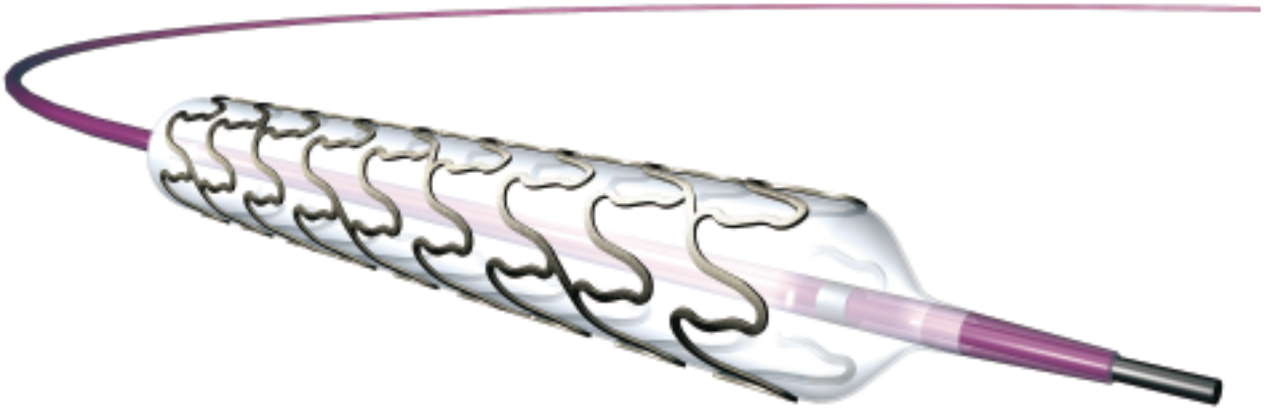
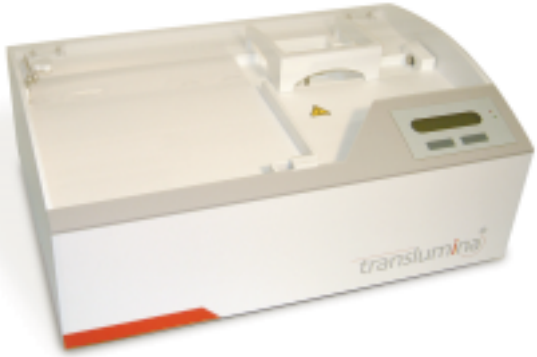
YUKON® DES

PEARL surface ®

Drug Eluting Stent System

Coronary Stent System for individual drug coating application





Stent coating machine

- ✓ Free choice of drug
- ✓ Individual dosage
- ✓ No polymer coating
- ✓ Sterile coating procedure

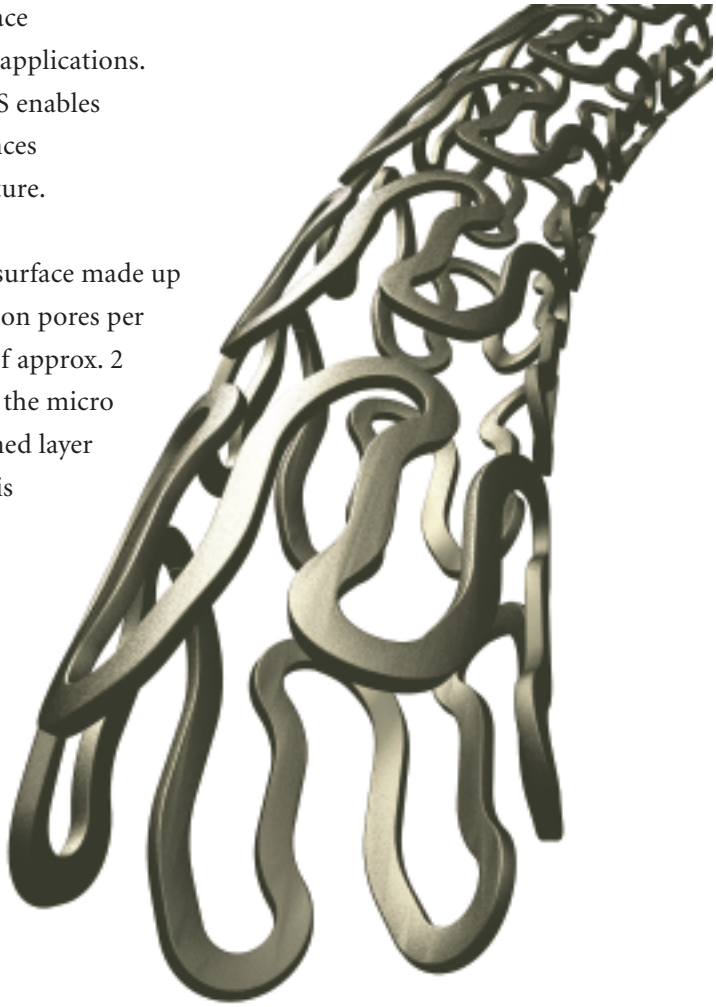
translumina®

New Surface Technology

PEARL SURFACE ®

Translumina has developed a new surface treatment technology for drug coating applications. The PEARL surface of the YUKON DES enables adsorption of different organic substances due to its mechanically modified structure.

The stent has a microscopically rough surface made up of micro pores with a density of 1 million pores per cm^2 and an average micro pore depth of approx. 2 micrometers. The coating solution fills the micro pores completely and creates a uniformed layer after evaporation of the solvent that it is dissolved in. (see fig. 1)



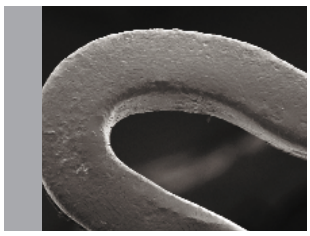


fig. 1

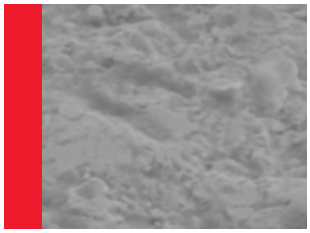
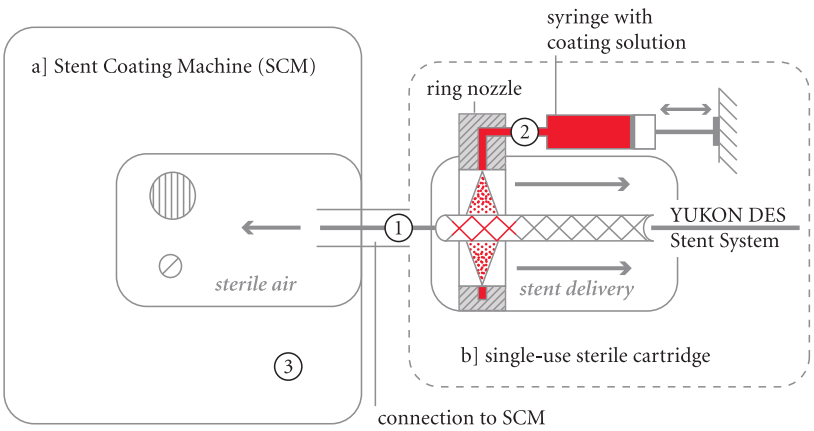


fig. 2

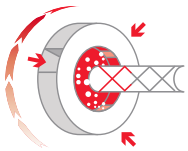
This Scanning Electron Microscope picture (fig. 2) illustrates the micro pores of the YUKON DES stent filled with Rapamycin, even after insertion in a circulatory system under comparable conditions experienced during an interventional procedure. At very high resolution the soft tissue-like structure of the amorphous Rapamycin film can be seen.

CONCEPT

The Translumina Stent Coating Machine (SCM) is an innovative system especially developed to allow application of a free choice of drugs at individual dosages on the YUKON DES. The SCM enables the drug coating process to take place directly in the Cath Lab allowing the interventionalist freedom to adjust treatment dependant on the patients requirements.



1 Stent system with coating cartridge
2 Syringe for individual choice of drug and dosage by physician
3 Stent Coating Machine initiates the drug coating process in the cartridge



ring nozzle with spray-units
for perfect coating results

fig.3 The translumina in-cathlab drug-coating concept

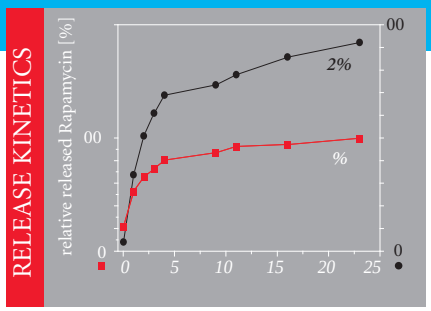
FEATURES

- Convenient computer controlled table top device for direct use in the Cath Lab
- LCD display for process control and monitoring
- Easy drug application using a syringe
- Exact and uniform application of the required drug over the entire stent length
- Finest drug spraying due to tubular nozzle air-jet
- Short coating process

a]

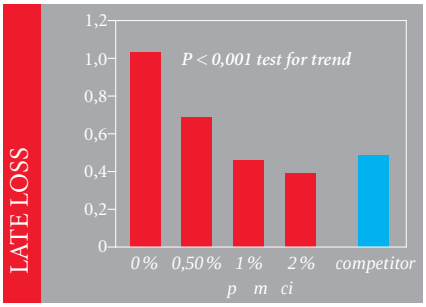
b]

PERFORMANCE



Release kinetics show that the 1% Rapamycin coated YUKON DES releases 80% of the drug within the first 10 days. After approximately 30 days the drug has eluted completely and leaves a bare metal stent with micro porous surface and no polymer. With a 2% Rapamycin coating a longer release can be achieved.

fig.4 1% and 2% Rapamycin coated Translumina YUKON DES
Release in Ringer solution, 37°C, artificial circulation



The late loss data illustrates a dosage dependant reduction of late lumen loss. The YUKON DES coated with 1% or 2 % Rapamycin solution shows even better late loss results than other available drug eluting stents.

fig.5 Late loss data [1]

[1] Data on file at translumina GmbH,
"ISAR-Project 1" Dose-Finding-Study,
Deutsches Herzzentrum, Munich

CASE STUDY

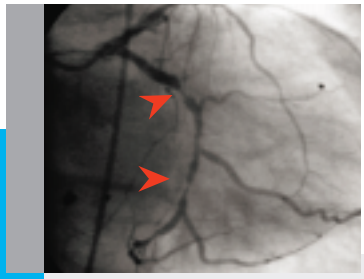
Male patient, age 79 years

Presented with stable AP CCS III
CVR: hypertension, hypercholesterolemia

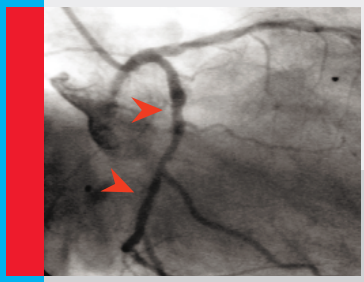
Stents used

— **YUKON DES,** diameter: 3.0, length 16 mm, coated with 2% Rapamycin
— **YUKON DES ,** diameter: 2.5, length 16 mm, coated with 2% Rapamycin

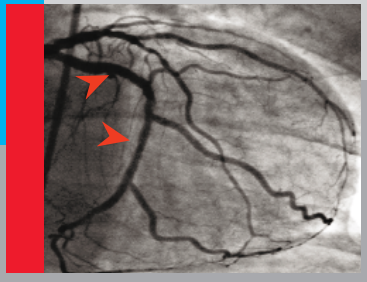
Lesion prior PCI



Result immediately after PCI



Result at 12-month follow-up

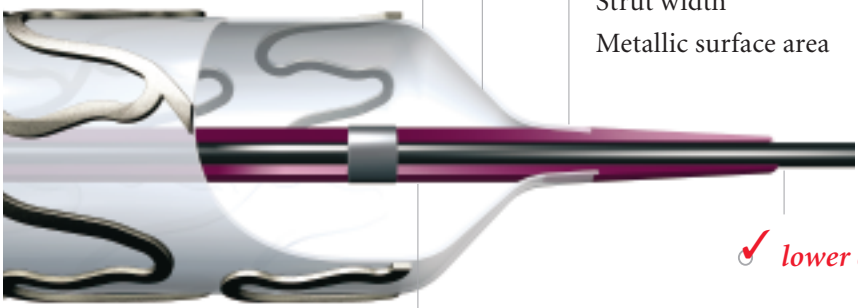


TECHNICAL INFORMATION

✓ *laser welded balloon fixation*

✓ *short balloon arm*

✓ *minimal balloon overhang*



✓ *lower crossing profile*

✓ *radiopaque marker*

Medical Stainless Steel, 316 LVM, mechanically treated surface containing micro pores

Strut thickness	0.115 mm
Strut width	0.14 mm
Metallic surface area	16 – 18%

Balloon marker material	Platinum / Iridium
Proximal shaft diameter	2,0 F
Distal shaft diameter	2,7 F
Entry Profile	0,44 mm
Crossing profile	0,98 – 1,00 mm [ø 3,5 mm]
Guiding catheter	5 F
Recommended guide wire	0,014”

COMPLIANCE CHART

Inflation pressure [bar]		2	3	4	5	NP 6	7	8	9	10	11	12	13	14	15	RBP 16	17	18	ABP 20
2,50	Balloon ø [mm]	2,36	2,39	2,43	2,46	2,50	2,53	2,57	2,61	2,64	2,68	2,71	2,75	2,78	2,82	2,85	2,89	2,93	3,00
3,00		2,85	2,89	2,92	2,96	3,00	3,04	3,08	3,12	3,16	3,20	3,24	3,28	3,32	3,36	3,40	3,44	3,48	3,56
3,50		3,30	3,35	3,40	3,45	3,50	3,55	3,60	3,66	3,71	3,76	3,81	3,86	3,91	3,96	4,02	4,07	4,12	4,22

NP = Nominal Pressure 6 [bar] / RBP = Rated Burst Pressure 16 [bar] / ABP = Average Burst Pressure 20 [bar]

YUKON® DES
PEARL surface®

Drug Eluting System

ORDERING INFORMATION

NP = Nominal Pressure 6 [bar] /
RBP = Rated Burst Pressure 16 [bar]

ARTICLE NO.	Stent ø [mm]	Stent length [mm]	NP [bar]	RBP [bar]
T-CMC2508C	2,5	8	6	16
T-CMC2512C	2,5	12	6	16
T-CMC2516C	2,5	16	6	16
T-CMC2518C	2,5	18	6	16
T-CMC2520C	2,5	20	6	16
T-CMC2523C	2,5	23	6	16
T-CMC2525C	2,5	25	6	16
T-CMC3008C	3,0	8	6	16
T-CMC3012C	3,0	12	6	16
T-CMC3016C	3,0	16	6	16
T-CMC3018C	3,0	18	6	16
T-CMC3020C	3,0	20	6	16
T-CMC3023C	3,0	23	6	16
T-CMC3025C	3,0	25	6	16
T-CMC3508C	3,5	8	6	16
T-CMC3512C	3,5	12	6	16
T-CMC3516C	3,5	16	6	16
T-CMC3518C	3,5	18	6	16
T-CMC3520C	3,5	20	6	16
T-CMC3523C	3,5	23	6	16
T-CMC3525C	3,5	25	6	16

----------pre-mounted coronary stent system with cartridge for drug coating application----------

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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