Product/Family: Yukon® Chrome PC Sirolimus Eluting Coronary Stent System	If applicable, subsystem / component: N/A	Manufacturer Translumina GmbH		
Development project: Drug eluting CoCr-Stent	Project number: E060	Delimitation, if applicable: N/A		
Version number: 002	Document purpose / Classification: TD according to MDR	Released on 2024-06-20	Released by (area and name) Dr. Michael Stöver	Signature

1 Device Description and Specification (including Variants and Accessories)

1.1 Device Description and Specification

1.1.I) Technical specification

This chapter lists all the technical specifications of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product. The technical specifications include the details of the dimensions, performance attributes, coating, specifications that relate to accessories and further characteristics of the sterile product.

Dimensions/ Design of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product

This subsection lists the dimensions and design of the stent delivery system and stent of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product.

The table below lists the specifications of the stent delivery system (SDS). The SDS has the same design for all sizes / variants of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System and differs only in the balloon length / balloon diameter. This difference also affects some other specified dimensions, therefore the range from smallest size to largest size is given for some attributes in the table below.

In addition, the table indicates whether the specifications are made available to the user (e.g. in brochures).

Attribute	Specification	Available to user [YES / NO]
Catheter usable length	1360 mm to 1480 mm	YES
Marker for guiding catheter a) from tip to distal marker b) from tip to proximal marker	 909 mm ...947 mm 1009 mm ... 1047 mm	NO
Length of guide wire lumen	257 mm ... 295 mm	NO
X-ray marker distance	8,5 mm ... 43 mm (for individual sizes s. product drawings)	NO
Crossing profile	0.94 ... 0.96 mm (Ø 2.0 mm ... 2.5 mm; SV) 0.97 ... 1.20 mm (Ø 2.75 mm ... 4.0 mm; MV) Tolerance: + 5%	YES
Balloon working length	9 mm ... 42 mm	NO
Proximal shaft diameter (Hypotube, PTFE coated)	0.65 mm (1.9F)	YES
Distal shaft diameter	0.87 mm to 0,91 mm (2.7F)	YES
Tip length	3.5 mm ... 4.5 mm	NO
Tip entry profile	≤ 0,49 mm	NO
Tip design	soft tip	YES
Balloon folding	trifold (memory)	NO
Hub	female luer lock catheter connector	NO

Two stent designs of cobalt-chromium alloy L605 are used for the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System:

- small vessel (SV) stent for diameter Ø 2.0 mm to Ø 2.5 mm
- medium vessel (MV) stent for diameter Ø 2.75 mm to Ø 4.0 mm

Within Small Vessel product range (2.0 mm to 2.5 mm) and within Medium Vessel product range (2.75 mm to 4.0 mm) there is no difference of stent design.

The table below lists the specifications of the two stent designs. The stent designs (SV & MV) are characterized by a homogeneous pattern of rings and links. Therefore, the only difference between shorter and longer stents is the number of identical rings. This difference in the number of identical rings also affects some other specified dimensions, therefore the range from smallest size to largest size is given for some attributes in the table below.

In addition, the table indicates whether the specifications are made available to the user (e.g. in brochures).

Attribute	Specification	Available to user [YES / NO]
Strut thickness	68 µm (SV) 79 µm (MV)	YES
Strut width (straight section)	78 µm (SV) 88 µm (MV)	NO
Strut width (bow)	88 µm (SV) 108 µm (MV)	NO
Strut width (connector)	75 µm (SV) 76 µm (MV)	NO
Relative Stent surface (crimped)	32% (Ø 2.0 mm) ... 33% (Ø 4.0 mm)	NO
Relative Stent surface (expanded)	11.9 ... 14.9% (SV) 9.1 ... 13.3% (MV)	YES
Stent weight	4.9 mg ... 19.0 mg (SV) 6.9 mg ... 32.9 mg (MV)	NO
Smallest approx. mesh diameter (for side branch access)	Ø 0.96 mm (SV) Ø 1.11 mm (MV)	NO
Cell circumference	13.3 mm (SV) 18.4 mm (MV)	NO
Roughness	Homogenous microroughness by microporous surface (R_{Zmax} = 10 µm)	NO

Performance attributes of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product

The table below lists the mechanical performance attributes of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product. The specifications cover all test criteria applicable to the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System by DIN EN ISO 25539-2.

In addition, the table indicates whether the specifications are made available to the user (e.g. in brochures).

Attribute	Specification	Available to user [YES / NO]
Balloon deflation time	≤ 30 sec.	YES
Balloon nominal pressure	11 bar	YES
Balloon rated burst pressure	16 bar	YES
Balloon fatigue / Multiple Inflation	10 cycles at RBP without leak	NO
Dogboning	≤ 5%	NO
Stent dislodgement force	≥ 1N	NO
Tensile bond strength	Acc. To 10555-4	NO
Torsional bond strength	Pass deflation spec. at 5 rotations	NO
Visibility X-ray	Pass acc. to 25539-2	NO
Magnetic resonance imaging safety (MRI)	Pass acc. to 25539-2	YES
Fatigue and durability of stent	Pass acc. to 25539-2	NO
Crush resistance of stent (radial applied load)	≥ 3 N	NO
Kink resistance (flexibility) of stent	Pass with Radius 5 mm (SV) / 10 mm (MV) acc. to 25539-2	NO
Stent diameter to balloon inflation pressure (Compliance)	According to Compliance Chart (with tolerance +10% / -10%)	YES
Stent length (Foreshortening)	≤ 5%	NO
Recoil	≤ 7%	NO

Specification of Coating of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product

The coating solution is a mixture of:

- Poly(D,L-lactide) (Resomer R 202 S)
- Rapamycin (Sirolimus)
- Ethylacetate

with a ratio of 1:1, which is equivalent to a solution concentration of 4 mg Rapamycin and 4 mg Polylactide per 1 ml Ethylacetate.

As described in a separate process description coating is not applied to stent only, but to the stent, which already is crimped onto the balloon. The nominal Sirolimus content as specified in the product description of Yukon® Chrome PC therefore represents the overall amount of Rapamycin applied to stent and balloon.

The average ratio of the amount of Rapamycin on the stent is 48 % (T-CMG3016PC (Yukon® Chrome PC Sirolimus Eluting Coronary Stent System, $Ø_{nom}$: 3.0 mm, L_{nom}: 16 mm)) of the total amount of Rapamycin applied to stent and balloon. According to the specification the nominal Sirolimus content is 200 µg (T-CMG3016PC).

The stent is coated only on the abluminal surface.
The nominal amount of Rapamycin on stent surface is:

- 1.9 µg / mm² (stent surface)
- 6.2 µg / mm (stent length)

Specifications related to accessories

The table below lists the specifications related to accessories of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product.

In addition, the table indicates whether the specifications are made available to the user (e.g. in brochures).

Description	Specification	Available to user [YES / NO]
Recommended guide wire	0.36 mm (0.014")	YES
Recommended guiding catheter	5 F	YES
Luer connection	Acc. To standard ISO 80369-1 to -3	NO

Further characteristics of the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product

The table below lists further characteristics specified for the Yukon® Chrome PC Sirolimus Eluting Coronary Stent System product.

In addition, the table indicates whether the specifications are made available to the user (e.g. in brochures).

Description	Specification	Available to user [YES / NO]
Number of applications	Single-use	YES
Particle burden	Specification on finished product incl. coating particles: >10 µm : max. 12000 >25 µm : max. 1200 >50 µm : max. 120 Specification for product without the coating: >10 µm : max. 6000 >25 µm : max. 600 >50 µm : max. 60 removable particles visible with the bare eye are not allowed	NO
Sterility	Sterile product	YES
Sterilization type	EO (ethylene oxide gas sterilization)	YES
Product shelf-life	24 months	YES
Storage conditions	8 – 25 °C (short term 40°C)	YES
Application time (stent)	> 30 days (permanent implant)	NO
Application time (catheter)	< 24 h	NO

Revision History

Rev.No.	Date	Created by	Description
001	2023-10-12	PHA	New document for TD according to MDR
002	2024-06-20	MST	Adaption for inclusion of Natec variants