

MedTech Materials Webinars

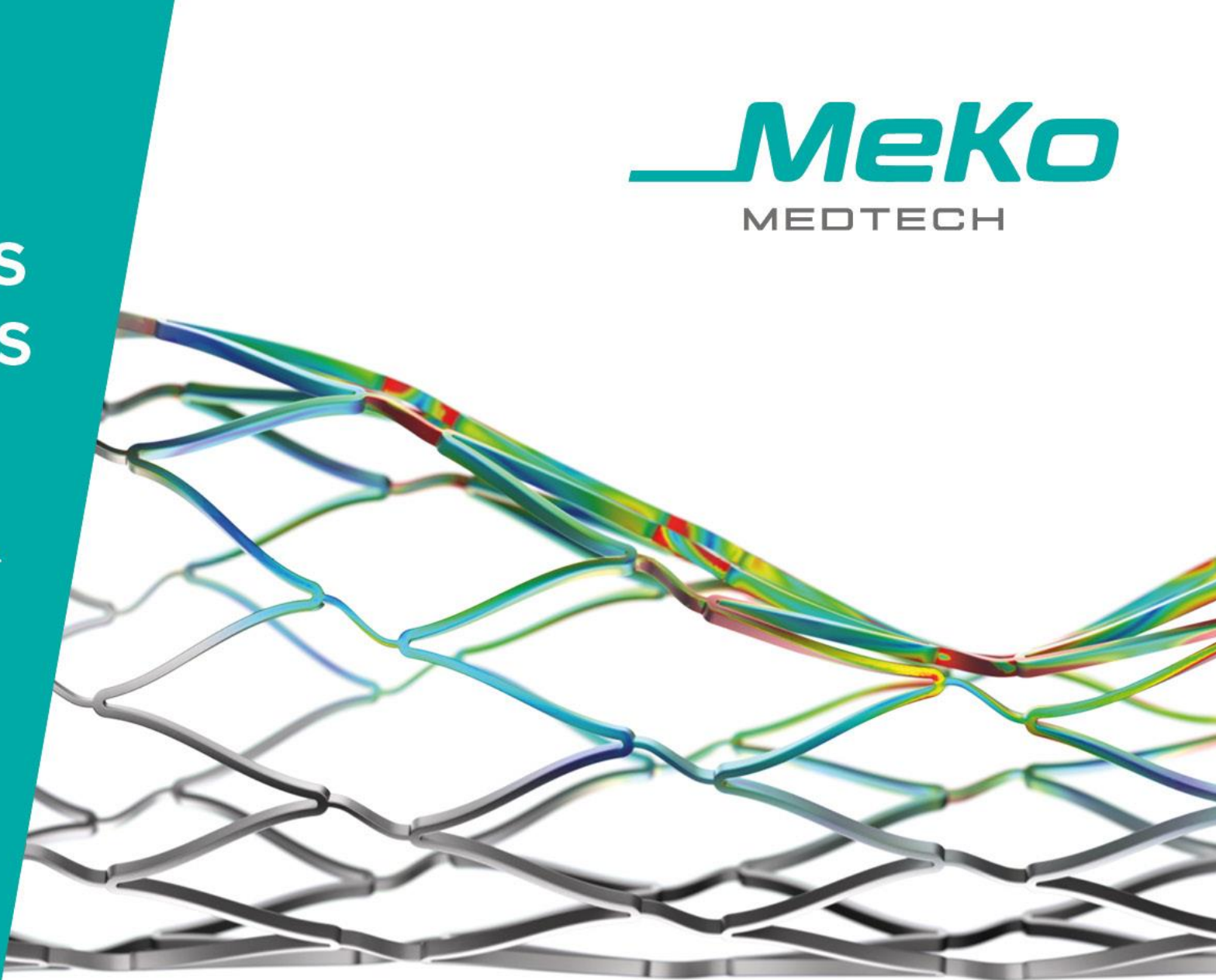
SIMULATION SERVICES FOR MEDICAL DEVICES

Validation of a finite element model regarding material properties and specified boundary conditions is crucial. This ensures the accuracy and reliability of simulation results, providing a precise representation of actual system behavior.

SEPTEMBER 4, 2024
5 TO 6 P.M. CEST, UTC+2

SEPTEMBER 5, 2024
9 to 10 a.m. CEST, UTC+2

MeKo
MEDTECH

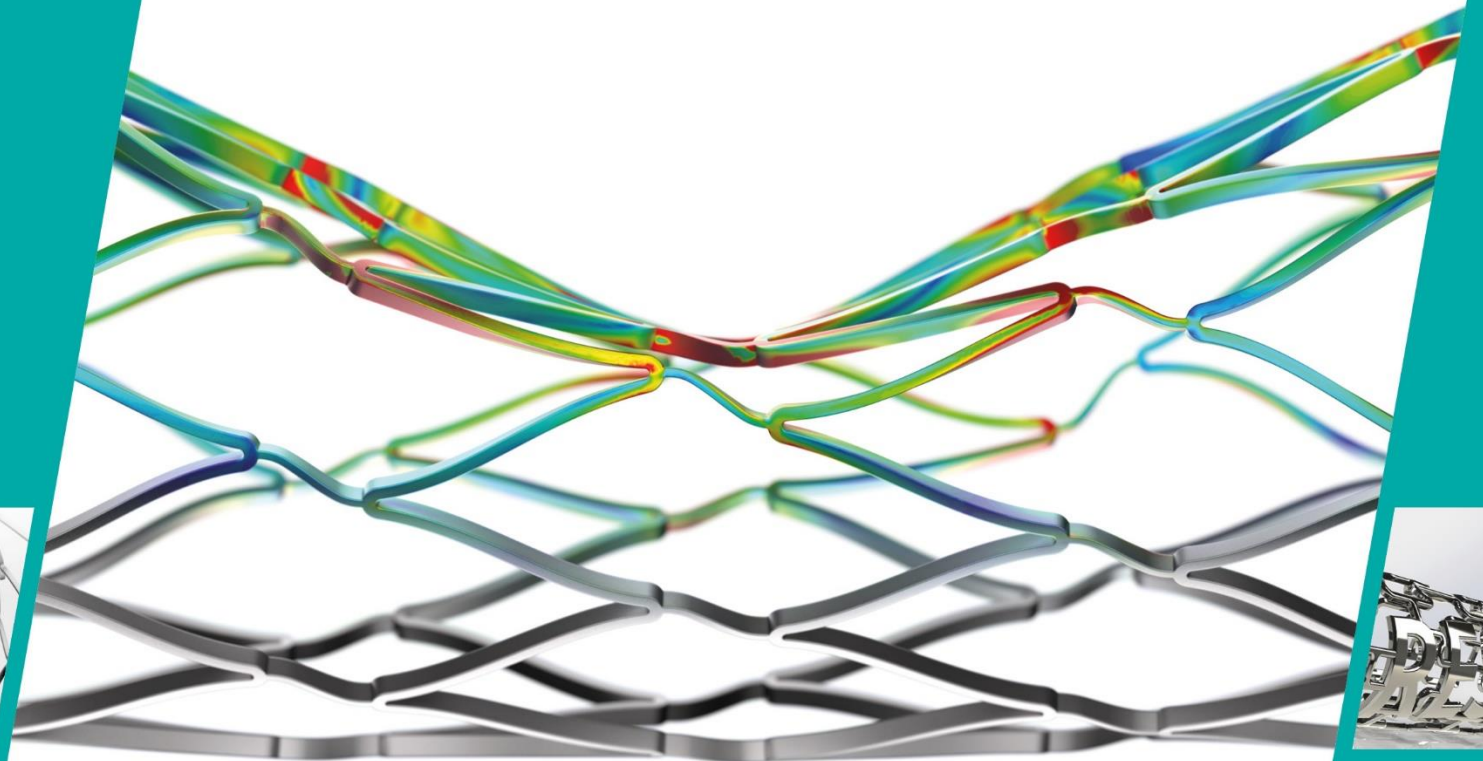


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Simulation Services for Medical Devices



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Agenda

MeKo MedTech

Simulation for Medical Devices

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
approved

160.000
sq. ft.

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Working for the Future

Our dedicated team is constantly innovating and elevating standards.

- Materials
- Manufacturing Processes
- Inspection & Analysis
- Automation

Manufacturing Processes



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

Material for Fast Prototyping

More than **3000** different tube and sheet lots in stock, including:

- > Nitinol
- > 304 & 316 Stainless Steel
- > Cobalt Chrome, MP35N
- > Bioresorbables including [Resoloy®](#) and [PolymediX®](#)
- > Nickel-free [Vasculoy®](#)

Redefining Possibilities

- **Equipment Solutions**
 - > Our machines are custom designed to enable peak performance
- **Automation Solutions**
 - > Built in-house and validated to provide scalable, repeatable results
- **Analysis Solutions**
 - > Confocal laser scanning microscope (CLSM)
 - > Electrochemical Impedance Spectroscopy (EIS)
 - > Potentiodynamic Tests
 - ... and even more

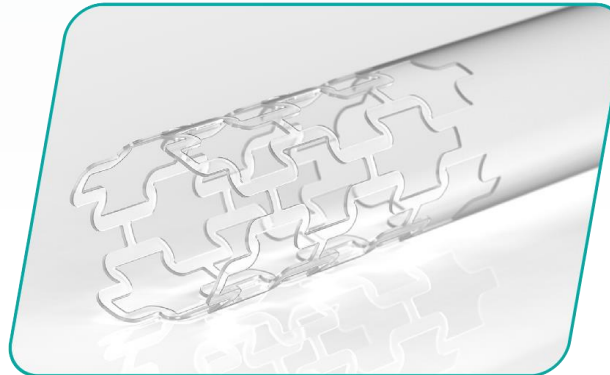
Redefining Possibilities

- Material Solutions

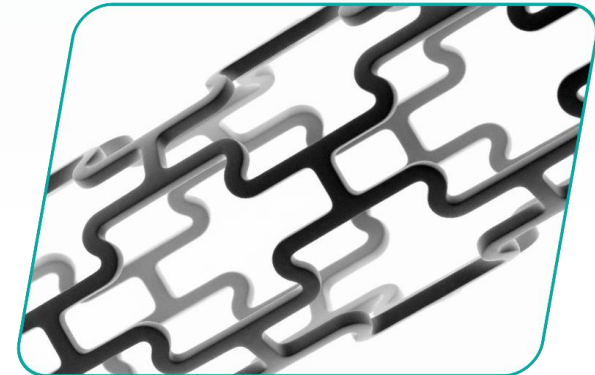
- > **Resoloy®**:
new magnesium alloy with > 30%
break elongation



- > **PolymediX®**:
high-precision polymer
tubes with **drug**
integration into tube wall



- > **Vasculoy®**:
enhanced biocompatibility
in balloon expandable
stents



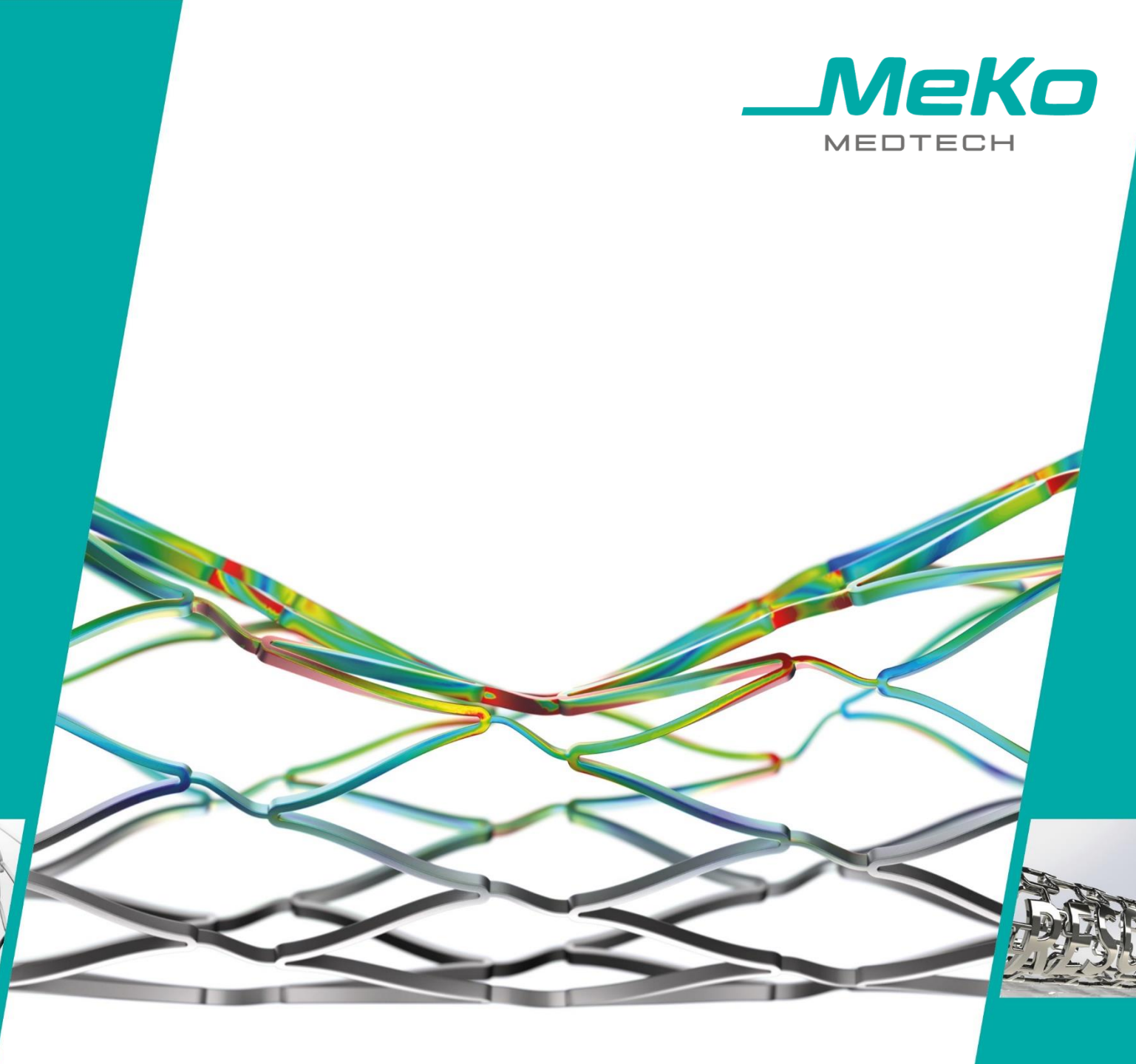
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Simulation Services for Medical Devices

Finite Element Analysis (FEA)

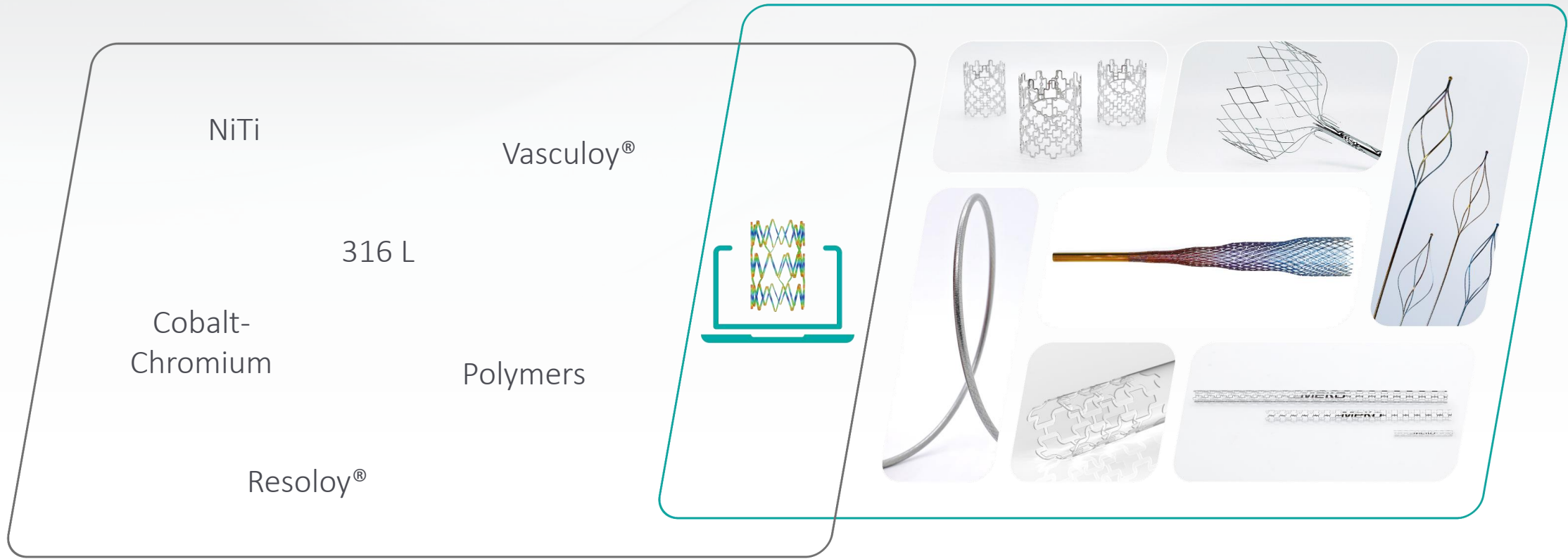


Agenda

- ① Medical Components & Applications for Simulation Techniques
- ② Simulation in a Device Lifecycle
- ③ FEM Introduction
- ④ FEA Process
- ⑤ Mechanical Material Properties
- ⑥ Use Cases
- ⑦ Conclusion

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- 2
- 3
- 4
- 5
- 6
- 7

Medical Components & Applications for Simulation Techniques



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Simulation in a Device Lifecycle

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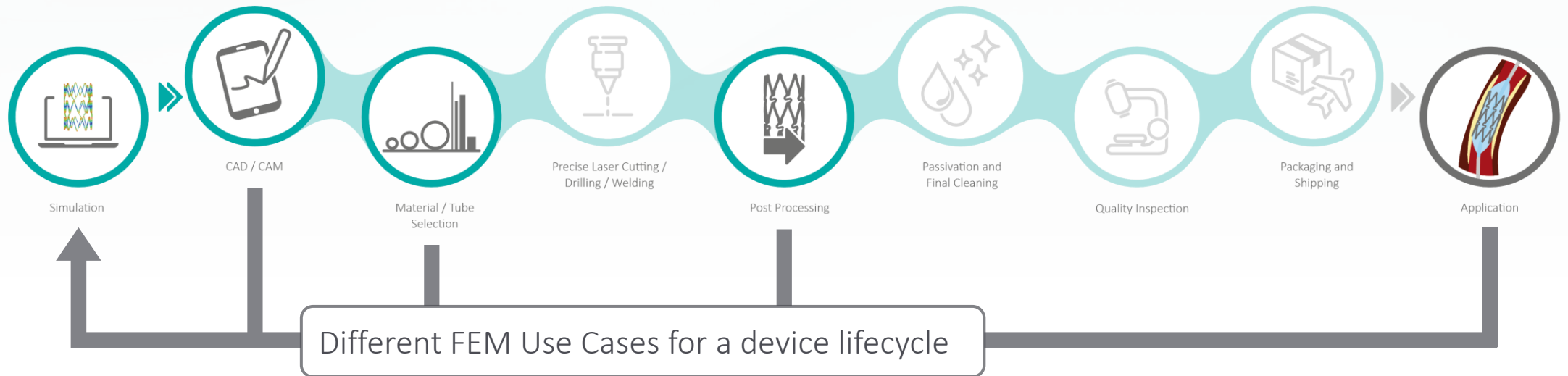
- Consider the whole device lifecycle during the development phase.

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- Many possible applications for the FEM.

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FEA during development process

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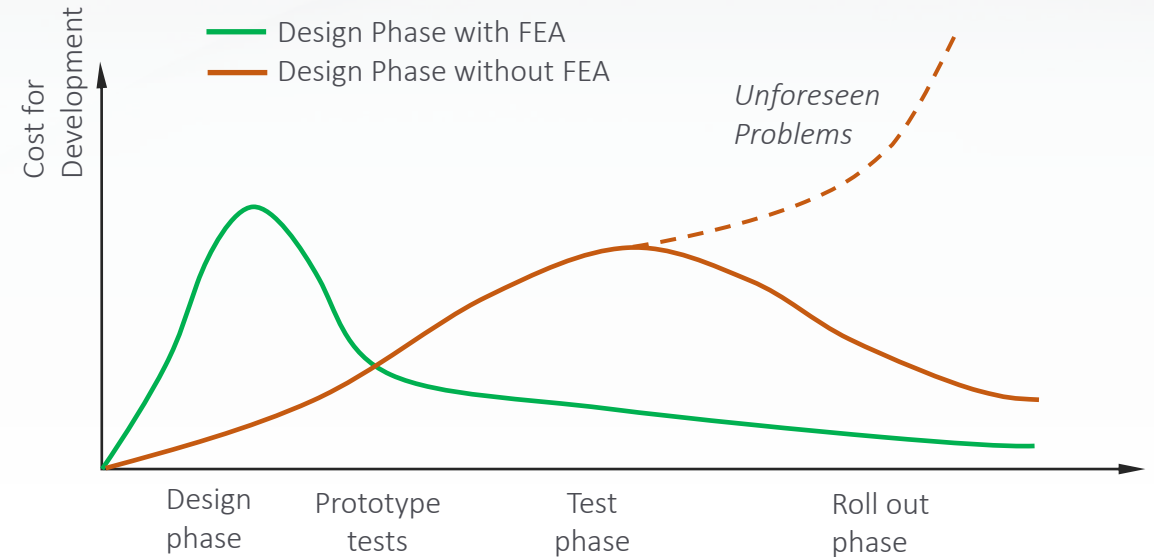
Early integration of FEA into the development process has advantages over conventional development based solely on prototypes

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- The need for physical prototypes and experiments can be reduced.
- Can reduce the development time.
- Less problems in the late stages of the development process.
- Lowering the overall costs during the development process.



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FEM introduction

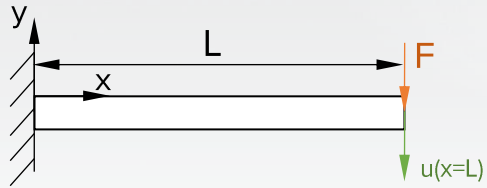
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Analytical Solution



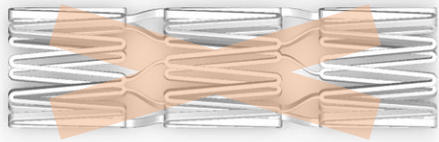
$$M(x) = -E \cdot I \frac{d^2 \cdot \delta(x)}{d \cdot x^2}$$

$$I = \frac{b \cdot h^3}{12}$$

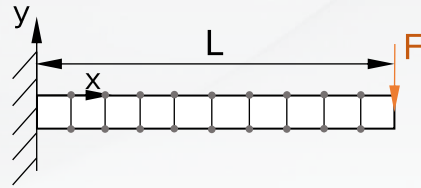
⋮

$$u(x=L) = \frac{F \cdot L^3}{3 \cdot E \cdot I}$$

No analytical solution for complex parts



FEM Theory



$$F = K \cdot u \quad \text{Basic FEM equation}$$

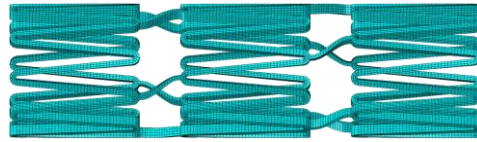
$$K = E \int_V \vec{B} \vec{B}^T dV \cdot u \quad \text{Stiffness}$$

$$\begin{bmatrix} F_1 \\ F_2 \\ \vdots \\ F_n \end{bmatrix} = \begin{bmatrix} k_{11} & k_{12} & \dots & k_{1n} \\ k_{21} & k_{22} & \dots & k_{2n} \\ \vdots & \vdots & \ddots & \vdots \\ k_{n1} & k_{n2} & \dots & k_{nn} \end{bmatrix} \cdot \begin{bmatrix} u_1 \\ u_2 \\ \vdots \\ u_n \end{bmatrix} \quad \text{System of equations}$$

$$\epsilon = \frac{\partial u}{\partial x} \quad \text{Strains}$$

$$\sigma = \epsilon \cdot E \quad \text{Stresses}$$

Complex part discretized



- FEA results
 - Deformations
 - Stresses, strains
 - Reaction Forces, Contact Forces
 - Temperatures, Energies
 - ...
- > Compare results with allowable values
- > Further geometry useability
 - 3D part for follow up analysis or marketing purposes
 - 2D geometry for production

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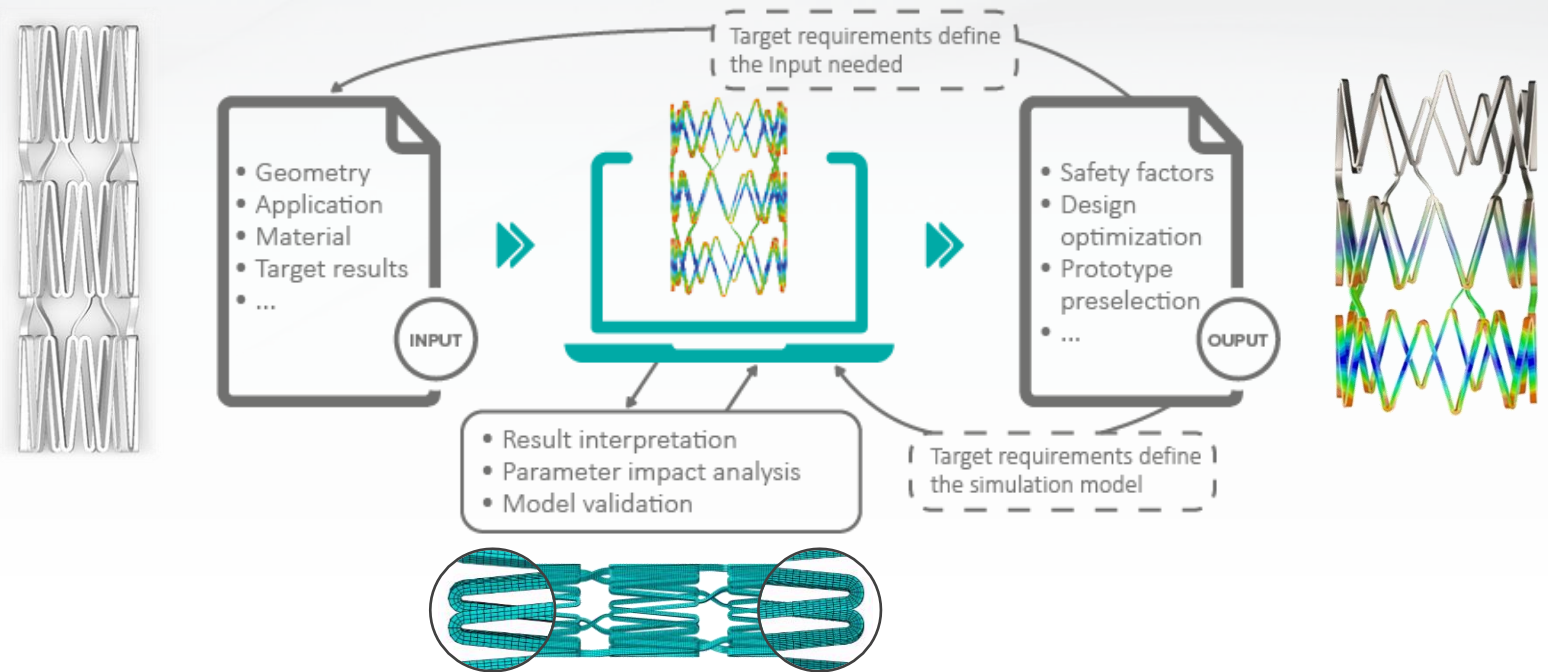
FEA process

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- Defining the desired results in advance is of crucial importance.
- The set of input data contributes to the quality of the results.



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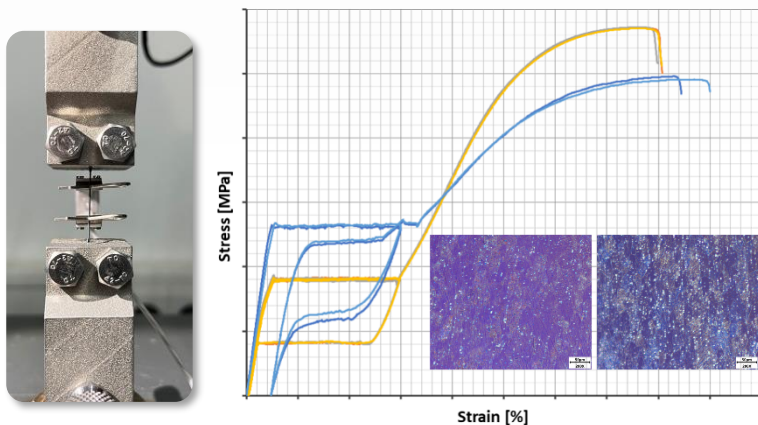
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Mechanical Material Properties

- The input of correct material parameters is important for an FEA.
- If the material is not part of the existing material database, tests can be performed to determine the material parameters.
- A validation of the material parameters, using additional tests, is also part of the process.

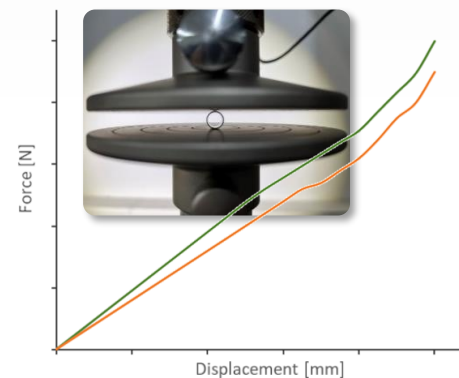
Material parameters

Tensile Test

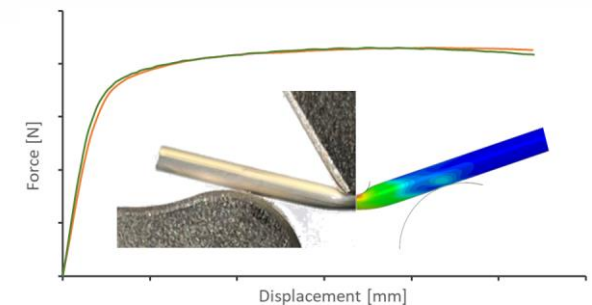


Additional tests for validation

Crush test



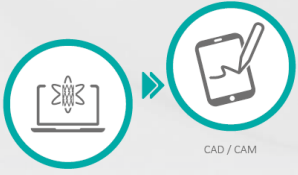
Three-point bend test



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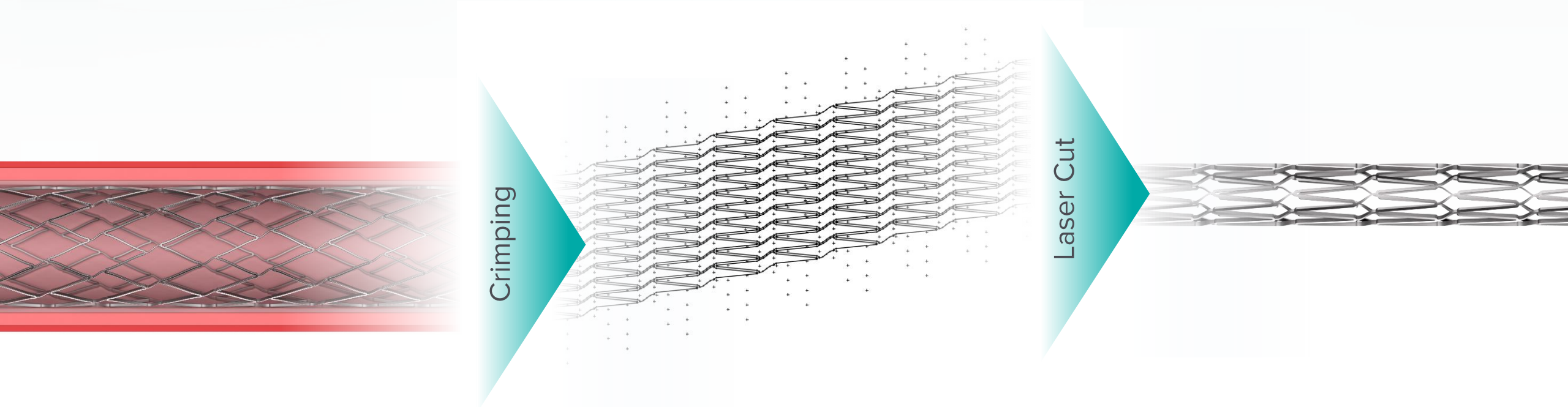
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Use Cases Derivation of 2D cutting geometry

- Customer develops a 3D part in the real application and needs the file for laser cutting.
- Shape setting of an existing component does not results in the required final shape.
- Downsizing the catheter of an existing device by reducing the tube size the part is cut from.



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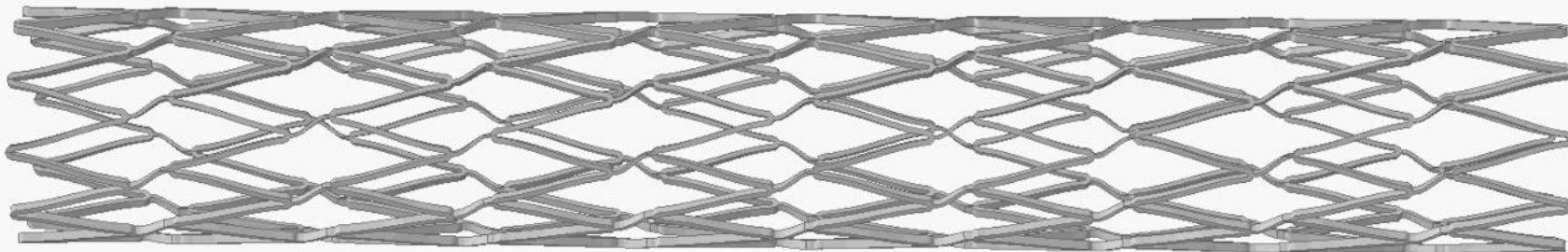
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Use Cases Shape setting

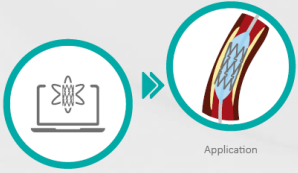
- Can the final shape be achieved with a given laser cut design?
 - How does the shape set part look with the given boundary conditions?
 - Which boundary conditions are needed so that the part looks as desired?
- ➔ A deformation analysis of the shape setting process helps to check the design and gives the possibility to derive design adaptations before the manufacturing of prototypes.



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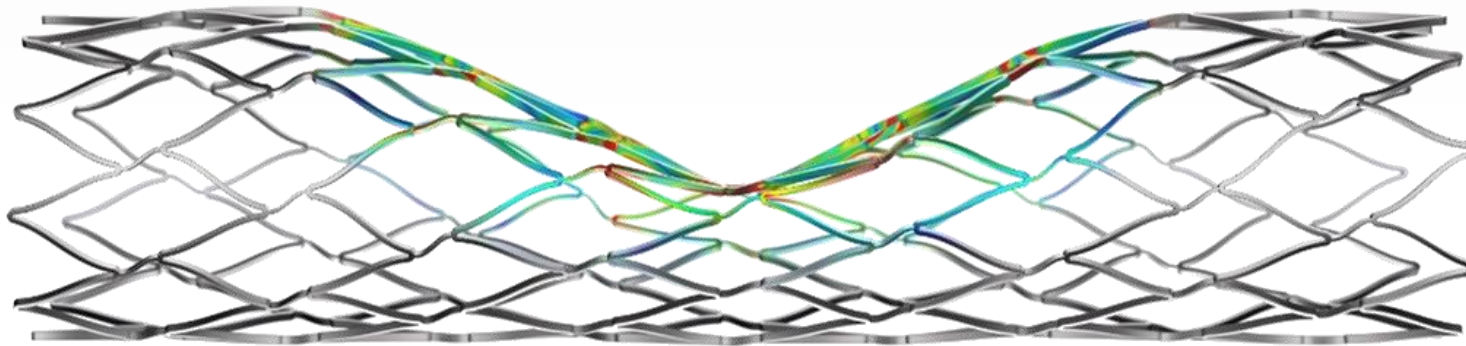
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Use Cases Device Application

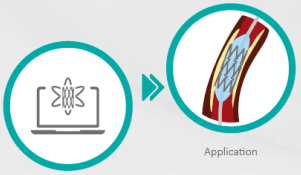
- Depending on the application and the requirements, various simulations can be carried out.
- Design aspects can be analyzed regarding subsequent component performance.
- Worst-case scenarios can be identified for the choice of in vitro testing.
- There is a general selection of applications, but in consultation with the customer various kinds of customized studies are possible.



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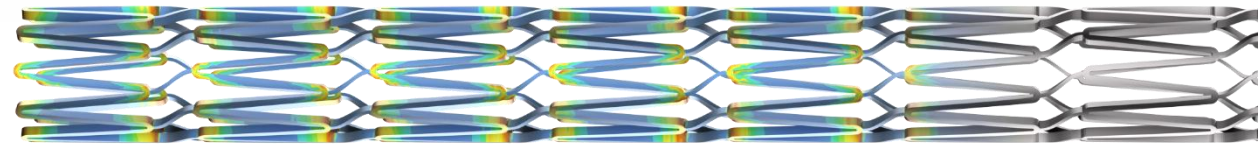
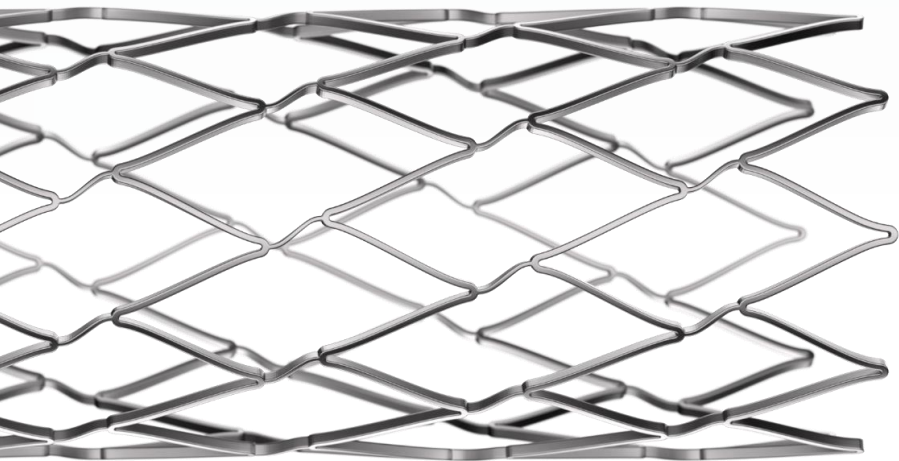
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Use Cases Application - Crimping

- Crimpability
 - ➔ Are critical stress / strain values exceeded?
 - ➔ Is the material damaged?
 - ➔ Which effect do plastic deformations have on the released shape?



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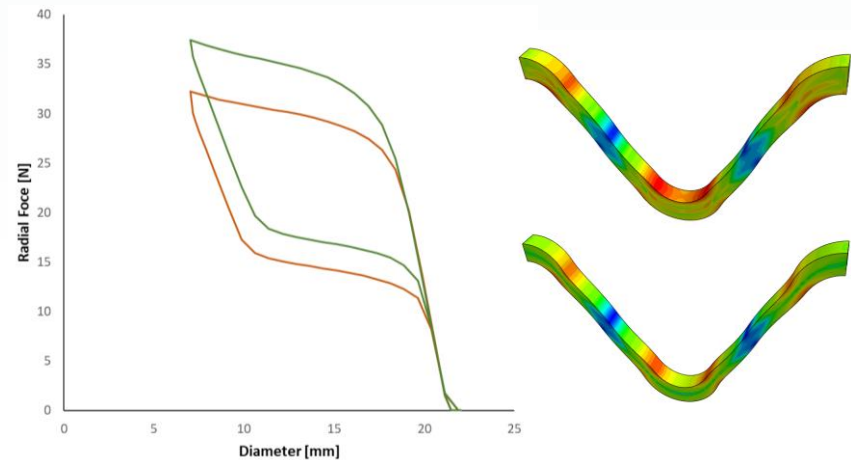
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Use Cases Application - Radial Force

- With the help of simulation, it is possible to investigate the radial force of different designs before prototype manufacturing.
- Influence of different designs and geometry aspects like strut width can be analyzed.
- In addition to that different materials, transformation temperatures etc. can also be investigated.

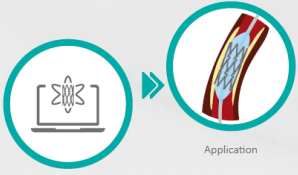


Force-displacement-curve shows the influence of the strut width on the component stiffness

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Use Cases Application - Thermal load

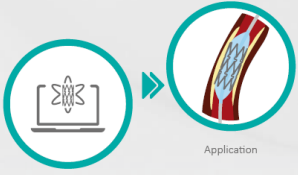
- Temperature load cases before, during and after implantation can have an unexpected negative influence on the mechanical behavior of the components and damage them.
- An often-neglected case is the unplanned heating of devices already crimped in the catheter during storage and transportation.
- Taking thermal influences into account in advance improves the safety and the useability of the device.



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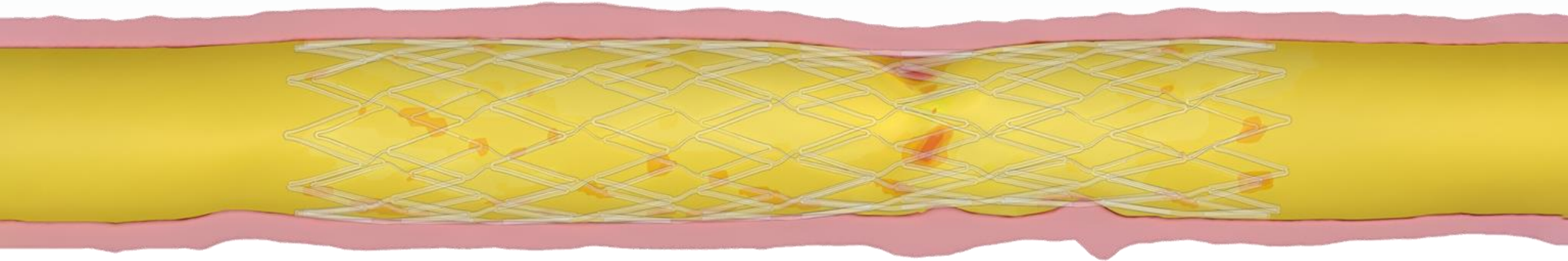
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Use Cases Application - Deployment mechanism

- Deployment errors can lead to failure of the stent or damage to the tissue.
- Simulation of the deployment of self-expanding and balloon-expandable stent is possible.
- ➔ Optimization of the release mechanisms to minimize complications such as incomplete expansion, vessel injury or misalignment of the stent.



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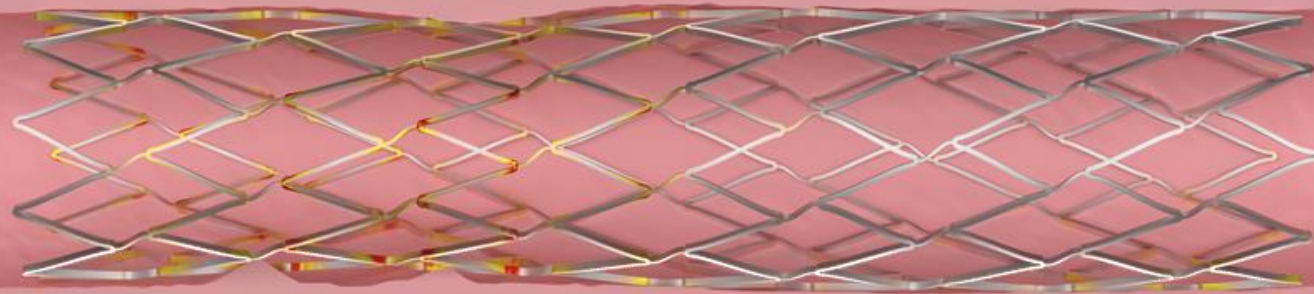
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Use Cases Application - Durability

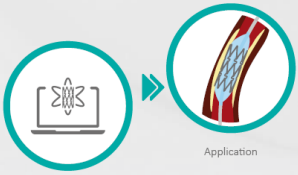
- After deployment, stents are permanently exposed to cyclic loads.
- FEA fatigue analyses is probably the most elaborate use case.
 - > Cyclic load simulation
 - > Stress and strain distribution
 - > Fatigue analysis
- Optimization of the stent design to maximize fatigue strength and minimize the risk of fatigue and long-term failure.



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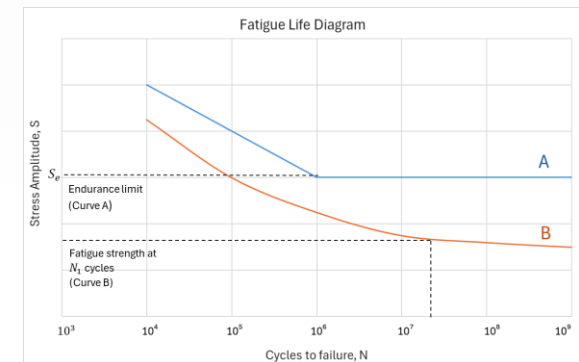
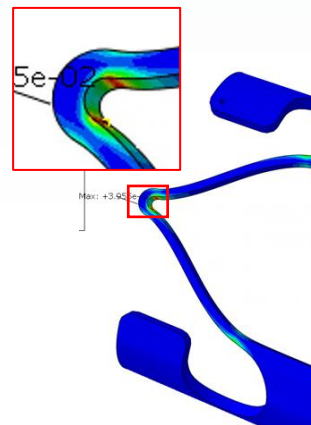
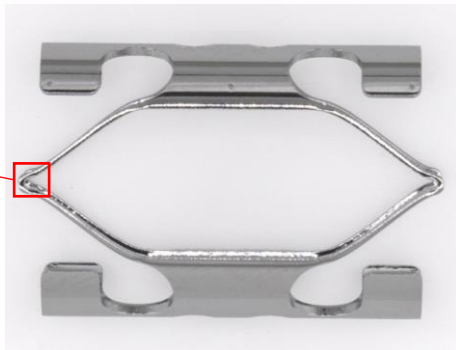
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Use Cases Application - Durability

- Calculation of the stress distribution in the stent under different loading conditions enables the identification of potential weak points that could lead to fatigue and premature failure.
- An FEA allows to adjust the design or material at an early stage.
- Identifying worst-case scenarios helps to reduce the scope of fatigue testing.

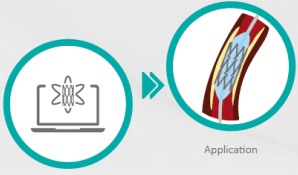
Critical area:



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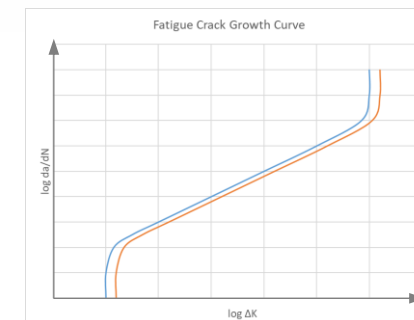
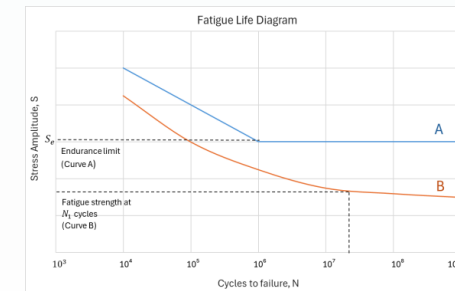
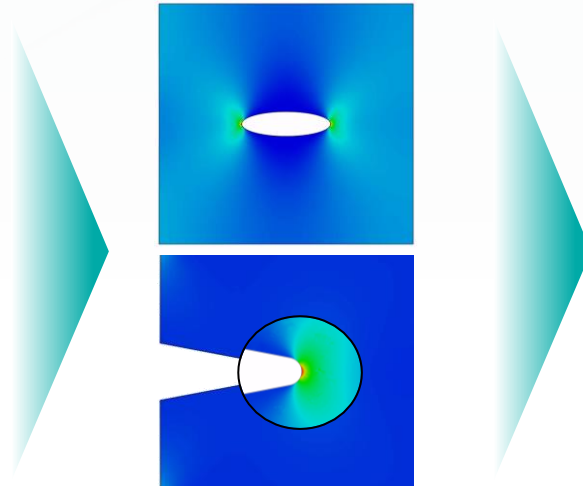
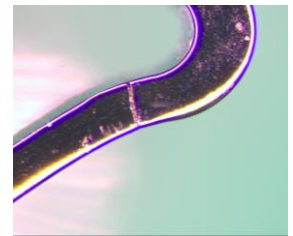
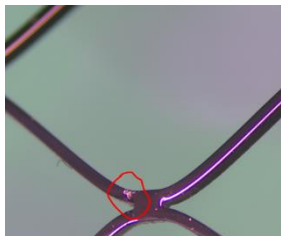
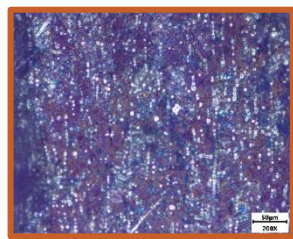
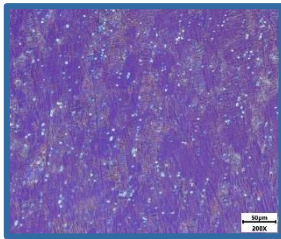
Application

Use Cases Application - Durability

- Considering material irregularities like non-metallic inclusions or surface defects allows the customer to optimize the material and process.
- The correlation between geometry and material is an important design factor.

A: Small inclusion size

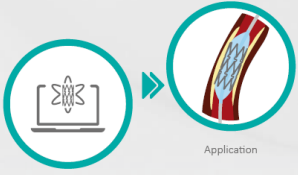
B: Larger inclusion size



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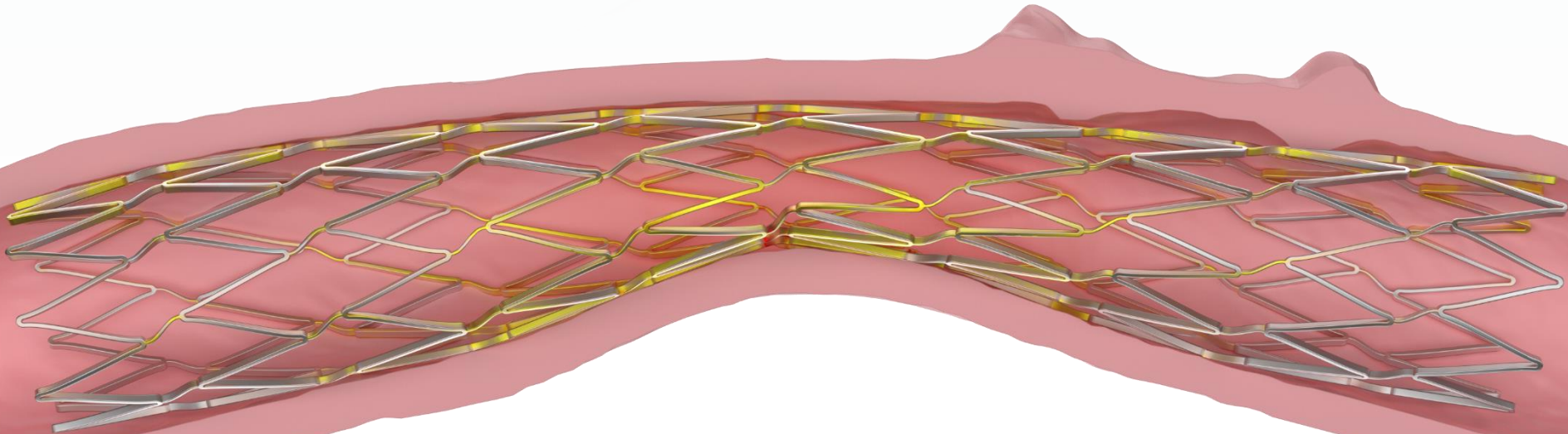
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Use Cases Application - Non-cyclic Loading Events

- Singular or short-term load cases can occur during or shortly after deployment:
 - > Sudden and intense contractions of the artery.
 - > Collision during insertion or positioning.
 - > Bending and compression during artery motion.

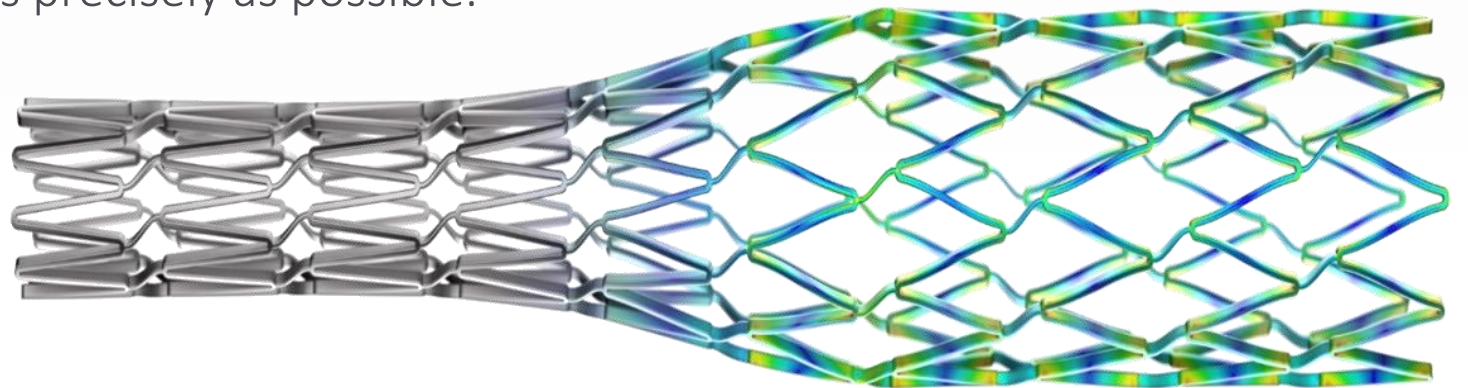


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Conclusion

- FEA is always a good solution: for a feasibility study, design development or optimization of existing designs.
- FEA helps to avoid faulty designs and speeds up the development process.
- To get the best out of an FEA:
 - ➔ Start as early as possible to integrate FEA in the development process.
 - ➔ Define the desired results as precisely as possible.



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laser@meko.de



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