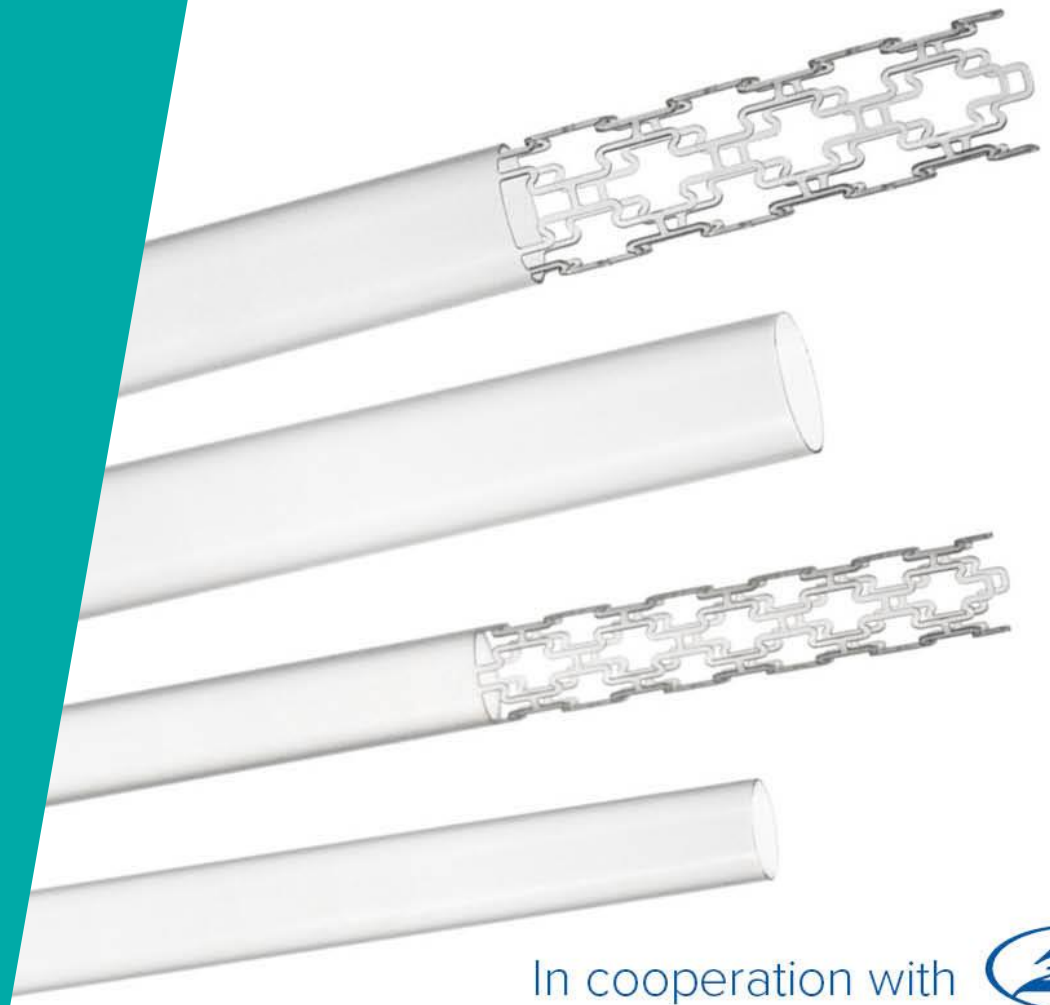
PRECISION IS OUR PROFESSION

MeKo.de

MeKo MEDTECH

Developing Next Gen Bioresorbable Scaffolds

From Oriented Polymer Tubing to Final Implant



In cooperation with ZEUS

Speakers

Laura Denzer

Project Manager

MeKo

Fridtjof Strass

Project Manager

MeKo

James Lindsey III

Senior Research Engineer

ZEUS

Wayne Black

Product Marketing Manager

ZEUS

MeKo.de

PARTNERS IN PRECISION

Zeus is a global leader in precision oriented bioabsorbable tubing and collaborates with MeKo, a global leader in precision laser cutting of bioabsorbable stents, enabling medical device companies with next generation BRS products.

ZEUS®

X

MeKo MEDTECH

Zeus is headquartered in Orangeburg, SC, USA. Its core business is the development and precision extrusion of advanced polymeric materials. The company employs over 2,000 people worldwide with manufacturing and sales facilities in Aiken, Columbia, Gaston, Orangeburg, South Carolina; Branchburg, New Jersey; Chattanooga, Tennessee; San Jose, California; Guangzhou, China; and Letterkenny, Ireland. Zeus products and services serve companies in the medical, automotive, aerospace, fiber optics, energy, and fluid management markets.

MeKo is a globally active supplier specialized in laser material processing for the medical industry. Our ISO-certified quality management passed FDA inspections. Based on the designs of our customers, we manufacture medical devices like stents, heart valve frames and other medical products with small tolerances and perfect surface quality. With its extremely precise laser systems, MeKo processes stainless steel and nickel titanium as well as new bioresorbable materials like magnesium alloy and bio-polymers.

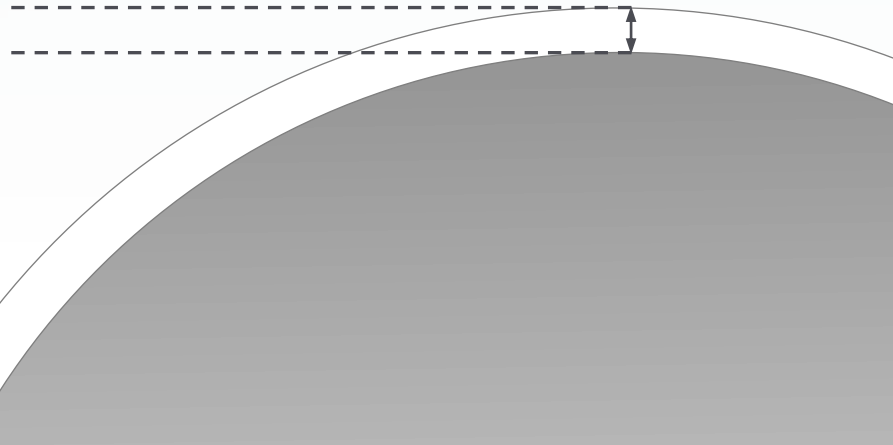
MeKo.de

High-Tech Manufacturer

MeKo MEDTECH

ZEUS

Precise Tube Manufacturing



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High-Tech Manufacturer

MeKo MEDTECH

MeKo MEDTECH

Precise Laser Cutting

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PRECISION IS OUR PROFESSION

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MeKo MEDTECH

Agenda

Company Presentations

MeKo MedTech

Zeus

Technical Parts

Uniformity & Orientation: Critical for Design Success

Experience of Manufacturing Polymer Components

PRECISION IS OUR PROFESSION

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MeKo MEDTECH

MeKo Manufacturing

Overview

MeKo Manufacturing e.K.

MeKo MEDTECH

2026* 1997 2000 2007 2022 2023

MeKo.de

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

MeKo.de

Range of Activities
for Medical Devices

MeKo MEDTECH

Laser Micro Machining	Cutting / Welding / Drilling
Post Processing	Heat Treatment / Shape Setting / Electropolishing
	Passivation / Final Cleaning / Quality Inspection

ISO **13485**

30 Years of **EXPERIENCE**

Made in **GERMANY**

ZEUS®

UNIFORMITY & ORIENTATION:

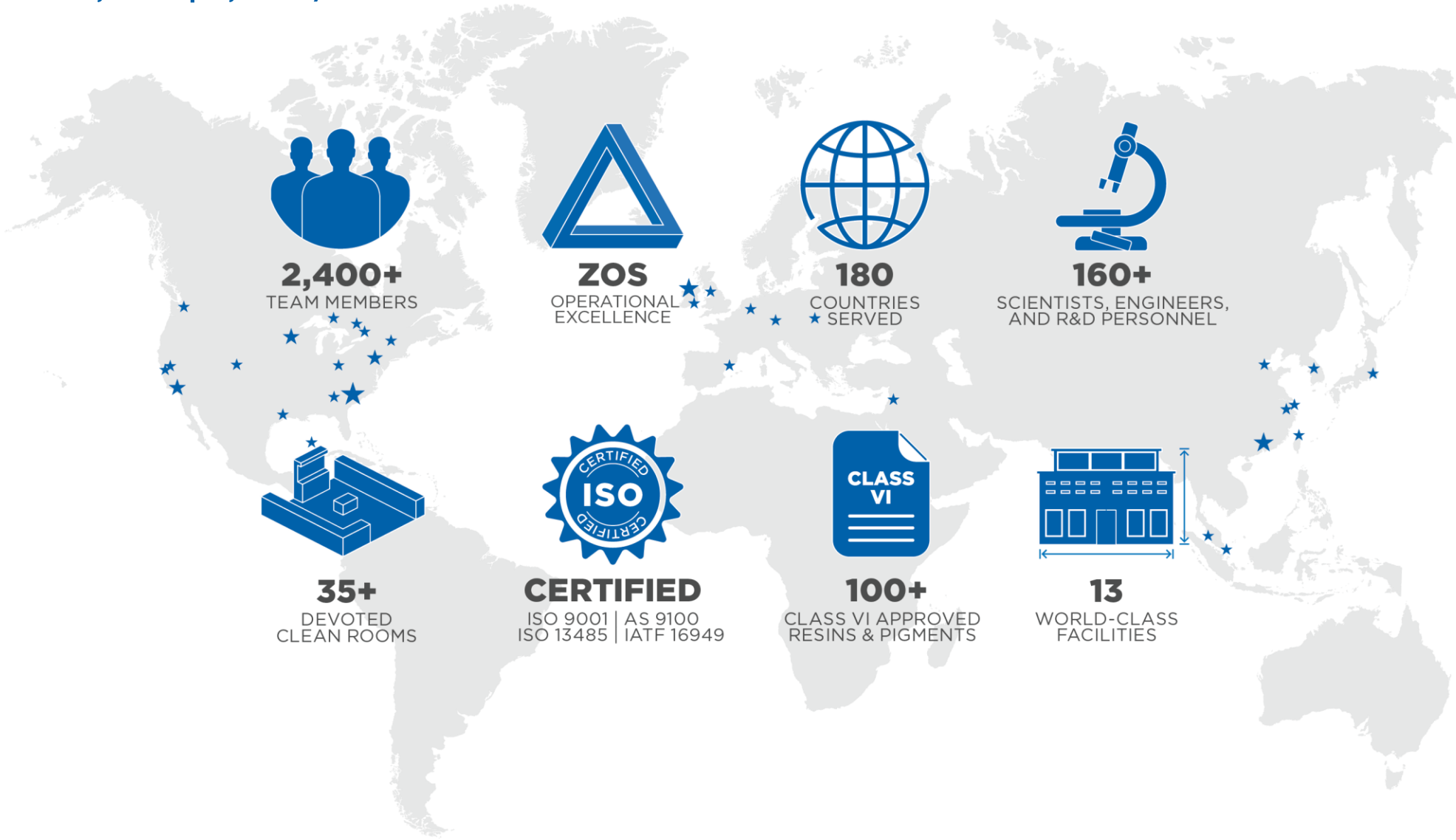
CRITICAL FOR DESIGN SUCCESS

Jay Lindsey, Senior Research Engineer

Wayne Black, Product Marketing Manager

Global Footprint

Americas, Europe, Asia/Pacific



Corporate Facilities

Americas, Europe, Asia/Pacific

Aiken, South Carolina
Manufacturing Plant

Arden Hills, Minnesota
Manufacturing Plant

Branchburg, New Jersey
Manufacturing Plant

Chattanooga, Tennessee
Manufacturing Plant

Columbia, South Carolina
Manufacturing Plant

Gaston, South Carolina
Manufacturing Plant

Guangzhou, China
Sales Office

Letterkenny, Ireland
Manufacturing Plant, Sales

Orangeburg, South Carolina
Manufacturing Plant

Orangeburg, South Carolina
Engineering Center

Orangeburg, South Carolina
Sales and Marketing, R&D

San Jose, California
Manufacturing Plant

St. Matthews, South Carolina
Logistics Center

MARKET NEEDS

Market Problems & New Opportunities

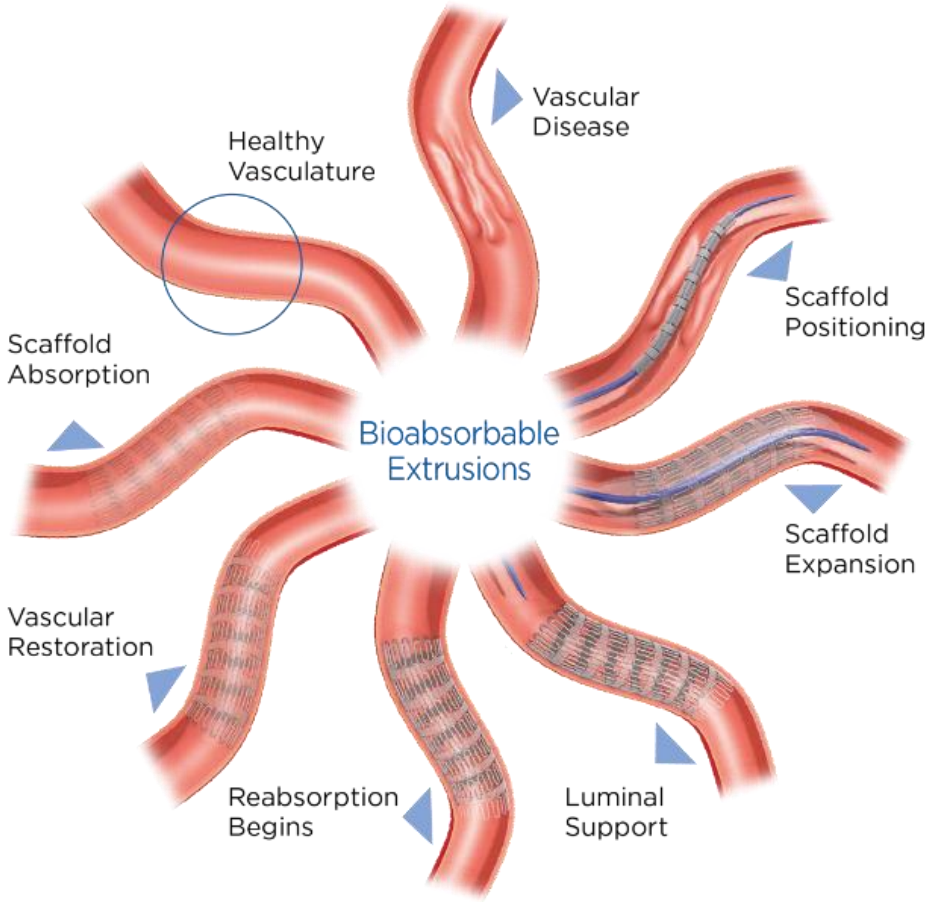
Issues Medical Markets Need to Address for Wide Adoption of BRS Over Metallic Stents

ISSUES:

- Large scaffold strut thickness (150μm+) – increases risk of scaffold thrombosis in coronary arteries
- Absorption rate: PLLA = too slow (?), Mg = too fast (?)
- Potential variation in strut thickness – leading to non-uniform properties
- Low radial strength (compared with DES counterparts)
- Few options in larger diameters to explore markets outside cardio

HOW RECENT INNOVATIONS ADDRESS THESE ISSUES:

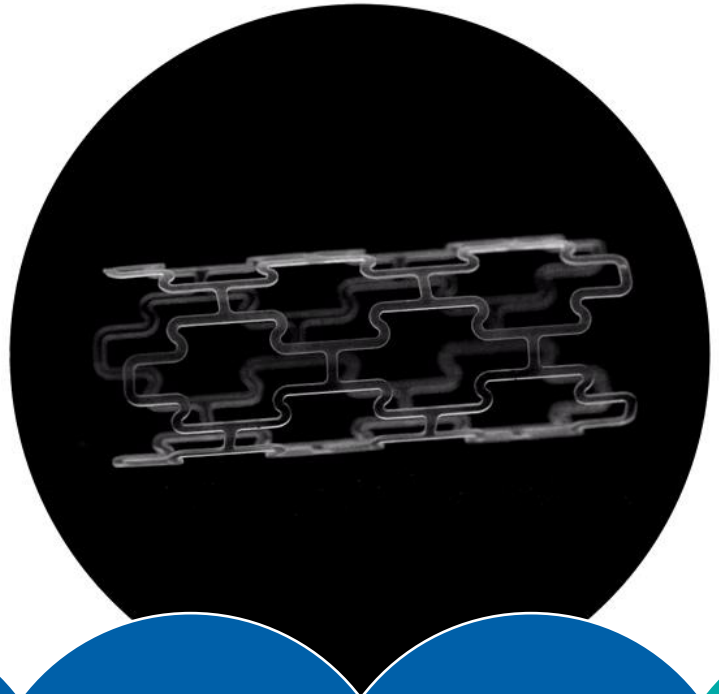
- Optimal molecular orientation enables new designs to be investigated with strut/wall thicknesses as low as 80μm
- Expanded polymer options allow for tailored absorption profiles
- Novel processing techniques allow for higher dimensional and morphological uniformity vs. previous tubing generations
- A combination of optimal molecular orientation and uniformity enables high radial strength BRS
- Circumferentially oriented options in development up to 15 mm diameters



ZEUS & MEKO

Why Uniformity & Orientation are Critical for Design Success

The BRS Value Chain



Materials

ZEUS

Tubing Size Range

ZEUS

Tubing Uniformity

ZEUS

Tubing Mechanicals

ZEUS

Laser-cutting Precision & Automation

MeKo MEDTECH

New Scaffold Design

Device OEM

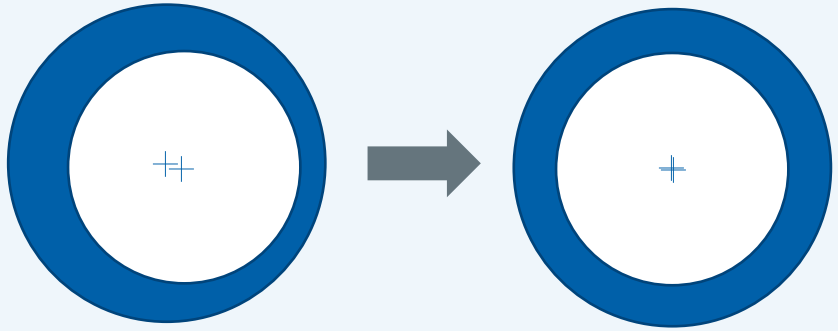
ZEUS

PRECISION PERFECTED
UNIFORMITY GUARANTEED

Dimensional Uniformity: Wall Thickness

Two Sources of Dimensional Variation that Impact Design & Performance

CIRCUMFERENTIAL
(within cross section)



POOR CONCENTRICITY

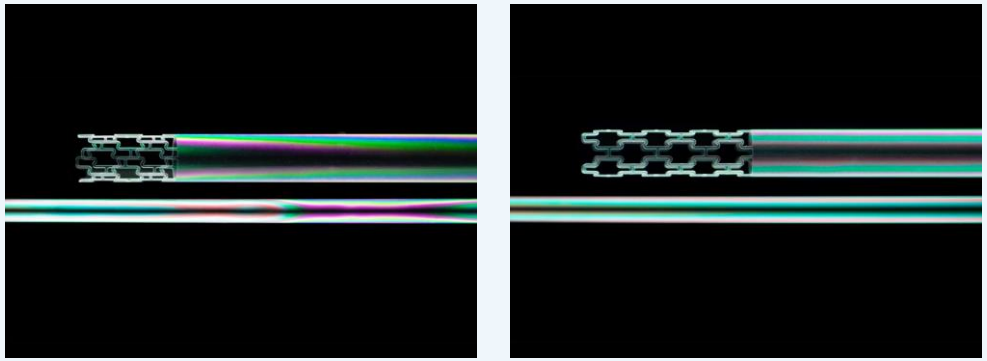
GOOD CONCENTRICITY

SCAFFOLD IMPACT:
non-uniform
radial strength

AXIAL
(down-the-length)

PREVIOUS GENERATION

ABSORV™ XSE



SCAFFOLD IMPACT:
radial strength variation
(within-scaffold or scaffold-to-scaffold)

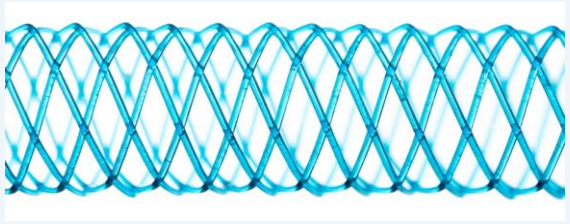
DIGGING DEEPER: MOLECULAR ORIENTATION

Stent Types

Design Considerations

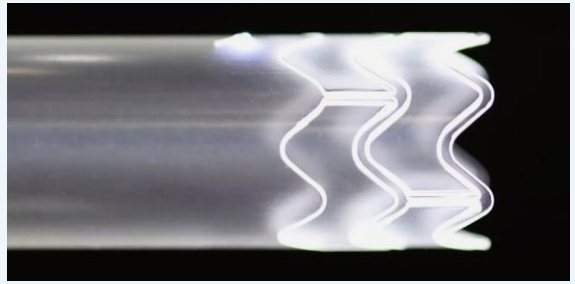
SELF EXPANDING

- **Construction:** Braided wire or fiber
- **Delivery:** Released from a sheath
- **Strain Level:** Low = elastic deformation
- **Size Range:** Large diameters available



BALLOON-EXPANDABLE

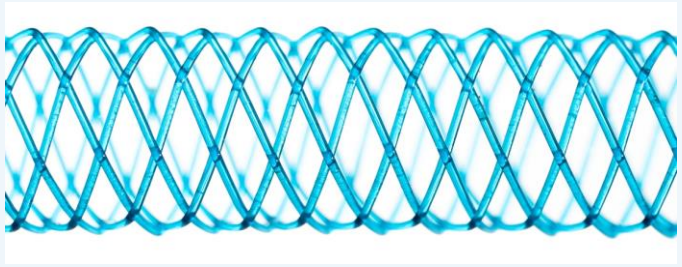
- **Construction:** Laser-cut tube
- **Delivery:** Deployed with a balloon
- **Strain Level:** High = plastic deformation
- **Size Range:** Historically limited diameters



Device Design

A Focus on Orientation

BRAIDED SCAFFOLD



DESIGN PARAMETER #1
BRAID DESIGN/CONFIGURATION

DESIGN PARAMETER #2
FIBER PROPERTIES

MOLECULAR ORIENTATION
The Primary Tool for Property Enhancement

LASER-CUT SCAFFOLD

DESIGN PARAMETER #1
SCAFFOLD DESIGN/GEOMETRY

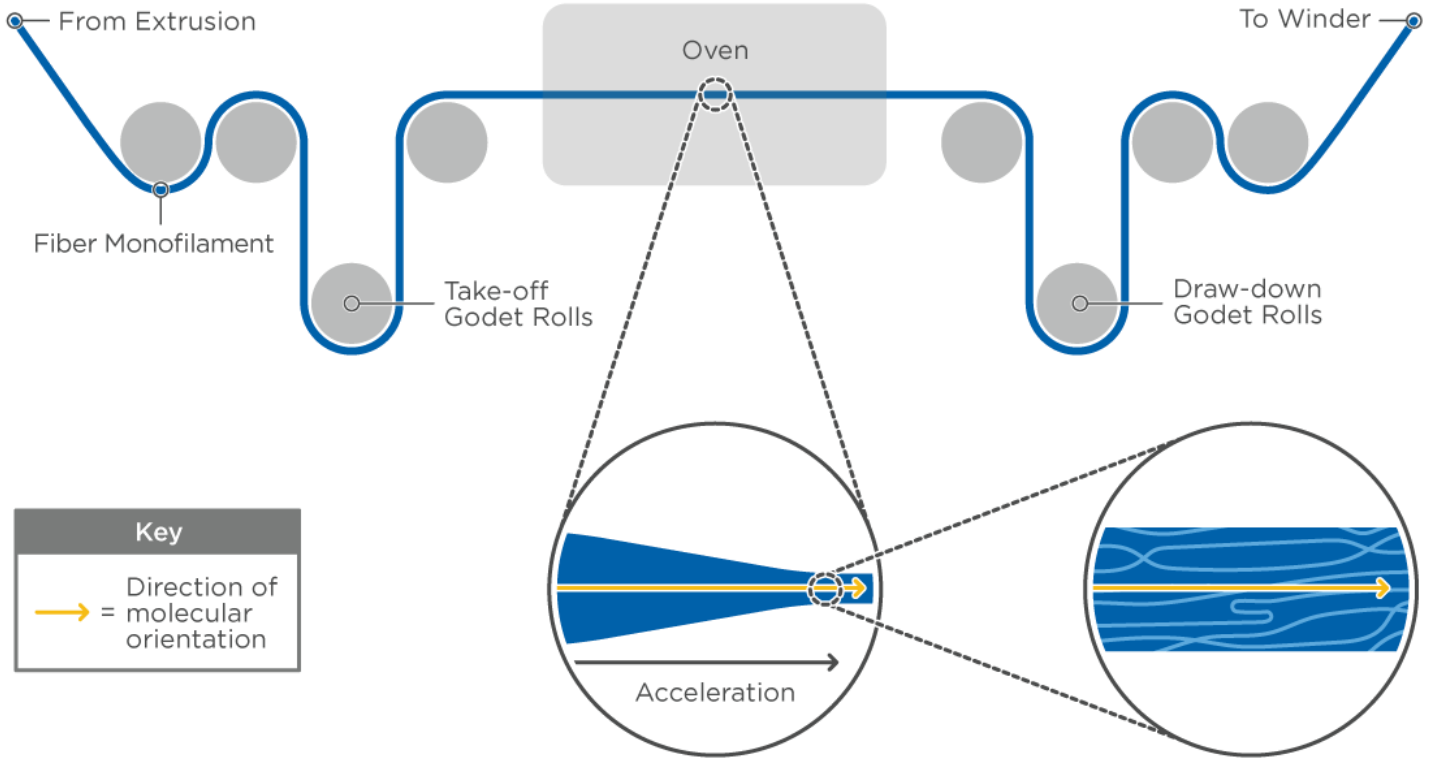
DESIGN PARAMETER #2
TUBING PROPERTIES

WHAT IS MOLECULAR ORIENTATION?

Molecular Orientation

Drawn Fiber (Uniaxial)

- Molecular orientation is induced in the direction of draw stress = axial direction

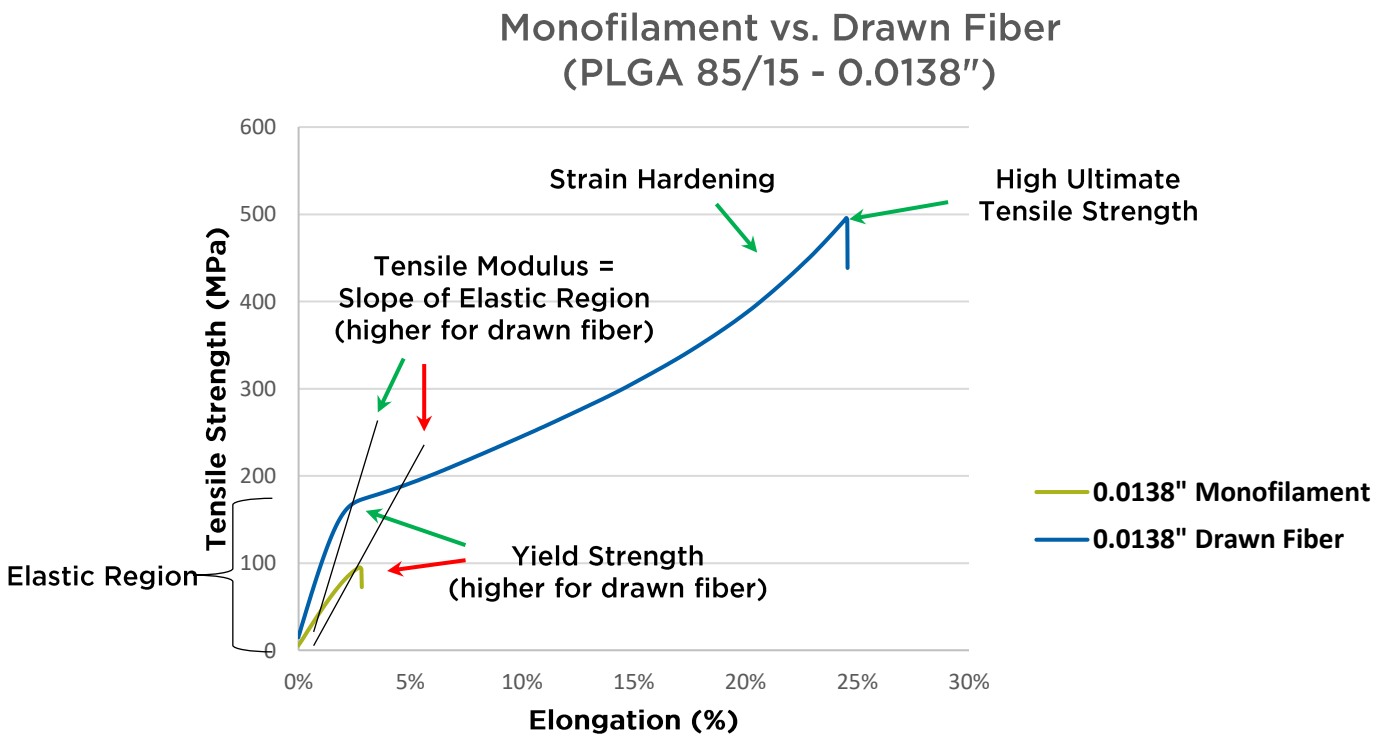


Molecular Orientation

Drawn Fiber (Uniaxial)

- Molecular orientation is induced in the direction of draw stress = axial direction

MONOFILAMENT = NON-ORIENTED
DRAWN FIBER = ORIENTED



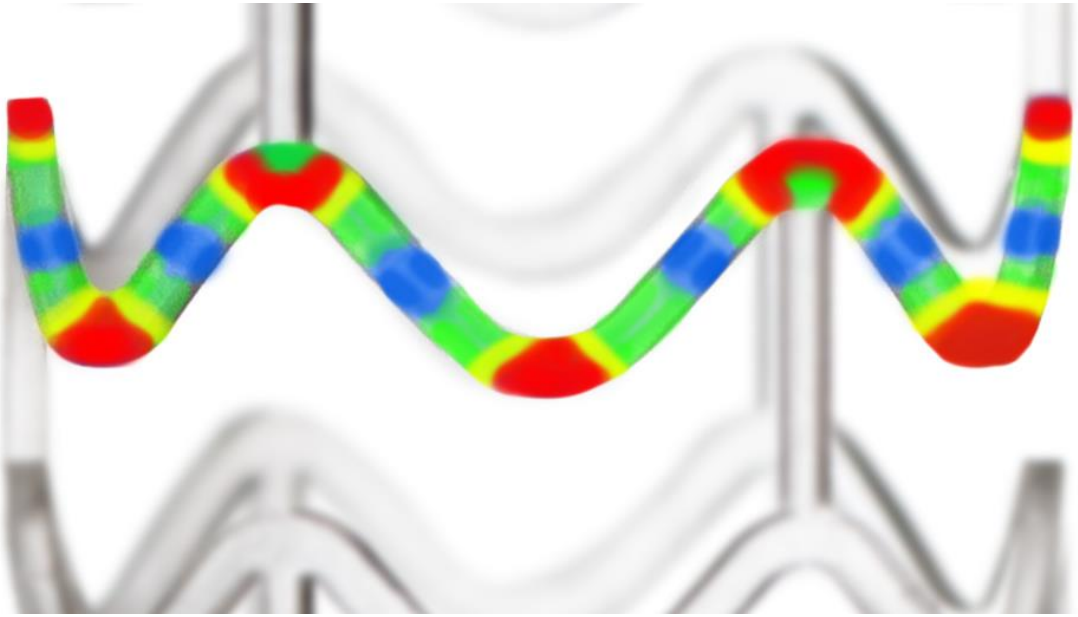
Molecular Orientation

For Laser-Cut BRS

WHY ORIENTED TUBING?

- Laser-cut, balloon expandable scaffolds are designed to plastically deform, requiring regions of high strain
- High-lactide polymers (e.g. PLLA, PLC, PLGA) are inherently brittle and thus susceptible to brittle fracture, even at relatively low strains
- High-lactide polymers also lack the strength and rigidity of metals – requiring thicker struts
- Molecular orientation is used to overcome these challenges
    - Higher strength enabling thinner struts with high radial force
    - Greater toughness for crimping, deployment, and over-expansion

LASER-CUT SCAFFOLD PLASTIC STRAIN

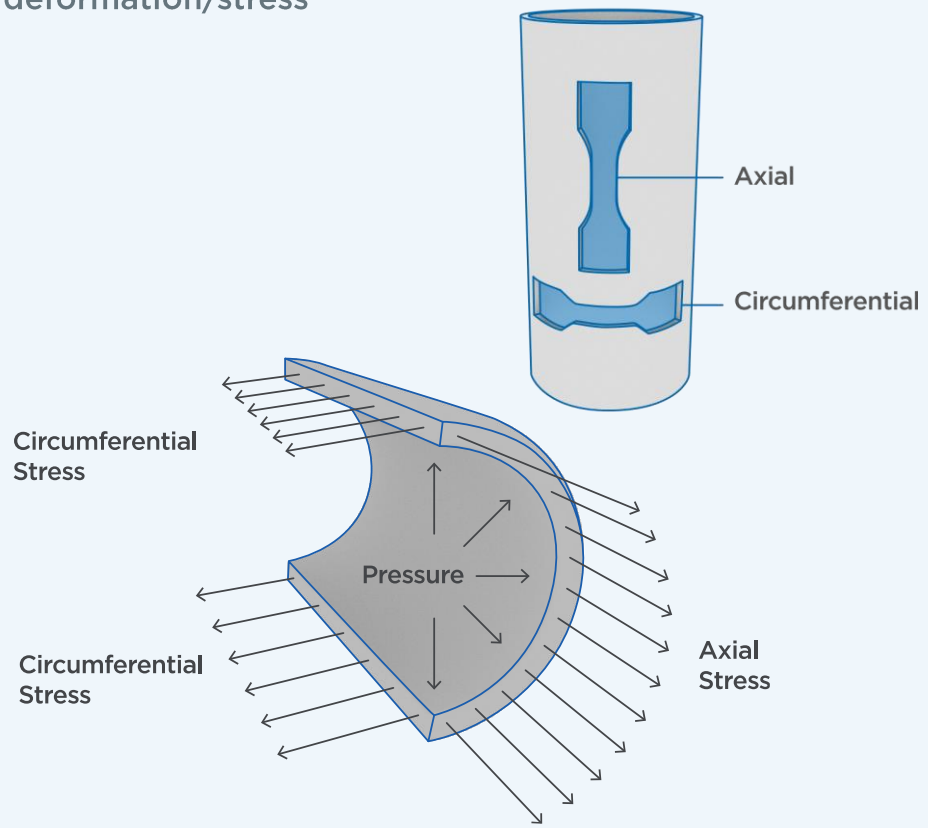


Molecular Orientation

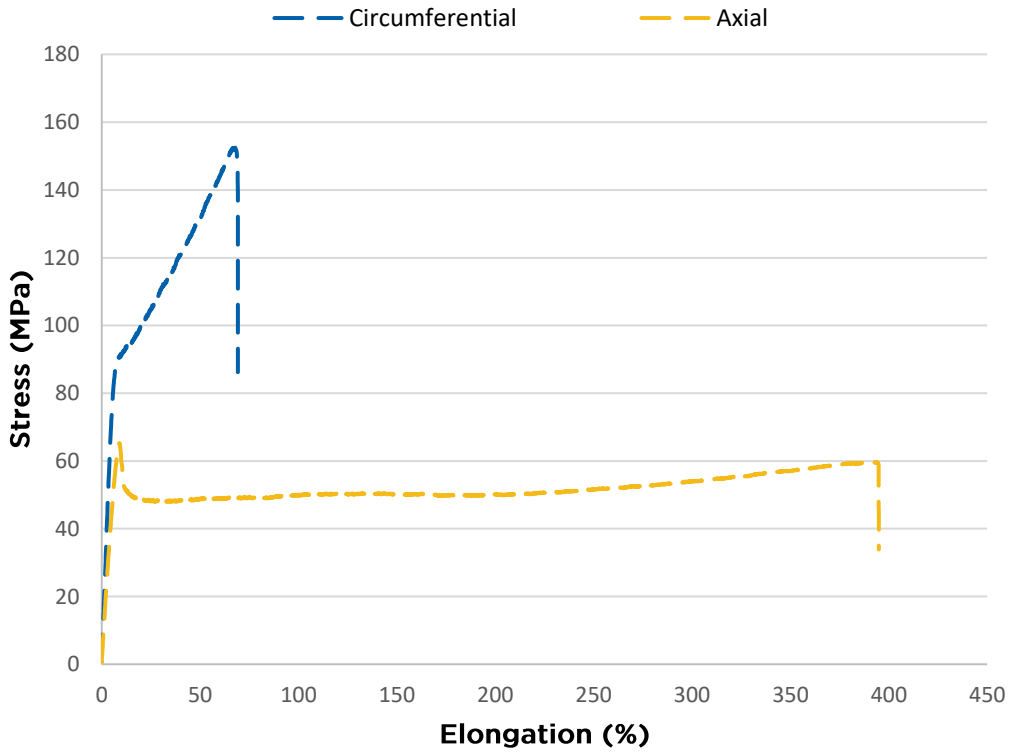
Biaxially Oriented Tubing

BIAXIAL ORIENTATION IN BOTH THE CIRCUMFERENTIAL AND AXIAL DIRECTIONS

Molecular orientation is induced in the direction of deformation/stress



CIRCUMFERENTIAL VS. AXIAL STRESS-STRAIN RELATIONSHIP



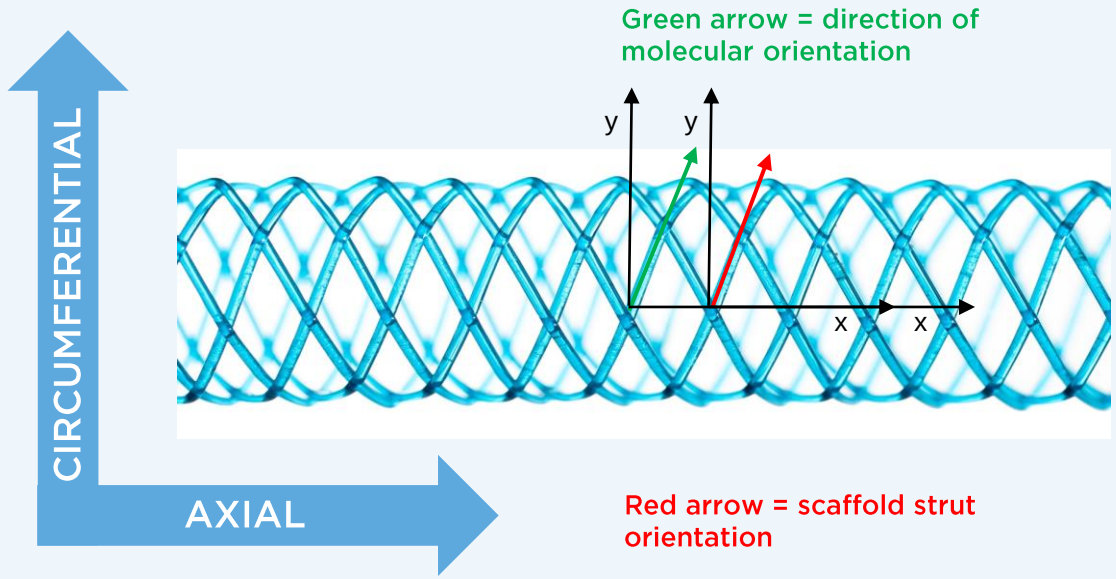
WHY ELSE MIGHT WE NEED BIAXIAL ORIENTATION?

Molecular Orientation

Braided Scaffolds

CHARACTERISTICS:

- For braided scaffolds, the molecular orientation within the scaffold is controlled solely by the scaffold design
- For braided scaffolds, molecular orientation is always parallel to the scaffold strut orientation



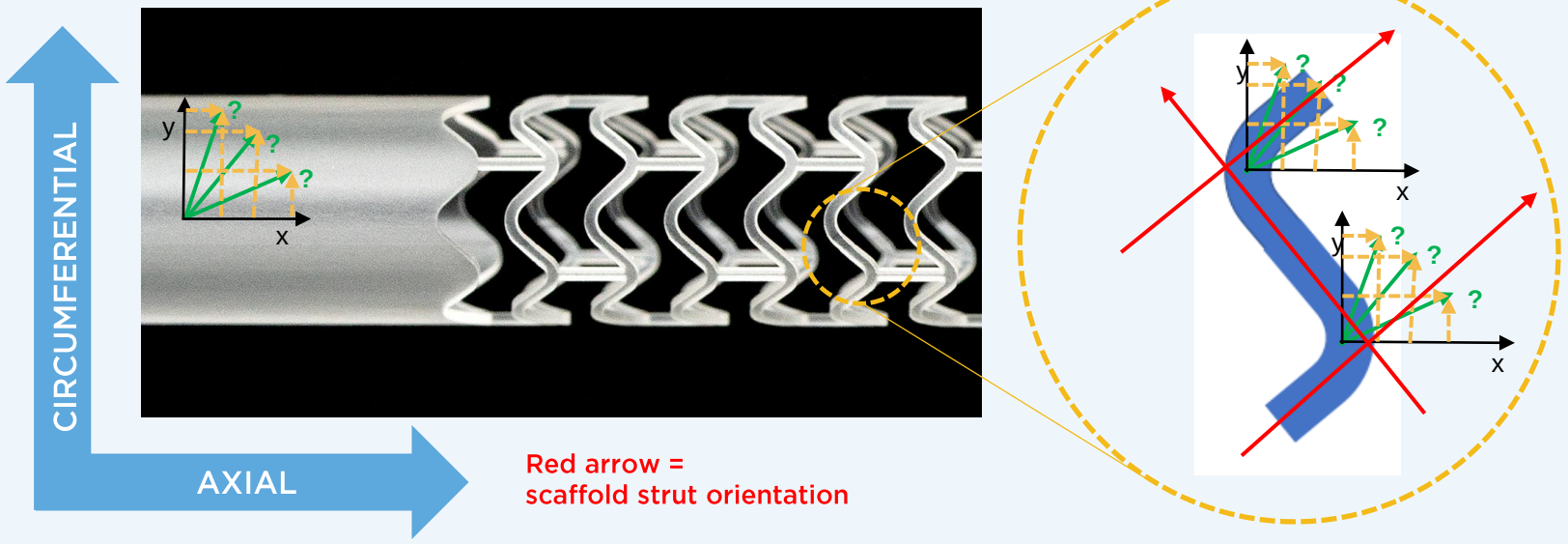
Molecular Orientation

Lased Scaffolds

CHARACTERISTICS:

- Molecular orientation within the scaffold is controlled by both the scaffold design and the molecular orientation in the tubing
- Molecular orientation is not automatically parallel to the scaffold strut orientation, but is rather superimposed onto the scaffold geometry

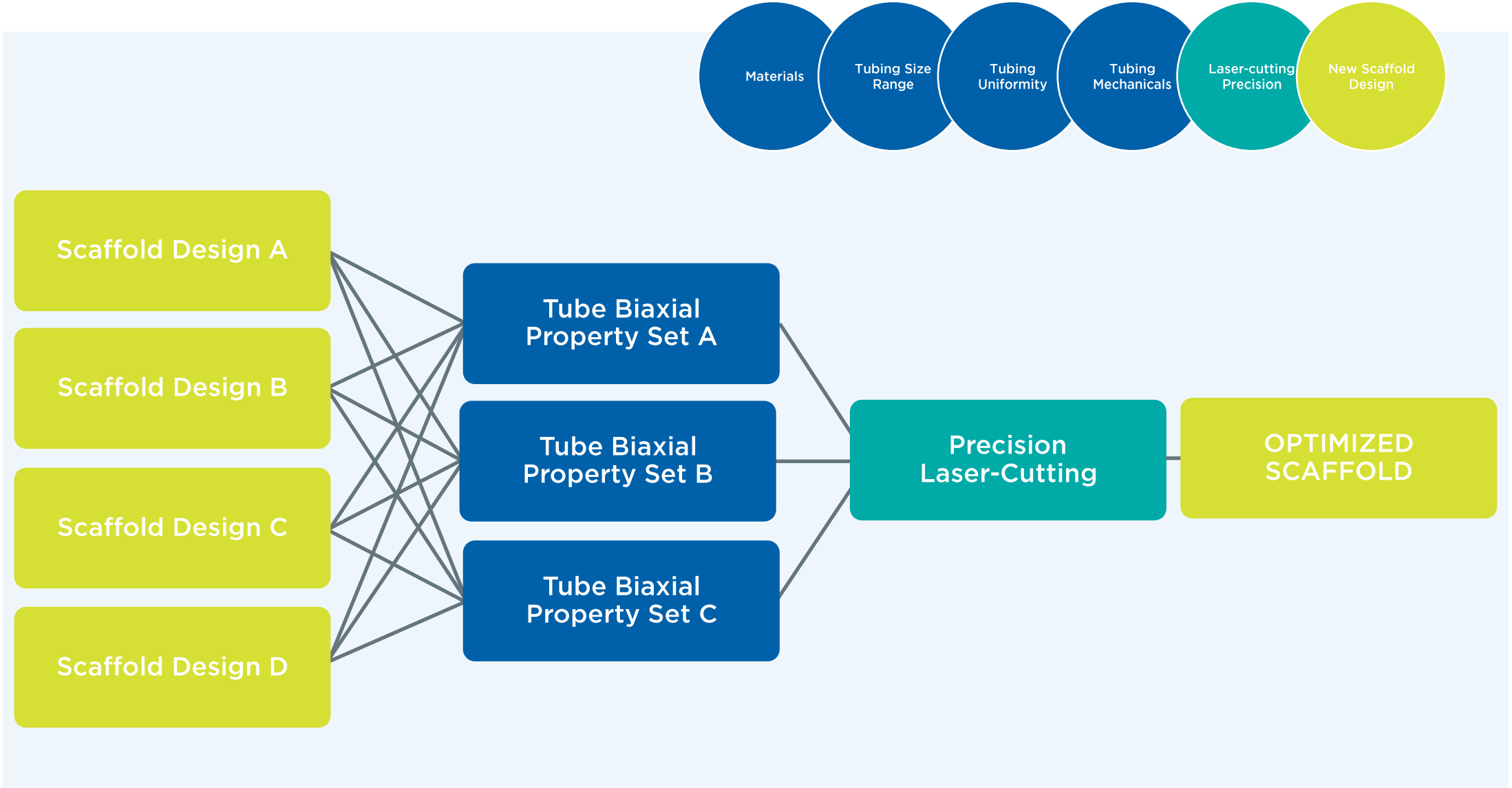
Green arrow =
direction of molecular orientation



Red arrow =
scaffold strut orientation

Bringing It All Together

Combining Design & Properties for Optimization



OUR LATEST INNOVATION
ABSORV™ XSE

A Biaxially Oriented Product Platform

Absorv™ XSE

Oriented to Replace Metallic Stents

Carotid (4.0 – 6.0 mm)

Pediatric Aorta (7.0 – 15.0 mm)

Coronary (2.0 – 5.0 mm)

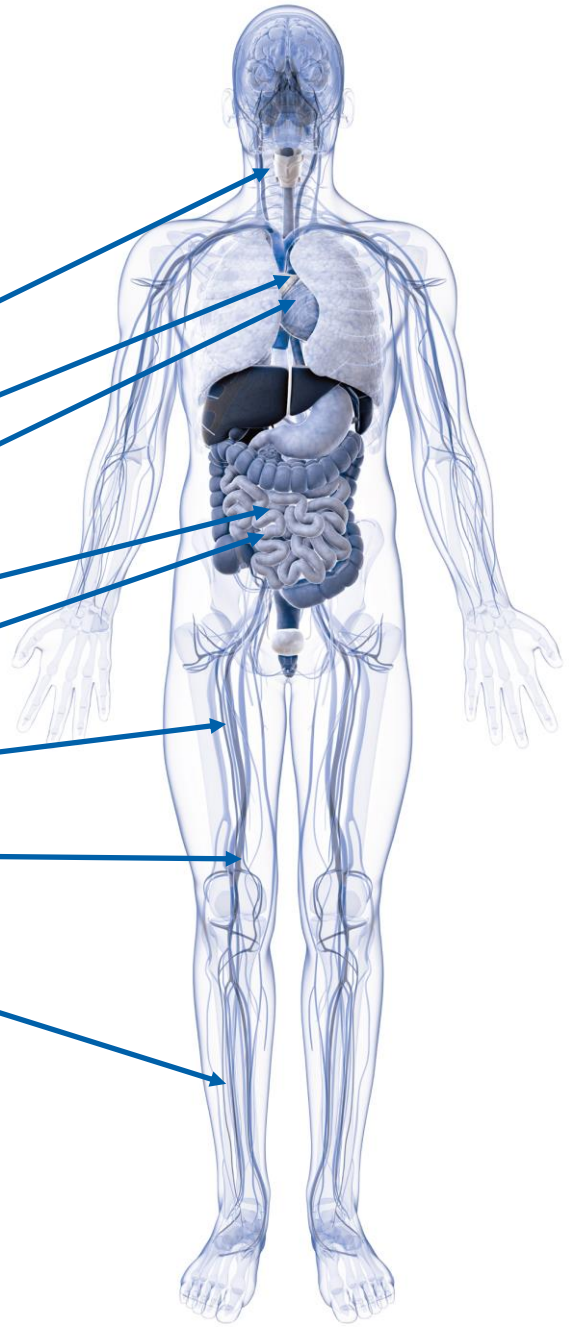
Renal (5.0 – 6.0 mm)

Iliac (5.0 – 10.0 mm)

Femoral & Superficial Femoral (5.0 – 8.0 mm)

Popliteal (5.0 – 6.0 mm)

Tibial (3.0 – 4.0 mm)



Absorv™ XSE

Oriented to Replace Metallic Stents

EVOLUTION – ABSORV™ XSE

- New 100μm uniform wall thicknesses available
- Larger OD range (1.5-15 mm OD) development
- Increased uniformity provides predictable design outcomes

PLATFORM FOR INNOVATION

- Innovation across the tubing platform, helps you to create new designs in:
  - Cardio, Neuro, Peripheral Stents
  - ENT Devices
  - GI Devices

SUPERIOR ECONOMIC VALUE IS KEY

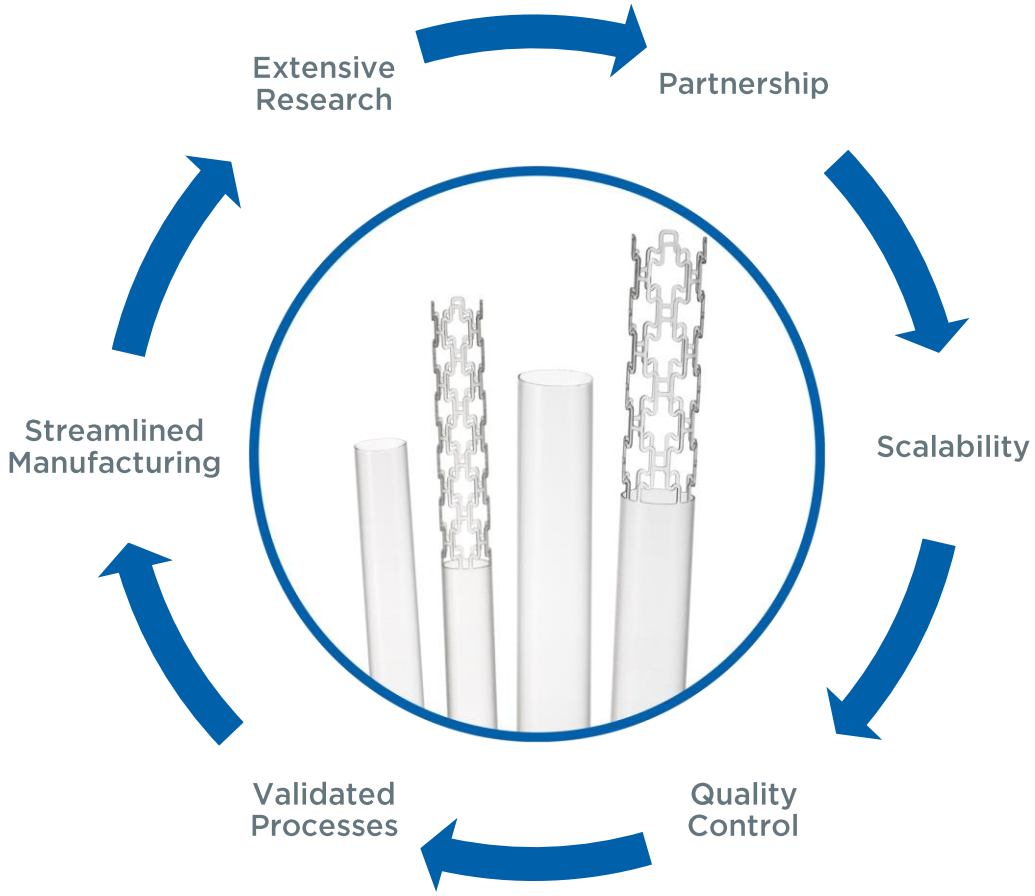
- Get more prototypes and production parts from precision laser cutting and increase the economic value of your purchase:
  - Up to 25% Improvement

DELIVER NEW DEVICES

- Enable physicians with cutting-edge devices

HELP TRANSITION AWAY FROM METAL

- Patient-first materials make a better future



***Disclaimer on Economic Value:** This is a representative study based on Zeus' former Absorv™ tubing products compared to the new Absorv™ XSE products. Results may vary based on the material used, scaffold design, change in size, or inspection requirements. There are no guarantees or assurances implied, these are estimates based on one study.*

The BRS Value Chain

Device OEM / ZEUS

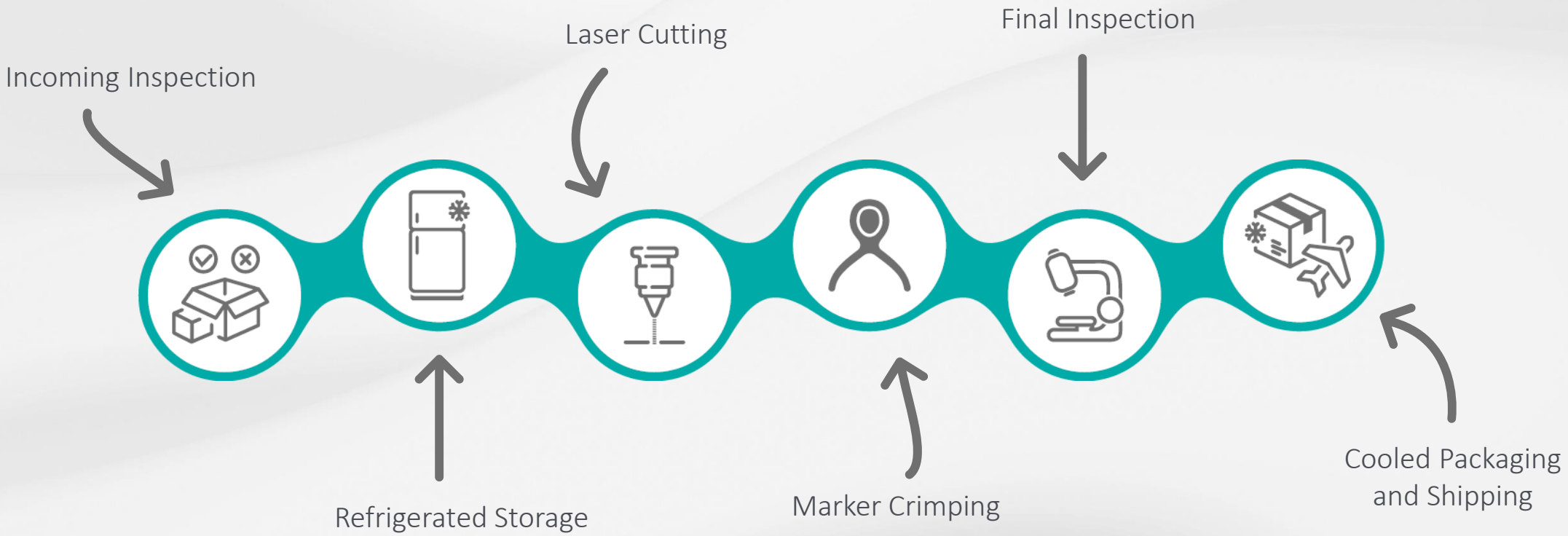
MeKo

MeKo / Device OEM

Polymer

Processing Capabilities

MeKo MEDTECH



Polymer Know-How

Test Abilities for Materials & Scaffolds

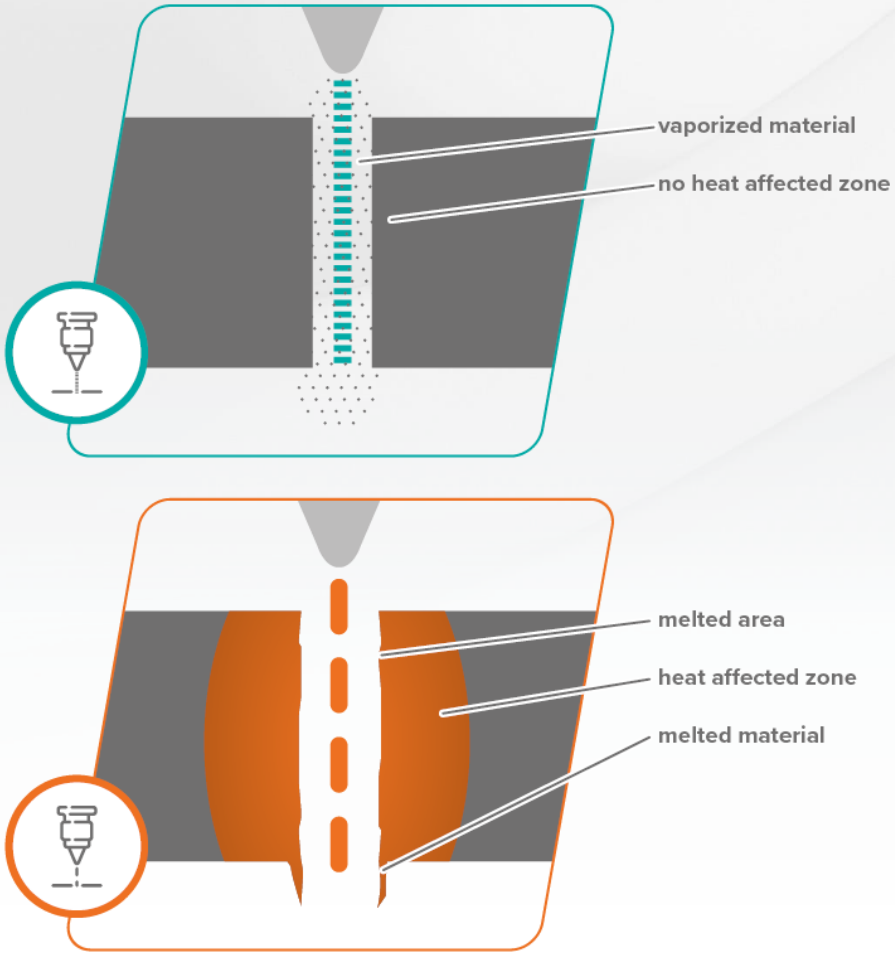
MeKo MEDTECH

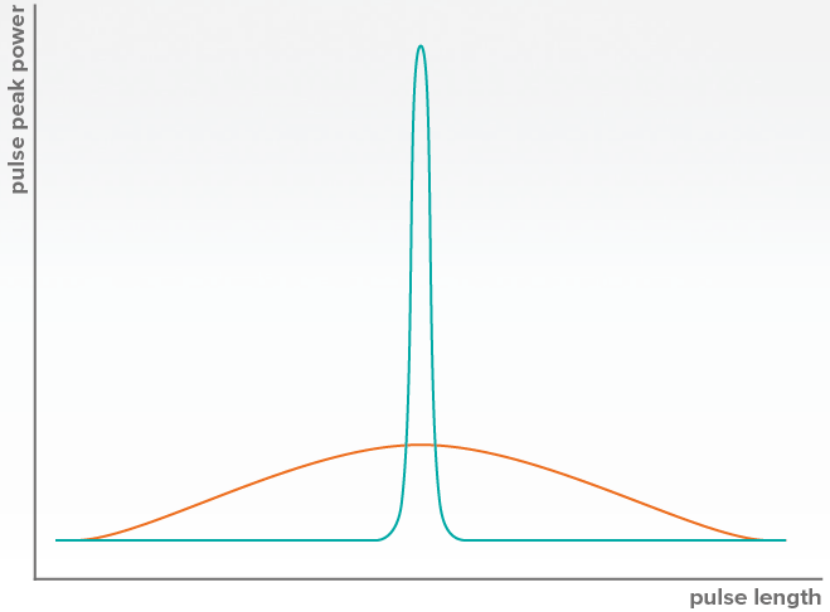
- Tensile Testing
- Radial Force Testing
- Measurement of Intrinsic Viscosity (IC)
- Scanning Electron Microscope (SEM)
- Differential Scanning Calorimeter (DSC)
- Atomic Force Microscope (AFM)
- Fourier-transform infrared spectroscopy (FTIR)
- Confocal Laser Scanning Microscopy (CLSM)
- High Performance Liquid Chromatography (HPLC)

MedLab by MeKo

MeKo.de

Conventional pulsed laser vs. Ultra short pulse laser



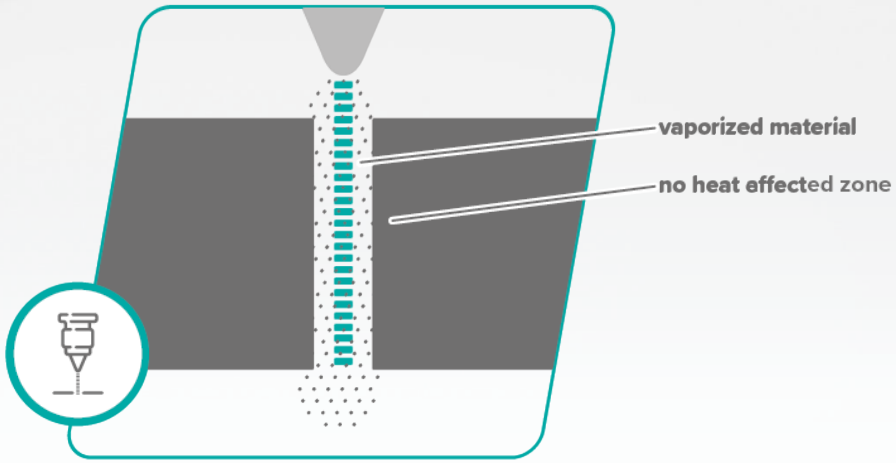


Definition and Realization

Ultra Short Pulse (USP) Laser

- Pulse length needs to be < 10 ps (10^{-12} s)
- Laser pulses with very high peak power of up to several GW
- „Cold“ ablation of material
- Almost all materials can be processed – metal, polymer, glass, ceramics, precious metals and more

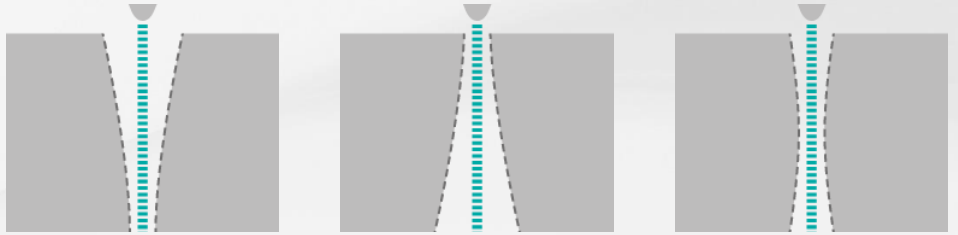
> Realization at MeKo:
  - Pulse length down to 190 fs (10^{-15} s)
  - Common wavelength: Ultraviolet (~300 nm) to Infrared (~1050 nm)
  - Wavelength is adjustable for the specific material

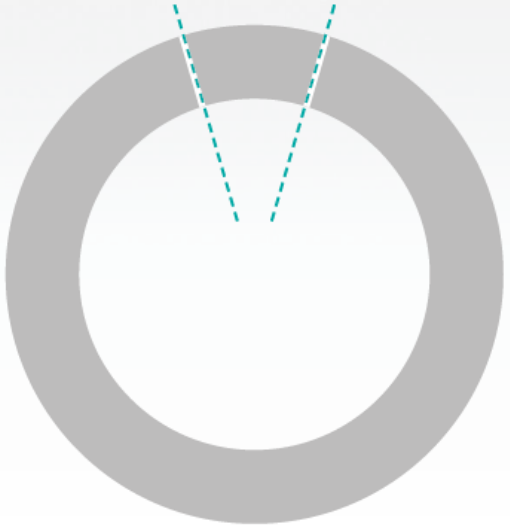


Precision

Processing of Polymer Tubing

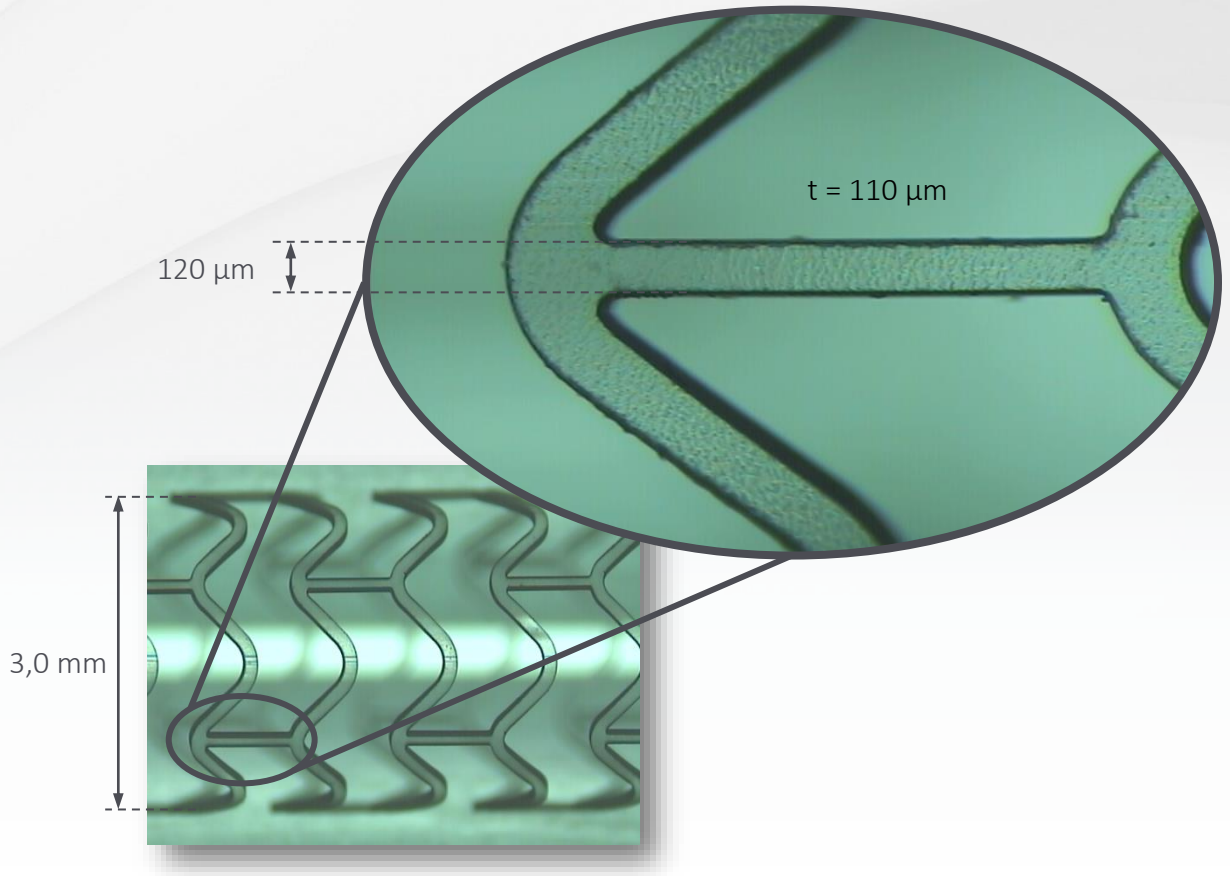
- cross sectional shape of a single laser cut can be influenced/triggered
  - > Ratio cutting width to depth: up to 1:20
- Laser is always aligned to center of the tube
  - cross sectional area of a strut has always a trapezoid shape
  - > ratio between inner and outer width of the same strut depends on tubing ID and OD
- Reduced curvature and better wall thickness tolerances of tubing
  - > Enable tighter tolerances of struts
  - > Are beneficial for devices with dimensions close to edge of feasibility





Processing of polymers with USP lasers

- Significantly reduced heat affected zone
- Effect on material properties is reduced to a minimum (compared to standard laser cutting)
- No deburring required
- Tolerances below ± 10 µm (0.0004”) can be achieved
- Clean environment is ensured
- Radio-opaque markers can be fitted to stents to ensure radio-visibility



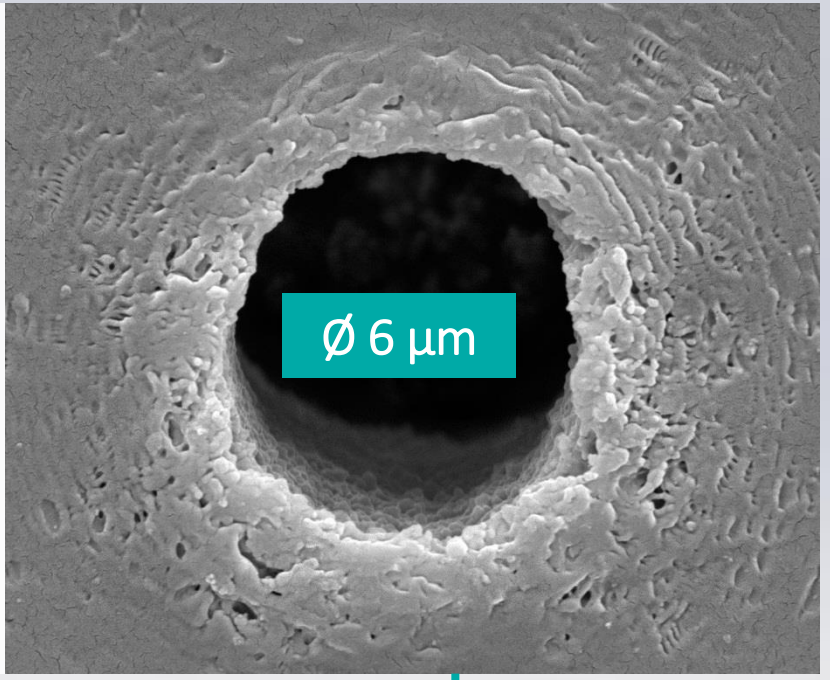
Microholes

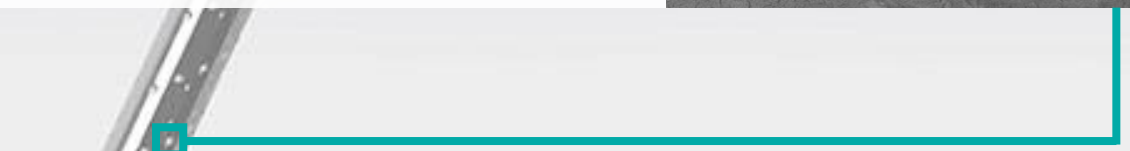
For Drug Delivery Balloons (DDB)

MeKo MEDTECH

Laserdrilling of thin-layer polymers

- Drilled diameters < 6 µm possible
  - > Depends on material thickness
- Adjustable hole sizes in steps of 1 µm (0.00004”)
- Hole distribution can be adapted flexibly to your requirements
- All kind of balloons: peripheral and coronary
  - > Cylindrical and conical balloons can be processed





Automation

Processing of Zeus Polymer Tubing

- Improved initial length (209 mm vs 108 mm / 8.25“ vs 4.25“)
  - > Enables higher level of automation
    - Automated feeding process
    - Each individual tube needs to be handled manually
    - Doubled tube length:

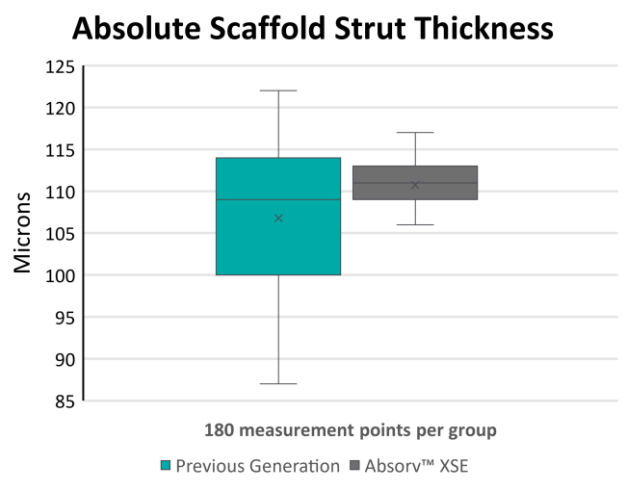
      operator only needs to intervene half as often
  - > Improves material utilization
    - Due to clamping a certain length per tube cannot be processed
    - Doubled tube length:

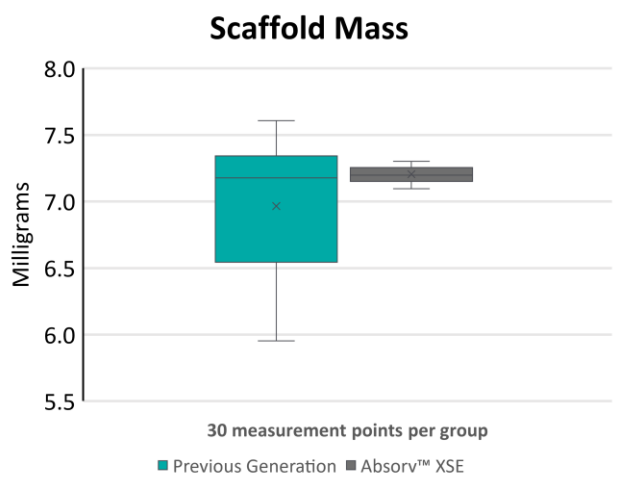
      higher number of scaffolds can be cut

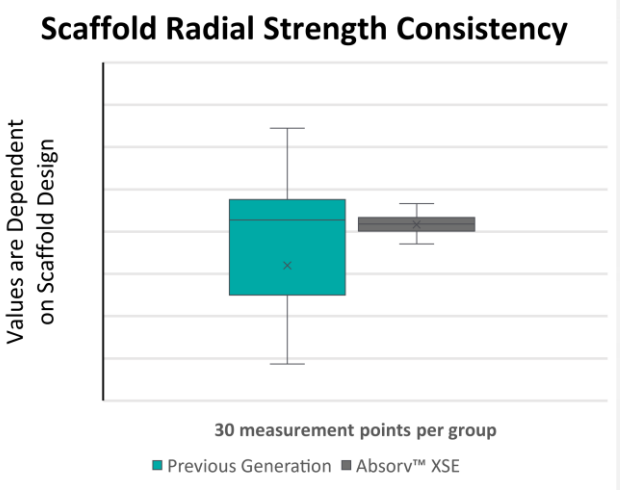
Scaffold Properties

Processing of Zeus Polymer Tubing

Overview of measurement results:







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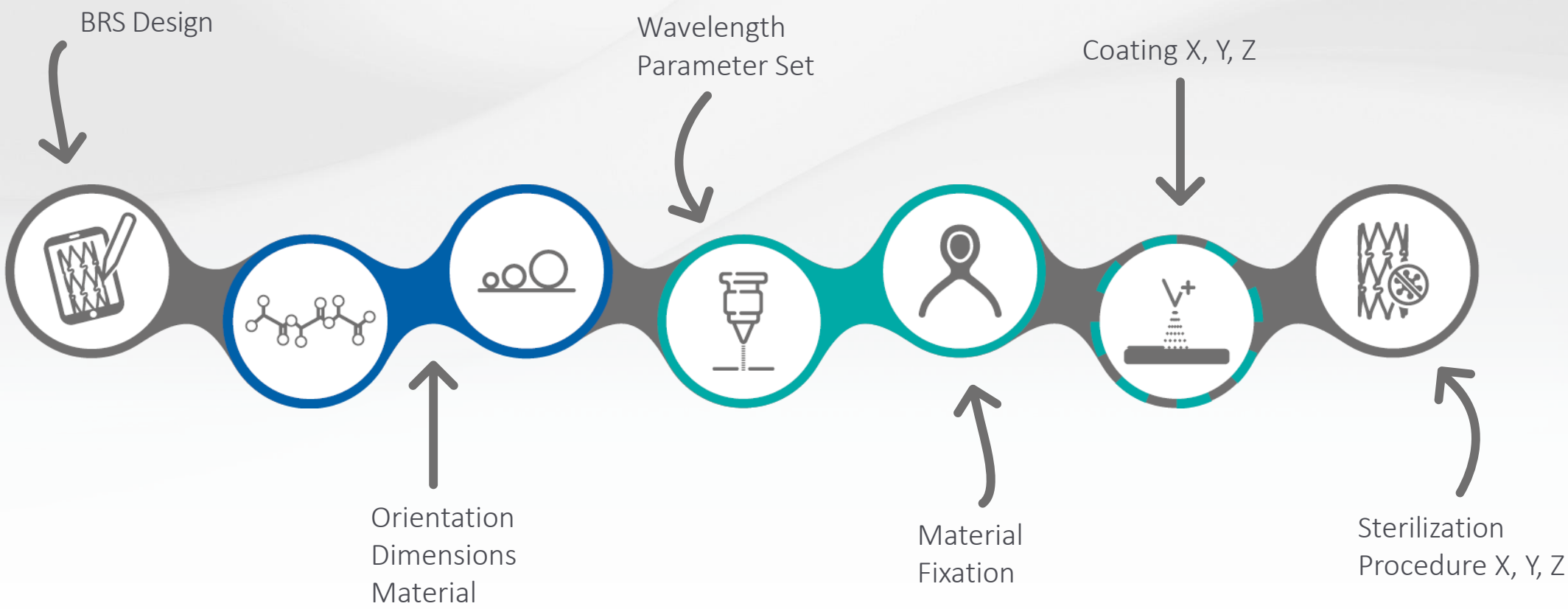
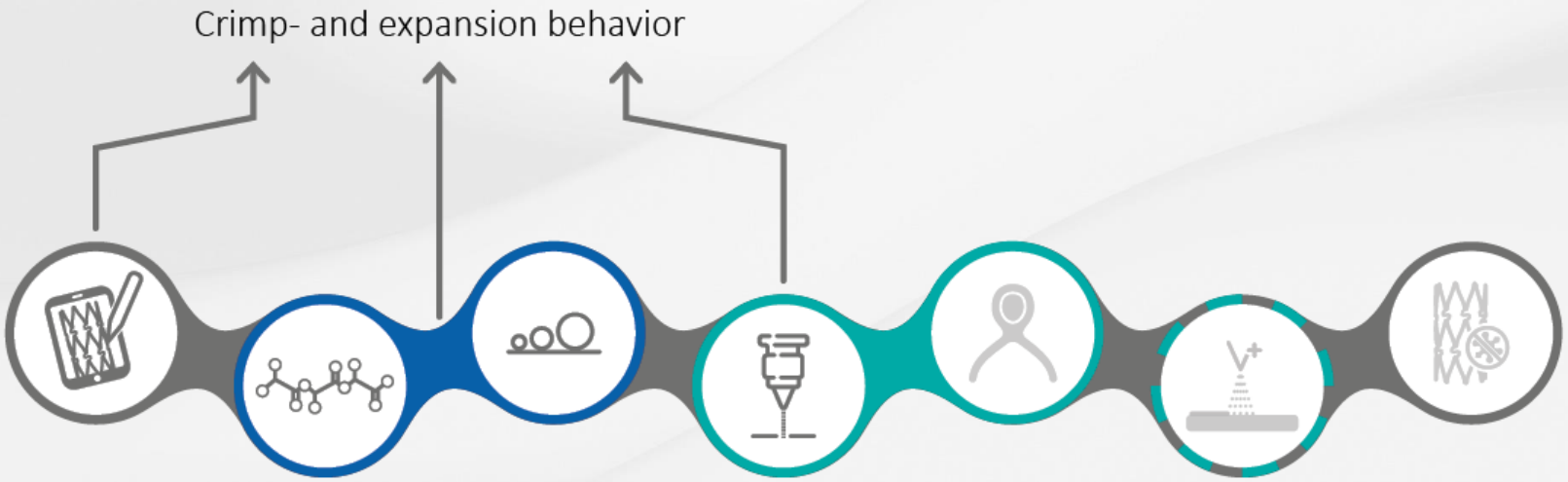
Zeus x MeKo

Absorv™ XSE Platform



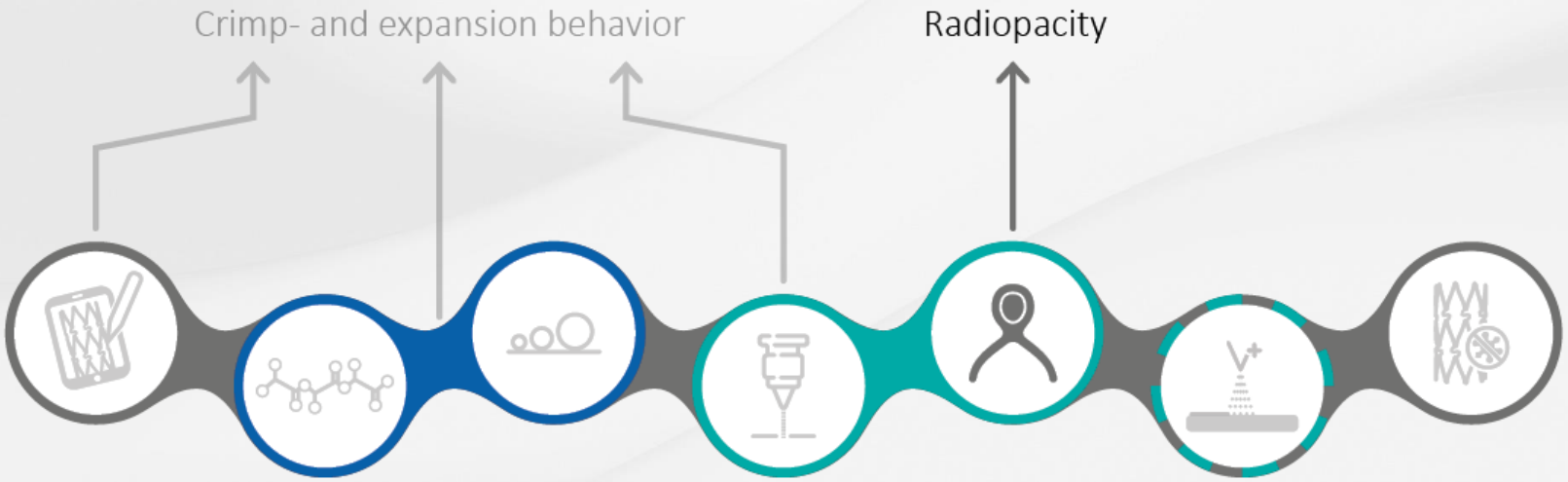
Zeus x MeKo

Absorv™ XSE Platform



Zeus x MeKo

Absorv™ XSE Platform



Zeus x MeKo

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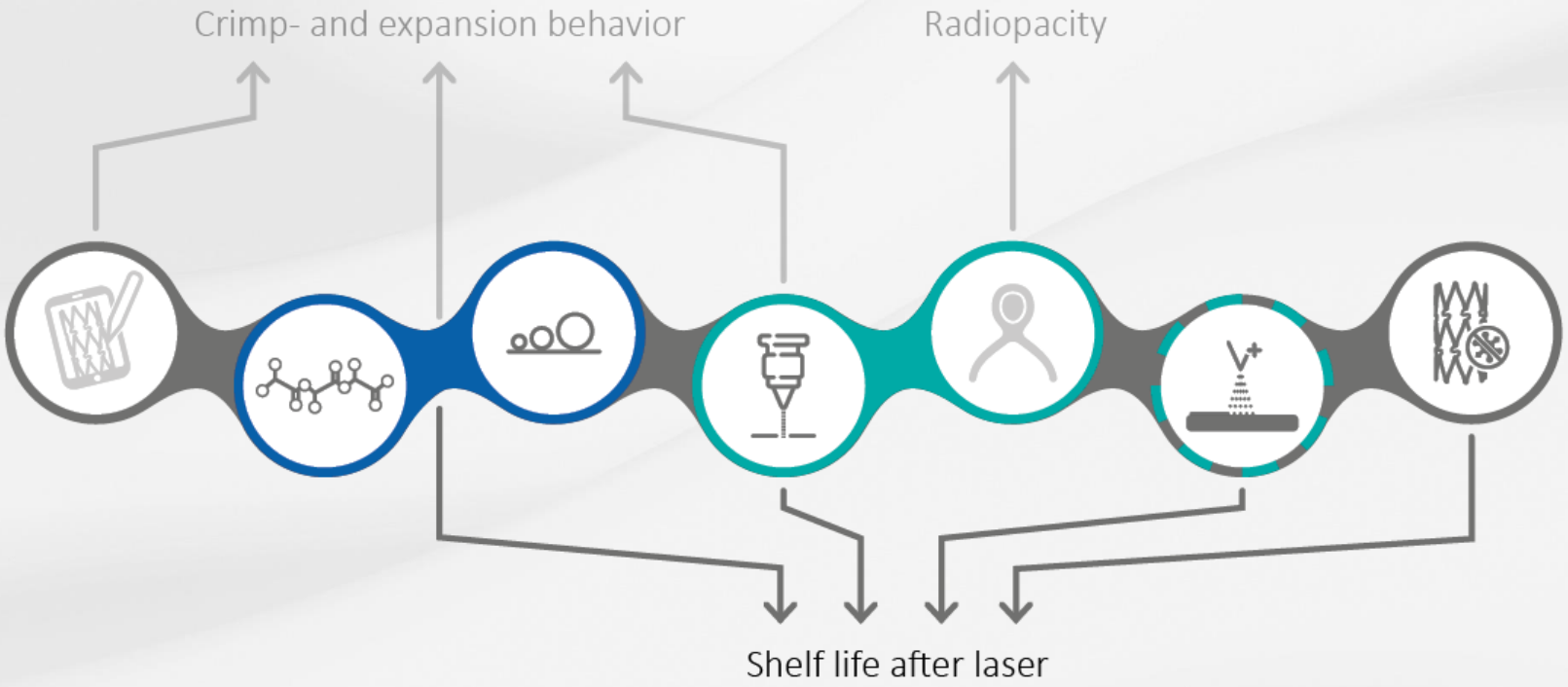
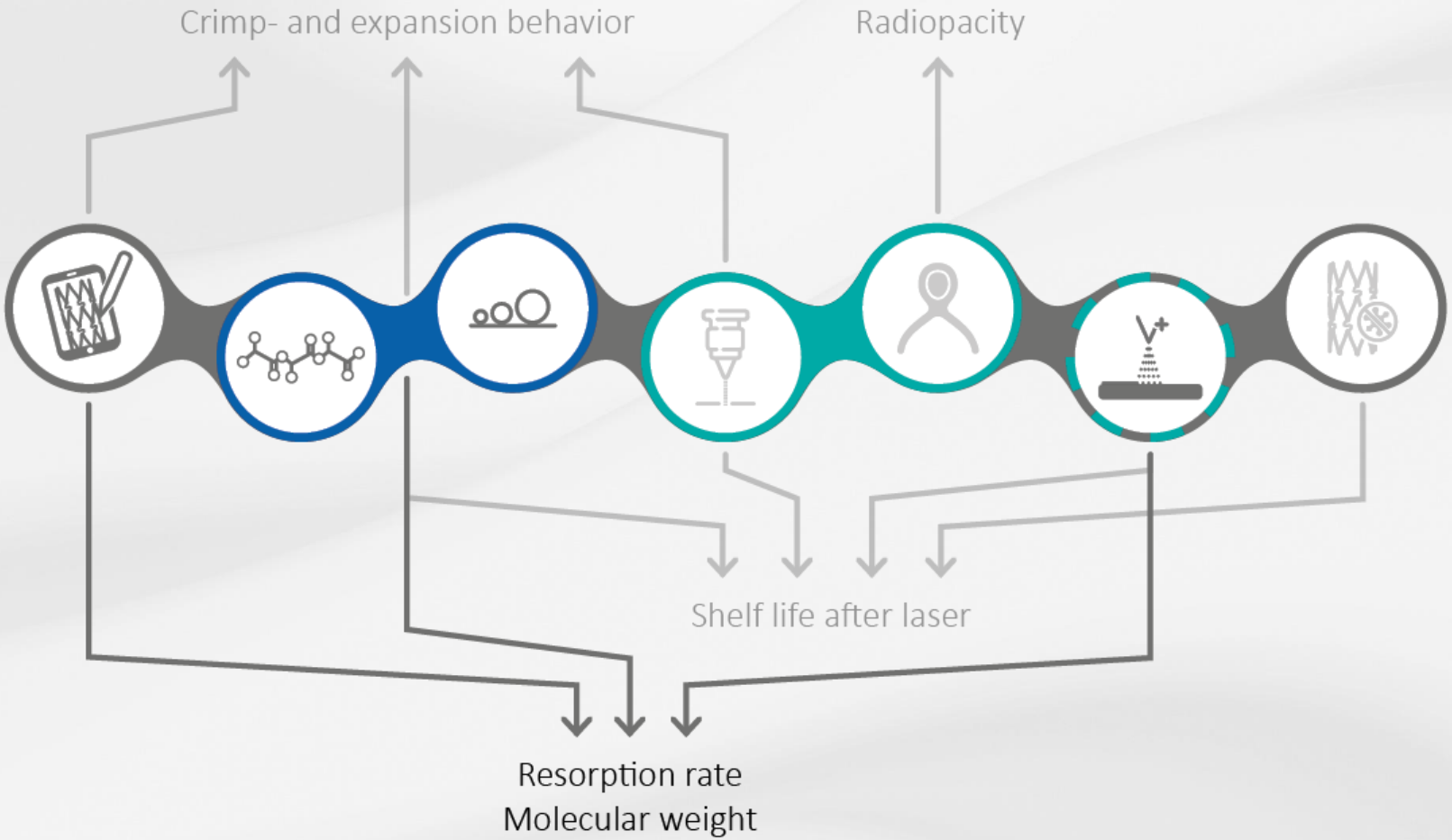


Zeus + MeKo

Absorv™ XSE Platform



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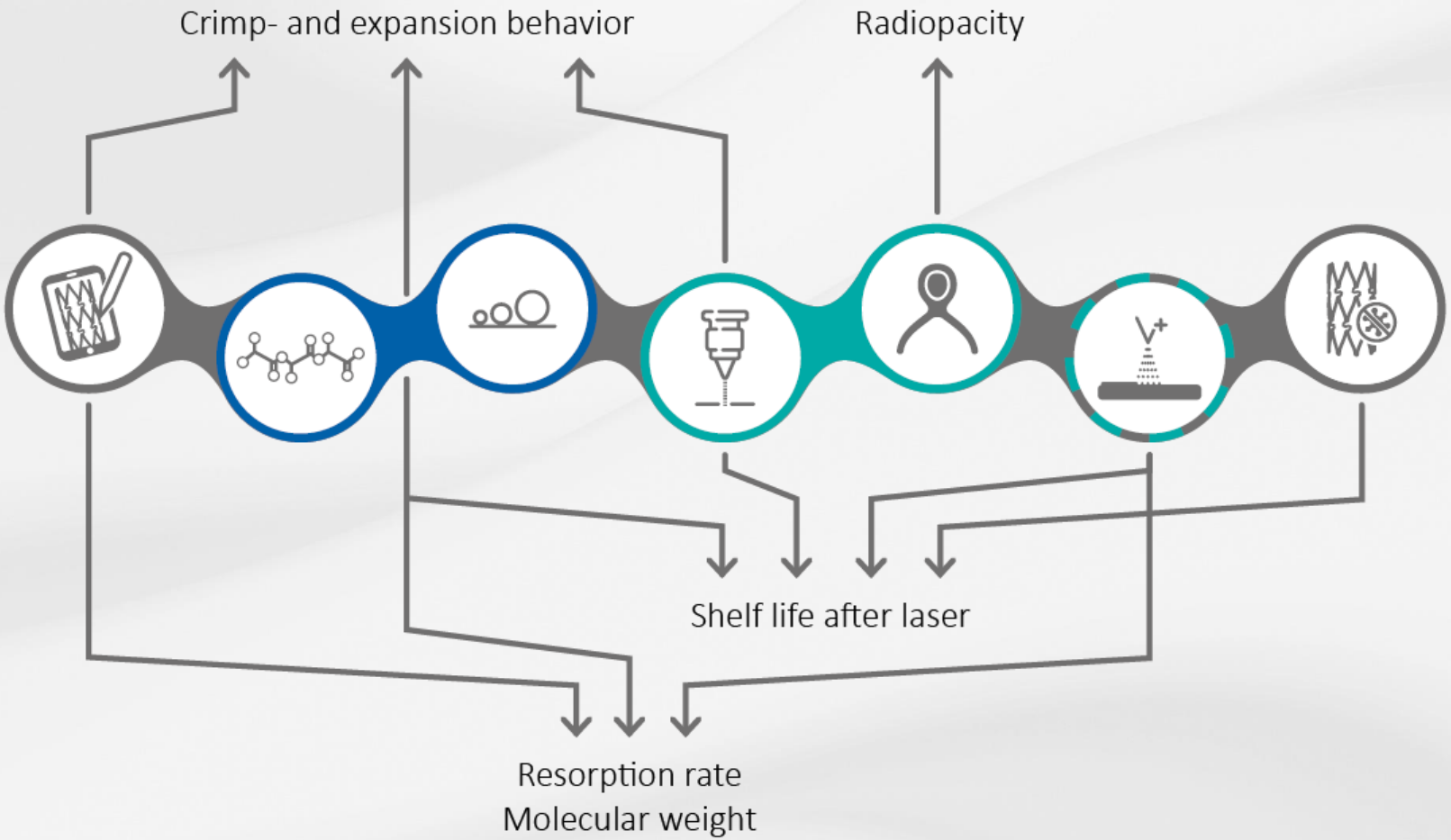

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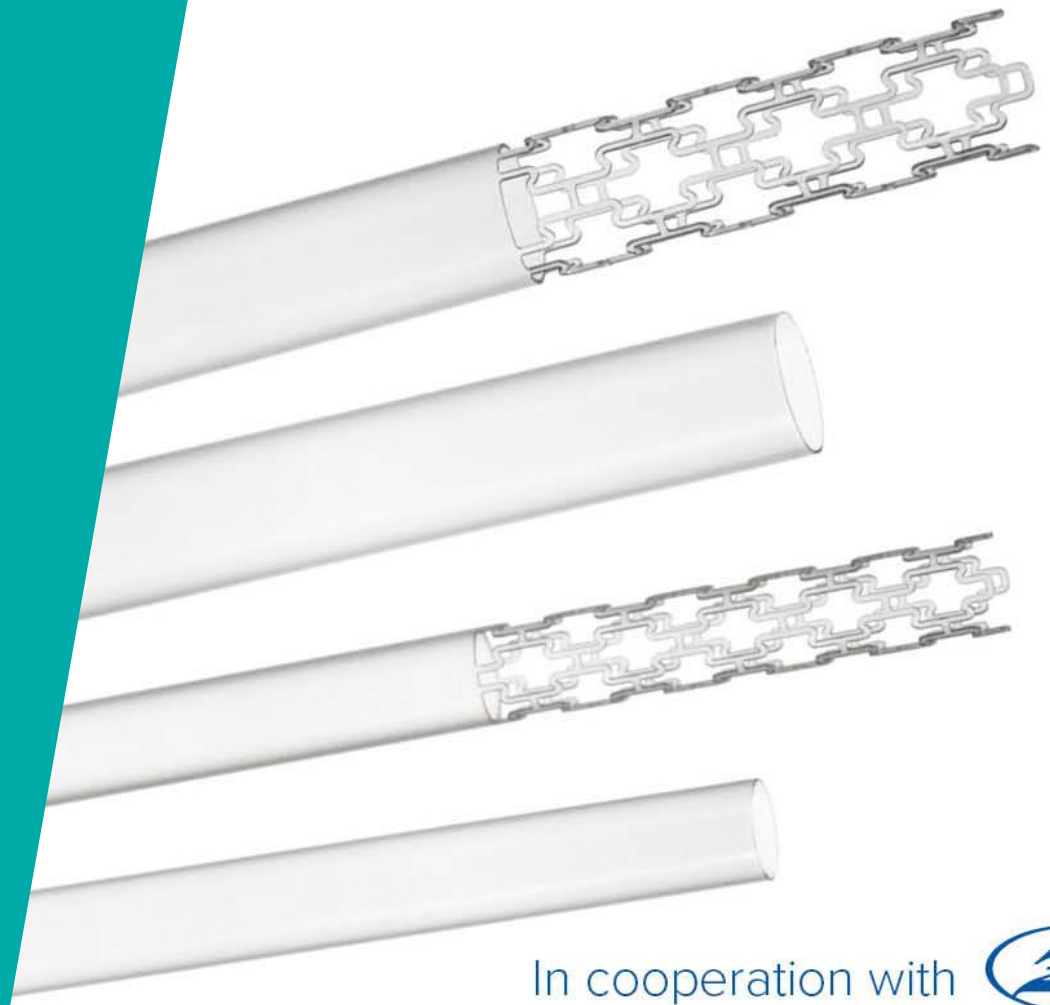

In cooperation with ZEUS