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MeKo MEDTECH

MedTech Materials Webinars

NiTi

Find out what you need to know when manufacturing NiTi components to ensure perfect geometry and consistent mechanical properties.

JUNE 28, 2023
5 to 6 p.m. CEST, UTC+2

JUNE 29, 2023
9 to 10 a.m. CEST, UTC+2

Register now for free:
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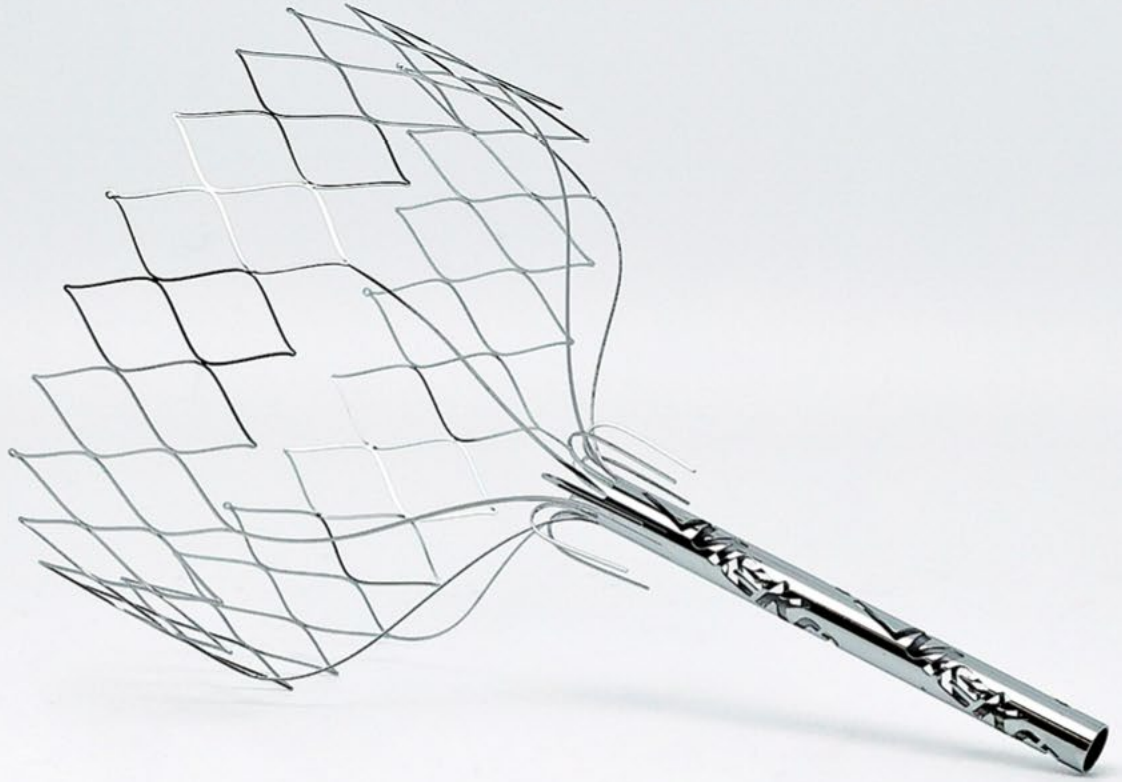
UNLOCK THE FULL POTENTIAL OF NITI.



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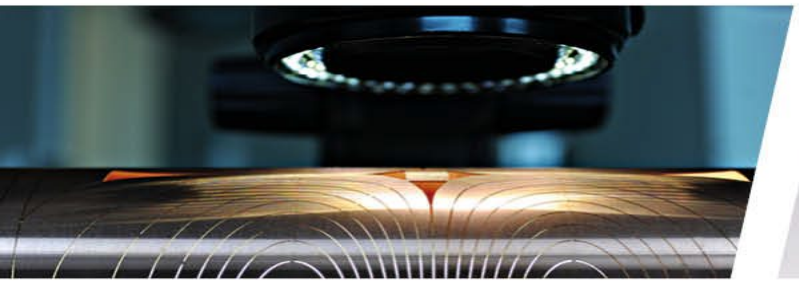

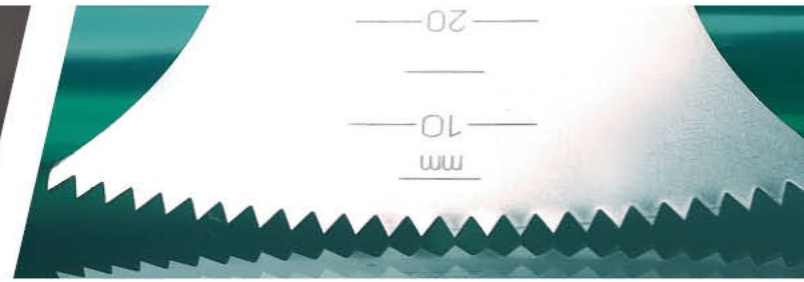


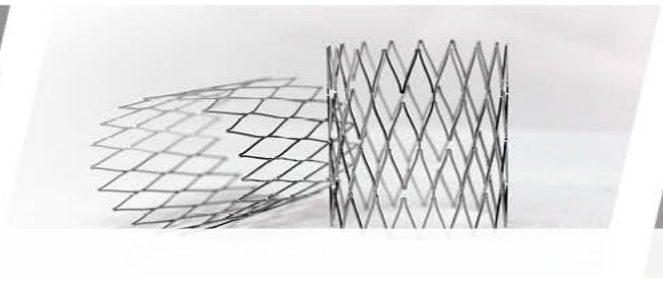
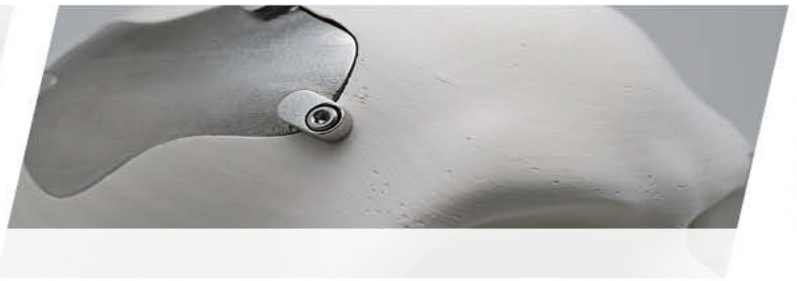


NiTi

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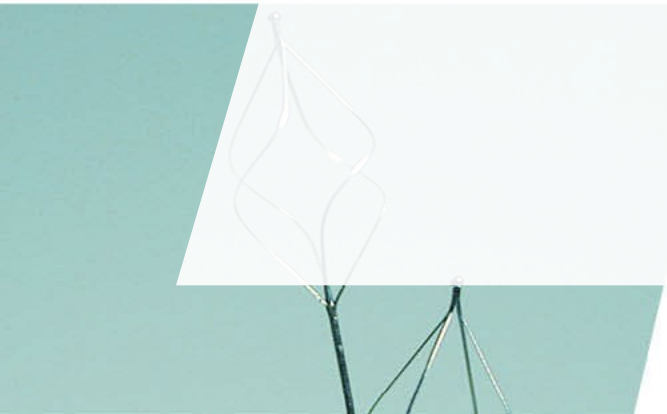


29.06.2023

Agenda

MeKo Manufacturing e.K.

MeKo MEDTECH

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

Business Units

MeKo MANUFACTURING

MEDTECH

Contract Manufacturing of Medical Devices

Cardiology
Radiology
Neurology
Ophthalmology
Urology
…

METALWORKS

Contract Manufacturing for different Industries

Filter Industry
Aerospace
Automotive
Machine Engineering
Plant Engineering
…

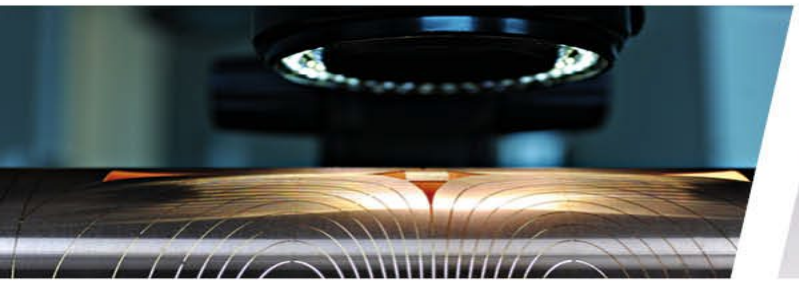
ISO 13485

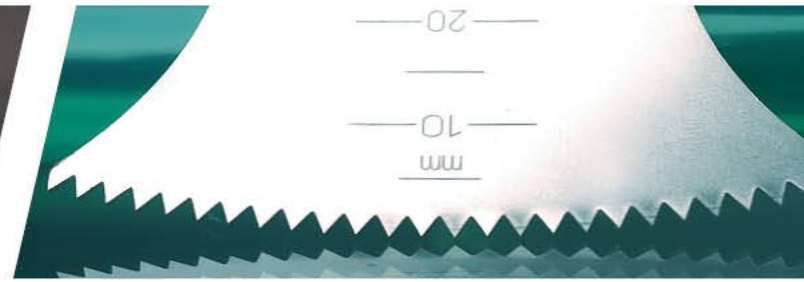
30 Years of EXPERIENCE

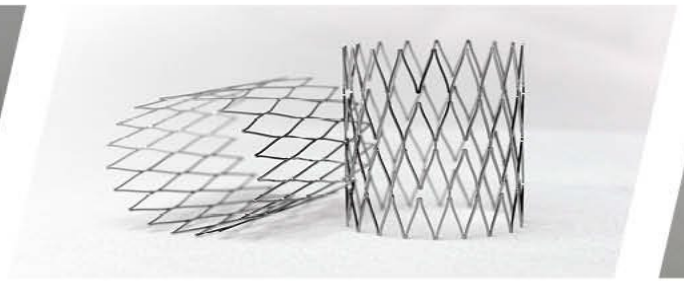
Made in GERMANY

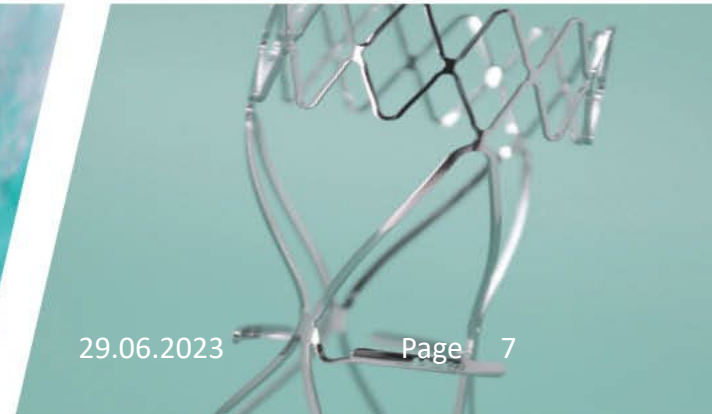
Contract Manufacturing of Medical Devices

MeKo MEDTECH









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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

Range of Activities
for Medical Devices

Laser micro machining	Laser cutting / welding / drilling
Post processing	Heat treatment / Shape setting / Electropolishing
	Passivation / Final cleaning / Quality inspection

Additive Manufacturing
of Metallic Implants

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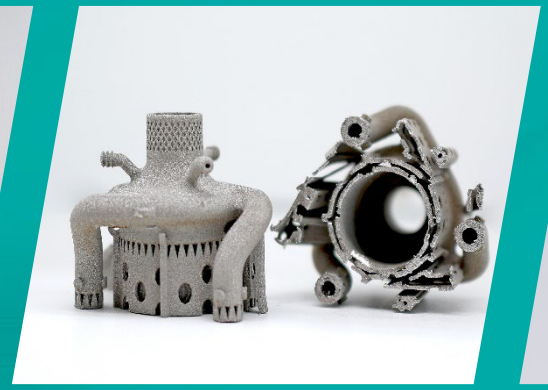
For the production of implants, we offer high-quality and precise metal prints - especially for complex geometries.

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

Workpiece specifications upon request.

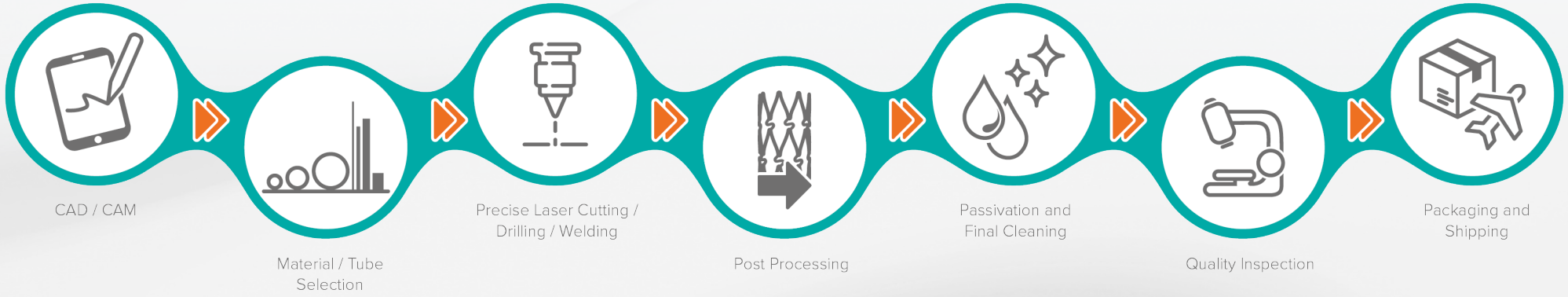

Research and Development

- 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

Manufacturing Options

Rapid Prototyping

‚It's really great to have production parts at rapid prototyping speeds, very cool.'



Manufacturing Options

Rapid Prototyping

- Each implant starts out as a prototype giving you good feedback of where you are at terms of long-term feasibility
- We make sure that the prototype from the beginning is as close to a serial production part as somehow possible
- Usage of serial production machines as well for prototypes leads to a very smooth and efficient upscaling process

Huge Stock for

Rapid Prototyping

- 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

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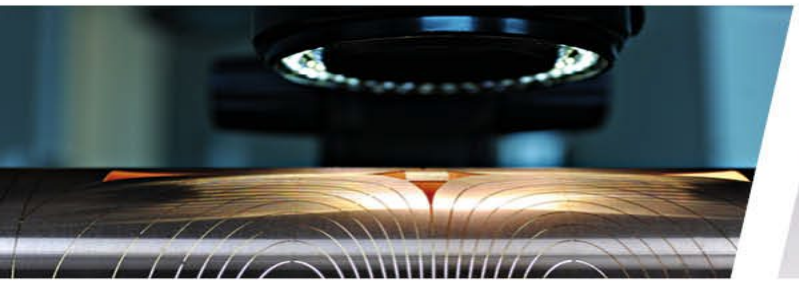
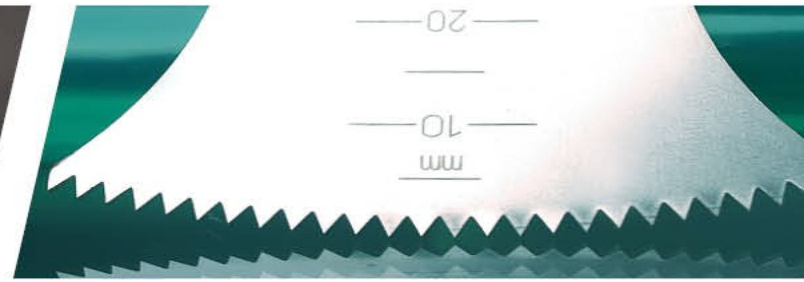
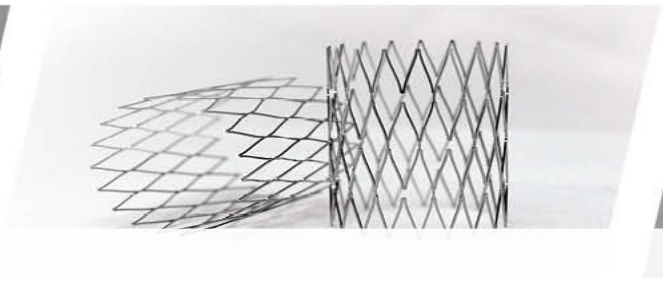
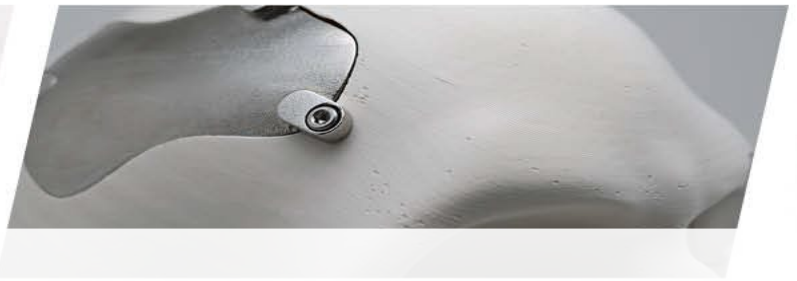
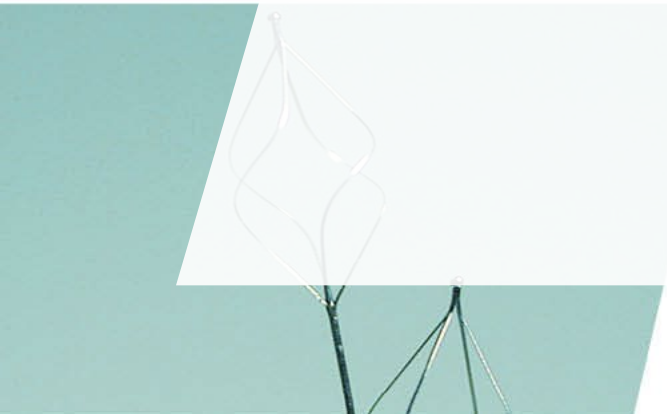





NiTi

UNLOCK THE FULL POTENTIAL OF NITI



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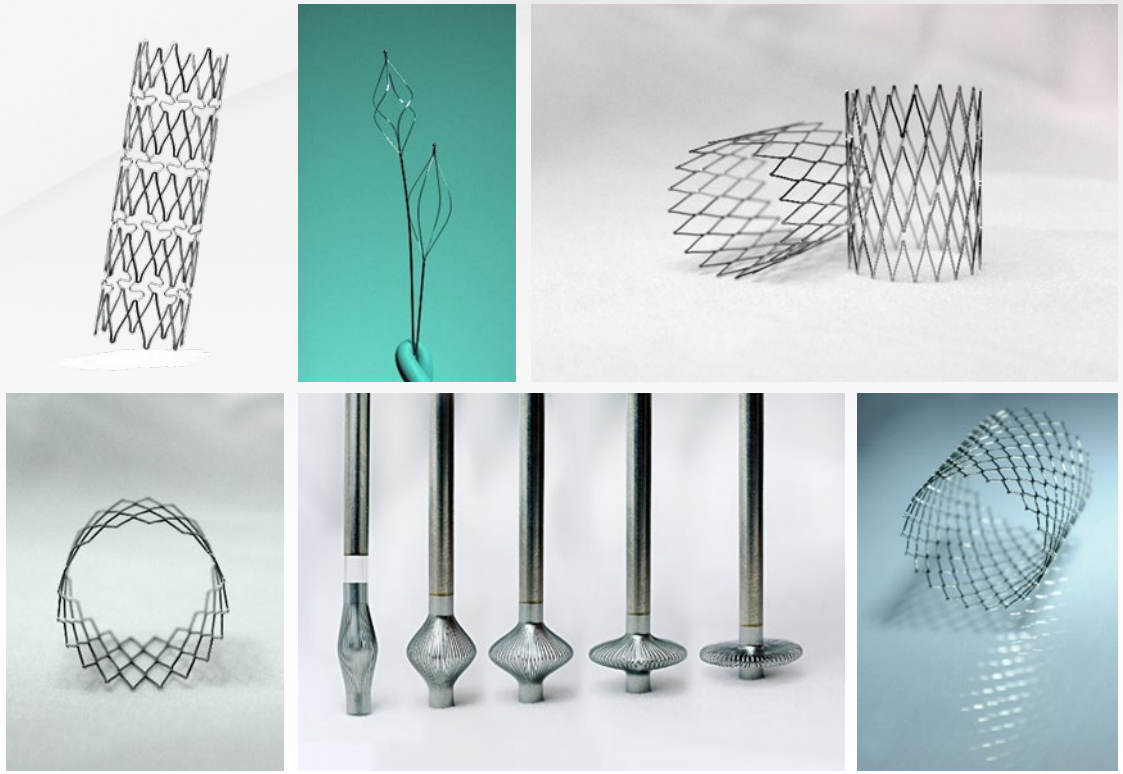
Why using NiTi?

- NiTi or Nitinol is an intermetallic bound of Nickel and Titanium
- Preloaded stress is making the material flexible and springy – leading to the known super elasticity
- NiTi alloys are reversing to its original shape after deformation:
  - > After changing the temperature >> thermal shape memory
  - > Due to stress induced phases leading to super elasticity >> mechanical shape recovery
- Thermal processes allow complex shaping and tuning of the material for having specific properties at defined temperatures
- This ability plus the excellent biocompatibility makes the material predestined for medical applications

Typical products made from NiTi

Production portfolio is strongly increasing

- Stents
  - > Neurological
  - > Peripheral
  - > Thrombectomy
- Valve frames
  - > Aortic
  - > Tricuspid, Mitral
  - > Occluder
- Stone Baskets
- Guide catheters

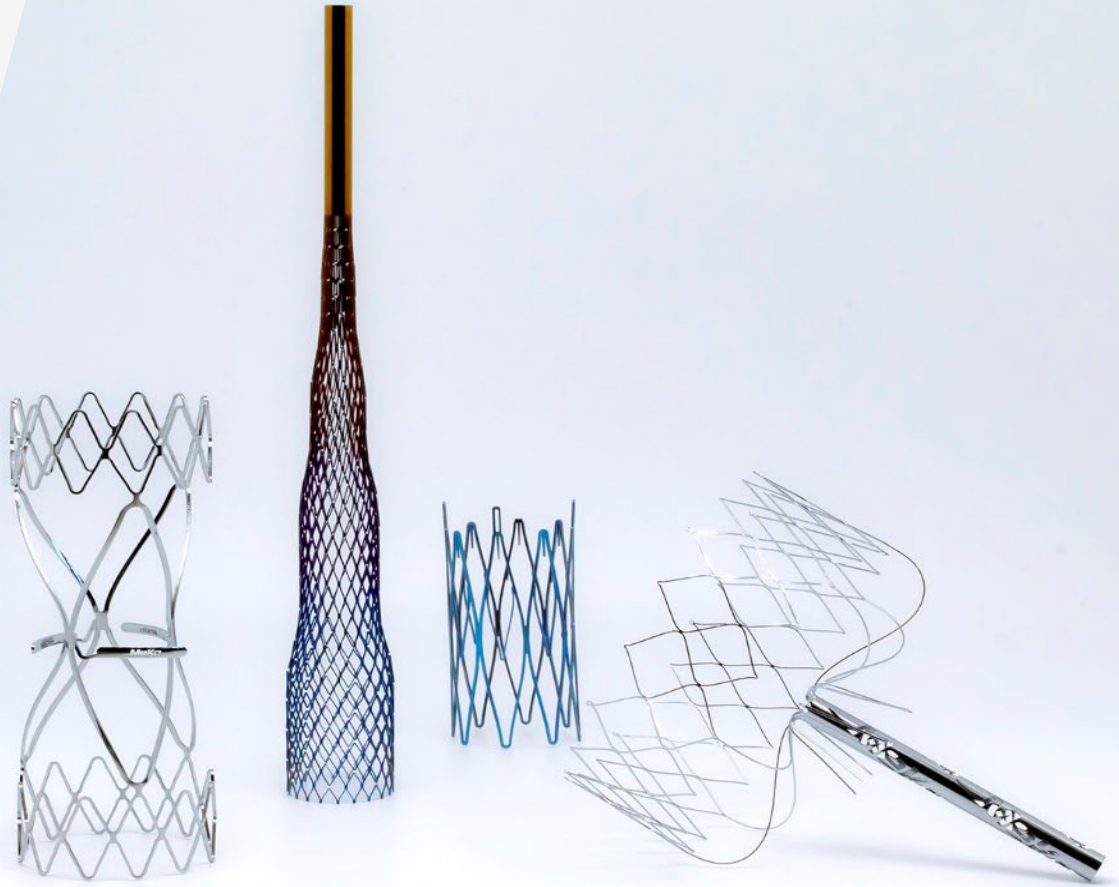


Precision is our profession

What is required to manufacture reliable medical components made from NiTi?

- Professional manufacturing and related tests
- A good understanding of the material in relation to the applied processes is essential

Let’s speak about key features of the production of NiTi components



All starts with the laser

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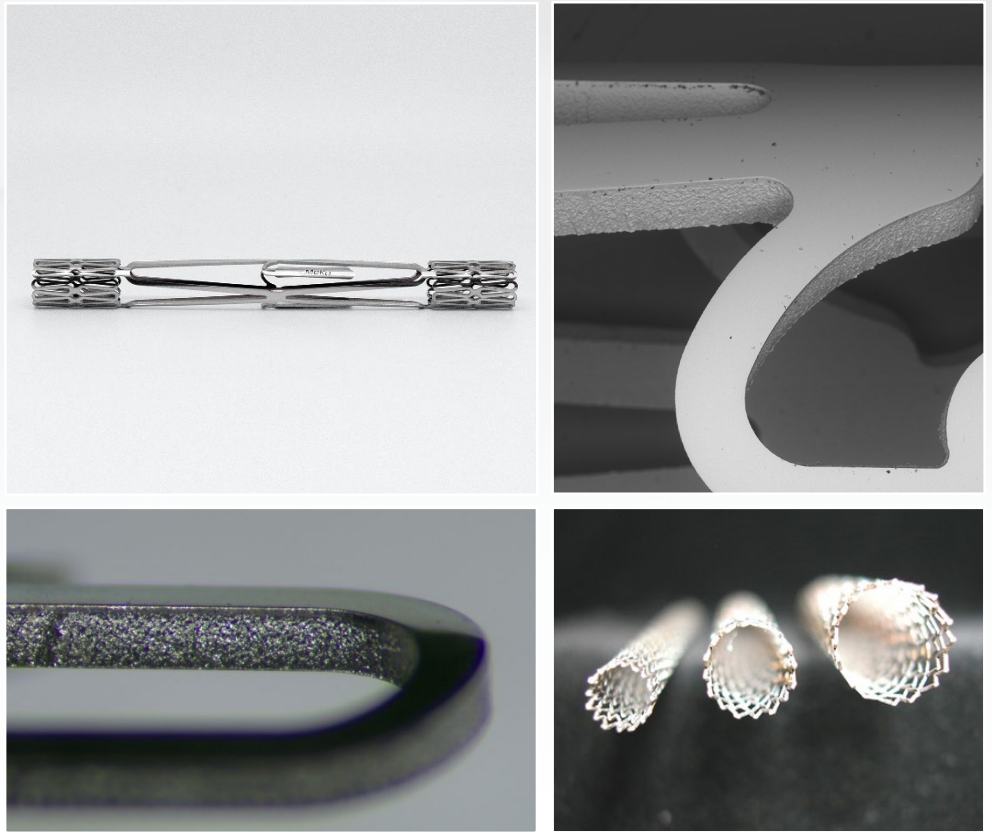
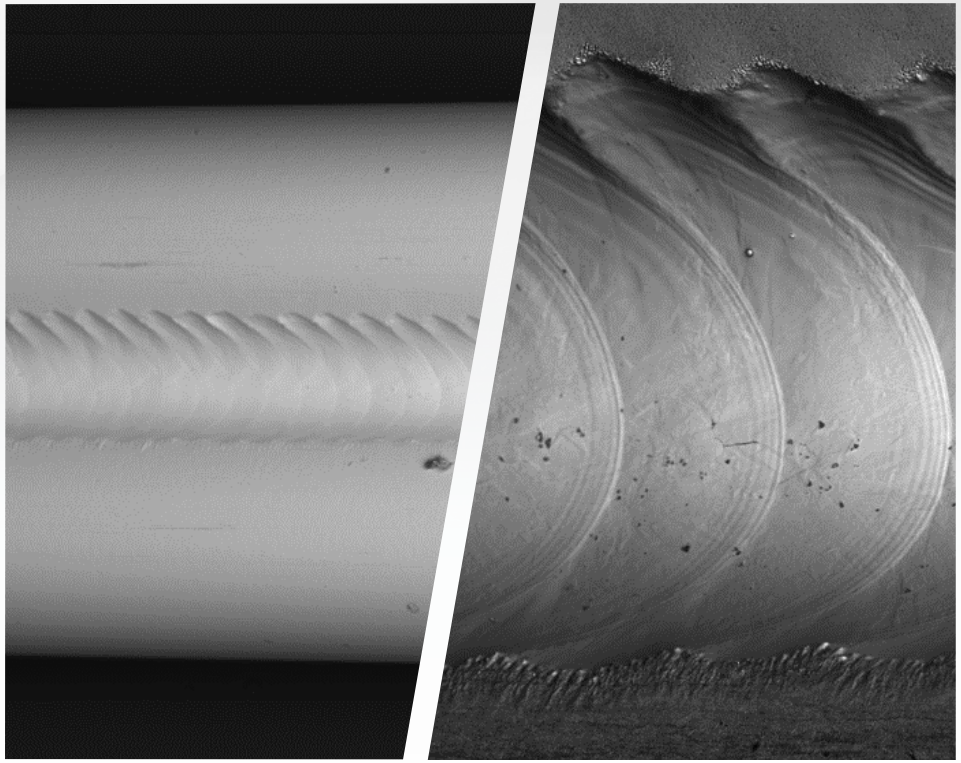
Cutting quality matters – not only dimensionally

- Laser cutting technologies
  - > Classic fiber laser
  - > Short pulse laser
- NiTi is heat sensitive
- Dimensional accuracy as well as surface quality is essential
- Typical tolerances at cutting are in the range of ± 10 µm



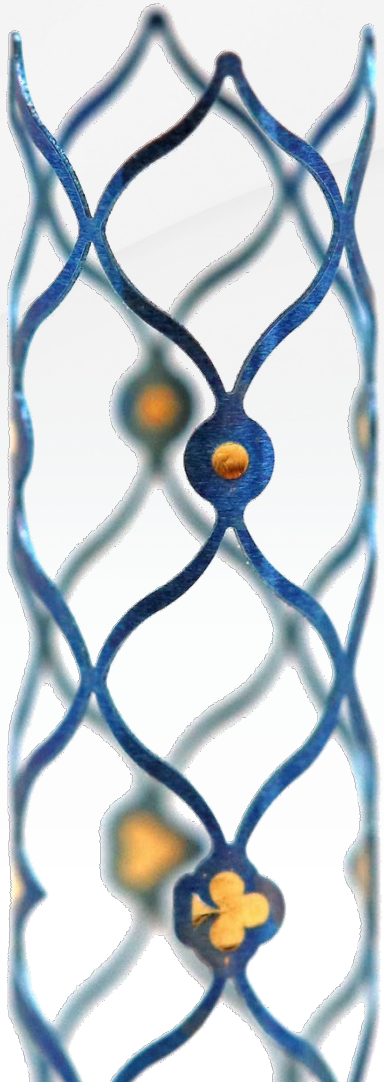
Welding of NiTi

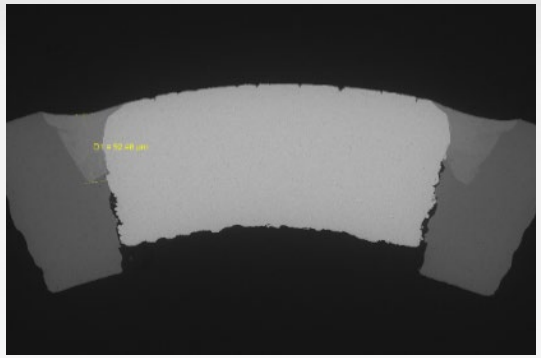
- Welding of NiTi is beneficial
- Requires defined surrounding condition
- Very efficient and reliable solution
- Typical welding combinations are
  - > NiTi / NiTi
  - > NiTi / Ta
  - > NiTi / MP35N

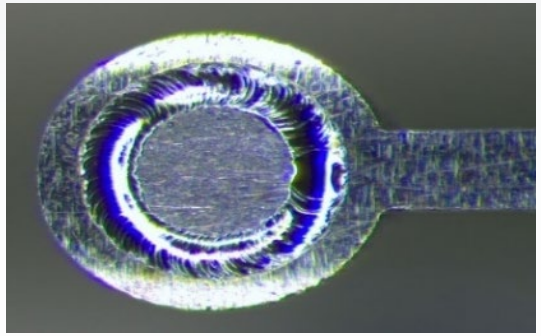


Marker welding and crimping

- Crimping or welding marker in NiTi is required to make parts visible
- Many material/shape combinations are possible
- Typical marker materials are Pt-Ir, Pt, Au, Ta
- Some of them can be welded to NiTi







Set the shape // tune the properties

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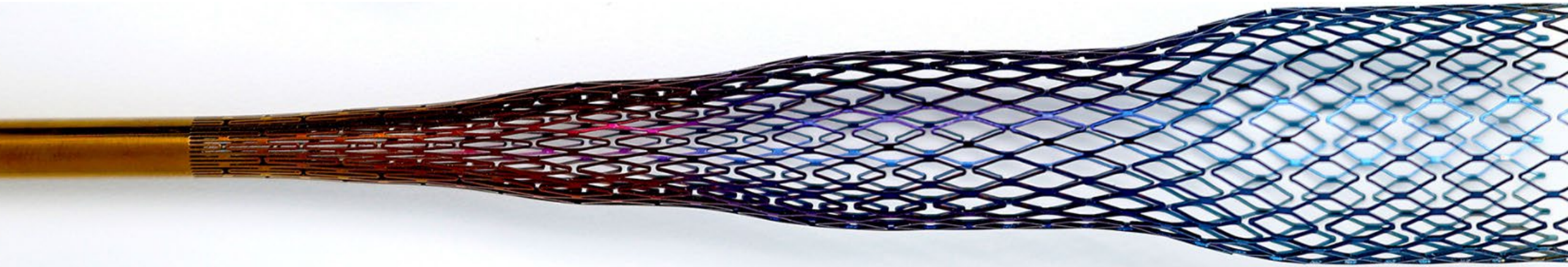
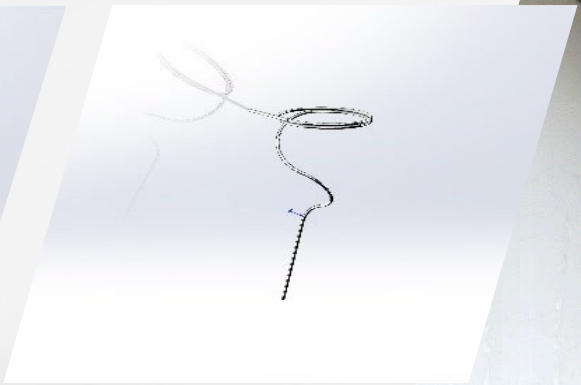
Precise heat treatments are essential

- To thermally shape set the geometry
- To adjust - tune the transformation temperature
- Multiple treatment steps are common
- Different heating concepts are applied



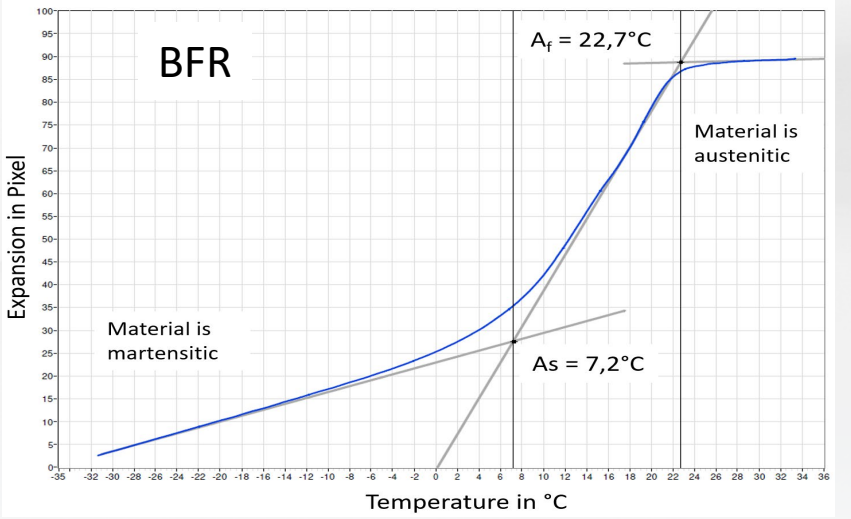
Set the shape // tune the properties

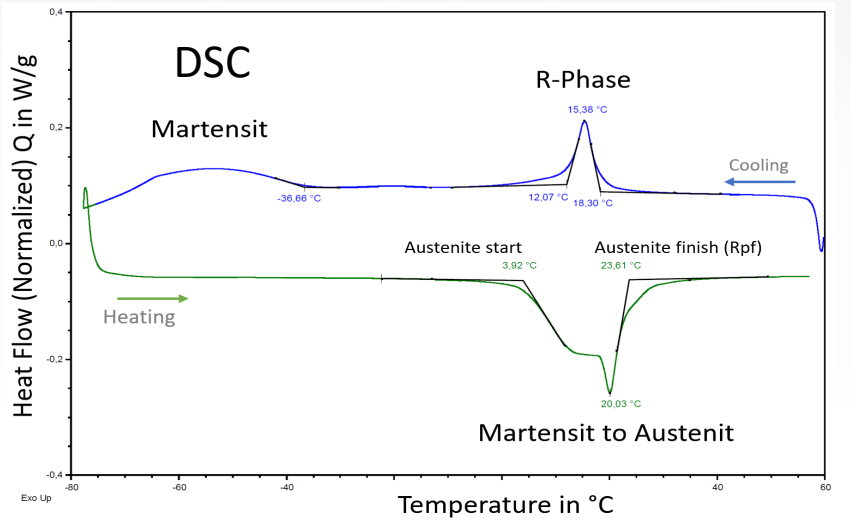
- Shape setting is requiring precise tooling
  - > tool manufacturing is a key
- Tools are manufactured in-house by using milling, turning and 3D metal printing



Set the shape // tune the properties

- Precise measurement of the transformation temperatures is important
  - > Bend and Free Recovery (BFR) per ASTM F2082 - It is nondestructive!
  - > Differential Scanning Calorimetry (DSC) (inspired) per ASTM F2004
- Mechanical properties are dependent of the adjusted Austenite finish (Af) temperature
- The active Af (of the component) is the one of interest

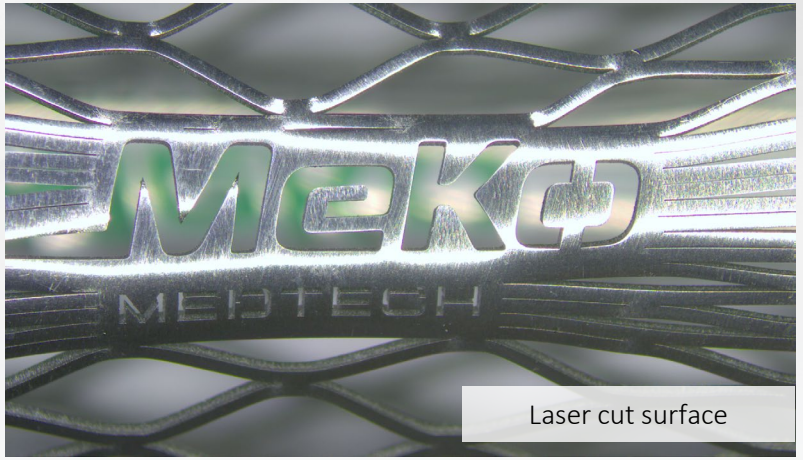




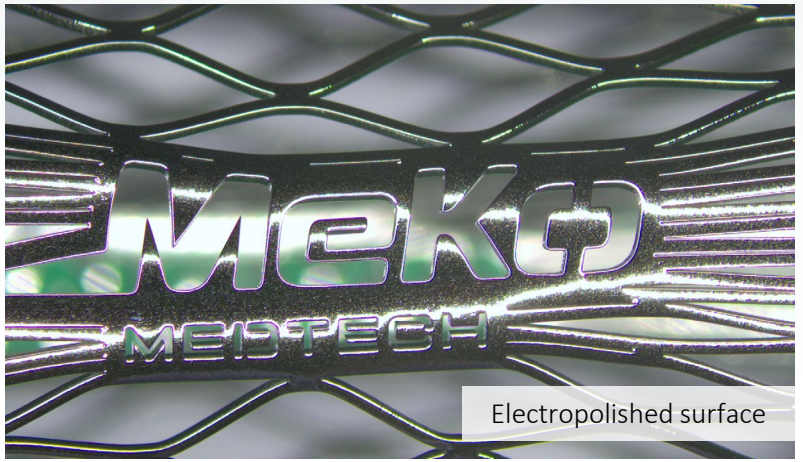
Electropolishing

Polishing is essential to make the part implantable

- Polishing is conditioning the surface
  - > Mechanically
  - > Chemically
- Best surface functionality is achieved by Electropolishing
  - > Homogeneous
  - > Preventing mechanical load
  - > Allowing defined material removal rates



Laser cut surface

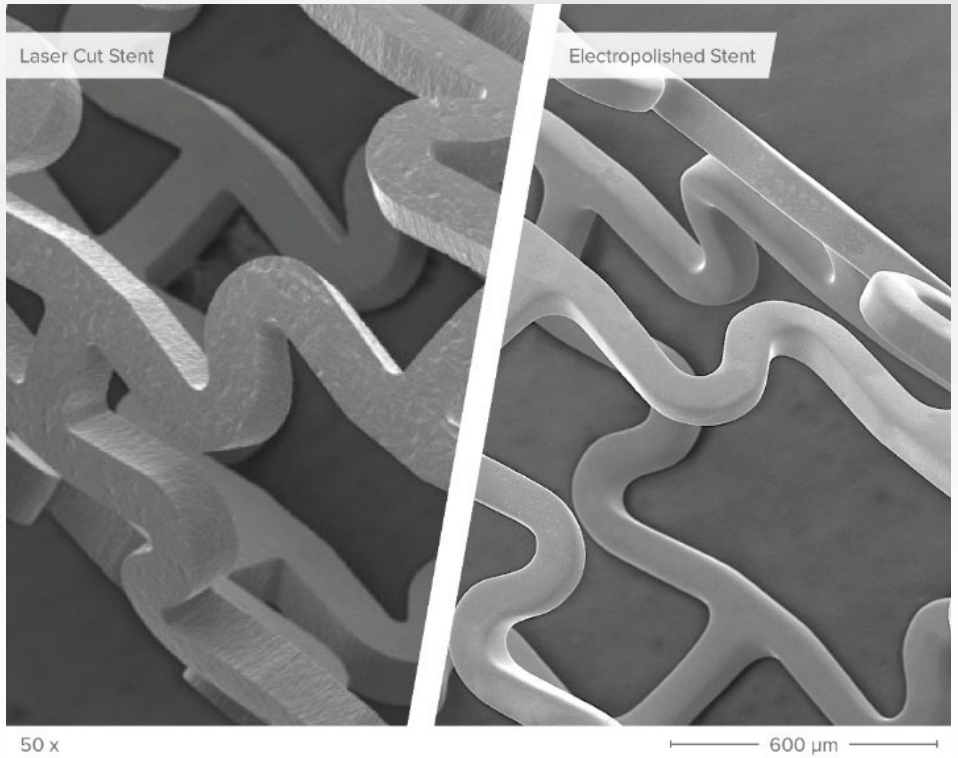


Electropolished surface

On the surface

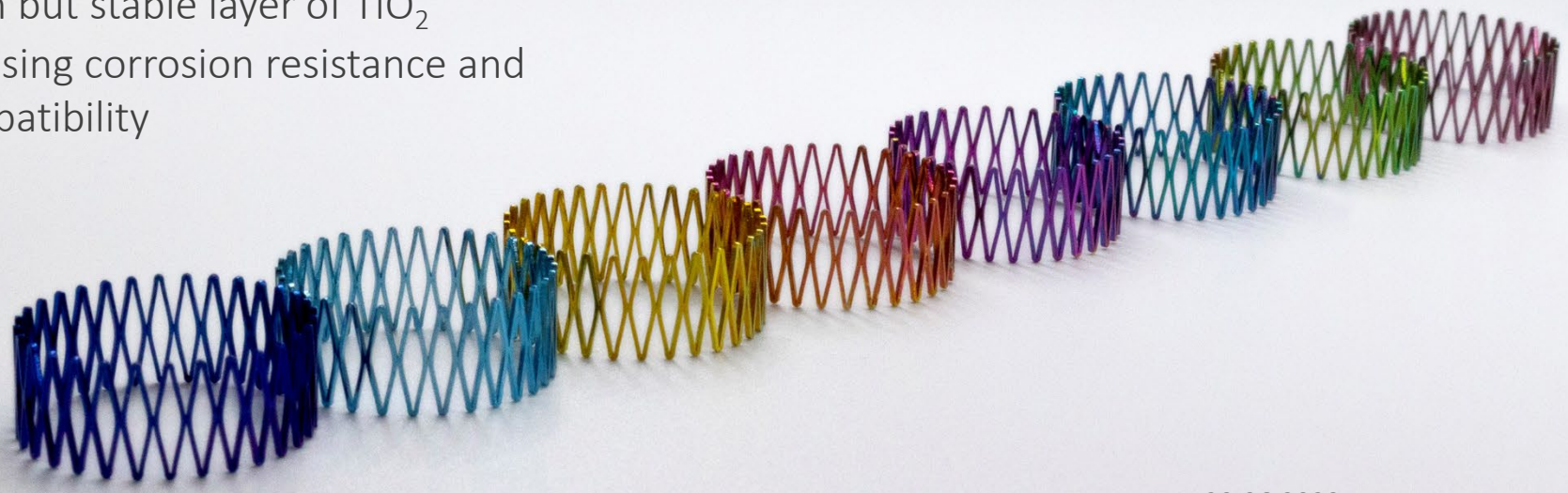
Are surfaces after electropolishing and passivation functional? – Absolutely, in many ways!

- Increasing functionality e.g., by smooth surface conditions
- Assuring biocompatibility
- Preventing corrosion
- Increasing fatigue life
- Make the component look nice…



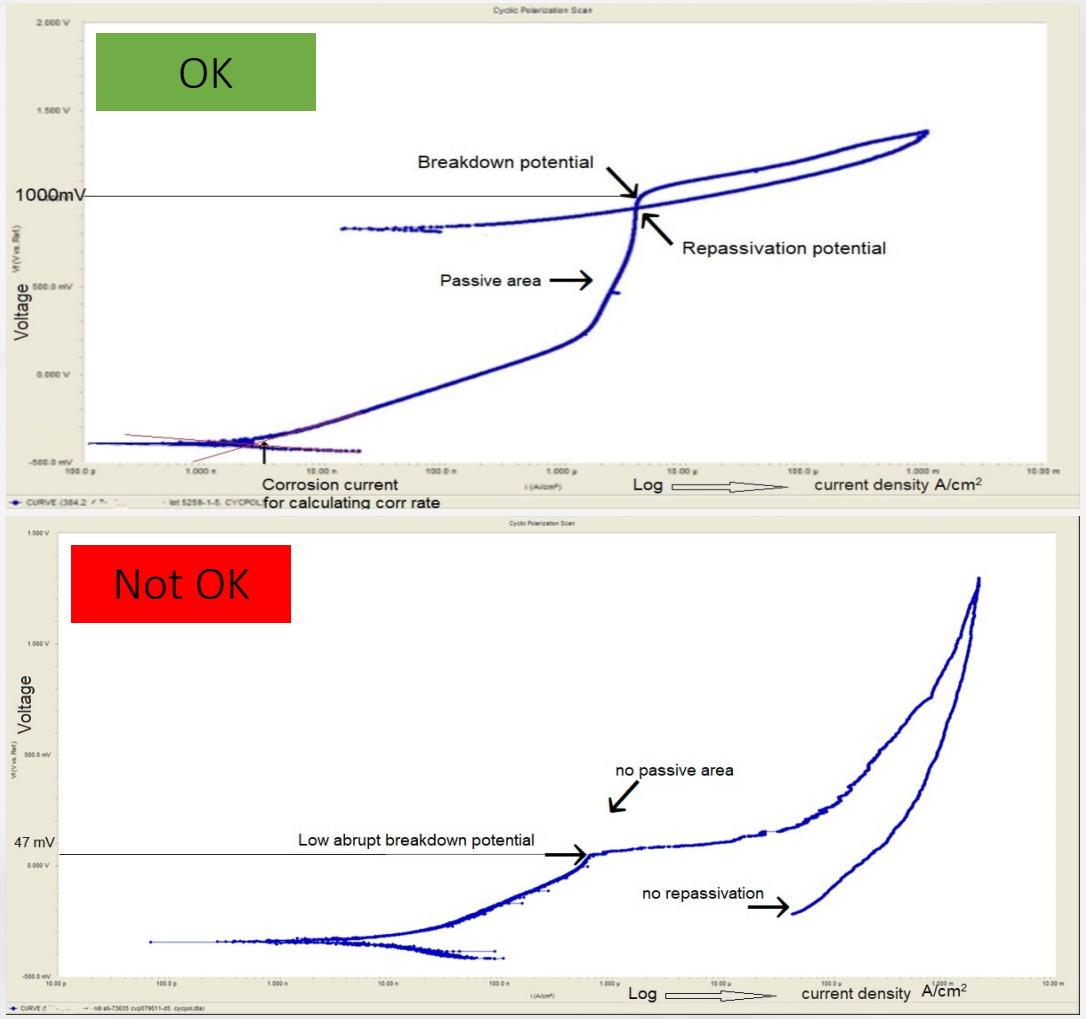
Electropolishing and Passivation

- Electropolishing is essential to achieve high quality surfaces
  - > Removes Ni out of the upper surface layer
  - > Removes surface related defects like scratches or potential heat affected zones
  - > Increases fatigue life
- Passivation is finalizing the functionality of the implant surface
  - > Is forming a thin but stable layer of TiO_2
  - > Is further increasing corrosion resistance and assures biocompatibility



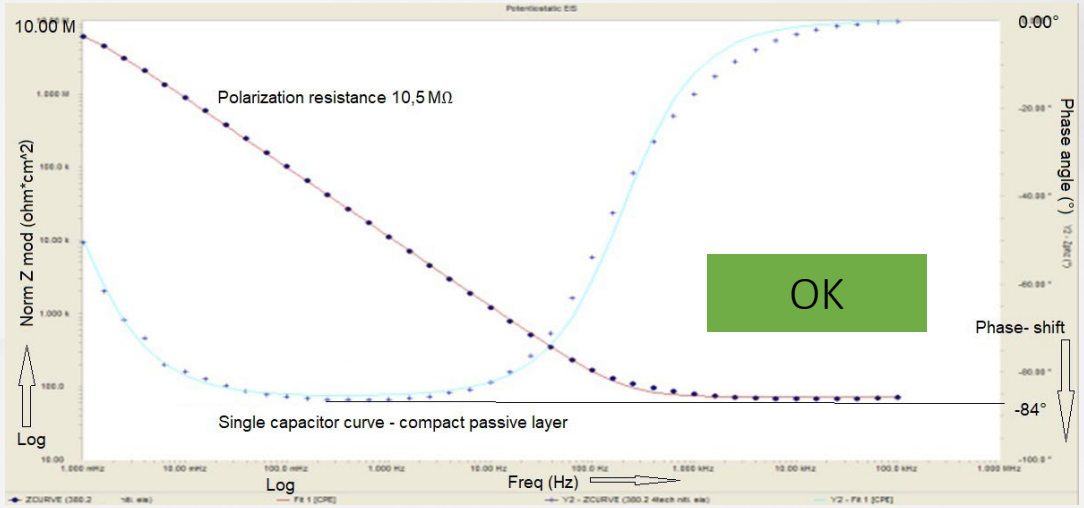
Corrosion can be displayed

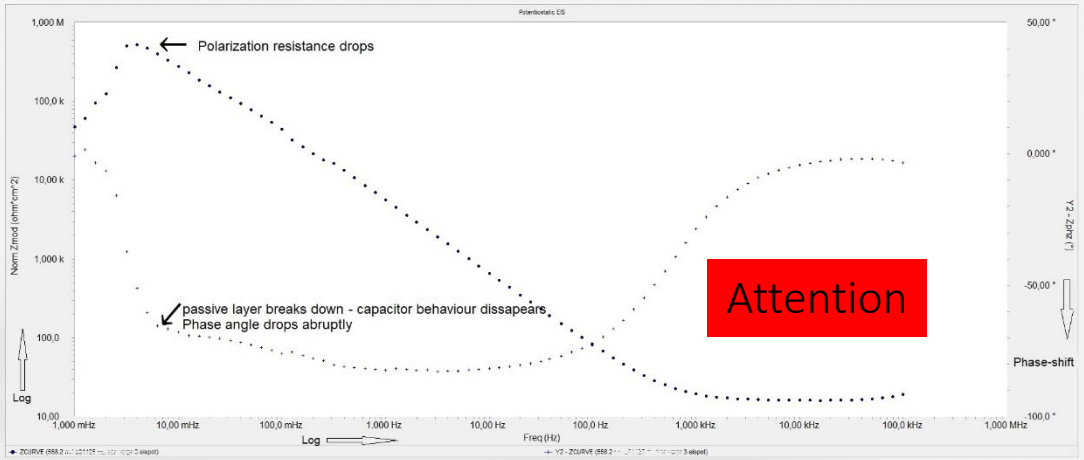
- Cyclic potentiodynamic analysis according to ASTM F2129 is used to study the corrosion behavior of metallic materials – using a potentiostat
- The cyclic potentiodynamic curve delivers key parameters, including corrosion potential, passivation potential, breakdown potential, and protection potential
- Breakdown and re-passivation behavior are important
- A corrosion rate can be calculated



Electrochemical Impedance Spectroscopy (EIS)

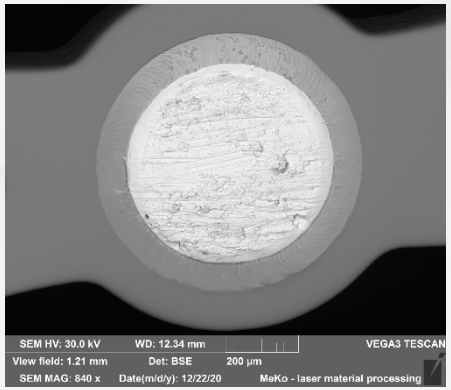
- The good barrier properties of the passive layer depend on its, porosity, compactness, thickness and it's Titanium/Nickel ratio
- Impedance and phase angel of the Bode plots allow calculations of the compactness of a passive layer
- EIS is not part of the ASTM 2129 standard but is allowing to gain additional knowledge about the functional behavior of the passive layer

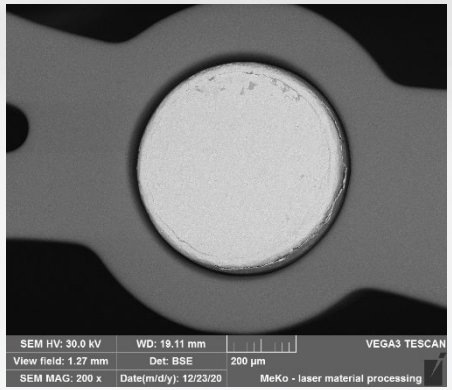


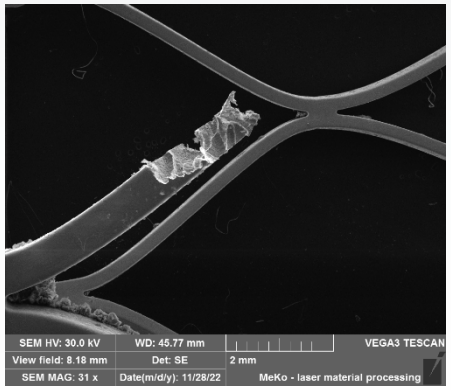


Galvanic potential (ASTM F3044)

- Galvanic potential is existent if the device consists two or more different metals
- Stent marker material inside a stent structure is a galvanic element (forms a cathode) that potentially can cause corrosion
- If the marker area is negligible in comparison to the stent area, the galvanic current is low, so galvanic corrosion will not occur
- Investigations can report corrosion – but:
  It also allows to verify working combinations





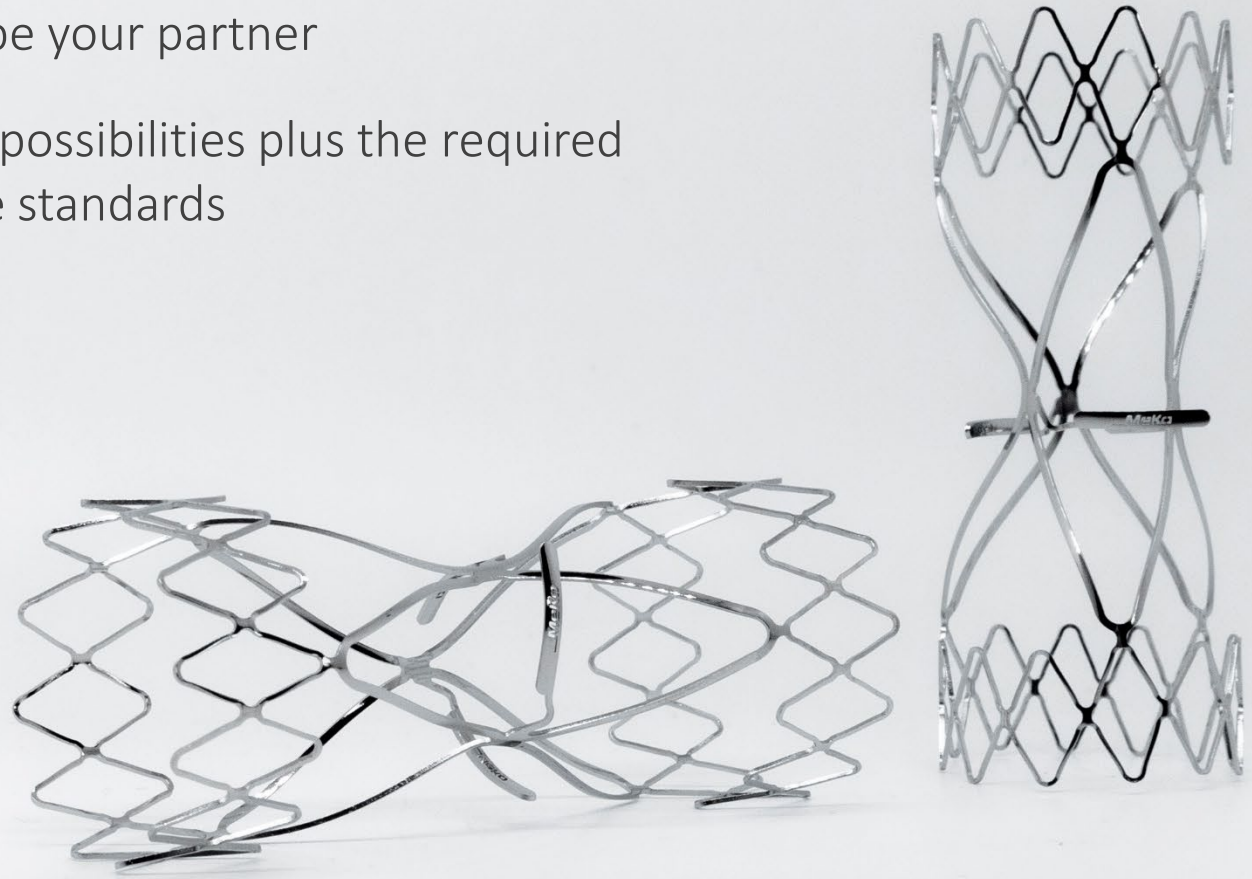


Potentiodynamic analysis, electrochemical impedance plus galvanic potential - use them all

- A stent with a high breakdown potential is expected to have good corrosion resistance
- Good corrosion resistance is essential for device life - without nickel leaching
- Compactness of the passivation layer assures biological stability of the implant surface
- High protect potential (E_p) and the associated re-passivation is important if the TiO_2 passive layer gets damaged (e.g. during implantation)
- Prevent critical galvanic elements

How do we assure that all of the seen is applied to your component?

- Tell us your requirements and allow us to be your partner
- Our production is offering a wide range of possibilities plus the required testing technology according to up-to-date standards
- Don’t hesitate – contact us



Why NiTi ?
Of course - because of its unique features…

…and the fun of working with something
with a little portion of mystery!

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Quality you can rely on!

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