Sirolimus Eluting Coronary Stent System

Yukon® Choice PC

5-Years Randomized Clinical Follow-Up

Translumina – trust is what counts
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 infarct. [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:

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.

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Literature

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.
7. Subgroup-Analysis STEMI: A. de Waha et al, Eurointervention 2014, published online.
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.

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
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.

The new distal shaft

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

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.

Yukon Choice PC

Sirolimus Eluting Coronary Stent System

The new stent delivery system

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

<table>
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<tr>
<th>Balloon Ø [mm]</th>
<th>Stent length [mm] &amp; Article number</th>
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### Compliance chart

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<tr>
<th>Balloon Ø [mm]</th>
<th>Inflation pressure [bar or 10^5 Pascal]</th>
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* 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.

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