

DRUG ELUTION DONE BETTER

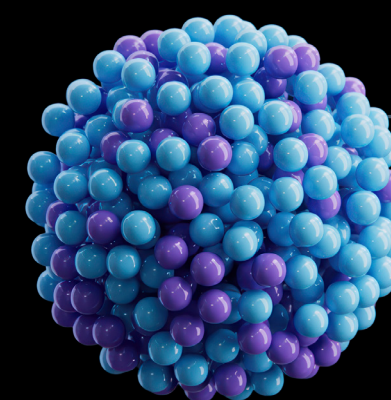
SELUTION SLR DEB UNIQUELY DELIVERS SIROLIMUS

The drug of choice for coronary intervention



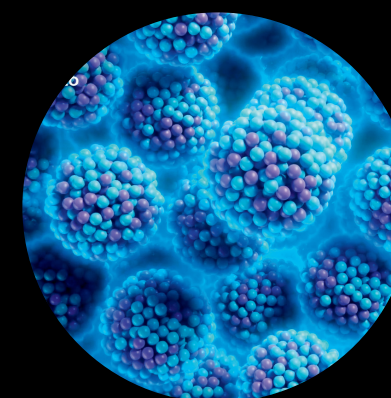
MICRORESERVOIRS

- ~4 μm spheres of sirolimus mixed with biodegradable polymer
- Controlled release of sirolimus



PHOSPHOLIPID BLEND COATING

- Phospholipid blend containing and protecting microreservoirs at 1 $\mu\text{g}/\text{mm}^2$ sirolimus dose
- Enhances drug transfer efficiency



SELUTION SLR™
DRUG-ELUTING BALLOON



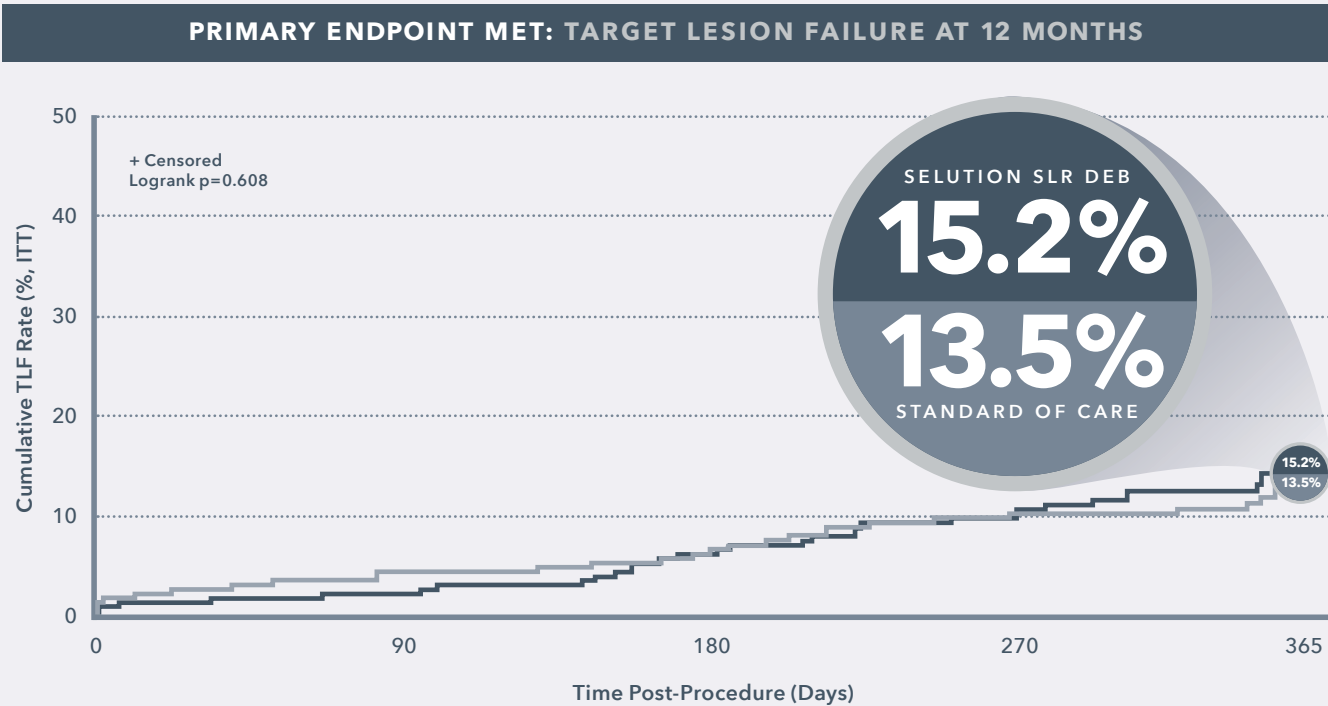
THE ONLY DEB WITH PROVEN EFFICACY

AGAINST THE CURRENT ISR STANDARD OF CARE IN A RANDOMIZED CLINICAL TRIAL

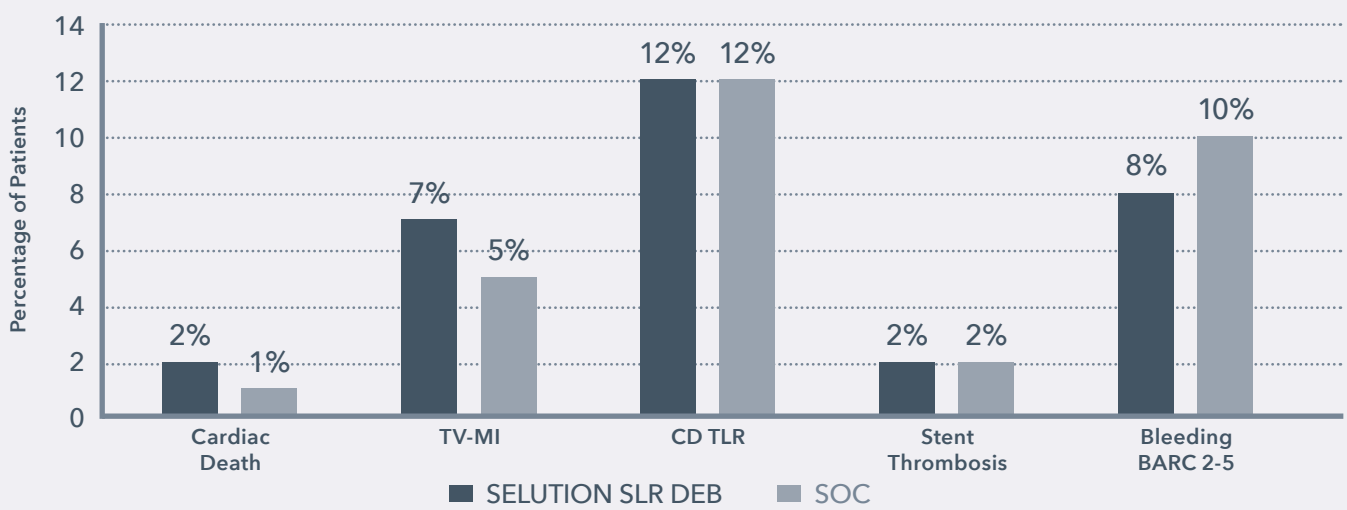
SELUTION4ISR
FDA IDE STUDY

SELUTION SLR DEB ACHIEVED TLF RATE OF 15.2% COMPARED TO STANDARD OF CARE OF 13.5%*

A prospective, multi-center, randomized, single blind, controlled, non-inferiority clinical trial to demonstrate safety and efficacy of SELUTION SLR DEB vs. Standard of Care (SOC) in ISR.



SELUTION SLR DEB IS A SAFE ALTERNATIVE TO DES AND POBA ACROSS VARIOUS COMPARATIVE ARMS³



80% DES-TREATED
IN SOC ARM



418

Randomized
Patients

48 SITES

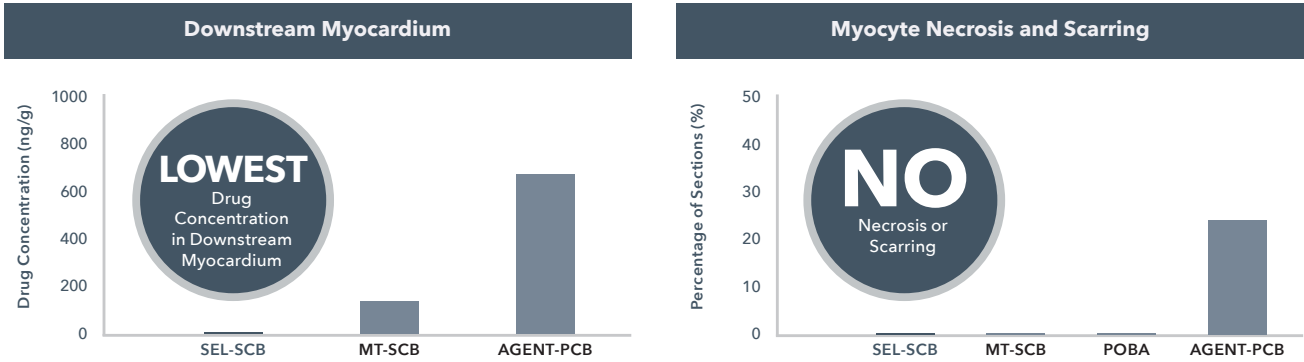


US
CANADA
BRAZIL
EUROPE

*Intent to treat population. The primary analysis was the per protocol population (SELUTION SLR DEB 16.2% vs SOC 14.5%).

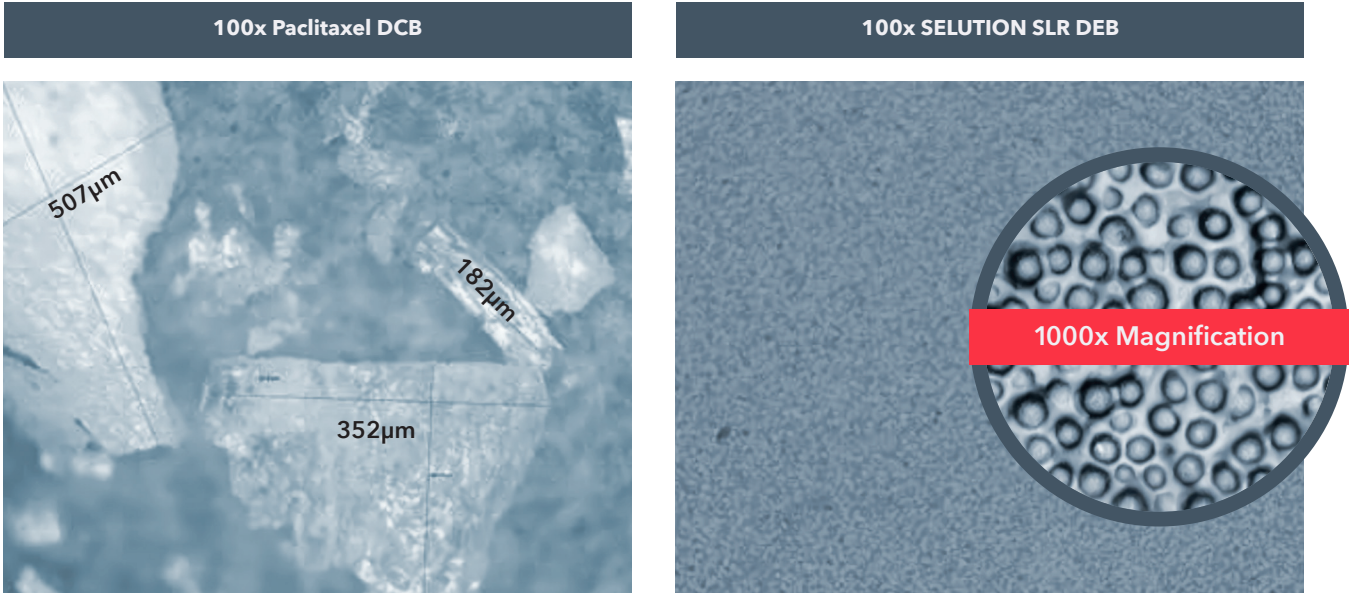
SELUTION SLR DEB DEMONSTRATED REDUCED EMBOLIZATION RISK AND NO DISTAL TISSUE SCARRING COMPARED WITH AGENT DCB⁴

Vascular response of the coronary artery and the embolization after treatment in a porcine model at 28 days



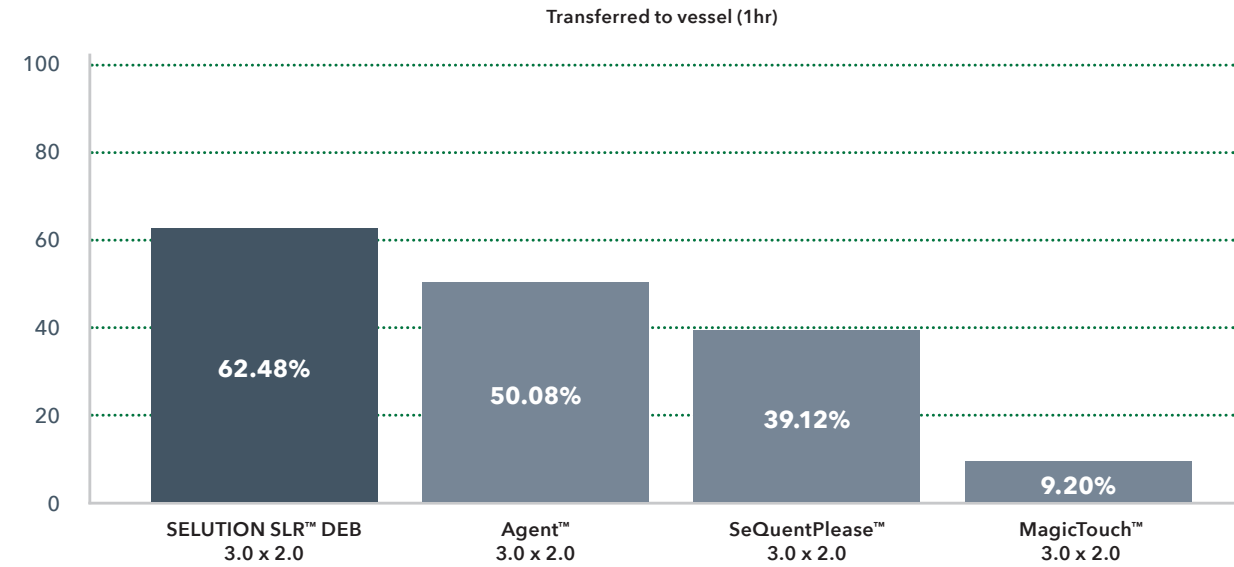
SEL-SCB = SELUTION SLR™ DEB, MT-SCB = MagicTouch™, AGENT™-PCB = Paclitaxel balloon

Compared to paclitaxel crystalline particles, SELUTION SLR™ DEB provides small, uniform 4µm micro-reservoirs, reducing the risk of embolization⁵

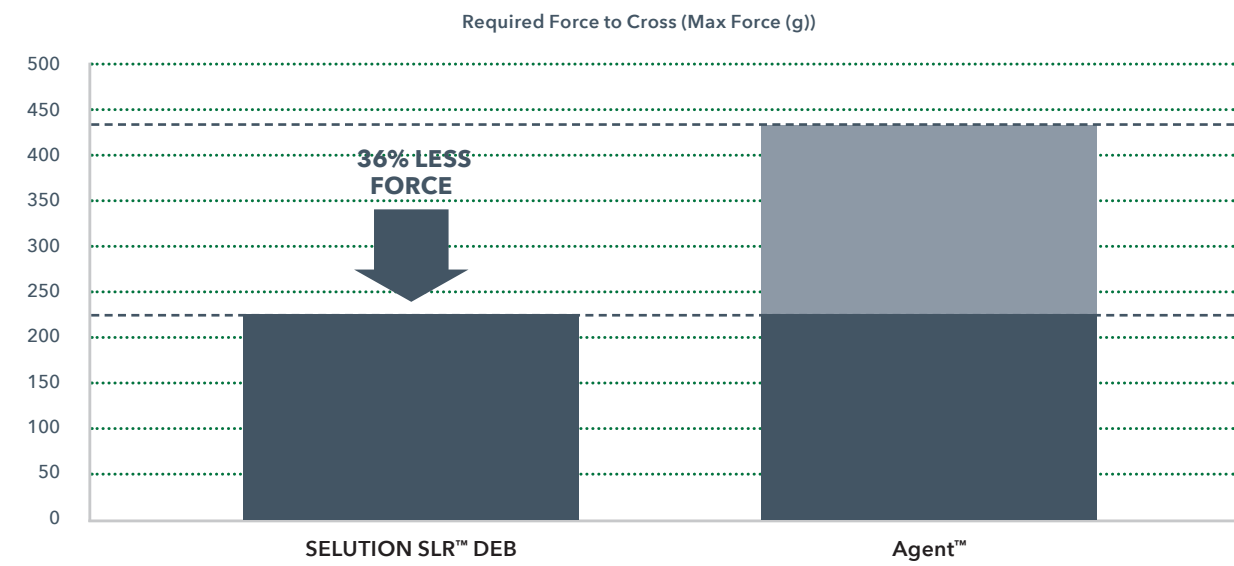


100x Magnification 0.45µ filter used in all tests

HIGHEST DRUG TRANSFER ENABLED WITH SELUTION SLR DEB PHOSPHOLIPID BLEND COATING⁵

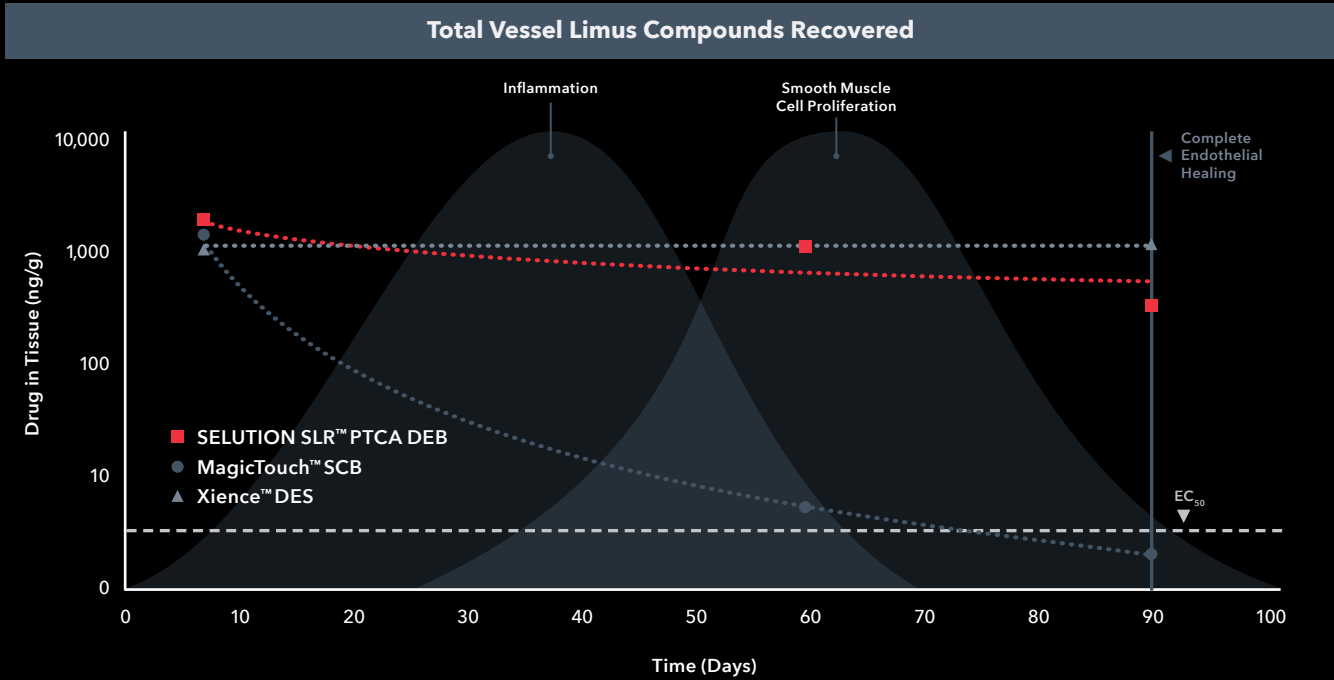


SELUTION SLR DEB REQUIRES 36% LESS FORCE TO DELIVER COMPARED WITH AGENT DCB⁵



DESIGNED FOR IMPROVED DELIVERY AND SUSTAINED RELEASE OF SIROLIMUS

SELUTION SLR PTCA DEB has demonstrated sustained release of sirolimus through 90 days with a pharmacokinetic profile comparable to a DES¹

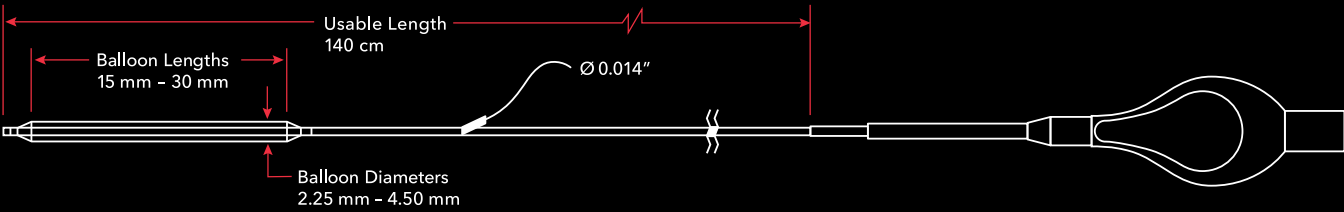


Sirolimus compared to paclitaxel²

Sirolimus	Paclitaxel
Cytostatic	Cytotoxic
mTOR inhibition with reversible modulation of cell-cycle activity and natural vessel function	Causes irreversible cell-cycle arrest and cell death, which may impact vessel health (aneurysm and vessel wall thinning) and physiological healing processes, potentially leading to thrombosis
Demonstrated anti-inflammatory properties	No intrinsic anti-inflammatory effect
Reduced distal embolization with sirolimus*	Potential risk of downstream embolization*

* Sirolimus as delivered by SELUTION SLR DEB as compared to paclitaxel coated balloon.

SELUTION SLR™ PTCA DRUG-ELUTING BALLOON



DEVICE COMPONENT CHARACTERISTICS

Catheter Design	Rapid Exchange (RX) PTCA	Guidewire Compatibility	Compatible with 0.014-inch (0.36 mm) guidewire diameter
Catheter Usable Length	140 cm	Drug Component	Active Pharmaceutical Ingredient: Sirolimus (1.0 µg/mm² dose density) Excipients: Poly(lactic-co-glycolic acid) or PLGA, lipid blend
Nominal Pressure	6 ATM	Lubricious Hydrophilic Coating	Covering 18-21 cm of the distal catheter shaft, 10 ± 5 mm from the balloon proximal bond to 4 cm away from RX Port
Rated Burst Pressure (RBP)	14 ATM	Tip Entry Profile (OD)	0.0181"
Guide Catheter Compatibility (minimum size)	2.25 to 4.00 mm Diameters: 5F 4.50 mm Diameters: 6F		

ORDERING INFORMATION

Balloon Diameter (mm)	Balloon Length (mm)			
	15	20	25	30
2.25 mm	SCB14U-225015D	SCB14U-225020D	SCB14U-225025D	SCB14U-225030D
2.50 mm	SCB14U-250015D	SCB14U-250020D	SCB14U-250025D	SCB14U-250030D
2.75 mm	SCB14U-275015D	SCB14U-275020D	SCB14U-275025D	SCB14U-275030D
3.00 mm	SCB14U-300015D	SCB14U-300020D	SCB14U-300025D	SCB14U-300030D
3.25 mm	SCB14U-325015D	SCB14U-325020D	SCB14U-325025D	SCB14U-325030D
3.50 mm	SCB14U-350015D	SCB14U-350020D	SCB14U-350025D	SCB14U-350030D
4.00 mm	SCB14U-400015D	SCB14U-400020D	SCB14U-400025D	SCB14U-400030D
4.50 mm	SCB14U-450015D	SCB14U-450020D	SCB14U-450025D	SCB14U-450030D



Scan for product information

1. T Tanaka et al, Cardiovasc Revasc Med 2025; 51553-8389(25)00464-6
2. Wessely R, Blaich B, Belaiba RS, Merl S, Görlach A, Kastrati A, Schömig A. Comparative characterization of cellular and molecular anti-restenotic profiles of paclitaxel and sirolimus. Implications for local drug delivery. Thromb Haemost. 2007 Jun;97(6):1003-12. PMID: 17549304.
3. Cutlip DE, Mehran R, Sharma S, et al. Sirolimus eluting balloon versus repeat drug-eluting stent or balloon angioplasty for coronary in-stent restenosis. J Am Coll Cardiol (2026) (Investigational Devices for FDA IDE Study)
4. Kawai K et al. Vascular Response, Downstream Effect, and Pharmacokinetics After Sirolimus- and Paclitaxel-Coated Balloons in Porcine Coronary Arteries. Catheter Cardiovasc Interv. 2025 Mar 6. doi: 10.1002/ccd.31482. Epub ahead of print. PMID: 40051028. (CE marked device)
5. Cordis 2025 Data on file.



Scan for safety information

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