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Level 2, Hong Kong Convention and Exhibition Centre
Hong Kong College of Cardiology

Overcoming Challenges in LAAO: Looking Forward to a FLEXible Treatment Option

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Hong Kong

伊利沙伯醫院
QUEEN ELIZABETH HOSPITAL

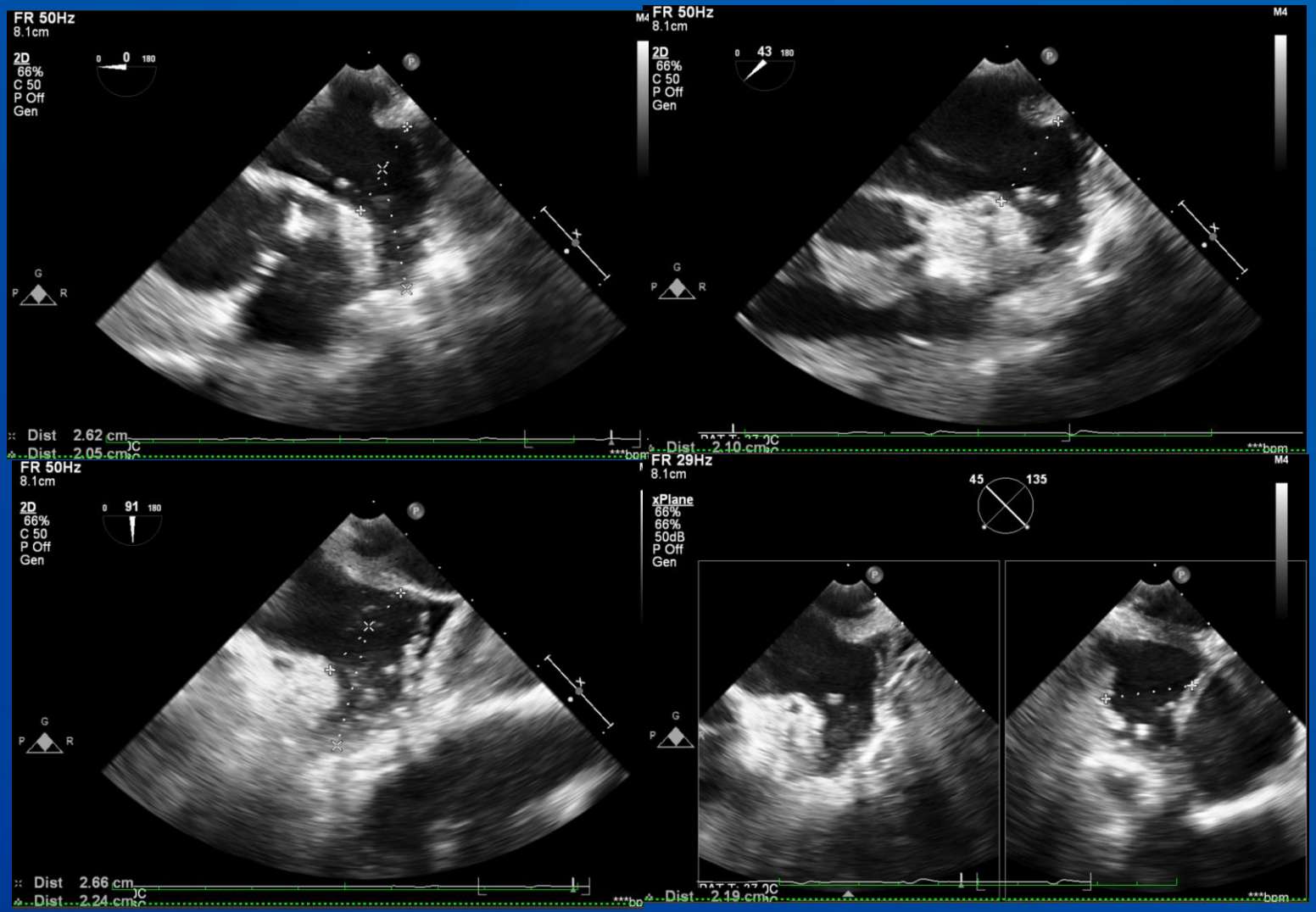
Disclosure

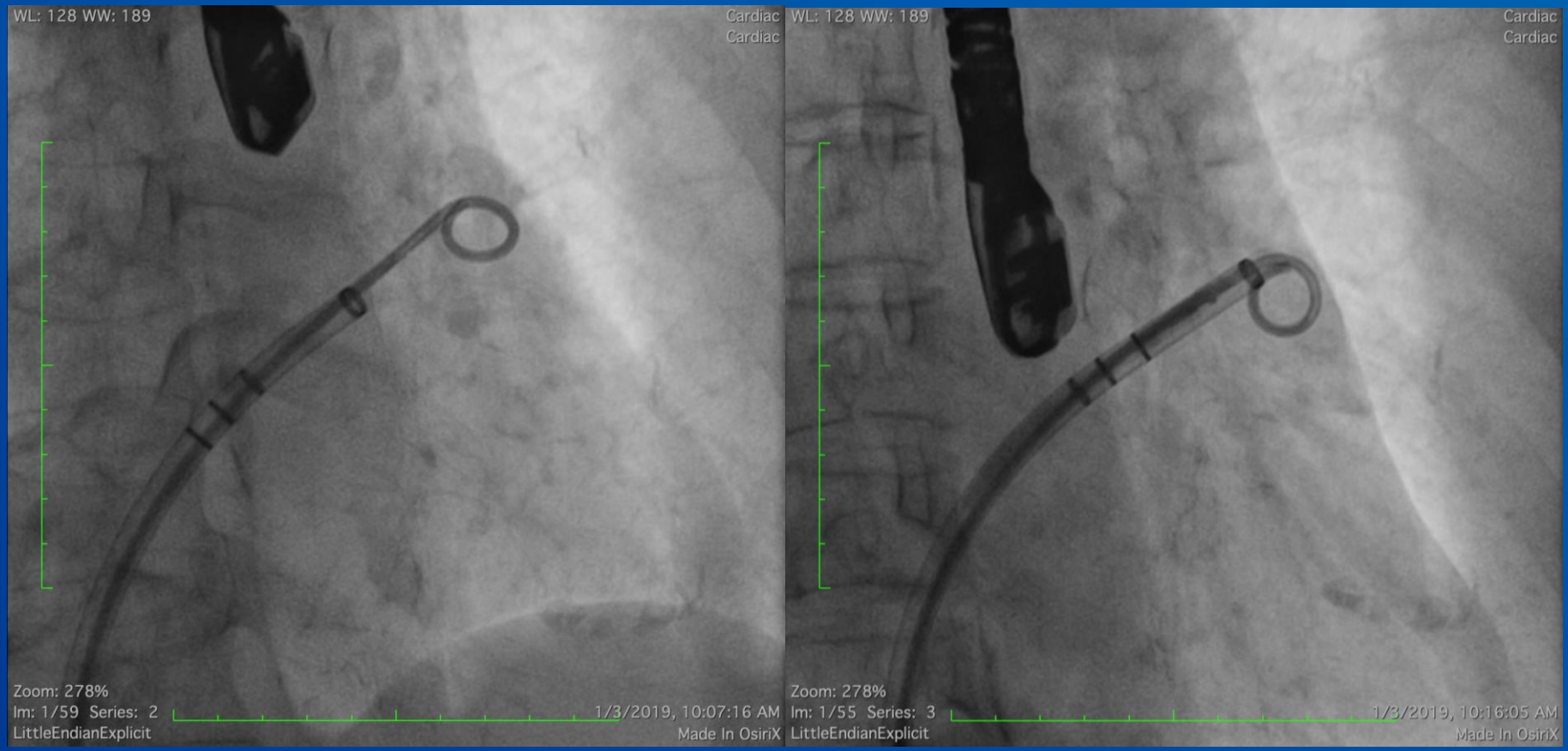
Proctor Boston Scientific Watchman Device

Patient

- 78/F
- Hx of DM, HT, AF with CVA, previously on NOAC
- Recurrent massive GIB with extensive GI workup showed diverticulosis
- Referred for LAAO
- CHADS-VAS score 7
- HAS-BLED score 4

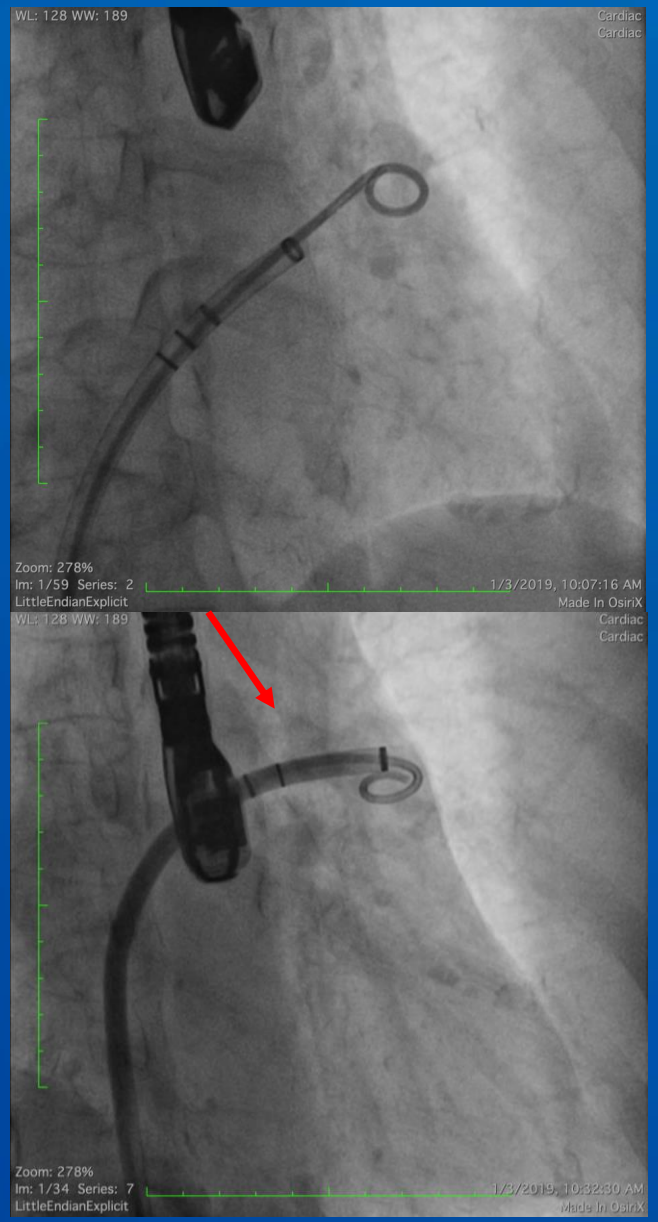
Plan for a 27mm Watchman device



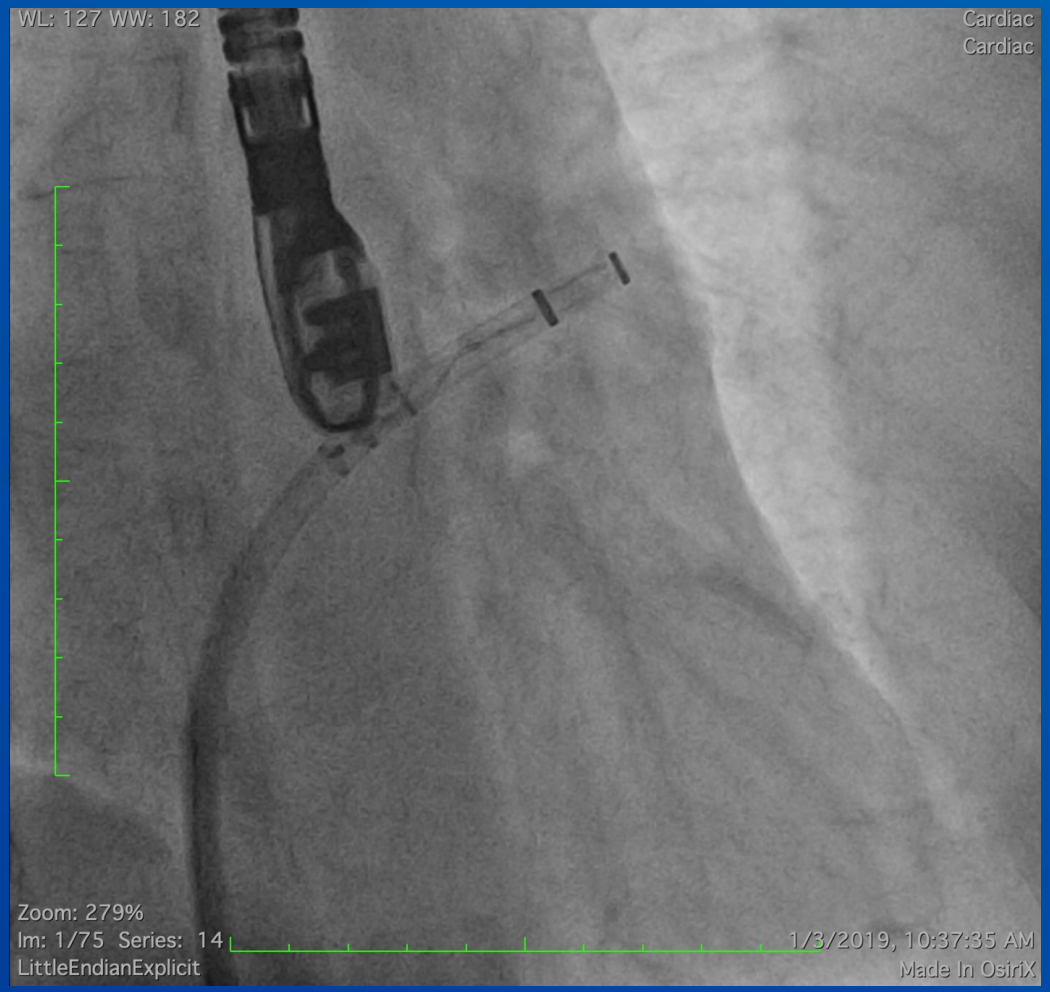

WL: 128 WW: 189
Cardiac
Cardiac
Zoom: 278%
Im: 1/59 Series: 2
LittleEndianExplicit
1/3/2019, 10:07:16 AM
Made In OsiriX
WL: 128 WW: 189
Cardiac
Cardiac
Zoom: 278%
Im: 1/55 Series: 3
LittleEndianExplicit
1/3/2019, 10:16:05 AM
Made In OsiriX

Strategy

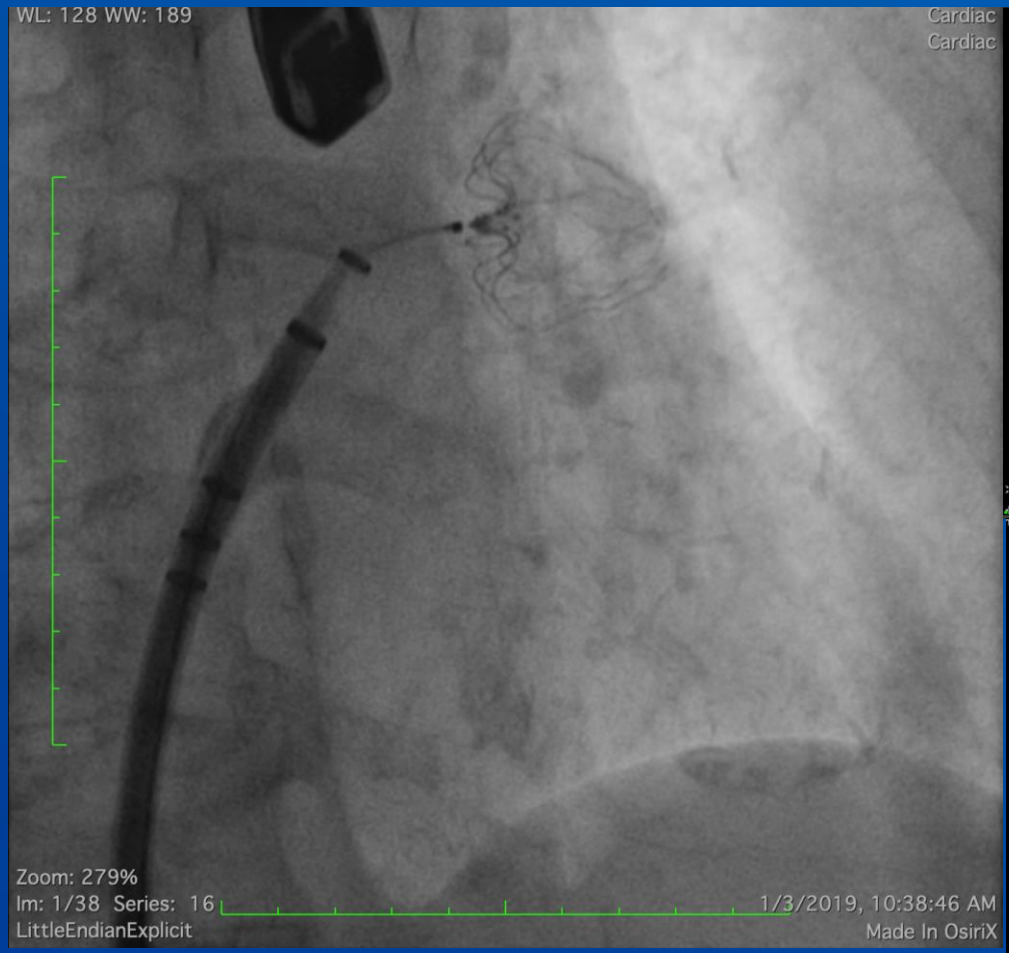
- ?Counter-clockwise rotation
- ?Deep implantation
- ?Kissing Watchman
- ?Use another device
  - Sandwich technique
- ?Continue oral anticoagulation



Gentle “push” just before deployment



PASS


WL: 128 WW: 189
Cardiac
Cardiac
Zoom: 279%
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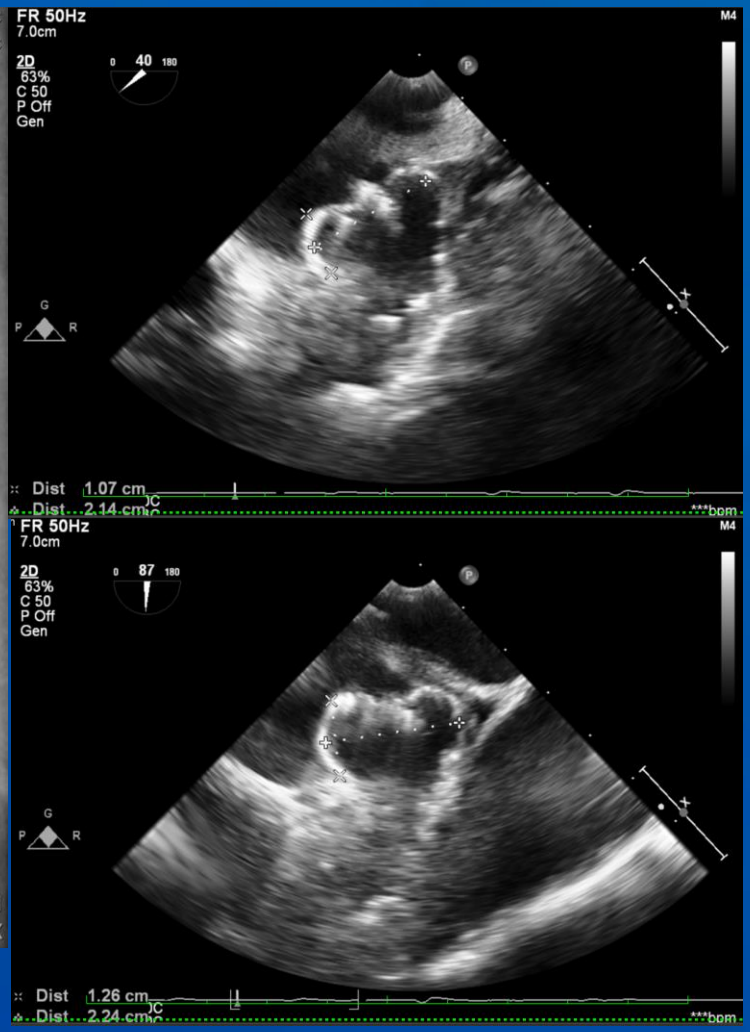
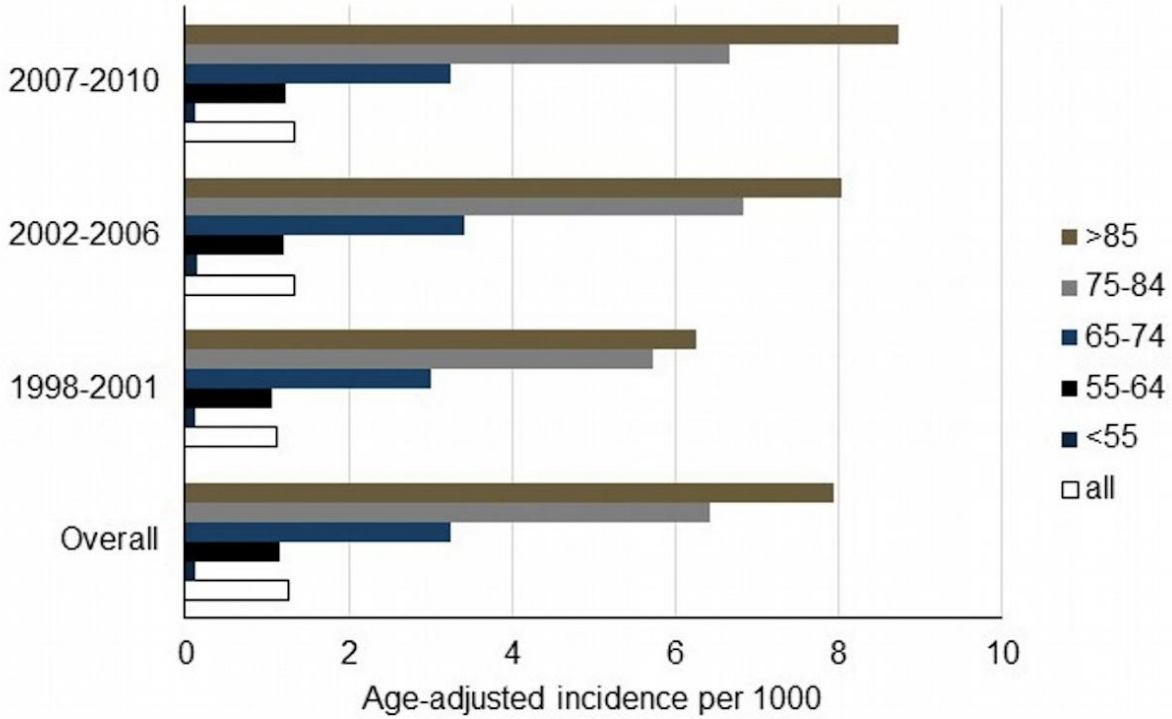
Made In OsiriX

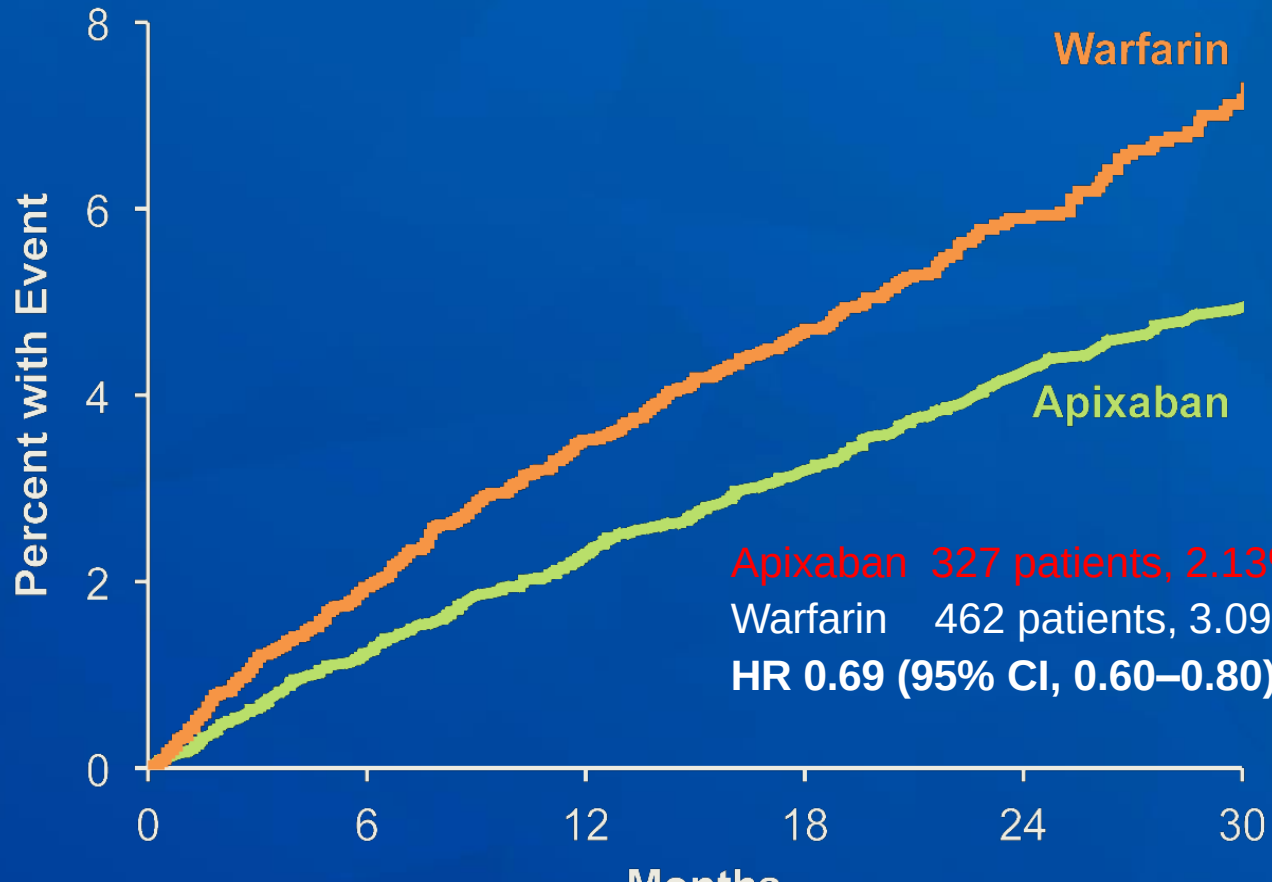

FR 50Hz
7.0cm
M4
2D
63%
C 50
P Off
Gen
40
Dist 1.07 cm
Dist 2.14 cm
FR 50Hz
7.0cm
M4
2D
63%
C 50
P Off
Gen
87
Dist 1.26 cm
Dist 2.24 cm

Incidence of AF increases with age



DA Lane et al; J Am Heart Ass 2017

Major Bleeding on OAC

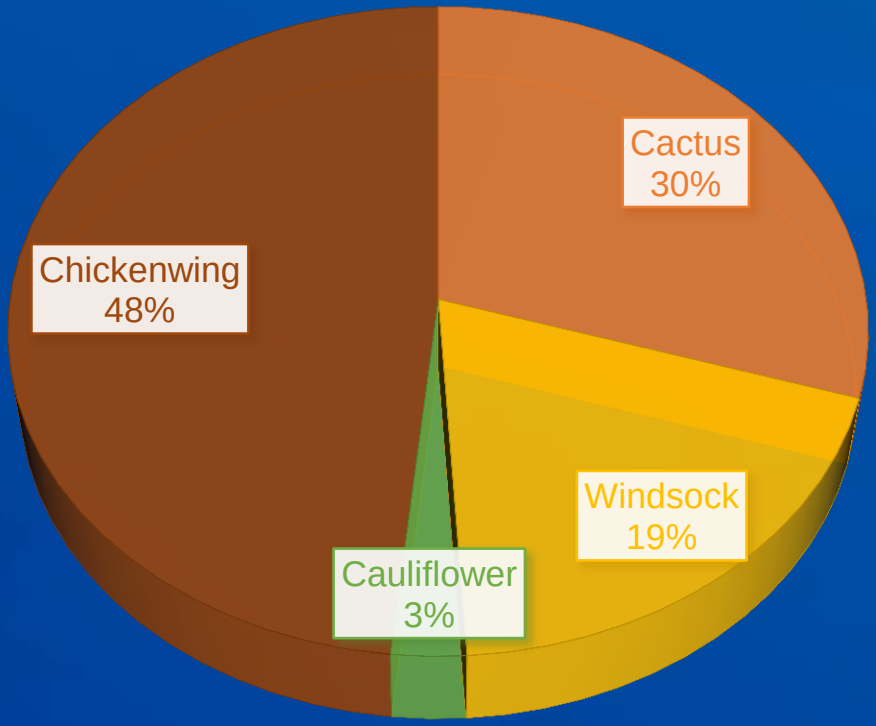


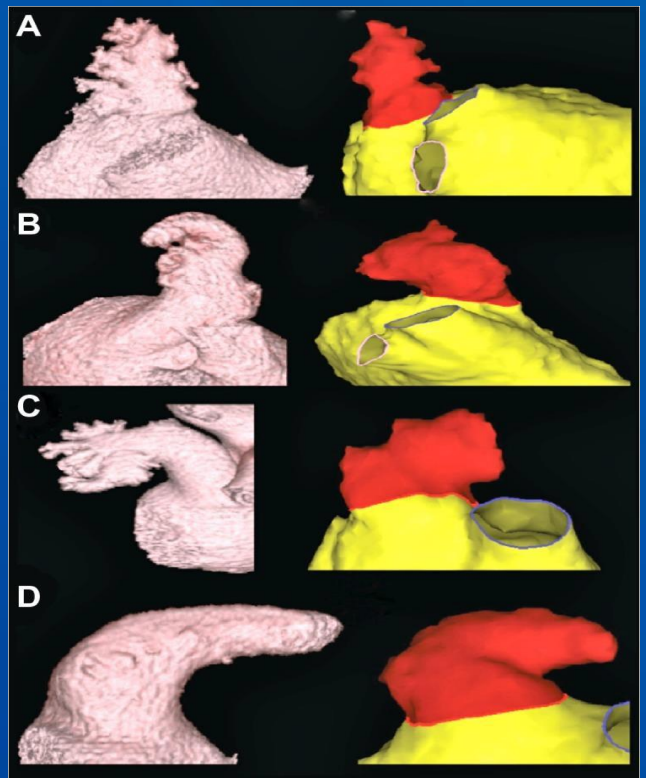
Apixaban 327 patients, 2.13% per year
Warfarin 462 patients, 3.09% per year
HR 0.69 (95% CI, 0.60–0.80); P<0.001

No. at Risk						
Apixaban	9088	8103	7564	5365	3048	1515
Warfarin	9052	7910	7335	5196	2956	1491

Connolly et al. *N Eng J Med*. 2011

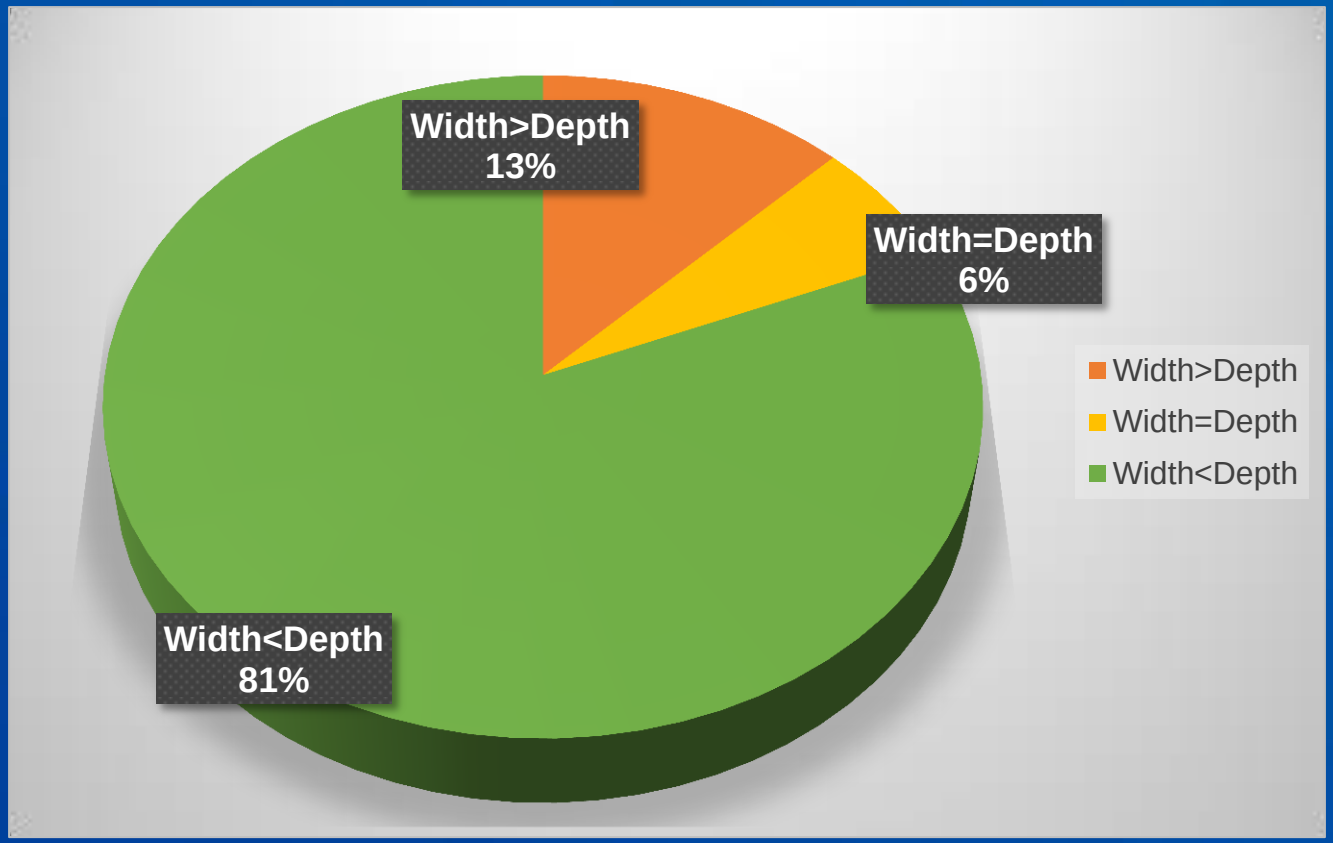
LAA morphology





Di Biase et al; JACC Vol. 60, No. 6,2012:531–8

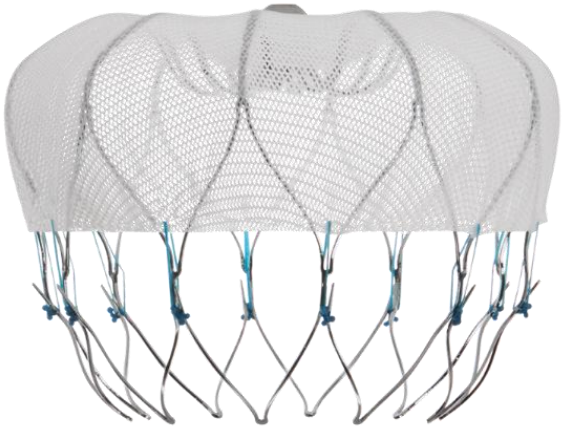
Shallow LAA



Faisal AWK, et al., J Clin Exp Cardiolog 2017, 8:9

New Left Atrial Appendage Closure Device

WATCHMAN FLX™



WATCHMAN™

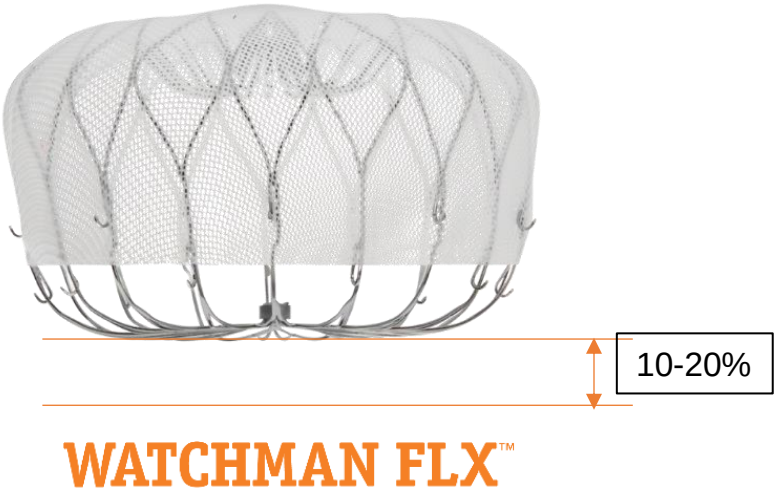
Designed to:

- Treat more patient anatomies, offer greater Flexibility
- Have improved maneuverability, ease-of-use
- Have enhanced stability, with new anchor design, and additional anchors
- Greater apposition to LAA wall, better seal and heal

Julia Seeger a et al.; First experience with theWatchman FLX occluder for percutaneous left atrial appendage closure, Cardiovascular Revascularization Medicine

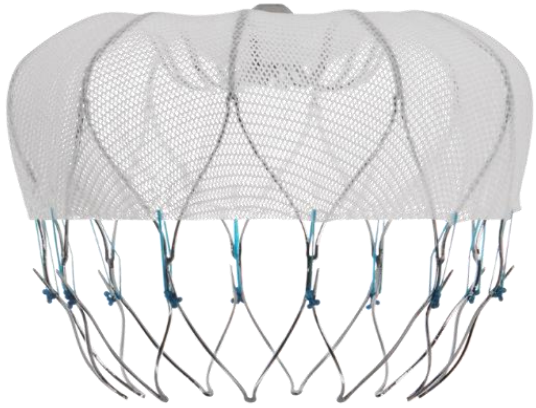
More Flexibility in Patient Treatment

Minimum LAA Depth = ½ Device Size



WATCHMAN FLX™

Minimum LAA Depth ≈ Ostium Dia.



WATCHMAN™

Less appendage depth needed for deployment
(i.e. 20mm device ≈ 10mm depth)

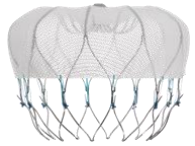
Polyethylene terephthalate fabric covering 90% of the device

Julia Seeger a et al.; First experience with theWatchman FLX occluder for percutaneous left atrial appendage closure, Cardiovascular Revascularization Medicine

More Flexibility in Patient Treatment

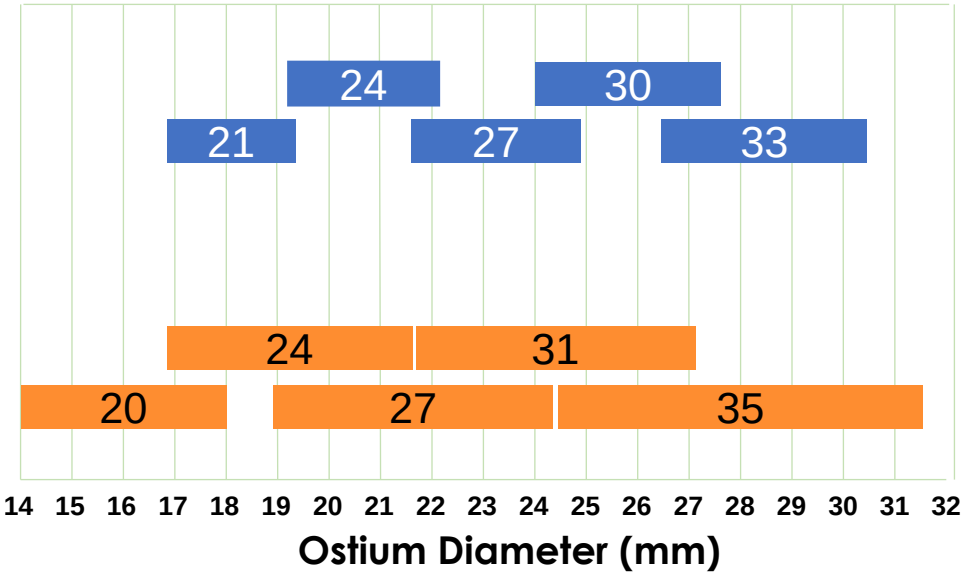
Wider treatment range, greater device sizing overlap

Sizing Charts



WATCHMAN™

WATCHMAN FLX™



8-20%
Compression

10-30%
Compression

Intuitive, safe and precise positioning

WATCHMAN FLX™ features a soft, closed, atraumatic distal end to enable advancement within the LAA when partially deployed.

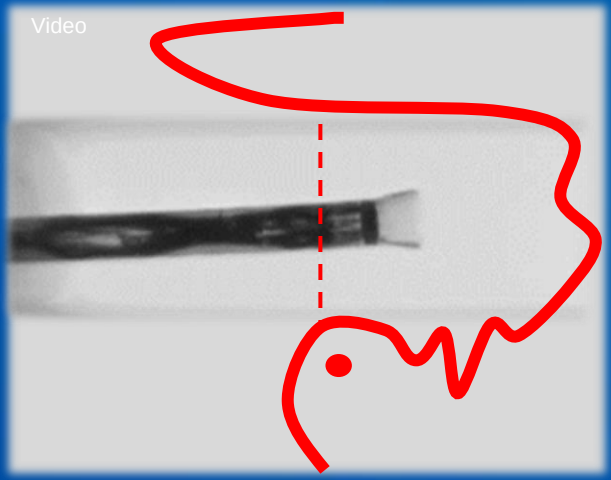
The distal fluoroscopic marker allows high visibility of the device in relation to the LAA during device positioning and enhances atraumatic maneuverability.

More Control and Ease of Use

Closed distal end allows greater maneuverability into the LAA

WATCHMAN FLX™

FLX Ball



Forms a bulb or ball when partially released, allowing safe antegrade negotiation of LAA depth

More Control and Ease of Use

WATCHMAN FLX™

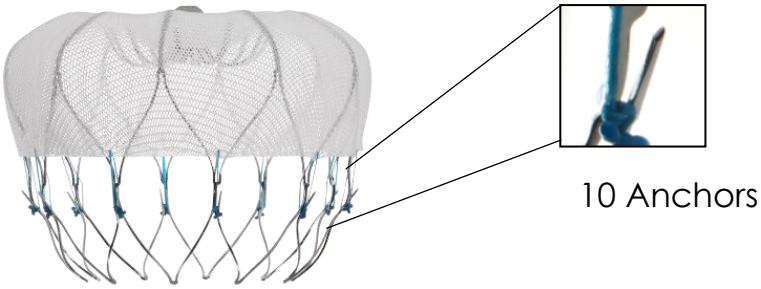
'J' anchor

18 Anchors

It allows **Full or Partial Recapture**

WATCHMAN™

'Straight' anchor



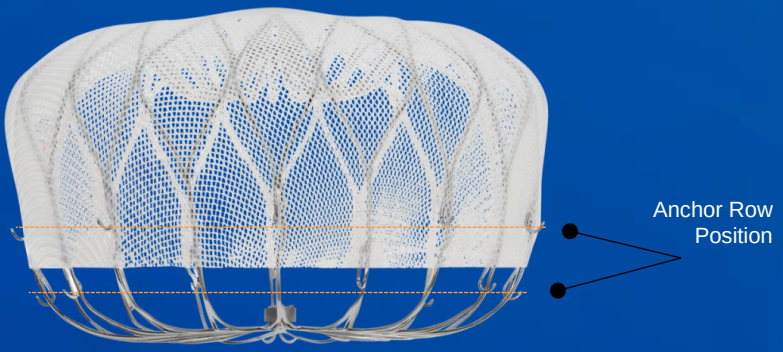
10 Anchors

Technically speaking,
only allows **Partial Recapture**

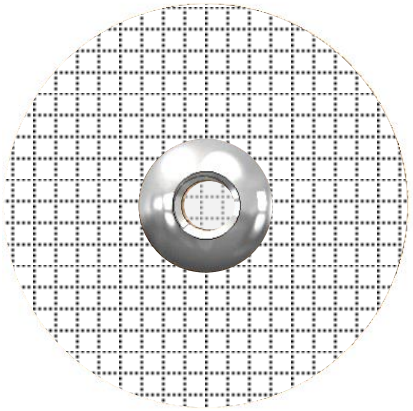
Better Seal and Heal

The 18 struts Nitinol frame conforms to even challenging LAA anatomies providing optimal apposition of the long PET fabric to the LAA walls, minimizing the risk of peri-device leaks.

The 18 anchors staggered in two rows ensure confident stability in the LAA.

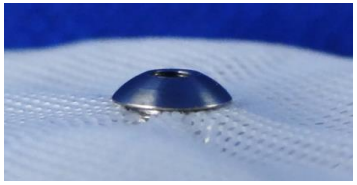


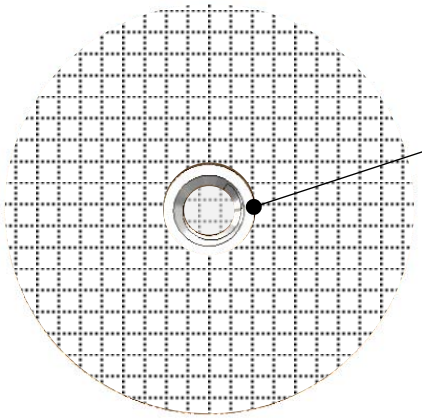
Threaded Insert Designs



WATCHMAN™

Exposed metal area: 6.7mm^2

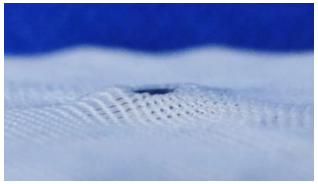




WATCHMAN FLX™

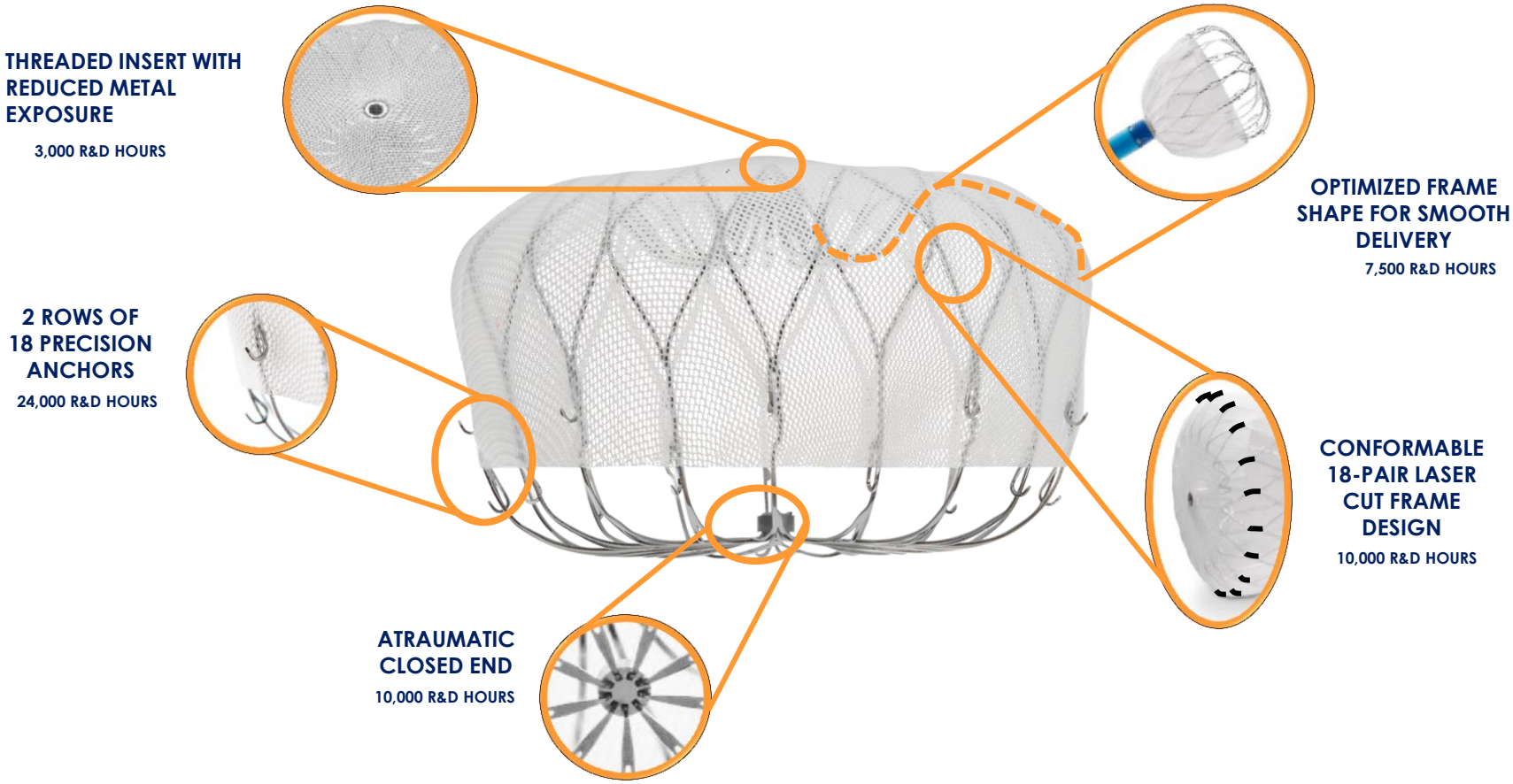
Exposed metal area: 1.5mm^2

Less Exposed Metal



Note: Values do not include the area of the threaded hole

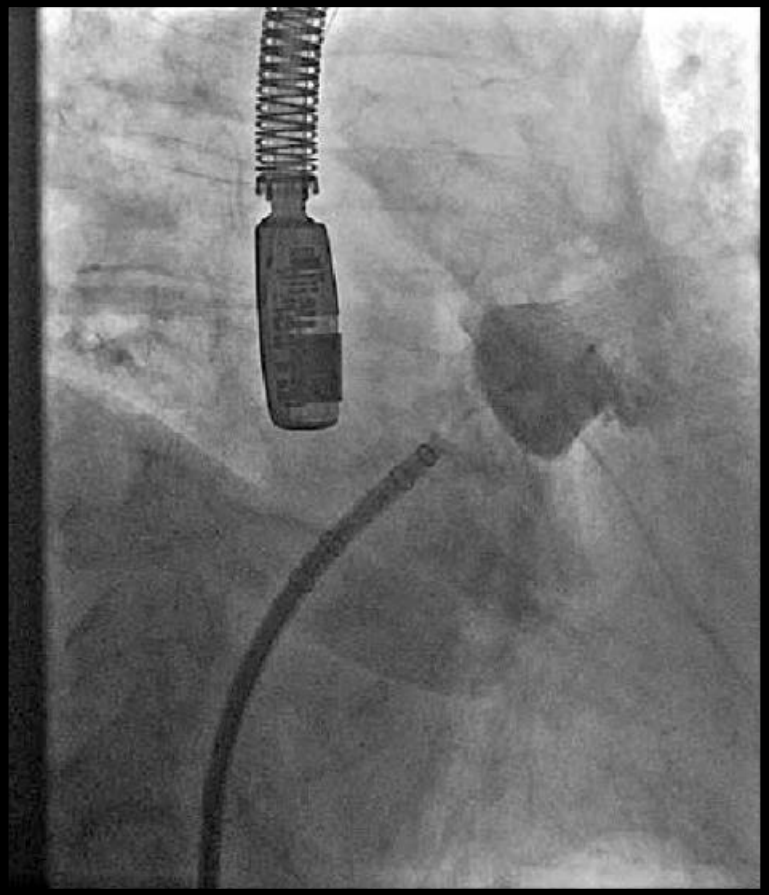
New Left Atrial Appendage Closure Device

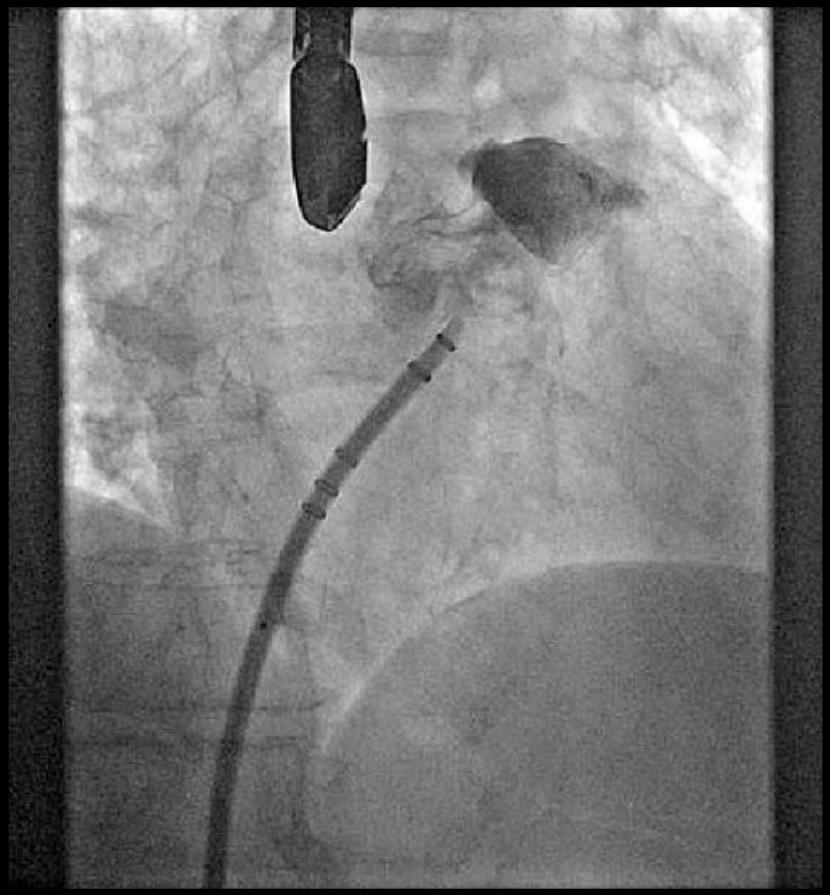


Deployment of WATCHMAN FLX™

FLX Ball Deployment Video

Final Result of WATCHMAN FLX





WATCHMAN'S Clinical Plan to Emcompasses All Patients with NVAF

Non-Valvular Atrial Fibrillation Patient Population

- NCDR Registry (ongoing)
- SALUTE: JPN approved trial (2017E complete)
- ASAP Too (2021 complete)
- WM with TAVR ISR (2017E start)
- WM with Ablation (2018E start)
- PINNAFLCLE-X (2019E start)
- Prior Intracranial Hemorrhage (2018E start)
- Prior GI Bleeds (2019E start)
- Renal Dysfunction (2019E start)
- Ablation with WM vs Ablation with NOAC (2019E start)

Holmes, David R. ; LAA Watchman Next Cliniccal Trials and Next LAA Closure Devices, CRT 2019

PINNACLE FLX IDE STUDY

- Single arm non-randomized study design
  - DOAC only options for post-implant drug regimen
  - Non-inferiority to performance goal based on WATCHMAN 2.5
- Up to 490 enrollments (includes 90 roll-ins)
- Up to 45 US sites
- Primary Safety Endpoint
  - The occurrence of one of the following events between the time of implant and within 7 days following the procedure or by hospital discharge, whichever is later: all-cause death, ischemic stroke, systemic embolism, or device- or procedure- related events requiring open cardiac surgery or major endovascular intervention such as pseudoaneurysm repair, AV fistula repair, or other major endovascular repair.
- Primary Effectiveness Endpoint
  - The rate of effective LAA closure defined as any peri-device flow $\leq$ 5mm demonstrated by TEE at 12 months (US)
- Secondary Endpoints
  - The occurrence of ischemic stroke or systemic embolism at 24 months from the time of enrollment
- Follow-up at 45 days, 6, 12, 18 and 24 months

PINNACLE FLX
CLINICAL TRIAL

SH-546922-AA APR 2018

Conclusion

- Incidence of AF increases with age
- Current generation LAA closure device still has limitations
- With modified, flexible designs, more patients with AF and high bleeding risks can be treated with the new Watchman FLX device

Thank you