FiberTech Medical Devices
Fiber Optic medical device solutions

The Quality Connection

LEONI
Specializing in custom fiber optic medical device solutions for OEMs and distributors.

LEONI has been a reliable partner for a diversity of markets since 1917
- Access to all LEONI’s competencies and technologies worldwide
- OEM/ODM service and development partner
- Fiber Optics experts with extensive value chain

With clean rooms around the globe, LEONI offers a turnkey solution that spans a wide range of expertise for the medical device industry. LEONI has a complete value chain including:
- Preform manufacturing
- Fiber drawing
- Assembly in one of our global clean rooms
- Sterilization and packaging

LEONI offers the following services to OEM & ODM business partners:
- From design input and design specification document to the finished product
- For variations and changes of existing and approved medical devices, as well as new developments
- In consulting about the various possibilities of different wavelengths, numerical apertures and connector types
- Commercialization and high volume analysis to ensure the highest quality and profitability for our partners

LEONI offers experienced laser medicine, diagnostics and spectroscopy
- In-house production of
  - Biocompatible & medical fibers
- Medical devices and laser probes for
  - pulsed and CW lasers in medicine
  - production of surgical, urological, ophthalmic, dental and endovascular probes with biocompatible materials

Customer specific product design
- OEM service and development partner
- High volume commercial production capabilities with clean rooms around the globe

Certifications & approvals
- Products CE marked according to medical device directive 93/42/EEC
- EN ISO 9001 certified
- EN ISO 13485 certified
- FDA Reg. No. 3005128587 & 3007336385

Business Unit Fiber Optics online
www.leoni-fiber-optics.com
Please note >>

Starting on page 12 you will find an excerpt of our standardized medical devices with FiberTech branding, for which we operate as legal manufacturer. Marketing authorizations varying according to region and product. Please contact our sales team.
Innovative Fiber Optics Solutions
Let's care about health together

The Business Unit Fiber Optics in the LEONI Group is a leading provider of ultrapure Fused Silica, preforms, rods and Fiber Optics for demanding applications in industry, energy, communications, Life Science, optical metrology, and transportation. We offer a unique product portfolio at every stage along the value chain: from Fused Silica to preform and the drawn fibers through to fiber optical cables and complete fiber optic systems with optical components that we have developed in-house. Along this value chain, we can adjust and optimize many factors independently according to your requirements without needing support from external partners.

Our strengths
- Global fiber optics experts with decades of experience
- Extended value chain we can intervene at every stage without external support
- Fiber optical products for an integrated system solution
- OEM and ODM development and service partner

Fiber Optics in the digital era
Being a technology partner we jointly develop with our customers energy and data management systems and create added value by means of digital intelligence: fiber optic solutions are among other fields employed in real time system monitoring and help to recognize and prevent system defaults at an early stage.

LEONI solutions for Healthcare
We offer a comprehensive range of products and services in the field of cabling, especially for medical applications. As a system supplier, we work with you in a development-supporting role and define individual cable harnesses for imaging devices. We develop and manufacture solutions for endoscopy and inner body according to the DIN ISO 13485 standard. For example, our products offer maximum safety through excellent image transmission.

The intuitively operable patient positioning system LEONI ORION also shows the kind of innovative solutions with which we can support our customers when we combine our knowledge of medical technology applications with our many years of industrial robotics experience.

Inform yourself about our complete Healthcare portfolio under www.leoni-healthcare.com or simply get connected with us.

Further information: www.leoni.com
Extensive Fiber Optics value chain
Your benefits

In-house production of:

- Raw materials (SQ Fused Silica)
- Preforms and rods
- Special optical fibers
- Biocompatible materials
- Medical laser probe assemblies

In-house services:

- ISO class 8 clean room assembly
- Product engineering and design
- Various tip designs and configurations
- Sterilization and packaging
- Regulatory affairs support

Our strengths – your advantage

- Unique value chain
- Client specific product and system solutions
- International development and system partner
- OEM & ODM service and development partner
- Worldwide presence

www.leoni-fiber-optics.com
Due to our extensive value chain and expertise in the manufacturing of medical probes we are an attractive partner for the development of medical devices for new fields of applications.

We specialize in:
- High volume commercial production
- Design and development
- Regulatory affairs consultancy for your product's registration needs

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- High volume commercial production
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Design possibilities
It all starts with the development of solutions

Full range of biocompatible fibers and assemblies
Tailor-made solutions

Customer-specific laser probes for therapeutic and diagnostic applications

OEM & ODM partner

Product and Process engineering services to meet your needs

Our strengths – your benefits
- Clean room assembly
- Product packaging
- EtO sterilization
- Global distribution
- Commercial production
- German engineering and efficiency
- Global cleanrooms

Fibers
- for different wavelengths
- with different fiber dimensions
- with different fiber materials
- with different buffer and jacket materials
- with different numerical apertures (NA)
- particularly low OH content available

Probes with customer-specific adaptations such as
- distal and proximal tip design
- different colors
- diameters
- ring markings and
- lengths are possible for all products and designs

Development
- finding individual solutions together with customers and partners

OEM / ODM service and development partner
- from the idea to the tested and optimized product

Development of new products and applications in Fiber Optics
- laser medicine
- diagnostics
- spectroscopy

Our strengths – your benefits
- Clean room assembly
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www.leoni-fiber-optics.com
Innovative solutions for medical applications

Various distal tip designs
- FlatTip
- SideFiring
- RadialTip
- FlatRounded
- BallTip
- CurvedBall
- SphericalTip
- TaperedTip

Features
- Capillaries
- Ring markings
- Connector options & design (for assembly)
  - customer specific connector assembly
- Customer specific variations
  - laser inscription of connectors
  - label design
  - color, etc.

www.leoni-fiber-optics.com
Medical devices are subject to strict legal requirements to ensure safe and effective products worldwide. With our Regulatory Affairs team, we offer you assistance in approval or market clearance processes and all topics concerned. We have the knowledge and experience to support you in your target markets.

Regulatory affairs for our medical laser probes
- Offering support for the approval or market clearance of our medical laser probes in your target markets worldwide
- Products CE marked according to medical device directive 93/42/EEC
- FDA Reg. No 300512587 & 3007336385, various FDA cleared products
- CFDA approved products available
- Extensive experience in Regulatory Affairs
- Support in case of design changes of products
- Maintenance and supervision of our Quality Management System
- Qualification of suppliers

Quality management system
- ISO 9001 certified
- ISO 13485 certified
- Complies with 21 CFR Part 820 Quality System Regulation

Biological assessments
- 10993-5 Cytotoxicity
- 10993-4 Hemocompatibility
- 10993-10 Sensitization
- 10993-10 Irritation/Intracutaneous reactivity
- 10993-10 Systemic toxicity

Validated sterilization Process
- EtO sterilization for disposable products
- Autoclave sterilization for reusable products
Product support
along the whole product development and lifecycle process

Support during product development
- Design input
- Concept phase
- Design output
- Verification and validation
- Design transfer
- Series production
- Risk management

Support of process for PLM, ODM and distributors
- Provide documents relevant for approval
- Legalization of documents
- Manage customer change request

Management of medical devices
- Risk management
- Monitor regulatory changes
- Implement customer requirements
- Manage change notices
- Manage design changes
  and manufacturing process changes
- Ensure customer satisfaction
- Postmarket surveillance
### Special optical fibers

Optical fibers with customer-specific design

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**Shape and size of the fiber core can be adjusted to the application's demands.**

The use of an appropriate coating material and/or an additional layer helps to protect the fiber under different mechanical, thermal or chemical environmental conditions. All fibers can be customer-specifically assembled according to your application fields.

**Benefit from our competence in influencing the fiber properties and creating customer-specific fiber solutions.**

We can rely on an entire value chain – from ultrapure fused silica to the assembly of the finished fiber.

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**Core | Clad | Coating | Jacket | Cable design | Assembly**

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**NCS fibers – Step-index fiber series with non-circular core or cladding geometries**

NCS is our fluorine-doped step-index multimode fiber series, with fibers featuring a non-circular undoped fused silica core and/or a corresponding fluorine-doped fused silica cladding. NCS fibers can be customized concerning structure and thickness of the cladding and also regarding the numerical aperture (NA).

In addition it is possible to optimize the most important fiber parameters – such as their performance at UV/VIS and VIS/IR wavelengths – by specifying the OH content of the core. Thereby we can offer innovative solutions for the special requirements of laser technology, high-performance data transmission, imaging and spectroscopy or medical applications.
Special optical fibers
NCS fibers (Non Circular Shape)

Hexagonal step-index fibers ➔
are especially suited for the manufacturing of compact fiber bundles, improving transmission efficiency in industrial and medical applications. As part of fiber optic cables, our innovative fiber shapes help to optimize the guiding of laser light to the operation area.

Fibers with square core shape ➔
generating a nearly square output beam, they are the choice for several high-power applications. Light from a square diode laser can be coupled into a square fiber a lot easier. Compared to a circular fiber profile, this allows a more uniform treatment of the material – particularly in welding technology and heat treatment, as the beam moves laterally over the material’s surface.

Fibers with rectangular shape ➔
can improve the signal strength in fiber laser applications by minimizing the energy density decrease at the end of the fiber core. This decrease occurs in particular when the emitted power is launched into a circular fiber from a rectangular solid state laser. An improved coordination of dimensions and profiles enables the transmission of light by laser diodes with energy densities as needed for medical applications in particular.
Disposable BareFibers
Biocompatible fiber made of silica for a wide range of wavelengths and applications

Properties
- Wavelength: 532 – 2,200 nm
- NA: 0.22
- Distal tip: flat
- Standard length: 3 m
- Connectors: F-SMA905 connectors compatible to most standard connectors
- Sterilization: EtO sterilized

Optional features
- F-SMA extension sleeve available in various colors
- Laser inscription possible
- Customer-optimized designs on request
- Various accessories available
- Specialized version for Holmium lasers
  - with standard extension sleeve (Ø 12mm)
  - or slim extension sleeve (Ø 10mm) available in various colors
- Available as slim version

<table>
<thead>
<tr>
<th>Core Ø (µm)</th>
<th>Clad Ø (µm)</th>
<th>Outer Ø (fiber) (µm)</th>
<th>NA</th>
</tr>
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<tbody>
<tr>
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<td>600</td>
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<td>0.22</td>
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<tr>
<td>800</td>
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<tr>
<td>1,000</td>
<td>1,100</td>
<td>1,500</td>
<td>0.22</td>
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Reusable BareFibers
Autoclavable, biocompatible fiber made of silica for a wide range of wavelengths and applications

Properties
- Wavelength: 532 – 2,200 nm
- NA: 0.22
- Distal tip: flat
- Standard length: 3 m
- Connectors: F-SMA905 connectors compatible to most standard connectors
- Sterilization: EtO sterilized for first use

Optional features
- F-SMA extension sleeve available in various colors
- Laser inscription possible
- Customer-optimized designs on request
- Various accessories available

<table>
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<tr>
<th>Core Ø</th>
<th>Clad Ø</th>
<th>Outer Ø (fiber)</th>
<th>NA</th>
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<tr>
<td>[μm]</td>
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Disposable HardClad BareFiber

Biocompatible fiber for a wide range of wavelengths with an increased NA (NA=0.37), excellent beam quality and glue-free connectors

Properties

- Wavelength: 532 – 2,200 nm, low OH
- NA: 0.37
- Distal tip: flat
- Standard length: 3 m
- Connectors: high-power F-SMA905 connector
- Sterilization: EtO sterilized

Optional features

- Customer-specific connectors can be assembled
- Customer-optimized designs on request
  (extension sleeve, LuerLock for catheter etc.)
- Various accessories available

<table>
<thead>
<tr>
<th>Core Ø</th>
<th>Clad Ø</th>
<th>Outer Ø (fiber)</th>
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<tr>
<td>600 µm</td>
<td>630 µm</td>
<td>950 µm</td>
<td>0.37</td>
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Disposable BareFiber dentistry
The polyimide fibers with biocompatible protection tube (Ø 2 mm) guarantee very high mechanical stability and excellent beam quality

Properties
- Wavelength: 532 – 2,200 nm
- NA: 0.22
- Distal tip: flat
- Standard length: 3 m, distal 10 cm free-standing fiber
- Connectors: standard F-SMA Connector
- Sterilization: EtO sterilized

Optional features
- Customer-optimized designs on request
- Customer-specific connectors can be assembled
- Various accessories available

<table>
<thead>
<tr>
<th>Core Ø [µm]</th>
<th>Clad Ø [µm]</th>
<th>Outer Ø (fiber) [µm]</th>
<th>Outer Ø (tube) [µm]</th>
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<tbody>
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<td>720</td>
<td>1,750</td>
<td>1,750</td>
<td>0.22</td>
</tr>
<tr>
<td>600</td>
<td>720</td>
<td>2,050</td>
<td>2,050</td>
<td>0.22</td>
</tr>
<tr>
<td>400</td>
<td>440</td>
<td>465</td>
<td>2,000</td>
<td>0.22</td>
</tr>
<tr>
<td>600</td>
<td>660</td>
<td>685</td>
<td>2,000</td>
<td>0.22</td>
</tr>
</tbody>
</table>
Reuable BareFiber dentistry
Autoclavable polyimide fibers with biocompatible protection tube (Ø 2 mm) guarantee very high mechanical stability and excellent beam quality

Properties
- Wavelength: 532 – 2,200 nm
- NA: 0.22
- Distal tip: flat
- Standard length: 3 m, distal 10 cm free-standing fiber
- Connectors: standard F-SMA Connector
- Sterilization: EtO sterilized for first use

Optional features
- Autoclavable
- Available with Germanium-doped silica / silica fibers (NA = 0.37)
- Customer-optimized designs on request
- Customer-specific connectors can be assembled
- Various accessories available

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<tbody>
<tr>
<td>200</td>
<td>240</td>
<td>265</td>
<td>2,000</td>
<td>0.22</td>
</tr>
<tr>
<td>320</td>
<td>385</td>
<td>410</td>
<td>2,000</td>
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<td>400</td>
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<td>465</td>
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LEONI is rising to meet the challenges of the digital era

In the future, we will be taking past technical product solutions and the knowledge on which these have been based over the last 100 years and combining these with new insights. These include integrated sensor technology, active electronics, embedded software, and the digital functional simulation for a wide range of customer requirements and markets.

This will make LEONI an even more attractive partner for strategic partnerships, digital ecosystems and international development networks.

Enriched with technological intelligence, this new range of products and services is the basis of our reorientation and the foundation for entirely new value propositions for our customers, both now and in the future – always building on our current core expertise.

We call this Connected Intelligence!

www.leoni.com

Your Fiber Optics contact

<table>
<thead>
<tr>
<th>Business Unit Fiber Optics</th>
<th>LEONI Fiber Optics GmbH</th>
<th>LEONI Fiber Optics Inc.</th>
<th>LEONI Fiber Optics China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nalepastrasse 170–171</td>
<td>209 Bulifants Blvd.</td>
<td>c/o LEONI Cable China Co. Ltd.</td>
<td></td>
</tr>
<tr>
<td>12459 Berlin</td>
<td>Williamsburg, VA 23188</td>
<td>No. 21 Taihu West Road, New Area</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>USA</td>
<td>213022 Changzhou, Jiangsu Province</td>
<td></td>
</tr>
<tr>
<td>Phone +49 30 5300-58-0</td>
<td>Phone +1 757-258-4805</td>
<td>Phone +86 519-8988-7783</td>
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<tr>
<td>Fax +49 30 5300-58-58</td>
<td>Fax +1 757-258-4694</td>
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<tr>
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<td>E-mail <a href="mailto:fo-americas@leoni.com">fo-americas@leoni.com</a></td>
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