CSC 2025
CORONARY AND STRUCTURAL CONGRESS
CONGRESO CORONARIO Y ESTRUCTURAL
MADRID

5, 6 y 7 NOVIEMBRE
HOTEL RIU PLAZA DE ESPAÑA

SIROLIMUS E INNOVACIÓN:
REDEFINIENDO LA ANGIOPLASTIA CON BALÓN

Marcel Almendarez Lacayo, MD, MSc, PhD
Cardiólogo intervencionista
Hospital Universitario Central de Asturias (HUCA)

5 de Noviembre de 2025

Conflictos de interés

Honorarios recibidos por parte de Cordis

- Participación como ponente en esta presentación.

Why device Choice still matters in PCI

- First POBA by Gruentzig 1977

- Acute vessel closure
- Recoil

- Solved elastic recoil and dissection

- Resteno thrombos

- Improved

ts

ent

- Thinner struts
- Polymer Free

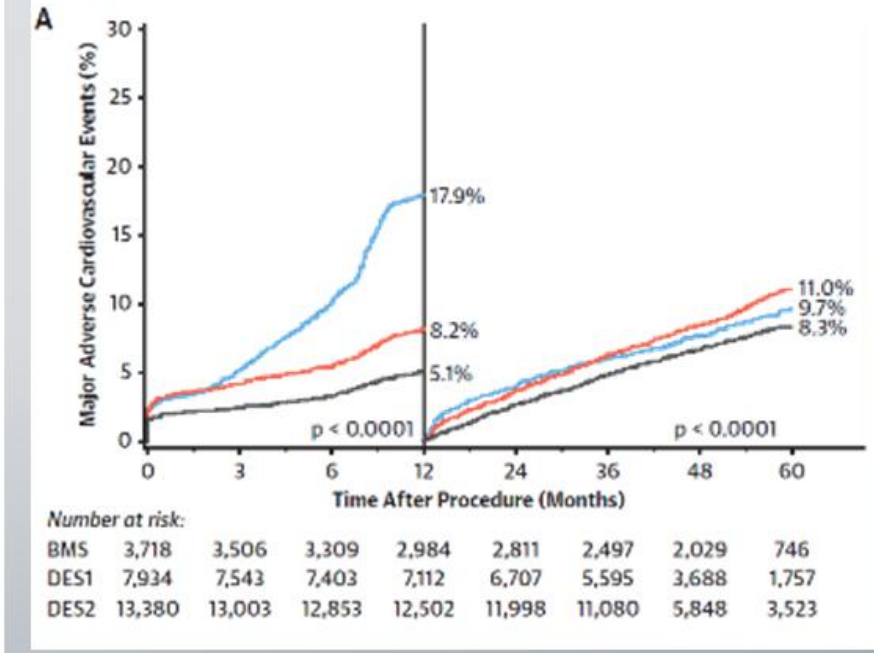
- MACE rate 2-3 %

~2% p/y thr. 5 years

Meta-analysis [3]

25032 Patients (19 RCTs)

MACE



Level I evidence

annual e

ncreasing 2-3%

years

Eisenberg MJ. *Patient Management Following PCI*. JACC: Advances, 2024.

Leave Nothing Behind:
The Rationale for Scaffold-Free Coronary Intervention

MECHANISTIC:
avoid stent-related issues

- Avoid chronic inflammation
- Maintain physiological vasomotion, pulsatility and allow for uneventful positive remodeling
- Avoid stent fractures and ISR treatment burden

CLINICAL:
improve outcomes through the long run

- Interrupt the 2-3% annual MACE cadence observed with DES.
- Reduce DAPT regimen and associated burden
- Leave future treatment options f[illegible]
  - Allows for CT / non-invasive FU imaging
  - May simplify the procedure

•Colombo A et al. *Drug-Coated Balloons for De Novo Lesions*, EuroIntervention, 2024.
•Madhavan MV et al. *Stent-Related Adverse Events >1 Year*, JACC, 2020.
•Colombo A, Leone PP. *Redefining PCI Strategy*, Eur Heart J, 2023

Why Sirolimus (and analogs) DCB/DEB?

Limus presents known advantages vs. Paclitaxel

However, technology challenges (drug transfer/uncontrolled rapid elution) prevented Limus to be the DCB drug of choice

Characteristics	Paclitaxel	Sirolimus (or analogs)
Mode of action	Cytotoxic	Cytostatic
Safety margin	100x	10,000x
Therapeutic range	Narrow	Wide
Anti-inflammatory	No	Yes
Tissue deposition	Sub-intimal with significant partition in adventitia	Throughout arterial wall
Coating application	Easy	Difficult
Tissue absorption	Fast	Slow
Tissue retention	Long	Short
Drug Nature	Highly lipophilic	Less lipophilic

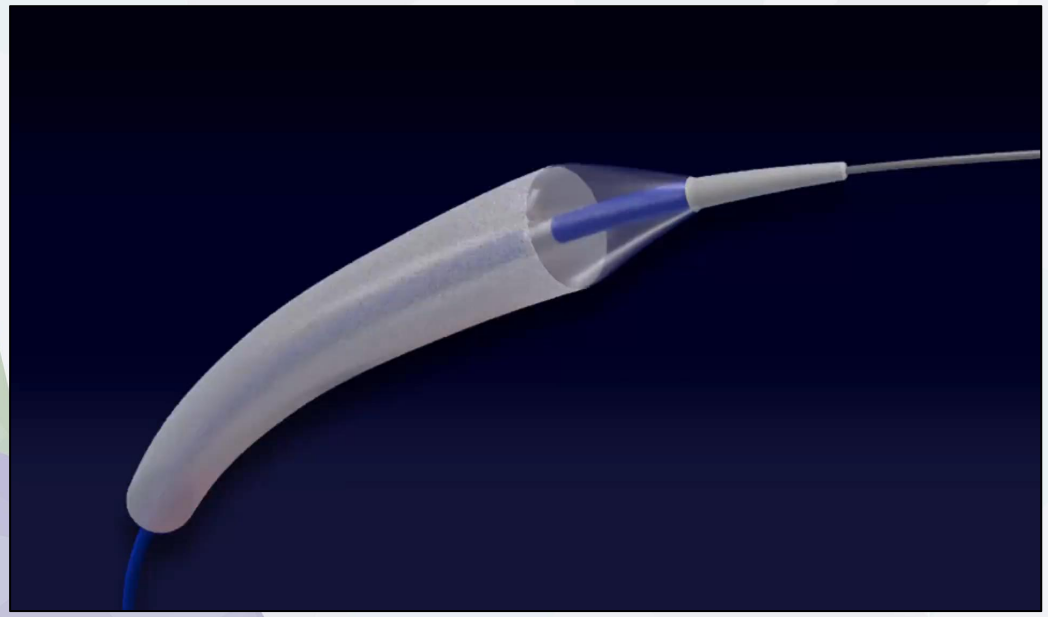
Favorable Unfavorable

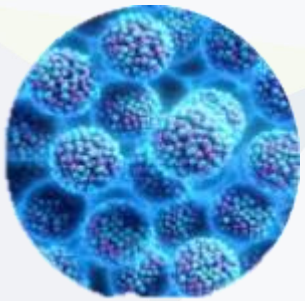
1. El Khoury R, Brodmann M, Schneider PA. Progress on developing an effective below-the-knee drug-coated balloon. Rev Cardiovasc Med. 2021 Sep 24;22(3):585-595. doi: 10.31083/j.rcm2203070. PMID: 34565062.

Cordis

SELUTION SLR™ DRUG-ELUTING BALLOON (DEB) TECHNOLOGY

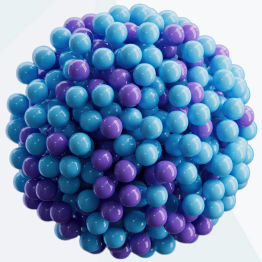
2 key features define the unique performance of SELUTION SLR™ DEB





CELL ADHERENT TECHNOLOGY (CAT)™

- Phospholipid blend containing and protecting MicroReservoirs at 1 µg/mm² Sirolimus dose
- **Enhanced Drug Transfer Efficiency**



MicroReservoirs

- ~4 µm spheres of Sirolimus mixed with biodegradable polymer
- **Sustained Drug Release**

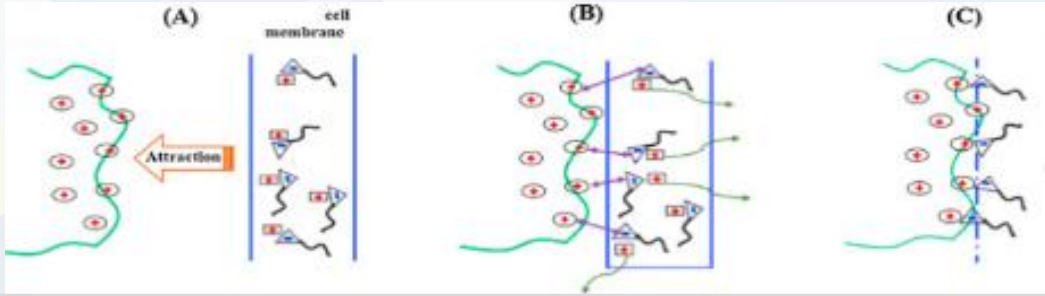
SELUTION SLR™ DEB DRUG DELIVERY TECHNOLOGY

4 µm MicroReservoirs

Sustained drug release system targets effective drug levels in tissue

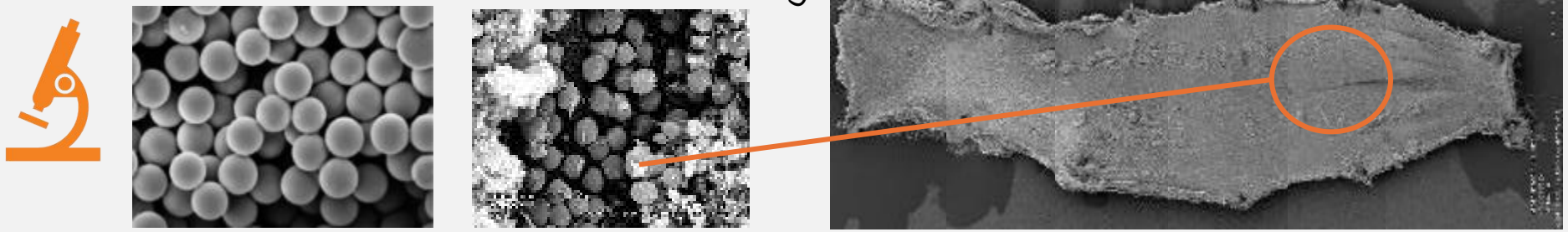
CAT transfer coating

Phospholipid coating protects, delivers and binds MicroReservoirs to vessel lumen



View from a Scanning Electron Microscope

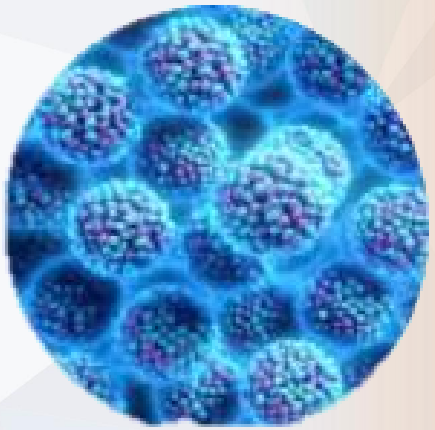
MicroReservoirs Transferred Coating

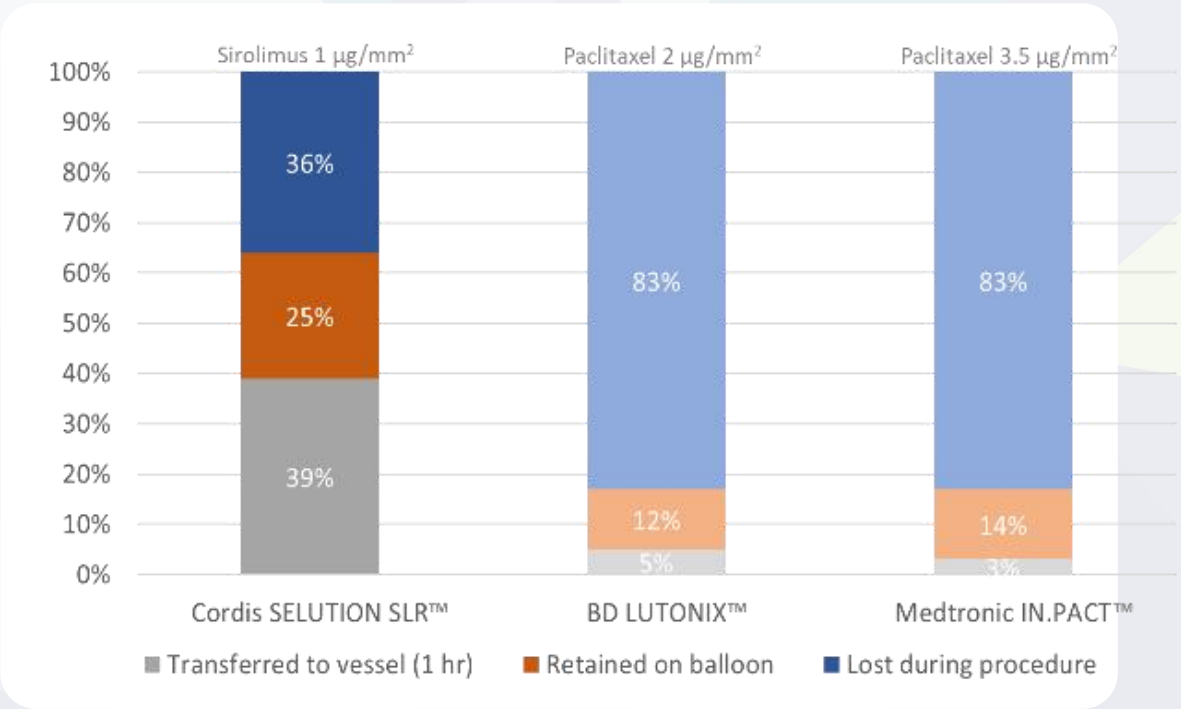


SELUTION SLR™ DEB - ENHANCED DRUG TRANSFER EFFICIENCY

CELL ADHERENT TECHNOLOGY (CAT)™: Phospholipid blend + MicroReservoirs featuring a 1 µg/mm² Sirolimus dose, uniform coating with durability, efficient and homogeneous tissue transfer and minimized drug loss.

CAT

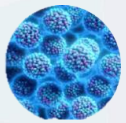
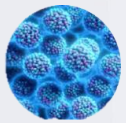
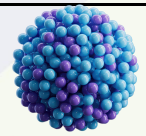
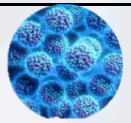
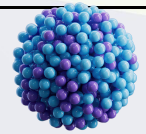


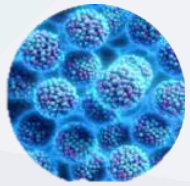


Source: Med Alliance – Bench Test Data on File / Bard-LUTONIX & Medtronic-IN.PACT – Presentation Granada at CRT 2014.

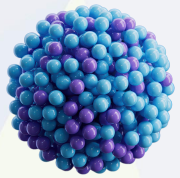
SELUTION SLR™ DEB >>>> Next Generation DEB

Design Goals Met with SELUTION SLR™ DEB: CELL ADHERENT TECHNOLOGY (CAT)™ and MicroReservoirs

	DEB DESIGN GOALS	SELUTION SLR™ DEB	
1	**Coating Durability** drug adherence on balloon surface during transit to avoid drug loss	✓	
2	**Rapid and Efficient Tissue Transfer** rapid and enhanced tissue absorption upon balloon inflation	✓	
3	**Sustained Tissue Retention** tissue persistence at therapeutic levels to allow sustained release	✓	
4	**Homogeneous in-Tissue Distribution** no drug concentration peaks and vacancies (as typical of crystal formulations)	✓	 



CELL ADHERENT TECHNOLOGY (CAT)™



MicroReservoirs

1. Cordis 2024 Data on file.

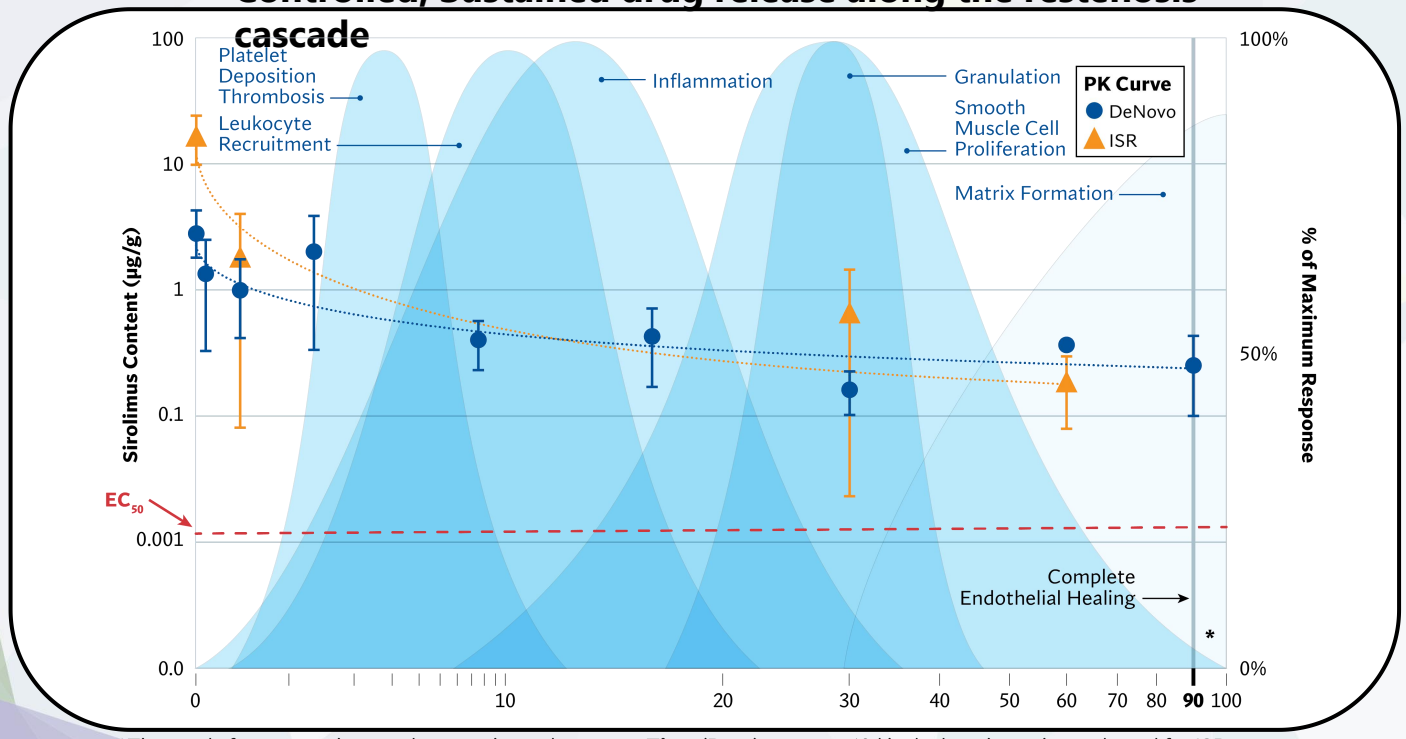
Approved in the United States for Investigational Use Only. Not available for Commercial Sale in the US.

Cordis.

SELUTION SLR™ DEB ADVANTAGE:

CORONARY ARTERY TISSUE PK IN PORCINE MODEL SHOWS EFFECTIVE DRUG CONCENTRATION THROUGH 90 DAYS

Controlled, Sustained drug release along the restenosis cascade

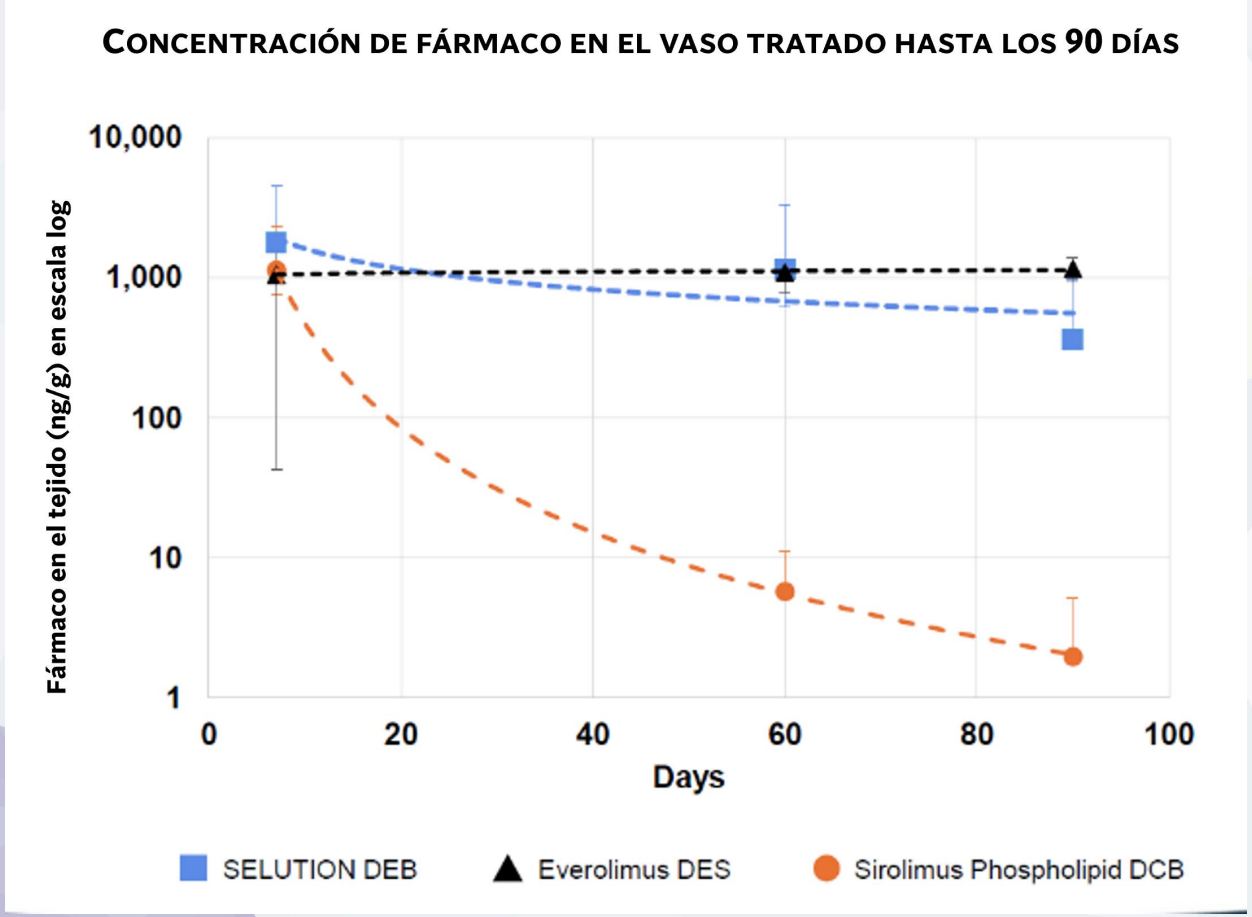


*Time scale for restenosis cascade approximated

60d is the last timepoint evaluated for ISR

- **Sustained drug release** is critical for targeting all elements of the restenosis cascade.
- Similar PK observed for both ***De Novo*** **and ISR** treatment settings.

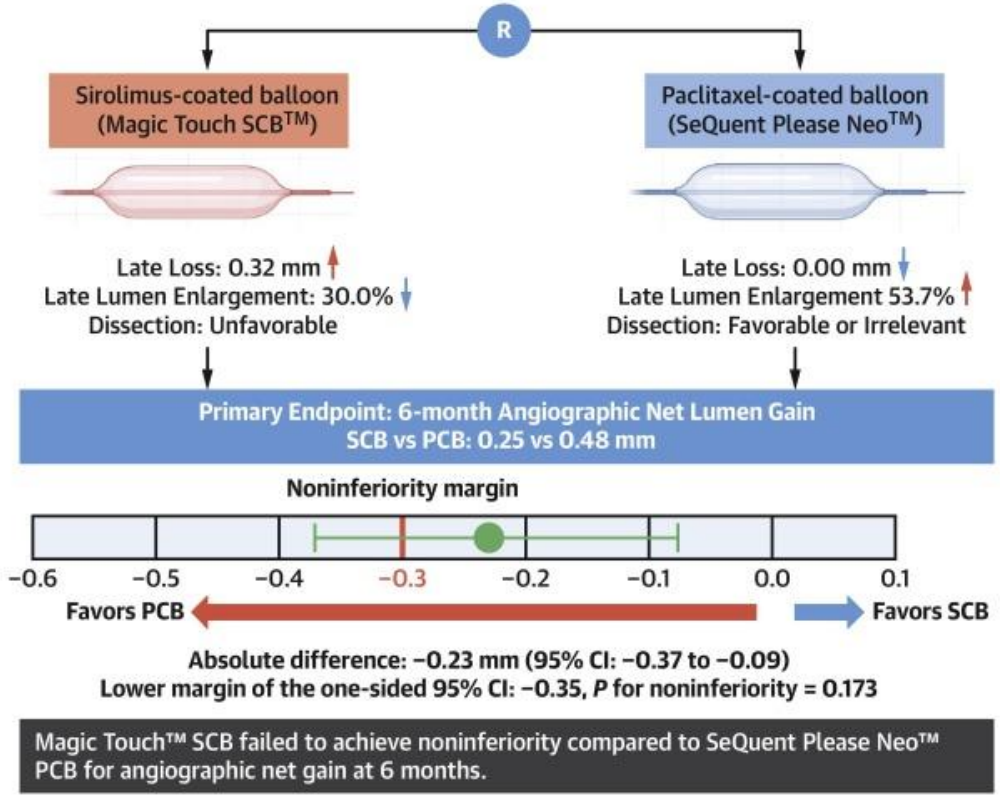
Comparative Pharmacokinetics of Sirolimus DEBs and Everolimus DES in a Swine model



Sustained drug release should enable durable outcomes without a permanent implant.

NO DEB CLASS EFFECT

CENTRAL ILLUSTRATION: TRANSFORM-I Trial: A Prospective, Multicenter, Noninferiority Trial in Patients With De Novo Small Vessel Coronary Artery Disease



Ninomiya K, et al. J Am Coll Cardiol Intv. 2023;16(23):2884-2896.

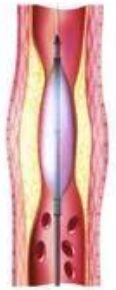
Sirolimus vs. Paclitaxel Coated Balloons for de novo coronary lesions

Mauro Gitto, Nicola Ryan

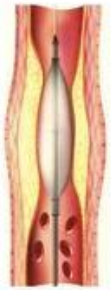
Source: PCRonline.com

70 Patients undergoing DCB-based PCI for de novo coronary lesions

Primary endpoint: Late lumen loss at 6 months



Sirolumus (SeQuent SCB)
0.11±0.37 mm



Paclitaxel (SeQuent Please Neo)
0.04±0.39 mm

Mean difference 0.07 mm (95% CI: −0.12 to 0.26) - pre-specified NI margin: 0.35

The novel Sequent sirolumus coated balloon was angiographically non-inferior to the Sequent paclitaxel coated balloon in de-novo coronary lesions

TCT25 LATE BREAKING TRIALS

Sirolimus drug-eluting balloon strategy achieves non-inferior outcomes to DES at one year.

SELUTION DeNovo Clinical Trial

CRF®
TCT® OCTOBER 25-28, 2025
MOSCONE CENTER
SAN FRANCISCO, CA

#TCT2025

Primary endpoint (TVF):

5.3% in the **SELUTION DEB group**
vs **4.4%** in the **DES group.**

0.91% (95% CI -0.55 to 2.38)
non-inferiority met (p = 0.02).

Take home messages…

WHY DCB

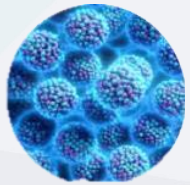
- Potential to reduce / eliminate 2-3% YOY observed DES-related MACE through the long run
- Avoid ISR related burden
- Improves outcomes in specific subsets (SVs, CTOs, DM, …)
- Simplify PCI in specific settings (SVs, Long Lesions, Bif, CTOs, …)
- Hybrid approach possible and beneficial

WHY SIROLIMUS

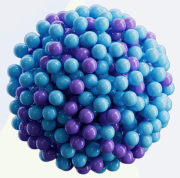
- Wider therapeutic window and higher safety margin vs. PTX
- Better targeting of all triggers of the restenosis cascade: not only SMC but also Inflammation, healing, EF restoration
- Allows for vessel healing while eliminating risk of aneurysm degeneration

WHY SELUTION SLR™ DEB

- Sirolimus Drug Eluting Balloon made possible by technology
- High transfer efficiency and optimized tissue distribution
- Sustained tissue release up to 90 days at therapeutic levels
- Reduced of distal embolization



CELL ADHERENT TECHNOLOGY (CAT)™



MicroReservoirs

CSC 2025

CORONARY AND STRUCTURAL CONGRESS
CONGRESO CORONARIO Y ESTRUCTURAL

MADRID

5, 6 y 7 NOVIEMBRE

HOTEL RIU PLAZA DE ESPAÑA

Muchas gracias por su atención

Marcel Almendárez Lacayo

@maralm08

marcel.almendarez@gmail.com