

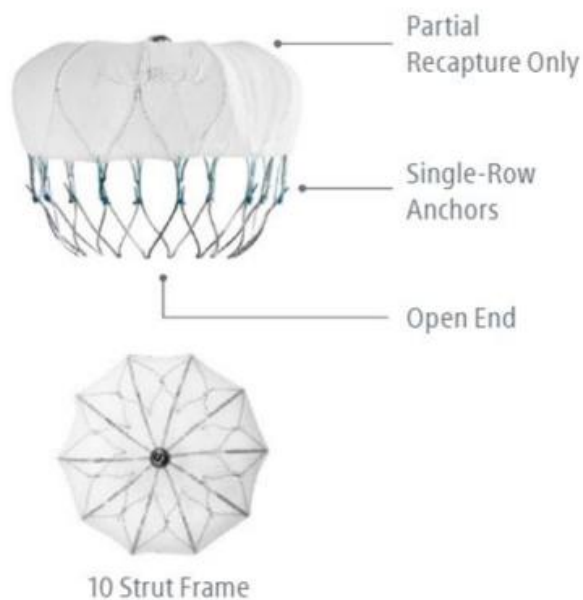
Última tecnología para el cierre de orejuela izquierda:

# **WATCHMAN FLX PRO**

Iván Gómez Blázquez  
Hospital Universitario 12 de Octubre

### Legacy WATCHMAN™ LAAC Device

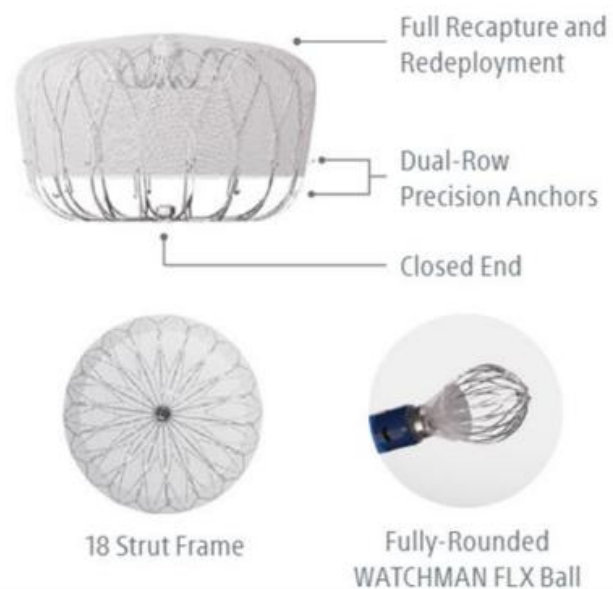
Treatment Range 16.8– 30.5 mm Ostium Width



**FDA Approval  
March 2015**

### WATCHMAN FLX™ LAAC Device

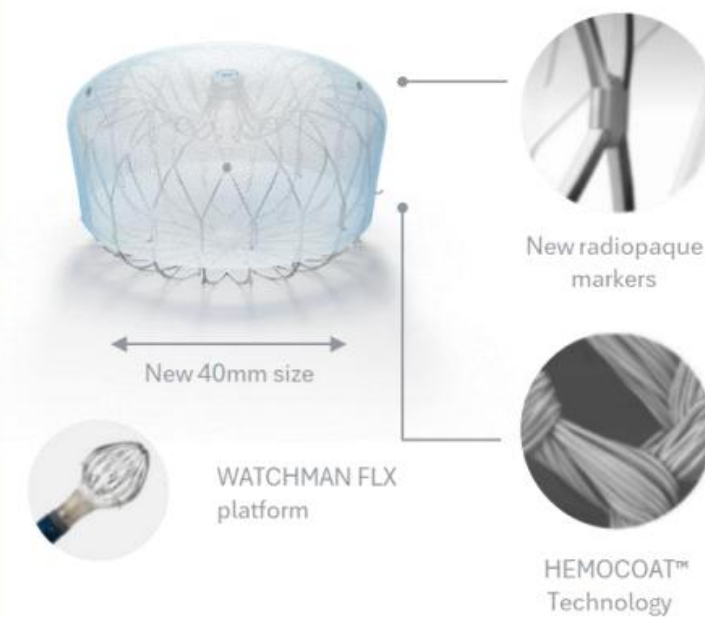
Treatment Range 14.0– 31.5 mm Ostium Width



**FDA Approval  
July 2020**

### WATCHMAN FLX™ Pro LAAC Device

Treatment Range 14.0– 36.0 mm Ostium Width



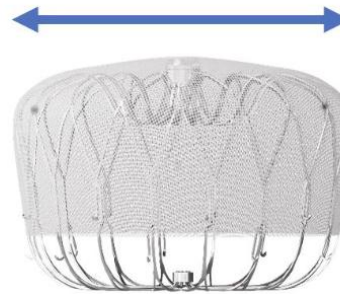
**FDA Approval  
September 2023**

# Características novedosas

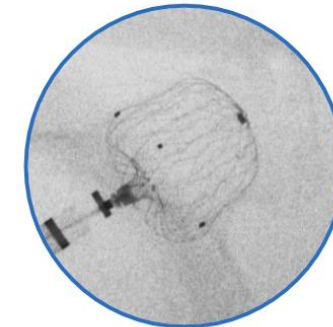
1. Thromboresistant coating
2. Expanded range of sizes  
(40 mm device)
3. Increased fluoroscopic visibility  
for positioning and deployment



Fluoropolymer coating



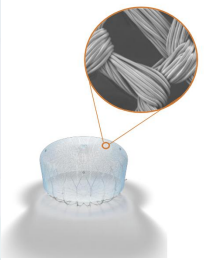
40 mm device



Radiopaque markers



# Tecnología HEMOCOAT

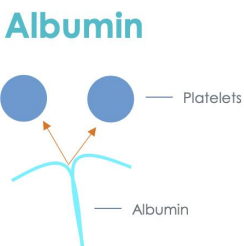


**PVDF-HFP:**  
**Poly(vinylidene-fluoride-co-hexafluoropropylene)**  
A fluorinated copolymer

$$\left[ \begin{array}{c} \text{H} \quad \text{F} \\ | \quad | \\ -\text{C}-\text{C}- \\ | \quad | \\ \text{H} \quad \text{F} \end{array} \right]_n \left[ \begin{array}{c} \text{F} \quad \text{F} \\ | \quad | \\ -\text{C}-\text{C}- \\ | \quad | \\ \text{F} \quad \text{CF}_3 \end{array} \right]_m$$

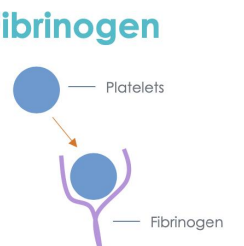
PVDF (85%)      HFP (15%)

**Albumin**



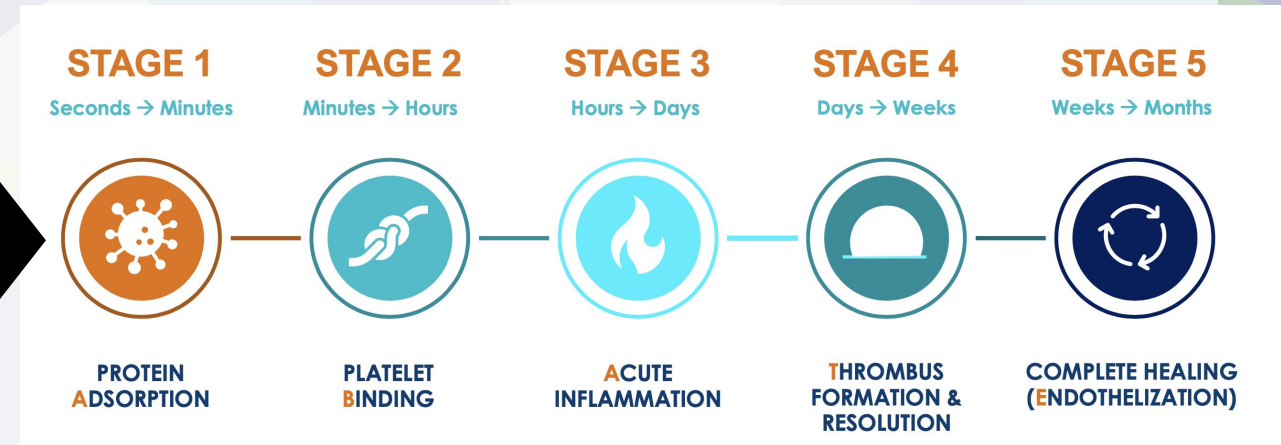
Albumin is considered a passive protein; **it does not possess platelet binding sites.**

**Fibrinogen**

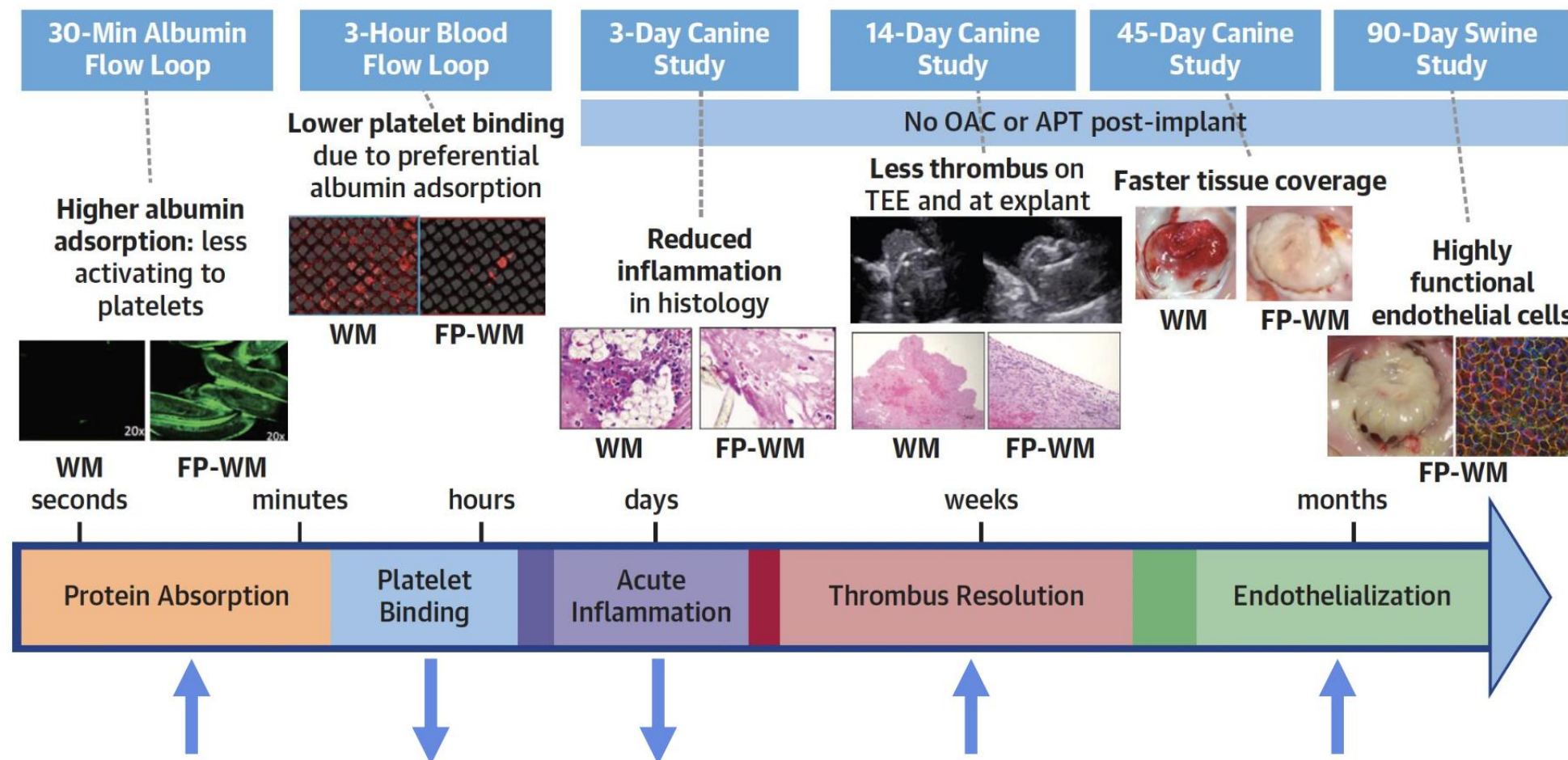


Fibrinogen is not considered a passive protein; **it does possess platelet binding sites.**

Platelets do not bind to the albumin proteins.



# Datos preclínicos



WM FLX Pro vs WM FLX

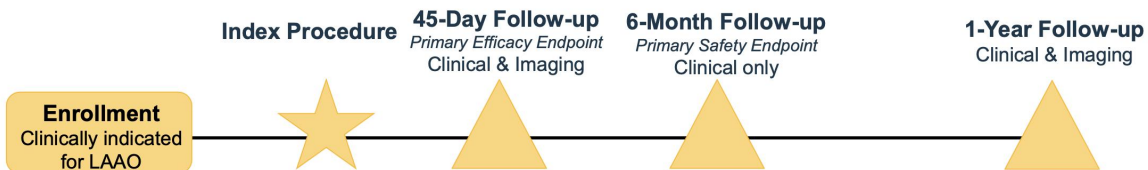
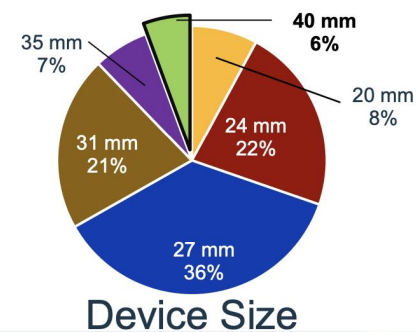
Saliba et al. JACC EP 2023



# HEAL LAA

CLINICAL TRIAL

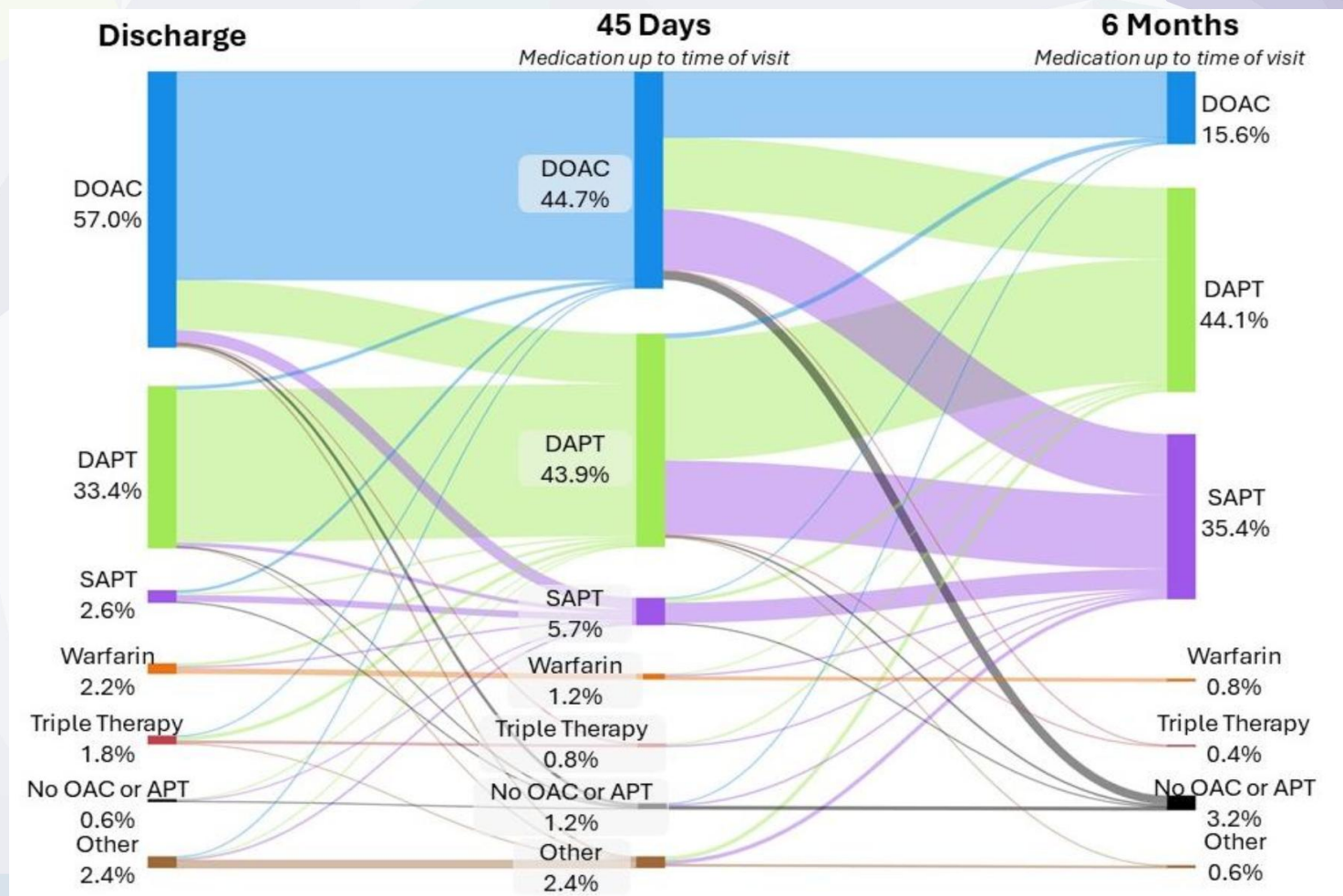
- Prospective, multicenter, post-market clinical study
- 32 centers in United States
- Primary Analysis Set = first 500 patients enrolled



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

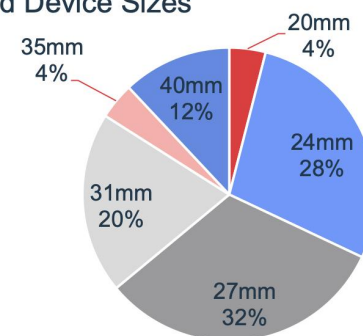


# Watchman FLX Pro CT Pilot Study

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)

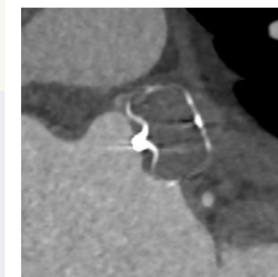
Procedural Characteristics	N = 25
Device success*	100% (25/25)
1 Device implanted	100% (25/25)
Discharge medications	
DAPT	4.0% (1/25)
SAPT	96.0% (24/25)

Implanted Device Sizes

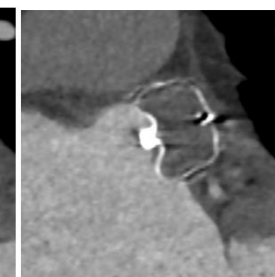


## CT Analysis

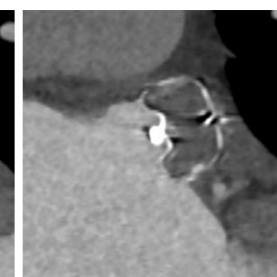
	14 Days	45 Days
Subfabric HAT or No HAT	10	17
Low-grade HAT	13	6
• Flat sessile	1	1
• Protruding sessile -- LA wall continuity and smooth surface	1	0
High-grade HAT	0	0
• Protruding sessile -- No LA wall continuity and/or irregular surface	0	0
• Pedunculated	0	0
No CT	1	1



14-days  
Flat sessile HAT



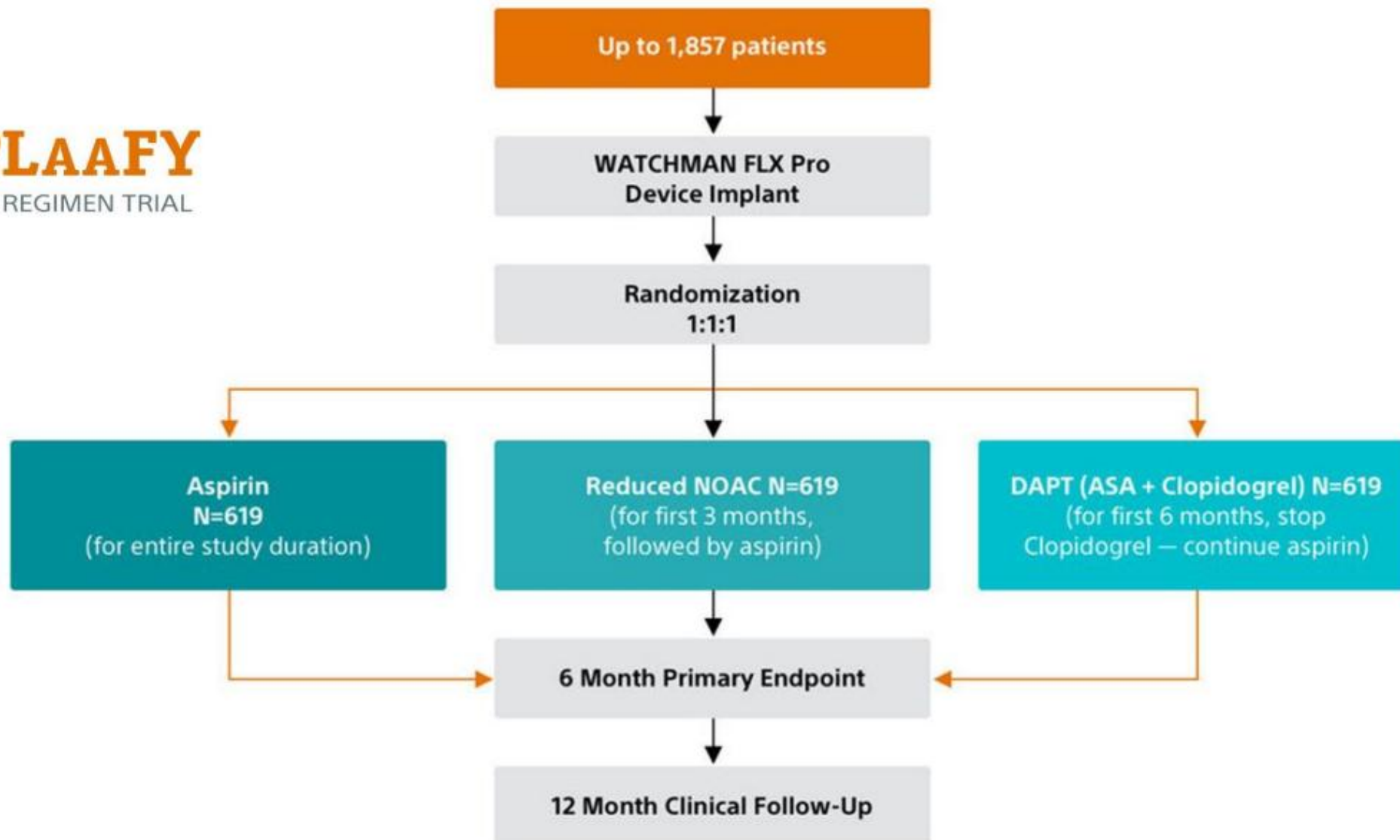
45-days  
No HAT



90-days  
No HAT

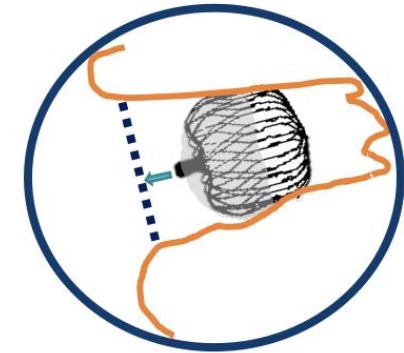
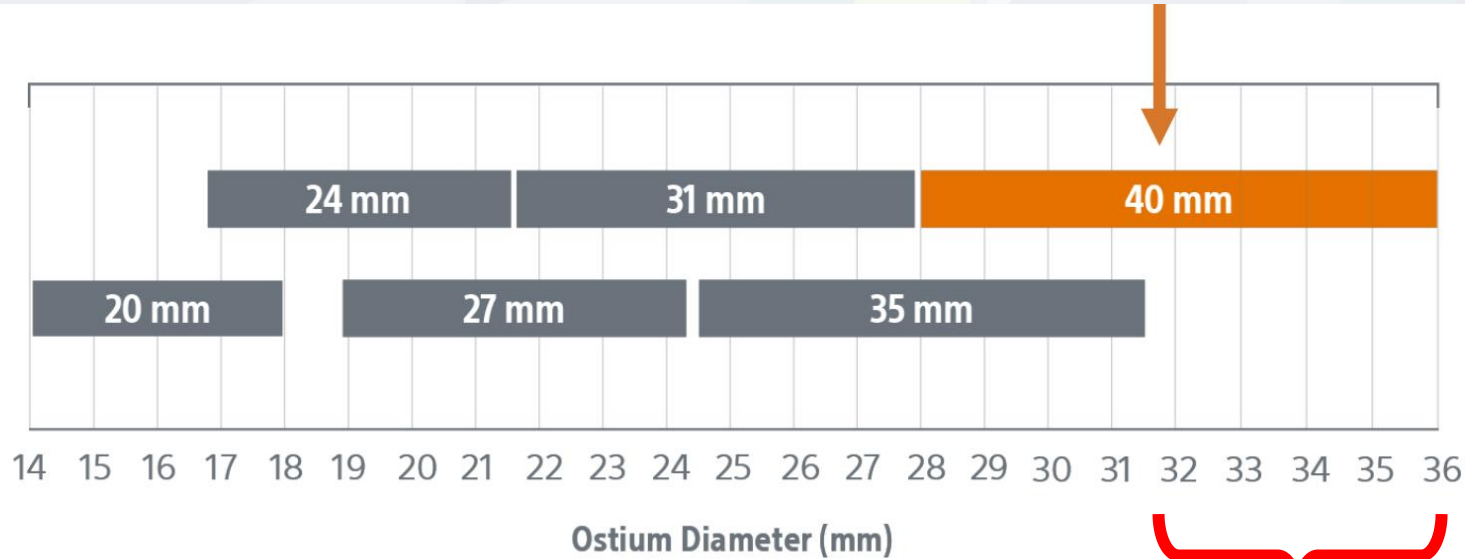
# **SIMPLAAFY**

LAAC DRUG REGIMEN TRIAL

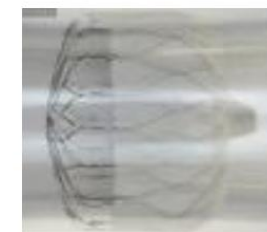




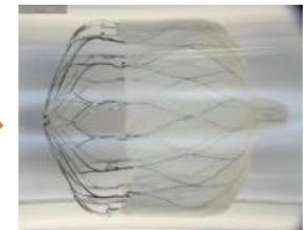
# Dispositivo de 40 mm



Dispositivo 35 mm

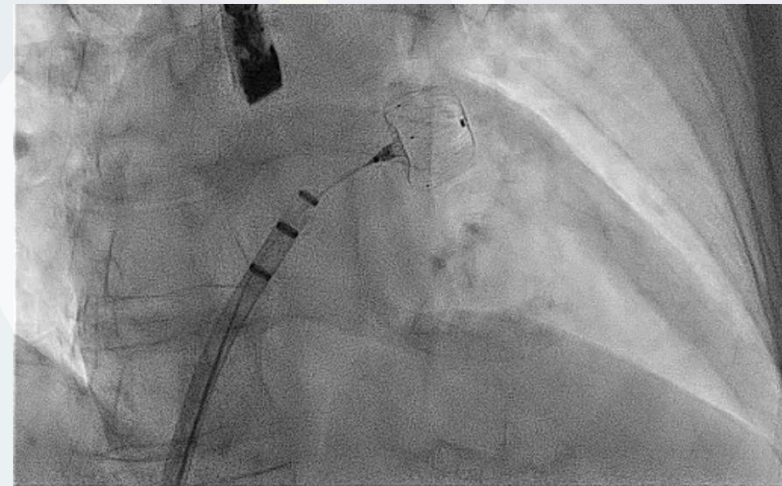
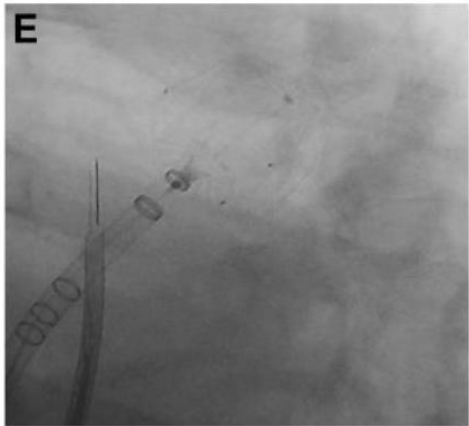
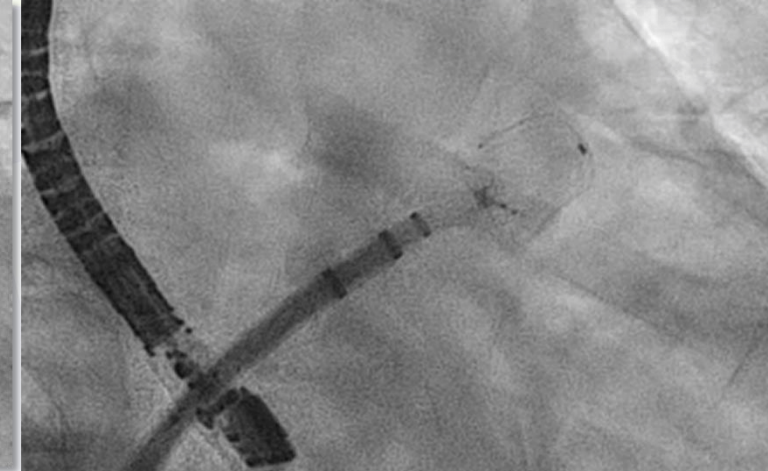
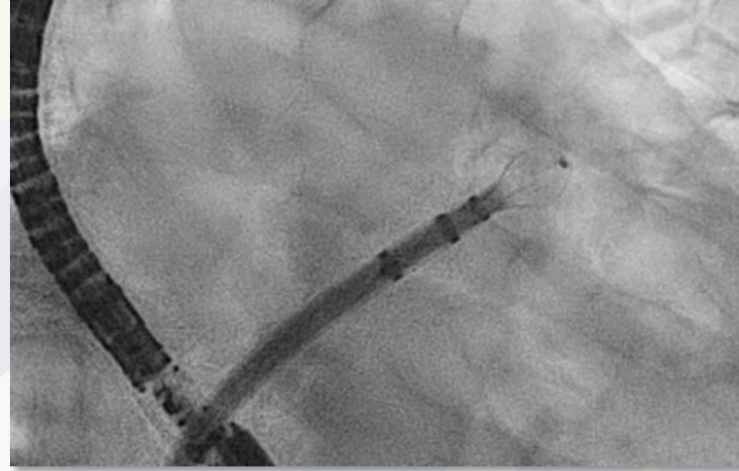
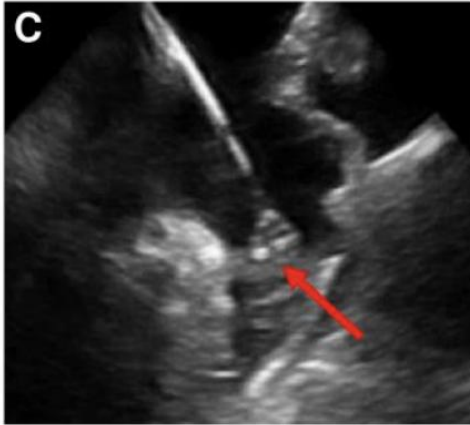
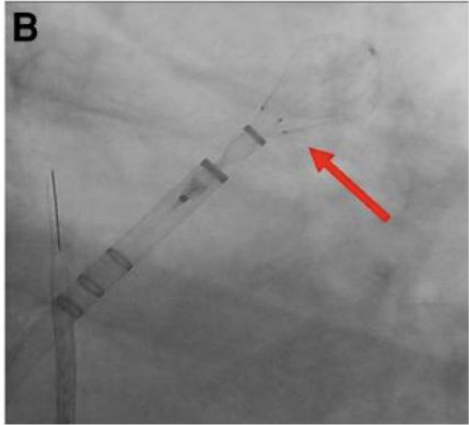


35mm @ 10%  
compression



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 ocluser de 40 mm.