Synsiro® Pro DES

The Next Level of Deliverability.
Proven Clinical Performance.[Δ]

- The next level of deliverability[1]
- Ultrathin struts[2]
- Outstanding patient outcomes[3]

BIOTRONIK
excellence for life

Synsiro® Pro DES

Vascular Intervention Coronary

The Synsiro Pro Sirolimus-Eluting Coronary Stent System is a drug-eluting balloon-expandable stent pre-mounted on a rapid-exchange PTCA catheter delivery system.

Indication

Synsiro Pro DES 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 (length ⩽ 40 mm) in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm including the following patient and lesion subsets:

Acute Coronary Syndrome (ACS)	Long Lesions (LL) (e.g. ⩾ 20 mm)
ST-Elevation Myocardial Infarction (STEMI)	Small Vessels (SV) (e.g. ⩽ 2.75 mm)
Diabetes Mellitus (DM)	Multi-Vessel Disease (MVD)
Complex Lesions (B2/C)	Male/Female
High Bleeding Risk (HBR)	Old Patients (e.g. > 65 y)

Technical Data

Stent

Stent material	Cobalt chromium, L-605
Strut thickness	ø 2.25 – 3.0 mm: 60 µm (0.0024"); ø 3.50 – 4.0 mm: 80 µm (0.0031")
Passive coating	proBIO (Amorphous Silicon Carbide)
Active coating	BIOlute bioabsorbable Poly-L-Lactide (PLLA) eluting a limus drug
Drug dose	1.4 µg/mm²

Delivery System

Catheter type	Rapid exchange
Recommended guide catheter	5F (min. I.D. 0.056")
Guide wire diameter	0.014"
Usable catheter length	140 cm
Balloon material	Semi crystalline polymer
Coating (Distal shaft)	Hydrophilic
Coating (Proximal shaft)	Hydrophobic
Marker bands	Two swaged platinum-iridium markers
Lesion entry profile	0.017"
Distal shaft diameter	2.7F: ø 2.25 – 3.0 mm; 2.9F: ø 3.5 – 4.0 mm
Proximal shaft diameter	2.0F
Nominal pressure (NP)	10 atm
Rated burst pressure (RBP)	16 atm

Storage

Use Before Date (UBD)	24 months
Temperature	Between 15°C (59°F) and 25°C (77°F), short term excursions between 10°C (50°F) and 40°C (104°F) are allowed

Ordering Information

Stent ø (mm)	Stent Length (mm) 9	13	15	18	22	26	30	35	40
2.25	419155	419161	419167	419173	419179	419185	419191	419197	419203
2.5	419156	419162	419168	419174	419180	419186	419192	419198	419204
2.75	419157	419163	419169	419175	419181	419187	419193	419199	419205
3.0	419158	419164	419170	419176	419182	419188	419194	419200	419206
3.5	419159	419165	419171	419177	419183	419189	419195	419201	419207
4.0	419160	419166	419172	419178	419184	419190	419196	419202	419208

1. In comparison to Xience Sierra, Resolute Onyx and Synergy for bench tests on pushability, trackability and crossability, BIOTRONIK data on file; 2. As characterized with respect to strut thickness in Bangalore et al. Meta-analysis; 3. Based on investigator's interpretation of BIOFLOW-V primary endpoint result.

Δ Clinical data collected with Orsiro and Orsiro Mission bench performance testing can be used to illustrate Synsiro Pro clinical safety and performance.

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