www.meko.de

MedTech Materials Webinars

POLYMER COATINGS FOR IMPLANTS

Learn how advanced polymer coatings provide tailored, biocompatible, and drug-releasing solutions – while seamless in-house processing fast-tracks your path to market.

OCTOBER 8, 2025
5 to 6 p.m. CEST, UTC+2

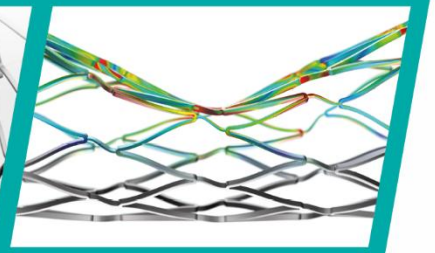
OCTOBER 9, 2025
9 to 10 a.m. CEST, UTC+2

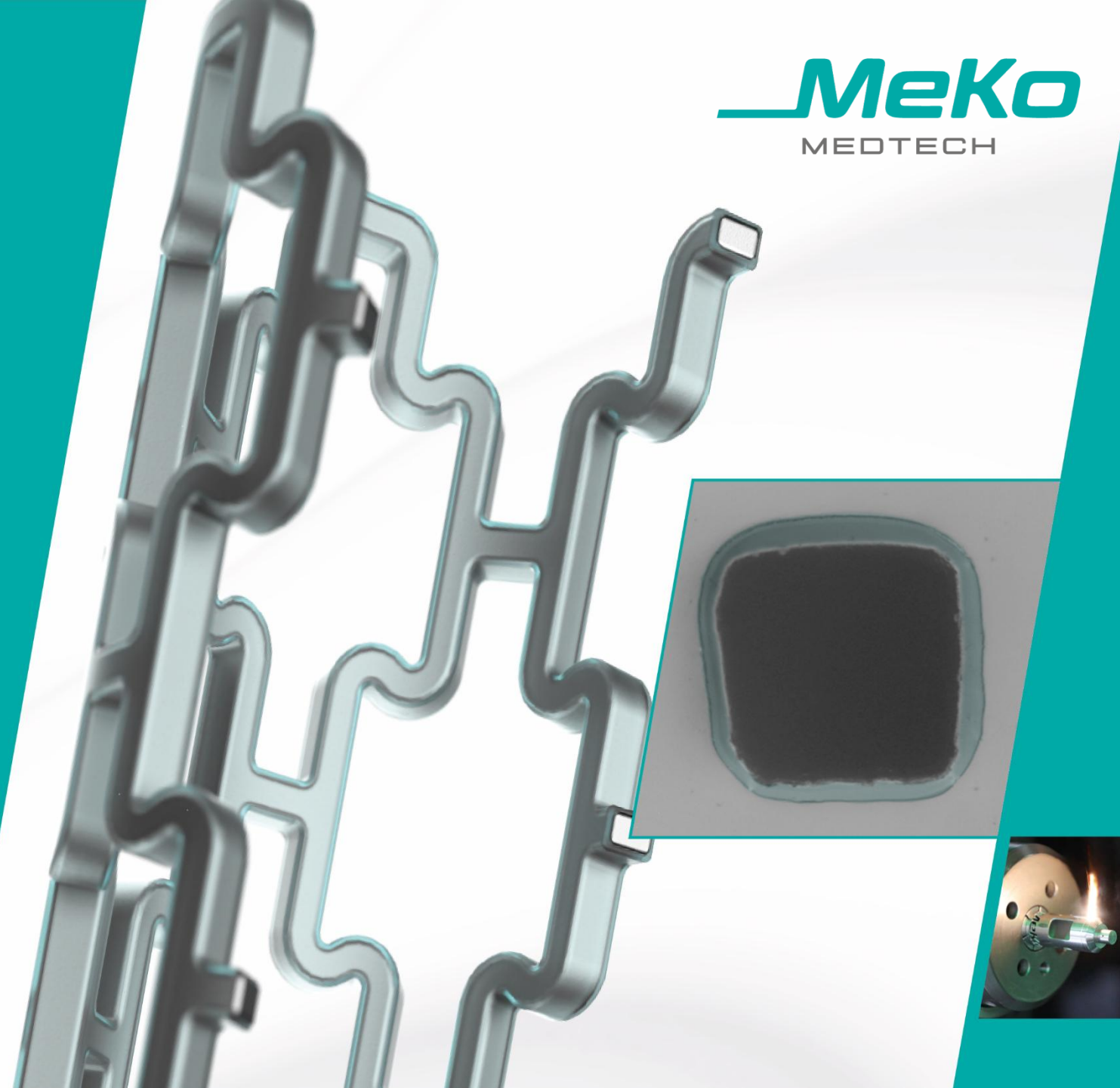
MeKo MEDTECH

PRECISION IS OUR PROFESSION

MeKo.de

Polymer Coatings for Implants





MeKo MEDTECH

Agenda

MeKo MedTech

Polymer Coatings for Implants

Questions & Answers

Our History

In 1991 Clemens Meyer-Kobbe started with one laser in a garage near Hannover, Germany.

In 1995 MeKo was one of only two companies in the world laser cutting human-use stents.

Present Day

ISO **13485**
ISO **9001**

FDA
registered

160,000
sq. ft.

Working for the Future

Our dedicated team is constantly innovating and elevating standards.

- Materials
- Manufacturing Processes
- Inspection & Analysis
- Automation

Working for the Future

Our dedicated team is constantly innovating and elevating standards.

Materials

- Resoloy®: new magnesium alloy with **>30% break elongation currently used in FIH-study**
- PolymediX®: high-precision polymer tubes with **drug integration** into tube wall
- Vasculoy®: **enhanced biocompatibility due to absence of Nickel and Cobalt** in balloon expandable stents

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Manufacturing Processes

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Manufacturing Processes

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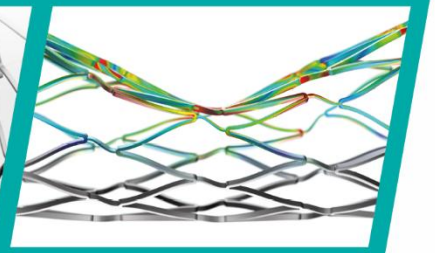
Polymer Coatings

For Medical Devices



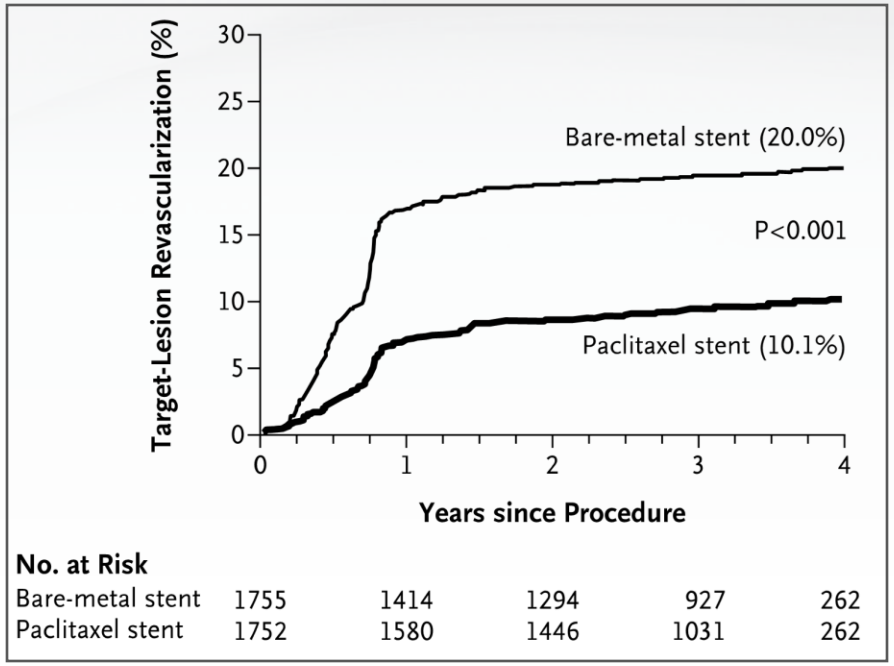
Why Coating Makes the Difference

Objective: Controlled drug release to reduce complications

- Use of Active Pharmaceutical Ingredients (API)
- Combination of stent + polymer + API → Drug Eluting Stents (DES)

Current use of DES

- DES have largely replaced Bare Metal Stent (BMS)
- Since 2023, >90% of all PCI procedures use DES
- Especially beneficial for high-risk patients and complex lesions



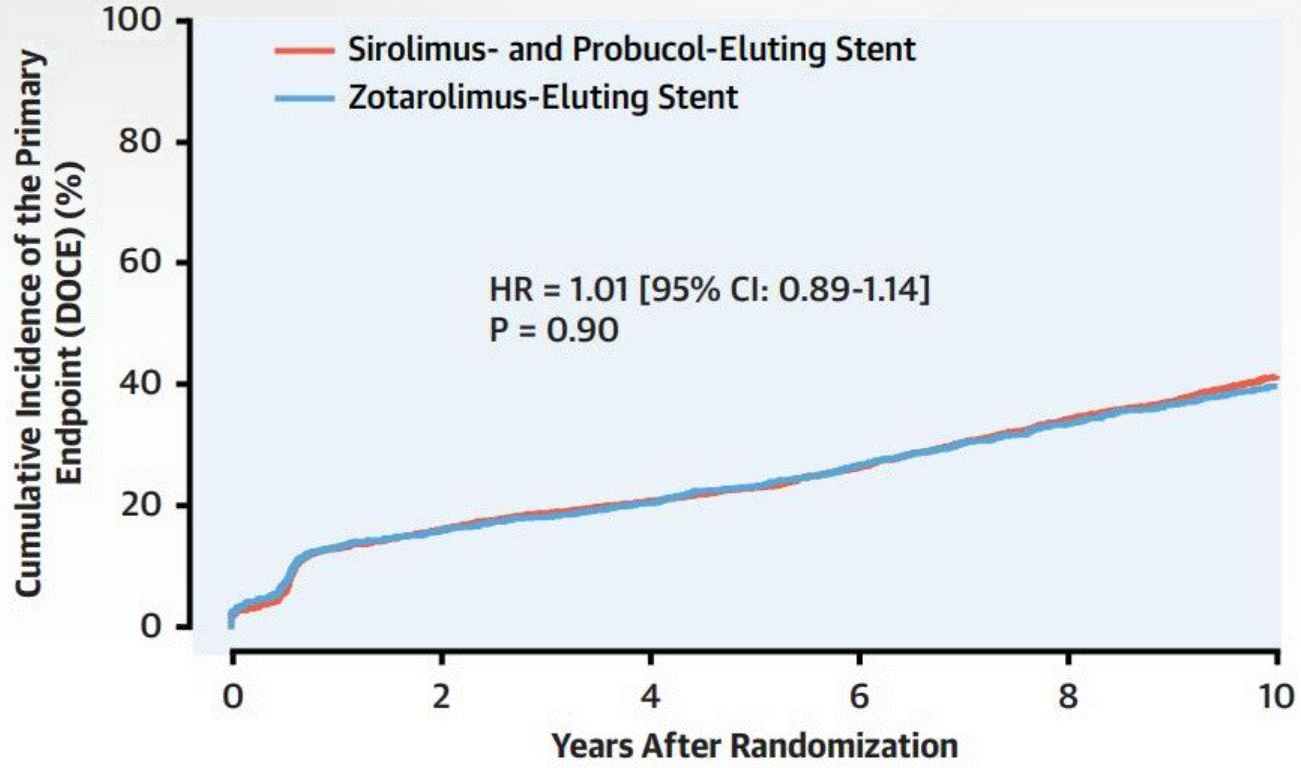
Stone, Gregg W., et al. "Safety and efficacy of sirolimus-and paclitaxel-eluting coronary stents." New England Journal of Medicine 356.10 (2007). doi: 10.1056/NEJMoa067193.

Our First Step into Drug-Integrated Polymers

- PolyMediX® – Development of high-precision polymer tubes with integrated Active Pharmaceutical Ingredients
- Start of our in-house expertise in combining polymers with pharmaceuticals
- Long-standing experience in polymer development, processing and functionalization
- Established analytical know-how in drug release and stability testing

PolyMediX®
by MeKo

Controlling Degradation of Resoloy®

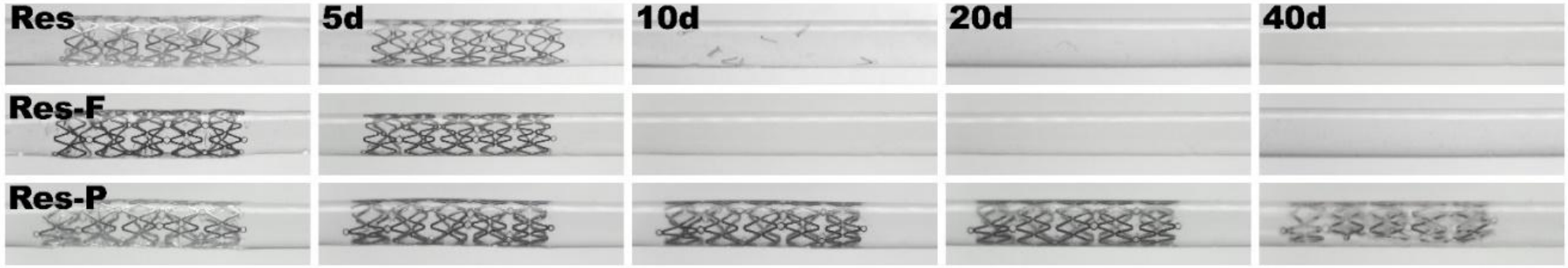


Kufner S, et al. 10-Year Outcomes From a Randomized Trial of Polymer-Free Versus Durable Polymer Drug-Eluting Coronary Stents. Journal of the American College of Cardiology. 2020; 76(2):146–158. doi:10.1016/j.jacc.2020.05.026

Controlling Degradation of Resoloy®

- Development of coatings to control the degradation of Resoloy® (bioresorbable magnesium alloy)
- In-house solution for rapid testing of various coatings

Key challenge: achieving homogeneous, reproducible coatings – beyond drug delivery



Degradation of Resoloy with different coatings
Menze R, Wittchow E. In vitro and in vivo evaluation of a novel bioresorbable magnesium scaffold with different surface modifications. 2021 Sep. doi: /10.1002/jbm.b.34790

Two Pillars of Our Coating Expertise

Resoloy® by MeKo

PolyMediX® by MeKo

- Precise coatings for degradation control – beyond drug release
- Focus on homogeneity, reproducibility and quality

- Broad expertise in polymer development and processing
- Proven know-how in controlled drug release

Result: Integration of coating as a new production step at MeKo

Coating Process

Manufacturing Processes
From Solution to Coated Stent

Polymer Solution
- Formulation to customer needs

Weighing
- Precise measurement of component before coating

Precision Coating
- Tailored to customer needs

Drying
- Controlled solvent removal

Final Weighing & Control
- Verification of coating mass and thickness

API Analysis
- Optional quantification

Quality Inspection
- 100 % inspection of all implants

Shipping
- Cooled, under nitrogen atmosphere (on request)

Polymer Solutions
The First Step in Coating

Laboratory preparation

- Processing under controlled conditions (fume hoods, precision weighing)
- Dissolving polymers in suitable solvents

Polymer

- Established materials: PLGA, PLA, PLC
- Flexible testing of customer-specific polymers
- Requirement: solubility of polymer in solvent

API & Additives in Final Coating

API integration

- Tailored to customer requirements
  (e.g., Sirolimus, Everolimus)

API concentration in the coating depends on solution formulation and the drug itself

- Formulation – developed by MeKo or customer

Analytical control

- HPLC and DAD testing for API concentration

Additives: optional stabilizers, preservatives

Compliance: GLP-based, GMP readiness ongoing

High-Precision Coating
in Cleanroom Conditions

Cleanroom environment

- Process conducted in ISO 7
- Coating stations in flow benches

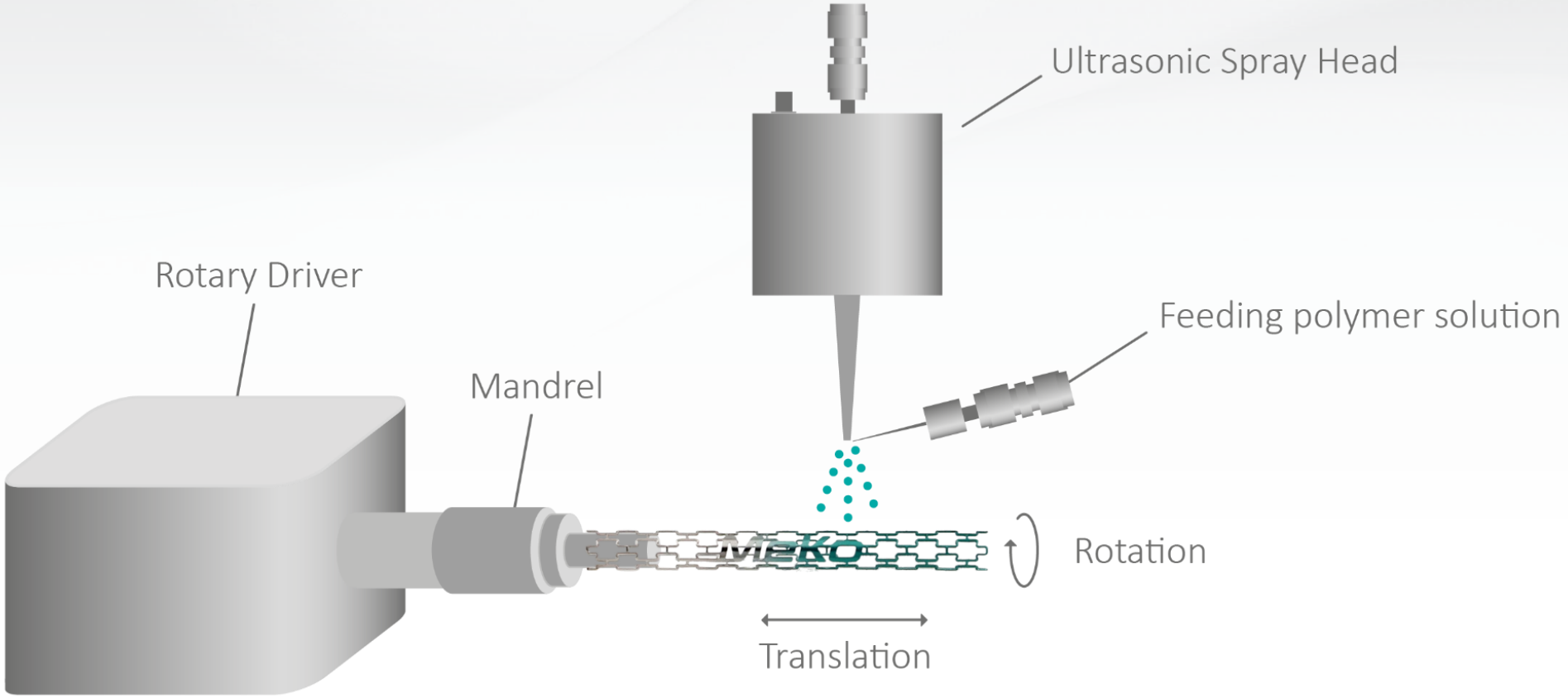
Component compatibility

- Wide material choice:
  Resoloy®, Vasculoy®, L605, stainless steel, Nitinol
- Cylindrical shapes, stent lengths tested: 9-45 mm
- Overly flexible parts may deform during coating

Process adaptation

- Polymer formulation tailored to material, API load and geometry
- 100% mass verification and optical inspection

Coating Process



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Coating Analytics

Comprehensive Coating Analytics

Mass control

- 100% verification as proxy for thickness and API load

Thickness analysis

- Point measurements or line scans (300µm) along stent length for homogeneity
- Optional cross-section analysis, material-dependent

API Analytics

- HPLC testing for drug concentration and release profile

Special analytics

- Effect on radial force
- Corrosion tests polymer and substrate behavior

Quality assurance

- 100% visual inspection of coating

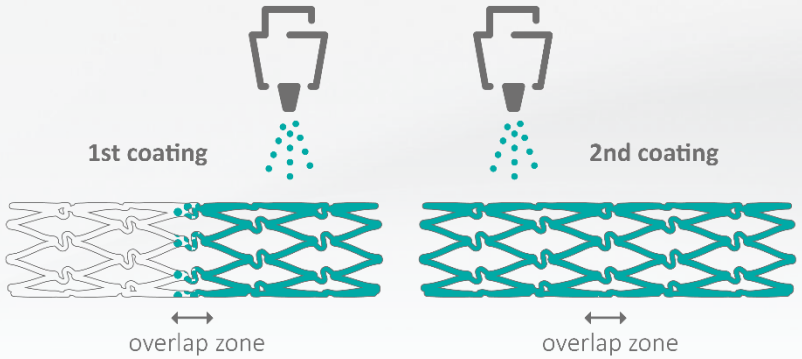
High-Precision Thickness Analytics

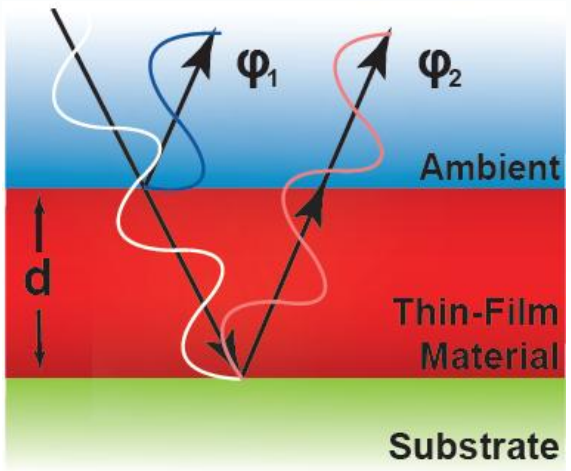
Two-sided coating

- Overlap zone in middle, adjusted for uniform thickness

Reflection spectroscopy

- Non-contact measurement (transparent coatings only)
- Measurement range:
  20 nm to 45 µm, spot size 25 µm
- System capability:
  ±2 nm / ±0.2%, precision up to 0.02 nm





Principle of thin-film thickness measurement by reflection spectroscopy

High-Precision Thickness Analytics

Two-sided coating

- Overlap zone in middle, adjusted for uniform thickness

Reflection spectroscopy

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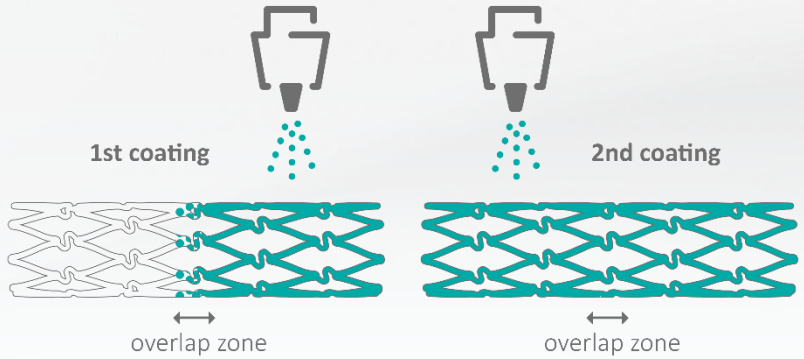
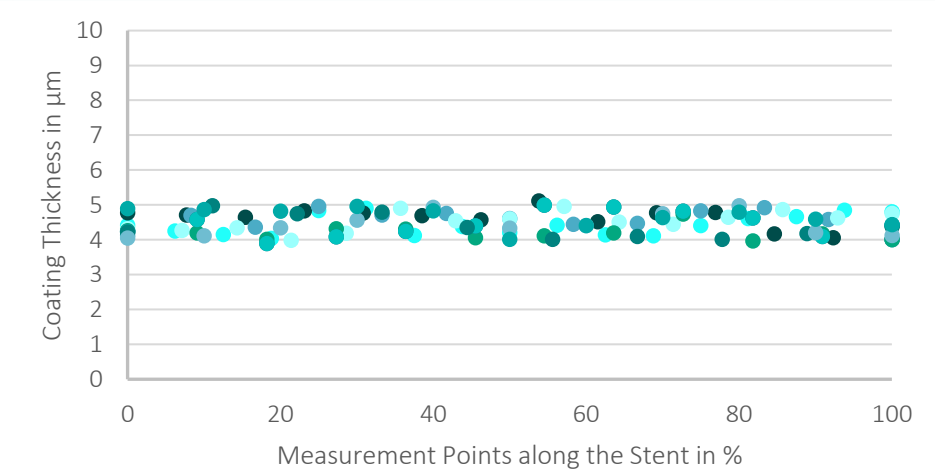




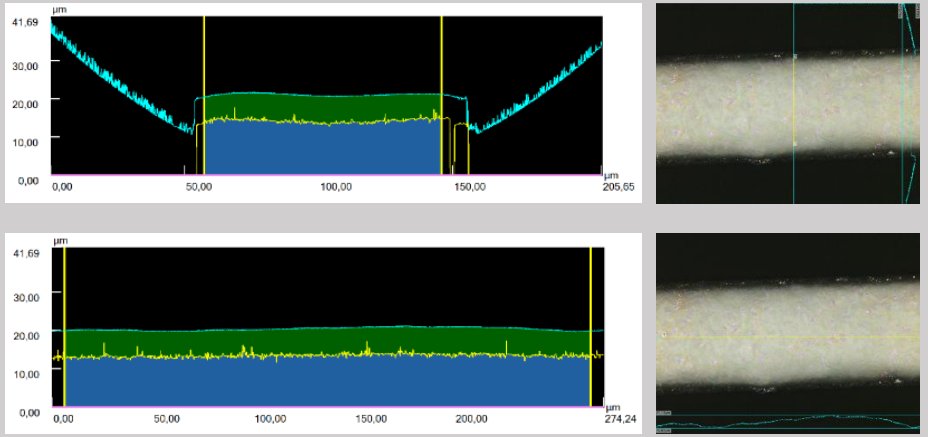
Coating thickness uniformity along stent length
– verified across 10 measured stents

Advanced Methods for Coating Thickness Analysis

Confocal Laser Scanning Microscopy (CLSM)

- Suitable for rough or complex surfaces

Coating Thickness Analysis of the abluminal layer using Confocal Laser Scanning Microscopy (CLSM)



Advanced Methods for Coating Thickness Analysis

Confocal Laser Scanning Microscopy (CLSM)

- Suitable for rough or complex surfaces

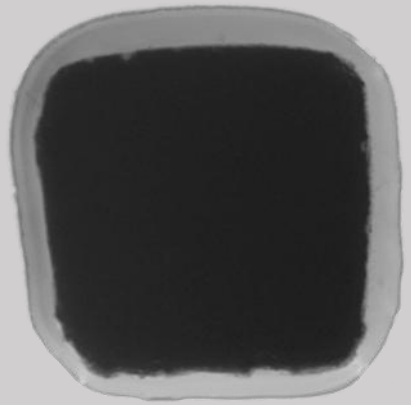
Cross-Section Analysis

- Sample preparation must be feasible **(material-dependent)**
- Direct visualization of luminal vs. abluminal layers

Outcome:

- Both methods confirm homogeneous coatings
- Established coating thickness ranges:
  - > Resoloy® ~6-7 µm (polymer dependent)
    Optimized for degradation control and drug delivery
  - > L605, Vasculoy® ~4-5 µm
    Optimized for drug delivery

Cross-Section of Resoloy® Stent – Luminal vs. Abluminal Coating



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API Analytics

API Quantification & Control

Accurate quantification

- High-Performance Liquid Chromatography (HPLC) with UV/diode-array detector (DAD)

Dual control

- API content of polymer solution (before coating)
- API content of coated component (after coating)
- Typical drug loads for DES-type applications are around ~50-300 µg

Consistency

- Batch-to-batch verification of API load

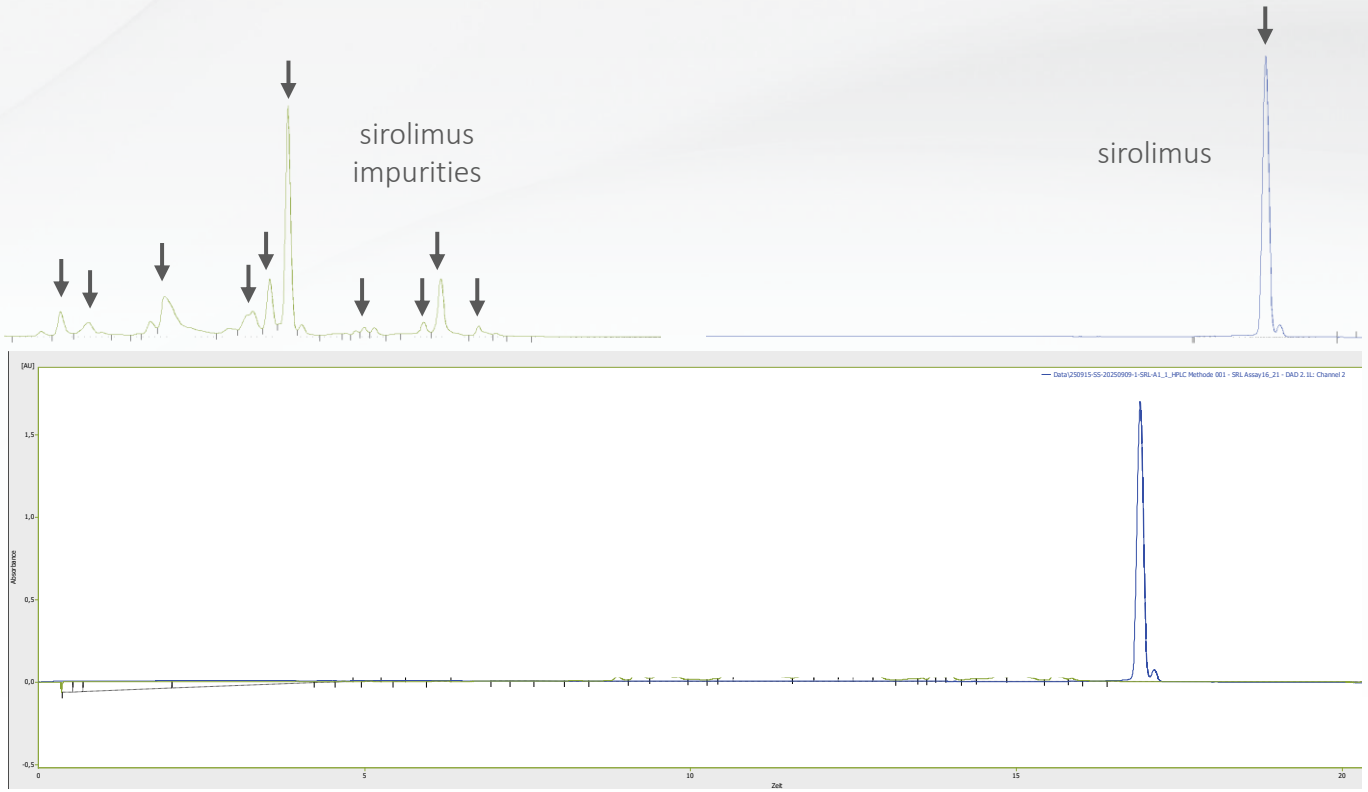
Drug stability check

- Detection of degradation or impurities (e.g., SRL derivatives)

HPLC Chromatograms
API Content & Degradation

Reliable HPLC analysis

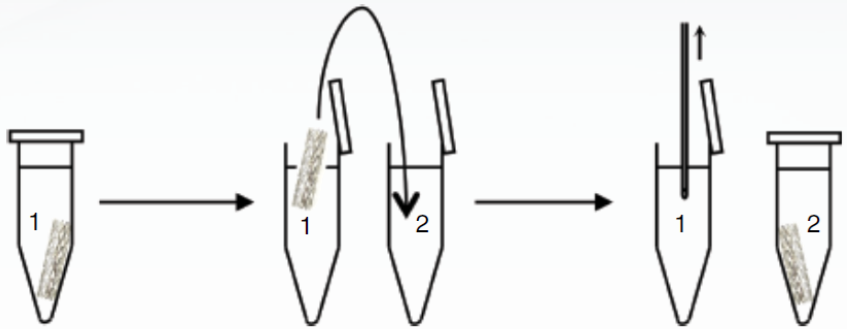
- API stability determined from peak distribution
  - > Degradation leads to extra peaks – impurities become visible
- API content determined from the peak area
  - > Ensures your coating remains consistent and effective



HPLC chromatogram of degraded sirolimus (green chromatogram) and intact sirolimus (blue chromatogram) – additional peaks indicate impurities and degradation products

API Release Testing (in-vitro)

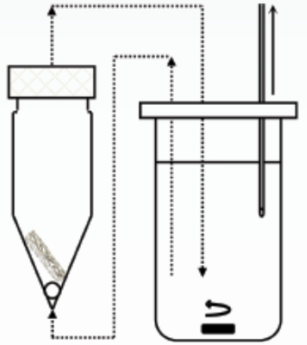
- Reliable in-vitro testing of drug release over time
  - > Incubation setup: simple and flexible



Anne Seidlitz: Drug-Eluting Stents. In: In Vitro Drug Release Testing of Special Dosage Forms (2019), S. 87–117. doi:10.1002/9781118675748

API Release Testing (in-vitro)

- Reliable in-vitro testing of drug release over time
  - > Incubation setup: simple and flexible
  - > USP 4 system (flow-through-cell): standardized, dynamic, regulatory aligned



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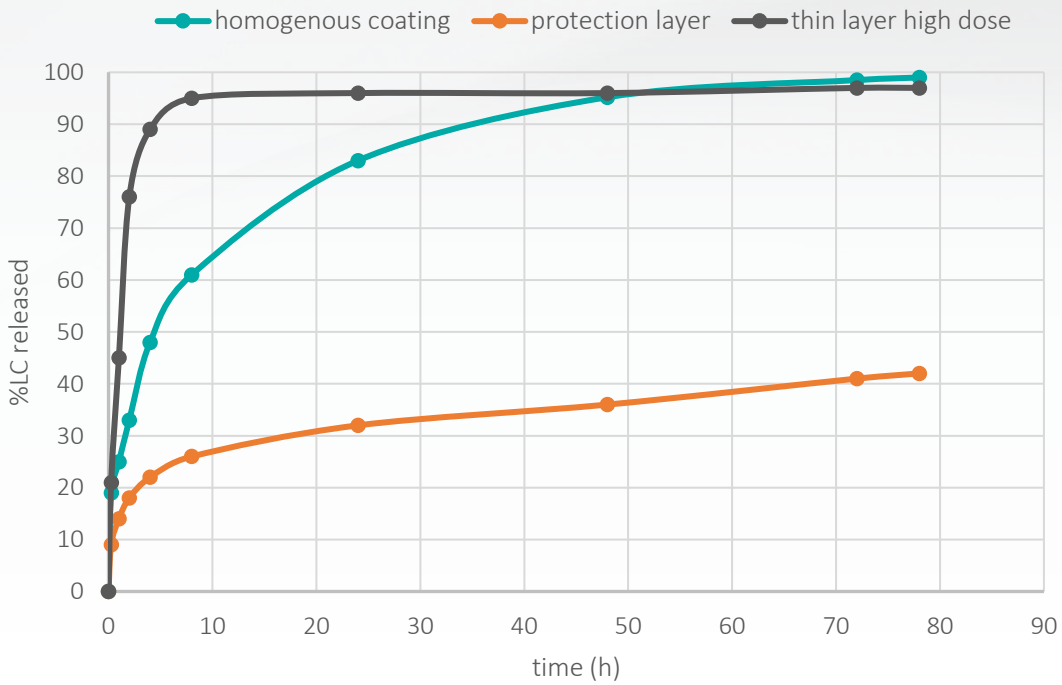
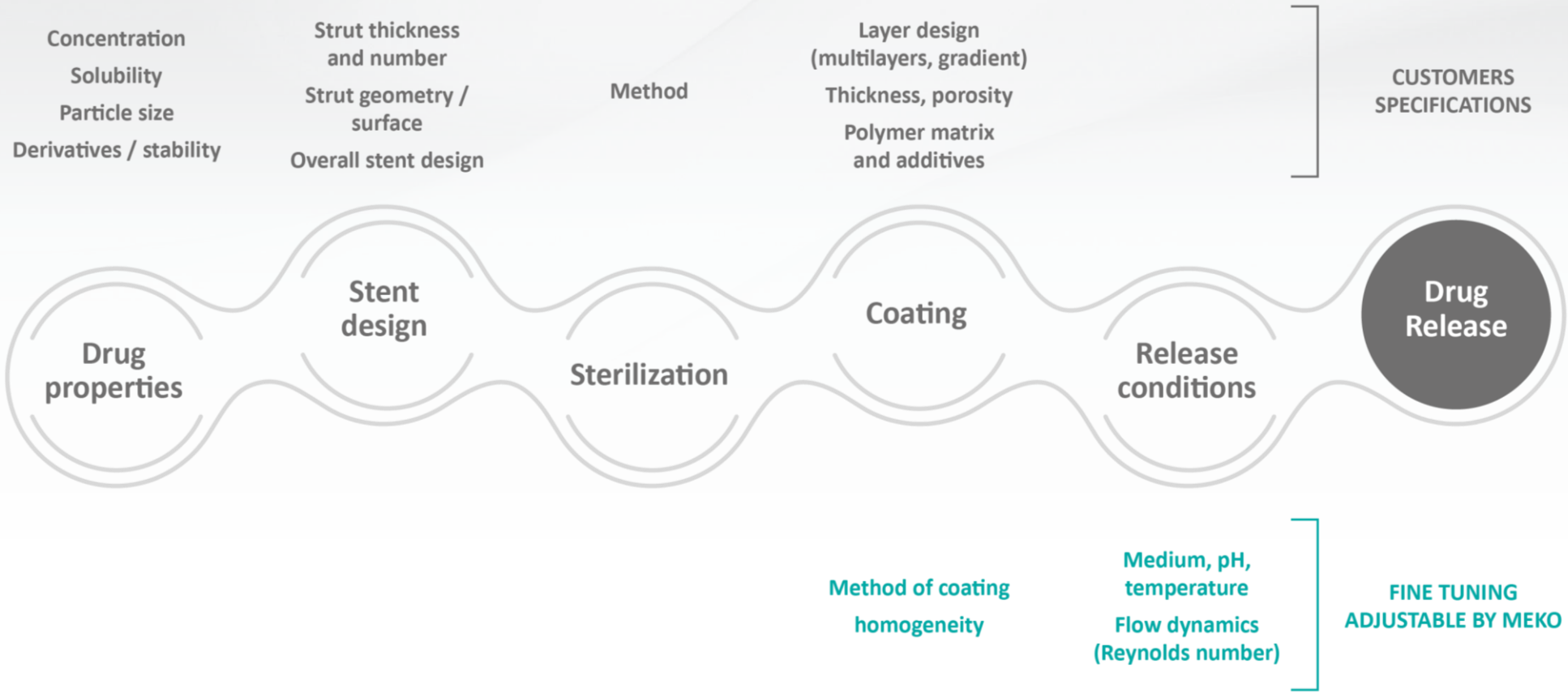
API Release Testing (in-vitro)

- Reliable in-vitro testing of drug release over time
  - > Incubation setup: simple and flexible
  - > USP 4 system (flow-through-cell): standardized, dynamic, regulatory aligned
- We help define and optimize your desired release behavior



Exemplary release curve of different coating configurations
Dissolution Test, 37°C, shaking at 80 rpm

Controlled Release
Influencing Factors



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Challenges & Solutions

Coating Uniformity
Post-Stent Dilatation

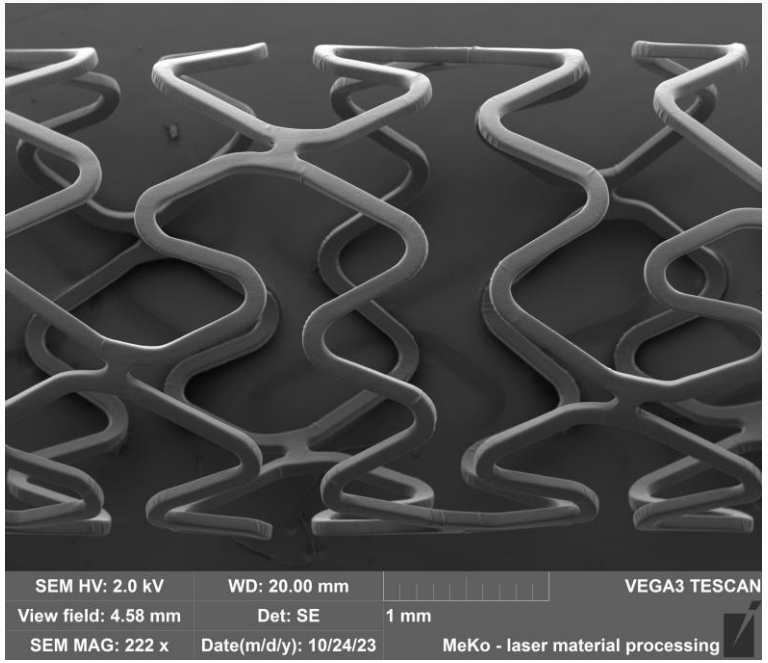
Coating must withstand crimping and dilatation without delamination

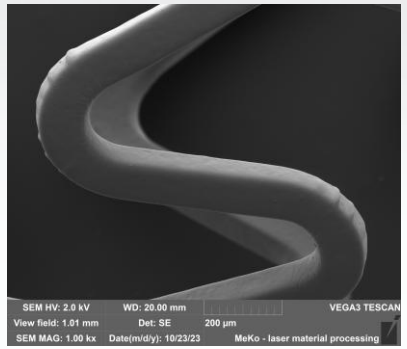
Our capability

- Testing Stents under crimping/dilatation and analyzing coating behavior with SEM
- Supported by in-house FEM simulation expertise

Optimization

- Achievable through adapted parameters or thinner coating layers
- Coating performance during dilatation is strongly dependent on polymer and design





Dilated stent with a PLLA coating. With optimized settings, only tension lines without cracks or holes (SEM)

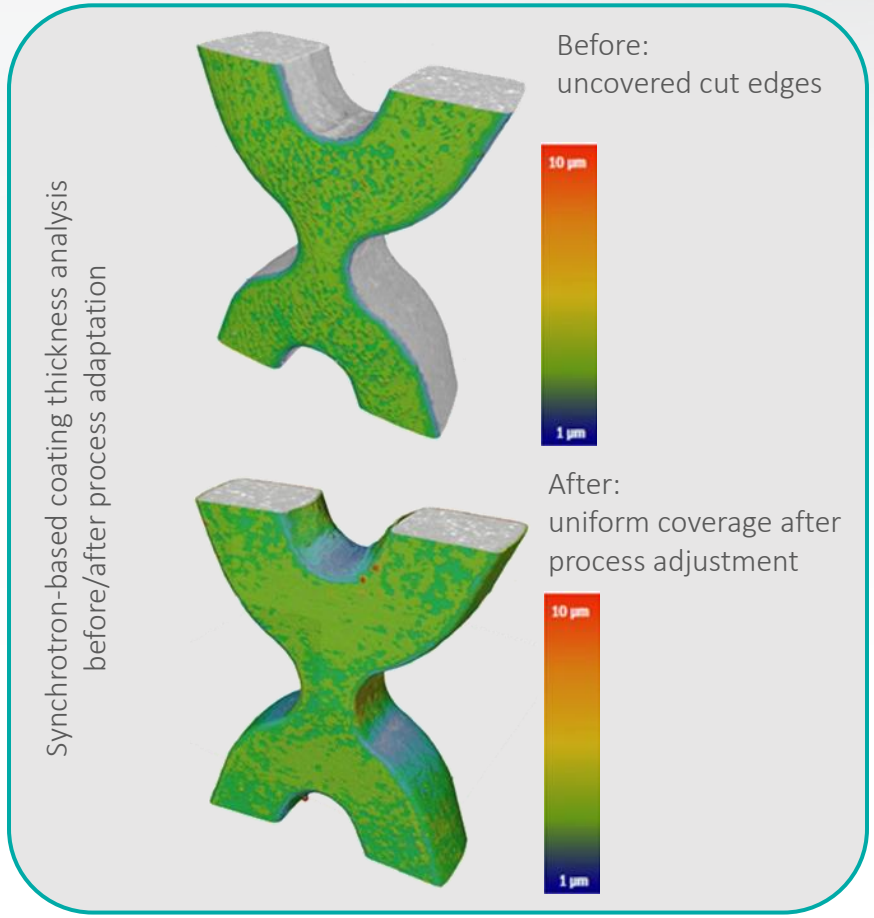
Coating Uniformity
Large-diameter Components

Challenges with components in large diameter

- For example, valve frames with OD ~15 mm
- With standard axial coating setup, cut edges initially remained uncoated

Process optimization

- Enabling uniform coating on all sides, including edges



Beyond Coating
Covering as an Option

Project status

- Currently in R&D phase

Customer-driven

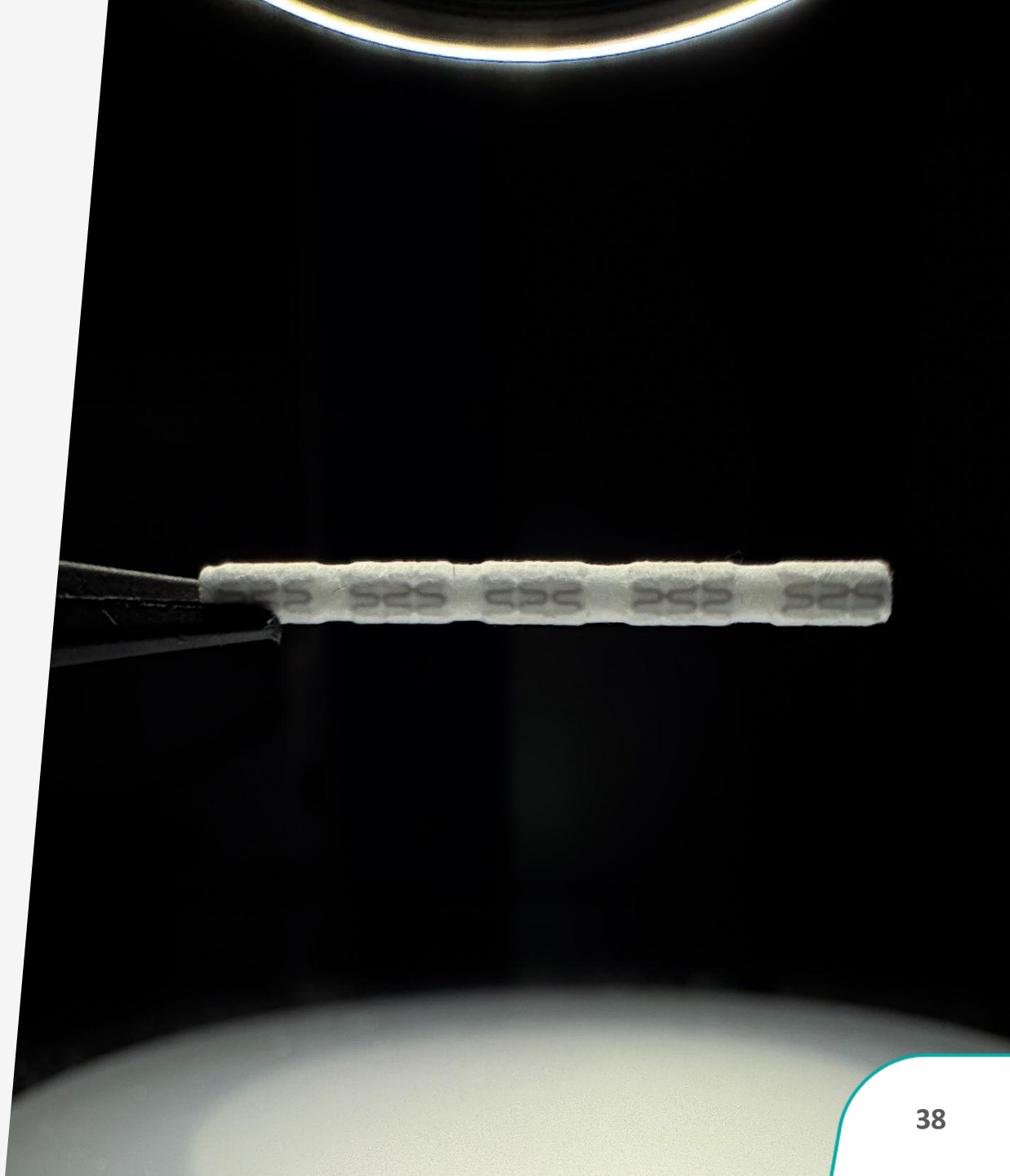
- Further development possible upon request

Requirements

- Tolerance specifications and component details needed

Opportunities

- Ready to expand with customer demand



Customized Coating Solutions

Your input for a tailored coating solution:

- **Component details:** design, dimensions, tubing material
- **Polymer selection:** proven biopolymers novel candidates can be evaluated jointly
- **API specification:** drug type desired concentration (total, per length or per surface area)
- **Coating thickness:** specification for individual layers in multilayer designs

You know our capabilities
– now it’s time to bring your project to life.

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