

# 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.

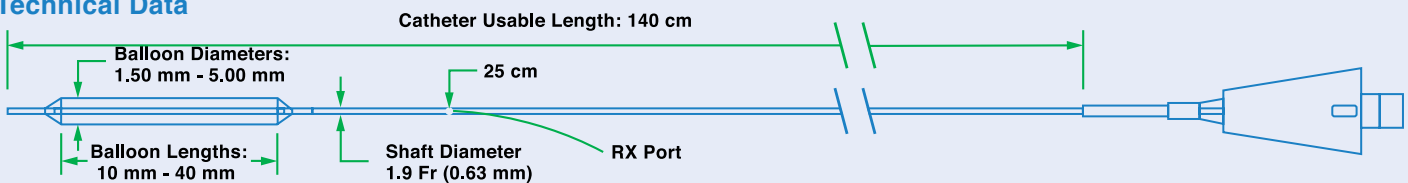
## Indications for Use

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 preparation refer to the Instructions for Use.

## Technical Data



Feature	Specification
Sirolimus Drug Dose	1.0 µg/mm <sup>2</sup>
Drug Carrier	Cell Adherent Technology (CAT™) Amphipathic Lipid Carrier
Catheter Design	Rapid Exchange (RX)
Shaft Diameter	1.9 Fr (0.63 mm)
Catheter Usable Length	140 cm
Guidewire Compatibility	0.014"

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

## Sirolimus Drug Dosage per Balloon Length and Diameter

Drug dose density is 1.0 µg/mm<sup>2</sup>

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

## 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

## Introducer Sheath Compatibility

5 Fr for balloon diameters 1.50 - 3.75 mm / 6 Fr for balloon diameters 4.00 - 5.00 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 PTCA Balloon Catheter - CE Mark Approved. Not available for sale in United States.

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