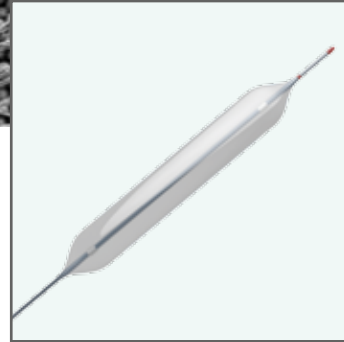
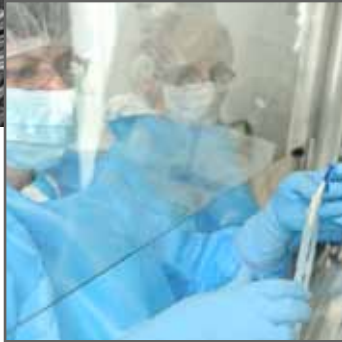
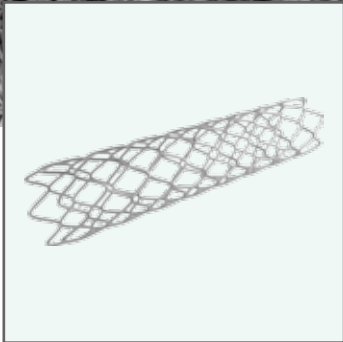
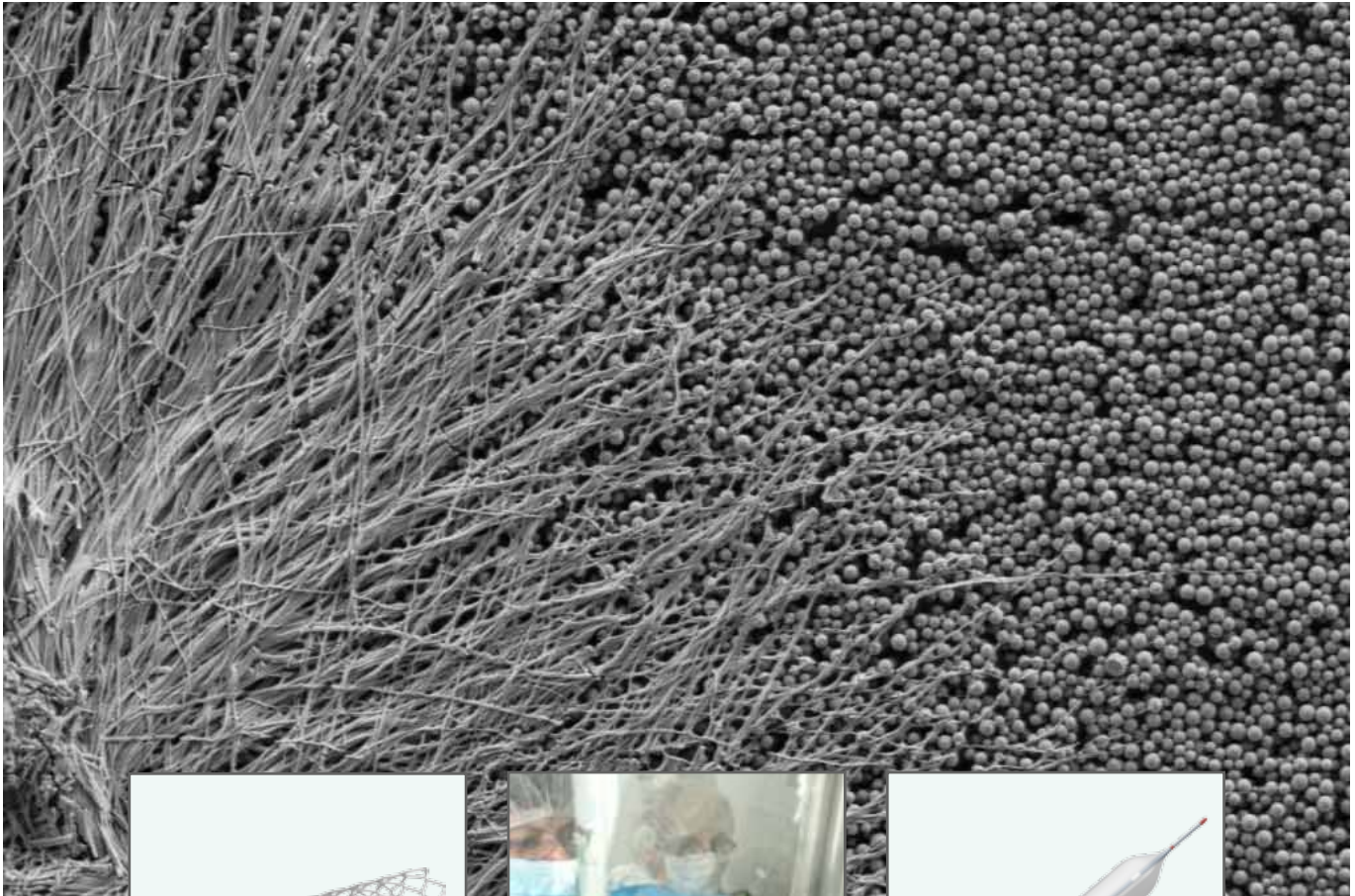


# Innovative Coatings for Vascular Products



The coating of vascular products is one of the innovative business lines of DOT GmbH. In this area, stents and balloon catheters are coated with special substances to prevent the formation of restenosis or a renewed vascular obliteration.

Based on her long-standing experience in medical surface treatments, DOT has developed several state-of-the-art coating technologies, which enable for a stable drug-coating quality in accordance with the customer's requirements. Since 2009 DOT has coated more than 40,000

stents and 100,000 balloon catheters with different carrier substances and drugs. Generally, each coating is a combination of carrier substance and drug. For example, polylactide acids or shellac have been employed as carrier substances whilst Paclitaxel, Sirolimus but as well other innovative active agents have been used as drugs. DOT has developed adequate test methods to determine the drug release.

DOT is constantly working on improved techniques and innovative coating solutions for vascular products.

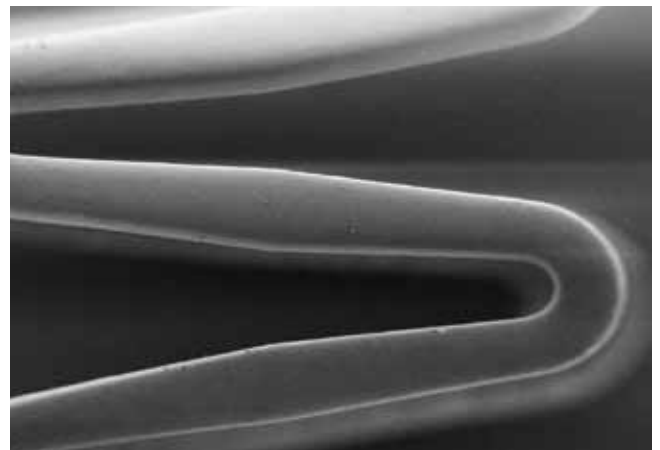
Patents are pending or have been issued (US 8, 911, 817 B2) for several technical innovations.

DOT is not only providing coatings for vascular devices. As a full service contractor, DOT offers cleanroom packaging and final packaging in cardboard boxes as well as subsequent sterilisation by outside contracting. All coating and packaging activities of DOT are in accordance with the ISO 13485 standard and FDA quality System Regulations.

### Coating of Stents



Quality control of drug coated stent



Sirolimus PLLA coated stent

### Technology

At DOT, the stents are coated with immunosuppressive drugs, which possess an anti-proliferative effect and are applied homogeneously on the stent using a carrier substance.

The result is a so-called Drug Eluting Stent (DES). This DES releases small

amounts of the drug over a defined time period, inhibits the formation of new cells and therefore reduces the risk of restenosis in this area. Within 30 days, approximately 70 % of the anti-proliferative drug is transferred into the neighbouring arterial tissue.

### Properties

- Homogenous, thin coating
- Release of drugs over a longer time period

## Range of Application

- Stent angioplasty in blood vessels and coronary vessels, in particular to reduce the risk of restenosis

## Advantages

- Effective inhibition of new cell formation
- Permanent local effectiveness of released drugs over a longer time period

## Literature

1. Briguori, C. et.al.: Performance of the XLIMUS sirolimus-eluting coronary stent in very complex lesions, *Minerva Cardioangiol*, 2014, 62:1-8
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## Coating of Balloon Catheters



Packaging of drug-coated balloon



Drug-coated balloon

## Technology

At DOT, the balloon catheters are coated with cytostatic drugs. The application of these active substances is carried out with a defined deposition of an adjusted solution and their drying.

The cytostatic drugs are applied on the balloon catheter using a carrier sub-

stance and generate a so-called drug eluting balloon (DEB).

During the dilatation of the balloon in the blood vessel, the cytostatic drug will be released from the balloon into the vessel wall and minimises the risk of restenosis for a longer period of time.

## Properties

- Homogenous, thin coating
- Drug release over a longer time period

## Range of Application

- Balloon catheters for angioplasty of peripheric and coronar blood vessels
- In-stent restenosis
- Bifurcations in the coronar area as well as renal vessels, femoral arteries and lower leg arteries in the peripheral area

### Advantages

- No foreign body remaining in the vessel after the surgical intervention
- Effective inhibition of new formation of cells
- Permanent local effectiveness of the released substances over a longer time period

### Literature

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9. Schulte, K-L. et.al.: TCT-269 Drug-coated balloon vs. standard balloon for the PTA treatment of lesions in the SFA and popliteal artery – First interim results of the FREERIDE study, J Am Coll Cardiol, 2014, 64 (11\_S)

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medical implant solutions

### DOT – coating specialist for orthopaedic and dental implants

DOT is one of Europe's leading providers of medical coating solutions for orthopaedic and dental implants and instruments and also their cleanroom packaging.

We also develop and manufacture products for regenerative medicine for dental and orthopaedic applications.

Our comprehensive supply chain concept makes us an ideal medical technology partner. Our activities help restore the health of patients worldwide and thus make a major contribution to the improvement of their quality of life.