Sirolimus Eluting Coronary Stent System

Yukon® Choice PC

translumina

LIMITLESS POSSIBILITIES

Yukon® Choice PC

DES with excellent long-term clinical outcome

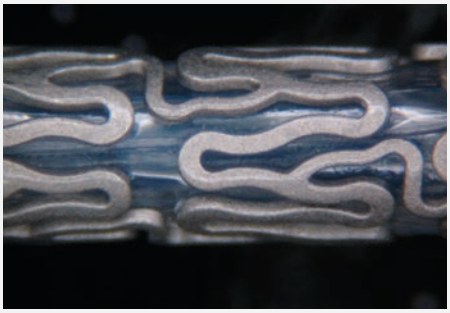
The Translumina Yukon Choice PC drug-eluting stent, coated with Rapamycin (Sirolimus) and the biodegradable component polylactide (PLA), has an excellent history of pre-clinical and long-term clinical results.[1-10]

In two independent trials ISAR-TEST 3 and ISAR-TEST 4 the Yukon Choice PC showed improved long-term performance compared to 1st. Generation DES over a time period of 10 years clinical follow-up in the randomized controlled clinical trial.[3,4]

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 bio-degradable 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]



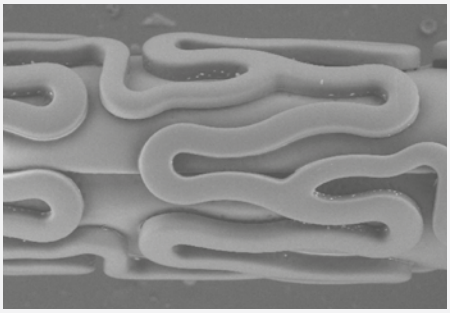


Figure 1: Optical and Electron Microscope Pictures of the Yukon Choice PC. The unique microporous stent surface is coated abluminal with Sirolimus and PLA. The PLA ensures a better binding of the Sirolimus to the microporous stent surface and controls the release of the drug. The PLA is fully degradable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

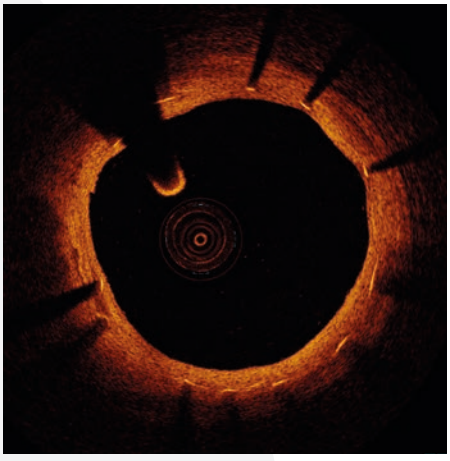
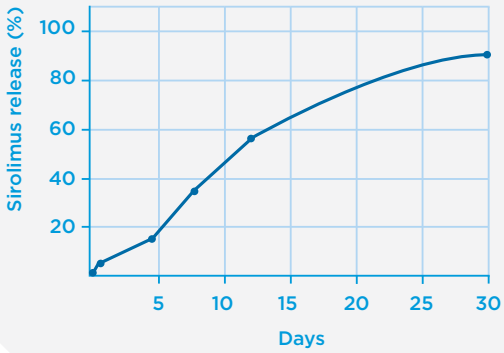
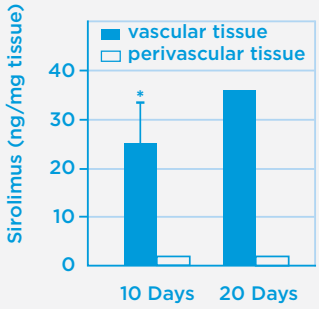


Figure 2: OCT follow-up 3 years after implantation of a Yukon Choice PC.

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

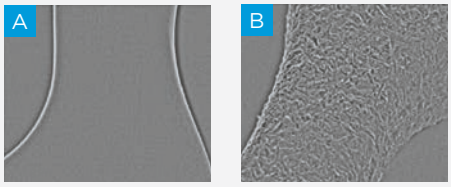
Extensive pre-clinical evaluations prove the safety of Yukon Choice PC over BMS and conventional DES:





Yukon Choice PC shows a release of sirolimus up to 4 weeks with a significant tissue concentration in the arterial segments. [1]

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. [2]

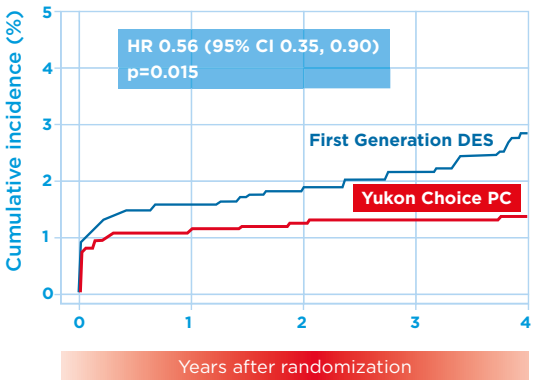
Meta-Analysis Data and ESC Recommendation [5-8]

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.

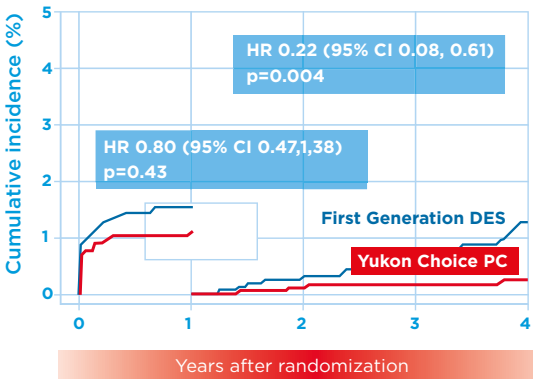
At 4 years follow-up, the Yukon Choice PC shows a reduction of risk by 50% in definite Stent Thrombosis and by 78% in Very Late Stent Thrombosis (VLST) compared to First Generation DES without compromising on efficacy.

Additionally, the Yukon Choice PC achieved highest recommendations in the latest ESC Guidelines for myocardial revascularization (2018) due to the excellent clinical outcome.[8]

Definite stent thrombosis



Definite stent thrombosis



Excellent 5 and 10 year long-term clinical data [9, 10]

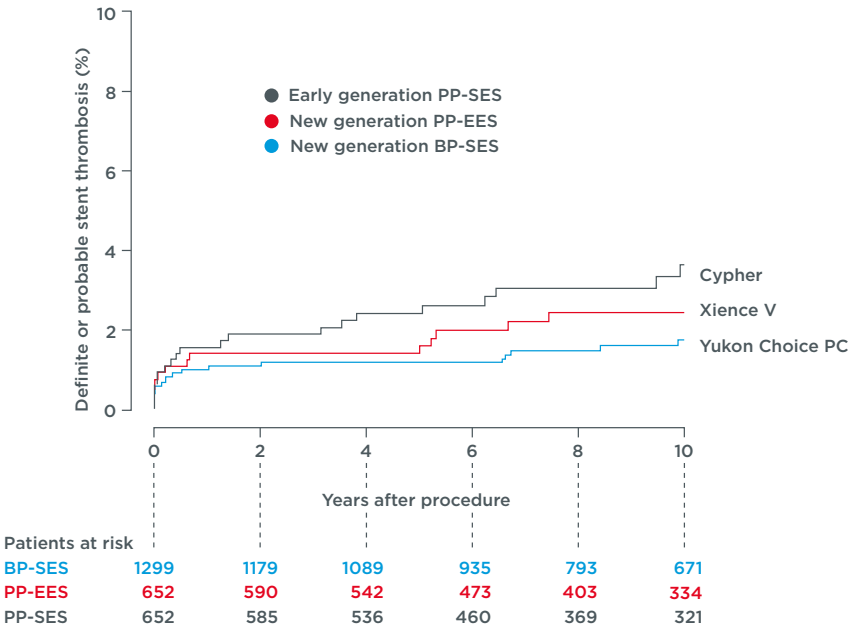
Made in Germany

The final 10 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 1,8% for the Yukon compared to 2,5% and 3,7% for the 2 permanent polymer coated competitor DES.

10 YEAR SAFETY

10 year clinical follow-up with lowest stent thrombosis rates

ARC definite or probable stent thrombosis



Patients at risk						
BP-SES	1299	1179	1089	935	793	671
PP-EES	652	590	542	473	403	334
PP-SES	652	585	536	460	369	321

Circulation. 2018

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

Relevant literature of the Yukon DES product family

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 / Xience V): R.Byrne et al, European Heart Journal, 2009 ; 30, 2441-2449.
4. ISAR-TEST 4 trial, 3 year data (comparison with Cypher / Xience V): R.Byrne et al, JACC, 2011 ; 58, 1325-1331.
5. Meta-Analysis ISAR-TEST 3 + 4, LEADERS, 4 years follow-up (Comparison of Yukon Choice PC + Biomatrix versus Cypher): G.Stefanini, European Heart Journal, 2012; 33, 1214-1222.
6. Subgroup-Analysis of the Meta-Analysis with regard to Diabetics: A. de Waha et al, International Journal of Cardiology 2013, 168, 5162-6.
7. Subgroup-Analysis of the Meta-Analysis with regard to STEMI patients: A. de Waha et al, Euro-Intervention 2014, published online.
8. F.-J. Neumann et al., 2018 ESC/EACTS Guidelines on Myocardial Revascularization, European Heart Journal (2018) 00, 1–96 and supplement.
9. S.Kufner et al, 5-year long-term follow-up of the ISAR-TEST 4 trial (Yukon Choice PC versus Cypher / Xience V), Euro-Intervention 2016; 11:1372-1379.
10. S.Kufner et al, 10-year long-term follow-up of the ISAR-TEST 4 trial (Yukon Choice PC versus Cypher / Xience V), Circulation, 2018; 139, 325–333.

Yukon® Choice PC

Sirolimus Eluting Coronary Stent System

The new stent delivery system

The 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 distal shaft

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

The 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.

SEM of the microporous stent 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 of 87µm in the range of CoCr platforms

Technical specifications of the stent

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

Crossing profile (Ø 2,5 mm)	0,94 mm (Ø 2,5 mm)
Strut thickness	90 µm (SV), 95 µm (MV)
Metallic surface area	13 - 20%
No foreshortening	
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

Sirolimus Eluting Coronary Stent System

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
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
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
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
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
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
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

CE 1434

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

Made in Germany

translumina

Art.Nr. MK0059/REV005