



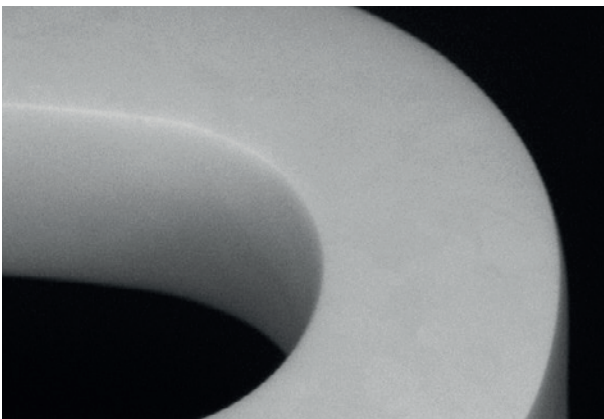
Corrosion Resistance of Stents

Corrosion resistance has the biggest impact on the biocompatibility of implantable metals but is still an underestimated material property. In vessels with corrosive fluids like blood, all alloys show a continuous release of metal ions up to a certain degree.

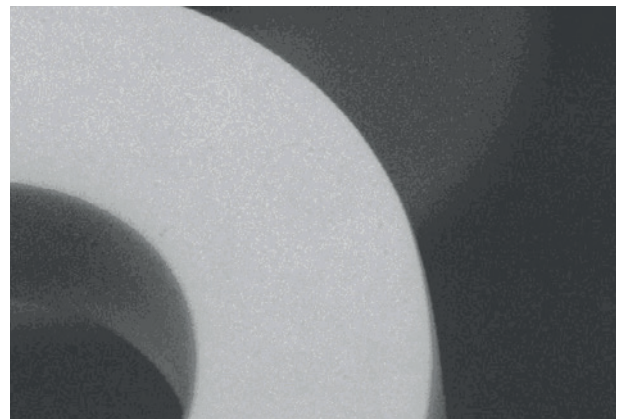
The leaching of Nickel ions has been observed and has prompted a focus to avoid negative body reactions of Ni-allergic patients: see FDA Draft Guidance¹. The corrosion resistance should be tested according to the ASTM 2129 standard.

Besides the appropriate choice of the suitable metal alloy, the processing of the implant, especially the electropolishing and passivation, have a significant influence on the corrosion resistance of the device.

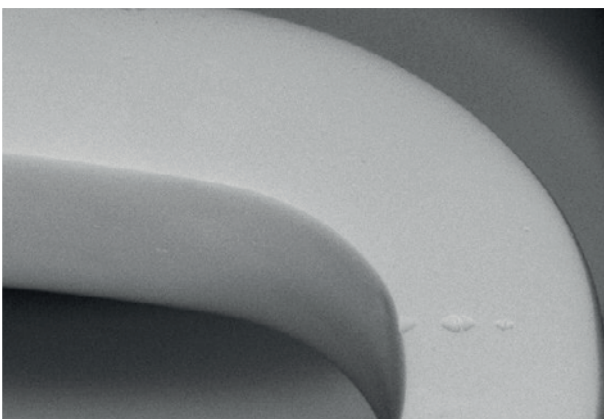
With years of experience in corrosion testing MeKo has developed the special passivation process **CorReSurf** with optimized corrosion resistance for stents as shown in the following pictures.



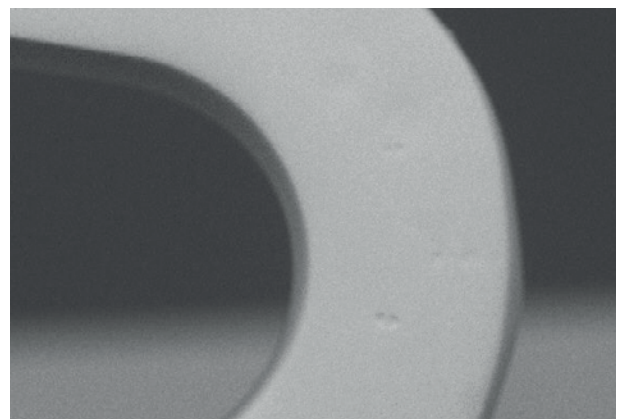
MeKo 316LVM Sample: electropolished and passivated stent **before** corrosion test



MeKo 316LVM Sample: electropolished and passivated stent **after** corrosion test



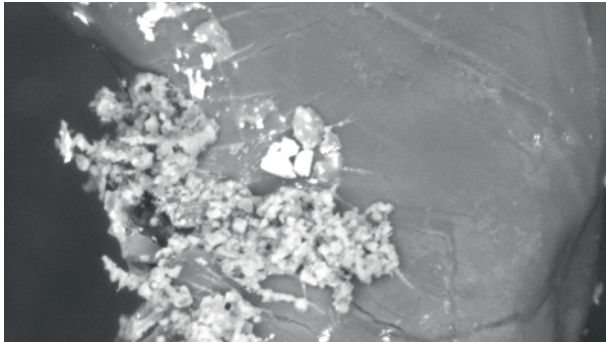
MeKo VASCULOY® Sample: electropolished and passivated stent **before** corrosion test



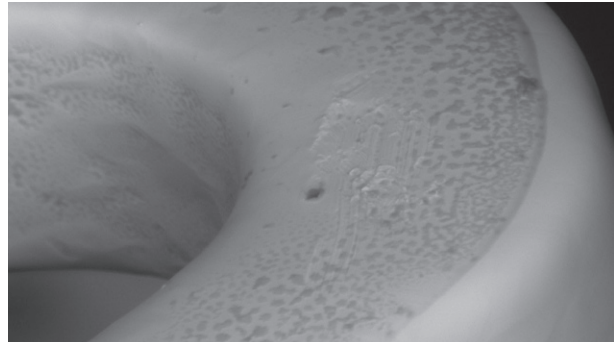
MeKo VASCULOY® Sample: electropolished and passivated stent **after** corrosion test

The following pictures show the importance of corrosion of stents. These stents underwent corrosion testing per ASTM 2129.

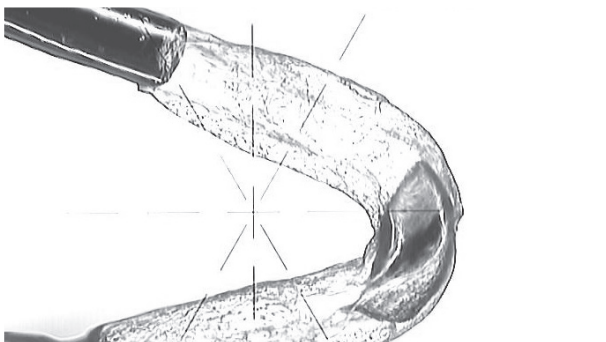
In particular, coated stents are susceptible to corrosion more so than non-coated stents. Every gap, crevice or hole of the coating forms a galvanic potential due to local concentrations of released ions which causes the so called crevice corrosion.



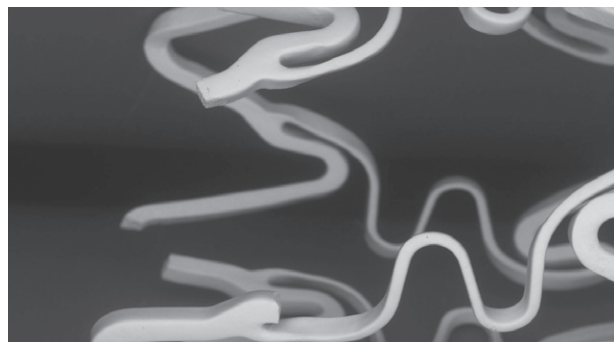
Sample A: coated stent, all cracks in the coating are filled with insoluble salts



Sample B: uncoated stent with flat (planar) corrosion signs



Sample C: complete strut elements resolved by corrosion (polymer coating remains)



Sample C: SEM picture of the missing strut elements after polymer coating removal

The cracks and missing strut elements of sample C look quite similar to the pictures shown in the publication of Nakazawa et.al.². In addition to fatigue, corrosion impacts the lifetime of stents.

References

1. FDA Draft Guidance for Industry and Food and Drug Administration Staff: "Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems", released Aug. 30th, 2013.
2. Gaku Nakazawa, Renu Virmani et.al.: Incidence and Predictors of Drug Eluting Stent Fracture in Human Coronary Artery, JACC Vol. 54, No. 21, 2009

MeKo - Competence in Stent and Vascular Implant Supply

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The MeKo logo, featuring the company name in a bold, white, sans-serif font with a stylized underline for the 'M' and 'K'.