Specifications

Device Component Description

Available Stent Lengths	8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 mm
Available Stent Diameters	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50 mm
Stent Material	Surgical Grade L605 Co-Cr alloy
Stent Design	Laser cut from seamless tubing in a serpentine pattern
Stent Strut Thickness	0.06 mm (60 µ)
Nominal Stent Foreshortening	< 3 %
Recoil	< 4 %
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 0.014 inch.
Catheter Shaft Outer Diameter	Proximal : 0.67 mm Distal : 0.89 mm
Balloon Inflation Pressure	*NP = 8 atm for 2.00 mm to 2.25 mm, 10 atm for 2.50 mm to 3.00 mm, 11 atm for 3.50 mm to 4.50 mm RBP = 16 atm for all sizes
Guide Catheter	5 Fr compatible
Guidewire Diameter	0.014 inch

* Assure full deployment of the stent deployment pressures should be based on lesion characteristics.
Note: 1F is equivalent to 0.33mm. 1 atm =1.01 bar

Compliance Chart

Pressure [atm]	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.50 mm	4.00 mm	4.50 mm
8	**2.02**	**2.23**	2.46	2.69	2.92	3.27	3.86	4.28
9	2.06	2.27	2.48	2.73	2.97	3.32	3.92	4.34
10	2.10	2.30	**2.50**	**2.76**	**3.02**	3.37	3.97	4.41
11	2.13	2.33	2.52	2.78	3.05	**3.50**	**4.01**	**4.50**
12	2.16	2.35	2.53	2.81	3.09	3.56	4.05	4.56
13	2.18	2.37	2.55	2.83	3.13	3.61	4.08	4.62
14	2.20	2.39	2.57	2.86	3.16	3.65	4.12	4.68
15	2.23	2.43	2.60	2.89	3.19	3.69	4.16	4.72
16	**2.26**	**2.45**	**2.63**	**2.93**	**3.22**	**3.72**	**4.18**	**4.75**

Nominal Pressure (NP) **Rated Burst Pressure (RBP)** 1 atm = 1.01 bar

Nominal Pressure = 8 atm for 2.00 mm to 2.25 mm, 10 atm for 2.50 mm to 3.00 mm, 11 atm for 3.50 mm to 4.50 mm RBP = 16 atm for all sizes

Size Matrix

Vessel Size (mm)	Length (mm) 8	12	16	20	24	28	32	36	40	44	48
2.00	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2.25	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2.50	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2.75	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3.00	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3.50	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4.00	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4.50	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Caution: This product is intended for use by or under the direction of a physician. Prior to use, refer to the "Instructions for use" supplied with these devices for indications, contraindications, side effects, suggested procedure warnings and precautions. As part of our continuous product development policy we reserve the right to change product specifications without prior notification.
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Check the regulatory status of the device before distribution in areas where CE marking is not the regulation in force. Tests performed by and data on file at Sahajanand Medical Technologies Pvt. Ltd. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Sahajanand Medical Technologies Pvt. Ltd.

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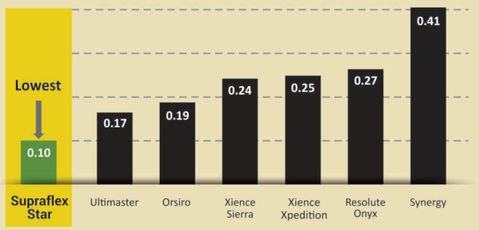
VP/BRO/N/EN01 REV 01

Supraflex Star

Sirolimus Eluting Cobalt Chromium Coronary Stent System

CE 2460

Mean push force in Newton (N) for stents with 38 to 40 mm length

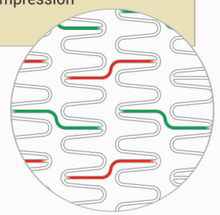


Bench test results may not necessarily be indicative of clinical performance. Test performed by and data on file at Sahajanand Medical Technologies Pvt. Ltd. Testing performed on Supraflex Cruz Stent System (2.50 x 40 mm) n=5, Ultimaster Stent System (2.5 x 38 mm) n=4, Orsiro Stent System (2.50x40 mm) n=5, Xience Sierra Stent System (2.5 x 38 mm) n=4, Xience Xpedition Stent System (2.5 x 38 mm) n=5, Resolute Onyx Stent System (2.5 x 38 mm) n=4, Synergy Stent System (2.5 x 38 mm) n=5, Catheter performance crossability test measures average force to cross a challenging path model

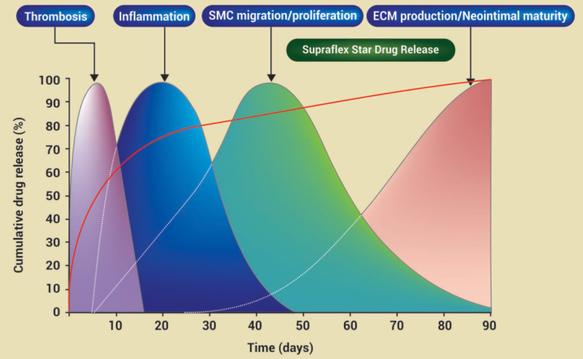
Alternate LDZ Link

- Improves flexibility of the stent
- Transmits 'Push force' with higher efficiency
- Improves overall radial strength
- Resists longitudinal compression

LDZ Link = Long Dual 'Z' Link



Drug Release Profile



Nearly 80% of sirolimus drug is released within one month (Initial burst).
Remaining drug is programmed to get released for 3 months.
Designed to cover the entire period of arterial wound healing in real-world patients.

Ultra-thin stent with 60µm strut thickness across all diameters

120	84-88	81	81	81	80	80	79	74	60	60
BioFreedom	BioMatrix Alpha	Xience V Xience Alpine Xience Prime Xience Xpedition Xience Sierra	Resolute Onyx	Synergy[1]	Ultimaster	Orsiro[2]	Synergy[1]	Synergy[1]	Orsiro[2]	Supraflex Star

[1]Synergy: 74 µm for 2.25 to 2.75 mm, 79 µm for 3.0 to 3.5 mm, 81 µm for > 3.5 mm diameter
[2]Orsiro: 60 µm for ≤ 3 mm, 80 µm for > 3 mm

Note: Data from marketing materials of respective brands (2018), strut cross section shapes are for representation purpose only, actual shapes may differ.
Ref: Foin et al. Impact of stent strut design in metallic stents and biodegradable scaffolds. Int J Cardiol.2014 Dec 20;177(3):800-8

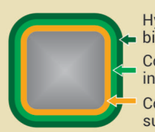
Scaffolding Overview and Design Characteristics

- Provides enhanced structural support
- Aids in optimal apposition to vessel wall
- Prevents plaque prolapse
- Leads to uniform expansion of stent

Maximum Circular Unsupported Surface Area (MCUSA)

- MCUSA=0.73 mm^2
  (Value measured on expanded stent of 2.5 mm diameter)
- Lower MCUSA aids in uniform drug distribution
- Scaffolding is more uniform

Strut cross section



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