

IMPLANTS / INSTRUMENTS / ORTHOPAEDICS

## MEDICAL DEVICE MANUFACTURING

PRECISION IS OUR PROFESSION

At MeKo, medical devices are manufactured to their perfection. Based on the designs of our customers, we manufacture a wide range of medical devices with small tolerances and perfect surface quality.

MeKo manufactures medical devices with quality you can rely on.

www.meko.de



MeKo is a globally active supplier specialized in laser material processing. Our ISO-certified quality management passed FDA inspections.

We manufacture medical components like stents, heart valve frames, minimally invasive instruments, bone nails, stone retrieval baskets and medical saw blades.

MeKo has more than 30 years of experience in laser cutting, laser drilling and laser welding of metals and other materials. More than 100,000 different components have already been manufactured.



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Our greatest strength is the expertise of our employees. This enables us to manufacture components at an unrivaled quality. Especially for complex queries and niche products, we are the right partner for you.

Dr. Jakob Dohse and Dr. Clemens Meyer-Kobbe



### Full flexibility for your device

With its extremely precise laser systems, MeKo processes flat and tubular materials such as stainless steel and nickel titanium as well as new bioresorbable materials like magnesium alloy and bio-polymers. More than 2,000 materials and tube sizes are available in stock.

Thanks to the 24/7 manufacturing and our rapid prototyping, orders can be processed quickly. The components are shipped worldwide. As MeKo uses its series production machines for prototyping, it is possible to convert to series production with high quantities with little effort.

Thanks to our actions to maintain technological leadership, clients receive an added value for their products.

Dr. Clemens Meyer-Kobbe (CEO) and Dr. Jakob Dohse (CEO)

### **MEDICAL DEVICES**



Orthopaedic Devices / Balloon with Microholes / Bone Nails

### Implants, Instruments and **Orthopedic Devices**

#### MeKo's manufacturing processes are adjustable to almost any design.

We manufacture implants for all medical branches like cardiology, radiology, neurology, ophtalmology and urology.

- Implants: stents, heart valve frames, spinal cages,...
- Instruments: for minimally invasive surgery (MIS), clot and stone retrieval baskets, bone saw blades and root-canal files,...
- Orthopedic devices: prostheses, ortheses,...

With our modern ultrashort-pulse lasersystems (USP), we achieve smallest tolerances. The USP-systems are used for microcomponents or microhole drilling for Drug Delivery Balloon Catheters (DBB) with hole-diameters from  $2\,\mu m$  on.

Stone Retrieval Baskets



### The Stent Manufacturing Experts

MeKo has been the pioneer in stent manufacturing since 1995. Today, we are one of the largest stent contract manufacturers worldwide and considered a quality leader. Thanks to unique processes and our expertise, we bring even most challenging projects to life.



### **NITI COMPONENTS**

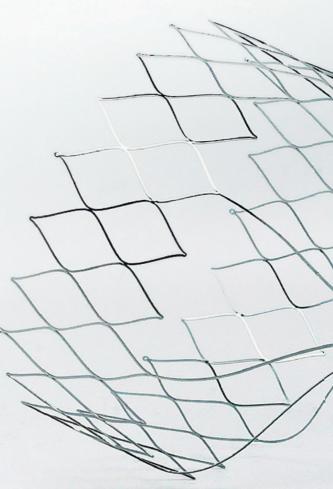
### Unlock the full potential of NiTi

With our profound expertise as pioneer in stent manufacturing and our technological leadership, today we are one of the main suppliers for NiTi components like stents and valves worldwide.

Our high-precision laser cutting, combined with a stable and reliable shape setting process, ensures perfect geometry and reliable mechanical properties for the manufacturing of your NiTi devices.

#### MeKo is your specialist for NiTi components:

- Perfect geometry
- Highest surface quality
- Superior corrosion resistance
- 100 % visual inspection





### **EXPERIENCE IN QUALITY**

High level in-process inspection mechanisms fulfill stringent quality requirements.

Final visual inspections ensure a quality MeKo's clients trust. More than 100 special high-end microscopes are available to ascertain quality at any stage of manufacturing.

Clean rooms according to ISO 8 (Class 100,000) are available. Extensive tests are performed in our laboratories.



ISO 8 Clean Room

Fite ut more: www.meko.de/niti

### PROFESSIONAL MEDICAL DEVICE MANUFACTURING

MeKo's production is optimized for a maximum flexibility with best quality

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#### CAD / CAM

- Import of your design
- Finite Element Analysis (FEA)

#### Material / Tube Selection

We use material of highest quality only and perform a 100% incoming inspection.

- Stainless Steel: 316L medical (316LVM), Cobalt Alloys: L605, Phynox, MP35N
- NiTi (Nitinol)
- Magnesium: Resoloy<sup>®</sup>
- Nickel Free: Vasculoy®
- Polymers: PolyMediX<sup>®</sup>, PLLA, PGA, ...

#### Precise Laser Cutting / Drilling

- High-end laser systems
- Precise, burr-free laser cutting
- Tolerances less than  $\pm\,5\,\mu\text{m}$  (± 0.0002")

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#### Laser Welding

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

#### **3D Metal Printing**

- Any component geometries
- Stainless steel, titanium, ...
- High precision: Tolerances  $\pm$  0,2 %, for smaller parts less than  $\pm$  100  $\mu m$
- High resolution: Minimum detail size x = 100  $\mu$ m, y = 100  $\mu$ m, z = 20  $\mu$ m

#### Heat Treatment / Annealing

- Extremely fine grain sizes
- For CoCr: LowElast process for precise
  adjustment of mechanical properties
- For NiTi: Shape setting and Af temperature setting

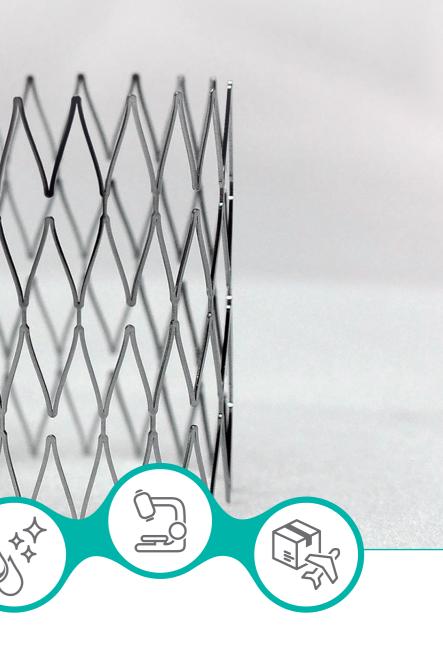
#### Electropolishing

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- Special equipment developed in-house
- Exceptional smooth surfaces
- Round edges
- Superior corrosion resistance

#### Marker Crimping

• Pressing-in and welding for a wide selection of materials, e.g. Ta, Au, Pt, Pt-Ir



#### **Passivation and Final Cleaning**

- Automated passivation / cleaning line for consistent results
- Superior corrosion resistence verified by potentiodynamic measurements

#### **Quality Inspection**

- 100% inspection of all implants
- More than 100 special high-end microscopes visual and automatic

### Packaging & Shipping

- Worldwide shipping
- Express delivery

### RESEARCH AND DEVELOPMENT

# Research for your competitive advantage

MeKo's R&D teams develop new customeroriented solutions in close cooperation.

With our R&D competence, we develop e.g.:

- ultrathin devices
- new materials like Vasculoy<sup>®</sup>
- biodegradable materials like bio-polymers (PolyMediX<sup>®</sup>) and magnesium (Resoloy<sup>®</sup>)
- new surfaces
- better material properties
- better manufacturing processes.



Degradation Test Lab (DTM)



## \_Meko.LAB

Medical devices, especially implants, require outstanding quality, which can only be achieved by controlled processes and continuous inspections and measurements.

Our MeKo.LAB offers extensive inspection and measurement procedures.

### Inspection and Measurements

- More than 120 stereo microscopes (Olympus, Zeiss, Leica, Vision Engineering) and more than 100 special telecentric high-end inspection microscopes
- Stent scanners
- Rotational scanner
- Automated 2D/3D measuring systems
- Confocal laser scanning microscope
- Tensile testing

Stent image of a Scanning Electron Microscope (SEM)





High-precision bioresorbable polymer tubes with drug integration. www.meko.de/polymedix



Proprietary unique magnesium alloy for bioresorbable scaffolds. www.meko.de/resoloy



Nickel- and cobalt-free alloy for allergic patients. www.meko.de/vasculoy

#### Radial strength testing

- Cross-section and grain analysis
- Surface roughness analysis
- Scanning electron microscopes (SEM)
- Energy dispersive X-ray spectroscopy (EDS)
- Bend and free recovery (BFR)
- Degradation tests of bioresorbable materials
- Differential scanning calorimeter (DSC)
- ...







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