

A PERFECT CONNECTION

■ MEDICAL DEVICE TECHNOLOGY ■ LASERS ■ ROFIN



WE
THINK
LASER

In medical device technology, lasers are the key to miniaturization



Outstanding solutions to extraordinary challenges

When developing and manufacturing medical devices, your expectations can't be high enough as far as the manufacturing technology involved is concerned. Higher precision and better quality in existing medical devices and implants are highly beneficial to the patients. Especially since new products become available through the efficient and economic use of innovative production technologies. A future-proof range of products and applications therefore are good for your company – and for the patients.

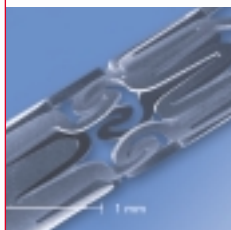
Medical device technology lives by innovative transfer of new scientific findings into product technology, with a focus on the characteristic advantages – and limits – of used materials and available production methods.

Today, miniaturization is one of the dominating trends in the medical device industry: for implants and tools, the micron range has been reached. As components become ever smaller and more sensitive, precision and selectivity in the machining process become imperative.

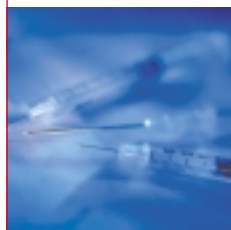
Almost every form of material processing leaves unwanted traces on the workpiece, in the production of medical devices almost always a problem. Perfectly hygienic surfaces free from burrs, grooves and residues are a must. Sophisticated finishing processes of surfaces to remove unwanted traces are time-consuming and costly.

Medical science has no tolerance of errors or inaccuracies. This calls for a perfect, faultless quality of the tools used. Production tools and processes of consistently high quality are the best prerequisites for 100% safety in deploying your products.

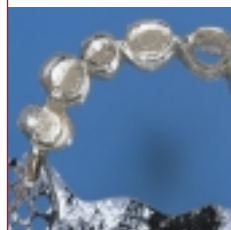
Miniaturization of implants can often only be achieved through laser technology



Aseptic polymer welding – colored or transparent



Biocompatible joining without filler material



Ultimate perfection welding for highest demands



Durable annealing marking



Today, laser technology has reached a level that makes it ideal for the medical device industry in more than one way. Wavelength, output power level and beam quality can be adapted for cutting, welding, structuring or marking of a wide range of materials.

Laser welding of polymers is one example for new production technologies. All thermoplastic resins and thermoplastic elastomers can be joined pressure-tight and with nearly base material strength. Given the right choice of wavelength and additives, laser welding achieves perfect surfaces without residual microparticles and adhesives or roughness.

In metal processing, with excellent beam qualities and flexible pulse shaping, lasers have come to set seam and spot welds in the micron range. This new precision is the key to processing ever smaller and more sensitive workpieces, such as micro-welding of Nitinol wires of 20 microns in diameter.

The high quality of laser-cut edges, almost without unwanted burrs, edge hardening and tapering, drastically reduces the need for finish processing. For example, in cutting very fine wires to be used in special implants, the cut ends are melted and rounded, so they have no edges or burrs.

Since the laser beam as cutting- or welding tool does not wear out, consistent quality of cuts and joints and thus the quality of workpieces can be maintained. Intelligent controls guarantee constant laser power, beam quality and pulse form. Because all the processing is contact-free, a number of optical inline monitoring methods are available.

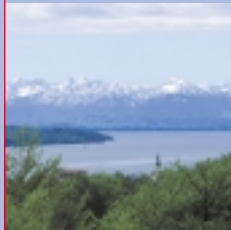
Requirements of medical device technology

- Innovative products
- Miniaturization
- Precision
- Quality and reliability
- Immaculate surfaces

Advantages of laser systems

- Innovative product design and construction
- Excellent focussing capabilities
- Simple automation
- Optical process monitoring
- Contact-free processing

ROFIN / BAASEL LASERTECH,
based in Starnberg, near
Munich, is responsible for all
Laser Micro activities of the
ROFIN Group.



Laser systems by ROFIN: Solutions from a single source

For the innovative use of laser technology in the medical device industry we draw on three decades of experience in material processing in every conceivable area. For more than 15 years, ROFIN has offered system solutions for a wide range of tasks in the production of medical devices, from the base of an extensive product portfolio: laser sources of every output power level, beam systems, deflection units, control and automation engineering, software development including image recognition and processing, high-precision positioning systems and customized system engineering. Working closely with our clients and partners we have established a considerable expertise for customer-specific solutions.

We aim at complete system solutions: From the exact definition of the task at hand, the selection of suitable laser sources and the concept of the system to its implementation and on-site training of operators. We develop innovative solutions together with our customers – always on the basis of confidentiality. We consider ourselves to be partners, taking on responsibility for complete solutions, helping with all kinds of problems reliably and competently, always with an open mind for improvements and new fields of application.

ROFIN / BAASEL LASERTECH

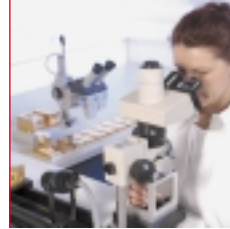
Laser technology and application development are keys to success



Innovative solutions are the result of working closely with the client



High-precision quality assurance



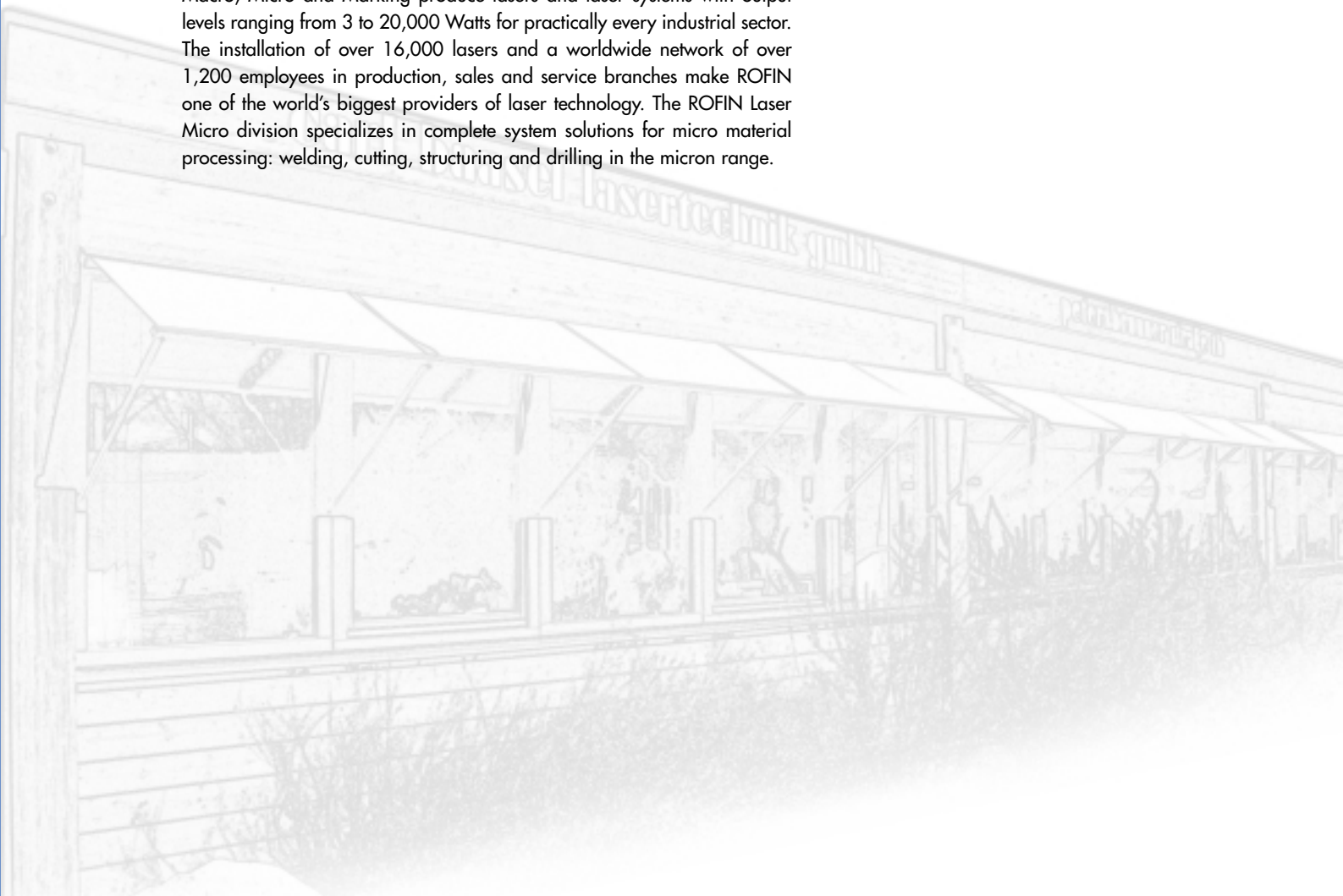
Competence in customized solutions



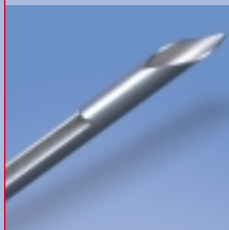
About ROFIN

Since 1975 ROFIN has developed lasers and laser-based system solutions for industrial material processing.

Our expertise comprises all key technologies relevant to successful production – from laser sources (Diode, Nd:YAG, CO₂ and disc lasers) to system construction, process customization and development. The three divisions Macro, Micro and Marking produce lasers and laser systems with output levels ranging from 3 to 20,000 Watts for practically every industrial sector. The installation of over 16,000 lasers and a worldwide network of over 1,200 employees in production, sales and service branches make ROFIN one of the world's biggest providers of laser technology. The ROFIN Laser Micro division specializes in complete system solutions for micro material processing: welding, cutting, structuring and drilling in the micron range.



Micro tube cutting – new
design through non-radial cuts



Laser cutting: minimal burrs, edge hardening and tapering

For example, we have been perfecting the fine cutting of microtubes for the production of stents and medical implants for some time now. Today, we can process tubes with diameters of less than 200 microns with cutting widths of less than 20 microns at radial and non-radial cutting angles – without any damage to the opposite wall. Thus it becomes possible to open tubes laterally or to cut hollow needle points. Even new and unusual cutting geometries are possible – like spiral cuts or interlinked structures – in just one process operation (e.g. for flexible instruments).

Solid-state lasers can cut nearly all metals used in medical device technology. Minimal heat input prevents damage to temperature-sensitive materials, e.g. frequently used shape memory alloys like Nitinol. Commonly used films of polymethylmethacrylate, polypropylene or colored polycarbonate can be cut and perforated with high speed and precision by CO₂ lasers with fast scanner heads.

The flexibility of cutting geometries is almost unlimited – including edges with variable cutting angles. Through a CAD system, any new outline can be defined in a matter of minutes. The high quality of the cutting edges – with almost no deleterious burrs, edge hardening and tapering – drastically reduces the need for finishing. For example, after cutting fine wires for special implants, the cut ends are automatically melted and rounded, so there are no pinch points or burrs as with mechanical processing.

Speed and productivity of laser fine cutting go beyond those of competing mechanical or chemical processes or even micro plasma cutting. Full automation can be achieved for many applications, such as automatic feeding of long tubes for cutting.



Cutting finest tubes with tight contours without damaging the opposite wall

Even temperature-sensitive materials such as shape memory alloys like Nitinol can be processed by laser

3D cuts with minimal heat-affected zone and less need for finishing

CNC-controlled cutting with large working field

Finest cuts under 20 microns – the granite base provides stability for high precision cutting

StarCut Tube

StarCut Tube is a complete system designed for high-precision cutting of thin tubes of any geometry, featuring cutting widths of under 20 microns, very high precision, fully automated tube handling and a contour accuracy of less than five microns. Typical workpieces are micro tubes with diameters from 0.2 to 10 mm. Cutting speed can be as high as 50 mm/s. Dynamic power control maintains constant energy input per unit length, thus keeping the kerf width constant even while accelerating in curves. Field experience shows that the throughput of StarCut Tube is higher than that of competing systems. Processing of sheet metal and non-radial cuts, e.g. for hollow needles or flexible instruments, are made available through an upgrade to the 4-axis StarCut 2+2 system.

StarCut Universal

StarCut Universal offers a large working chamber and three high-precision CNC axes with a travel range of 600 x 300 x 200 mm³. If even more is needed, a few easy alterations turn the system into an open class IV device – thanks to the modular housing concept. Even complex 3D geometries can be processed fast and with a precision of 50 microns. With an optional rotary axis the system literally makes heads turn. The integrated CNC controlling software is compatible with all prevalent CAD formats and manages many changes and adaptations – such as the changing of workpieces – through a comfortable, PC-based panel. It includes a crosshair monitoring system and extensive teleservice functions for all eventualities. From the picture-in-picture camera monitoring to the gas supply and a large L-shaped door that gives access to the working chamber – everything is neatly integrated within the system.

Advantages of laser systems

- Micro cutting (< 20 microns)
- Easy automation
- Minimal heat-affected zone
- Burr-free cuts
- High flexibility
- New product designs

Welding of highly sensitive components



Welding with CNC



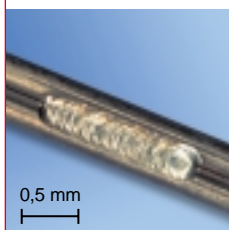
Laser welding: filigree, high-strength and even transparent

Lasers can be used for seam butt and overlap welding of nearly all metal used in medical device technology, like stainless steel, gold, platinum or shape memory alloys and especially titanium resp. titanium alloys. With this material used abundantly in this industrial sector, traditional processing methods come up against their limitations. With up to date laser technology, spot and seam welds in the micron range can easily be produced, even in places that are difficult to access. Using the flexible, material adapted pulse shaping, the heat-affected zone remains minimal and allows the joining of highly sensitive components previously impossible to weld with other technologies. This filigree joining technology allows for new product designs that had previously been impossible or uneconomic to realize.

The laser is a tool that is very flexible in adapting to the production environment: manually operated and controlled through a microscope, at a manual workstation or in automated production, with fixed or fiber optics and with image recognition and scanner heads for high processing speeds. Its typical process advantages, though, are preserved for all applications: laser welded joints are high-strength, compatible with high-temperature sterilization (unlike adhesive joints) and, without finishing, yield pore-free, sterile surfaces that are essential for biocompatible materials.

In medical device technology, laser welding of polymers is a matter of particular interest, which we are currently advancing intensely in cooperation with partners like Treffert. All thermoplastic resins and thermoplastic elastomers – unfilled or filled to a degree – can be joined pressure-tight and with nearly base material strength. For the typical overlap welding method, the joining region is completely inside the welded parts. In contrast to competing methods like adhesive bonding or ultrasonic welding there is no deleterious generation of micro particles, adhesive residues or roughness. Provided that one of the joining members is absorbing the laser beam, both bio-polymers (transparent) and colored polymers can be welded. Some application examples are: sensors, filters, micro cameras, plastic bags for fluids, tube connectors, balloon-tipped catheters and microfluidic devices.

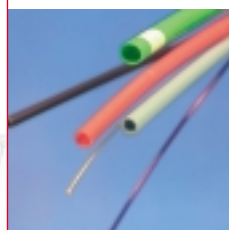
Finest wires can easily be welded



High-strength seam welds with pore-free surface quality



Polymer welding with lasers – simple design, no microparticles and high-quality production



Turnkey manual welding unit for prototype and small batch production – also with CNC-control



All-in-one system for polymer welding with diode or YAG laser



StarWeld Performance

The bestselling manual laser welding unit worldwide! More than 4,000 customers use this system for fine-welding stainless steel, titanium, gold or platinum. With this tool they create seam welds under 100 microns and work with materials as thin as 10 microns or wires of 20 microns in diameter. Learning to operate this system is a matter of hours. StarWeld Performance also comes in a CNC-controlled version that allows easy switching between manual mode and a cost-effective partial automation – only one example of successful laser system solutions from ROFIN.

PolyScan

PolyScan is a new turnkey system for contour welding and quasi-simultaneous welding of polymers. Depending on the pigmentation of the material it uses diode or Nd:YAG lasers. Everything is integrated in the compact housing: Laser source, deflection unit, controller, power supply, cooling system and a flat display with a multiscreen function.

One application example: Welding of sensors in the medical device industry. They have to be small, antiseptically sealed and efficient. Because the laser beam applies the heat of fusion very accurately, seam welds can be placed adjacent to temperature- and vibration-sensitive electronic components.

Advantages of laser systems

- Micro welding (< 100 microns)
- Excellent welding quality
- Biocompatible welds
- Immaculate surfaces
- Easy automation
- High flexibility

Biocompatible,
abrasion-proof
marking



Laser structuring and marking: selective and durable

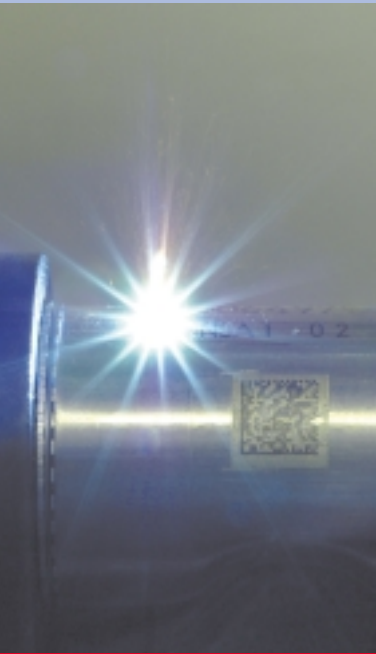
Lasers can ablate very selectively and accurately material from metals, ceramics or polymers. The basic principle of these applications is the ablation of material through short high-energy laser pulses. This process can be controlled to create microstructures smaller than 15 microns as well as the ablation of entire surface layers. For example, it can remove polymer layers in catheter production. The same technique can create tailored surfaces with structures in the micron range to improve the biological interaction of implants, or create filigree tools for plastic microcomponents such as die casting molds with very fine channels or opening mechanisms for packagings.

While ablation of material generates engravings, coloring or discoloring is another powerful technique of laser marking – as durable and without adding any undesirable substances: annealing marking of metals and carbonization or foaming of polymers creates corrosion-free markings without surface modification by corrugations or burrs. Technically, shapes and contents of laser markings are almost without limits, whether it is marking implants, medical devices or surgical instruments with data matrix codes to ensure traceability.

Especially for marking, the flexible, computer-aided control is an important feature. It allows for the individual marking of each workpiece, and even on-the-fly marking of fast moving parts is no problem.

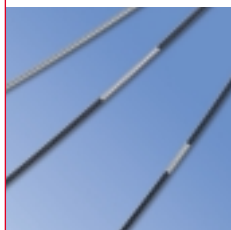
Try us!

...with your specific application. Our specialists in medical device technology are looking forward to meeting you. Extensive development and test facilities are at your disposal worldwide – to help you realize a laser-based solution that gives you the decisive edge.



Annealing marking

Precise and selective ablation of material in the guide wires for setting tangible marks for a cardiologist



Easy Opening – selective weakening of individual layers in packaging



Laser marked pacemaker



User-friendly tabletop unit for laser marking



Sealed-off CO₂ laser for ablation and structuring of metals, ceramics and polymers



StarShape

In the precise and selective ablation from the surface of a workpiece, the StarShape series makes use of the excellent beam qualities of Q-switched solid state lasers. Depending on the size of the structure, lasers with up to 20 W TEM00 or low order mode lasers of up to 100 W with a wavelength of 1064 nm are available. For applications, where heat-affected zones are critical, we offer Vanadate lasers with 355, 532 and 1064 nm. Their extremely short laser pulses minimize heat conduction. The result: very high process efficiency and minimal heat load – ideal for microstructures. The solid state lasers StarShape E/D/L are ideal for processing metals, semiconductors, ceramics or polymers. For processing polymers, glass, paper and natural materials such as leather, rubber or wood, we recommend our StarShape C systems.

EasyMark

EasyMark is a new turnkey marking laser in a very compact desktop housing: mobile, air-cooled and practically maintenance-free. EasyMark can be programmed using just about any computer, using the comfortable and powerful LaserCAD control software. For high-contrast marking and rapid processing, the system uses leading technology of the end-pumped PowerLine E laser, featuring the best beam quality, high pulse peak power and short pulse duration. This makes EasyMark ideal for a wide range of applications like marking of polymers, engraving or annealing marking of metals.

Advantages of lasers in structuring and drilling

- Miniaturization (< 15 microns)
- Fast
- Consistent quality
- Process integrity through material selectivity
- Flexible

Advantages of lasers in marking

- Abrasion-resistant markings
- Flexible
- Micro-marking (< 60 microns)
- Minimal heat load
- Biocompatible markings
- Fast

SOLUTIONS FROM A SINGLE SOURCE
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MARKING