

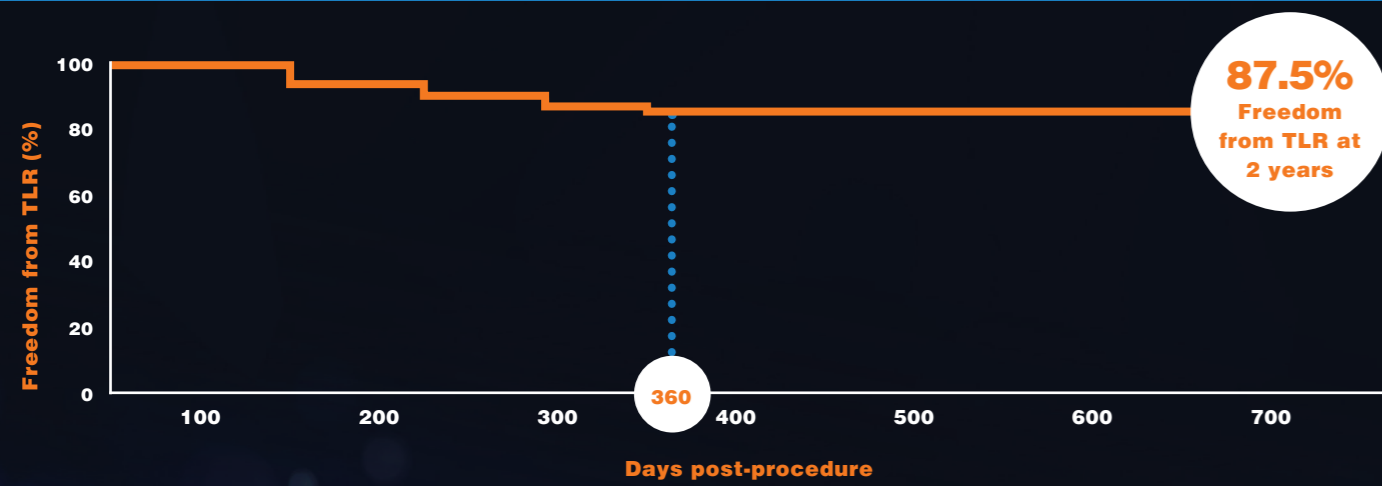
# Delivering Long-Term Clinical Benefits in Peripheral Artery Disease<sup>4</sup>

## SELUTION SFA – First-in-Man Clinical Trial

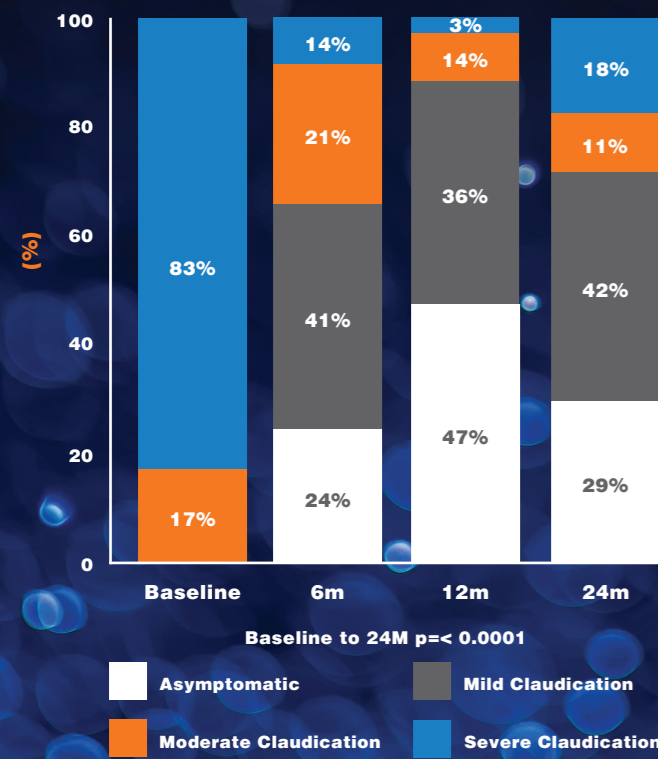
Principal Investigator: Thomas Zeller, MD, Germany (ClinicalTrials.gov ID: NCT02941224)

- Prospective, controlled, multi-center, open, single-arm clinical investigation
- 50 patients in 4 German Centers
- Met Primary Endpoint of Late Lumen Loss at 6 Months with 0.19mm\*\*

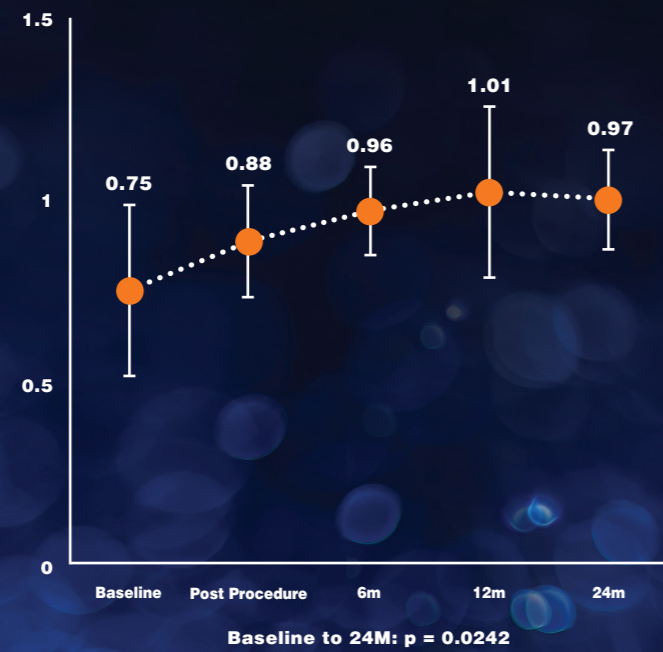
### SELUTION SFA – Freedom from TLR



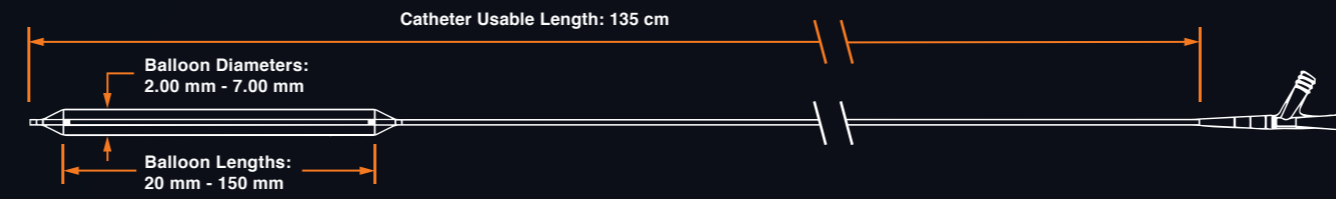
### 84% of patients improved in Rutherford Classification out to 24M



### Clinical Improvement in ABI



## Technical Specification



Feature	Specification	Balloon	
Sirolimus Drug Dose	1.0 µg/mm <sup>2</sup>	Nominal Balloon Pressure (NP)	6 bar
Drug Carrier	Cell Adherent Technology (CAT™) Amphipathic Lipid Carrier	Rated Burst Pressure (RBP)	20 – 40 mm: RBP 12 bar 60 – 150 mm: RBP 10 bar
Catheter Design	Over-the-Wire (OTW)	Balloon Diameter	2.00 mm – 7.00 mm
Catheter Usable Length	135 cm	Balloon Lengths	20, 40, 60, 80, 100, 120, 150 mm
Guidewire Compatibility	0.018"		
Intruder Sheath Compatibility	5 Fr for balloon diameters 2.00 – 3.00 mm 6 Fr for balloon diameters 3.50 – 5.00 mm 7 Fr for balloon diameters 6.00 – 7.00 mm		

## Ordering Information

### SELUTION SLR™ Sirolimus Eluting PTA Balloon Catheter

Balloon Diameter (mm)	Balloon Length (mm)						
	20	40	60	80	100	120	150
2.00	SE18-020020	SE18-020040	SE18-020060	SE18-020080	SE18-020100	SE18-020120	SE18-020150
2.50	SE18-025020	SE18-025040	SE18-025060	SE18-025080	SE18-025100	SE18-025120	SE18-025150
3.00	SE18-030020	SE18-030040	SE18-030060	SE18-030080	SE18-030100	SE18-030120	SE18-030150
3.50	SE18-035020	SE18-035040	SE18-035060	SE18-035080	SE18-035100	SE18-035120	SE18-035150
4.00	SE18-040020	SE18-040040	SE18-040060	SE18-040080	SE18-040100	SE18-040120	SE18-040150
5.00	SE18-050020	SE18-050040	SE18-050060	SE18-050080	SE18-050100	SE18-050120	SE18-050150
6.00	SE18-060020	SE18-060040	SE18-060060	SE18-060080	SE18-060100	SE18-060120	SE18-060150
7.00	SE18-070020	SE18-070040	SE18-070060	SE18-070080	SE18-070100	SE18-070120	SE18-070150

\*\* Presented as median value. 1. Drug concentration evident in MicroReservoirs and tissue. - Data on file at M.A. Med Alliance SA. 2. Data on file at M.A. Med Alliance SA. 3. Granada. J - Oral Presentation CRT 2014. 4. Zeller. T - Oral Presentation VIVA 2019. SELUTION SLR and CAT are trademarks of M.A. Med Alliance SA. © 2021 M.A. Med Alliance SA.

Indication, contraindications and warnings can be found in the instructions for use supplied with each device. SELUTION SLR Sirolimus Eluting PTA Balloon Catheter - CE Mark Approved. Not available for sale in United States.

M.A. Med Alliance SA, Rue de Rive 5, 1260 Nyon, Switzerland  
T: + 41 22 363 78 90 | E: info@medalliance.com | W: www.medalliance.com



0344

SAM-0002 REV F



Sirolimus Eluting PTA Balloon Catheter



# A Breakthrough in Drug-Eluting Balloon Technology

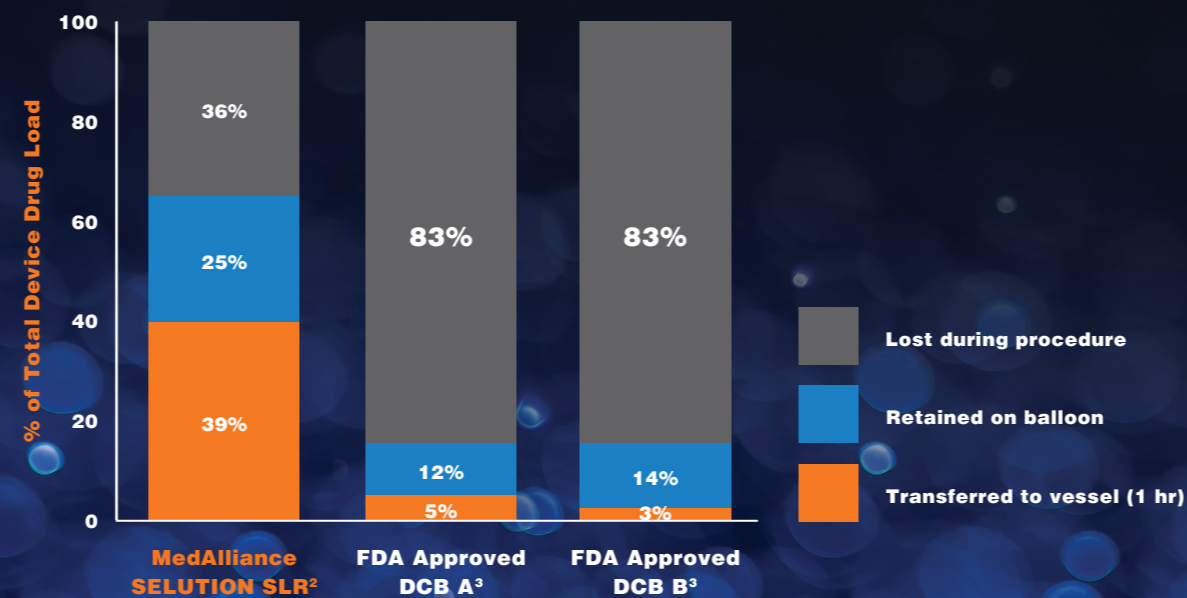
## The First Sirolimus Drug Eluting Balloon Specifically Designed to Treat Peripheral Artery Disease.

**SELUTION SLR™** uniquely combines the proven safety and efficacy of sirolimus with advanced MicroReservoir and Cell Adherent Technology (CAT™) to offer a sustained therapeutic effect for up to 90 days.<sup>1</sup>

## Breakthrough\* Technology to Deliver Sustained Limus Release for up to 90 days<sup>1</sup>

### SELUTION SLR – Drug Transfer Efficiency

The CAT amphipathic coating maximises drug bioavailability



**MicroReservoirs** form millions of precision-engineered drug delivery systems, combining sirolimus with a biodegradable polymer, achieving consistent and predictable drug release;

- Optimizing MicroReservoir size to achieve a pharmaco-kinetic release profile comparable to the latest generation DES technology.



**Cell Adherent Technology (CAT™)** is a proprietary amphipathic lipid technology which binds the MicroReservoirs to the balloon surface, protecting them during balloon insertion and inflation;

- Enhancing drug retention and bioavailability, allowing for a lower drug dose concentration on the balloon surface (1 µg/mm<sup>2</sup>).
- Optimizing transfer of MicroReservoirs to the tissue and maximizing the cellular uptake of sirolimus.



### Latest Generation of PTA Balloon

- Offering a broader portfolio for peripheral indications with balloon diameters ranging from 2.00 mm to 7.00 mm and lengths from 20 mm to 150 mm.

\* MedAlliance is the first drug-eluting balloon (DEB) company in the world to be awarded US Food and Drug Administration (FDA) Breakthrough Device Designation Status.