

Última tecnología para el cierre de orejuela izquierda:

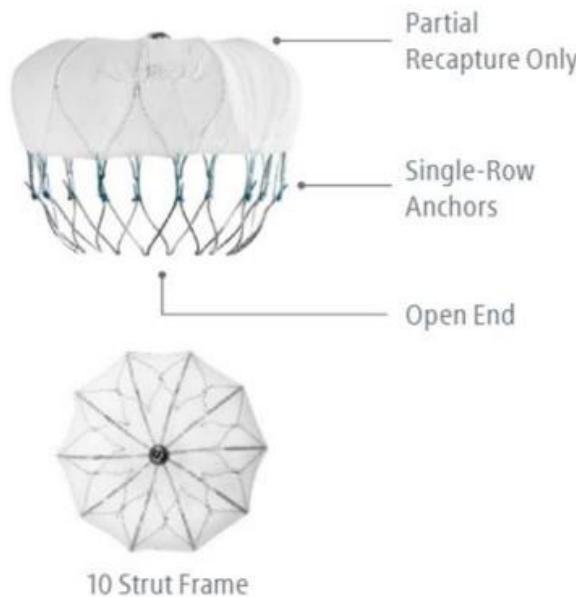
# **WATCHMAN FLX PRO**

Iván Gómez Blázquez

Hospital Universitario 12 de Octubre

### Legacy WATCHMAN™ LAAC Device

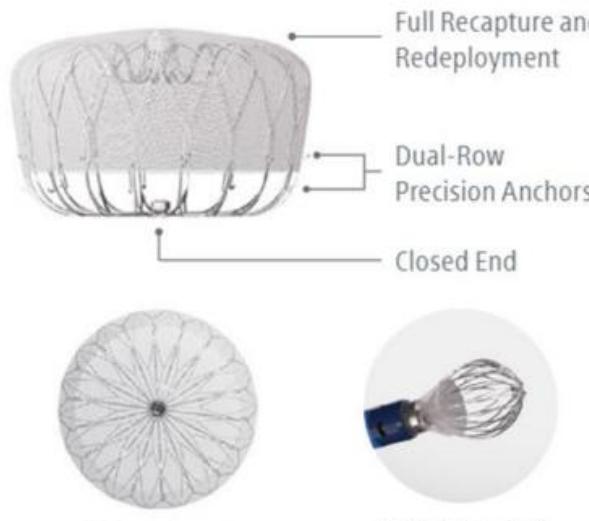
Treatment Range 16.8– 30.5 mm Ostium Width



FDA Approval  
March 2015

### WATCHMAN FLX™ LAAC Device

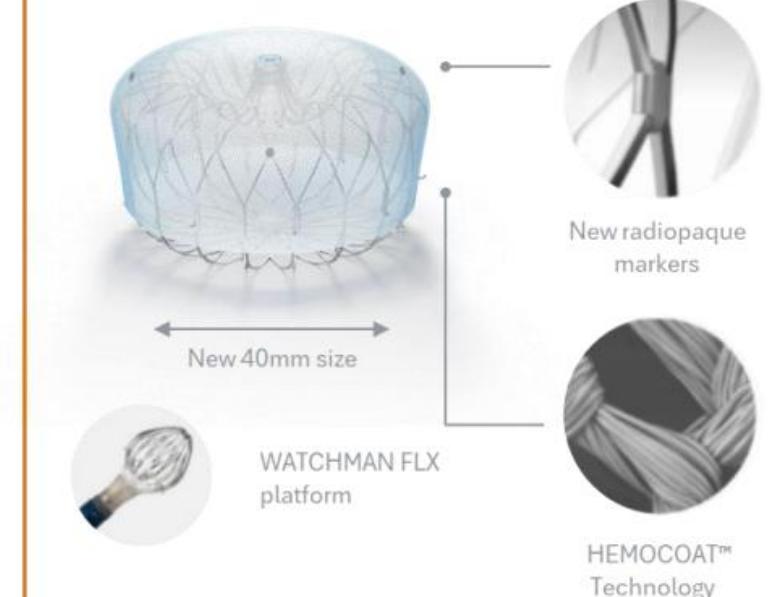
Treatment Range 14.0– 31.5 mm Ostium Width



FDA Approval  
July 2020

### WATCHMAN FLX™ ProLAAC Device

Treatment Range 14.0– 36.0 mm Ostium Width



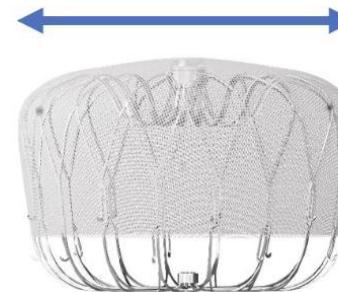
FDA Approval  
September 2023

# Características novedosas

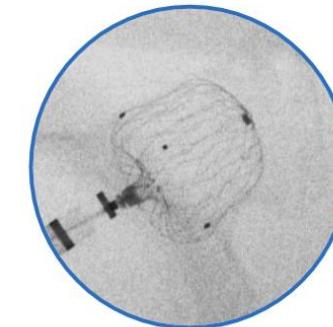
1. Thromboresistant coating
2. Expanded range of sizes  
(40 mm device)
3. Increased fluoroscopic visibility  
for positioning and deployment



Fluoropolymer coating

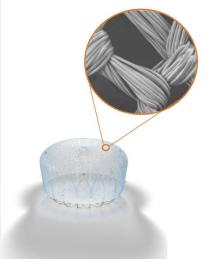


40 mm device

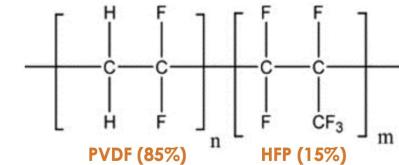


Radiopaque markers

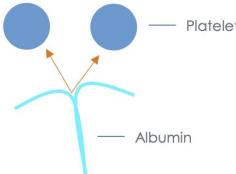
# Tecnología HEMOCOAT



**PVDF-HFP:**  
Poly(vinylidene-fluoride-co-hexafluoropropylene)  
A fluorinated copolymer



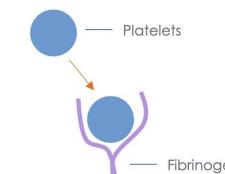
Albumin



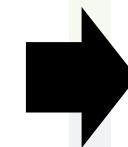
Albumin is considered a passive protein; it does not possess platelet binding sites.

Platelets do not bind to the albumin proteins.

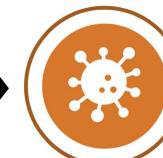
Fibrinogen



Fibrinogen is not considered a passive protein; it does possess platelet binding sites.

**STAGE 1**

Seconds → Minutes



PROTEIN ADSORPTION

**STAGE 2**

Minutes → Hours



PLATELET BINDING

**STAGE 3**

Hours → Days



ACUTE INFLAMMATION

**STAGE 4**

Days → Weeks



THROMBUS FORMATION &amp; RESOLUTION

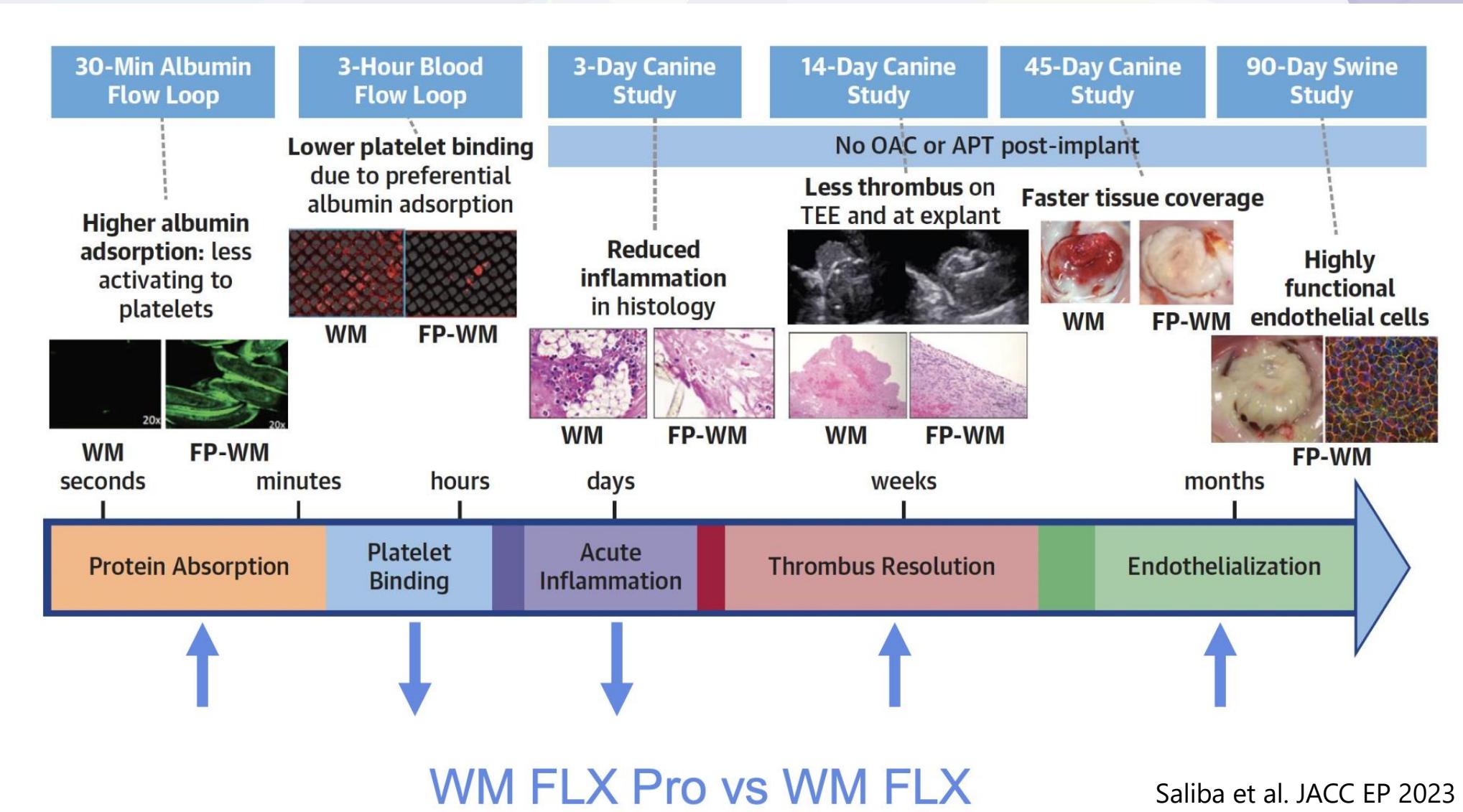
**STAGE 5**

Weeks → Months



COMPLETE HEALING (ENDOTHELIALIZATION)

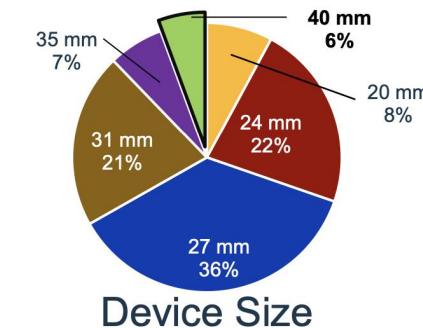
# Datos preclínicos



# HEAL LAA

CLINICAL TRIAL

- ❖ Prospective, multicenter, post-market clinical study
- ❖ 32 centers in United States
- ❖ Primary Analysis Set = first 500 patients enrolled



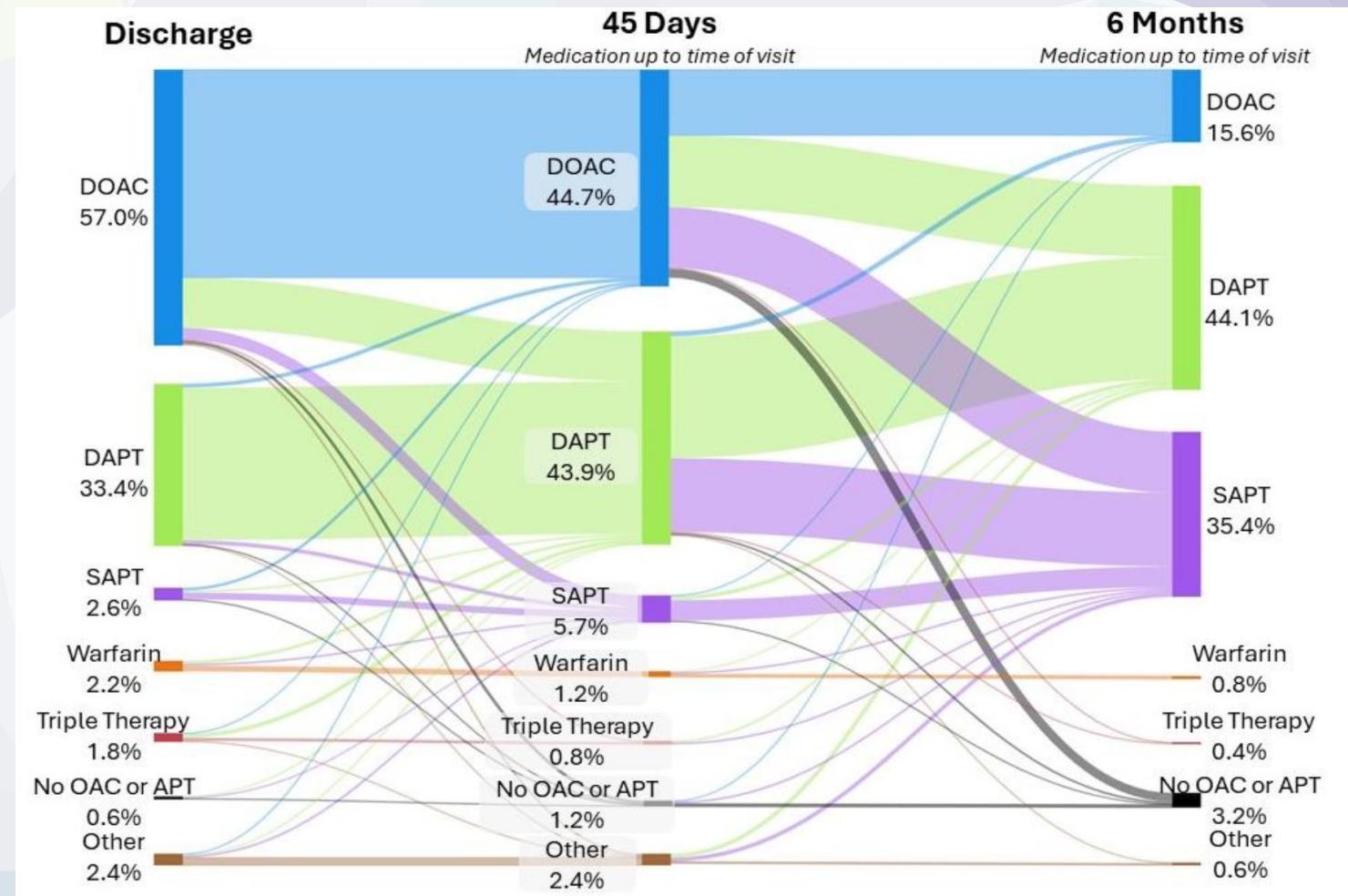
5, 6 y 7 NOVIEMBRE  
HOTEL RIU PLAZA DE ESPAÑA

LAA Seal	Post Implant	45 Days
Complete seal	92.5% (331/358)	82.7% (334/404)
>0-3 mm leak	7.5% (27/358)	17.1% (69/404)
>3-5 mm leak	0.0% (0/358)	0.2% (1/404)
>5 mm leak	0.0% (0/358)	0.0% (0/404)

Imaging Data		45 Days
Imaging Modality		
TEE		96.6% (456/472)
CT		3.4% (16/472)
Device-related Thrombus		1.6% (7/448)

Alli et al. TCT 2024

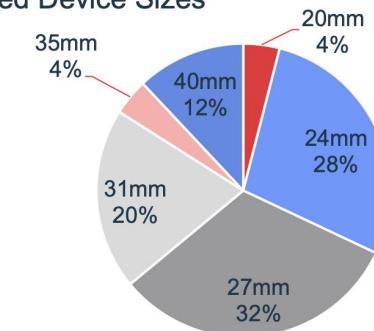


# Watchman FLX Pro CT Pilot Study

Patient Characteristics	N = 25
Age	73.6±8.4 (25)
Female	36.0% (9/25)
CHA <sub>2</sub> DS <sub>2</sub> -VASc score	3.3±1.1 (25)
HAS-BLED Score	2.8 ± 0.8 (25)
Atrial fibrillation	
Paroxysmal	60.0% (15/25)
Persistent	8.0% (2/25)
Permanent	32.0% (8/25)
Peripheral vascular disease	4.0% (1/25)
Prior stroke	40.0% (10/25)
History of TIA	0.0% (0/25)
History of diabetes mellitus	8.0% (2/25)
History of hypertension	76.0% (19/25)
History of major bleeding	52.0% (13/25)

Procedural Characteristics	N = 25
Device success*	100% (25/25)
1 Device implanted	100% (25/25)
Discharge medications	
DAPT	4.0% (1/25)
SAPT	96.0% (24/25)

Implanted Device Sizes



## CT Analysis

### Subfocal HAT or No HAT

- Flat sessile
- Protruding sessile -- LA wall continuity and smooth surface
- Protruding sessile -- No LA wall continuity and/or irregular surface
- Pedunculated

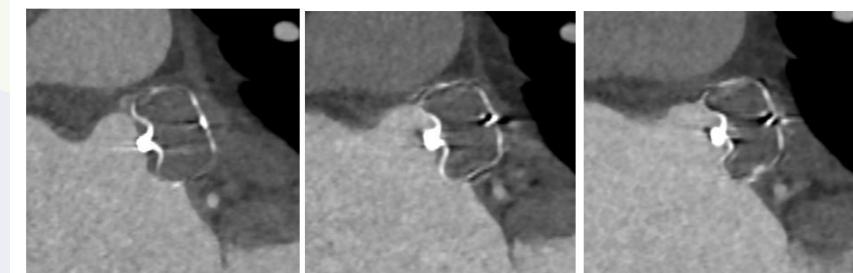
### Low-grade HAT

### No CT

	14 Days	45 Days
10	17	
13	6	
1	1	
0	0	
1	1	

1

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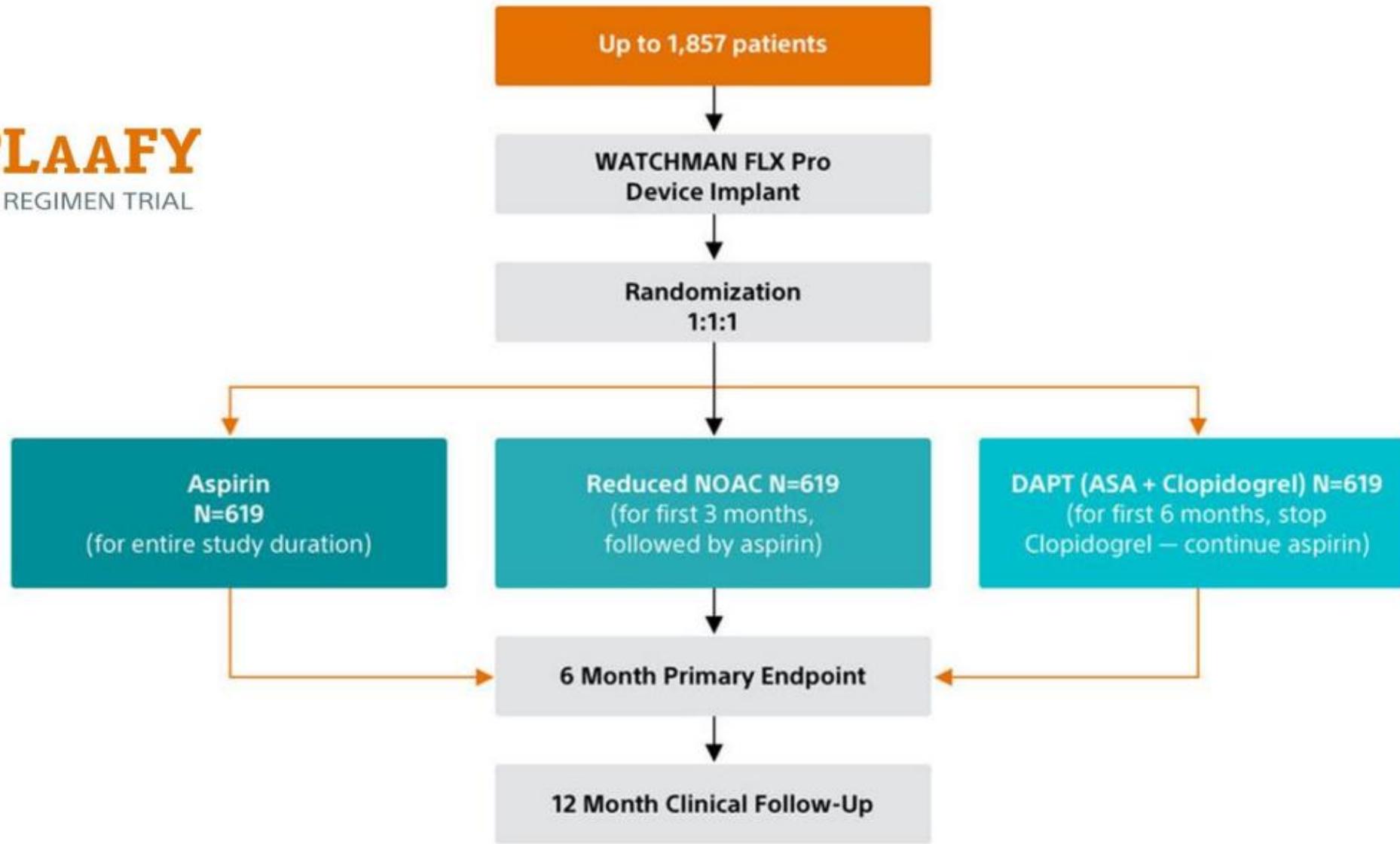
14-days  
Flat sessile HAT

45-days  
No HAT

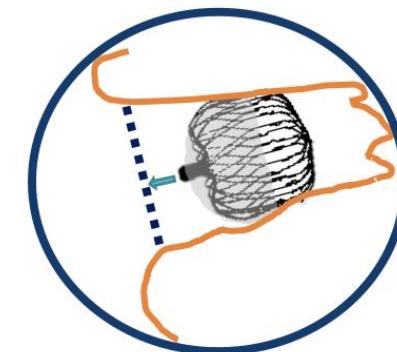
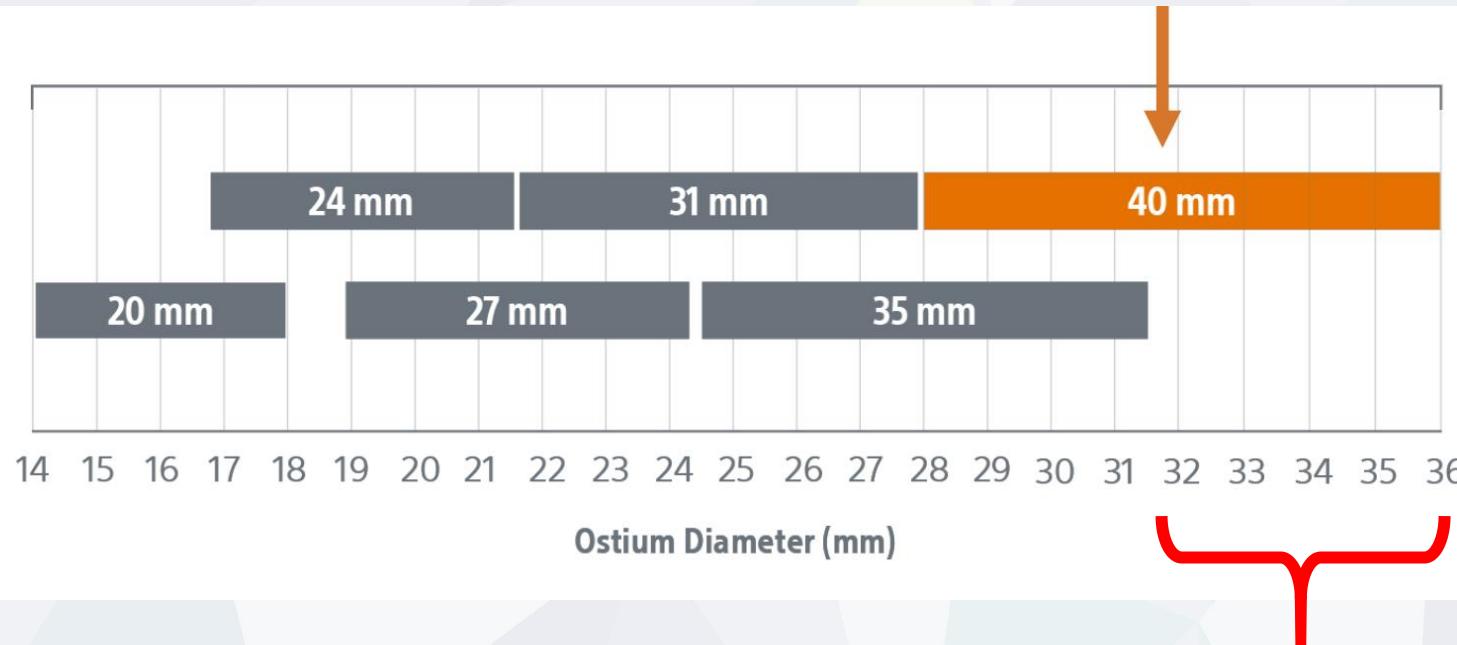
90-days  
No HAT

# SIMPLAAFY

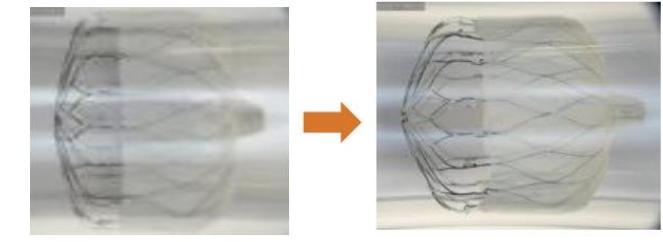
LAAC DRUG REGIMEN TRIAL



# Dispositivo de 40 mm



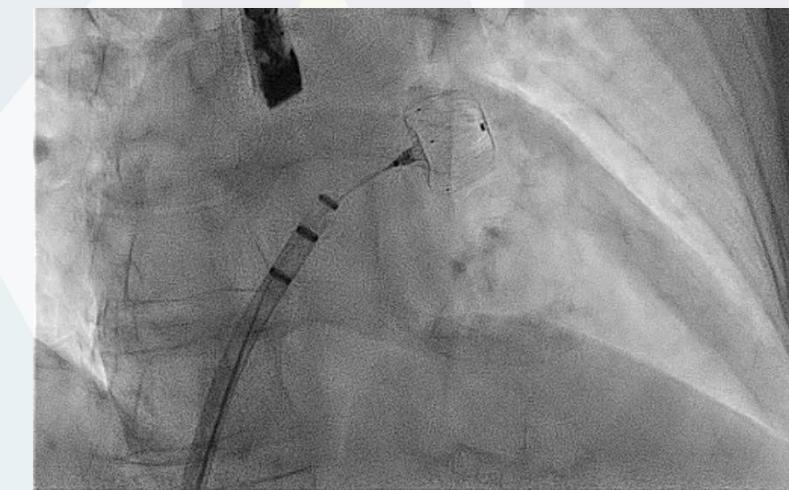
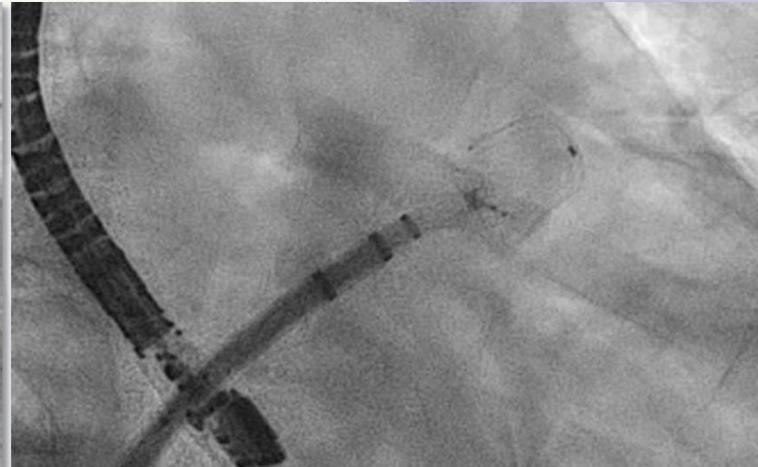
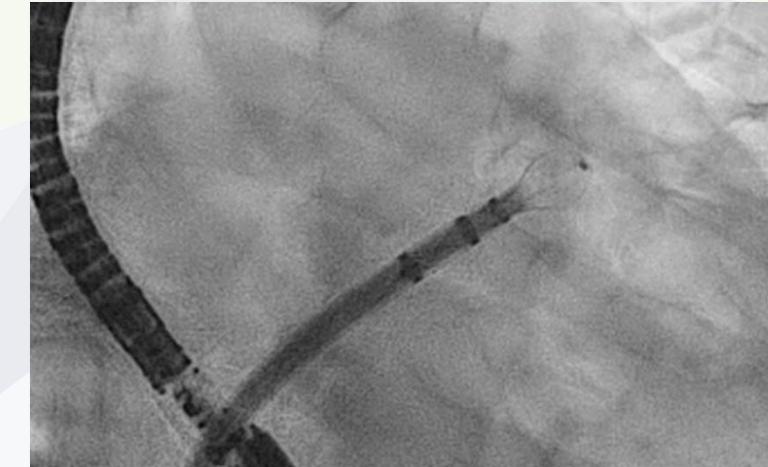
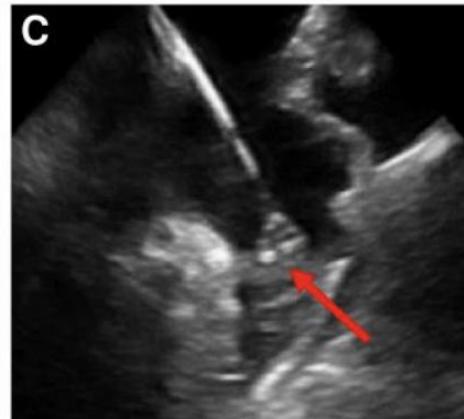
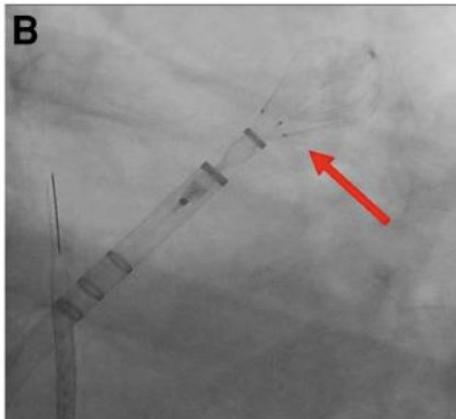
Dispositivo 35 mm



35mm @ 10%  
compression

40mm @ 21%  
compression

# Marcadores radiopacos



Nielsen-Kudsk et al. EHJ Case Reports 2024

# Mensajes

- WATCHMAN FLX Pro contiene un fluoropolímero en la membrana del dispositivo para disminuir la trombogenicidad y facilitar la cobertura endotelial.
- Estas propiedades en la superficie del dispositivo podrían favorecer un manejo antitrombótico simple tras el procedimiento.
- Tres marcas radiopacas en los hombros del dispositivo y disponibilidad de un oclusor de 40 mm.