

Sputtered Porous Columnar Coatings for Non-Polymeric Drug Delivery

Brent C. Bell and David A. Glocker, Isoflux Biomed, Rochester, NY

Introduction

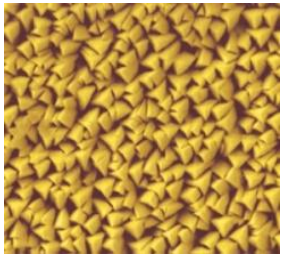
Sputtered porous columnar (SPC) metallic coatings provide a highly attractive platform for **polymer-free drug delivery** from vascular stents.

The coatings are biocompatible, corrosion resistant, durable and can significantly enhance the radiopacity of the entire stent framework.

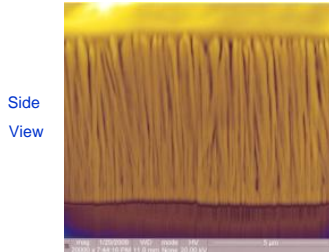
Cylindrical magnetron sputtering produces a low energy deposition process that maintains the original stent properties and achieves excellent coating adhesion.

SPC Coating Structure

- Individual non-connected columns
- Continuous and open pore space (every pore is open to the surface and connected to neighboring pores)
- Total porosity is approximately 20%
- Pore widths range from 5 to 30 nm



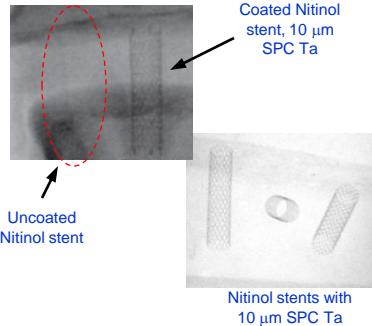
Top View



10 μm SPC Tantalum coating on SS

Tantalum SPC Coating on Nitinol

Radiopacity Enhancement

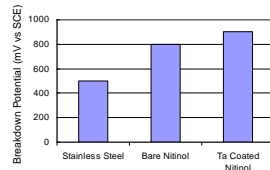


Uncoated Nitinol stent

Coated Nitinol stent, 10 μm SPC Ta

Nitinol stents with 10 μm SPC Ta

Corrosion



Breakdown potential for bare and Ta coated stents

The coating did not adversely affect the corrosion performance of the Nitinol.

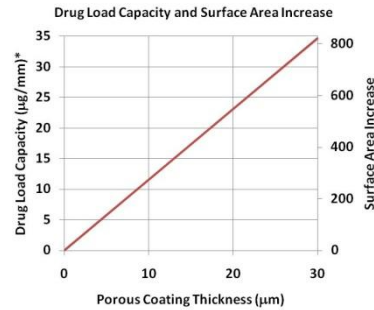
Histology

Typical 180 day porcine histopathology



There was no significant difference in the stenosis, intimal thickness and inflammation score between coated and uncoated stents in both the 30 day and 6 month studies.

Drug Loading

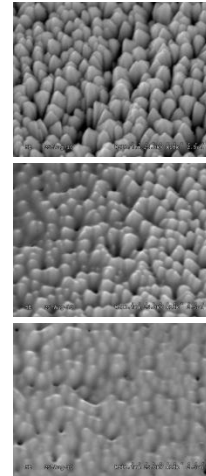


* Coronary stent, 5 mm²/mm and fully filled pores

- Pore volume provides a protected reservoir
- Open, interconnected pores load easily

Sirolimus Loaded into SPC Tantalum

Increasing Drug Load



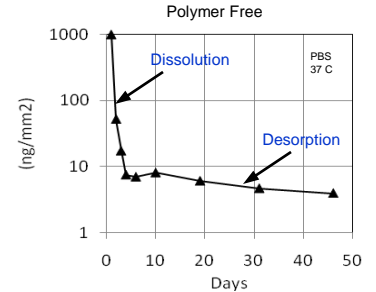
Drug Release

Drug release kinetics are described by a first phase controlled by **drug dissolution** and a second phase controlled by **drug desorption**.

The transition between these two phases occurs when the drug film approaches a monolayer in thickness.

The relative amount of drug released in each phase depends on the initial drug film thickness.

The very high surface area of a nanoporous columnar coating makes it possible to deliver a significant amount of drug during the desorption phase.



Sirolimus release from 20 μm SPC Cr coating

SPC Coating Summary

- Polymer free drug delivery
- 30 day+ release
- Open nanoporous structure
- Loads easily with drug
- Excellent coating integrity
- Enhanced radiopacity
- Large drug capacity
- Ta, Cr, CoCr demonstrated
- Other metals/alloys are possible
- Multilayer structures are possible