

Techno Commercial Details

Supra Family of DES: Sirolimus Eluting Cobalt Chromium Coronary Stent System

Brand Name: Supraflex Cruz, Supraflex Star, Tetriflex, Supralimus Grace & Supraflex

Design & Material

- **Open Cell Design only with two connectors between the rings**
- Stent Material & Design: L-605 Co-Cr Alloy with Laser cut seamless tubing in serpentine pattern.
- **60 μ ultra-thin struts across all diameters and lengths**
- **Crossing profile of ≤ 0.97 mm**
- **Tip entry profile: 0.017"**
- **LDZ Link: Long Dual 'Z' Link**
- **IFU labeled Overexpansion of the highest available diameter should be ≥ 5.50 mm (approved by DCGI or CE or USFDA)**
- Guiding Catheter: 5F Compatible
- RBP: 16 atm
- Length (mm): 8 to 48 mm (more SKUs the more is the preference)
- Diameter(mm): 2.0 to 4.50 mm (more SKUs the more is the preference)

Drug & Polymer

- Drug Dose: Sirolimus 1.4 μ g/mm²
- Complete drug release in 90 days.
- Polymer Type: Biodegradable Polymer including 3 polymers (PLLA, PLCL & PVP). Hydrophilic & Hydrophobic polymers
- Coating: Conformal coating

Clinical Data

- At least one RCT with publication in journals with Impact factor of 50 (current generation or of the previous generation)
- 3 years published RCT Data
- Publication in Meta analysis with follow up of more than 2 years
- Published benchmark data in journal with Impact factor of greater than 1
- Published data on Bifurcation in journal with Impact factor of greater than 1
- Published OCT healing data of ≤ 3 months
- Published OCT healing data of ≥ 6 months

Other Parameters

- Financial Qualification: Manufacturing Company should have more than 200 crores of Turn over per year for coronary stent division with the manufacturing capacity of more than 100,000 stents per annum.

Everolimus Eluting Cobalt Chromium Coronary Stent System

Brand Name: Tetrilimus and Everoflex

Design & Material

- **Open Cell Design only with two connectors between the rings**
- Stent Material & Design: L-605 Co-Cr Alloy with Laser cut seamless tubing in serpentine pattern.
- **60 μ ultra-thin struts across all diameters and lengths**
- **Crossing profile of ≤ 0.97 mm**
- **Tip entry profile: 0.017"**
- **LDZ Link: Long Dual 'Z' Link**
- IFU labeled Overexpansion of the highest available diameter should be ≥ 5.50 mm
- Guiding Catheter: 5F Compatible
- RBP: 16 atm
- Length (mm): 8 to 48 mm (more SKUs the more is the preference)
- Diameter(mm): 2.0 to 4.50 mm (more SKUs the more is the preference)

Drug & Polymer

- Drug Dose: Everolimus 1.0 $\mu\text{g}/\text{mm}^2$
- Complete drug release in 90 days.
- Polymer Type: Biodegradable polymers including 3 polymers (PLLA, PLCL & PVP). Hydrophilic & Hydrophobic polymers
- Coating: Conformal coating

Clinical Data

- Published OCT healing data of ≤ 3 months
- Published OCT healing data of ≥ 6 months

Other Parameters

- Financial Qualification: Manufacturing Company should have more than 200 crores of Turn over per year for the coronary stent division with a manufacturing capacity of more than 100,000 stents per annum.