

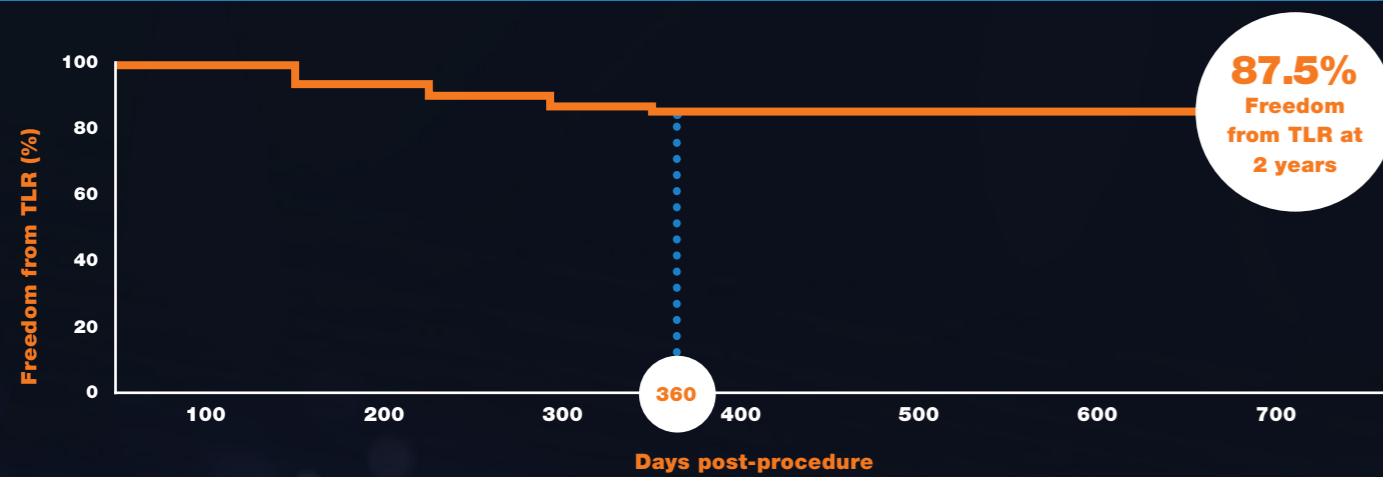
Delivering Long-Term Clinical Benefits in Peripheral Artery Disease¹

SELUTION SFA – First-in-Man Clinical Trial

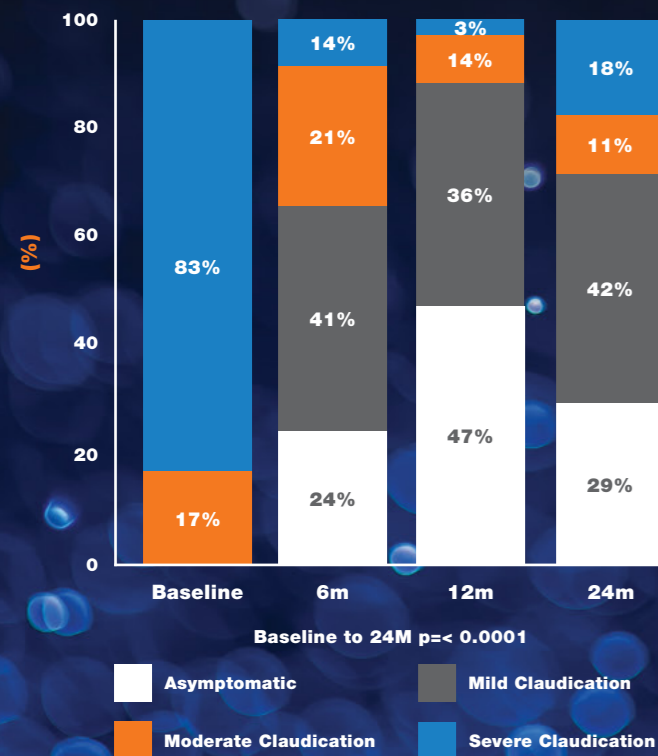
Principal Investigator: Thomas Zeller, MD, Germany (ClinicalTrials.gov ID: NCT02941224)

- 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**

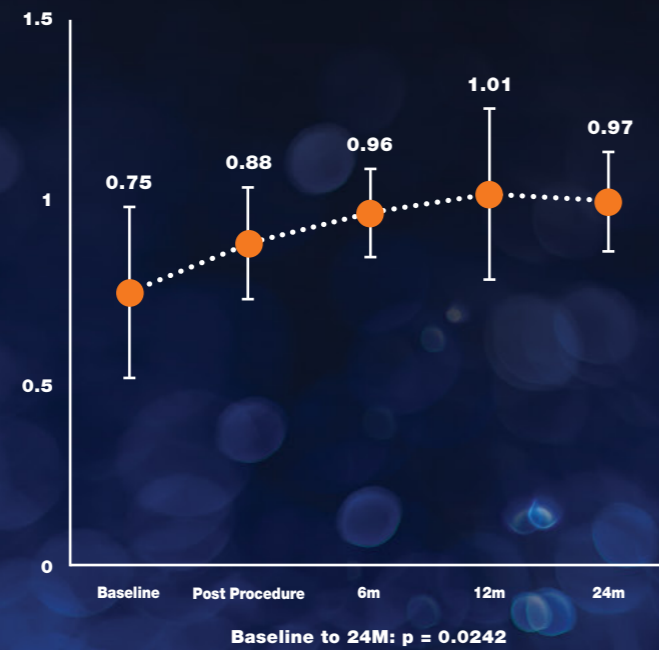
SELUTION SFA – Freedom from TLR



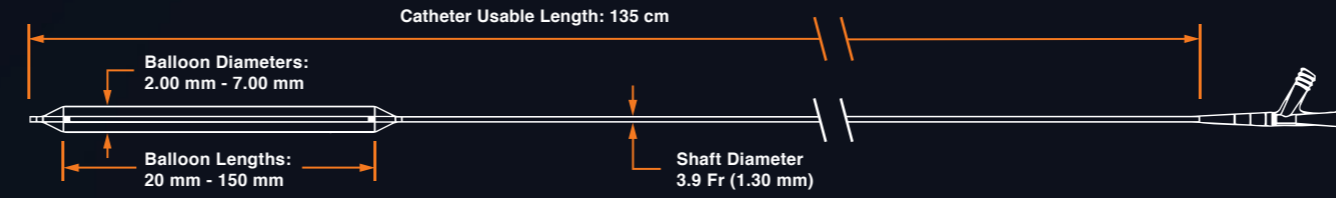
84% of patients improved in Rutherford Classification out to 24M



Clinical Improvement in ABI



Technical Specification



Feature	Specification
Sirolimus Drug Dose	1.0 µg/mm ²
Drug Carrier	Cell Adherent Technology (CAT™) Amphipathic Lipid Carrier
Catheter Design	Over-the-Wire (OTW)
Shaft Diameter	3.9 Fr (1.30 mm)
Catheter Usable Length	135 cm
Guidewire Compatibility	0.018"

Balloon	
Nominal Balloon Pressure (NP)	6 bar
Rated Burst Pressure (RBP)	20 – 40 mm: RBP 12 bar 60 – 150 mm: RBP 10 bar
Balloon Diameter	2.00 mm – 7.00 mm
Balloon Lengths	20, 40, 60, 80, 100, 120, 150 mm

Ordering Information

SELUTION SLR™ Sirolimus Eluting PTA Balloon Catheter

Balloon Diameter (mm)	Balloon Length (mm)	Sheath Compatibility (Fr)	Product Code
2.00	20	5	SE18-020020
2.00	40	5	SE18-020040
2.00	60	5	SE18-020060
2.00	80	5	SE18-020080
2.00	100	5	SE18-020100
2.00	120	5	SE18-020120
2.00	150	5	SE18-020150
3.00	20	5	SE18-030020
3.00	40	5	SE18-030040
3.00	60	5	SE18-030060
3.00	80	5	SE18-030080
3.00	100	5	SE18-030100
3.00	120	5	SE18-030120
3.00	150	5	SE18-030150
4.00	20	6	SE18-040020
4.00	40	6	SE18-040040
4.00	60	6	SE18-040060
4.00	80	6	SE18-040080
4.00	100	6	SE18-040100
4.00	120	6	SE18-040120
4.00	150	6	SE18-040150
5.00	20	6	SE18-050020
5.00	40	6	SE18-050040
5.00	60	6	SE18-050060
5.00	80	6	SE18-050080
5.00	100	6	SE18-050100
5.00	120	6	SE18-050120
5.00	150	6	SE18-050150
6.00	20	7	SE18-060020
6.00	40	7	SE18-060040
6.00	60	7	SE18-060060
6.00	80	7	SE18-060080
6.00	100	7	SE18-060100
6.00	120	7	SE18-060120
6.00	150	7	SE18-060150
7.00	20	7	SE18-070020
7.00	40	7	SE18-070040
7.00	60	7	SE18-070060
7.00	80	7	SE18-070080
7.00	100	7	SE18-070100
7.00	120	7	SE18-070120
7.00	150	7	SE18-070150

** Presented as median value. 1 - Zeller, T, Oral Presentation, VIVA Conference 2019. 2 - Data on File. 3 - Presentation Granada at CRT 2014.

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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.

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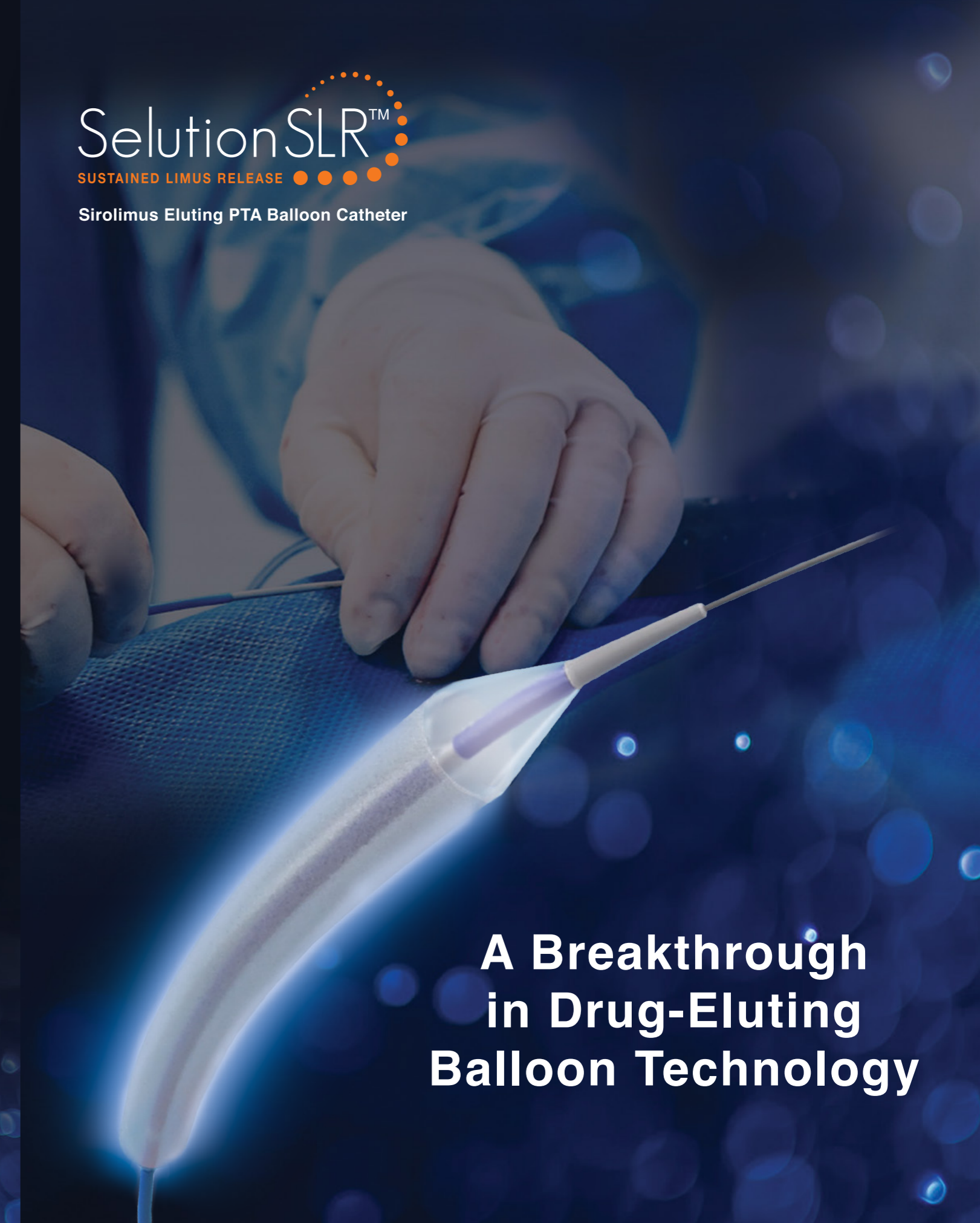


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SAM-0002 Rev.D



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 over 60 days, achieving long-term clinical benefits.¹



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 pharmacokinetic release profile comparable to the latest generation DES technology.



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.

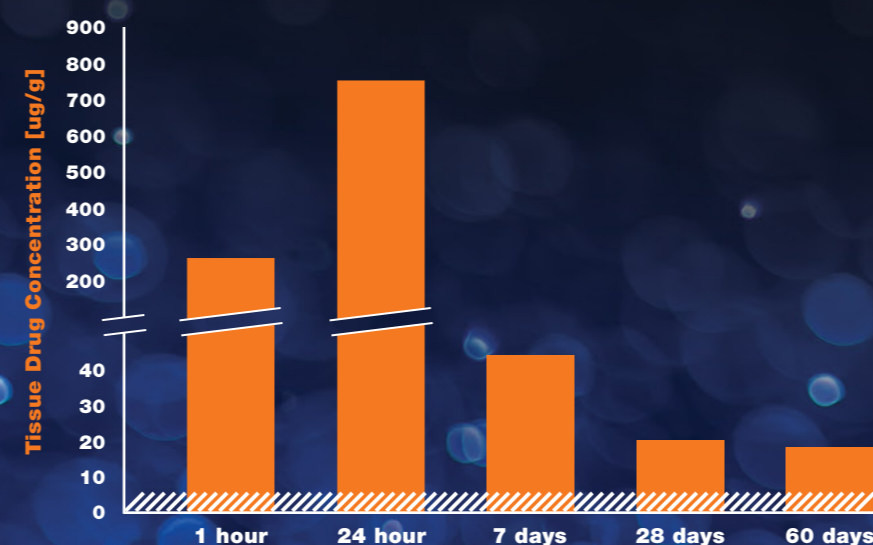


Cell Adherent Technology (CAT™) is a proprietary amphipathic lipid technology which binds the MicroReservoirs to the balloon surface, protecting them during balloon insertion and inflation;

- Enhancing drug retention and bioavailability, allowing for a lower drug dose concentration on the balloon surface (1 µg/mm²).
- Optimizing transfer of MicroReservoirs to the tissue and maximizing the cellular uptake of sirolimus.

Breakthrough* Technology to Deliver a Sustained Therapeutic Effect

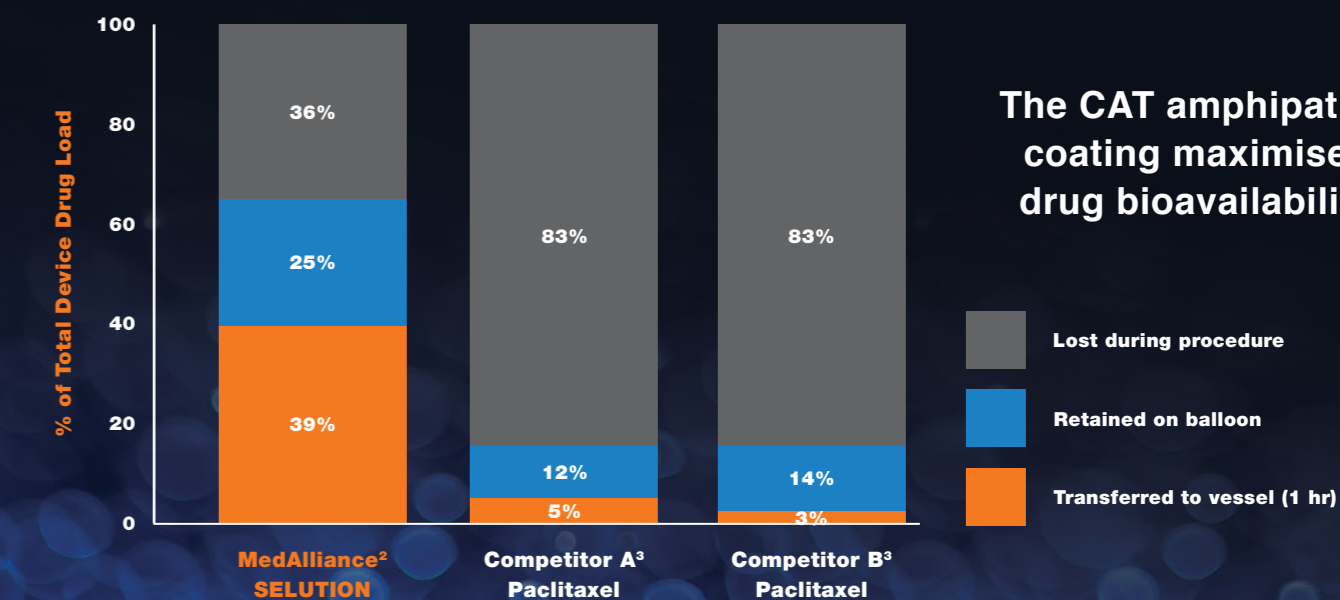
SELUTION SLR – Arterial Tissue Drug Concentration²



Effective, controlled and sustained drug release – extending therapeutic effect for more than 60 days

Effective minimum therapeutic dose is approximately $\geq 1 \mu\text{g/g}$ of tissue

SELUTION SLR – Drug Transfer Efficiency



The CAT amphipathic coating maximises drug bioavailability

* 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.