Device Design Dictates Closure Success – Watchman FLX and other New Generation LAAO Devices

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Closure Success

- Complete sealing without Leak
- Complication-free procedure
- Free from late complications including DRT
- Good long term results



Advancing science for life™

BOSTON SCIENTIFIC RECEIVES FDA APPROVAL FOR WATCHMAN[™] LEFT ATRIAL APPENDAGE CLOSURE DEVICE

First-Of-Its-Kind Alternative to Long-Term Warfarin Therapy for Stroke Risk Reduction in Patients with Non-Valvular Atrial Fibrillation

MARLBOROUGH, Mass. (March 13, 2015) / PR Newswire / — Boston Scientific Corporation (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the WATCHMAN Left Atrial Appendage Closure Device. The WATCHMAN Device offers a new stroke risk reduction option for high-risk patients with non-valvular atrial fibrillation who are seeking an alternative to long-term warfarin therapy. The WATCHMAN Device will be made available to U.S. centers involved in our clinical studies and additional, specialized centers as physicians are trained on the implant procedure.

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who are at increased risk for stroke and systemic embolism based on CHADS₂ or CHA₂DS₂-VASc scores, are deemed by their physicians to be suitable for warfarin; and have an appropriate



FDA Indications - to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who are <u>at increased risk for</u> <u>stroke</u> and <u>systemic embolism</u> based on CHADS₂ or CHA₂DS₂-VASc scores, are deemed by their physicians to be suitable for warfarin; and have *an appropriate rationale to seek a non-pharmacologic alternative to warfarin*, taking into account the safety and effectiveness of the device compared to warfarin.

Device Size Selection - WATCHMAN

Max LAA Ostium	Device Diameter	
17 – 19 mm	21 mm	CON
20 – 22 mm	24 mm	
23 – 25 mm	27 mm	
26 – 28 mm	30 mm	NON MIN
29 – 31 mm	33 mm	

Watchman

• minimal functional LAA length at least = device diameter

Queen Mary Hospital 0341-2017 XA Left Coronary 15 fps

RAO 30 CRAN 20

XA Left Coronary 15 fps

RAO 30 CAU 20



Ostium 20-23mm Watchman #27mm

Leic Coronary 15 Ips



Delivery Sheath – LAA alignment

• Watchman is more forgiving regarding sheath position/orientation



Delivery Sheath – Precautions for Deep Seating with inadequate LAA Depth



Boston Scientific WATCHMAN FLX

FLX Design Enhancements

Shape and Architecture

Scientific

Less Taper Opened TEX 2015 FLX

- Opened strut frame architecture for enhanced conformability
- Less taper angle for uniform apposition through a wider compression range



- 3X greater overall holding strength
- 50% more anchors with new design for more uniform circumferential contact
- Optimized position of anchor rows to provide greater stability throughout range of deployment configurations





Design Changes from WATCHMAN to WATCHMAN FLX Scientific



Closed distal end with fluoro marker



Wider LAA ostium range of 15-31.5mm



May be partially recaptured and advanced into LAA



Shorter device length





Atraumatic FLX-Ball design and Implantation technique

Watchman FLX has **less metal –** 366mm² 24mm FLX device vs 804mm² 25mm AMULET



PASS Release Criteria: SIZE / COMPRESSION

Table 1: FLX Sizin	g Table	Table 2: I	ength Ref. Values	Reference Information	/ Implant "plane of maximum diameter should be
Max Diameter Range (LAA Os & Device)	Device Size	Approx. Min LAA Length	Implant Length* Range @(10% - 30%)	Length*	Anchors sit on these
14.0 - 18.0	20	10	14-18	CH MA	straight beams
16.8 - 21.6	24	12	14-19	Stand	
18.9 - 24.3	27	13.5	15-20		Xanchor Xanchor
21.7 - 27.9	31	15.5	16-23	cmm to PP	d of Pro Tip: The length of the green dimension line (from face to tissue
24.5 - 31.5	35	17.5	18-26	Length increases with higher compression	contact) should not be greater than 1/3 the length of the blue dimension (face to distal end)















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RAO 30 CRAN 20 Ostium 22mm

RAO 30 CAU 20 Ostium 27mm







Queen Mary Hospital 1736-2019 XA Fluoroscopy

WATCHMAN FLX 35mm



WL: 115 WW: 213 [D] RAO: 30 CAU: 20

25/11/2019 10:46:22 am











Queen Mary Hospital 1736-2019 XA Left Coronary 15 fps

WATCHMAN FLX 35mm



WL: 129 WW: 190 [D] RAO: 30 CRA: 20

Im: 1/63 Se: 30












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WATCHMAN FLX 35mm



FLX release criteria Size / Compression



Anchors sit on these straight beams

Plane of max diameter









WL: 129 WW: 190 [D] RAO: 30 CAU: 20

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WL: 129 WW: 190 [D] RAO: 30 CRA: 20

19/6/2020 17:32:43

0720-2020

XA



Queen Mary Hospital 0720-2020 XA Left Coronary 15 fps

WATCHMAN FLX 24mm



WL: 129 WW: 190 [D] RAO: 30 CAU: 20

19/6/2020 17:35:29



WL: 129 WW: 190 [D] RAO: 30 CRA: 20

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Abbott AMULET



Left Atrial Appendage Occlusion Device

Lobe

- Positioned **inside** the LAA neck
- Designed **to conform** to different sizes and shapes of LAA anatomy



Stabilizing Wires

- Engage with the wall of the LAA
- Help hold the device in place

Disc

• Designed to completely seal the LAA at the orifice

Waist

- Maintains tension between lobe and disc
- Flexible connection allows device to self-orient

Sheath & device



Device Size Selection - Amulet

Maximum Landing Zone Width (mm)	Amulet™De vice Size	Lobe Length (mm)	Minimum LAA Depth (mm)	Disc Diameter (mm)	Sheath Diameter
11.0-13.0	16	7.5	≥ 10	22	
13.0-15.0	18	7.5	≥ 10	24	12 F
15.0-17.0	20	7.5	≥ 10	26	or 14 F
17.0-19.0	22	7.5	≥ 10	28	(with adaptor)
19.0-22.0	25	10	≥ 12	32	
22.0-25.0	28	10	≥ 12	35	
25.0-28.0	31	10	≥ 12	38	14 F
28.0-31.0	34	10	≥ 12	41	



Im: 1/57 Selanding Zone 25mm AMULET #28mm

Queen Mary Hospital 0342-2017 XA Left Coronary 15 fps

WL: 129 WW: 190 [D] RAO: 30 CAU: 20

10/3/2017 17:14:25











Special LAA Morphology

- Small LAA
- LAA with multiple lobes and restrictive septum
- Special design of LAmbre Device











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Device Sizes and Corresponding Delivery Systems of LAmbre









Cat.	Diameter of Umbrella(mm)	Diameter of Cover(mm)	Delivery system
LT-LAA-1622	16	22	8F-900 9F-900
LT-LAA-1824	18	24	10F-900
LT-LAA-2026	20	26	9F-900
LT-LAA-2228	22	28	10F-900
LT-LAA-2430	24	30	
LT-LAA-2632	26	32	
LT-LAA-2834	28	34	
LT-LAA-3036	30	36	105 000
LT-LAA-3236	32	36	10F-900
LT-LAA-3438	34	38	
LT-LAA-3640	36	40	

Cat.	Diameter of Umbrella(mm)	Diameter of Cover(mm)	Delivery system
LT-LAA-1630	16	30	9F-900 10F-900
LT-LAA-1832	18	32	
LT-LAA-2032	20	32	
LT-LAA-2234	22	34	10F-900
LT-LAA-2436	24	36	
LT-LAA-2638	26	38	





WL: 129 WW: 190 [D] RAO: 30 CAU: 20



The delivery system

- · double curves (45° X 30°) of distal tip
- single curve (45°) of distal tip

8-10 Fr. small delivery sheath





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- ACP/LAMBRE in poor defined landing zone/chicken wing anatomy with short neck – Sandwich technique
 - overcome challenging anatomies
 - extreme chicken wing type
 - secured position
 - forgiving extreme angles








Watchman FLX – Anterior Chicken Wing Anatomy







Watchman

Watchman FLX

PINNACLE FLX Study



A US-only IDE to evaluate the safety and efficacy of the new WATCHMAN FLX™Device

Study Design	 Single arm non-randomized study design DOAC + ASA Post-implant Non-inferiority to performance goal based on current generation WATCHMAN[™]
Enrollment	400 Patients at 29 U.S sites, 58 roll-in subjects (2 per site)
Objective	To establish the safety and effectiveness of the WATCHMAN FLX Left Atrial Appendage Closure (LAAC) Device for patients with NVAF who are eligible for anti-coagulation therapy to reduce the risk of stroke.
Follow-Up	45 d (+TEE), 6 mon., 12 mon. (+TEE), 18 mon., and 24 mon.
Antithrombotic	DOAC + ASA 45 day, Clopidogrel + ASA until 6 mon, ASA indefinitely





PINNACLE FLX showed procedure success* consistent with recent WATCHMAN studies







CHAMPION-AF Study



WATCHMAN FLX vs Contemporary OAC

- Global Multicenter Randomized Clinical Trial
- >2000 patients
- Up to 150 Global Centers
- Randomized 1:1
 - Next Generation WATCHMAN FLX
 - VS
 - Market Approved DOAC or warfarin
- Inclusion Criteria; CHADSVASC > 2/3
- Co-Chairman
 - Dr. Marty Leon
 - Dr. Ken Ellenbogen
- Study Co-Pl's
 - Dr. Saibal Kar
 - Dr. Shephal Doshi
- Anticipated FPI 2H 2020



WATCH-TAVR Study



Investigator-Sponsored Research evaluating the safety and effectiveness of LAA occlusion with the Watchman Device in NVAF patients undergoing TAVR.



National PIs: Samir Kapadia & Martin Leon; NCT03173534 Grant Support: Boston Scientific

CATALYST Study



BACK TO PRESS RELEASES

ABBOTT ANNOUNCES FIRST-OF-ITS-KIND TRIAL TO ASSESS NEW THERAPY OPTION FOR PEOPLE AT RISK OF STROKE

- The CATALYST trial will examine Abbott's AmplatzerTM AmuletTM device compared to non-vitamin K oral anticoagulants, the current standard in attempting to lower stroke and bleeding risks for patients with atrial fibrillation



Photos (1)

ABBOTT PARK, Ill., Feb. 3, 2020 /PRNewswire/ -- Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved a new trial designed to assess its AmplatzerTM AmuletTM Left Atrial Appendage Occluder for people with atrial fibrillation (AF) – a condition in which the normal rhythm of the heart's upper chambers is disrupted and becomes erratic – who are at risk of stroke. The CATALYST trial is the first-ever clinical trial comparing the effectiveness of a

LAA Closure Devices – Checklist

Device Name	Company	Design	Device Sizes	Approval Status	
Endocardial Devices					
PLAATO	Appriva Medical Inc.	Single-lobe occluder; nitinol cage; ePTFE membrane; hooks	15, 18, 20, 23, 26, 29, and 32 mm (14-F sheath)	Removed from market	
WATCHMAN	Boston Scientific	Single-lobe occluder; nitinol frame; PET membrane; hooks	21, 24, 27, 30, and 33 mm (14-F sheath)	CE mark	
ACP	St. Jude Medical	Lobe and disk (polyester mesh in both); nitinol mesh structure; stabilizing wires	16, 18, 20, 22, 24, 26, 28, and 30 mm (9, 10, and 13-F sheaths)	CE mark	
Amulet	St. Jude Medical	Lobe and disk (polyester mesh in both); nitinol mesh structure; stabilizing wires	16, 18, 20, 22, 25, 28, 31, and 34 mm (12- and 14-F sheaths)	CE mark	
WaveCrest	Coherex Medical	Single-lobe occluder; nitinol frame; polyurethane foam and ePTFE membrane; retractable anchors	22, 27, and 32 mm	CE mark	
Occlutech LAA Occluder	Occlutech	Single-lobe occluder; nitinol wire mesh; stabilizing loops; nanomaterial covering	15, 18, 21, 24, 27, 30, 33, 36, and 39 mm (12- and 14-F sheaths)	Clinical trial evaluation	
Sideris Transcatheter Patch	Custom Medical Devices	Frameless detachable latex balloon covered with polyurethane		Clinical trial evaluation	
LAmbre	Lifetech	Lobe and disk; nitinol; PET membrane; distal barbs anchors	16 to 36 mm (7- to 10-F sheaths)	Clinical trial evaluation	
Pfm	Pfm Medical	Dual disk (distal anchor, variable middle connector, proximal disk); nitinol frame	(8- and 9-F sheaths)	Pre-clinical trial evaluation	
Ultrasept	Cardia	Lobe and disk; nitinol frame; Ivalon covering; distal anchors	16, 20, 24, 28, and 32 mm (10-, 11-, and 12-F sheaths)	Clinical trial evaluation	
Epicardial Devices					
Lariat	SentreHeart	Endocardial and epicardial approach: magnetically-assisted snare over balloon in LAA	14-F epicardial sheath	FDA approval CE mark	
AtriClip	AtriCure	Surgical approach: parallel clip with polyester mesh	35, 40, 45, and 50 mm	FDA approval CE mark	
Aegis	AEGIS Medical Innovations	Epicardial subxiphoid approach: electrodes guide navigation to LAA and tissue capture		Clinical trial evaluation	
Cardioblate Closure System	Medtronic	Epicardial approach: silicone band covered by polyester fabric		Pre-clinical trial evaluation	

ACP = Amplatzer Cardiac Plug; CE = Conformité Européene; ePTFE = expanded polytetrafluoroethylene; FDA = Food and Drug Administration; LAA = left atrial appendage; PET = polyethylene terephthalate; PLAATO = Percutaneous Left Atrial Appendage Transcatheter Occlusion.

GORE[®] CARDIOFORM LAA Occluder

- Soft, conformable, with flat atrial surface
- Open distal end for minimal elongation when compressed
- Retractable anchors allow for full retrieval with low forces

CBAS® Heparin Surface

•The CBAS® Heparin Surface is utilized to bind heparin molecules to the ePTFE

via a proprietary covalent end-point attachment mechanism





Cormos LAA Occluder

Two types

- Type I with disc
- Cormos-LAA-Occluder MATRIX



- Type II without disc
- Cormos-LAA-Occluder RUBIN



In vivo study: Animal model (Started in March 2019) FIM 6/2020

Conclusion

- Advances in device design facilitate LAA closure
- Implantation techniques, safety precautions and procedural experiences remain as the basis for closure success
- Eg. Watchman FLX new design features further optimize closure efficacy and safety
- Ongoing clinical trials eg. PINNACLE FLX, CHAMPION AF, CATALYST **HKU**



See you on 17-18 Oct 2020!



Conference Secretariat hkvalve@hku.hk http://hkvalve.org

