

supralimus[®]

SIROLIMUS ELUTING CORONARY STENT SYSTEM



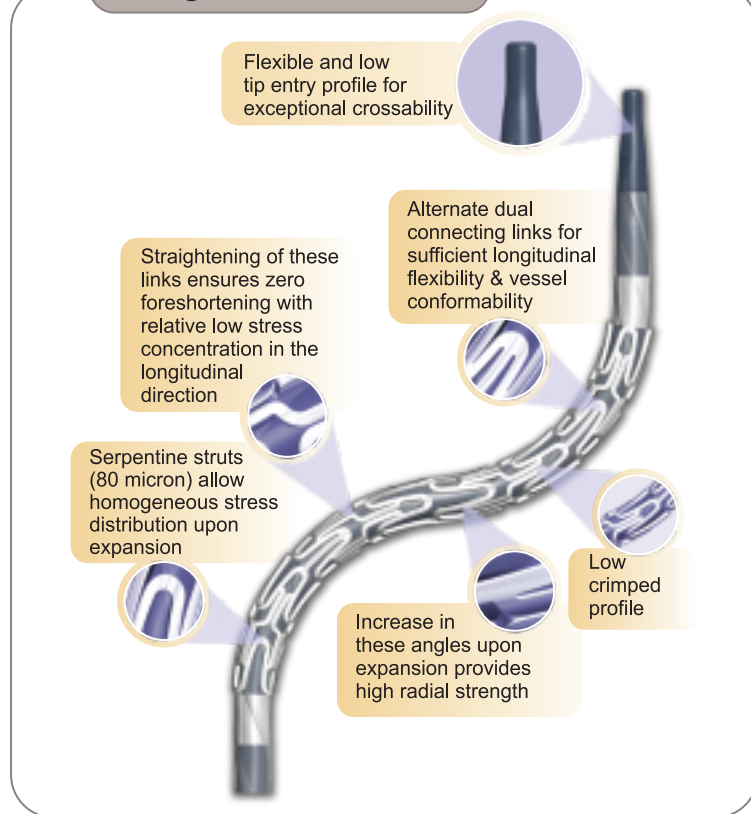
SAHAJANAND MEDICAL
TECHNOLOGIES PVT. LTD.

delivering science to life

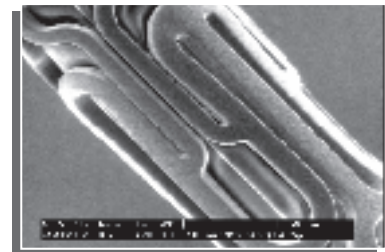
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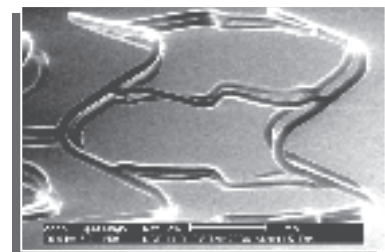
Design Characteristics



SEM Images after 1.5 years



Coating surface remains smooth after 18 months.



No micro-cracks and coating film peel off observed on the surface after expansion.

Specifications

Device Component Description

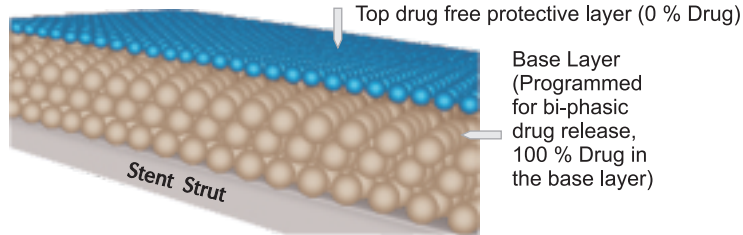
Stent Material	Electro polished 316L Stainless Steel (SS)
Stent Design	Laser cut from seamless tubing in a serpentine pattern
Stent Platform	The CE approved Millennium Matrix [®] Stent
Stent Strut Thickness	0.08 mm (80 μ)
Average Stent Foreshortening	< 1 %
Average Recoil	< 5 %
Metal to Artery Ratio (ϕ 3.0mm)	13.1 %
Drug	Sirolimus
Polymers Type	Biodegradable Polymers
Delivery System Usable Length	1400 mm (140 cm)
Delivery System	Single access port to inflation/deflation lumen. A guidewire exit port is located at 25 cm from the tip. Designed for guidewire 0.014 inch
Catheter Shaft Outer Diameter	Proximal: 0.60 mm Distal: 0.84 mm for ϕ (2.5-3.5) & 0.95 mm for $\phi \geq 4.0$
Balloon Inflation Pressure	*Nominal Pressure: 6 bar Rated Burst Pressure: 16 bar (**14 bar)
Guiding Catheter	5F compatible
Guidewire Diameter	0.014 inch

* Assure full deployment of the stent. Deployment pressures should be based on lesion characteristics.

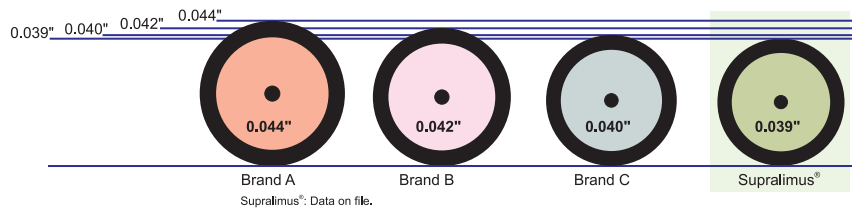
**14 bar for vessel diameter 4.0 mm with length >20 mm. Note: 1F is equivalent to 0.33 mm. 1 atm = 1.01 bar

Uses clinically proven, safe and effective drug Sirolimus elutes from *biodegradable* polymeric matrix

The drug-polymer average coating thickness is 4-5 μm



Crossing Profile

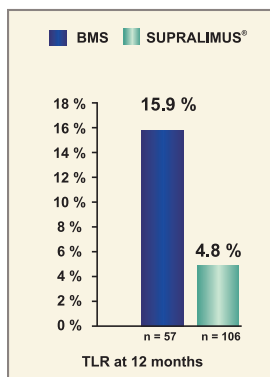


Evidence of Clinical Results*

Baseline Characteristics

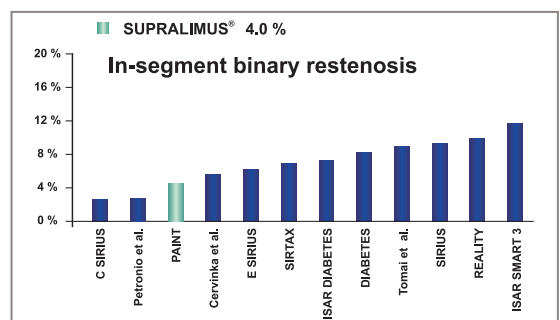
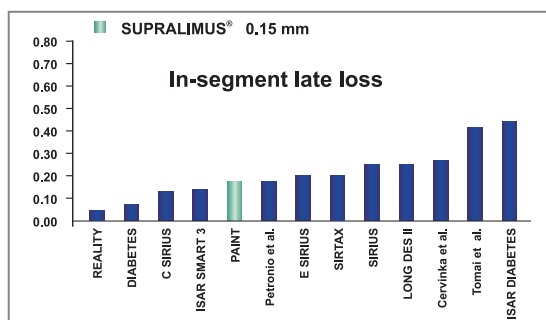
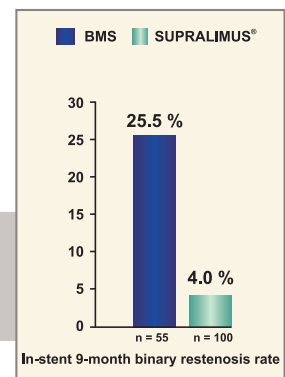
	BMS	Supralimus®		BMS	Supralimus®
N	57	106	Hypertension %	86	89
Diabetics %	26	35	Previous PCI %	18	15
Prior MI %	39	34	Previous CABG %	3.5	6
Unstable Angina %	65	63	RVD (mm)	2.69±0.5	2.72±0.48
Smoker %	23	22			

Principal Investigator: Dr. (Prof.) Pedro A. Lemos, MD PhD Published in Catheterization and Cardiovascular Interventions 74:665-673 (2009)



69.8 % Reduction in TLR with SUPRALIMUS® Stent as compared to BMS at 12 months

84.3 % Reduction in 9-month In-stent binary restenosis rate with SUPRALIMUS® Stent as compared to BMS



Ordering Information

Reference No.	Stent Length / Diameter (mm)	Balloon Length (mm)	Reference No.	Stent Length / Diameter (mm)	Balloon Length (mm)
FGSS250011	11/2.50	12	FGSS350023	23/3.50	24
FGSS275011	11/2.75	12	FGSS400023	23/4.00	24
FGSS300011	11/3.00	12	FGSS250023	29/2.50	30
FGSS350011	11/3.50	12	FGSS275029	29/2.75	30
FGSS400011	11/4.00	12	FGSS300029	29/3.00	30
FGSS250016	16/2.50	17	FGSS350029	29/3.50	30
FGSS275016	16/2.75	17	FGSS400029	29/4.00	30
FGSS300016	16/3.00	17	FGSS250033	33/2.50	34
FGSS350016	16/3.50	17	FGSS275033	33/2.75	34
FGSS400016	16/4.00	17	FGSS300033	33/3.00	34
FGSS250019	19/2.50	20	FGSS350033	33/3.50	34
FGSS275019	19/2.75	20	FGSS400033	33/4.00	34
FGSS300019	19/3.00	20	FGSS250039	39/2.50	40
FGSS350019	19/3.50	20	FGSS275039	39/2.75	40
FGSS400019	19/4.00	20	FGSS300039	39/3.00	40
FGSS250023	23/2.50	24	FGSS350039	39/3.50	40
FGSS275023	23/2.75	24	FGSS400039	39/4.00	40
FGSS300023	23/3.00	24			

Not available for sale in USA

Compliance Chart

Pressure [bar]	2.50 mm	2.75 mm	3.00 mm	3.50 mm	4.00 mm
6	2.50	2.75	3.00	3.50	4.00
8	2.56	2.82	3.07	3.58	4.09
10	2.61	2.87	3.13	3.65	4.17
12	2.65	2.92	3.18	3.71	4.24
14	2.70	2.97	3.24	3.78	4.32*
16	2.75	3.03	3.30	3.85	4.40
18	2.80	3.08	3.36	3.92	4.48

1 atm = 1.01 bar

Nominal Pressure (NP) Rated Burst Pressure (RBP)

* RBP= 14 bar for vessel diameter 4.0 mm with length >20 mm



SAHAJANAND MEDICAL
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