

Sirolimus Eluting CoCr Coronary Stent System

# Yukon<sup>®</sup> Chrome PC

5-Years Randomized  
Clinical Follow-Up

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trust is what counts*



trust is what counts

translumina<sup>®</sup>



# Yukon<sup>®</sup> Chrome PC

## DES coating with excellent long-term clinical outcome

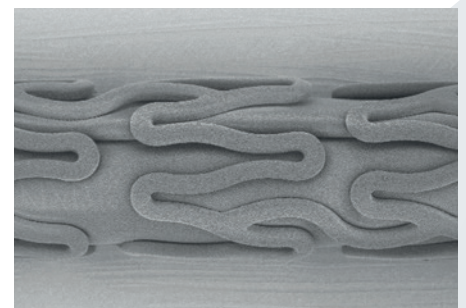
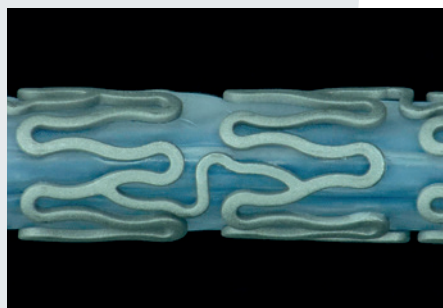
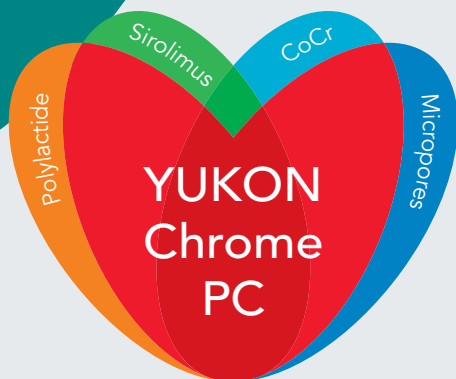
The Translumina **Yukon Chrome PC** drug-eluting stent, coated with Rapamycin (Sirolimus) and the biodegradable component polylactide (PLA), has an excellent history of pre-clinical and clinical results.<sup>[1,2]</sup>

The **Yukon Chrome PC** has the identical coating technique and coating properties (dosage, thickness) like the clinically proven Yukon Choice PC. In two independent trials ISAR-TEST 3 and ISAR-TEST 4 the Yukon DES platform showed angiographic and clinical equivalence with the Cypher stent after 1 year and 3 years of follow-up.<sup>[3,4]</sup>

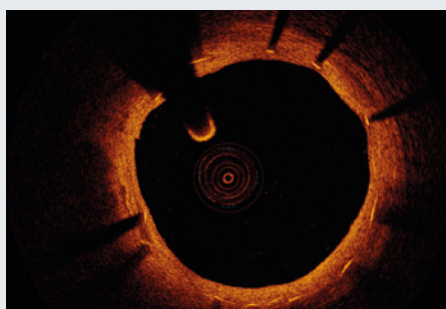
Latest clinical data, published by G. Stefanini et al <sup>[5]</sup>, show the excellent long-term outcome of the Yukon biodegradable polymer DES technology in a meta-analysis, comparing the clinical outcome after 4 years in more than 4000 patients with the Cypher stent. This analysis shows for the first 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 DES. An additional sub-group analysis shows also benefit in difficult patient groups like diabetics and patients with acute myocardial infarct. <sup>[6,7]</sup>

Due to this excellent clinical outcome the Yukon DES technology is recommended by the latest ESC guidelines for myocardial revascularization.<sup>[8]</sup>

**Yukon Chrome PC** now transfers this unique technology to the latest Translumina CoCr-stent platform featuring thin struts and a highly flexible 2-Connector stent design.



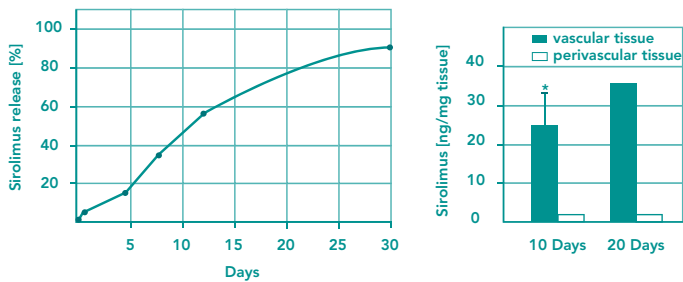
**Figure 1:** Optical and Electron Microscope Pictures of the **Yukon Chrome PC**. The unique microporous stent surface is coated abluminal with Sirolimus and PLA. The PLA ensures a better binding of the Sirolimus to the microporous stent surface and controls the release of the drug. The PLA is fully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



**Figure 2:** OCT follow-up 3 years after implantation of a Yukon stent with Sirolimus / PLA coating.

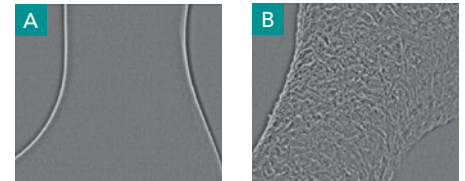
# Published Pre-clinical and BMS Data <sup>[1,2]</sup>

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



**Yukon DES** coating 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.

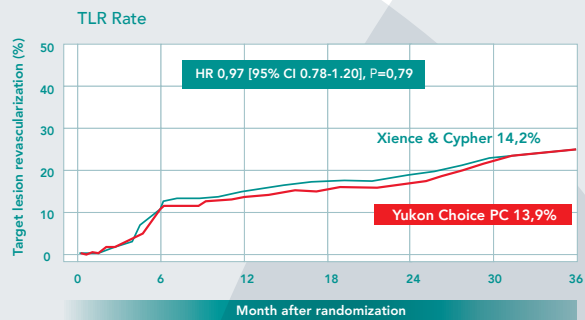
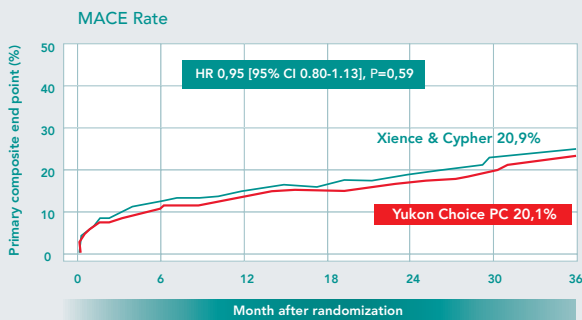


Comparison of smooth (electro-polished) stent surface (A) and rough (microstructured) stent surface (B). Magnification, 500x.

## Efficacy <sup>[3,4]</sup>

The **Yukon Chrome PC** is applying the same coating technique and is demonstrating the identical coating properties (dosage, thickness) like the Yukon Choice PC. The following charts are showing the clinical outcome taken from the ISAR-TEST 3 and ISAR-TEST 4 trials, including the Yukon Choice PC.

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.



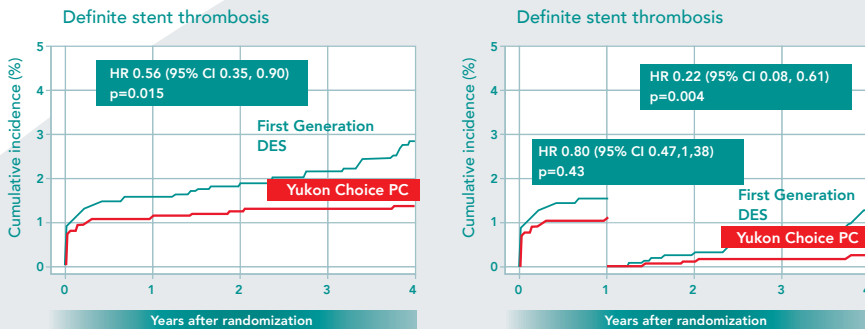
The Yukon Choice PC with biodegradable polymer proves equivalence to Xience and Cypher in terms of late loss, binary restenosis, TLR and primary composite MACE despite having minimal polymeric load.

### 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]

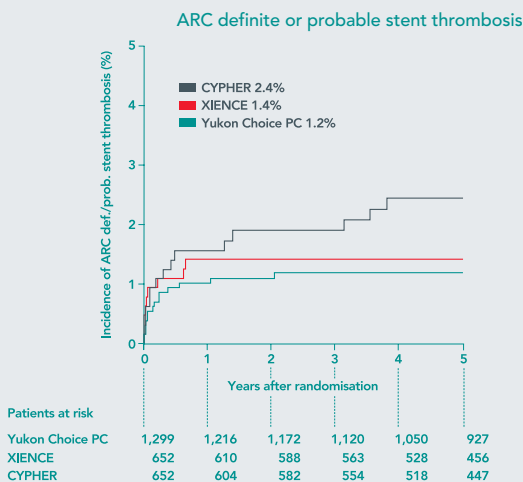
One of the largest meta-analysis involving more than 4000 patients, which compared biodegradable polymer based DES with permanent polymer based DES demonstrated the long term excellent safety profile of the Yukon Choice PC up to 4 years.



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.<sup>[8]</sup>

## 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.

Translumina DES Technology 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<sup>®</sup> Chrome PC

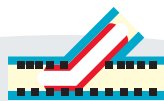
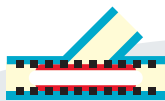
## Sirolimus Eluting CoCr Coronary Stent System

### The new high tech Cobalt Chromium Stent System

A CoCr Stent - designed for all lesions

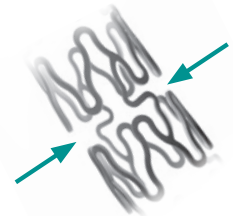
#### Bifurcation stenting

With a cell circumference of up to 18,5 mm the Yukon Chrome PC allows perfect side branch access which is essential for bifurcation stenting.



#### 2-Connector-Design

The new design with only 2 connector struts guarantees maximum flexibility and side branch access.



#### The suitable catheter

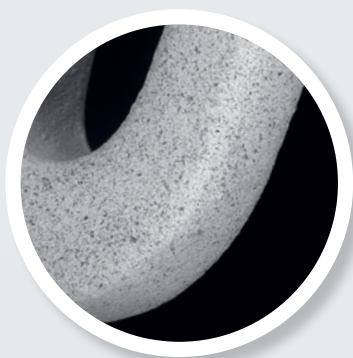
The luer is designed with an integrated kinking protection.



The flexible tip ensures perfect crossability and trackability.



#### Scanning Electron Microscope picture of the unique microporous surface



##### Surface features

- approx. 1 million pores per cm<sup>2</sup>
- average micro pore depth of approx. 2 µm
- 100% pore coverage of the surface

#### 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 only 68 µm for the Small Vessel Designs

#### Technical data & Stent features

Crossing profile (Ø 2,5 mm)	0,035" / 0,89 mm
Strut thickness (Ø 2,5 mm)	0,0027" / 68 µm (SV) 0,0031" / 79 µm (MV)
Metallic surface area	9,1 - 14,9%
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<sup>®</sup> Chrome 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	T-CMG2008PC	T-CMG2012PC	T-CMG2016PC	T-CMG2018PC	T-CMG2021PC	T-CMG2024PC	T-CMG2028PC	T-CMG2032PC
Ø 2,50	T-CMG2508PC	T-CMG2512PC	T-CMG2516PC	T-CMG2518PC	T-CMG2521PC	T-CMG2524PC	T-CMG2528PC	T-CMG2532PC

Medium vessel design (MV)

Balloon	Stent length [mm] & Article number								
Ø [mm]	8	12	16	18	21	24	28	32	40
Ø 2,75	T-CMG27508PC	T-CMG27512PC	T-CMG27516PC	T-CMG27518PC	T-CMG27521PC	T-CMG27524PC	T-CMG27528PC	T-CMG27532PC	T-CMG27540PC
Ø 3,00	T-CMG3008PC	T-CMG3012PC	T-CMG3016PC	T-CMG3018PC	T-CMG3021PC	T-CMG3024PC	T-CMG3028PC	T-CMG3032PC	T-CMG3040PC
Ø 3,50	T-CMG3508PC	T-CMG3512PC	T-CMG3516PC	T-CMG3518PC	T-CMG3521PC	T-CMG3524PC	T-CMG3528PC	T-CMG3532PC	T-CMG3540PC
Ø 4,00	T-CMG4008PC	T-CMG4012PC	T-CMG4016PC	T-CMG4018PC	T-CMG4021PC	T-CMG4024PC	T-CMG4028PC	T-CMG4032PC	T-CMG4040PC

## Compliance chart

Balloon	Inflation pressure [bar or 10 <sup>5</sup> Pascal]															
						NP						RBP				
Ø [mm]	6	7	8	9	10	11	12	13	14	15	16	17	18	19*	20*	
Ø 2,00	1,83	1,87	1,90	1,93	1,96	2,00	2,03	2,06	2,10	2,13	2,16	2,20	2,23	2,26	2,29	
Ø 2,50	2,33	2,36	2,40	2,43	2,47	2,50	2,53	2,57	2,60	2,64	2,67	2,70	2,74	2,77	2,81	
Ø 2,75	2,58	2,61	2,65	2,68	2,71	2,75	2,78	2,81	2,85	2,88	2,91	2,94	2,98	3,01	3,04	
Ø 3,00	2,81	2,85	2,89	2,92	2,96	3,00	3,04	3,07	3,11	3,15	3,18	3,22	3,26	3,29	3,33	
Ø 3,50	3,29	3,34	3,38	3,42	3,46	3,50	3,55	3,59	3,63	3,67	3,71	3,76	3,80	3,84	3,88	
Ø 4,00	3,75	3,80	3,85	3,90	3,95	4,00	4,06	4,11	4,16	4,21	4,26	4,31	4,36	4,41	4,46	

\* 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.

Translumina GmbH | Neue Rottenburger Strasse 50  
72379 Hechingen | Germany | info@translumina.de  
t + 49 7471 98 94 - 0 | f + 49 7471 98 94 - 360

www.translumina.de

**Yukon<sup>®</sup> Chrome PC**  
now available in more  
than 40 countries.

