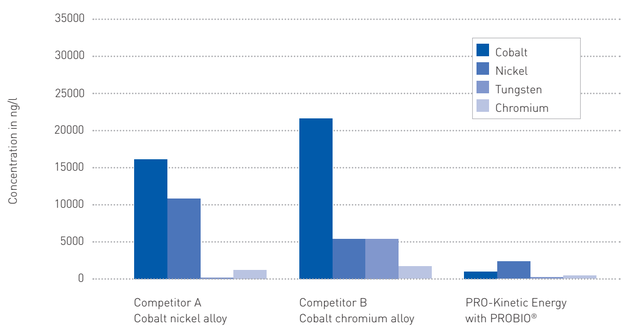
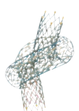
Reduced Metal Corrosion and Ion Release

PROBIO® acts as a diffusion barrier, sealing the bare metal surface and reducing ion release. In vitro studies have shown up to a 96 % reduction of allergenic metal ions[3] when the stent surface is coated with silicon carbide.

Ion Release from Stent Surface[3]



Coronary and Peripheral Stent Systems with PROBIO® Coating

Coronary Stent Systems		Peripheral Stent Systems				
						
Lekton Motion	PRO-Kinetic	PRO-Kinetic Explorer	Astron	Astron Pulsar	Dynamic	Dynamic Renal

References

[1] Shih CC, Shih CM, Su YY, Su LHJ, Chang MS, Lin SJ. Quantitative evaluation of thrombosis by electrochemical methodology. Thrombosis Research 2003; 111: 103-109.
[2] Rzany A, Harder C, Schaldach M. Silicon carbide as an antithrombogenic stent coating: an example of a science-based development strategy. Progress in Biomedical Research 2000; 5: 168-177.
[3] Data on file at BIOTRONIK.
[4] Rzany A, Schaldach M. Smart Material Silicon Carbide: Reduced Activation of Cells and Proteins on a-SiC:H-coated Stainless Steel. Progress in Biomedical Research 2001; May: 182-194.
[5] van Oeveren W. Reduced Deposition of Blood Formed Elements and Fibrin onto Amorphous Silicon Carbide Coated Stainless Steel. Progress in Biomedical Research 1999; February: 78-83.
[6] Hamm CW, Hugenholtz PG. Silicon carbide-coated stents in patients with acute coronary syndrome. Catheterization and Cardiovascular Interventions 2003; 60: 375-381.

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excellence for life

PROBIO® Amorphous Silicon Carbide Coating
Invisibility by Technology

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What is PROBIO®?

PROBIO® is a an amorphous silicon carbide (a-SiC:H) passive coating developed by BIOTRONIK to reduce the thrombogenic properties of metal stents. Passive coatings serve as a barrier between the metal stent and the surrounding tissue/blood. Instead of actively interfering with the process of intimal proliferation, PROBIO® adapts the surface of the stent to reduce the amount of protein activation that can occur – essentially, making the stent biologically invisible.

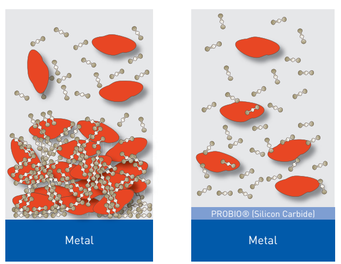
By improving the haemo- and biocompatibility, passively coated stents can reduce the risk of early and late complications.[1] In vitro results have shown PROBIO® to reduce the deposition of fibrin, platelets and leucocytes as well as enhance the growth of endothelial cells.

How does it work?

A stent can trigger thrombus formation by an electronic exchange between the stent's surface and blood. Dampening this electron transfer process between the stent surface and serum proteins results in reduced thrombogenicity.[2]

The surfaces of all BIOTRONIK coronary and peripheral stents are coated with PROBIO® to minimize unwanted interactions with the surrounding blood and tissue. The electronic structure of PROBIO® is adapted to the electronic structure of proteins, and therefore is a passive, «non-activating» biomaterial.

Electron Transfer Processes



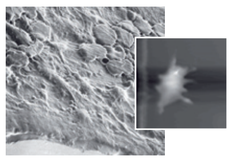
Uncoated Stent

Coated Stent

Reduces Platelet Aggregation[4]

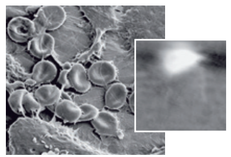
A barrier against metal ion release results in a reduction in platelet activation.[5]
When a platelet comes into contact with the PROBIO® coating, it remains in a resting state. Platelets that come into contact with uncoated stent surfaces have a higher incidence of adherence and activation.

Uncoated Metal



Scanning electron micrograph of the uncoated surface showing areas with a dense layer of blood proteins and formed elements, covered with fibrin strands. Platelets are activated, leading to the characteristic hedgehog-like shape shown in the image on the right.

Silicon Carbide Coated

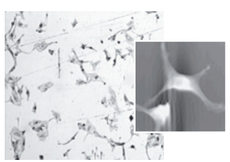


Scanning electron micrograph of the silicon carbide coated surface showing areas with thrombi and erythrocytes, but not densely packed or covered with fibrin. Platelets remain resting, which can be seen in the corresponding round shape of the platelet in the image on the right.

Facilitates Complete Endothelialization[4]

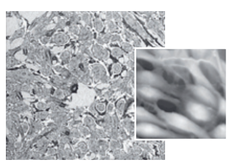
PROBIO® coated metal encourage a continuous endothelial layer to form on its surface. A sound endothelial layer interacts passively with proteins and platelets. Uncoated metal does not show the same endothelial development as coated.

Uncoated Metal



Endothelial cells after 24 hours of contact on uncoated metal: poor coverage with single cells that show marked pseudopodia.

Silicon Carbide Coated



Endothelial cells after 24 hours of contact on silicon carbide: complete endothelialization with characteristic pavement structure.

Clinical Effectiveness[6]

TRUST = Tenax for the prevention of restenosis and acute thrombotic complications – a useful stent trial

Purpose
A randomized trial of a silicon carbide coated stent versus uncoated reference stents in patients with acute coronary syndromes (unstable angina) of either Braunwald IIB or Braunwald IIIB Class.

Method
38 European and Canadian centers participated in the study, enrolling 485 patients in 1999 and 2000. Clinical follow-ups took place at 1, 3, 6 and 9 months. There were 314 patients in the Braunwald Class IIB group and 171 patients in the Braunwald Class IIIB group. Angiographic follow-up took place at 6 months. The two patient groups were comparable with regard to the major demographics and anamnestic data. Only 2.1 % of the patients received GP IIb/IIIa receptor blocker agents. All were given Aspirin and Ticlopidine or Clopidogrel.

Results
The 6-month follow-up shows that the MACE rate for the Braunwald IIB population is comparable for both groups. A statistically significant difference is observed in the Braunwald IIIB patient population with a MACE rate of 5.8 % for the PROBIO® coated stent as opposed to 15.7 % in the reference stent group. This trend continued at 9 months.

Conclusion
Stents coated with silicon carbide in this study reduced Major Adverse Cardiac Events during follow-up in the high-risk subgroup.

MACE Free Survival

Braunwald Class IIIB Patients