www.meko.de

MeKo MEDTECH

MedTech Materials Webinars

RESOLOY®

The resorbable magnesium alloy for scaffolds

APRIL 18, 2023
9 to 10 a. m. CEST, UTC+2

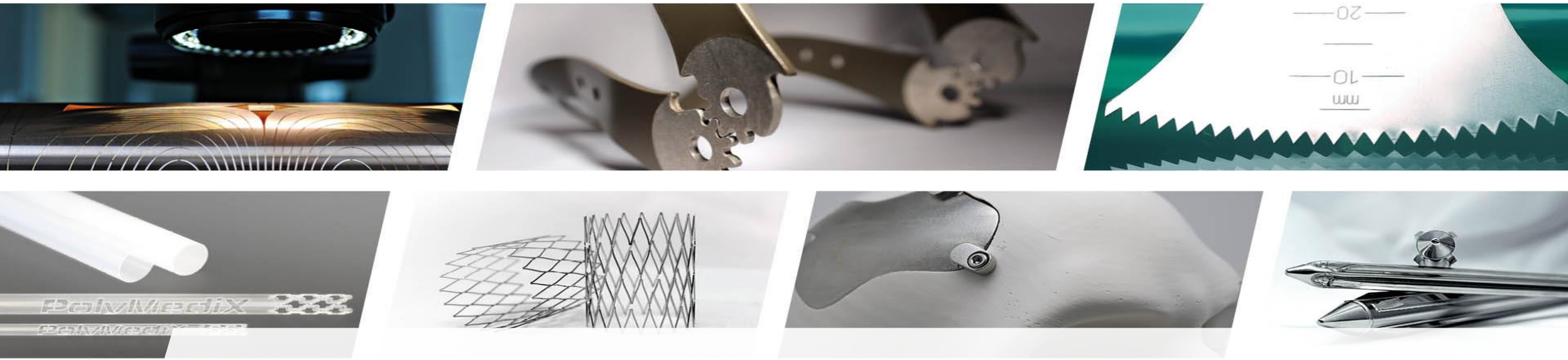
APRIL 19, 2023
5 to 6 p.m. CEST, UTC+2

Register now for free:
www.meko.de/webinars

PRECISION IS OUR PROFESSION

MeKo.de

MeKo MEDTECH



Resoloy®

THE NEW RESORBABLE MAGNESIUM ALLOY

26.04.2023

Agenda

MeKo Manufacturing e.K.

Founded 1991
near Hannover

Laser material processing and post processing as contract manufacturer

Dedicated to high precision and challenging processes

Development of new materials, optimizing of material properties

High export rate with > 50 % outside Europe

More than 300 qualified employees

Company Building

MeKo Group

ISO 13485

30 Years of EXPERIENCE

Made in GERMANY

MeKo MANUFACTURING

MeKo MEDTECH

Contract Manufacturing of Medical Devices

Cardiology
Radiology
Neurology
Ophthalmology
Urology
…

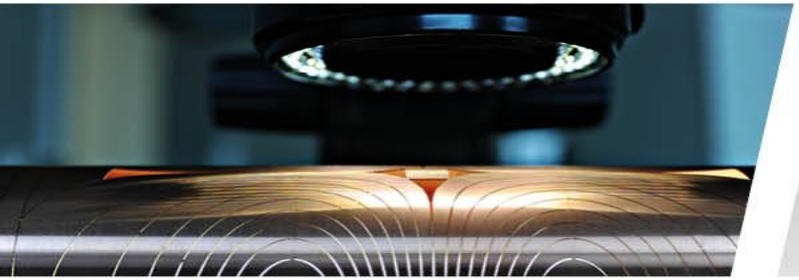
MeKo METALWORKS

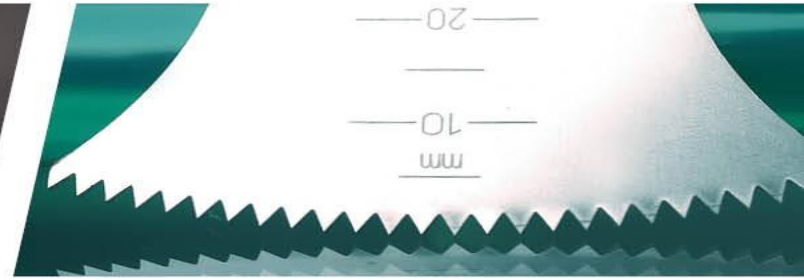
Contract Manufacturing for different Industries

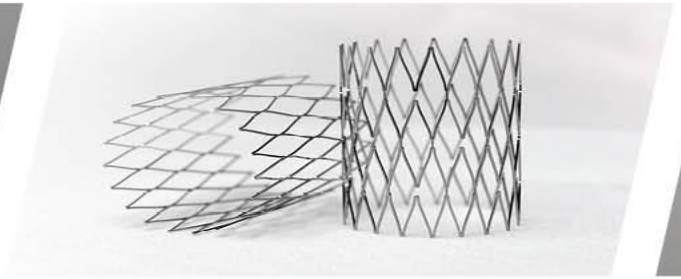
Machine Engineering
Plant Engineering
Aerospace
Automotive
Filter Industry
…

Contract Manufacturing of Medical Devices

MeKo MEDTECH







MeKo.de

30 Years of Experience

Stent Manufacturing Experts

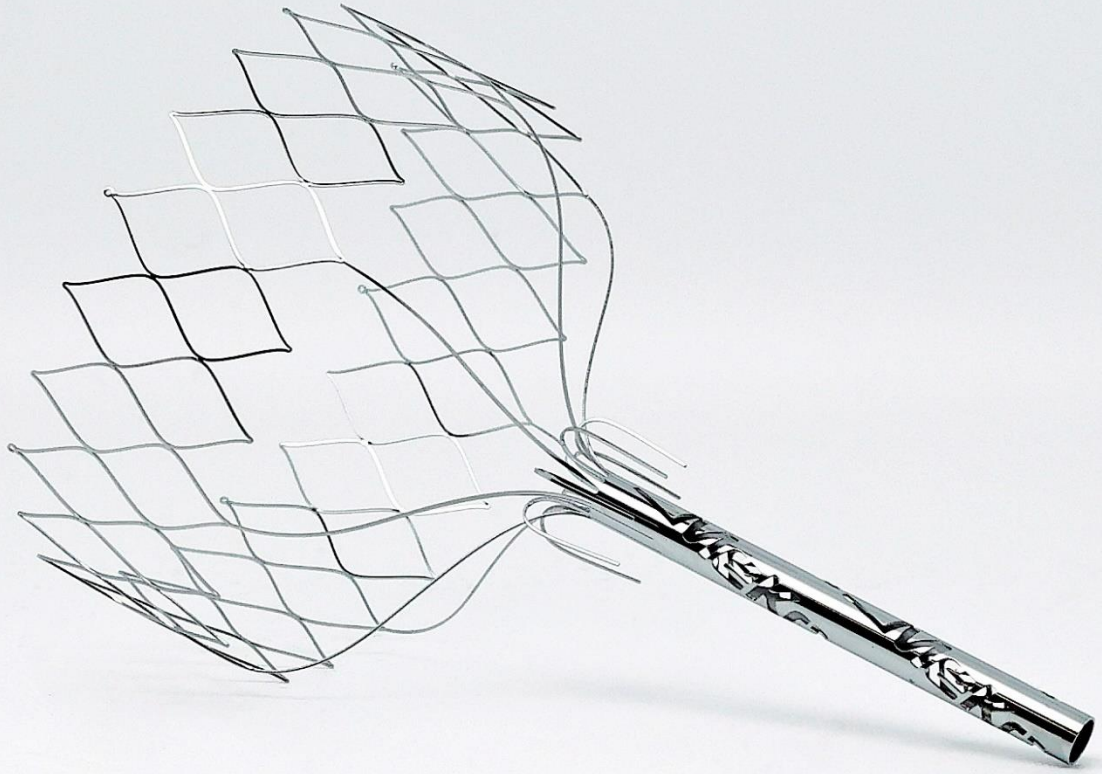
- Pioneer in stent manufacturing since 1995
- Globally active contract manufacturer
- Comprehensive material experience
- Usage of serial production machines for both prototypes and serial production
- 24/7 manufacturing and rapid prototyping
- Broad spectrum of post processing
- 100 % visual inspection of all implants

NiTi Components

Unlock the full Potential of NiTi

MeKo Manufacturing is one of the main suppliers for NiTi components worldwide

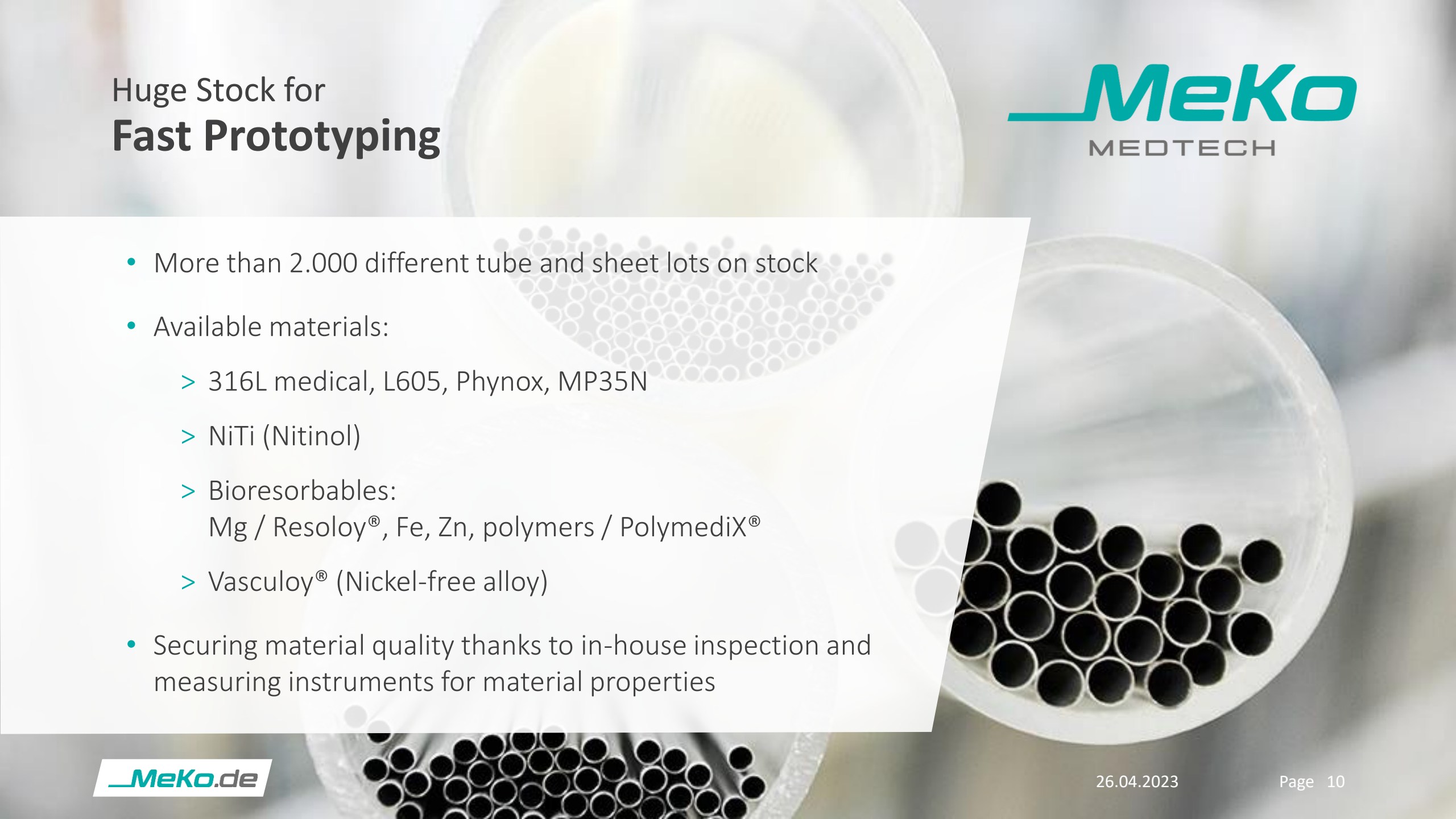
- Ideal alloy for many medical components due to its superelasticity and shape memory
- Technical support for FEA, simulation and design improvement
- Shape setting for perfect geometry and mechanical properties



Huge Stock for
Fast Prototyping

MeKo MEDTECH

- More than 2.000 different tube and sheet lots on stock
- Available materials:
  - > 316L medical, L605, Phynox, MP35N
  - > NiTi (Nitinol)
  - > Bioresorbables:
    Mg / Resoloy®, Fe, Zn, polymers / PolymediX®
  - > Vasculoy® (Nickel-free alloy)
- Securing material quality thanks to in-house inspection and measuring instruments for material properties



Manufacturing Processes
for Medical Devices

Laser Cutting / Drilling

- Nearly no limitations in cutting length and tube diameter
- Superior dimensional accuracy

Laser Welding

- Spot welding and seam welding
- In-process quality control

Heat Treatment / Shape Setting

- Extremely fine grain sizes
- Controlled heating cycles ensure reliable Af-temperature setting

Electropolishing

- Widely adjustable range of material removal

Passivation and Final Cleaning

- Automated passivation / cleaning line for consistent results
- Enhanced biocompatibility

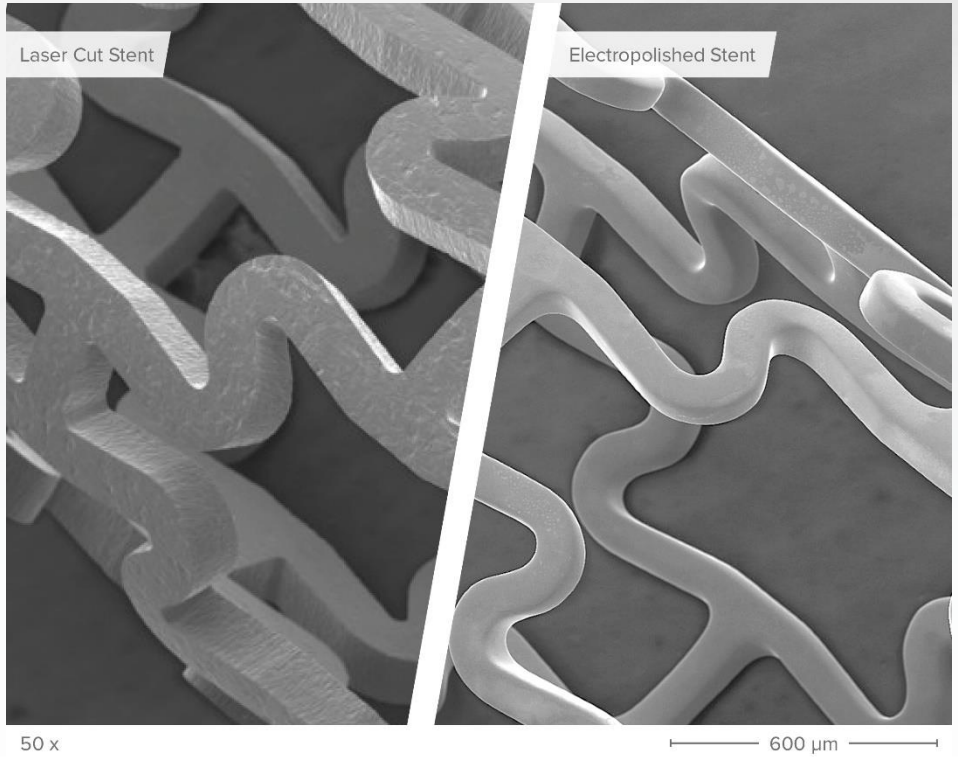
Quality Inspection

- 100 % inspection of all implants
- Visual and automatic microscopes

Manufacturing Processes

Electropolishing

- Sophisticated automated machines developed in-house
- Precise laser cut stents necessary
- Best results:
  - > Homogeneous and constant material removal
  - > Round edges
  - > Smooth metal surfaces
  - > Improved corrosion resistance



Manufacturing Processes

Quality Inspection

- Superior quality inspection
  - > 100 % final visual inspection (microscopes)
  - > Automated measuring systems
- Clean rooms (ISO 8)
- Flow cabins (ISO 5)
- In-house analysis and tests in our MeKo.LAB

Additive Manufacturing
of Metallic Implants

For the production of implants, we offer high-quality and precise metal prints - especially for complex geometries.

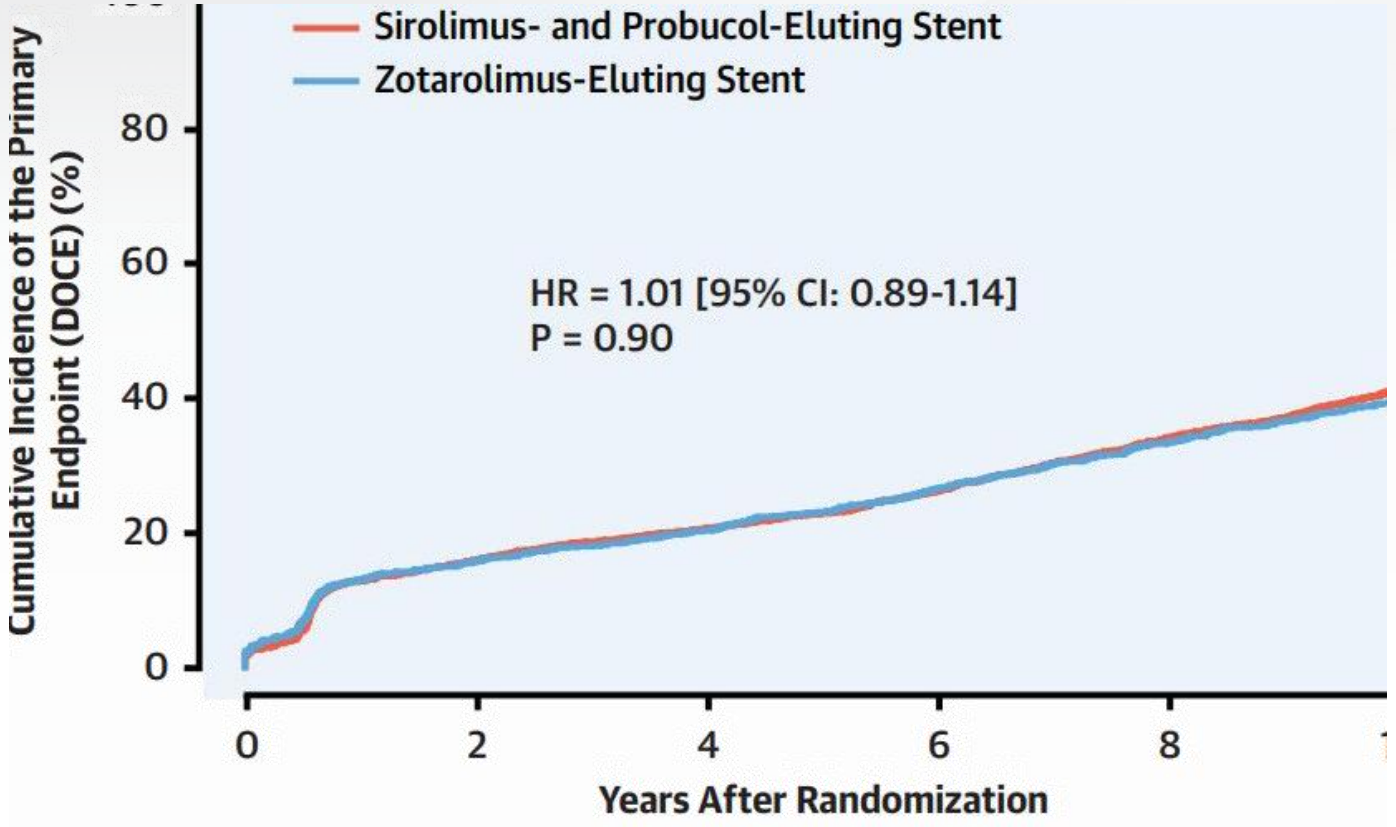
The reduced number of manufacturing steps enables a reduction in time and costs.

Workpiece specifications upon request.

Research and Development

- Production technologies for resorbable implants
  - > PolyMediX®, high-precision polymer tubes with drug integration in the tube wall
  - > RESOLOY®, the new magnesium alloy
- The alternative to the elaborated stent materials
  - > VASCULOY®, the nickel and cobalt free material for stents
- Surface conditioning
  - > ModiSurf+, surface with micro blind holes
  - > Coating technologies for magnesium

Contemporary Drug Eluting Stents (DES)



Publication:
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

Resoloy® by MeKo

MeKo MEDTECH

The magnesium resorbable alloy for implants

Patented magnesium alloy suitable for degradable medical devices:

- Stents/scaffolds (coronary, BTK, urinary tract, bile duct, etc.)
- Heart valve frames
- Clips
- Local drug delivery with coatings
- Fixation plates, fixation wires
- …

Resoloy® by MeKo Fabrication Process

MeKo

Technical Facts

270-275 MPa
>32% break elongation

Mg-alloy selection
investigation of
83 different alloys

Ingot melting
furnace
selection

Rod extrusion
extrusion
optimization

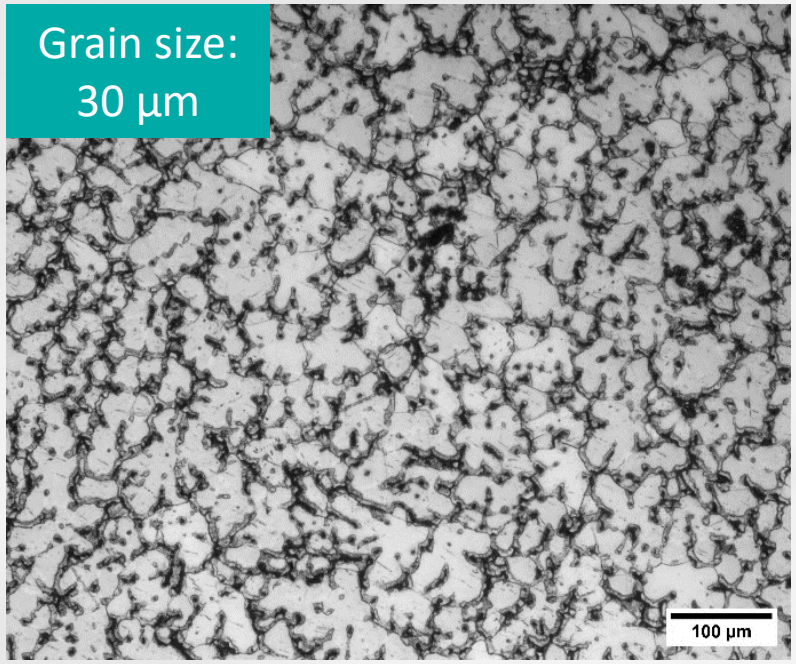
Tube extrusion
process
development

15 years of development →

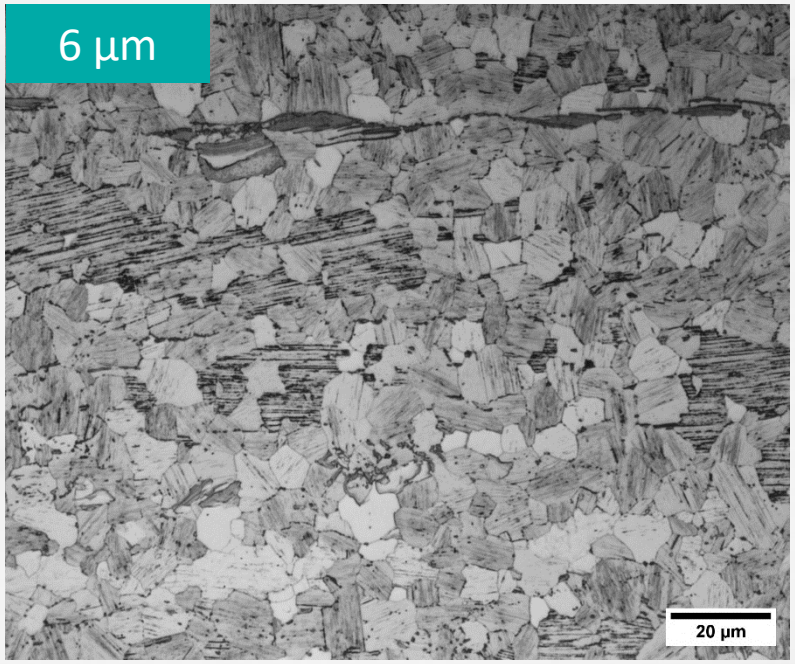
MeKo.de

Resoloy®

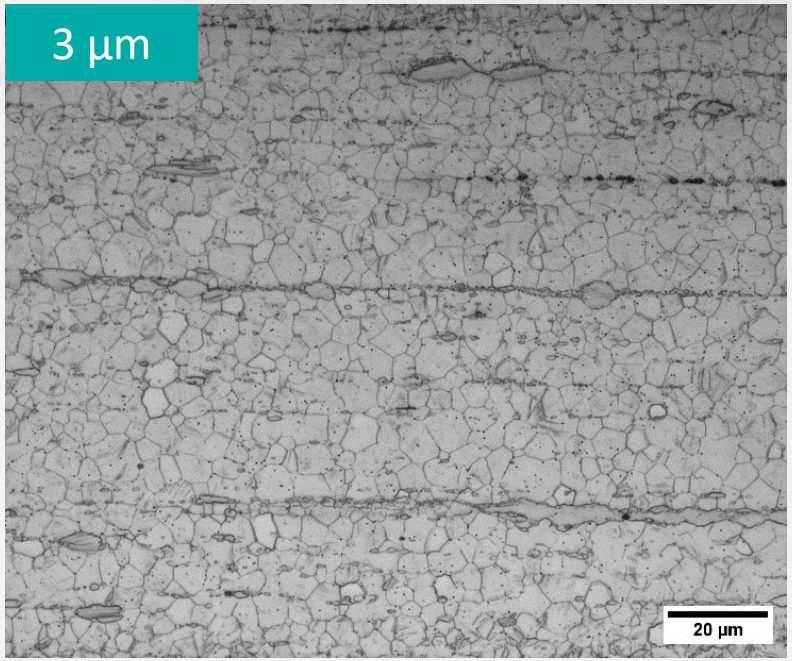
Microstructure



as cast



as extruded



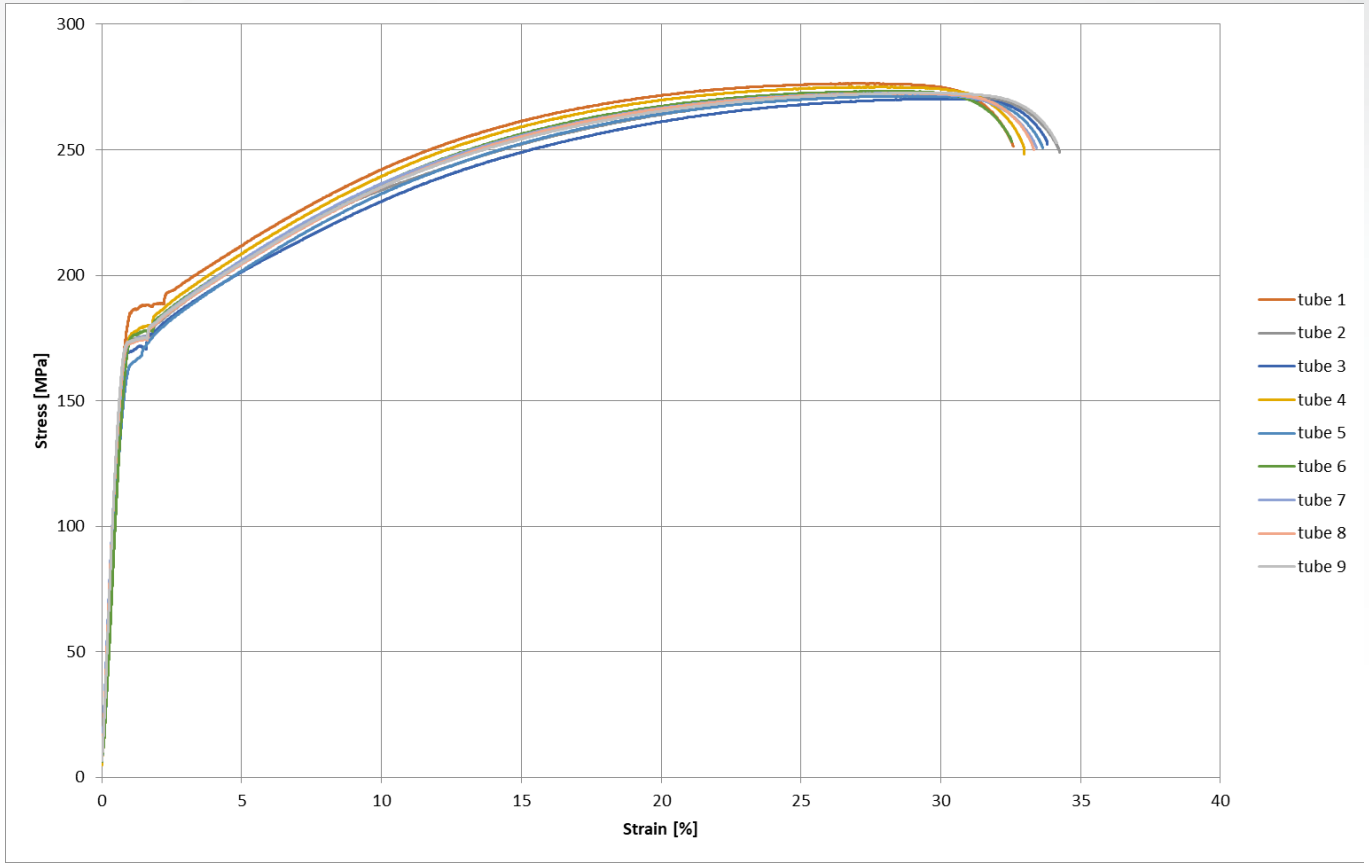
tube

Resoloy®

Characteristics

Tensile Test

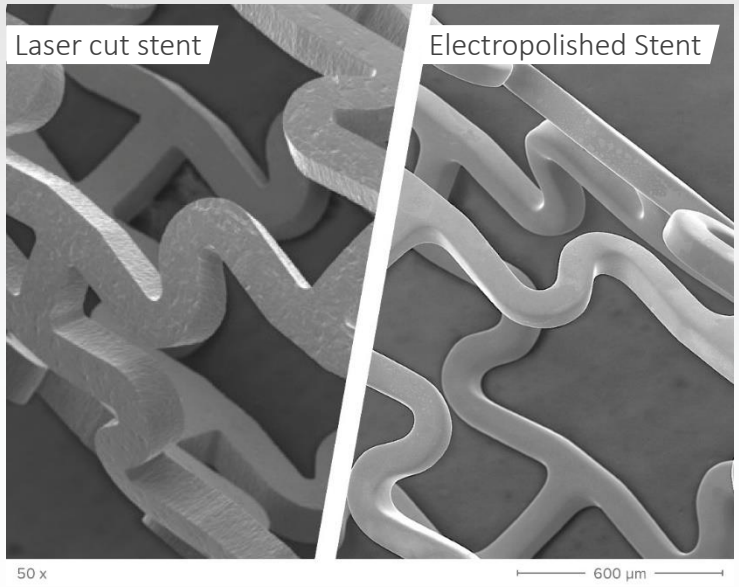
- Yield strength 170 ± 5 MPa
- Tensile strength 272 ± 2 MPa
- Strain 33 ± 1 %



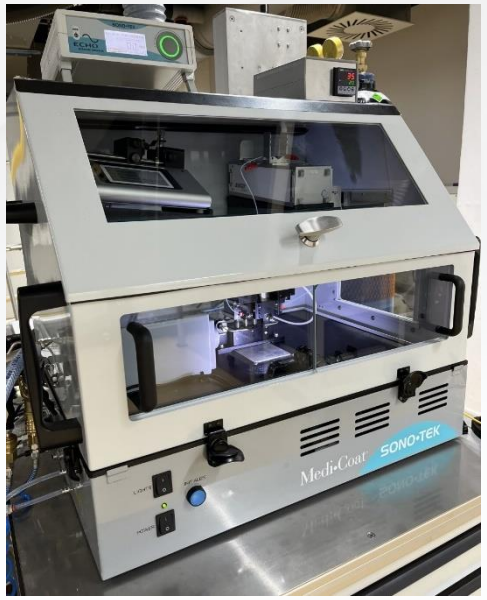
Resoloy®

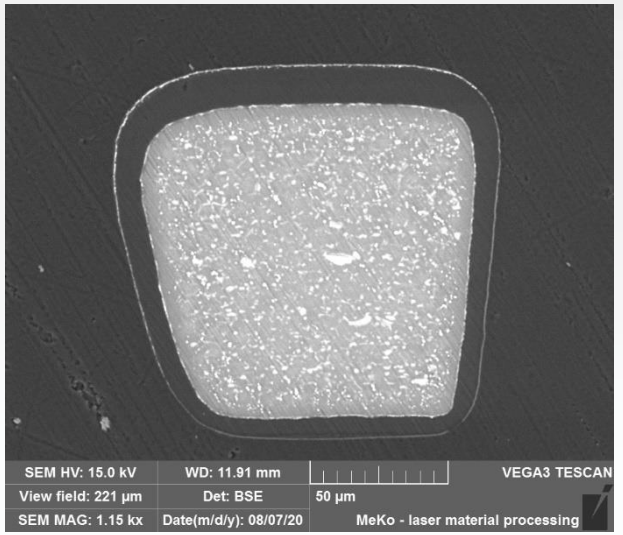
Processing Capabilities

- Laser cutting, electropolishing and cleaning



- Passivation and polymer-coating



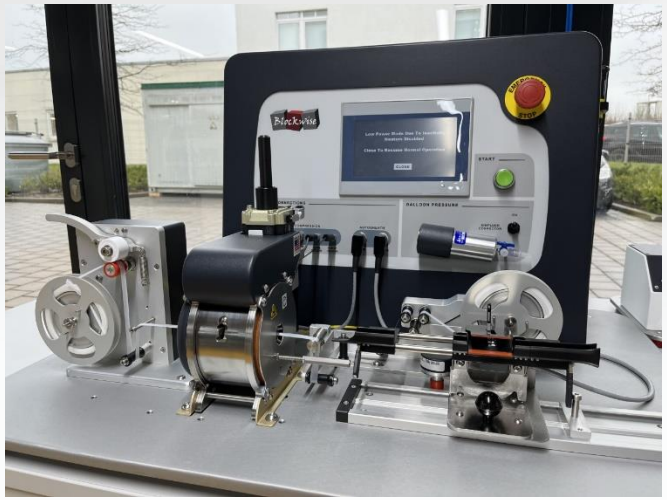


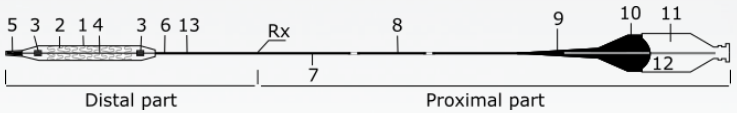
coated scaffold - cross section

Resoloy®

Processing Capabilities

- Stent/Scaffold-crimping and packaging
- Marker production and crimping
- External partner:
  OEM balloon-catheters and sterilization



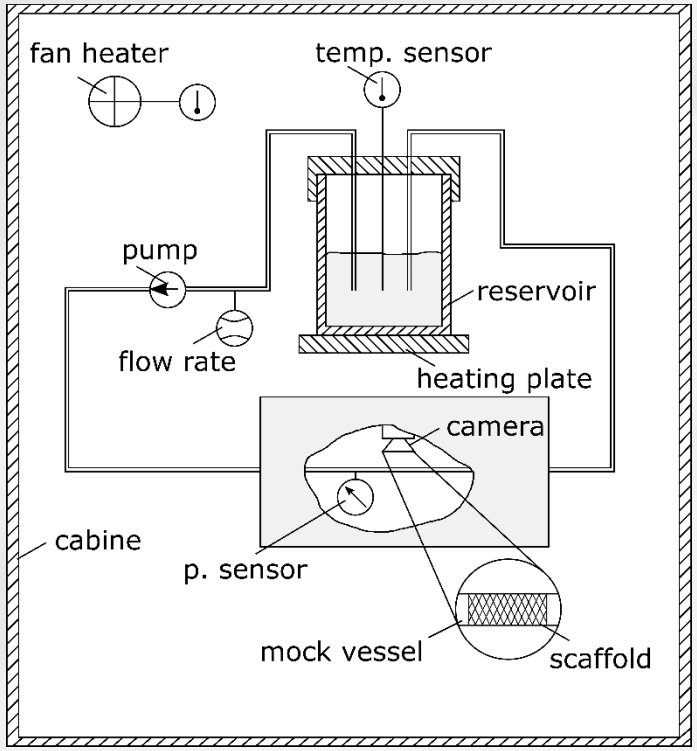


Degradation Test Machines (DTM)

- In-house developed machines
- Accelerated in vitro degradation tests of coated magnesium scaffolds
- Simulation of blood flow cycle:
  flow rate, pressure pulsation, temperature and simulated body fluids
- Investigation of the coating homogeneity
  → uniform degradation
- Degradation time versus
  coating type and thickness

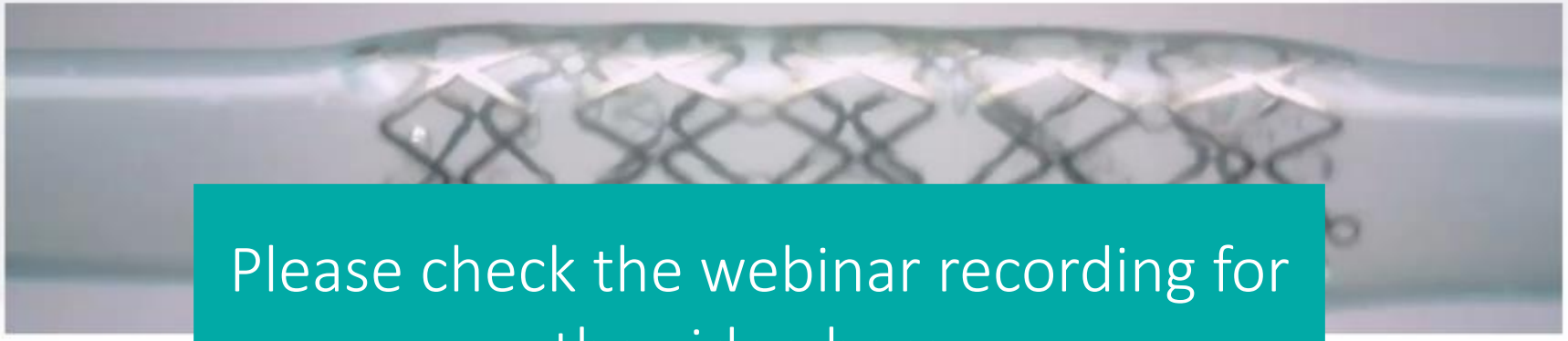
Degradation Research in a MeKo laboratory

Degradation Test Machines (DTM)



Degradation Research in a MeKo laboratory

Resoloy® Magnesium Resorption

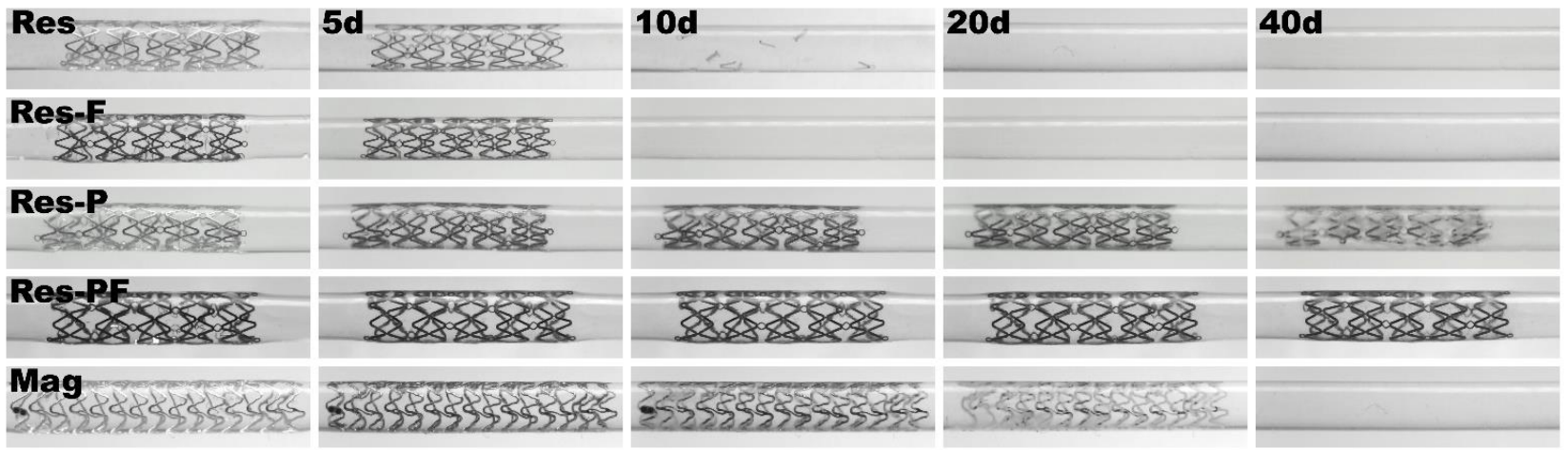


Please check the webinar recording for the video here:

https://youtube.com/@MeKoMedTech

DTM

Degradation Tests

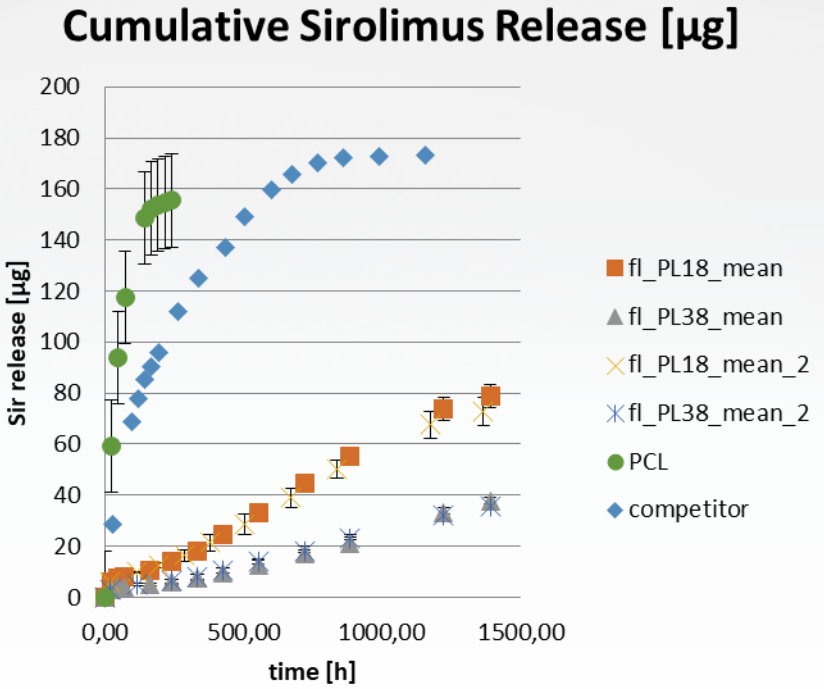


Publication:
Menze R, Wittchow E. In vitro and in vivo evaluation of a novel bioresorbable magnesium scaffold with different surface modifications. 2021 Sep. doi: 10.1002/jbm.b.34790.

Material Analysis
In vitro

- Sterile degradation tests

- Drug release via HPLC and spectrophotometer

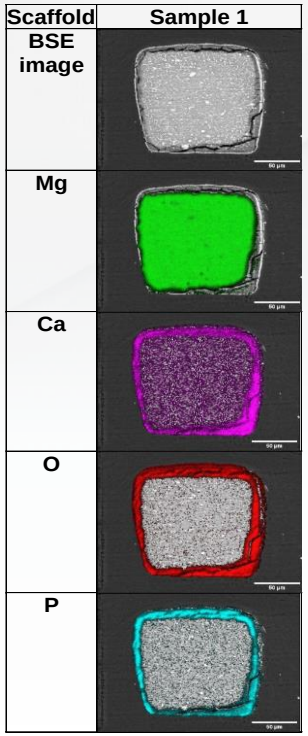


Material Analysis

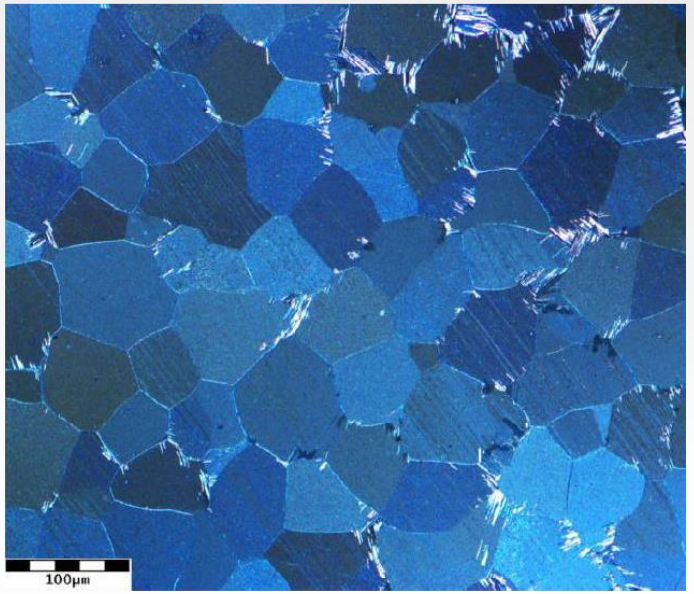
Mechanics and Microstructure

- Radial force testing

- SEM/EDX analysis

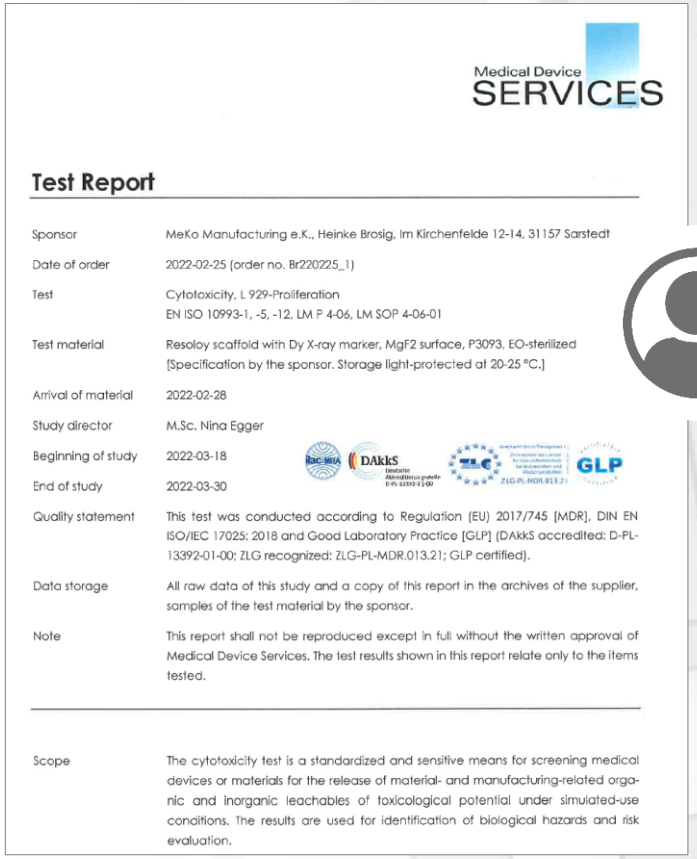


- Metallography and tensile tests



Resoloy®
Biocompatibility

Biocompatibility of Resoloy® confirmed by cytotox and hemolysis tests



Medical Device SERVICES

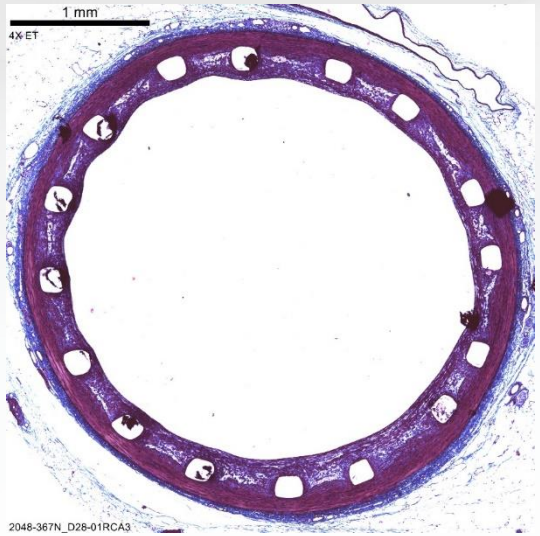
Test Report

Sponsor	MeKo Manufacturing e.K., Heinke Brosig, Im Kirchenfelde 12-14, 31157 Sarstedt
Date of order	2022-02-25 (order no. Br220225_1)
Test	Cytotoxicity, L 929-Proliferation EN ISO 10993-1, -5, -12, LM P 4-06, LM SOP 4-06-01
Test material	Resoloy scaffold with Dy X-ray marker, MgF2 surface, P3093, EO-sterilized [Specification by the sponsor. Storage light-protected at 20-25 °C.]
Arrival of material	2022-02-28
Study director	M.Sc. Nina Egger
Beginning of study	2022-03-18
End of study	2022-03-30
Quality statement	This test was conducted according to Regulation (EU) 2017/745 [MDR], DIN EN ISO/IEC 17025: 2018 and Good Laboratory Practice [GLP] (DAkkS accredited: D-PL-13392-01-00; ZLG recognized: ZLG-PL-MDR.013.21; GLP certified).
Data storage	All raw data of this study and a copy of this report in the archives of the supplier, samples of the test material by the sponsor.
Note	This report shall not be reproduced except in full without the written approval of Medical Device Services. The test results shown in this report relate only to the items tested.

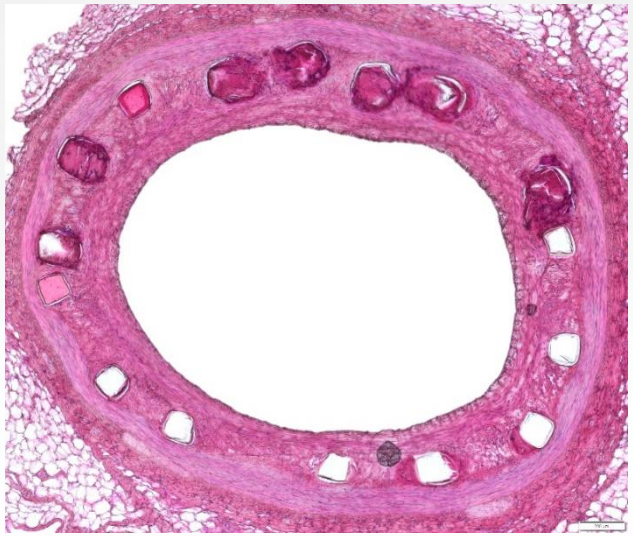
Scope	The cytotoxicity test is a standardized and sensitive means for screening medical devices or materials for the release of material- and manufacturing-related organic and inorganic leachables of toxicological potential under simulated-use conditions. The results are used for identification of biological hazards and risk evaluation.

Preclinical Trials

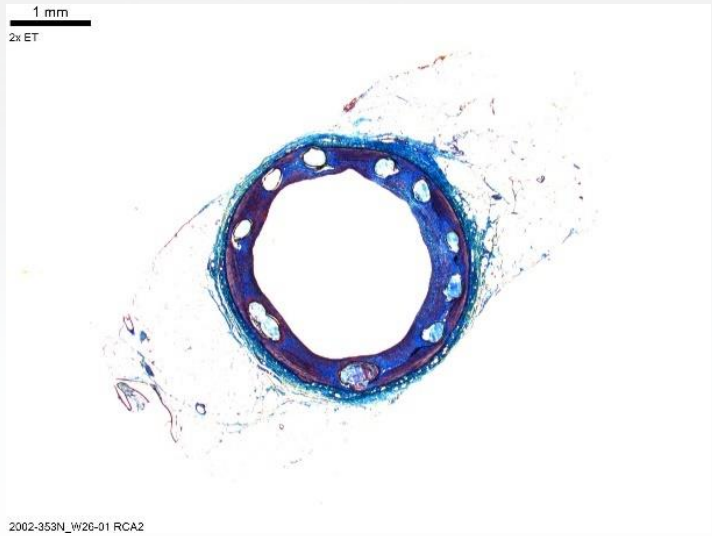
- > 100 Resoloy® scaffolds implanted in pigs and rabbits
- In vivo data for:



14d, 28d



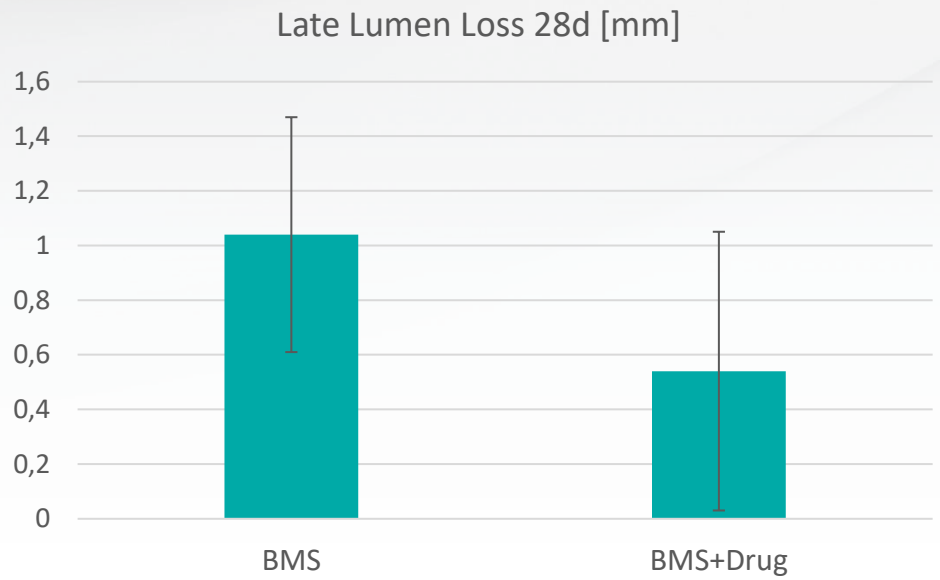
90d

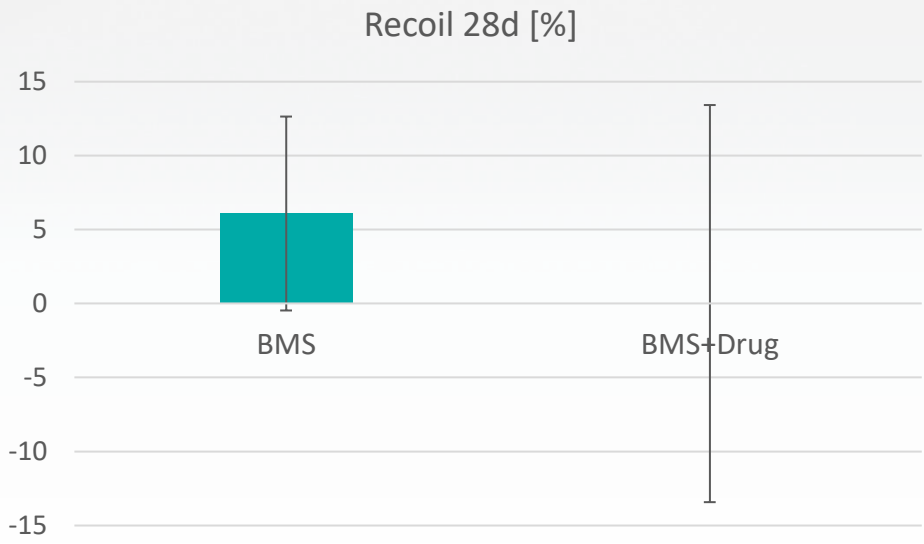


180d

Preclinical Trials

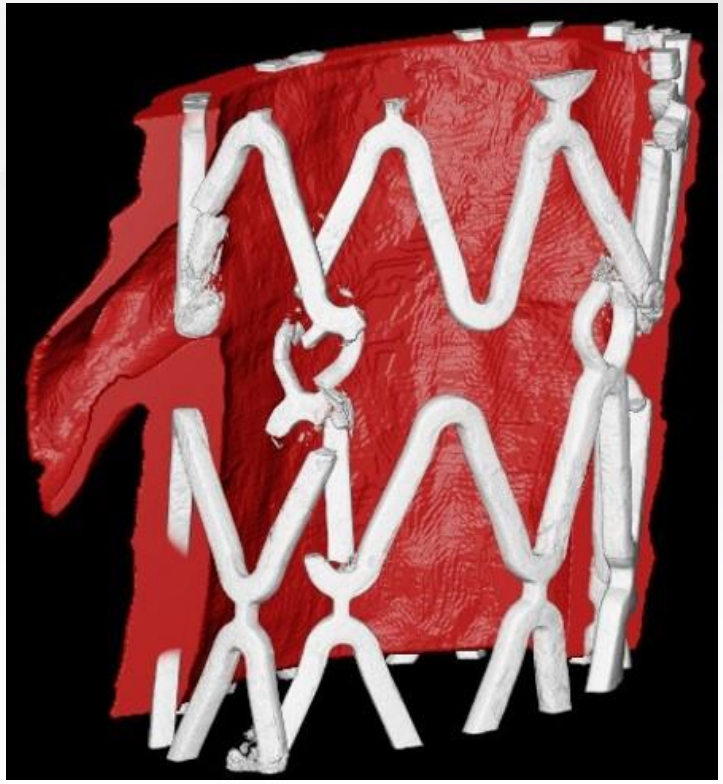
- No adverse effects
- No thrombotic events
- Complete endothelialization after 14 - 28 days





Preclinical Trials

- Synchrotron radiation based µ-CT for degradation analysis:
  - > Volumetric degradation quantification
  - > In depth analysis of strut breakages and degradation morphologies
  - > Soft tissue analyzing
- Resoloy® shows a very slow degradation rate in vivo (down to 5 vol.-% after 28 days) depending on coating and drugs



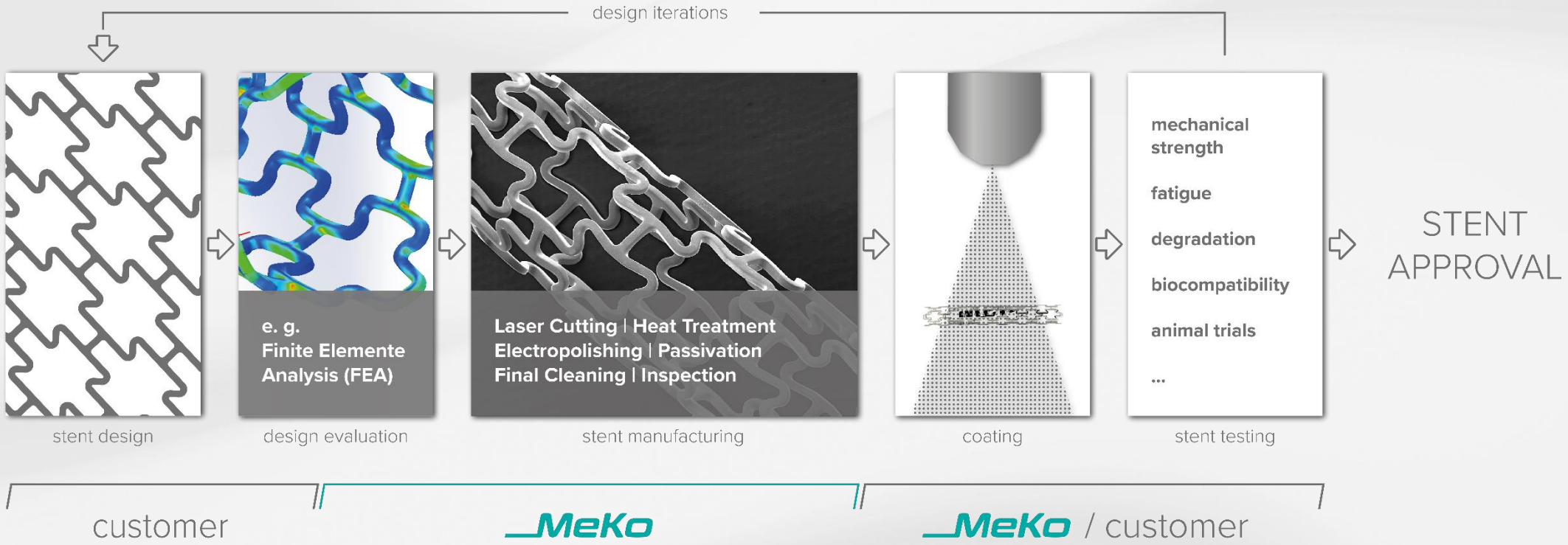
Resoloy® by MeKo

MeKo MEDTECH

The magnesium resorbable alloy for implants

- Deep scientific knowledge of magnesium processing, testing and product optimization
- Post processing steps like coating, crimping and choice of catheters
- In vitro and in vivo testing of scaffolds (degradation, drug release and bench tests)
- Big database of in vitro and in vivo trials

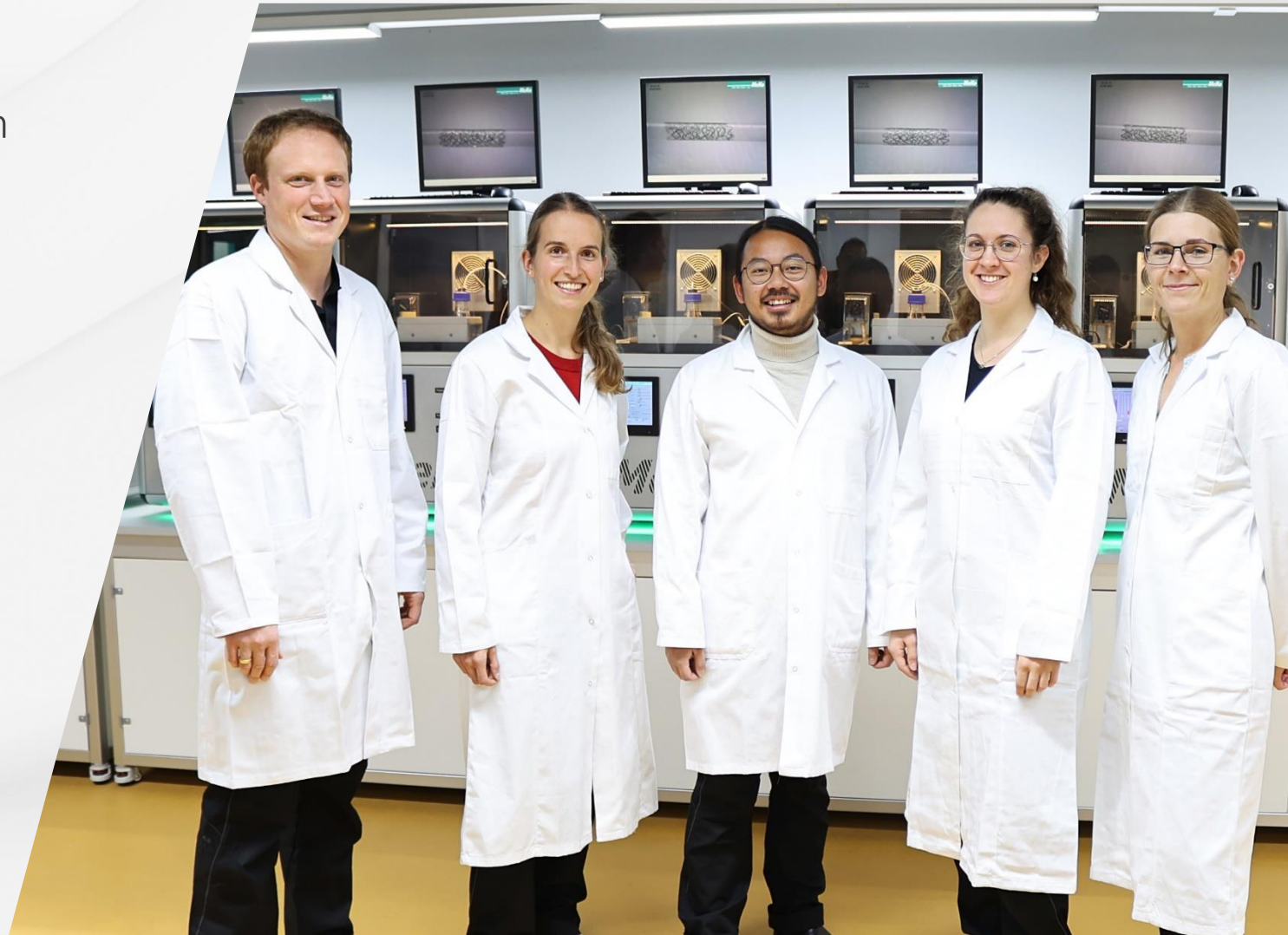
Development of
Bioresorbable Resoloy® Implants



Resoloy®

Your Project with MeKo

- Contact your MeKo Project Manager
- Connection between you and our Team Resoloy® will be established
- Opportunities for your device:
  - > Development of resorbable scaffolds
  - > Using flat or tubular materials
  - > Change of (wall) thickness and tube diameters
  - > Adjustable degradation time and mechanical properties
  - > Custom designed coatings



MeKo.de

PRECISION IS OUR PROFESSION

MeKo.de

MeKo MEDTECH

Quality you can rely on!

MeKo MEDTECH

MeKo Manufacturing e.K.
Im Kirchenfelde 12-14
31157 Sarstedt / Hannover
Germany

+49 5066 7079-0
+49 5066 7079-99
laser@meko.de
www.meko.de