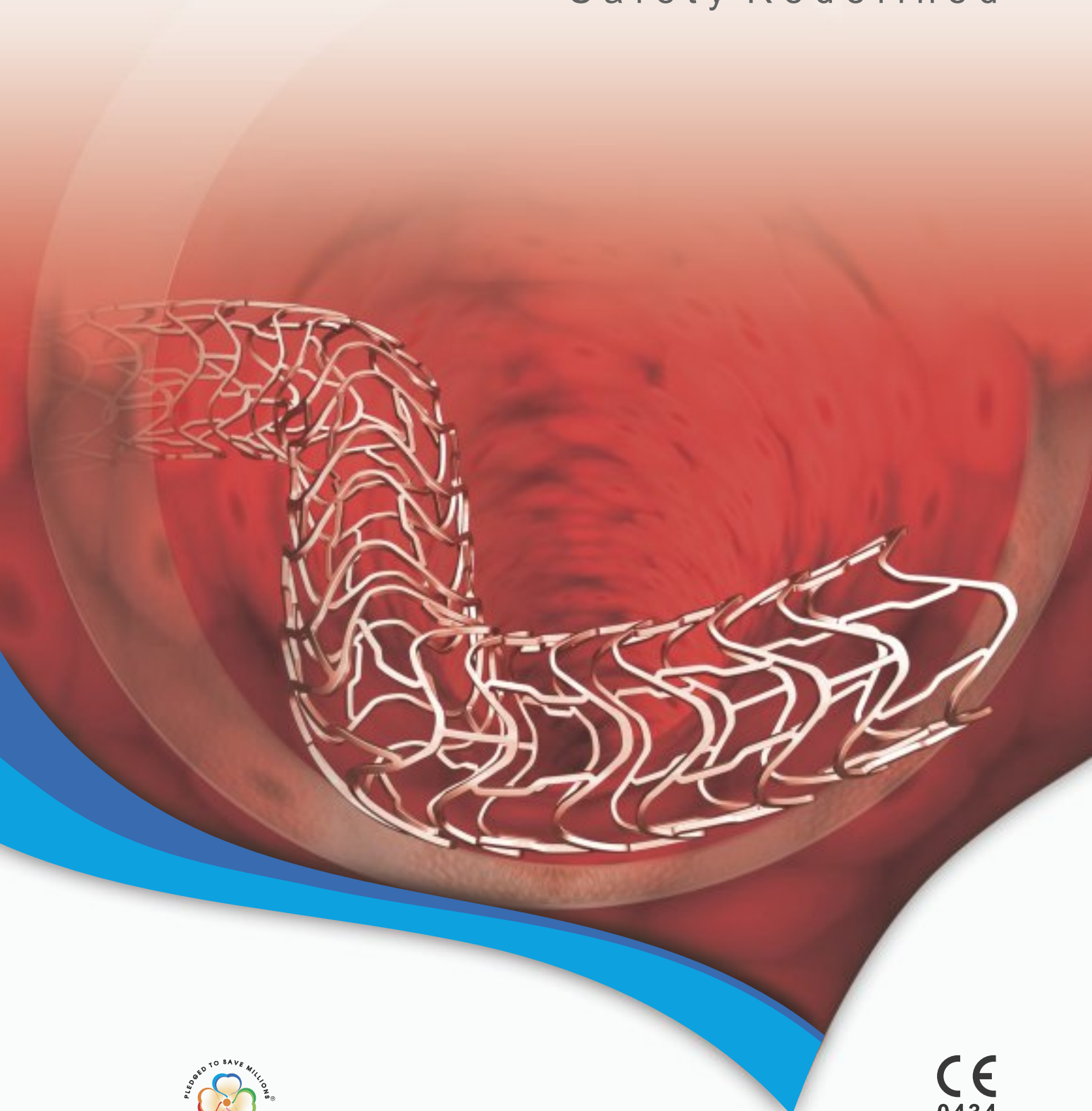


Infinnium®

Paclitaxel Eluting Coronary Stent System

Safety Redefined



**SAHAJANAND MEDICAL
TECHNOLOGIES PVT. LTD.**

delivering science to life

CE
0434



Design Characteristics

Flexible tip to improve guidewire trackability and to minimize vessel wall trauma

Straightening of these links ensures nearly zero foreshortening with relative low stress concentration in the longitudinal direction

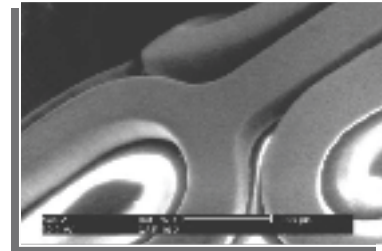
Serpentine struts allow homogeneous stress distribution upon expansion

Alternate dual connecting links for sufficient longitudinal flexibility & vessel conformability

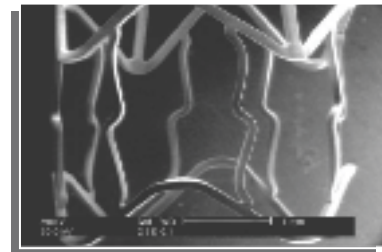
Increase in these angles upon expansion provides better radial strength by concentration of forces in the radial direction

Low crossing profile for lesion crossability

SEM Images of Infinnium® Coronary Stent System



Crimped stent



Post Expanded stent

- Uniform drug-polymers multilayer coating on stent surface
- Coating integrity maintained on stent expansion
- The drug-polymers coating thickness is 5 -7µ

Specifications

Device Component Description

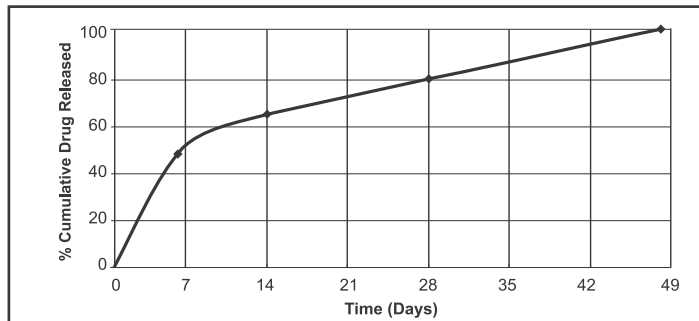
Stent Material	Electro polished 316L Stainless Steel (SS)
Stent Design	Laser cut from seamless tubing in a serpentine pattern
Stent Platform	The CE approved Millennium Matrix® Stent
Stent Strut Thickness / Width	0.08 mm (80µ)
Average Stent Foreshortening	< 1 %
Average Recoil	< 5 %
Average Radial Strength	Resists at least 1 bar
Metal to Artery Ratio (φ 3.0mm)	13.1 %
Drug	Paclitaxel
Polymers Type	Fully Biodegradable Polymers
Delivery System Usable Length	1400 mm (140 cm)
Delivery System Y - Adapter Ports	Single access port to inflation/deflation lumen. A guidewire exit port is located at 25 cm from the tip. Designed for guidewire 0.38 mm (0.014 inch)
Stent Delivery Balloon	Rilsan/Polyamide balloon, nominally 1 mm longer than stent. Mounted stent length and location is defined by radio opaque marker at proximal and distal to stent.
Catheter Shaft Outer Diameter	Proximal: 0.60 mm Distal: 0.84 mm for Ø (2.5-3.5) & 0.95 mm for Ø ≥ 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 Paclitaxel drug elution from **biodegradable** polymeric matrix

In-vitro Cumulative Drug Release Profile



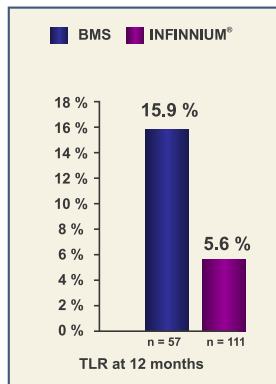
• Complete drug elution in 48 days • No residual drug or polymer left behind over the period of time

Evidence of Clinical Results

PAINT TRIAL*

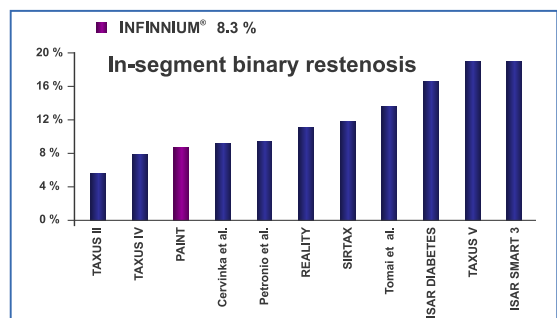
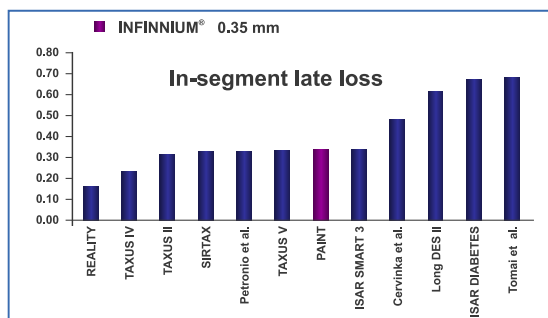
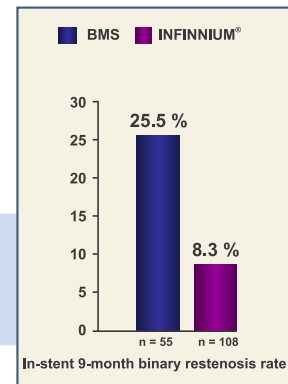
Baseline Characteristics

	BMS	Infinnium®		BMS	Infinnium®
N	57	111	Hypertension %	86	84
Diabetics %	26	29	Previous PCI %	18	15
Prior MI %	39	28	Previous CABG %	3.5	9
Unstable Angina %	23	24	RVD (mm)	2.69±0.5	2.72±0.49
Smoker %	23	20			



64.7 % Reduction in TLR with INFINNIIUM® Stent as compared to BMS at 12 months

67.4 % Reduction in 9-month In-stent binary restenosis rate with INFINNIIUM® Stent as compared to BMS



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

Ordering Information

Reference No.	Stent Length / Diameter (mm)	Balloon Length (mm)	Reference No.	Stent Length / Diameter (mm)	Balloon Length (mm)
10110250IP	11/2.50	12	10230350IP	23/3.50	24
10110275IP	11/2.75	12	10230400IP	23/4.00	24
10110300IP	11/3.00	12	10290250IP	29/2.50	30
10110350IP	11/3.50	12	10290275IP	29/2.75	30
10110400IP	11/4.00	12	10290300IP	29/3.00	30
10160250IP	16/2.50	17	10290350IP	29/3.50	30
10160275IP	16/2.75	17	10290400IP	29/4.00	30
10160300IP	16/3.00	17	10330250IP	33/2.50	34
10160350IP	16/3.50	17	10330275IP	33/2.75	34
10160400IP	16/4.00	17	10330300IP	33/3.00	34
10190250IP	19/2.50	20	10330350IP	33/3.50	34
10190275IP	19/2.75	20	10330400IP	33/4.00	34
10190300IP	19/3.00	20	10390250IP	39/2.50	40
10190350IP	19/3.50	20	10390275IP	39/2.75	40
10190400IP	19/4.00	20	10390300IP	39/3.00	40
10230250IP	23/2.50	24	10390350IP	39/3.50	40
10230275IP	23/2.75	24	10390400IP	39/4.00	40
10230300IP	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



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