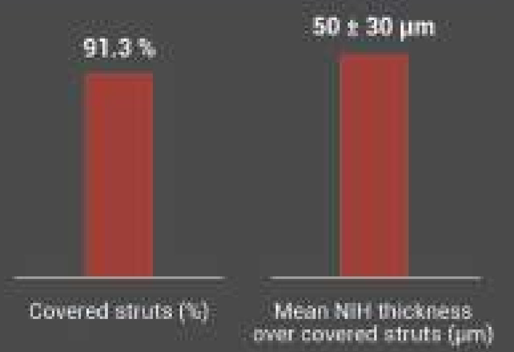
OCT Healing Pattern of Supraflex Cruz[1]

SiBi Study[1]

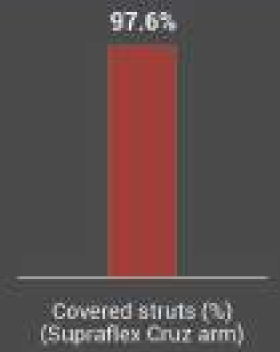
35.3 ± 5 days
Patients n = 29
Struts n= 14,024



'91.3% endothelialisation in Supraflex Cruz at 4–6 weeks as per the SiBi study.'[1]

TAXCO Study[1]

6 months
Patients n = 21
Struts n= 9,968



"97.6% endothelialisation in the Supraflex Cruz at 6 months as per the TAXCO study."[1]

NIH: Neointimal hyperplasia
1. Presented at EuroPCR 2019, 22 May 2019 [illegible]

Extensive size matrix
so that there is no compromise

Diameter (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	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

■ Long lengths (44mm & 48mm) available

TZ/BRO/EN/02 REV 05

Supraflex Cruz

Sirolimus Eluting Cobalt Chromium Coronary Stent System

CE 2460

Ultimate
Breakthrough
in Deliverability

SMT

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Supraflex Cruz

Sirolimus Eluting Cobalt Chromium Coronary Stent System

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

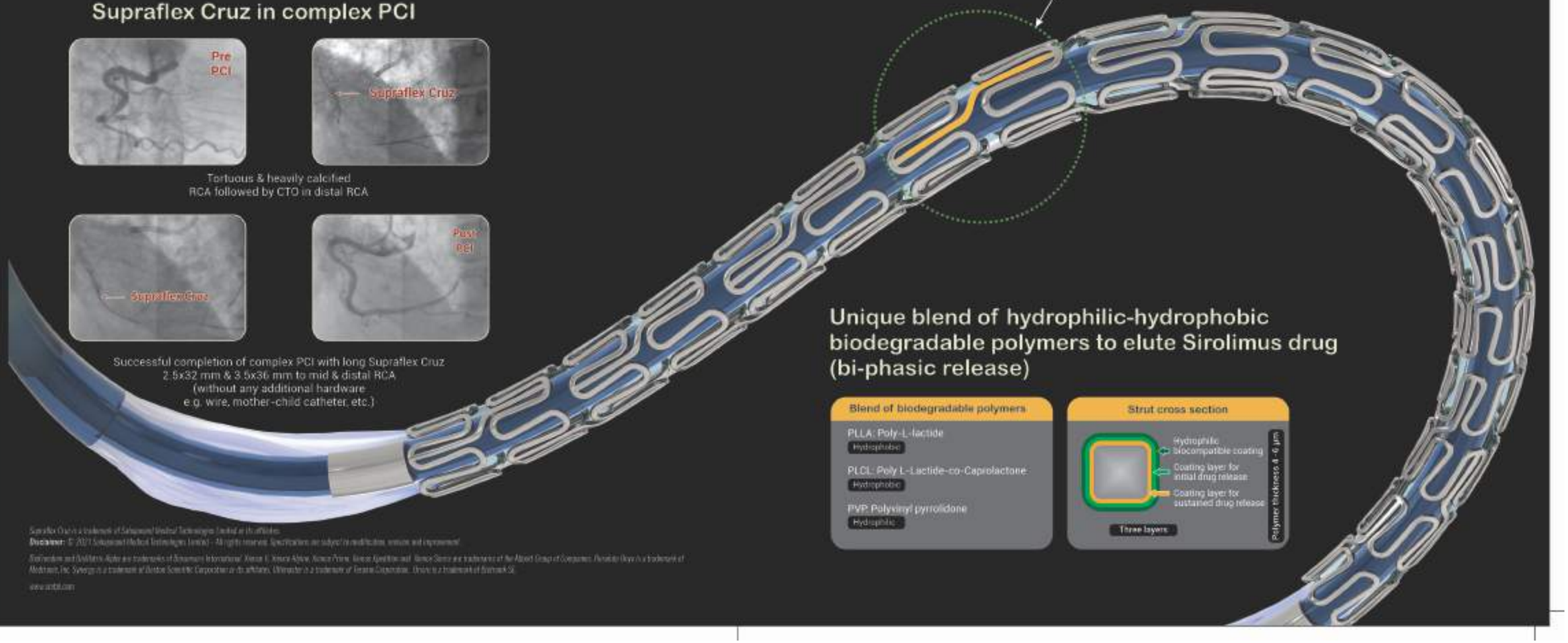
(Bench test results may not necessarily be indicative of clinical performance. Test performed by and data on file at Sahajanand Medical Technologies Pvt. Ltd.) Testing performed on Supraflex Cruz Stent System (2.50 x 40 mm) n=5, Ultimaster Stent System (2.5 x 38 mm) n=4, Orsiro Stent System (2.5x40 mm) n=5, Xience Sierra Stent System (2.5 x 28 mm) n=4, Xience Xpedition Stent System (2.5 x 38 mm) n=5, Resolute Onyx Stent System (2.5 x 28 mm) n=4, Synergy Stent System (2.5 x 36 mm) n=5. Catheter performance crossability test measures average force to cross a challenging path model

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

Supraflex Cruz in complex PCI

Tortuous & heavily calcified RCA followed by CTO in distal RCA

Successful completion of complex PCI with long Supraflex Cruz 2.5x32 mm & 3.5x36 mm to mid & distal RCA (without any additional hardware e.g. wire, mother-child catheter, etc.)



Unique blend of hydrophilic-hydrophobic biodegradable polymers to elute Sirolimus drug (bi-phasic release)

Blend of biodegradable polymers

PLLA: Poly-L-lactide
Hydrophobic

PLCL: Poly L-Lactide-co-Caprolactone
Hydrophobic

PVP: Polyvinyl pyrrolidone
Hydrophilic

Strut cross section

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	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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SMT

VP/BRD/MEM21 REV 03

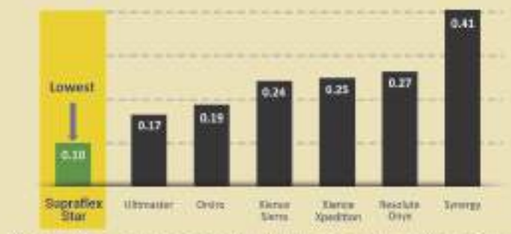
Supraflex Star

Sirolimus Eluting Cobalt Chromium Coronary Stent System

CE 2460

SMT

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

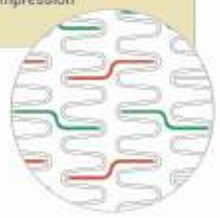


Bench test results may not necessarily be indicative of clinical performance. Test performed by and data on file at Sahajanand Medical Technologies Pvt. Ltd. Testing performed on Supraflex Star Stent System (2.50 x 40 mm) n=5, Ultimaster Stent System (2.5 x 38 mm) n=4, Orsiro Stent System (2.50x40 mm) 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 across a challenging path model

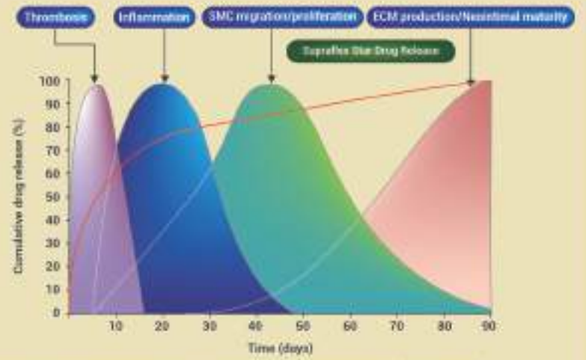
Alternate LDZ Link

- 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

*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
#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

Supraflex Star

Novolimus Eluting Cobalt Chromium Coronary Stent System

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 : 0.72 mm Distal : 0.95 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	4.66
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	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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Distributed and Marketed by:

TG/BRO/ENG1 REV.04

10+ years
Of Healing Experience that you can TRUST

Supralimus Grace

Sirolimus Eluting Cobalt Chromium Coronary Stent System

CE 2460

SMT

Supralimus Grace

Supralimus Grace is 2 times more flexible than Predicate device in Crimped State which infers that Supralimus Grace has better:

- Trackability
- Pushability
- Conformability

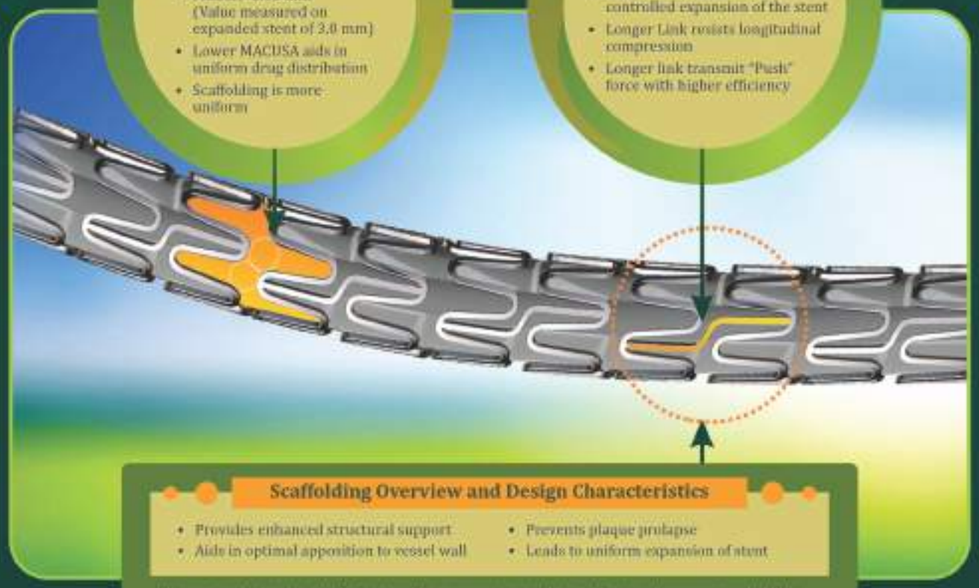
MCUSA

Maximum Circular Unsupported Surface Area

- MCUSA=0.95 mm^2 (Value measured on expanded stent of 3.0 mm)
- Lower MACUSA aids in uniform drug distribution
- Scaffolding is more uniform

Long Link

- Enhanced overall structural integrity
- Longer Links aid in well controlled expansion of the stent
- Longer Link resists longitudinal compression
- Longer link transmit "Push" force with higher efficiency



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

- Proprietary technology for Rx joint welding ensures minimal loss of force and improves pushability
- Faster & low deflation profile for smoother experience while retrieving the stent delivery system, post stent dilation
- Link between transition of hard shaft and soft shaft is engineered to have a kink free experience

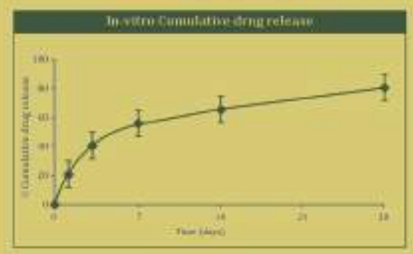
Strut Thickness (µ)

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

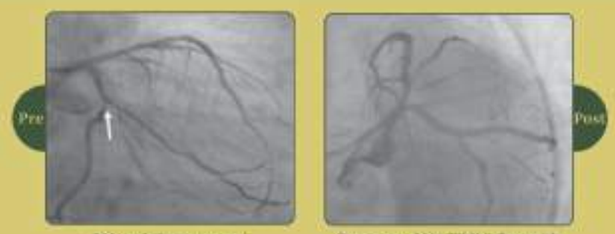
- Hydrophilic biocompatible coating
- Coating layer for initial drug release
- Coating layer for sustained drug release

Strut Cross section

Sirolimus drug release profile



- Drug Sirolimus dose: 3.4 µg/mm^2
- Release kinetics
  - 80% within 4 weeks
  - Precisely controlled release profile
  - Excellent coating integrity
  - Supralimus Grace does not have significant 'burst' release, which improves the overall safety while maintaining the efficacy
  - Sustained release for longer duration
  - Able to maintain adequate levels of drug at implant site to control cell growth



OM1 at bifurcation and mid tandem lesion

Post stent OM1 TIMI 3 flow with LCX proximal stent

Supralimus Grace (3.00mm x 40mm)

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	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
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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
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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
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15	2.23	2.43	2.60	2.89	3.19	3.69	4.16	4.72
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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

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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 Limited. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Sahajanand Medical Technologies Limited.

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Tetriflex™

Sirolimus Eluting Cobalt Chromium Coronary Stent System

CE 2460

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Tetriflex™

Sirolimus Eluting Cobalt Chromium Coronary Stent System

Strut Thickness

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79 µm for 3.0 to 3.5 mm,
81 µm for > 3.5 mm diameter

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80 µm for > 3 mm

Note: Data from marketing materials of respective brands (2018), strut cross section shapes are for representationspurpose 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

Long Link

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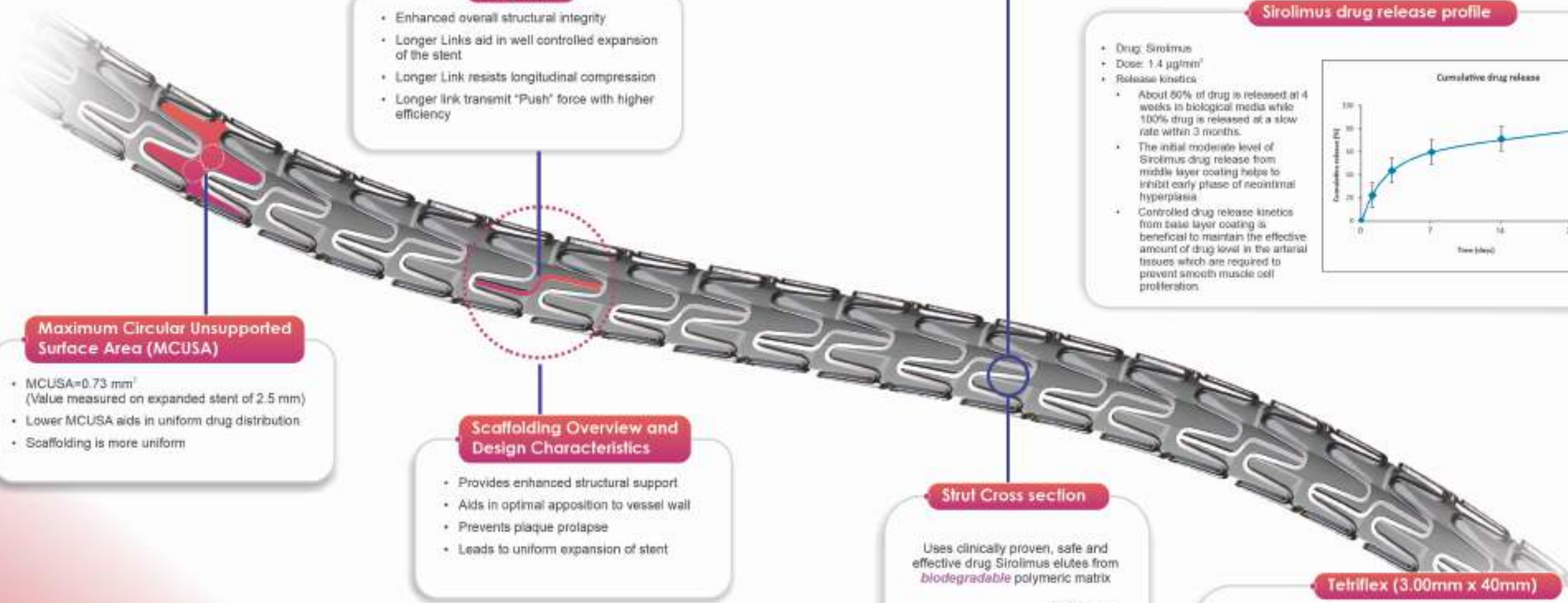
- Longer Link resists longitudinal compression
- Longer link transmit "Push" force with higher efficiency



Maximum Circular Unsupported Surface Area (MCUSA)

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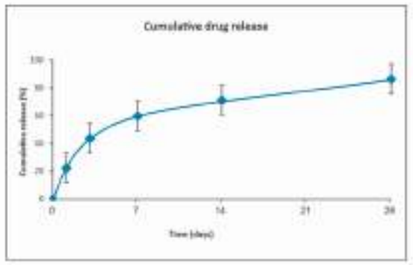
  (Value measured on expanded stent of 2.5 mm)
- Lower MCUSA aids in uniform drug distribution
- Scaffolding is more uniform

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

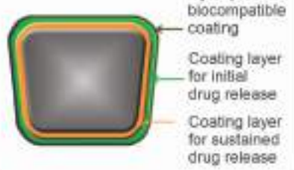
Sirolimus drug release profile

- Drug: Sirolimus
- Dose: 1.4 µg/mm^2
- Release kinetics
  - About 60% of drug is released at 4 weeks in biological media while 100% drug is released at a slow rate within 3 months.
  - The initial moderate level of Sirolimus drug release from middle layer coating helps to inhibit early phase of neointimal hyperplasia
  - Controlled drug release kinetics from base layer coating is beneficial to maintain the effective amount of drug level in the arterial tissues which are required to prevent smooth muscle cell proliferation



Strut Cross section

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



Tetriflex (3.00mm x 40mm)

Pre

OM1 at bifurcation and mid tandem lesion

Post

Post stent OM1 TIMI 3 flow with LCX proximal stent

Tetriflex is 2 times more flexible than Predicate device in Crimped State which infers that Tetriflex has better:

- Trackability
- Pushability
- Conformability

Ordering Information

Reference No.	Stent Length / Diameter (mm)	Balloon Length (mm)
FGSF200008	08/2.00	09
FGSF225008	08/2.25	09
FGSF250008	08/2.50	09
FGSF275008	08/2.75	09
FGSF300008	08/3.00	09
FGSF350008	08/3.50	09
FGSF400008	08/4.00	09
FGSF450008	08/4.50	09
FGSF200012	12/2.00	13
FGSF225012	12/2.25	13
FGSF250012	12/2.50	13
FGSF275012	12/2.75	13
FGSF300012	12/3.00	13
FGSF350012	12/3.50	13
FGSF400012	12/4.00	13
FGSF450012	12/4.50	13
FGSF200016	16/2.00	17
FGSF225016	16/2.25	17
FGSF250016	16/2.50	17
FGSF275016	16/2.75	17
FGSF300016	16/3.00	17
FGSF350016	16/3.50	17
FGSF400016	16/4.00	17
FGSF450016	16/4.50	17
FGSF200020	20/2.00	21
FGSF225020	20/2.25	21
FGSF250020	20/2.50	21
FGSF275020	20/2.75	21
FGSF300020	20/3.00	21
FGSF350020	20/3.50	21
FGSF400020	20/4.00	21
FGSF450020	20/4.50	21
FGSF200024	24/2.00	25
FGSF225024	24/2.25	25
FGSF250024	24/2.50	25
FGSF275024	24/2.75	25
FGSF300024	24/3.00	25
FGSF350024	24/3.50	25
FGSF400024	24/4.00	25
FGSF450024	24/4.50	25
FGSF200028	28/2.00	29
FGSF225028	28/2.25	29
FGSF250028	28/2.50	29
FGSF275028	28/2.75	29
FGSF300028	28/3.00	29
FGSF350028	28/3.50	29
FGSF400028	28/4.00	29
FGSF450028	28/4.50	29
FGSF200032	32/2.00	33
FGSF225032	32/2.25	33
FGSF250032	32/2.50	33
FGSF275032	32/2.75	33
FGSF300032	32/3.00	33
FGSF350032	32/3.50	33
FGSF400032	32/4.00	33
FGSF450032	32/4.50	33
FGSF200036	36/2.00	37
FGSF225036	36/2.25	37
FGSF250036	36/2.50	37
FGSF275036	36/2.75	37
FGSF300036	36/3.00	37
FGSF350036	36/3.50	37
FGSF400036	36/4.00	37
FGSF450036	36/4.50	37
FGSF200040	40/2.00	41
FGSF225040	40/2.25	41
FGSF250040	40/2.50	41
FGSF275040	40/2.75	41
FGSF300040	40/3.00	41
FGSF350040	40/3.50	41
FGSF400040	40/4.00	41
FGSF450040	40/4.50	41
FGSF200044	44/2.00	45
FGSF225044	44/2.25	45
FGSF250044	44/2.50	45
FGSF275044	44/2.75	45
FGSF300044	44/3.00	45
FGSF350044	44/3.50	45
FGSF400044	44/4.00	45
FGSF450044	44/4.50	45
FGSF200048	48/2.00	49
FGSF225048	48/2.25	49
FGSF250048	48/2.50	49
FGSF275048	48/2.75	49
FGSF300048	48/3.00	49
FGSF350048	48/3.50	49
FGSF400048	48/4.00	49
FGSF450048	48/4.50	49

Not available for sale in USA

Compliance Chart

Pressure [atm]	Stent Inner Diameter (ID) in mm by System Diameter							
	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	1.95	2.19	2.44	2.69	2.93	3.41	3.90	4.41
10	2.00	2.24	2.50	2.74	3.01	3.49	4.01	4.50
12	2.04	2.29	2.57	2.82	3.09	3.57	4.11	4.58
14	2.08	2.34	2.63	2.89	3.15	3.64	4.20	4.66
16	**2.12**	**2.37**	**2.68**	**2.96**	**3.21**	**3.71**	**4.28**	**4.74**
18	2.16	2.42	2.74	3.01	3.27	3.77	4.36	4.82

Nominal Pressure (NP) | Rated Burst Pressure (RBP)

The nominal data are based on in-vitro testing at 37°C and does not take into account lesion resistance

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Visit us at: www.smpl.com

Distributed and Marketed by:

Supraflex™

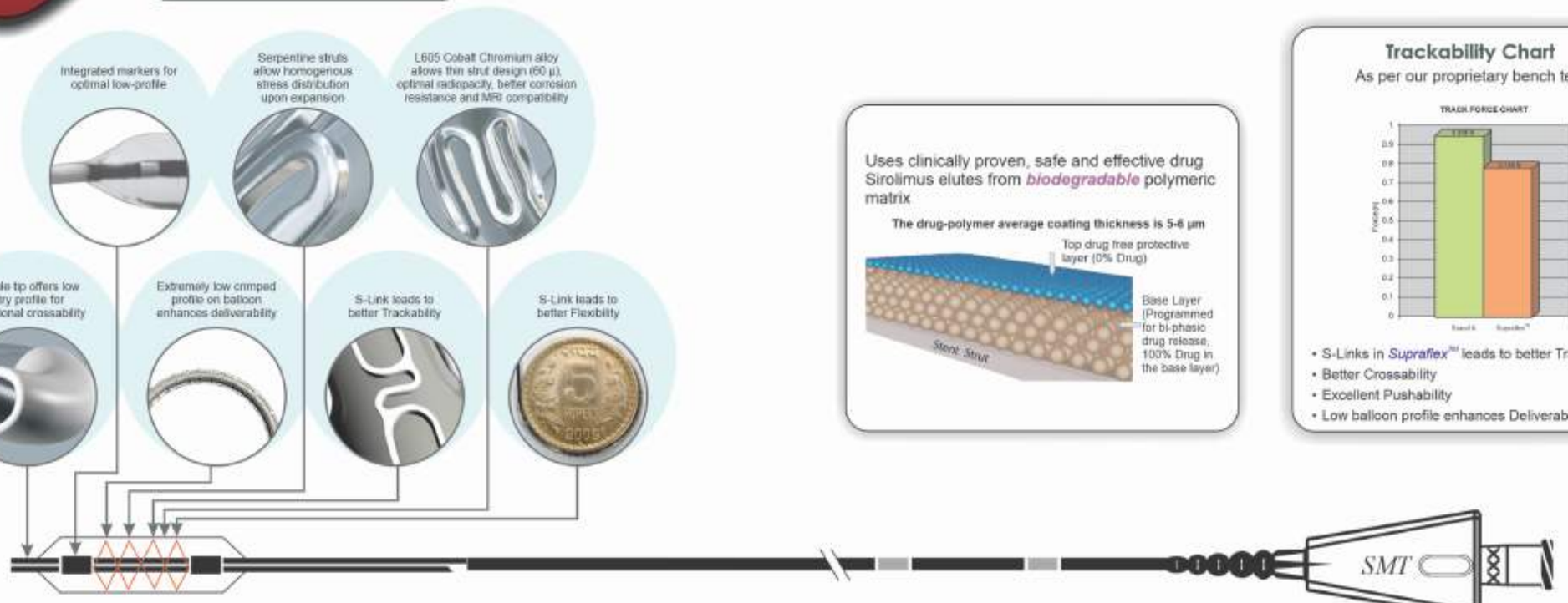
Sirolimus Eluting Cobalt Chromium Coronary Stent System

CE 2460

SMT

Supraflex™

Design Characteristics



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

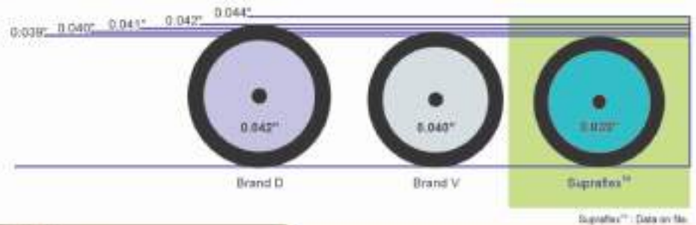
The drug-polymer average coating thickness is 5-6 µm

Trackability Chart

As per our proprietary bench test

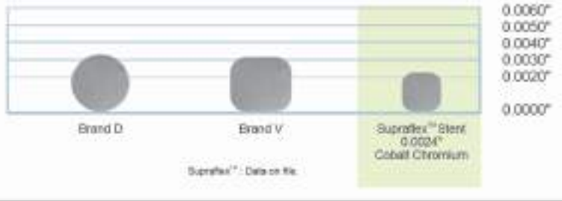
- S-Links in *Supraflex™* leads to better Trackability
- Better Crossability
- Excellent Pushability
- Low balloon profile enhances Deliverability

Crossing Profile



Supraflex™ : Data on file

Strut Thickness



Supraflex™ : Data on file

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	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 : 0.72mm Distal : 0.95mm
Balloon Inflation Pressure	*NP: 10 atm RBP: 16 atm
Guide Catheter	5 F 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

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, 4.5 mm
Stent Material	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	4.26
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	2.25	2.46	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	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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FOR UNMATCHED FLEXIBILITY

Tetrilimus™

Everolimus Eluting Cobalt Chromium Coronary Stent System

TLANBROVEN01 REV 03

Tetrilimus™

Everolimus Eluting Cobalt Chromium Coronary Stent System

Strut Thickness

Note: Data from marketing materials of respective brands (2018), strut cross section shapes are for representationpurpose 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

[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

Long Link

- Enhanced overall structural integrity
- Longer Links aid in well controlled expansion of the stent
- Longer Link resists longitudinal compression
- Longer link transmit "Push" force with higher efficiency

Tetrilimus (3.00mm x 36mm)

Pre

LCX diffused lesion at bifurcation of OM1 with 90 degree bend at the bifurcation of left main

Post

LCX Mid Post Stent TIMI Flow

Maximum Circular Unsupported Surface Area (MCUSA)

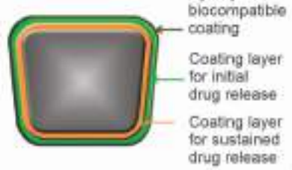
- MCUSA = 0.73 mm^2 (Value measured on expanded stent of 2.5 mm)
- Lower MCUSA aids in uniform drug distribution
- Scaffolding is more uniform

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

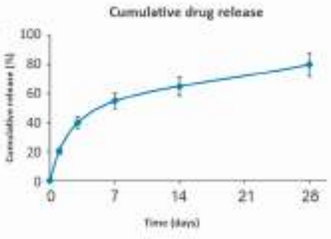
Strut Cross section

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



Drug release profile

- Drug Everolimus
- Dose: 1.0 µg/mm^2
- Release kinetics
  - About 80% of drug is released at 4 weeks in biological media while 100% drug is released at a slow rate within 3 months.
  - The initial moderate level of Everolimus drug release from middle layer coating helps to inhibit early phase of neointimal hyperplasia.
  - Controlled drug release kinetics from base layer is beneficial to maintain the effective amount of drug level in the arterial tissues which are required to prevent smooth muscle cell proliferation.



Tetrilimus is 2 times more flexible than Predicate device in Crimped State which infers that Tetrilimus has better:

- Trackability
- Pushability
- Conformability

Ordering Information

Reference No.	Stent Length / Diameter (mm)	Balloon Length (mm)	Reference No.	Stent Length / Diameter (mm)	Balloon Length (mm)	Reference No.	Stent Length / Diameter (mm)	Balloon Length (mm)
FGEF200008	08/2.00	09	FGEF400020	20/4.00	21	FGEF300036	36/3.00	37
FGEF225008	08/2.25	09	FGEF450020	20/4.50	21	FGEF350036	36/3.50	37
FGEF250008	08/2.50	09	FGEF200024	24/2.00	25	FGEF400036	36/4.00	37
FGEF275008	08/2.75	09	FGEF225024	24/2.25	25	FGEF450036	36/4.50	37
FGEF300008	08/3.00	09	FGEF250024	24/2.50	25	FGEF200040	40/2.00	41
FGEF350008	08/3.50	09	FGEF275024	24/2.75	25	FGEF225040	40/2.25	41
FGEF400008	08/4.00	09	FGEF300024	24/3.00	25	FGEF250040	40/2.50	41
FGEF450008	08/4.50	09	FGEF350024	24/3.50	25	FGEF275040	40/2.75	41
FGEF200012	12/2.00	13	FGEF400024	24/4.00	25	FGEF300040	40/3.00	41
FGEF225012	12/2.25	13	FGEF450024	24/4.50	25	FGEF350040	40/3.50	41
FGEF250012	12/2.50	13	FGEF200028	28/2.00	29	FGEF400040	40/4.00	41
FGEF275012	12/2.75	13	FGEF225028	28/2.25	29	FGEF450040	40/4.50	41
FGEF300012	12/3.00	13	FGEF250028	28/2.50	29	FGEF200044	44/2.00	45
FGEF350012	12/3.50	13	FGEF275028	28/2.75	29	FGEF225044	44/2.25	45
FGEF400012	12/4.00	13	FGEF300028	28/3.00	29	FGEF250044	44/2.50	45
FGEF450012	12/4.50	13	FGEF350028	28/3.50	29	FGEF275044	44/2.75	45
FGEF200016	16/2.00	17	FGEF400028	28/4.00	29	FGEF300044	44/3.00	45
FGEF225016	16/2.25	17	FGEF450028	28/4.50	29	FGEF350044	44/3.50	45
FGEF250016	16/2.50	17	FGEF200032	32/2.00	33	FGEF400044	44/4.00	45
FGEF275016	16/2.75	17	FGEF225032	32/2.25	33	FGEF450044	44/4.50	45
FGEF300016	16/3.00	17	FGEF250032	32/2.50	33	FGEF200048	48/2.00	49
FGEF350016	16/3.50	17	FGEF275032	32/2.75	33	FGEF225048	48/2.25	49
FGEF400016	16/4.00	17	FGEF300032	32/3.00	33	FGEF250048	48/2.50	49
FGEF450016	16/4.50	17	FGEF350032	32/3.50	33	FGEF275048	48/2.75	49
FGEF200020	20/2.00	21	FGEF400032	32/4.00	33	FGEF300048	48/3.00	49
FGEF225020	20/2.25	21	FGEF450032	32/4.50	33	FGEF350048	48/3.50	49
FGEF250020	20/2.50	21	FGEF200036	36/2.00	37	FGEF400048	48/4.00	49
FGEF275020	20/2.75	21	FGEF225036	36/2.25	37	FGEF450048	48/4.50	49
FGEF300020	20/3.00	21	FGEF250036	36/2.50	37			
FGEF350020	20/3.50	21	FGEF275036	36/2.75	37			

Not available for sale in USA

Compliance Chart

Pressure [atm]	Stent Inner Diameter (ID) in mm by System Diameter							
	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.50 mm	4.00 mm	4.50 mm
8.00	1.95	2.19	2.44	2.69	2.93	3.41	3.90	4.41
10.00	**2.00**	**2.24**	**2.50**	**2.74**	**3.01**	**3.49**	**4.01**	**4.50**
12.00	2.04	2.29	2.57	2.82	3.09	3.57	4.11	4.58
14.00	2.08	2.34	2.63	2.89	3.15	3.64	4.20	4.66
16.00	**2.12**	**2.37**	**2.68**	**2.96**	**3.21**	**3.71**	**4.28**	**4.74**
18.00	2.16	2.42	2.74	3.01	3.27	3.77	4.36	4.82

Nominal Pressure (NP) | Rated Burst Pressure (RBP)

The nominal data are based on in-vitro testing at 37°C and does not take into account lesion resistance

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Visit us at : www.smtpl.com
CIN: U33119GJ2001PTC040121

Distributed and Marketed by:

Important Information : 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.

EFBROVEN01 REV 03

everoflex™

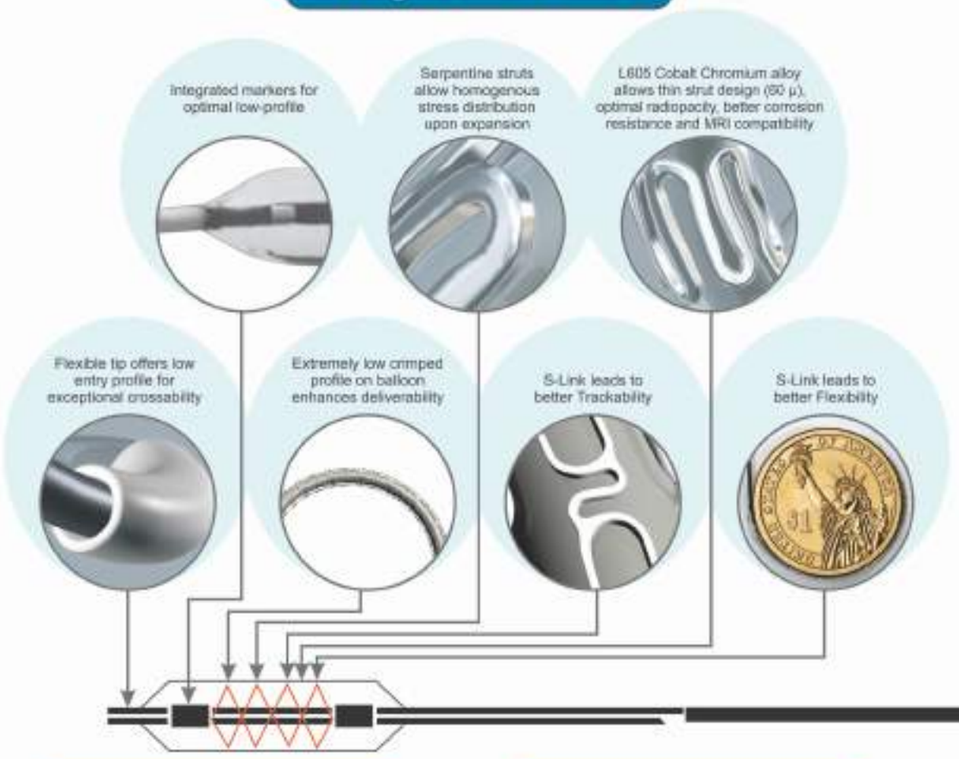
Everolimus Eluting Cobalt Chromium Coronary Stent System

10+ years
Of Healing Experience that you can TRUST

everoflex™

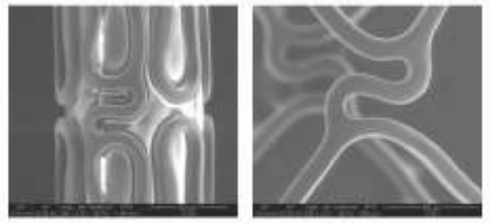
Everolimus Eluting Cobalt Chromium Coronary Stent System

Design Characteristics



Coating Integrity

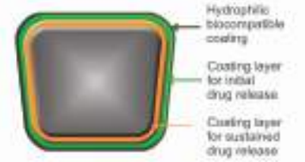
- Process optimized to minimize webbing, bridging and other coating defects.
- Coating integrity maintained even after simulated use and post expansion up to RBP.



Crimped Stent | Post-expanded Stent (at RBP)

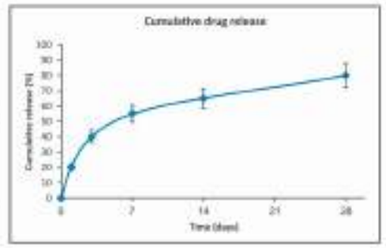
Strut Cross section

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



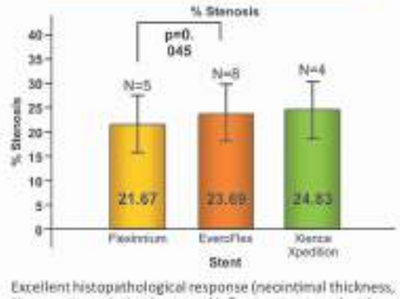
Everolimus drug release profile

- Drug Everolimus dose: 1.0 µg/mm²
- Release kinetics
  - 80% within 4 weeks
  - Low initial burst
  - Sustained release for longer duration
  - Able to maintain adequate levels of drug at implant site to control cell growth



Crossing Profile

Pre Clinical Data



Excellent histopathological response (neointimal thickness, % stenosis, neointimal area and inflammation score) with no significant difference compared to Xience Xpedition stent

Strut Thickness

Everoflex™ : Data on file.

Specifications

Device Component Description	
Available Stent Lengths, (mm)	8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48
Available Stent Diameters (mm)	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50
Stent Material	L-605 Co-Cr Alloy
Stent Design	Laser cut from seamless tubing in a serpentine pattern
Stent Platform	Flexinnium™ coronary stent system
Stent Strut Dimension	Thickness: 0.06 mm (60µ)
Nominal Stent Foreshortening	< 3%
Recoil	< 4%
Drug	Everolimus
Polymers Type	Biocompatible and biodegradable polymers
Delivery System Usable Length	1400mm (140 cm)
Delivery System Y - Adapter Ports	Single access port to inflation/deflation lumen. A guidewire exit port is located 25cm away from the tip. Designed for guidewire of Ø0.014inch.
Stent Delivery Balloon	Polyamide balloon, nominally 1 mm longer than the stent. Mounted stent length and location is defined by two radio opaque markers at proximal and distal ends of the stent.
Catheter Shaft Outer Diameter	Proximal : 0.72mm Distal : 0.95mm
Balloon Inflation Pressure	*NP: 10 atm RBP: 16 atm
Guiding Catheter	5 F compatible (min.)
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