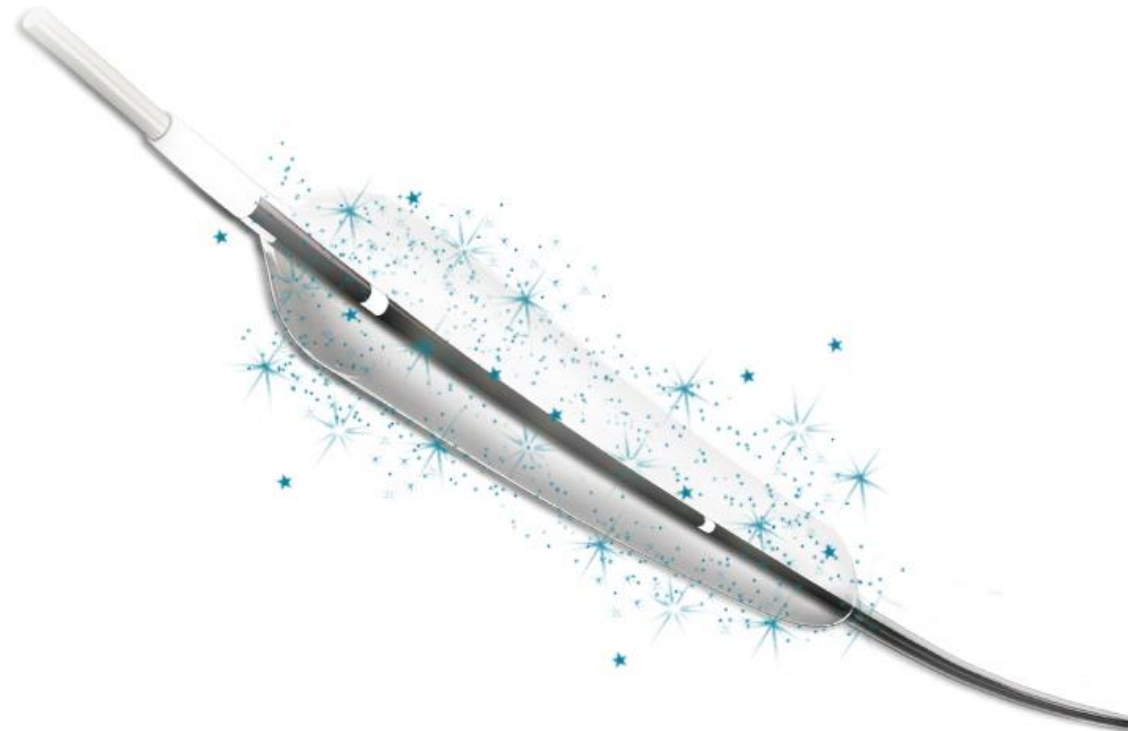


# Devoir Sirolimus Coated Balloon Catheter

Description and technical features

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2. CE mark indications
3. Bio-sphere technology
4. Coating process
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6. Specifications
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## OVERVIEW



SIROLIMUS  
1.27 $\mu$ g/mm<sup>2</sup>

BIO-SPHERE TECHNOLOGY  
Phospholipid carrier

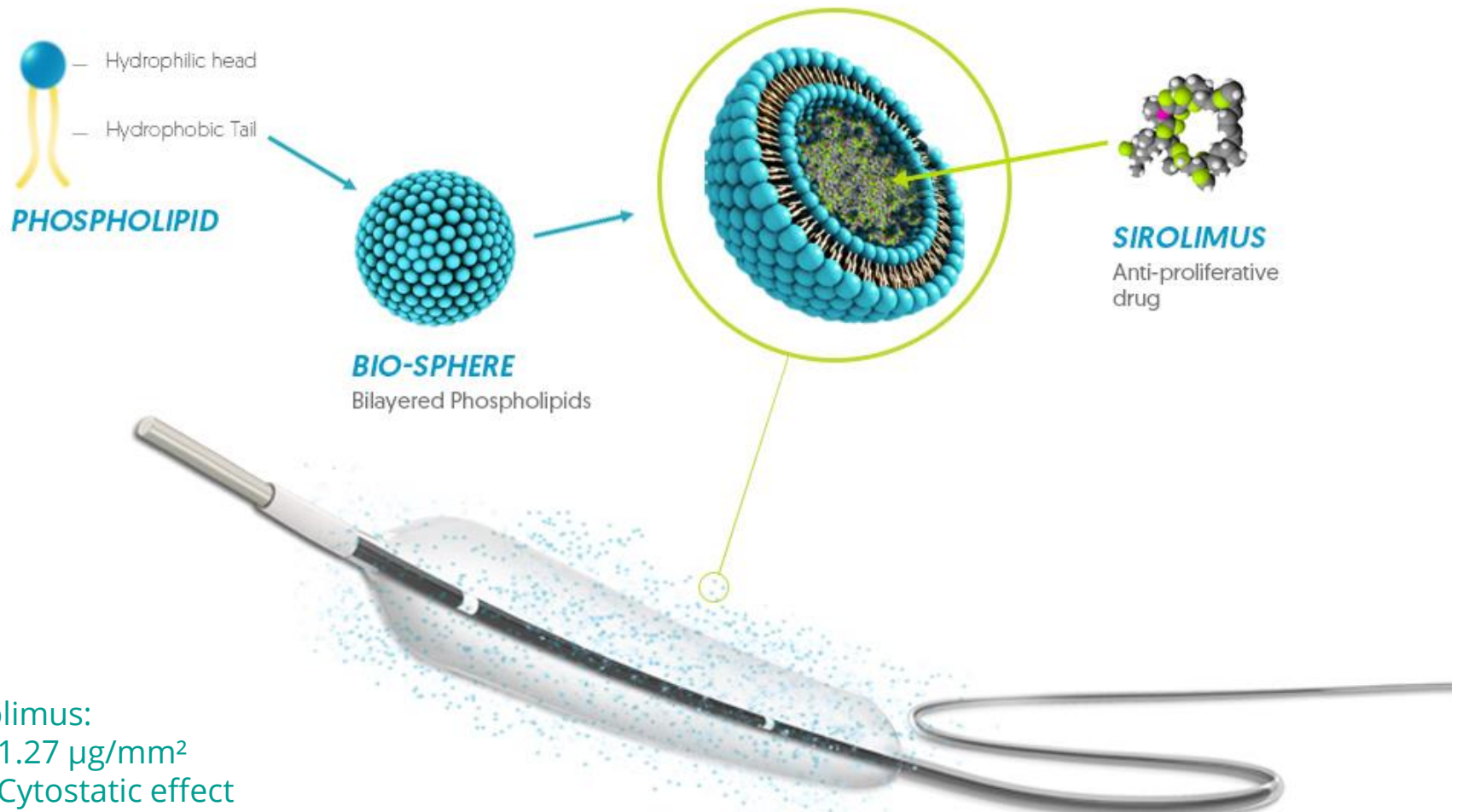
5Fr COMPATIBLE  
From 1.5 -4.0mm diameter



The Devoir Sirolimus coated balloon is indicated to dilate the diseased segment(s) and deliver drug in a coronary artery to improve myocardial perfusion with lesion lengths ranging from 8 to 38 mm and diameters ranging from 1.50 mm to 4.00 mm. Usage of one Devoir is recommended, beyond 38 mm length there should be use of two devices in summation of the lesion.

The device is intended for use in following conditions:

- Patients with in-stent restenosis of previous stent implantation
- Patients with disease in small vessels where drug eluting stent implantation is either not feasible or involving higher risk of restenosis
- Patients with bifurcation lesions, where side branch treatment increases risks of dissection and a balloon dilation treatment is more advised.
- Stenotic portions also including total occlusions, it can be used also for the post dilatation of stents

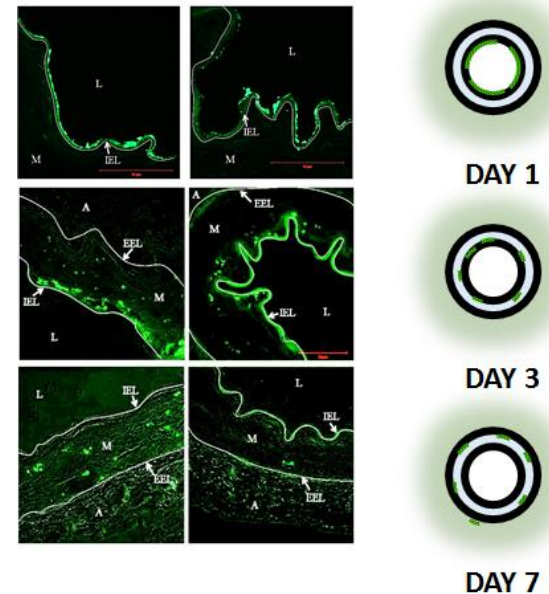


## Sirolimus:

- 1.27  $\mu\text{g}/\text{mm}^2$
- Cytostatic effect
- Drug most widely used for drug eluting stents

## Features:

- Cell membrane bio-mimicking carrier for reduced drug rejection
  - Better compatibility and acceptance in tissue
  - Promotes healing and assists in endothelialisation
- Small size for higher uptake
  - Easier and faster transfer in to arterial tissue
- Bio-sphere drug encapsulation
  - Stabilisation and protection
- Two-steps release
  - First: bio-spheres transfer in to tissue
  - Second: drug release from bio-spheres



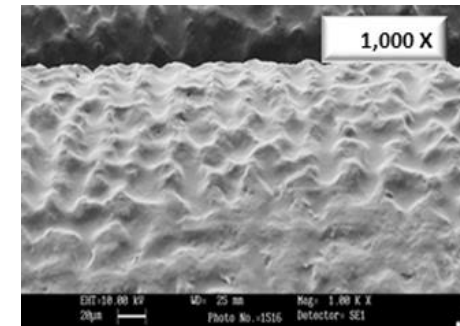
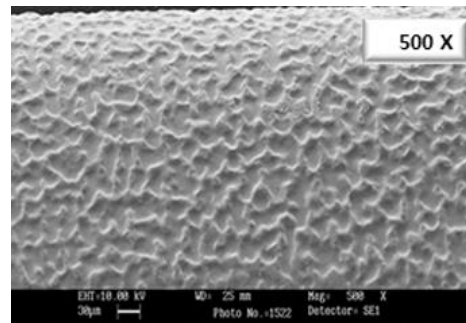
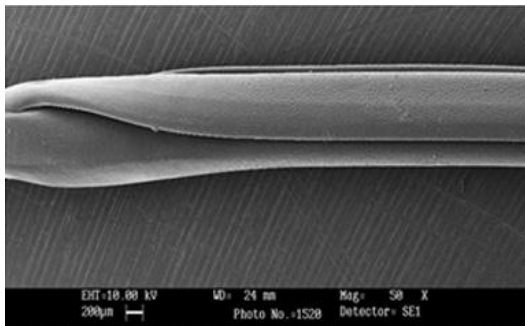
Homogeneous Drug Repartition  
within 7 days

## Balloon surface application

- **Effective adhesion to balloon surface**
  - No coating delamination
  - Low 'particulate' generation
- **Uniform surface coating**
  - Homogenous drug distribution
  - Protection during transit (between the folds)



10% in-transit loss



# RELIABLE DRUG DELIVERY PLATFORM



- Guiding catheter **5Fr** compatible
- Distal shaft hydrophilic coating
- Entry profile **0.016"**
- Semi-compliant balloon material



Yangtze  $\mu$  catheter system physicians feedback: 642 cases (data on file)



Drug	Sirolimus
Drug dose	1.27 $\mu\text{g}$ / $\text{mm}^2$
Drug carrier	Phospholipid based excipient
Balloon material	Polyamide blend (semi-compliant)
Catheter design	Rapid exchange
Shaft diameter - prox.	1.7F
Shaft diameter - dist.	2.5F
Usable catheter length	140cm
Tip profile	0.016"
Nominal Pressure (NP)	6 bar
Rated Burst Pressure (RBP)	16 bar (14 bar for 4.00 / 25 to 40mm)
Guide catheter compatibility	5Fr (0.056" ID) for all sizes
Guidewire compatibility	0.014" maximum recommended

# SIZE RANGE & CODES



Diameter (mm)	Length						
	10	15	20	25	30	35	40
1.50	CDE15010	CDE15015	CDE15020	CDE15025	CDE15030	CDE15035	CDE15040
2.00	CDE20010	CDE20015	CDE20020	CDE20025	CDE20030	CDE20035	CDE20040
2.25	CDE22510	CDE22515	CDE22520	CDE22525	CDE22530	CDE22535	CDE22540
2.50	CDE25010	CDE25015	CDE25020	CDE25025	CDE25030	CDE25035	CDE25040
2.75	CDE27510	CDE27515	CDE27520	CDE27525	CDE27530	CDE27535	CDE27540
3.00	CDE30010	CDE30015	CDE30020	CDE30025	CDE30030	CDE30035	CDE30040
3.50	CDE35010	CDE35015	CDE35020	CDE35025	CDE35030	CDE35035	CDE35040
4.00	CDE40010	CDE40015	CDE40020	CDE40025	CDE40030	CDE40035	CDE40040

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