

## Synsiro Drug Eluting Stent

### Device Description

The Synsiro Hybrid Drug Eluting Stent system consists of a coronary stent premounted on a rapid exchange delivery system.

The PRO-Kinetic Energy, coronary, stent platform is laser cut from a single tube of L-605 cobalt chromium alloy (CoCr).

Synsiro is a hybrid DES solution consisting of passive and active components:

- *Passive components* - Our PRO-Kinetic Energy stent system provides superior deliverability with state-of-the-art stent design, encapsulated within our **proBIO** passive coating that eliminates interaction between the metal stent and the surrounding tissue.

- *Active component* - Our active bioabsorbable polymer coating **BIOLute**, contains a limus drug and utilizes the advantage of controlled drug release from a highly biocompatible polymer matrix. In the long term, the patient is left with only a PROBIO coated stent.

**Table 1: Synsiro Stent characteristics**

Stent						
Diameter (mm)	2.25	2.5	2.75	3.0	3.5	4.0
Stent platform	PRO-Kinetic Energy					
Stent material	Cobalt Chromium, L-605					
Stent design	Double helix					
Passive coating	proBIO amorphous silicon carbide coating					
Active coating	BIOLute High molecular weight Poly-L-Lactide (PLLA) eluting a limus drug					
Drug dose	1.4 µg/mm <sup>2</sup>					
Strut thickness	60 µm (0.0024")				80 µm (0.0031")	
Recoil	4.7 %				4.6%	

**Table 2: Synsiro Delivery system characteristics**

Delivery system	
Catheter type	Rapid exchange
Balloon material	Semi crystalline polymer material
Coating (distal shaft)	Hydrophilic coating
Marker bands	Two swaged platinum-iridium markers
Guide wire diameter	0.014"
Lesion entry profile	0.017"
Crossing Profile	0.99 mm (0.039") average for Ø 3.00 mm stent
Recommended guide catheter	5F (min inner diameter 0.0056")
Usable catheter length	140 cm
Proximal shaft diameter	2.0 F
Distal shaft diameter	2.6F: Ø 2.25– 3.5 mm / 2.8F: Ø 4.0
Nominal pressure	8 atm
Rated burst pressure	16 atm

**Table 3: Synsiro Unique Selling Points**

	<b>Feature</b>	<b>Benefits</b>
<b>Implant</b>	Cobalt Chromium	For the thinnest strut design, optimal radiopacity and excellent vessel support.
	PRO-Kinetic Energy stent platform	Modern stent design that offers exceptional bending flexibility without compromising scaffolding or fatigue resistance.
	PROBIO coating	Acts as a diffusion barrier, eliminating contact between blood/tissue and allergenic metal components for long-term haemo- and biocompatibility.
	BIOLute coating	The proprietary PLLA polymer coating ensures biocompatibility, gentle degradation and optimal drug release kinetics.
	Limus drug	Expect clinical performance with the most the most proven class of drugs of the DES era.
<b>Delivery System</b>	Pantera® balloon technology	Flexible material and new balloon shaping technology gives greater crossability and trackability.
	Low profile system	Stent and delivery device designed with lower profiles to track and cross with ease.
	Double welded Enhanced Force Transmission (EFT) shaft	Unique joint between the hypotube and distal tubing for unsurpassed device pushability and kink resistance.
	Soft tip and minimal balloon overhang	Additional safety during direct stenting procedures.
	Advanced DES specific crimping	Ensures a low crossing profile and secure stent retention without affecting the BIOLute coating.

**Table 4: Synsiro Product ordering information**

<b>Ø (mm)</b>	<b>Stent lengths (mm)</b>						
	<b>9</b>	<b>13</b>	<b>15</b>	<b>18</b>	<b>22</b>	<b>26</b>	<b>30</b>
<b>2.25</b>	396927	396933	396939	396945	396951	396957	396963
<b>2.50</b>	396928	396934	396940	396946	396952	396958	396964
<b>2.75</b>	396929	396935	396941	396947	396953	396959	396965
<b>3.00</b>	396930	396936	396942	396948	396954	396960	396966
<b>3.50</b>	396931	396937	396943	396949	396955	396961	396967
<b>4.00</b>	396932	396938	396944	396950	396956	396962	396968