Orsiro

Hybrid Drug-Eluting Stent
Indicated for discrete de novo stenotic lesions and in-stent restenotic lesions

- Performs as best in class
- Bioabsorbable polymer for controlled drug release of a limus drug
- Proven PRO-Kinetic Energy / PK Papyrus stent design provides exceptional deliverability to access a wider range[1] of lesions

[1] Indication as per IFU

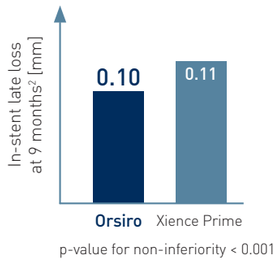
BIOTRONIK
excellence for life

Orsiro Hybrid DES

The Orsiro Hybrid Drug-Eluting Stent brings the optimal combination of effortless deliverability, coupled with a hybrid coating for treating coronary artery stenosis. This unique concept opens a new generation of drug-eluting stents for improving patient outcomes even with long lesions.

Performs as best in class

Met the primary non-inferiority endpoint of the BIOFLOW-II RCT versus Xience Prime.



p-value for non-inferiority < 0.001

Proven PRO-Kinetic Energy / PK Papyrus stent design

- Orsiro uses the proven PRO-Kinetic Energy platform that offers exceptional bending flexibility without compromising scaffolding or fatigue resistance. This stent design allows for expansion of the stent without affecting the **BIOlute** coating.
- Struts of only 60 µm[3] result in exceptional flexibility and ensure minimal vessel wall injury, leading to better patient outcomes.

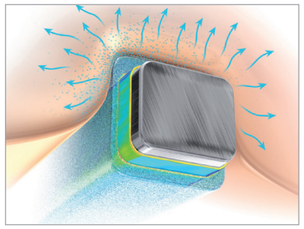
[2] Late breaking clinical trial presentation, S. Windecker, EuroPCR 2013
[3] 2.25 - 3.0 mm stent

Advanced technology, better results

Hybrid coating – **BIOlute** and **proBIO** – for optimal performance

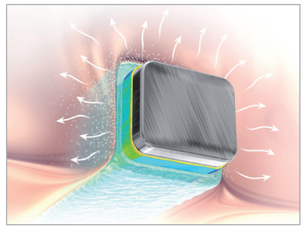
- **BIOlute** active coating consists of the most proven limus family drug and a bioabsorbable polymer matrix (PLLA) which achieves a controlled drug release.
- **proBIO** passive coating is a silicon carbide, semi conductive sealant, that reduces the interaction between tissue or blood with the metallic surface of the stent.

1. Controlled drug release



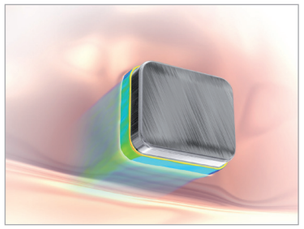
Immediately following implantation the drug elution from **BIOlute** starts. In vivo studies show complete drug release in approximately 100 days.

2. Bioabsorption



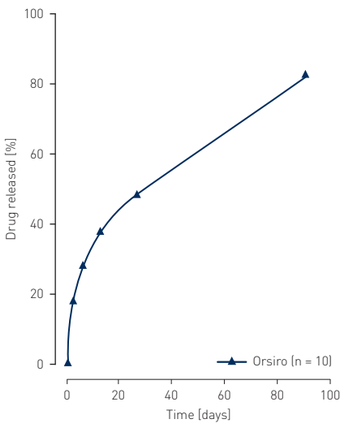
The gentle break down of the **BIOlute** polymer matrix into CO_2 and H_2O causes minimal tissue burden and avoids inflammation.

3. Inert backbone

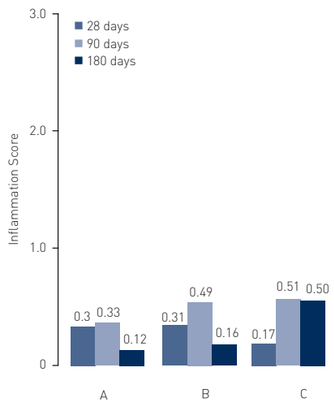


When the **BIOlute** coating is gone only a **proBIO** sealed stent is left in the arterial wall.

Optimal and complete drug release[4]

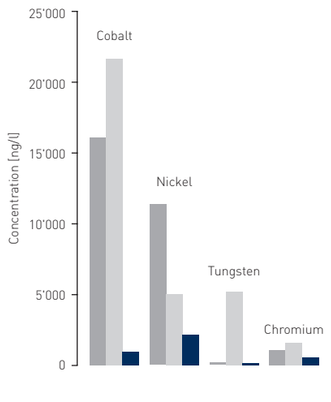


Low inflammatory response due to Poly-L-Lactide (PLLA) polymer matrix[5]



A) PRO-Kinetic Energy with **proBIO** coating
B) PRO-Kinetic Energy with **proBIO** and PLLA coating
C) Orsiro with **proBIO** and **BIOlute** coating

Up to 96 % reduction of allergenic metal ions with **proBIO** coating[6]



Competitor A cobalt nickel alloy
Competitor B cobalt chromium alloy
PRO-Kinetic Energy with **proBIO** coating

[4] BIOTRONIK data on file
[5] Histopathological preclinical results, inflammation score. Overstretched minipig coronary artery model. Number of vessels 88. BIOTRONIK data on file
[6] BIOTRONIK data on file

Orsiro

Hybrid Drug-Eluting Stent

Technical Data

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

Delivery system	
Catheter type	Rapid exchange
Recommended guide catheter	5F (min. I.D. 0.056")
Lesion entry profile	0.017"
Guide wire diameter	0.014"
Usable catheter length	140 cm
Balloon material	Semi Crystalline Polymer material
Coating (distal shaft)	Hydrophilic coating
Marker bands	Two swaged platinum-iridium markers
Proximal shaft diameter	2.0F
Distal shaft diameter	2.6F: ø 2.25 - 3.5 mm; 2.8F: ø 4.0 mm
Nominal pressure (NP)	8 atm
Rate burst pressure (RBP)	16 atm

Compliance Chart

		Balloon diameter x length (mm)					
		ø 2.25 x 9-40	ø 2.50 × 9-40	ø 2.75 × 9-40	ø 3.00 × 9-40	ø 3.50 × 9-40	ø 4.00 × 9-40
Nominal Pressure	atm*	8	8	8	8	8	8
(NP)	ø (mm)	2.25	2.50	2.75	3.00	3.50	4.00
Rated Burst Pressure	atm*	16	16	16	16	16	16
(RBP)	ø (mm)	2.50	2.77	3.05	3.33	3.88	4.44

* 1 atm = 1.013 bar

Ordering Information

Stent ø (mm)	Catheter length 140 cm Stent length (mm)								
	9	13	15	18	22	26	30	35	40
2.25	364469	364475	364481	364487	364499	364505	364511	391234	391238
2.50	364470	364476	364482	364488	364500	364506	364512	391235	391239
2.75	364471	364477	364483	364489	364501	364507	364513	391236	391240
3.00	364472	364478	364484	364490	364502	364508	364514	391237	391241
3.50	364473	364479	364485	364491	364503	364509	364515	391018	391020
4.00	364474	364480	364486	364492	364504	364510	364516	391019	391021

Orsiro is part of the BIOTRONIK coronary solutions portfolio, including:

- Stents: **PRO-Kinetic Energy, PK Papyrus**
- Balloons: **Pantera Lux, Pantera LEO, Pantera, Pantera Pro**
- Guide Wires: **Galeo, Galeo Pro, Cruiser, Magnum**

For ordering please contact your local sales representative

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