

Technical Specification

Device Description

SELUTION SLR™ 014 PTCA Balloon Catheter is a Drug-Eluting Balloon (DEB) catheter for Percutaneous Transluminal Coronary Angioplasty (PTCA) 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 PTCA balloon catheter to dilate *de novo* or restenotic coronary lesions, for the purpose of improving myocardial 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 30 seconds and a target of 1 minute if tolerated. 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 balloon preparation refer to the Instructions for Use.

Technical Data



Feature	Specification
Sirolimus Drug Dose	1.0µg/mm ²
Drug Carrier	Cell Adherent Technology (CAT™) Amphipathic Lipid Carrier
Catheter Design	Rapid Exchange (RX)
Shaft Diameter	1.9 Fr (0.63mm)
Catheter Usable Length	140cm
Guidewire Compatibility	0.014"
Minimum Guide Catheter Compatibility (Fr)	≥ 5Fr: 1.50 – 3.75mm balloon diameter ≥ 6Fr: 4.00 – 5.00mm balloon diameter

Balloon	
Nominal Balloon Pressure (NP)	6 bar
Rated Burst Pressure (RBP)	12 bar
Balloon Diameters	1.50mm – 5.00mm
Balloon Lengths	10, 15, 20, 25, 30, 35, 40mm

Sirolimus Drug Dosage per Balloon Length and Diameter

Drug dose density is 1.0µg/mm²

		Balloon Length (mm)						
		10	15	20	25	30	35	40
Balloon Diameter (mm)	1.50	47µg	71µg	94µg	118µg	141µg	165µg	188µg
	2.00	63µg	94µg	126µg	157µg	188µg	220µg	251µg
	2.25	71µg	106µg	141µg	177µg	212µg	247µg	283µg
	2.50	79µg	118µg	157µg	196µg	236µg	275µg	314µg
	2.75	86µg	130µg	173µg	216µg	259µg	302µg	346µg
	3.00	94µg	141µg	188µg	236µg	283µg	330µg	377µg
	3.25	102µg	153µg	204µg	255µg	306µg	357µg	408µg
	3.50	110µg	165µg	220µg	275µg	330µg	385µg	440µg
	3.75	118µg	177µg	236µg	295µg	353µg	412µg	471µg
	4.00	126µg	188µg	251µg	314µg	377µg	440µg	503µg
4.50	141µg	212µg	283µg	353µg	424µg	495µg	565µg	
5.00	157µg	236µg	314µg	393µg	471µg	550µg	628µg	

Compliance Chart

Pressure (bar)	Balloon Diameter (mm)											
	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
4	1.47	1.96	2.21	2.45	2.70	2.94	3.19	3.43	3.68	3.92	4.41	4.90
5	1.49	1.98	2.23	2.48	2.73	2.97	3.22	3.47	3.72	3.96	4.46	4.95
6	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
7	1.52	2.02	2.27	2.52	2.77	3.03	3.28	3.53	3.78	4.03	4.54	5.04
8	1.53	2.03	2.28	2.54	2.79	3.05	3.30	3.55	3.81	4.06	4.57	5.08
9	1.55	2.05	2.30	2.56	2.81	3.07	3.33	3.58	3.84	4.09	4.61	5.12
10	1.56	2.06	2.32	2.58	2.83	3.09	3.35	3.61	3.86	4.12	4.64	5.15
11	1.58	2.08	2.34	2.60	2.85	3.12	3.38	3.64	3.89	4.15	4.67	5.19
12	1.59	2.09	2.35	2.61	2.87	3.14	3.40	3.66	3.92	4.18	4.70	5.23

Nominal Balloon Pressure
 Rated Burst Pressure

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 PTCA Balloon Catheter

Balloon Diameter (mm)	Balloon Length (mm)						
	10	15	20	25	30	35	40
1.50	SC14-150010	SC14-150015	SC14-150020	SC14-150025	SC14-150030	SC14-150035	SC14-150040
2.00	SC14-200010	SC14-200015	SC14-200020	SC14-200025	SC14-200030	SC14-200035	SC14-200040
2.25	SC14-225010	SC14-225015	SC14-225020	SC14-225025	SC14-225030	SC14-225035	SC14-225040
2.50	SC14-250010	SC14-250015	SC14-250020	SC14-250025	SC14-250030	SC14-250035	SC14-250040
2.75	SC14-275010	SC14-275015	SC14-275020	SC14-275025	SC14-275030	SC14-275035	SC14-275040
3.00	SC14-300010	SC14-300015	SC14-300020	SC14-300025	SC14-300030	SC14-300035	SC14-300040
3.25	SC14-325010	SC14-325015	SC14-325020	SC14-325025	SC14-325030	SC14-325035	SC14-325040
3.50	SC14-350010	SC14-350015	SC14-350020	SC14-350025	SC14-350030	SC14-350035	SC14-350040
3.75	SC14-375010	SC14-375015	SC14-375020	SC14-375025	SC14-375030	SC14-375035	SC14-375040
4.00	SC14-400010	SC14-400015	SC14-400020	SC14-400025	SC14-400030	SC14-400035	SC14-400040
4.50	SC14-450010	SC14-450015	SC14-450020	SC14-450025	SC14-450030	SC14-450035	SC14-450040
5.00	SC14-500010	SC14-500015	SC14-500020	SC14-500025	SC14-500030	SC14-500035	SC14-500040

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Indication, contraindications and warnings can be found in the instructions for use supplied with each device.

SELUTION SLR Sirolimus Eluting PTCA Balloon Catheter - CE Mark Approved. Not available for sale in United States.

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