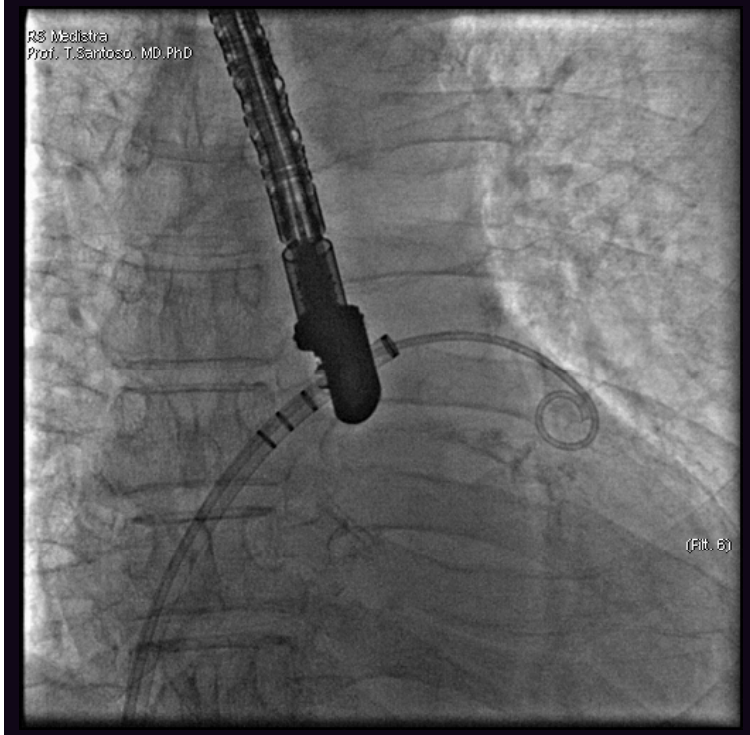


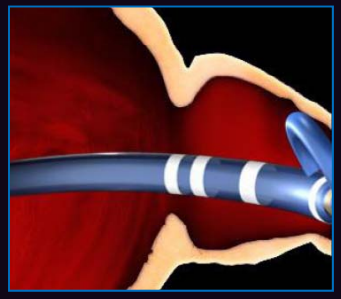
Watchman Access System (AS) curve configurations. Most commonly used is the *double curved* AS

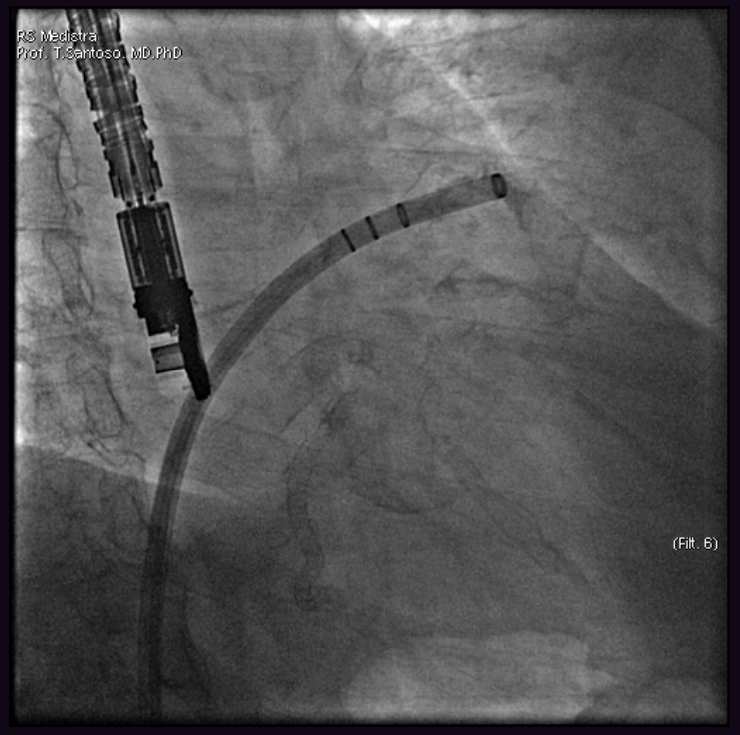


After flushing, insert AS & dilator over GW, then advance toward the *center of LA*. Hold dilator & GW in place & continue advancing AS to its initial position in the LA. Remove dilator & GW, leaving AS at initial position

Access To The LAA



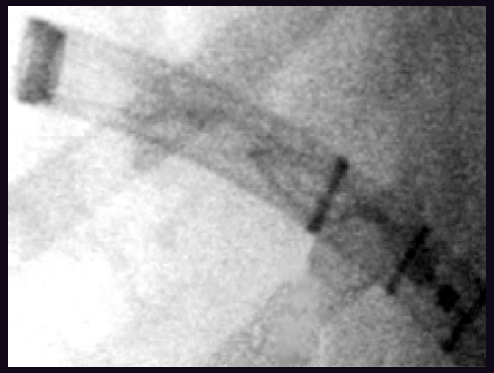




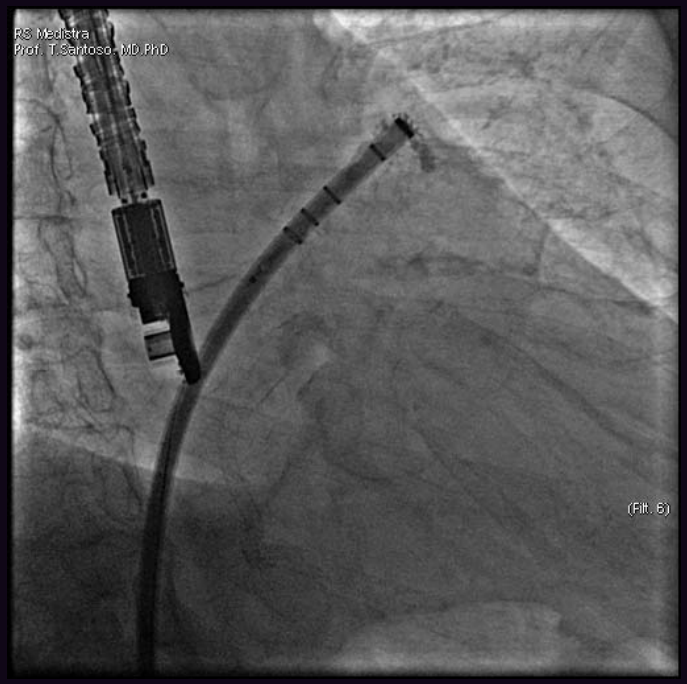
Insert pigtail into AS & advance to LAA. Rotate to desired orientation. Advance sheath. Cine-angio. *Avoid advancing past pigtail loop (prevent perforation)*

Make sure the proximal marker band that corresponds to the maximum device diameter is *at or just distal to the LAA ostium.* Remove pigtail catheter.

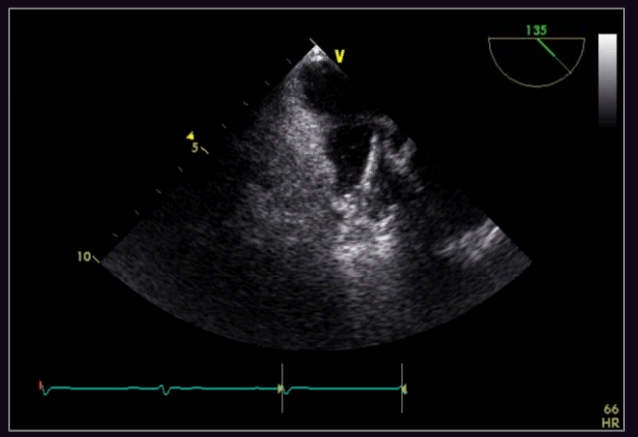
Delivery, Positioning & Deployment Of WD



Assure that the Watchman device (WD) is securely attached to the core wire. *Align the WD with the distal marker band of delivery catheter (DC)*.

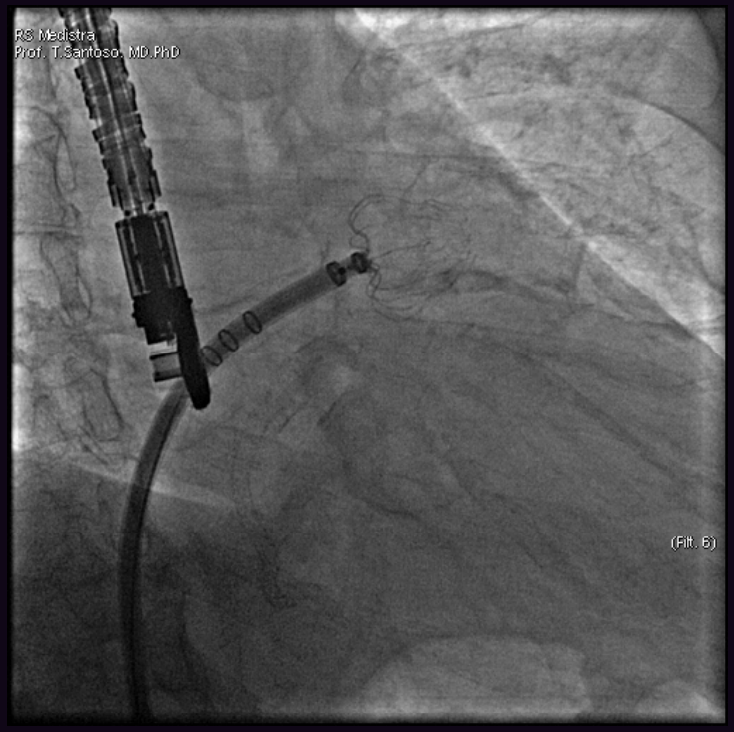


Flushing of DC, advance it into the AS. *Stop advancing* when the marker bands of the DC & AS are aligned with one another. *Snap AS to the DC* to make it a single AS/DC assembly

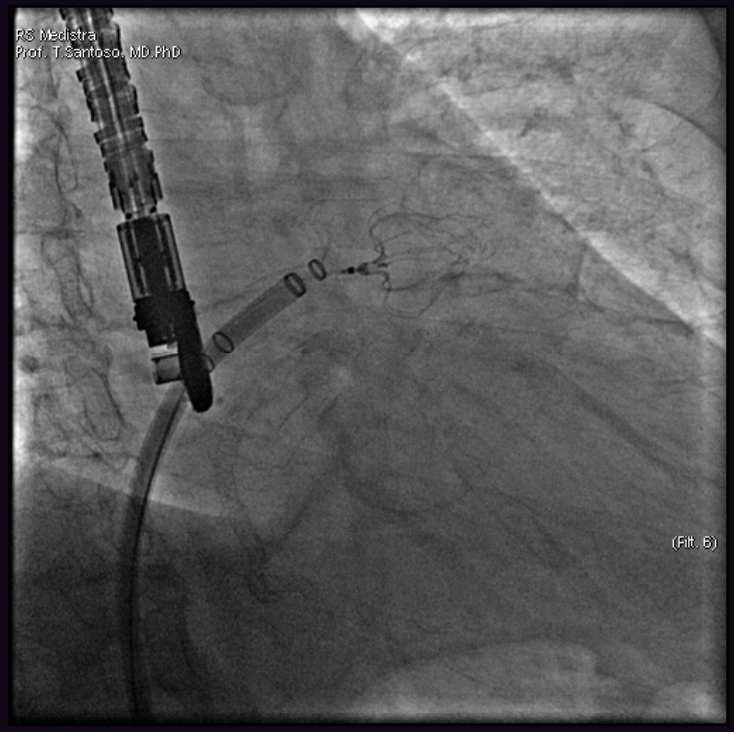


Secure the position of the AS/DC, loosen the hemostasis valve on DC. *Slow, hold respirator.* Then *slowly retract the AS/DC assembly until the WD is completely deployed (5 seconds)*

Checking Watchman Device Deployment

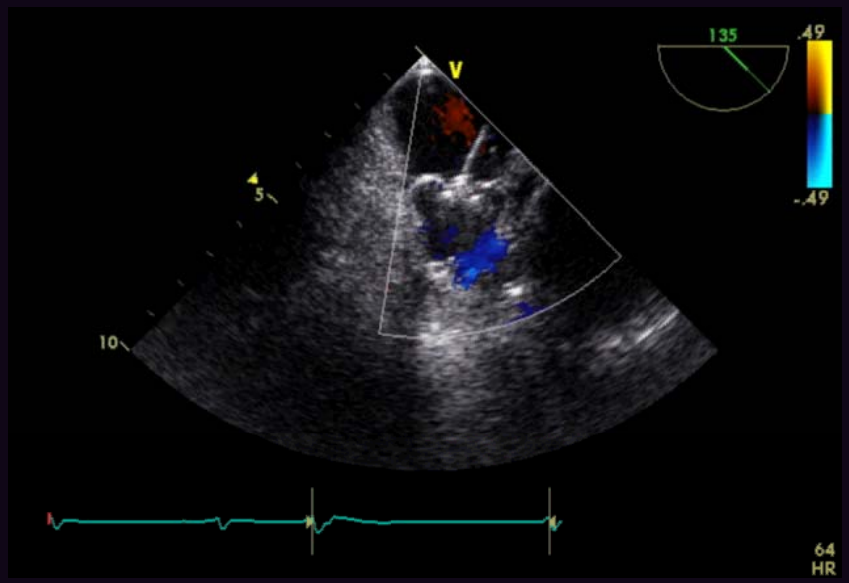


After deployment of WD, confirm WD position & seal on cine with contrast in multiple views. The WD should be positioned *at or distal to the LAA ostium & protrude only slightly into the LA*



Withdraw AS/DC assembly *about 1 cm* from proximal face of WD, leaving core wire attached. Perform *tug test*. The WD should *move in unison* with the LAA.

Checking Watchman Device Deployment



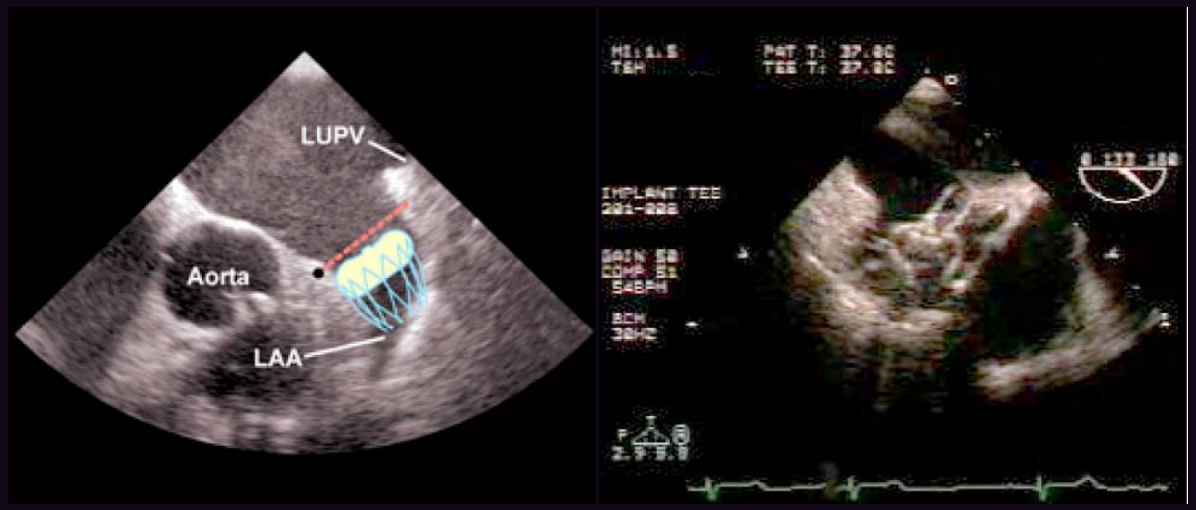
Check device protrusion into the LA

Original size	Acceptable protrusion
21 mm	≤ 4.2 mm
24 mm	≤ 4.8 mm
27 mm	≤ 5.4 mm
30 mm	≤ 6.0 mm
33 mm	≤ 6.6 mm

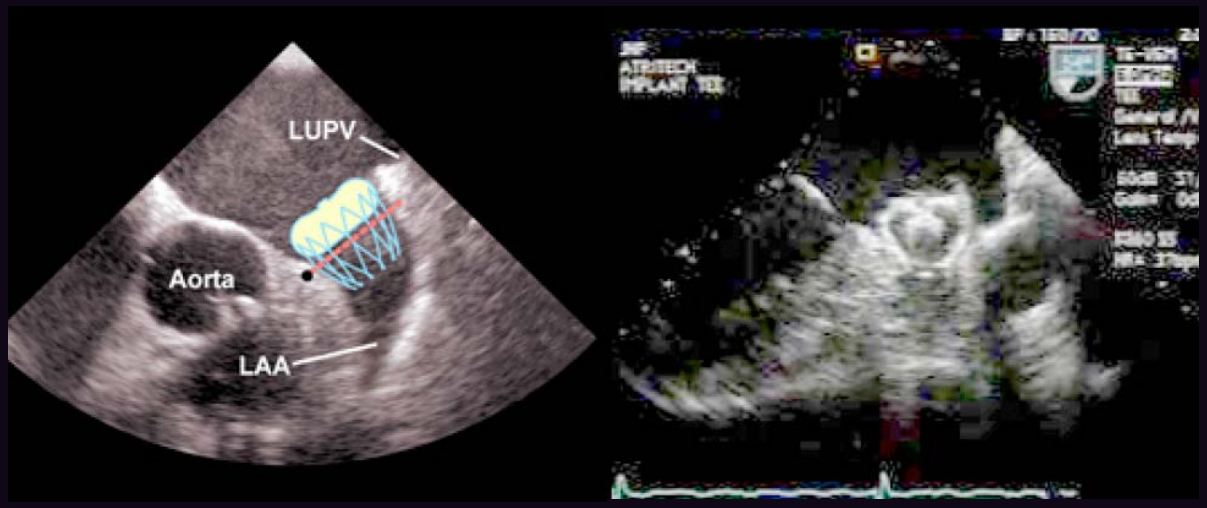
- Device size : 80-92% of its original size
- Device seal :
  - Ensure all LAA lobes are *distal to the proximal face* of the device.
  - With color Doppler, residual jet flow around the margins of the device ≤ 3 mm ± 2 mm

Avoid Improper Device Deployment

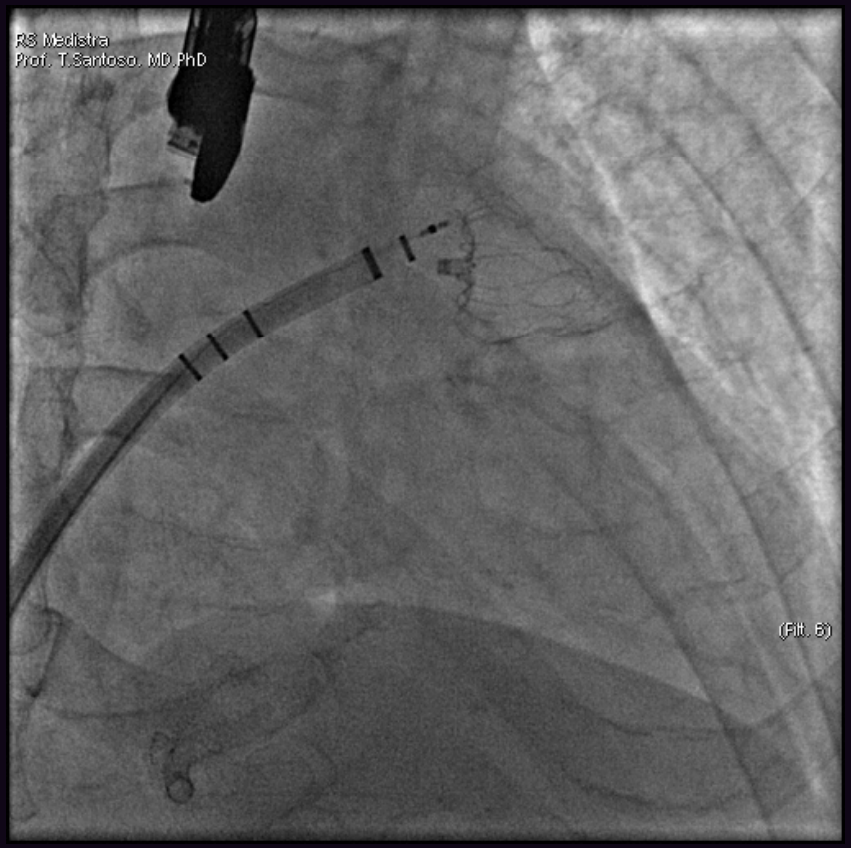
Device too distal:
Needs partial recapture & repositioning



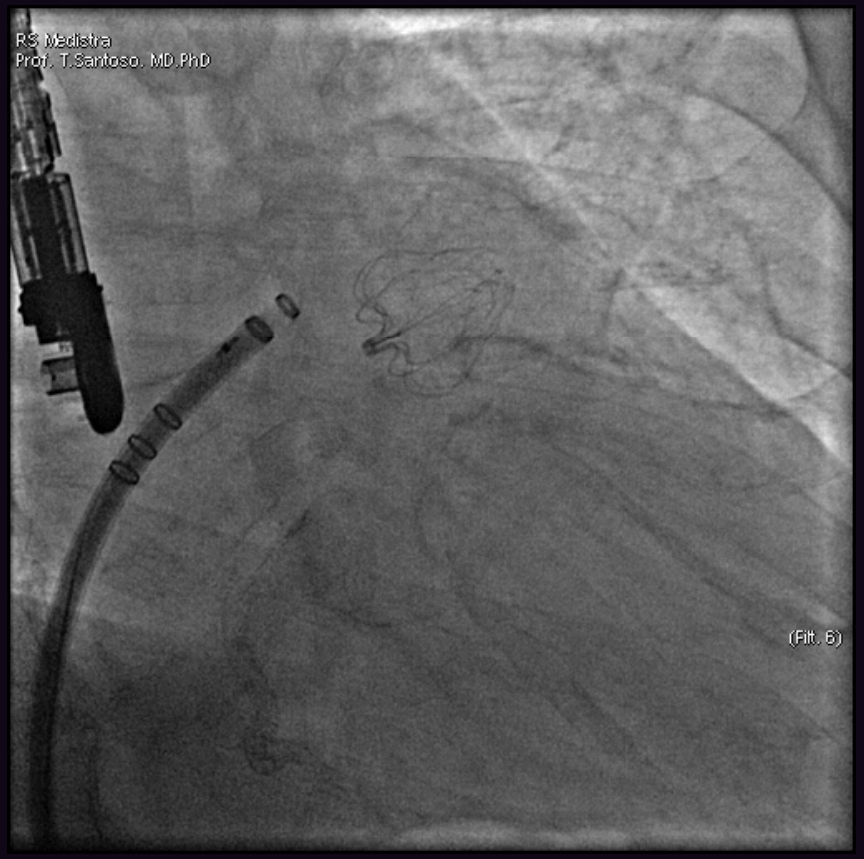
Device too proximal:
Needs full recapture & placement of a new device



Device Release

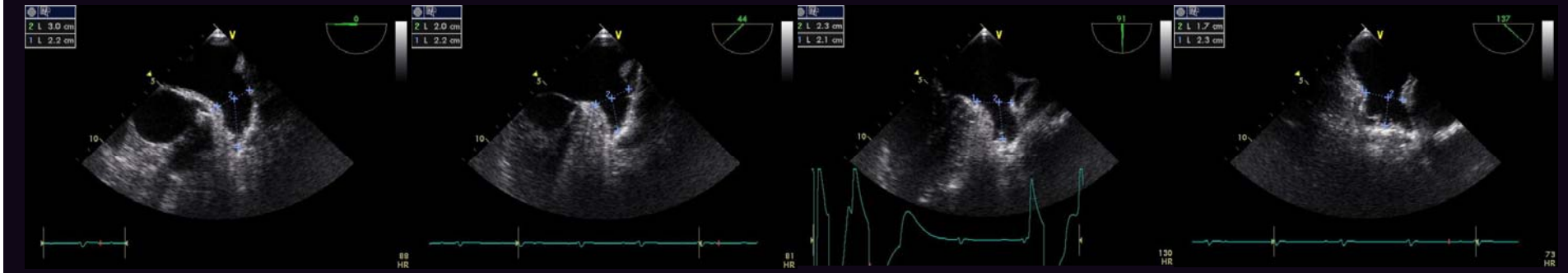


Rotate DC control handle *counterclockwise 3-5 full turns to unscrew* the core wire from the WD

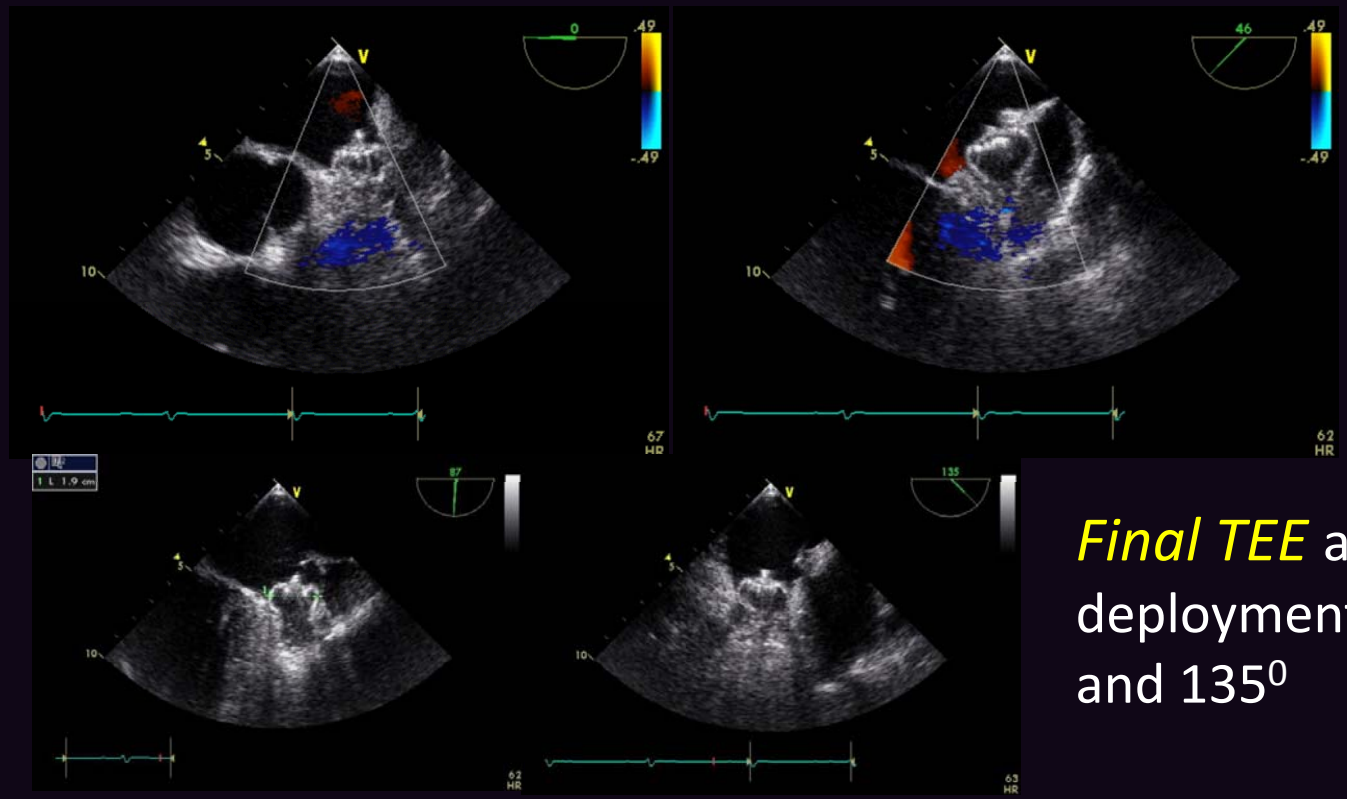


Obtain final image of the implanted WD. Check for pericardial effusion on echo

Final TEE Assessment



Baseline TEE at 0^0, 45^0, 90^0 and 135^0



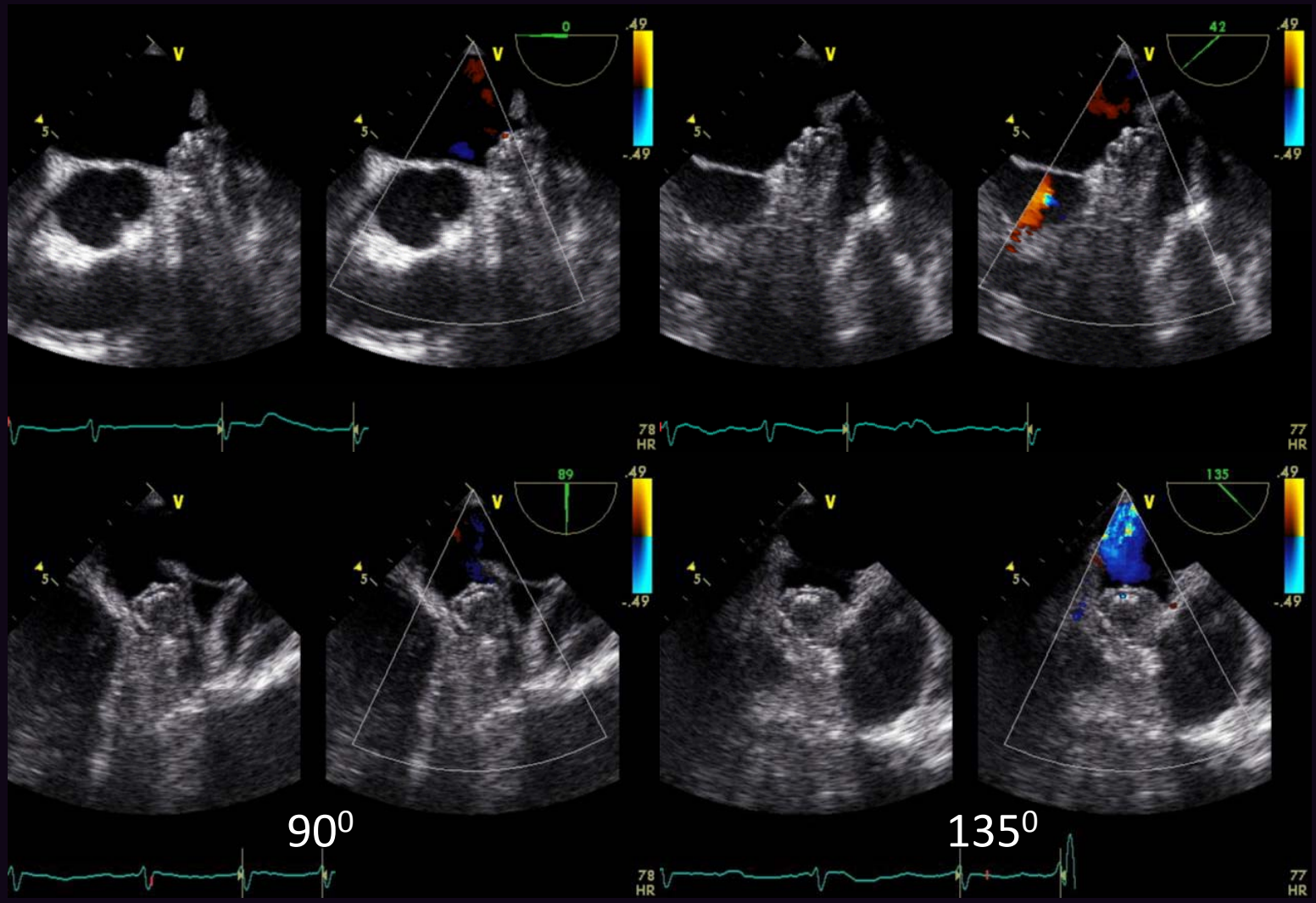
Final TEE after WD deployment at 0^0, 45^0, 90^0 and 135^0

Important Complications of LAA occlusion

Risk	Prevention
Tamponade – cardiac perforation	TEE guided transseptal puncture, great care in advancement of sheath in LAA, device deployment, or recapturing of device
Stroke – air or clot embolism	Look of LAA clot, great care in sheath de-airing & flushing, adequate anticoagulation (ACT > 200 secs)
Inappropriate device placement -- residual leaks & device embolization	TEE & fluoro guided proper device placement
Vascular complications – bleeding, hematoma, AV fistula	12F venous access sheath, 2nd small venous line (for fluids /autotransfusion), appropriate local hemostasis (manual compression, figure of 8 subcutaneous suture, or single Proglide). Avoidance of low
	molecular weight heparin for 12 hrs after procedure

Kar S. TCT 2011

Follow Up At 45 Days



Watchman Clinical Studies

Study	Patients	Sites	Remarks
Pilot	66	8	• 318 pt yrs of f-up • 30 pts with 5+ yrs of f-up
PROTECT AF	800	59	• 1,500 pt yrs of f-up • 27 months average f-up per pt
Continued Access Registry (CAP)	566	26	• Significantly improved safety results
ASAP	143	4	• Treat pts contra-indicated for warfarin
EVOLVE	69	3	• Evaluate next generation WATCHMAN
PREVAIL	268	≤50	• Same endpoints as PROTECT AF • Revised inclusion/exclusion criteria • Initiate enrollment October 2010

TOTAL 1912

PROTECT AF Study

Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial

David R Holmes, Vivek Y Reddy, Zoltan G Turi, Shephal K Doshi, Horst Sievert, Maurice Buchbinder, Christopher M Mullin, Peter Sick, for the PROTECT AF Investigators*

- WATCHMAN first implanted 2002
- Initial human experience in 66 pts reported 2007

PROTECT AF:

- Prospective study of pts with *non-valvular AF ; CHADS2 score ≥ 1* randomised *2:1 to WATCHMAN or warfarin*
- *Endpoints :*
  - *Efficacy:* stroke, CV death, systemic embolism
  - Safety: major bleeding, pericardial effusion & device embolisation.
- *Warfarin 45 days, dual AP therapy to 6 months, then aspirin alone*

- 707 pts recruited : WATCHMAN – 463 / Control - 244
- Followed for 1065 pt years, mean f-up 18 +/- 10 pt months

Holmes DR, et al.Lancet 2009; 374:534-42

PROTECT AF - Proof of Concept

Per-Protocol: Primary Efficacy Results

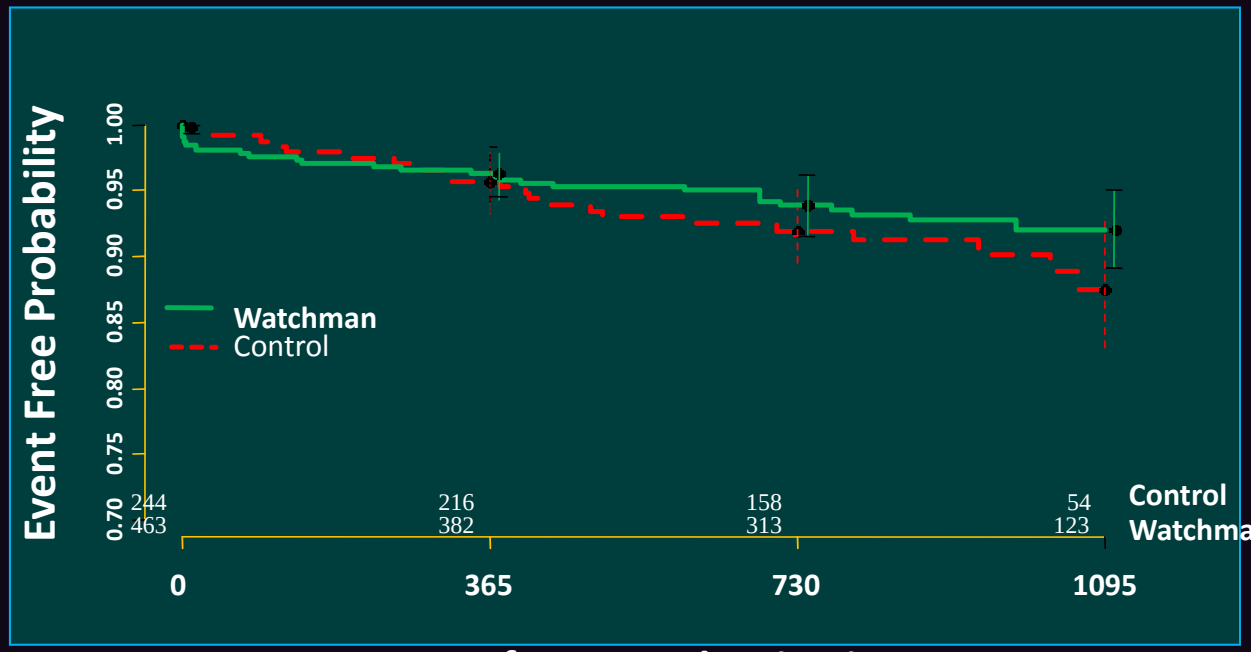
Cohort	WATCHMAN		warfarin		Rel. Risk (95% CI)		Posterior Probabilities*	
	Rate (95% CI)		Rate (95% CI)				Non-Inferiority	Superiority
600 pt-yrs	2.5	1.1-4.8	5.4	2.7-8.6	**0.47**	0.19-1.21	0.999	0.938
900 pt-yrs	2.1	1.0-3.7	4.7	2.6-7.2	**0.44**	0.20-1.03	>0.999	0.971
1050 pt-yrs	1.9	1.0-3.2	4.6	2.6-6.8	**0.40**	0.19-0.91	>0.999	0.986

*Closure without complication and warfarin discontinued

60% lower relative risk in WATCHMAN Group

Holmes DR, et al.Lancet 2009; 374:534-42

PROTECT AF: Primary Efficacy K-M Estimates

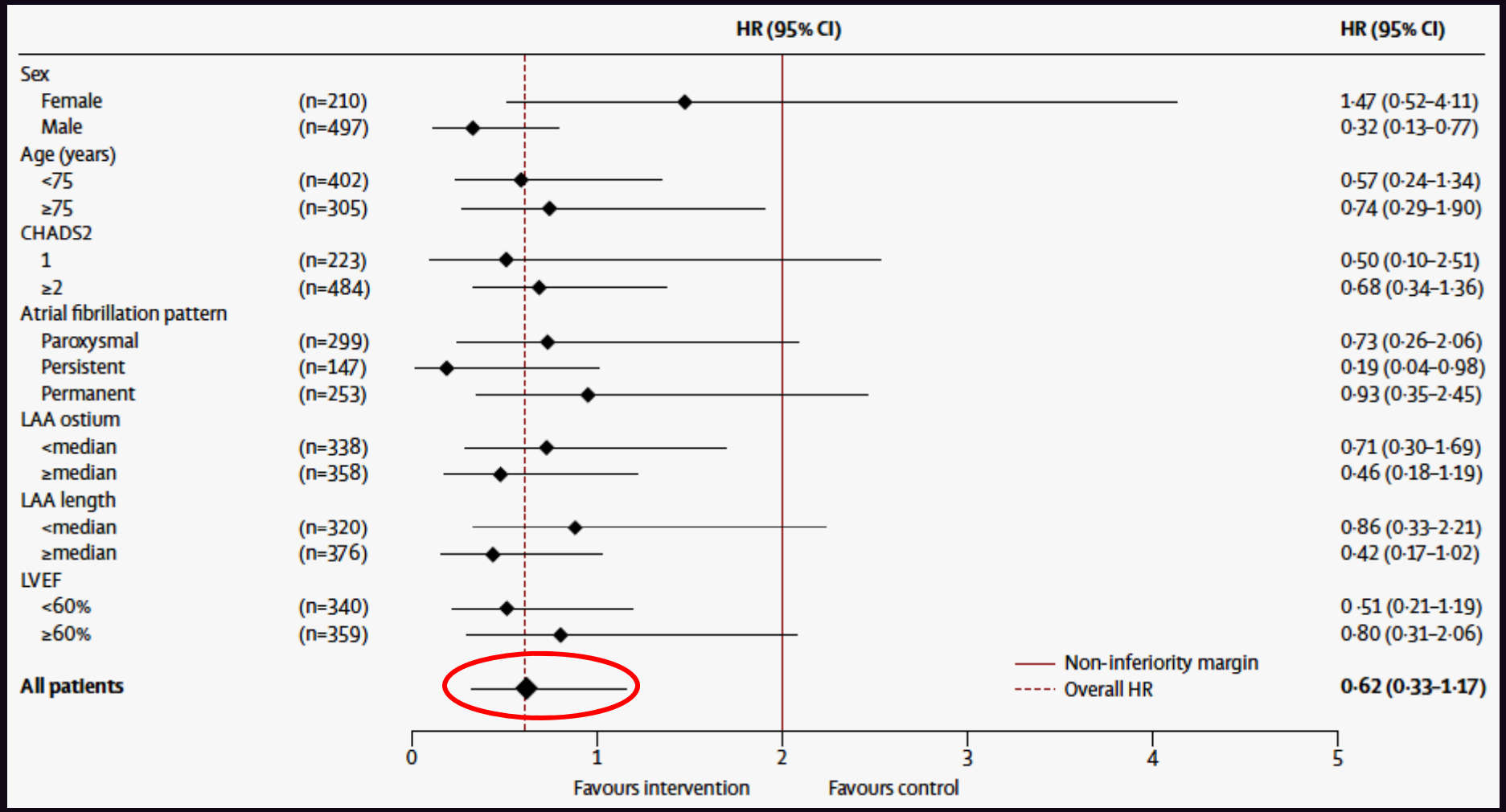


Cohort	1 Year Event Rate (95% CI)	2 Year Event Rate (95% CI)	3 Year Event Rate (95% CI)
WATCHMAN	3.7 (1.9, 5.4)	6.1 (3.8, 8.5)	7.9 (5.0, 10.9)
Control	4.3 (1.7 , 6.9)	8.0 (4.5, 11.6)	12.5 (6.9, 18.1)

1500 Patient-year Analysis

Holmes DR, et al.Lancet 2009; 374:534-42

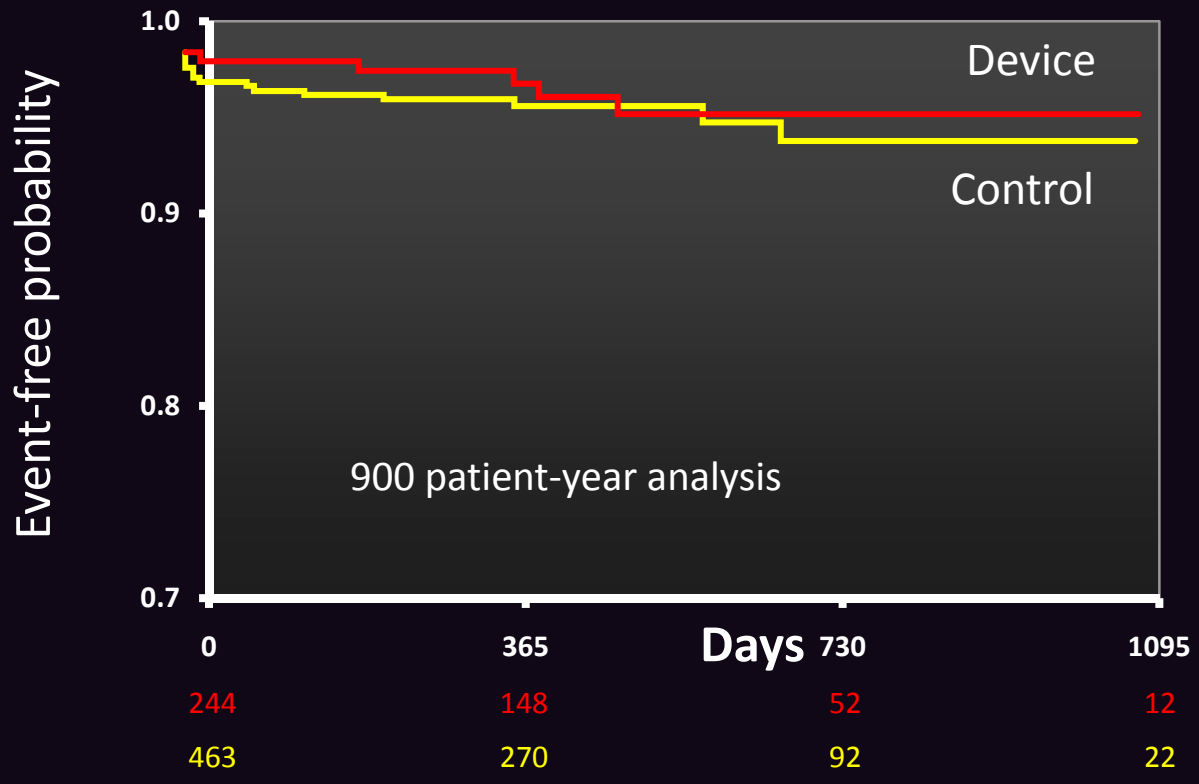
PROTECT AF: Primary Efficacy (By Pt-Subgroup)



Holmes DR, et al.Lancet 2009; 374:534-42

PROTECT AF : Ischemic Stroke*

	Device			Control			Posterior probability		
	Events cohort	Total no	Rate pt-yr	Events (95% CI)	Total no	Rate pt-yr	Rel . risk (95%CI)	Non (95% CI)	Superiority inferiority
600	13	409.3 pt-yr	3.2	4	224.0 (1.7, 5.2)	1.8	1.78	0.496 (0.5, 3.8)	0.105 (0.69, 7.45)
900	48	582.9 pt-yr	2.4	5	318.9 (1.3, 3.9)	1.8	1.53	0.617 (0.5, 3.1)	0.150 (0.64, 5.43)

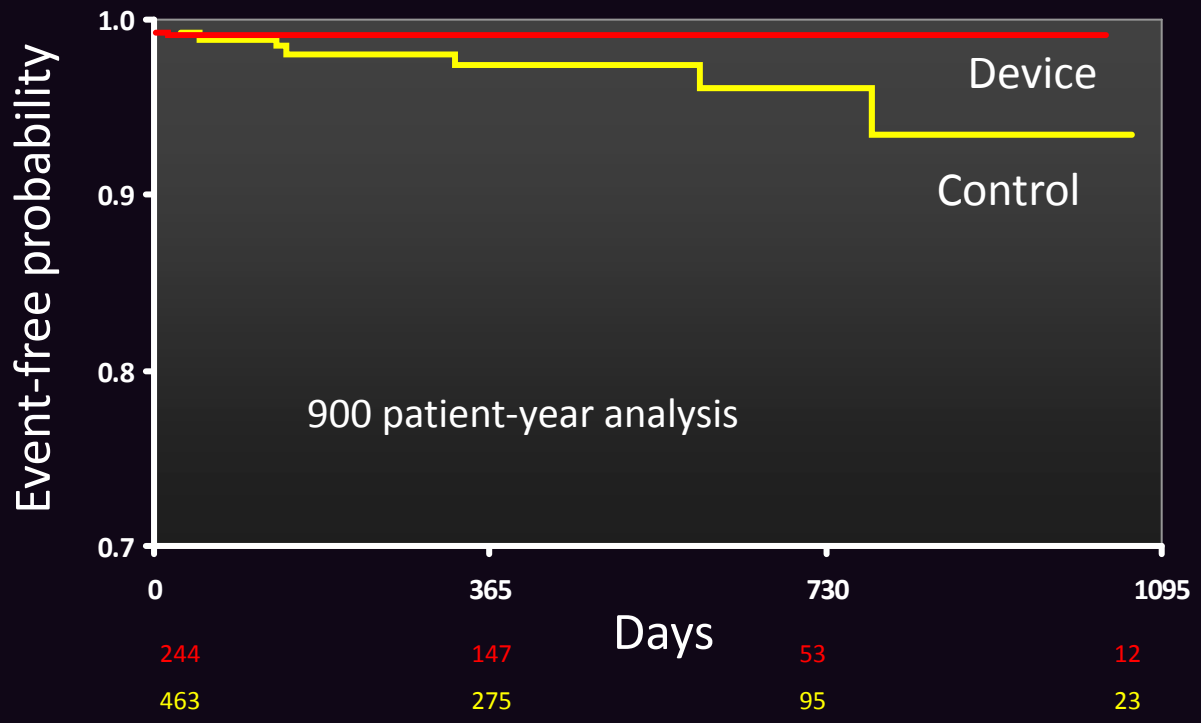


Randomization
(2 device:1 control)

*ITT Cohort:
pts analyzed based on their randomly assigned group (regardless of treatment received)

PROTECT AF : Hemorrhagic Stroke*

	Device			Control			Posterior probability		
	Events cohort	Total no	Rate pt-yr	Events (95% CI)	Total no	Rate pt-yr	Rel . risk (95%CI)	Non (95% CI)	Superiority inferiority
600	1	416.7 pt-yr	0.2	4	224.7 (0.0, 0.9)	1.8	0.13	0.998 (0.5, 3.9)	0.986 (0.00, 0.80.)
900	1	593.6 pt-yr	0.2	6	319.4 (0.0, 0.6)	1.9	0.09	>0.999 (0.7, 3.7)	0.998 (0.00, 0.45)

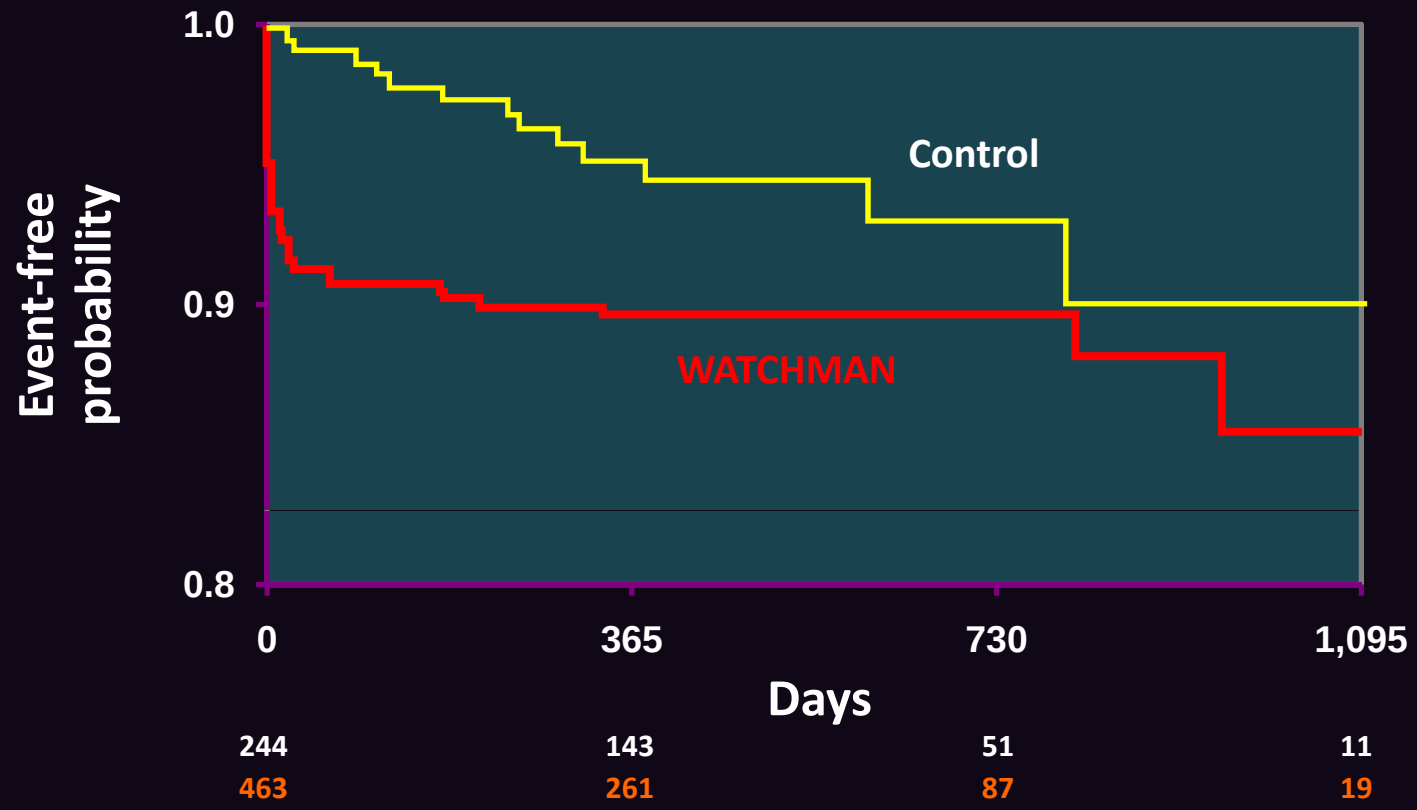


Randomization
(2 device:1 control)

*ITT Cohort:
pts analyzed based on their randomly assigned group (regardless of treatment received)

PROTECT AF : Primary Safety Results*

	Device			Control			
Cohort	Events (no)	Total pt-yr	Rate (95% CI)	Events (no)	Total pt-yr	Rate (95% CI)	Rel . risk (95%CI)
900 pt-yr	48	554.2	8.7 (6.4, 11.3)	13	312.0	4.2 (2.2, 6.7)	**2.08 (1.18, 4.13)**



*ITT Cohort:
pts analyzed based on their randomly assigned group (regardless of treatment received)

PROTECT AF & The CAP (Continued Access Registry)

Performance Metrics

	PROTECT AF	PROTECT AF		CAP	p-value*	p-value±
		Early	Late			
Procedure Time (Mean ± SD)	62 ± 34	67 ± 36	58 ± 33	50 ± 21	**<0.001**	**<0.001**
Implant Success	485/542 (89.5%)	239/271 **(88.2%)**	246/271 **(90.8%)**	437/460 **(95.0%)**	**0.001**	**0.001**
45-day Warfarin Discontinuation Among Implanted	414/478 (86.6%)	194/235 **(82.6%)**	220/243 **(90.5%)**	352/371 **(94.9%)**	**<0.001**	**<0.001**

*From tests comparing the PROTECT AF cohort with CAP

±From tests for differences across three groups (early PROTECT AF, late PROTECT AF, and CAP)

Reddy VY, et al. Circulation 2011;123:417-424; Kar S, TCT 2011

PROTECT AF & The CAP (Continued Access Registry)

Safety Event Rates

	PROTECT AF	PROTECT AF		CAP	p-value*	p-value ±
		Early	Late			
Procedure/Device Related Safety Adverse Events within 7 Days	42/542 (7.7%)	27/271 (10.0%)	15/271 **(5.5%)**	17/460 (3.7%)	0.007	0.006
Serious Pericardial Effusions within 7 Days	27/542 *(5.0%)*	17/271 **(6.3%)**	10/271 **(3.7%)**	10/460 **(2.2%)**	0.019	0.018
Procedure Related Stroke	5/542 *(0.9%)*	3/271 **(1.1%)**	2/271 **(0.7%)**	0/460 ***(0.0%)***	0.039	0.039

*From tests comparing the PROTECT AF cohort with CAP ±From tests for differences across three groups (early PROTECT AF, late PROTECT AF, and CAP)

- Improvements seen over time for acute safety events
- Fewer total procedure/device related events

Reddy V, et al. Circulation 2011;123:417-424; Kar S, TCT 2011

ASAP (ASA Plavix Feasibility Study)

- Implant device w/o Warfarin transition
  - Clopidogrel for 6 months & ASA for life
  - 4 European Centers
- 127 Contraindicated pts
  - Age 72.2 ± 7.9 (53 – 93); $CHADS_2$ = 2.6 + 1.1 (1 – 5)

- Age ≥ 75 in 39%
- HTN in 90%
- Diabetes in 31%
- CHF in 24%
- Prior TIA/CVA in 38%

- Successful implantation in 118/127 pts (93%)
- Periprocedural complications
  - Pericardial tamponade 1 (0.8%)
  - Device embolization 2 (1.6%)
  - Pseudoaneurysm (groin) 1(0.8%)
- Mean f up = 10.4 months (58 pts - to one year)

Sievert H, et al. TCT 2011

ASAP – Complications During F up

- Device related thrombus detected in 4/118 pts
  - One within 45 days; 2 in 3 months; 1 in 1 year f-up TEE
  - All were successfully treated with LMW heparin

Protect AF and CAP: Thrombi in 4.2 %

- Stroke in 3/118 pnts
  - Thrombus on the WATCHMAN device in one patient

✓ WATCHMAN device implant without Warfarin overlap is safe & feasible

✓ LAA closure may prove to be a viable alternative for AF pts with contraindications to Warfarin

Sievert H, et al. TCT 2011

Summary

- *Long-term warfarin* treatment of pts with AF has been found effective, but presents *difficulties & risk*
- *Technique* for Watchman LAA occluder implantation is *not difficult*
- In PROTECT AF & CAP, the efficacy of LAA closure was *non-inferior to that of warfarin therapy*
- In PROTECT AF: *Hemorrhagic stroke risk is significantly lower* with the device.
- Even though there are *early safety events*, specifically pericardial effusion; these events have *decreased over time*
- PROTECT AF/CAP/ASAP suggest that closure of the LAA is an *alternative strategy to chronic warfarin or oral anticoagulation therapy for stroke prophylaxis*