

TECHNOLOGY BACKGROUND

Dextran Gel Paclitaxel Coating

Balloon platform: Catheter produced in house

Sizes: length from 1 cm to 25 cm, diameter from 1,5 to 14 mm

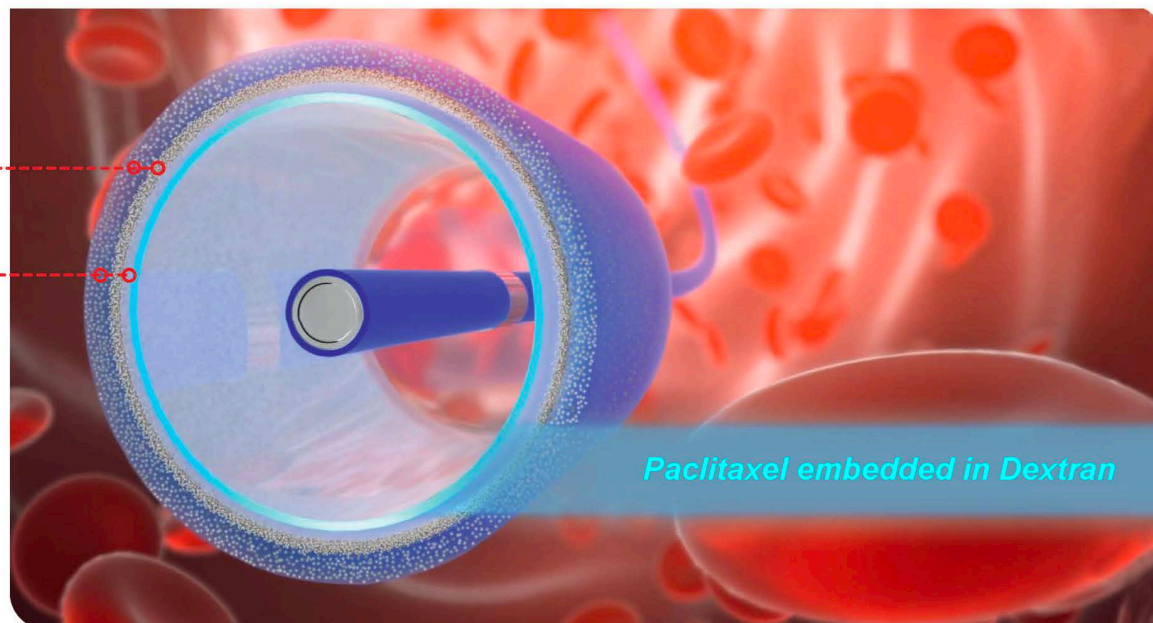
High flexible balloon catheter with low profile due to our Vortex Technology.

Multi Purpose Drug Matrix

- Homogenous coating
- Even and Consistent coating of inflated Balloons
- Drug Matrix (3 Dimensional Dextran – Paclitaxel Formation)
- Balloon with 360 Degree coating coverage
- Minimal Drug lost during passage in the body
- Minimal Drug lost from the balloon surface during maneuver or inflation
- Reliable quantitative Drug deposition into the vessel wall
- Target deposition Modus TDM - Drug is only released at higher pressure and contact the vessel wall
- Long Lasting EFFECT -Drug concentration in the vessel wall (intima, media, adventitia) for several weeks
- No Drug “Chunk” spreading - during inflation

Paclitaxel
Microcrystals

Dextran Gel



Paclitaxel embedded in Dextran

DRUG MATRIX PACLITAXEL+DEXTRAN



Multifunctional Coating
Dedicated: Dextran-Paclitaxel Formation

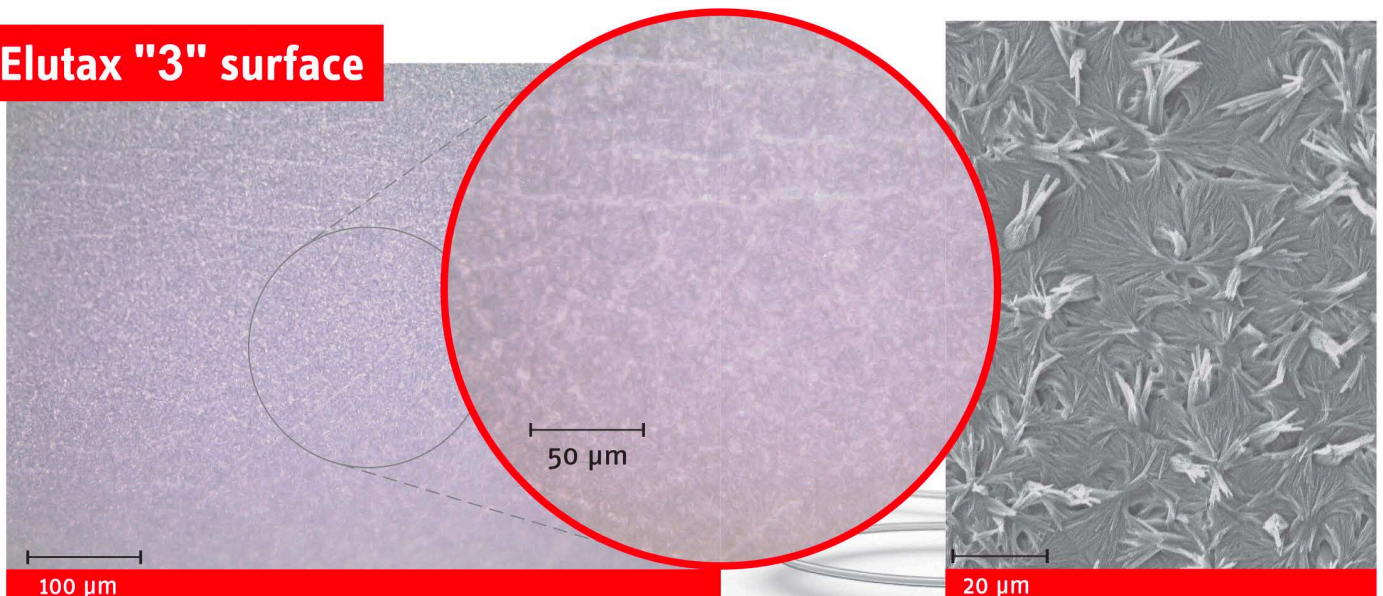
- 1. Seals the drug at the vessel
- 2. Therapeutic action time is longer
- + Better mechanical stability
- + Anti thrombogenic
- + Lesion protection
- + Reservoir Matrix
- + Local stability
- + Lowest wash off after deposition

“CONTROLLED HEALING OVER MONTHS”

Paclitaxel Tissue levels of different Drug eluting Balloons over 30 days

Coronary PORCINE	Elutax "3"	Competitor A	Competitor B
uniform coating	yes	no	no
360 degree	yes	no	no
Drug Dose 1 hour	~ 250 $\mu\text{mol/ml}$	~ 200 $\mu\text{mol/ml}$	~ 200 $\mu\text{mol/ml}$
Drug Dose 7 days	~ 70 $\mu\text{mol/ml}$	~ 0 $\mu\text{mol/ml}$	~ 10 $\mu\text{mol/ml}$
Drug Dose 30 days	~5-10 $\mu\text{mol/ml}$	~0 $\mu\text{mol/ml}$	~0.1 $\mu\text{mol/ml}$
Drug lost during maneuver	max 5%	high	up to 30% every 10 sec.

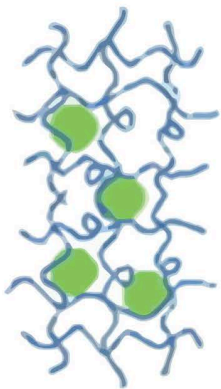
Elutax "3" surface



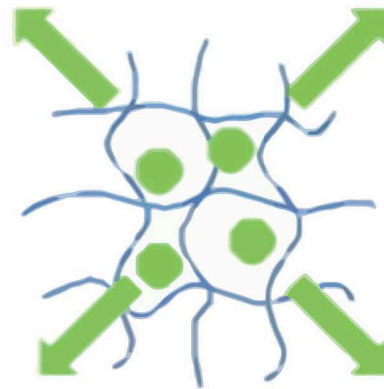
SUSTAINED VALUE

PRINCIPLE OF DRUG MAINTENANCE IN THE VESSEL WALL

Mechanism of Dextran-Hydrogel



Paclitaxel trapped in DEXTRAN structure. In this configuration the Drug is coated onto the balloon surface and pressed against the inner lumen of the vessel after inflation.



Paclitaxel Long-term diffusion out of DEXTRAN from the inner lumen into the vessel wall.

Important notice:

The Paclitaxel is bounded to the Dextran by non-covalent interactions. The Dextran, which is not interacting with the Paclitaxel has no influence on the drug uptake.

The additional focalized Dextran coating at the distal end of the catheter serves just as localized hydrophilic coating for a better push- and track-ability.

The special coating structure enables effective drug tissue levels up-to 60 days after intervention.