

Sirolimus Eluting Coronary Stent System

Yukon[®] Choice PC

5-Years Randomized
Clinical Follow-Up

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trust is what counts*



trust is what counts

translumina[®]

Yukon[®] Choice PC

DES with excellent long-term clinical outcome

The Translumina **Yukon Choice PC** drug-eluting stent, coated with Rapamycin (Sirolimus) and the biodegradable component polylactide (PLA), has an excellent history of pre-clinical and clinical results.^[1,2]

In two independent trials ISAR-TEST 3 and ISAR-TEST 4 the **Yukon Choice PC** showed angiographic and clinical equivalence with the Cypher stent after 1 year and 3 years of follow-up.^[3,4]

Latest clinical data, published by G.Stefanini et al ^[5], show the excellent long-term outcome of the **Yukon Choice PC** in a meta-analysis, comparing the clinical outcome after 4 years in more than 4000 patients with the Cypher stent. This analysis shows for the first time that the definite Very Late Stent Thrombosis (VLST) can be reduced statistically significant by using the biodegradable PLA polymer coating technology of the **Yukon Choice PC**.

An additional sub-group analysis shows also benefit in difficult patient groups like diabetics and patients with acute myocardial infarkt. ^[6,7]

Due to this excellent clinical outcome the **Yukon Choice PC** is recommended by the latest ESC guidelines for myocardial revascularization.^[8]

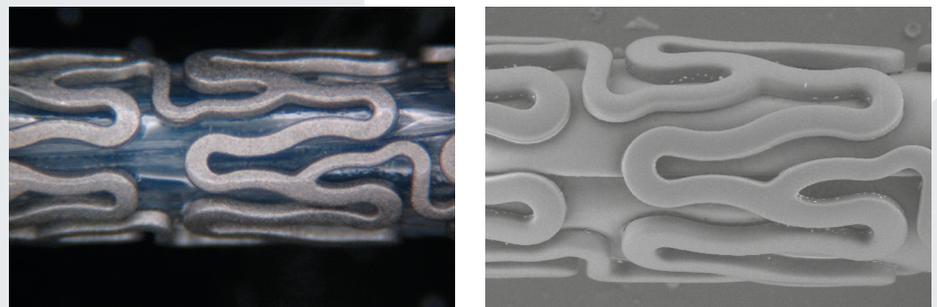
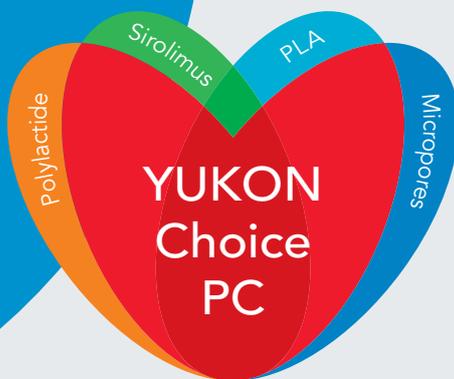


Figure 1: Optical and Electron Microscope Pictures of the **Yukon Choice PC**. The unique microporous stent surface is coated abluminal with Sirolimus and PLA. The PLA ensures a better binding of the Sirolimus to the microporous stent surface and controls the release of the drug. The PLA is fully degradable according to the Krebs cycle.

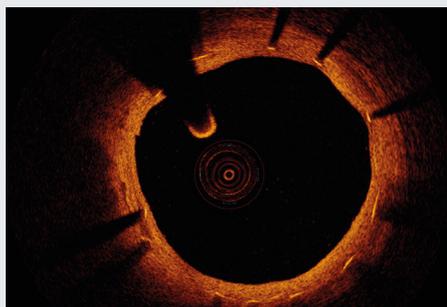
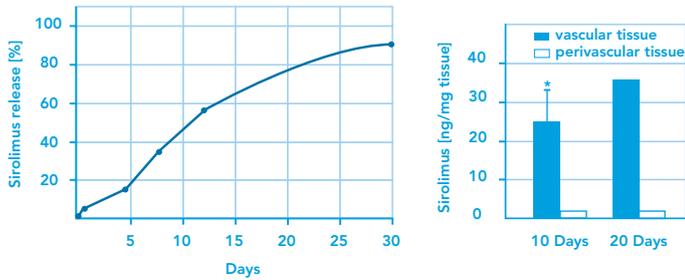


Figure 2: OCT follow-up 3 years after implantation of a **Yukon Choice PC**.

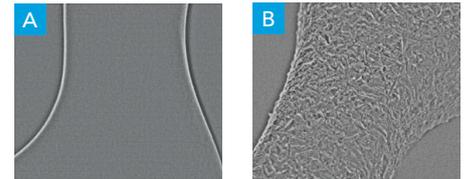
Published Pre-clinical and BMS Data ^[1,2]

Extensive pre-clinical evaluations prove the safety of **Yukon Choice PC** over BMS and conventional DES:



Yukon Choice PC shows a release of sirolimus up to 4 weeks with a significant tissue concentration in the arterial segments.

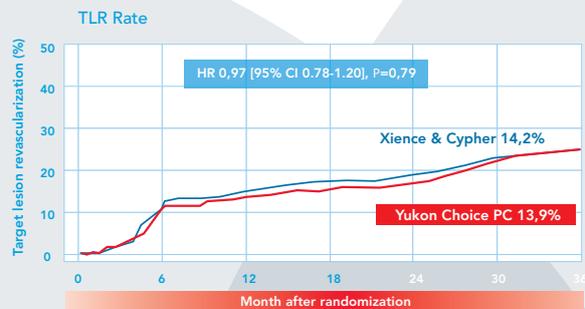
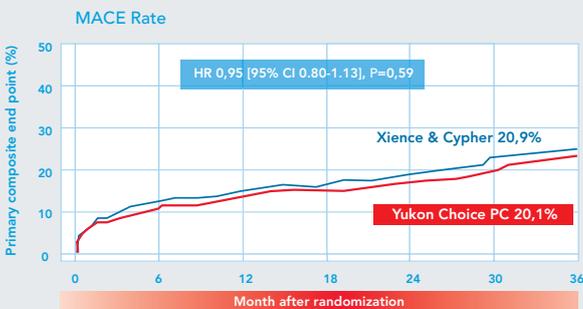
The microporous surface shows a trend towards a reduced rate of binary restenosis with equivalent safety, which proves that it is safe and feasible to use as a drug reservoir for a DES.



Comparison of smooth (electro-polished) stent surface (A) and rough (microstructured) stent surface (B). Magnification, 500x.

Efficacy ^[3,4]

The ISAR-TEST 4 is the first prospective randomized trial which compares different DES i.e. **Yukon Choice PC**, Xience and Cypher for their efficacy & safety in over 2600 patients.



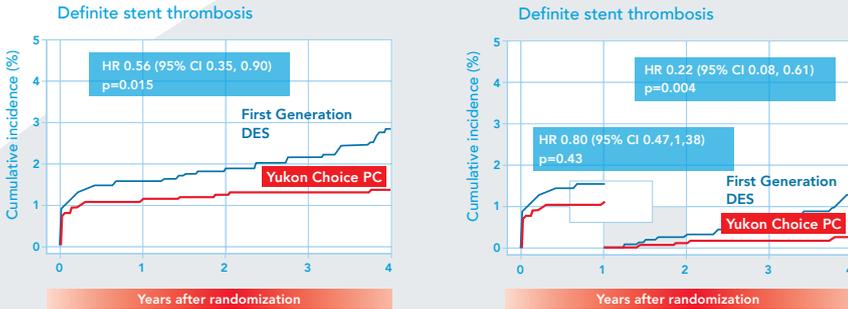
The **Yukon Choice PC** with biodegradable polymer proves equivalence to Xience and Cypher in terms of late loss, binary restenosis, TLR and primary composite MACE despite having minimal polymeric load.

Literature

- 1 YUKON Animal study: K.Steigerwald et al, Biomaterials, 2009; 4, 632-637.
- 2 Microporous Stent BMS study: Dibra et al, Cath. Cardiovasc.Interv., 2005; 65, 374-380.
- 3 ISAR-TEST 4 trial, 1 year data (comparison with Cypher): R.Byrne et al, European Heart Journal, 2009 ; 30, 2441-2449.
- 4 ISAR-TEST 4 trial, 3 year data (comparison with Cypher): R.Byrne et al, JACC, 2011 ; 58, 1325-1331.
- 5 Meta-Analysis ISAR-TEST 3 + 4, LEADERS, 4 years follow-up: G.Stefanini, European Heart Journal, 2012; 33, 1214-1222.
- 6 Subgroup-Analysis Diabetics: A. de Waha et al, International Journal of Cardiology 2013, 168, 5162-6.
- 7 Subgroup-Analysis STEMI: A. de Waha et al, Eurointervention 2014, published online.
- 8 S.Windecker et al, European Heart Journal (2014) 35, 2541-2619.
- 9 S.Kufner et al, EuroIntervention 2016;11:1372-1379.

Long Term Safety [5]

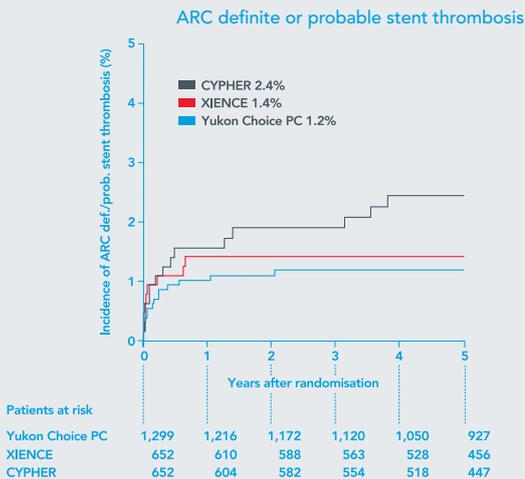
One of the largest meta-analysis involving more than 4000 patients, which compared biodegradable polymer based DES with permanent polymer based DES demonstrated the long term excellent safety profile of the Yukon Choice PC up to 4 years.



At 4 years follow-up, the **Yukon Choice PC** shows a reduction of risk by 50% in definite Stent Thrombosis and by 78% in Very Late Stent Thrombosis (VLST) compared to First Generation DES without compromising on efficacy. Additionally, the Yukon Choice PC achieved highest recommendations in the latest ESC Guidelines for myocardial revascularization (2014) due to the excellent clinical outcome.^[8]

Excellent 5 year long-term clinical data [9]

The final 5 year long-term clinical follow-up of the ISAR-TEST 4 randomized controlled clinical trial showed excellent safety and efficacy data for the Yukon Choice PC when compared with the Cypher and Xience V stent. The definite and probable stent thrombosis was only 1,2% for the Yukon compared to 1,4% and 2,4% for the 2 permanent polymer coated competitor DES.



Biodegradable Polymer technology enhances the long-term safety when compared to permanent polymer DES.



Bernd Beck
CEO
Translumina GmbH

Dear Reader,

Since its foundation in the year 2000 translumina® has been striving for unique product solutions to enhance patient outcome in the field of interventional cardiology.

Yukon Choice PC is our DES product that combines potent long-term clinical data with unique product performance. We are strongly committed to reliably support our customers with the most effective product solutions. Our production facility in Hechingen, Germany is designed to realize the highest standards for medical device manufacture and thus endorses our commitment of "Made in Germany".

From development to production and marketing, everything happens in our premises in Germany, thus guaranteeing optimal product reliability and best customer service.

With us,

trust is what counts.

Yours,
Bernd Beck

Yukon[®] Choice PC

Sirolimus Eluting Coronary Stent System

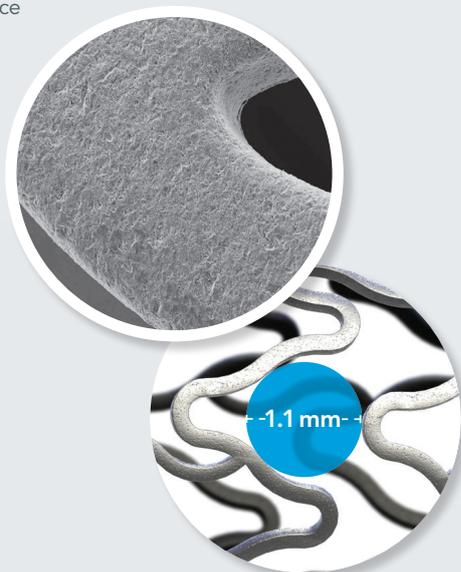
The new stent delivery system

The new distal shaft

High performance shaft provides excellent pushability and kink resistance. This feature allows for high manoeuvrability.

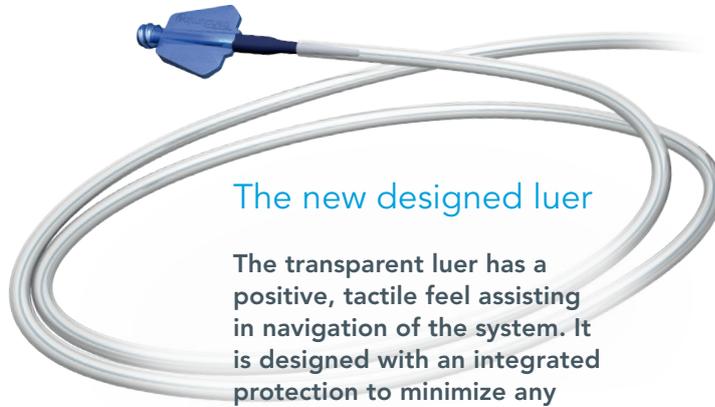


SEM of the microporous stent surface



The new designed luer

The transparent luer has a positive, tactile feel assisting in navigation of the system. It is designed with an integrated protection to minimize any kinking.



The new flexible tip

The soft tip material combined with an improved robust segment ensures perfect crossability and trackability. This feature allows easy access to all lesions.



Stent features

Unique stent surface

The micro-porous stent surface, called PEARL Surface, favours better endothelialisation, which is essential for avoiding thrombosis and restenosis.

Stent design

- homogeneous expansion
- increased radial force
- good side branch access

Low stent profile

- flexible and deliverable
- strut thickness of 87µm in the range of CoCr platforms

Technical specifications of the stent

Medical Stainless Steel, 316 LVM, Surface containing micro-pores

Crossing profile	0,035" / 0,89 mm (Ø 2,5 mm)
Strut thickness	0,0034" / 87 µm (Ø 2,5 mm)
Metallic surface area	16 - 18%
Balloon marker material	Platinum / Iridium
Entry profile	0,016" / 0,41 mm
Proximal shaft diameter	1,9 F
Distal shaft diameter	2,7 F
Recommended guide wire	0,014"
Guiding Catheter	min. 5 F

Yukon[®] Choice PC

Product matrix / Ordering information

Small vessel design (SV)

Balloon	Stent length [mm] & Article number							
Ø [mm]	8	12	16	18	21	24	28	32
Ø 2,00	YCPC2008	YCPC2012	YCPC2016	YCPC2018	YCPC2021	YCPC2024	YCPC2028	YCPC2032
Ø 2,50	YCPC2508	YCPC2512	YCPC2516	YCPC2518	YCPC2521	YCPC2524	YCPC2528	YCPC2532

Medium vessel design (MV)

Balloon	Stent length [mm] & Article number								
Ø [mm]	8	12	16	18	21	24	28	32	40
Ø 2,75	YCPC2708	YCPC2712	YCPC2716	YCPC2718	YCPC2721	YCPC2724	YCPC2728	YCPC2732	YCPC2740
Ø 3,00	YCPC3008	YCPC3012	YCPC3016	YCPC3018	YCPC3021	YCPC3024	YCPC3028	YCPC3032	YCPC3040
Ø 3,50	YCPC3508	YCPC3512	YCPC3516	YCPC3518	YCPC3521	YCPC3524	YCPC3528	YCPC3532	YCPC3540
Ø 4,00	YCPC4008	YCPC4012	YCPC4016	YCPC4018	YCPC4021	YCPC4024	YCPC4028	YCPC4032	YCPC4040

Compliance chart

Balloon	Inflation pressure [bar or 10 ⁵ Pascal]														
	NP				RBP										
Ø [mm]	6	7	8	9	10	11	12	13	14	15	16	17	18	19*	20*
Ø 2,00	1,90	1,94	1,97	2,00	2,03	2,07	2,10	2,13	2,17	2,20	2,23	2,27	2,35	2,38	2,41
Ø 2,50	2,40	2,43	2,47	2,50	2,54	2,57	2,60	2,64	2,67	2,71	2,74	2,77	2,81	2,84	2,88
Ø 2,75	2,65	2,68	2,72	2,75	2,78	2,82	2,85	2,88	2,92	2,95	2,98	3,01	3,28	3,31	3,34
Ø 3,00	2,89	2,93	2,97	3,00	3,04	3,08	3,12	3,15	3,19	3,23	3,26	3,30	3,34	3,37	3,41
Ø 3,50	3,37	3,42	3,46	3,50	3,54	3,58	3,63	3,67	3,71	3,75	3,79	3,84	3,88	3,92	3,96
Ø 4,00	3,85	3,90	3,95	4,00	4,05	4,10	4,16	4,21	4,26	4,31	4,36	4,41	4,46	4,51	4,56

* calculated



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Please refer to the Instruction for Use supplied with these devices for indications, contraindications, adverse effects, suggested procedures, warnings and precautions.

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Yukon[®] Choice PC
now available in more
than 40 countries.