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Laser Community

THE LASER MAGAZINE FROM TRUMPF

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Doctor's Tool

Surgical precision cashs in on laser technology

Laser Technology Sets

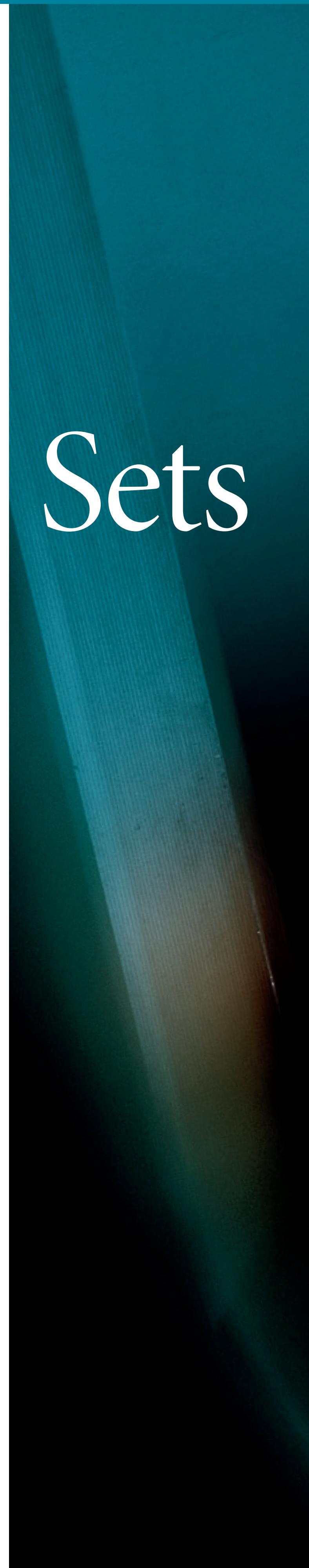
Flexible, precise, reproducible:
Lasers have marked, cut and welded their way
to the top of medical technology production.

Our health has never been as valuable as it is today. In addition to physician skill and medicine, medical technology is a decisive market factor for health and quality of life. About 11,000 companies and 150,000 people are working on the development and production of medical technology products in Germany. As varied as this industry is with the mostly small companies involved – innovation is the common lifeblood.

According to a study by the German Federal Ministry for Education and Research, German medical technology companies achieve more than half of their sales with products that are less than two years old. According to the 2006/07 annual report from the German Association of Medical Technology, an average of slightly more than seven percent of sales is invested in research and development. By comparison, the research-heavy chemical industry reinvests five percent in R&D while manufacturing reinvests 3.8 percent. According to the German Patent Office in Munich, medical technology heads the list for filed inventions with more than 14,700 patents, accounting for 11.4 percent of all applications. Next up are communications engineering with 10 percent and data processing with 6.7 percent. The situation is similar internationally. According to a survey of American doctors, technical products were six of the 10 most important medical innovations in the last 30 years.

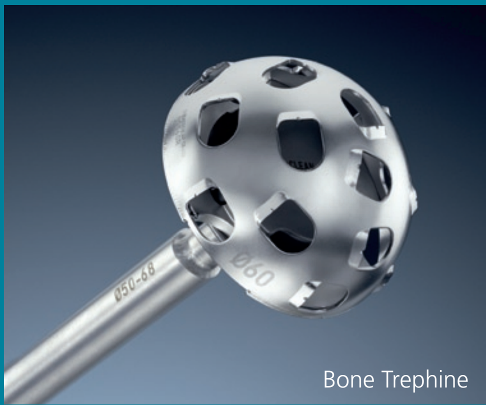
Technology for People

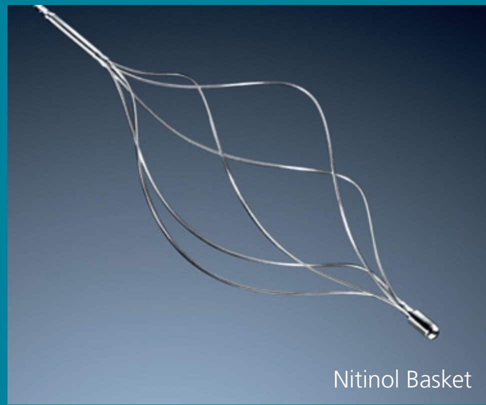
Innovative research requires innovative production. This is especially the case in an environment in which technology comes closer to people than any other field: Nothing cuts deeper than surgical instruments. Important implants like the aneurysm clip may look like a paper clip, but when it comes to neurosurgery it's a matter of life or death. And active implants like the pacemaker even become part of the human body. For good reason, the requirements for materials, production quality and process

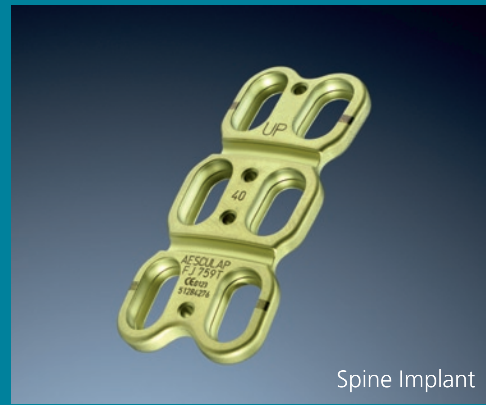


the Pace

The sensitive electronics of a pacemaker may not be jeopardized by excessive heat input during welding of the housing.


Bone Trephine


Nitinol Basket


Spine Implant

WHAT LASERS CAN DO FOR MEDICAL TECHNOLOGY

Cutting

- Precise and effortless
- Minimal radii for cut-outs of tubes and hollow parts
- Variable cutting angle
- Thickness ranging from < 0.1 to several millimeters
- Minimal heat influenced zone
- Minimal burr formation

Welding

- Small spot diameter and narrow seams
- Noncontact and free of forces
- Minimal heat influenced zone
- Free of pores and leak-proof
- Corrosion-resistant
- Biocompatible like the base material
- Intricate contours
- Manual and automated

Marking

- Durable and indelible
- High temperature sterilization resistant
- Biocompatible like the base material
- Minimal heat input
- Flexible and fast creation of words and images
- Metals and nonmetals
- Finest resolution up to 25 µm

documentation are high, making for a demanding environment for production technology and process planning – perfect for lasers.
Due to its versatility and special abilities, the laser is the best choice as a production tool for cutting, welding and marking medical technology products. “The laser is a pioneer of miniaturization and with minimal focus diameters around 25 micrometers for marking and 10 micrometers for removal and structuring it makes entirely new product designs possible. Even micro-welds on a magnitude of only a few micrometers are possible,” explains Dr. Alexander Knitsch, who is the responsible application manager for the Medical Technology division at TRUMPF. In addition, the laser can be accurately positioned to about one micrometer – a value that as yet is still theoretical and limited by the mechanical axes and the overall ability of the system. The laser can be accurately adjusted while the heat input can be precisely controlled and adapted to the characteristics of temperature-sensitive materials. The laser’s wide-ranging flexibility is especially useful in the field of instruments, which have a large variety of products, but are needed in small batch sizes. Small units can be produced manually or semiautomatically. For volume production, the laser can be easily automated and integrated in the production line. Quick tooling times and simple transfer of CAD data to the machine control unit increases efficiency. And depending on the requirements and the existing in-house abilities, turnkey solutions or individual system configurations of specialized integrators are available. Companies like integrator Innovative Laser Technologies Inc. (ILT) in the USA know what medical technology demands and recommend to consider laser options already in the planning process. “The success of the system really begins with the parts, how they are designed, and their joining applications,” explains Steven D. Weiss, co-founder and primary shareholder of ILT.

Reproducible quality Lasers work with the proverbial surgical precision. They accomplish their tasks quickly, reliably and the according pulse-to-pulse stability provided, with an

The laser works here: Seam welding and marking on the camera housing of a CCDEndocam and an NN instrument.

Welding of inlets: Multiple seams are welded in a clamp during automatic welding. Hard-to-reach areas on this endoscope can be manually welded.

“The greatest advantage of the laser is that there is only minimal, if any, reworking the workpiece.”

consistent, reproducible quality. “The greatest advantage of the laser for us is that there is only minimal, if any, reworking of the workpiece necessary”, explains Wolfgang Karl, foreman of the laser departement at the German endoscope specialist Karl Storz GmbH & Co. KG. “Using the laser also streamlines processes. We were able to reduce our throughput times by up to 50 percent for certain products,” he continues.

The quality of surfaces processed by lasers is flawless. No grooves, creases, burrs or furrows compromise hygiene. Laser welded seams on endoscope tubes, for example, have an impenetrable, smooth surface and the same biocompatibility as the base material. Filler materials are not necessary as a rule. Laser markings on instruments like wound spreaders remain immune to high alkaline cleaning and high temperature sterilization with the appropriate set of parameters. The cutting angles on intricate implant systems for bone fractures, for example, have smooth surfaces and edges with minimal burrs. And laser welded spots are very stable: →

Tiny weld spots of only a few micrometers in size on nitinol baskets, for example, can withstand forces up to 70 Newton.

Aside from the quality of the individual workpiece, vital components in production are consistency, reproducibility and verifiability. Changing quality and wide-ranging tolerances are excluded from the production of medical technology products; a less-than-perfect pacemaker is inconceivable. Highly developed beam management ensures uniform, reproducible quality from the very first workpiece.

> “The success of the system really begins with the design of the part.”

Up-to-date TRUMPF lasers compare the required power with the actual power on a microsecond scale – one million times per second. Every ten microseconds the pulse is regulated. For a pulse length of let’s say five milliseconds, consequently, the pulse formation can be modulated at will. The relevant parameters can be recorded and stored using a quality data storage tool. “With respect to the process quality, the laser has important advantages over other production methods. It works according to clearly defined parameters such as pulse length, pulse duration or pulse repetition rate that can be selected, stored, tested and reproduced at any time,” explains Dr. Knitsch. That’s a property of the laser that will become increasingly more important given the increasing demands of documentation and verifiability. ■

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Aggressive cleaning methods can disturb the oxide layers of stainless steel alloys. Corroded laser marking (left) and thanks to the right parameter set intact laser marking (right).

No Cause for Concern

Passivation and optimized parameter sets reduce annealing’s susceptibility to corrosion.

Whether an instrument or an implant, all medical technology products must be permanently labeled with a suitable marking process and be traceable. Noncontact and low impact annealing with the laser is now an established process: Stainless steel or titanium is heated in situ to below its melting point. This produces colored oxide layers on the workpiece surface. The surface quality remains fully intact; the color change is indelible, resistant to change during sterilization and biocompatible like the base material. The laser light functions without the addition of dyes, acids or solvents, and can even be applied with great accuracy to areas that would have been impossible to reach with other methods. In addition to serial numbers and plain text or data matrix codes, logos and images can also be created. Other advantages include high speeds and the ability to quickly change fonts without taking time for retooling.

Medical instruments and implants are often produced from stainless steels with various alloys. Stainless steel contains at least 10.5 percent chromium to obtain sufficient corrosion resistance. This resistance is based on an enrichment of the chromium on the surface, which in turn allows the formation of an oxide layer. High temperature sterilization and aggressive, high alkaline cleaning methods ($pH > 10$), which is necessary due to the resistance of the Creuzfeldt-Jakob pathogen, for example, can result in disturbances in the oxide layers of the stainless steel alloy.

Susceptibility to corrosion and the risk of bleaching around the annealing increase as a result. An interdisciplinary task force made up of members of science and industry, including TRUMPF, has taken on this problem. Among the things tested were passivation methods to improve the corrosion resistance and optimized parameter sets for various laser marking methods. One result were suitable laser parameters for permanent annealing without corrosive tendencies. In addition, passivation after the marking can significantly improve the Cr/Fe ratio, thereby drastically reducing susceptibility to corrosion. ■