

TECHNICAL SPECIFICATIONS

Product Description

The Supraflex Cruz Nevo, Sirolimus Eluting Cobalt Chromium Coronary Stent System is a combination product comprised of two regulated components: a device (Tetrinum™ coronary stent system as platform) and a drug product (a formulation of Sirolimus drug with the blend of biodegradable polymers).

Supraflex Cruz Nevo is available in various sizes ranging in diameter from 2.00 mm to 4.50 mm & 8 mm to 48 mm in length with a drug dose of sirolimus 1.4 µg/mm² for all lengths and diameters.

Coating Component Description

- The combination of hydrophilic and hydrophobic polymers gives elastomeric property to the coating in line with the stent expansion mechanism.
- Multi-layer coating technology with optimum balance between PLLA, PLCL and PVP allows precise control over drug elution to accommodate arterial drug requirement post stent implantation.
- The polymeric chains are cleaved by hydrolysis to form monomeric acids and are eliminated from the body through Krebs's cycle, primarily as carbon dioxide (CO₂) and water (H₂O) which are excreted through urine.

Indications

The Supraflex Cruz Nevo, Sirolimus Eluting Cobalt Chromium Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions in native coronary arteries with a reference vessel diameter of 2.00 mm to 4.50 mm.

Stent Delivery System

Catheter design	Rapid exchange
Usable shaft length	1400 mm (140 cm)
Proximal shaft design	Hypotube with tapered core wire at the distal end
Balloon compliance	Semi-compliant
Balloon folding	Tri-fold
Balloon Tip or Tip Entry Profile	0.017"(inch)
Balloon Tip Length	~ 2 mm
Catheter Shaft outer diameter	0.72 mm (Proximal shaft) 0.95 mm (Distal shaft)
Radiopaque markers	2 swaged platinum / iridium marker bands
Nominal pressure	Vessel Size: 2.00 & 2.25 mm; NP: 8 atm Vessel Size: 2.50 to 3.00 mm; NP: 10 atm Vessel Size: 3.50 to 4.50 mm; NP: 11 atm
Rated Burst Pressure	RBP: 16 atm
Guiding catheter	5F Compatible
Guide wire diameter	0.014" / 0.36 mm
Hub	Luer Taper and thread must meet ISO 80369-7:2016 gauging test

Component Description

- The Supraflex Cruz Nevo, Sirolimus Eluting Cobalt Chromium Coronary Stent System consists of a balloon expandable Sirolimus eluting stent, premounted on a stent delivery system.
- Single access port to inflation/deflation lumen. A guidewire exit port is located 25 cm away from the tip. Designed for guidewire of Ø0.014 inch.
- 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 which fluoroscopically mark the ends of the stent to facilitate proper placement.

Stent Platform

Stent material	Co-Cr (L605), ASTM F90
Stent platform	Tetrinum™
Shape of strut (Square/rectangle/ circular)	Square
Stent design	Laser cut from seamless tubing in a serpentine pattern
Link design	Unique Long Dual 'Z' Link (LDZ)
Stent crowns	SV - 4 crowns (2.00-2.25 mm) MV - 6 crowns (2.50-3.50 mm) LV - 8 crowns (4.00-4.50 mm)
Stent crossing profile (3x20 mm or 3x16 mm)	0.97 mm
Metal to artery ratio (6 Crown: 3x16 mm)	9.40%
Radial strength in mmHg	1093
Radial strength (3x48 mm)	0.94 Newton/mm²
Foreshortening/Elongation (3x20 mm or 3x16 mm)	Zero Foreshortening
Recoil (3x48 mm)	<4%
Ferromagnetism	Non-ferromagnetic (MRI safe)
Cell Perimeter (3x20 mm or 3x16 mm)	20.3 mm
Cell opening (Side branch access)	4 Crown (2.00-2.25 mm) 1.55 mm 6 Crown (2.50-3.50 mm) 1.97 mm 8 Crown (4.00-4.50 mm) 2.20 mm
MCUSA (3x20 mm or 3x16 mm)	0.96 mm²
Marker to Tip distance (Proximal and Distal)	Proximal: 1000 mm ± 100 mm Distal: 900 mm ± 100 mm
5F Compatible at 4, 4.5 mm diameter	Yes

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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= 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 to 4.50 mm RBP=16 atm
for all sizes
1 atm = 1.01 bar

Ordering Information

		Length										
		8 mm	12 mm	16 mm	20 mm	24 mm	28 mm	32 mm	36 mm	40 mm	44 mm	48 mm
Diameter (mm)	2.00	FGT0200008	FGT0200012	FGT0200016	FGT0200020	FGT0200024	FGT0200028	FGT0200032	FGT0200036	FGT0200040	FGT0200044	FGT0200048
	2.25	FGT0225008	FGT0225012	FGT0225016	FGT0225020	FGT0225024	FGT0225028	FGT0225032	FGT0225036	FGT0225040	FGT0225044	FGT0225048
	2.50	FGT0250008	FGT0250012	FGT0250016	FGT0250020	FGT0250024	FGT0250028	FGT0250032	FGT0250036	FGT0250040	FGT0250044	FGT0250048
	2.75	FGT0275008	FGT0275012	FGT0275016	FGT0275020	FGT0275024	FGT0275028	FGT0275032	FGT0275036	FGT0275040	FGT0275044	FGT0275048
	3.00	FGT0300008	FGT0300012	FGT0300016	FGT0300020	FGT0300024	FGT0300028	FGT0300032	FGT0300036	FGT0300040	FGT0300044	FGT0300048
	3.50	FGT0350008	FGT0350012	FGT0350016	FGT0350020	FGT0350024	FGT0350028	FGT0350032	FGT0350036	FGT0350040	FGT0350044	FGT0350048
	4.00	FGT0400008	FGT0400012	FGT0400016	FGT0400020	FGT0400024	FGT0400028	FGT0400032	FGT0400036	FGT0400040	FGT0400044	FGT0400048
	4.50	FGT0450008	FGT0450012	FGT0450016	FGT0450020	FGT0450024	FGT0450028	FGT0450032	FGT0450036	FGT0450040	FGT0450044	FGT0450048

Long lengths (44mm & 48mm) available

Usage Conditions

Single Use Product
Sterile unless package is opened or damaged
Do not reuse or re-sterilize

Sterilization method

Ethylene Oxide

Shelf life

24 Months

Storage Conditions

Store in a cool, dark, dry place.
Recommended storage conditions (20°C to 30°C) and
if the packaging is unopened and undamaged