

ELUTAX® Paclitaxel Eluting Coronary and Peripheral Balloon Catheter

pfm

ELUTAX[®] Drug-Eluting Balloon:

The revolutionary technology for treatment of coronary and peripheral stenosis.

- New therapy, but familiar PTA/PTCA-like handling
- One short Paclitaxel application, for long-term patency
- Treatment as PTA alone or in combination with a bare metal stent (BMS)

Short-term drug release – long-term patency:

The Drug-Eluting Balloon (DEB) is a further development of the common PTCA/PTA catheter. To prevent restenosis, the surface of the balloon is covered with Paclitaxel. The short-term contact with the vessel wall is sufficient, to provide effective drug transfer into the cells for long-term effects (1).

- ▶ excellent results
- ▶ no need for stent-in-stent re-interventions
- ▶ any following treatment option is still open
- ▶ homogenous drug distribution (not only areas covered by Drug-Eluting Stent struts) (2)

Paclitaxel function:

In smooth muscle (SMC) and endothelial cells (EC), effective Paclitaxel concentrations inhibit various cell functions, which normally lead to re-stenosis. The drug restrains the function of microtubuli and inhibits platelet derived growth factor (PDGF) and therefore prevents cell proliferation and migration.

- ▶ Inhibition of hyperplasia and stenosis.
- ▶ the drug action persists for at least 14 days after injury when neointimal reaction is acute (1)
- ▶ afterwards, the absence of the drug benefits re-endothelialisation
- ▶ reduced duration of antiplatelet therapy compared with Drug-Eluting Stents

Exceptional outcome in the following situations:

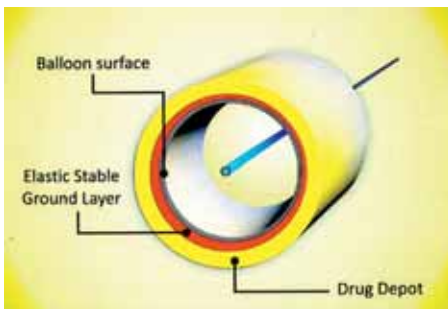
Indication	Target arteries					
	Coronary	Femoral	Renal	BTK	Intracranial	Main
De-Novo Lesions	X	X	X	X	X	
In-stent restenose	X	X	X	X	X	
Bifurcation	X	X	X	X	X	
Chronic Total Occlusion	X	X	X	X	X	
Small Vessel	X		X	X	X	
Diabetes	X	X	X	X	X	
Dialytic Fistula						X

The DEBIUT Registry (3)

„The use of paclitaxel-coated balloon catheters . . . [ELUTAX] . . . is effective and safe in PCI for coronary artery bifurcation lesions, without clinical signs of restenosis at 4 months follow up. Although all patients stopped Clopidogrel at 3 months after the index procedure so far no late thrombosis was reported.“

IASIS CE-Trial (Bulgaria)

43 patients with In-Stent Restenosis, treated with ELUTAX
Angiographic follow-up after 6 months: 0% Restenosis (4)



The Unique ICE and SNOW Layer Technologie:

A special **ICE**-like Paclitaxel serves as elastic and stable ground layer.

On top, a special **SNOW**-like Paclitaxel layer serves as drug depot and enables homogenous and reliable drug release.

Benefits of the Coating Technology:

- Drug Matrix of pure Paclitaxel (two layers **SNOW** and **ICE**)
- No additional Matrix necessary (e.g. Polymer)
- Even and homogenous coating of **inflated** balloons
- Balloon with 360 Degree coating coverage
- Minimal Drug loss during maneuver or inflation < 3%
- Safe and Reliable quantitative Drug deposition into the vessel wall (70 % of total drug)
- No Cracks
- Homogenous drug distribution



The effective tissue concentration of paclitaxel is from 56 nM/l to 50 µM/l (therapeutic window).

Concentrations over 100 µM/l are toxic in cell culture (1)

With ELUTAX, the Paclitaxel tissue concentration is within the therapeutic window 1h - 12h after treatment.

References:

(1) Axel, D. I. et al. Circulation. 1997 Jul 15;96(2):636-45 – (2) Hwang et al., Circulation. 2001 Jul 31;104(5):600-5 – (3) Fanggiday et al., Catheter Cardiovasc Interv. 2008 Apr 1;71(5):629-35) – (4) IASIS Trial, performed by Dr. Ivan Manukov, Head of Department Interventional Cardiology, UMBAL Sveti Georgi Hospital, Plovdiv, Bulgaria

- ▶ Flexible tip design
- ▶ Low profile
- ▶ excellent flexibility and optimal pushability

Technical Specifications:

Balloon:

Material	Polyamid
Folding	3-folded balloon
Nominal Pressure	6 bar
Rated Burst Pressure (RBP)	14 bar
Compliance	Semicompliant
Markers	2 zero profile markers
Coating	Paclitaxel (2 µg/mm ²)

Delivery System:

Catheter Type	Rapid Exchange
Usable length	135 cm
Distal Shaft Ø	2,6 F
Proximal Shaft Ø	2,2 F
Crossing profile	0,035"
Entry profile	0,022"
Marker on the catheter	80 cm and 100 cm (Brachial and Femoral Marker)
Max. recommended guide wire	0,014"
Guiding catheter compatibility	5F (I.D. 0,056")

Balloon Ø	Ballon Length										
	10 mm	13 mm	16 mm	18 mm	21 mm	24 mm	27 mm	30 mm	33 mm	36 mm	39 mm
2,00 mm	ELUTAX 10200	ELUTAX 13200	ELUTAX 16200	ELUTAX 18200	ELUTAX 21200	ELUTAX 24200	ELUTAX 27200	ELUTAX 30200	ELUTAX 33200	ELUTAX 36200	ELUTAX 39200
2,25 mm	ELUTAX 10225	ELUTAX 13225	ELUTAX 16225	ELUTAX 18225	ELUTAX 21225	ELUTAX 24225	ELUTAX 27225	ELUTAX 30225	ELUTAX 33225	ELUTAX 36225	ELUTAX 39225
2,50 mm	ELUTAX 10250	ELUTAX 13250	ELUTAX 16250	ELUTAX 18250	ELUTAX 21250	ELUTAX 24250	ELUTAX 27250	ELUTAX 30250	ELUTAX 33250	ELUTAX 36250	ELUTAX 39250
2,75 mm	ELUTAX 10275	ELUTAX 13275	ELUTAX 16275	ELUTAX 18275	ELUTAX 21275	ELUTAX 24275	ELUTAX 27275	ELUTAX 30275	ELUTAX 33275	ELUTAX 36275	ELUTAX 39275
3,00 mm	ELUTAX 10300	ELUTAX 13300	ELUTAX 16300	ELUTAX 18300	ELUTAX 21300	ELUTAX 24300	ELUTAX 27300	ELUTAX 30300	ELUTAX 33300	ELUTAX 36300	ELUTAX 39300
3,25 mm	ELUTAX 10325	ELUTAX 13325	ELUTAX 16325	ELUTAX 18325	ELUTAX 21325	ELUTAX 24325	ELUTAX 27325	ELUTAX 30325	ELUTAX 33325	ELUTAX 36325	ELUTAX 39325
3,50 mm	ELUTAX 10350	ELUTAX 13350	ELUTAX 16350	ELUTAX 18350	ELUTAX 21350	ELUTAX 24350	ELUTAX 27350	ELUTAX 30350	ELUTAX 33350	ELUTAX 36350	ELUTAX 39350
4,00 mm	ELUTAX 10400	ELUTAX 13400	ELUTAX 16400	ELUTAX 18400	ELUTAX 21400	ELUTAX 24400	ELUTAX 27400	ELUTAX 30400	ELUTAX 33400	ELUTAX 36400	ELUTAX 39400
4,50 mm	ELUTAX 10450	ELUTAX 13450	ELUTAX 16450	ELUTAX 18450	ELUTAX 21450	ELUTAX 24450	ELUTAX 27450	ELUTAX 30450	ELUTAX 33450	ELUTAX 36450	ELUTAX 39450
5,00 mm	ELUTAX 10500	ELUTAX 13500	ELUTAX 16500	ELUTAX 18500	ELUTAX 21500	ELUTAX 24500	ELUTAX 27500	ELUTAX 30500	ELUTAX 33500	ELUTAX 36500	ELUTAX 39500
5,50 mm	ELUTAX 10550	ELUTAX 13550	ELUTAX 16550	ELUTAX 18550	ELUTAX 21550	ELUTAX 24550	ELUTAX 27550	ELUTAX 30550	ELUTAX 33550	ELUTAX 36550	ELUTAX 39550
6,00 mm	ELUTAX 10600	ELUTAX 13600	ELUTAX 16600	ELUTAX 18600	ELUTAX 21600	ELUTAX 24600	ELUTAX 27600	ELUTAX 30600	ELUTAX 33600	ELUTAX 36600	ELUTAX 39600

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