



EPIC Online Meeting on Fibers for Medical Applications

Challenges and Opportunities from the viewpoint of a **Medical Device Manufacturer**

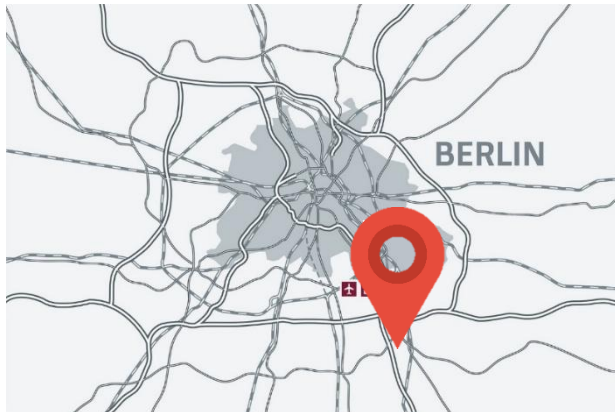
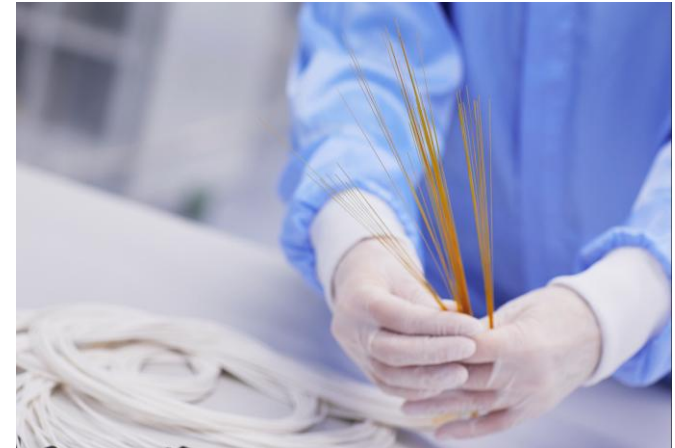


Who we are...



„We want to be as flexible as possible – for this reason OBERON was founded.“

- **OBERON Fiber Technologies** established in 2013 as a spin-off from LEONI Fiber Optics GmbH
- Typical SME with to date 57 employees and roughly 180 customers worldwide
- Located in the outskirts of Berlin
- 1600m² active production area



- State of the art production equipment and technology
- Modular ISO class-7 cleanroom
- Comprehensive quality management system and certification according to ISO 13485; ISO 9001; FDA; MDMA

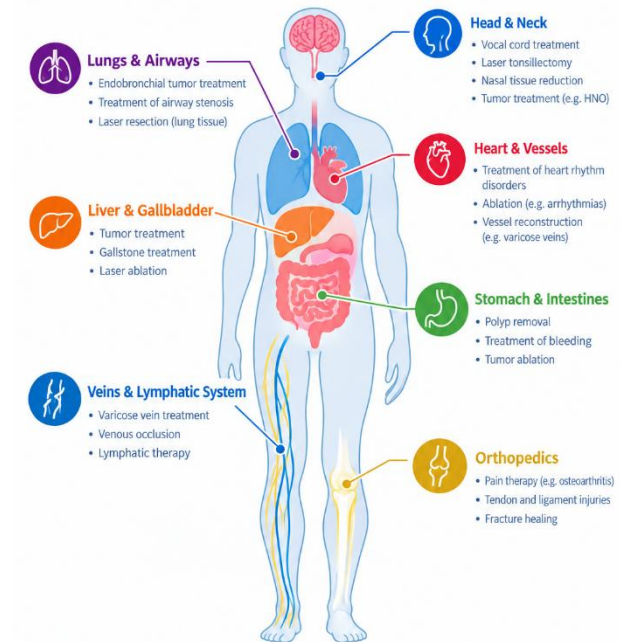


What we offer...



„minimally invase, precise and versatile“

- Large range of optical fibers for laser based medical treatments and diagnostics
- Large scale of production LOT's from 1 up to 1000pcs.
- Multimode fibers made of pure silica or hard plastic
- various NA applicable for wavelength between 400nm and 2200nm
- Sterile products available **disposable** or **reusable**



- Worldwide distribution network with over **27 distributors** and **local certifications**
- Products provided under **OBERON** brand and **OEM** manufacturing for international laser manufacturers





Challenges for medical device manufacturers

„How much regulatory efforts is proportionate to the actual risk?“

- Since May 2021 the **Medical Device Regulation (MDR)** – EU 2017/745 is in effect
 - Key objective: Patient safety & device performance
- OBERON as a medical device manufacturer, producing products under CE mark, risk class 2b is obliged to fulfill those requirements
- Strict requirements for:
 - Design
 - Manufacturing
 - Documentation
 - Clinical evaluation





Challenges for medical device manufacturers

„a fiber as medical device is a complete system instead of a isolated component“

- Although fibers itself are comparably simple products, the development of such is a complex, expensive and time consuming process
- Fiber + connector + distal tip + materials + manufacturing process + intended use
- In regard to EU MDR CE Certificate – Annex IX, Chapter I and III development or changes are strongly regulated

Innovation vs. documentation

Engineering:	“Can we improve it?”
Regulatory Affairs:	“Can we demonstrate that the change remains safe and effective?”
Manufacturing:	“Can we reproduce it?”
Quality:	“Can we control it?”

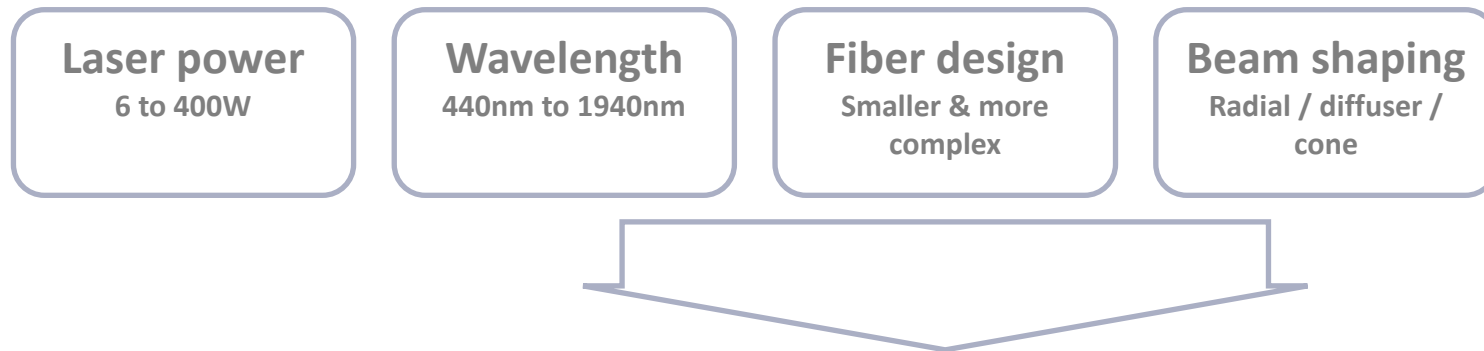
The change cascade





Opportunities for medical device manufacturers

„Can we make it work safely, reproducibly and economically?“



Project Introduction: **FaPaA**
(Faser-basierte Lichtdiffusoren mit Patientengerechter Abstrahlung)





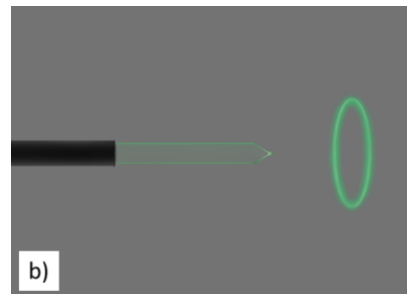
Opportunities for medical device manufacturers

Project Introduction: FaPaA

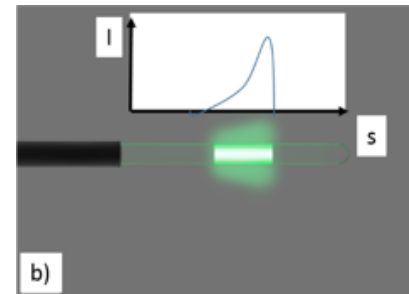
- Development of a fiber for ELT (endovenous laser therapy), which combines several advantages, such as:
 - Less components
 - Smaller diameter → access to smaller veins
 - Customizable beam / emission profile along the fiber axis
 - Less power emission, less pain



Bare Fiber with flat tip and conical flat emission profile (810nm to 980nm)



Radial Emission Fiber, with ringshaped conical emission profile (940nm to 1470nm)



FaPaA project, with ringshaped, cylindrical emission profile (1470nm to 1940nm)

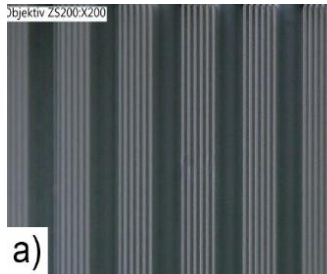




Opportunities for medical device manufacturers

Project Introduction: FaPaA

- Instead of conventional grinding and polishing, the approach consists of creating specific outcoupling by manipulating of the fiber core by ultrashort pulse laser along the fiber axis similar to FBG's
 - The refractive index of the core is changed in centers of 1-9 μ m



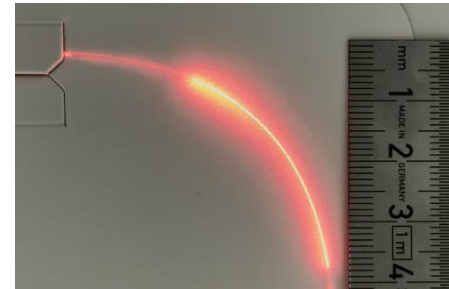
a) Preliminary test of structuration on silica plates



c) Transfer of the structures onto real silica fiber



Standard Radial Fiber 550/578/.../1800



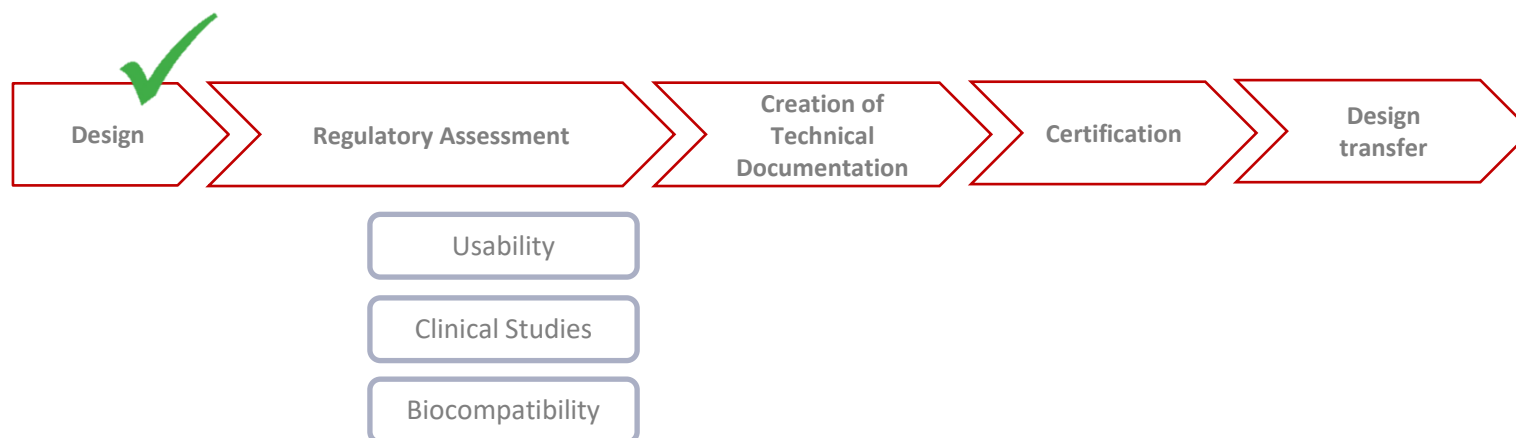
Diffuser Fiber 550/578/.../1300



Opportunities for medical device manufacturers

Outlook: FaPaA and the path to a CE certified medical product

- even though the projects shows promising results, we're still far from a market ready product!



Conclusion:

Especially the efforts in development of medical devices is often underestimated, but the better a company know the same, the more efficient a certification process can be carried out!



A close-up photograph of a hand holding a large bundle of optical fibers. The fibers are thin, white, and fan out from the hand. The background is a blurred laboratory or industrial setting with various equipment and a blue surface.

Thank you for your attention!