

Technical Specification

Device Description

SELUTION SLR™ 018 PTA Balloon Catheter is a Drug-Eluting Balloon (DEB) catheter for Percutaneous Transluminal Angioplasty (PTA) procedures. The balloon coating contains Sirolimus, a drug that acts both as an anti-proliferative agent and as an anti-inflammatory immunosuppressant.

Drug Coating Description

The coating of the **SELUTION SLR** DEB is formulated with sirolimus-loaded bioresorbable poly lactic-co-glycolic acid (PLGA) MicroReservoirs. The use of a solid solution of Sirolimus in PLGA MicroReservoirs allows for sustained drug release.

The coating is sprayed onto the inflated balloon surface. MicroReservoirs adhere to the balloon surface using Cell Adherent Technology (CAT™), which is a phospholipid blend layer. CAT is designed to prevent wash-off and facilitate absorption of the drug coated MicroReservoirs into the vessel wall.

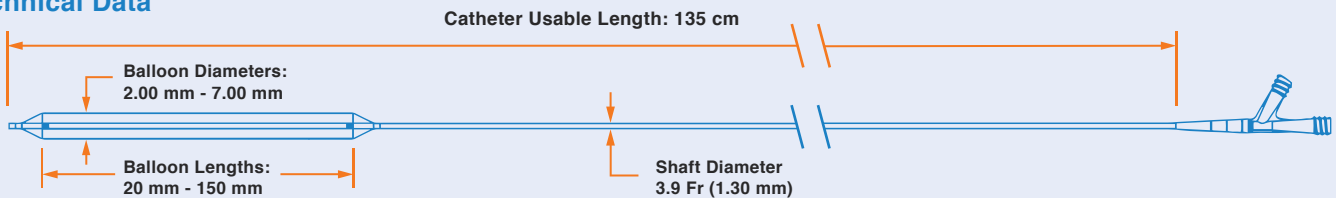
Indications for Use

The **SELUTION SLR** DEB is intended for use as a Percutaneous Transluminal Angioplasty (PTA) balloon catheter to dilate *de novo* or restenotic vascular lesions, for the purpose of improving limb perfusion and decreasing the incidence of restenosis.

Precautions

- Adequate vessel preparation including pre-dilatation is required before using **SELUTION SLR** DEB.
- Maintain balloon inflation for a minimum of 2 minutes. Use the maximum balloon inflation time per your institution's standard of care. **SELUTION SLR** DEB is intended for a single inflation only.
- For **SELUTION SLR** DEB preparation refer to the Instructions for Use.

Technical Data



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

Sirolimus Drug Dosage per Balloon Length and Diameter

Drug dose density is 1.0 µg/mm²

Balloon Diameter (mm)		Balloon Length (mm)						
		20	40	60	80	100	120	150
2.00	2.00	126 µg	251 µg	377 µg	503 µg	628 µg	754 µg	942 µg
	3.00	188 µg	377 µg	565 µg	754 µg	942 µg	1131 µg	1414 µg
	4.00	251 µg	503 µg	754 µg	1005 µg	1257 µg	1508 µg	1885 µg
	5.00	314 µg	628 µg	942 µg	1257 µg	1571 µg	1885 µg	2356 µg
	6.00	377 µg	754 µg	1131 µg	1508 µg	1885 µg	2262 µg	2827 µg
	7.00	440 µg	880 µg	1319 µg	1759 µg	2199 µg	2639 µg	3299 µg

Compliance Chart

Pressure (bar)	Balloon Diameter (mm)					
	2.00	3.00	4.00	5.00	6.00	7.00
4	1.94	2.91	3.88	4.90	5.88	6.86
5	1.97	2.96	3.94	4.95	5.93	6.93
6	2.00	3.00	4.00	5.00	6.00	7.00
7	2.02	3.02	4.03	5.04	6.05	7.05
8	2.03	3.05	4.06	5.08	6.09	7.11
9	2.05	3.07	4.09	5.11	6.14	7.16
10	2.06	3.09	4.12	5.15	6.18	7.21
11	2.08	3.11	4.15	5.19	6.23	7.26
12	2.09	3.14	4.18	5.23	6.27	7.32

■ Nominal Balloon Pressure
 ■ Rated Burst Pressure Balloon Length ≥ 60 mm
 ■ Rated Burst Pressure Balloon Length ≤ 40 mm

Use	Single use product
Storage Conditions	Store in its original packaging in a dry and dark location, at a temperature between 15-25°C (59-77°F).
Sterilization Method	E-Beam Radiation
Shelf Life	12 months from sterilization when stored in original packaging at storage conditions
Device Classification	Class III device according to 93/42/EEC including amendments to Directive 2007/47/EC (MDD).

Ordering Information

SELUTION SLR™ Sirolimus Eluting PTA Balloon Catheter

Diameter(mm)	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
3.00	SE18-030020	SE18-030040	SE18-030060	SE18-030080	SE18-030100	SE18-030120	SE18-030150
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

Introducer Sheath Compatibility

5 Fr for balloon diameters 2.00 - 3.00 mm / 6 Fr for balloon diameters 4.00 - 5.00 mm / 7 Fr for balloon diameters 6.00 - 7.00 mm

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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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