

Nile BiPax

Polymer Free Paclitaxel Coating

EBC 2008 - Prague



Nile Pax Platform

- CE marked since 2005
- 3 000 units
- Registries
- Publications

*Optimal Nile
Stent design*

**Optimal
Bifurcation
Eluting
Stent**

Paclitaxel

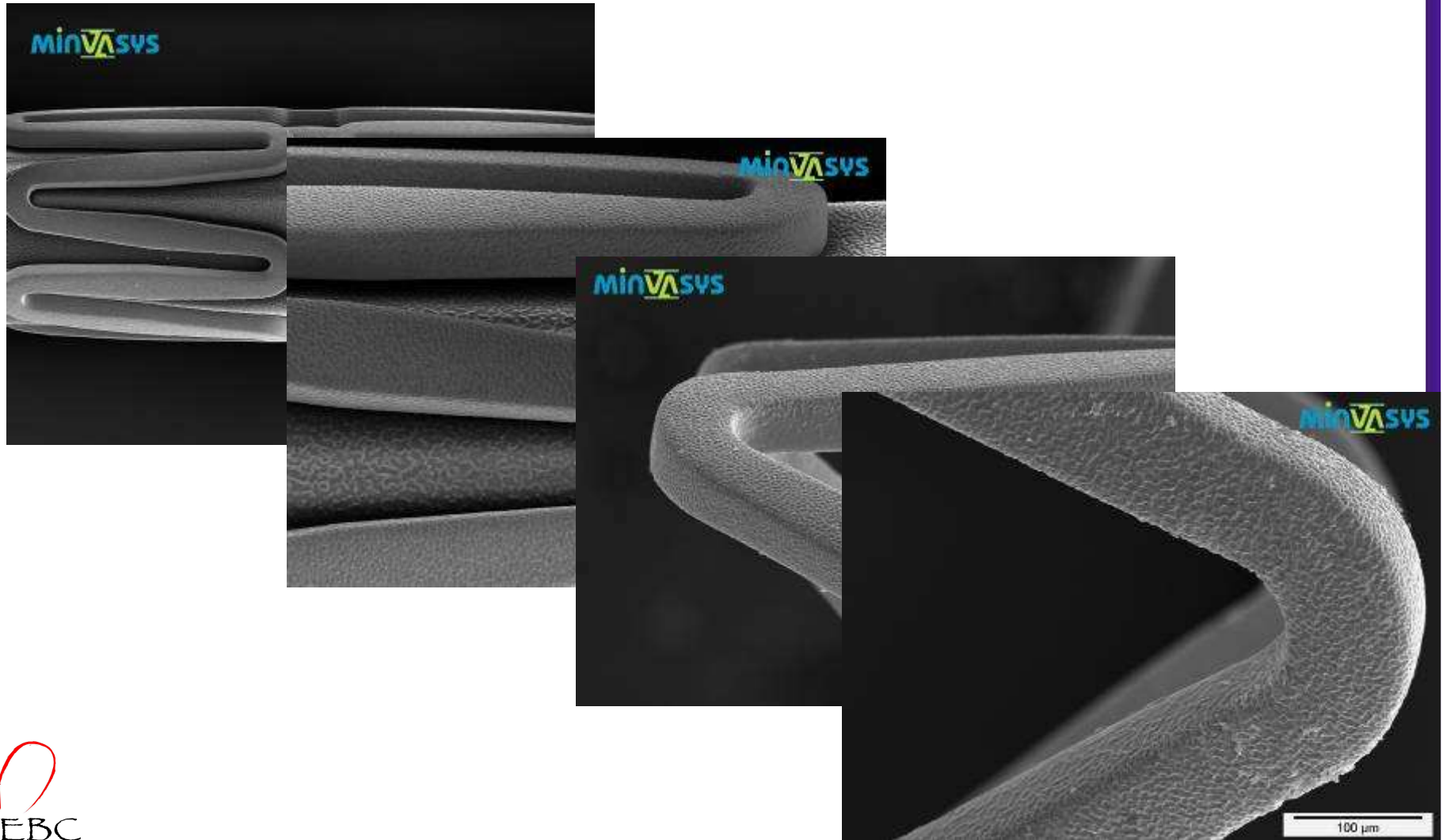
- CE marked cytotoxic agent
- Animal studies done



Paclitaxel rationale

- Proven efficacy by reducing neointimal hyperplasia.
- Anti-proliferative agent inhibiting Smooth Muscular Cells (SMC) by microtubules inhibition.
- Lipophilic properties ensuring fast drug delivery into arterial wall and long lasting action.

Loaded Paclitaxel on Stent



Abluminal coating

- No impact on crimping process, stent retention force and performances.
- Homogeneous coating of 5 μ regularly applied on stent surface, ensuring a predictable and repeatable elution time.
- No coating on intra-luminal stent surface for a better re-endothelization.

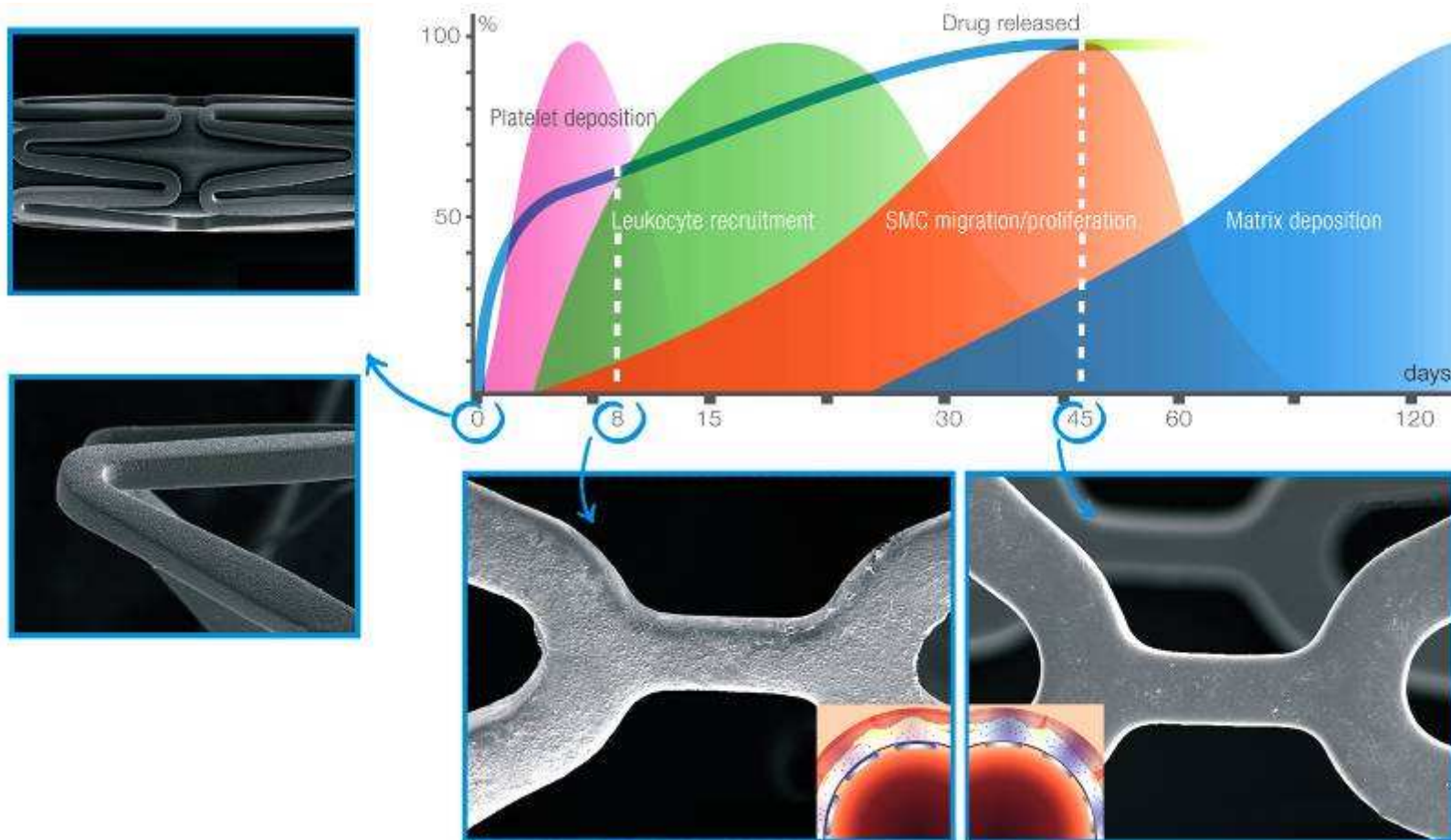


Polymer free coating

- Release profile clearly establish in 30 days.
- Consistent Paclitaxel morphism ensuring 98% of the drug delivered to the lesion.
- No additional inflammation due to degradation process.
- Complete reversion to regular chromium cobalt stent in 45 days.

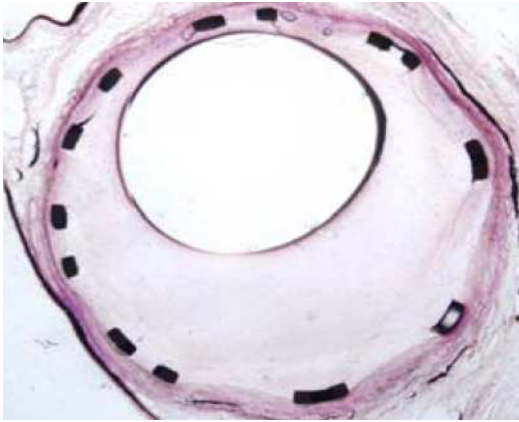


Elution profile 45 days

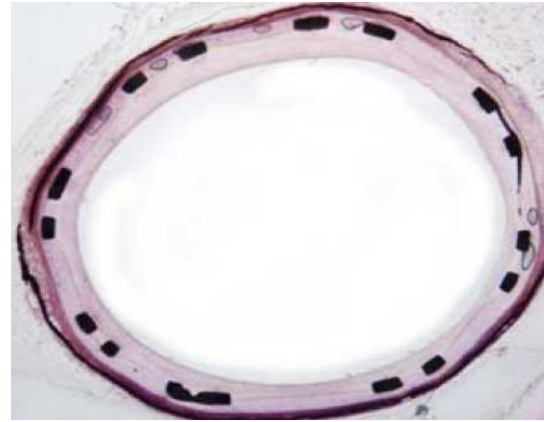


Adapted from : Atherosclerosis 1996 ;123:17-31
Costa MA, and Simon DI. Molecular of Restenosis and Drug-Eluting Stents. Circulation (2005) 111:2257-2273
Schwartz RS, chronos NA, and Virmani R. Preclinical Restenosis Models ans Drug-Eluting Stents. Still much to learn JACC (2004);44(7) : 1373-85

Histology



BMS – 28 days



PAX – 28 days



2PAX – 28 days



NPAX – 28 days

Purpose of the Bipax clinical trial

- Assess safety and efficacy of the NILE PAX® Bifurcation Drug Eluting Coronary Stent System.
- Treatment of single de novo bifurcation lesions in native coronary arteries.
- Main branch reference vessel diameter of 2.5-3.5 mm.
- Main branch reference vessel length \leq 14 mm



Design of the trial



- Assess safety and efficacy of the Nile Pax Drug Eluting Stent for the treatment of single de novo bifurcation lesions in native coronary arteries.
- The BiPax clinical trial will enroll 100 patients with QCA follow-up at 9 months. All patients will have a clinical follow-up at 1, 6 and 9 months and subsequently every year up to 5 years.

Primary endpoint

Restenosis of the main branch
and side branch .

Secondary endpoints

- Late lumen loss at 9 months
- Clinically driven MACE (TVF) at 8 months

Secondary Outcome Measures

- Acute success (device, lesion, and procedure)
- Late lumen loss
- Late loss index
- Minimum luminal diameter (MLD)
- Angiographic parameters (in-stent and in-segment) including: percent diameter stenosis (%DS)
- Major adverse cardiac event (MACE) rate at 30 days and 8 months post-procedure
- Clinically-driven TVF rate at 8 months post-procedure
- Clinically-driven TLR and TVR rate at 8 months post-procedure

