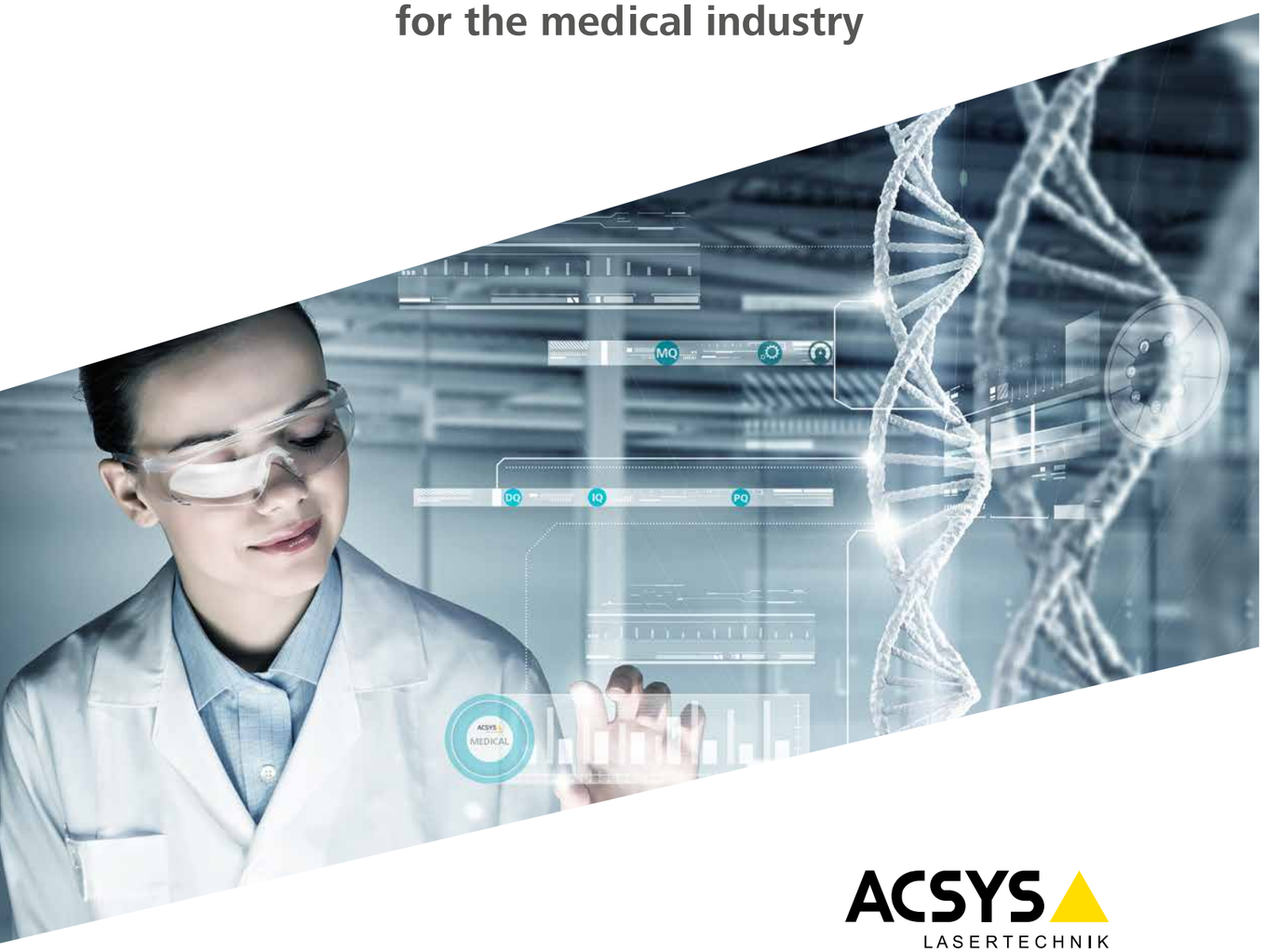
Laser systems
for the medical industry



ACSYS LASERTECHNIK

Laser marking · Laser engraving · Laser cutting · Laser welding · Laser digitizing

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ACSYS MEDICAL
Process validation
and device qualification

We support and accompany you at every stage of device qualification (DQ), and during the subsequent process validation process on the strength of our experience in laser material processing. From Day One, our guiding principles are quality and process reliability.

More on page 8

ACSYS LASERTECHNIK
MEDICAL

ACSYS MEDICAL
Laser processing systems

ACSYS Lasertechnik GmbH develops and produces laser machining systems for the medical industry, which ACSYS MEDICAL then installs and expands in a modular fashion. The aim is to achieve seamless integration of the complete laser process into a production environment.

More on page 45

ACSYS MEDICAL
Complete laser process

The ACSYS MEDICAL complete laser process is sub-divided into three stages: Optical product verification, optimized laser machining and optical marking evaluation with automatic read-back of texts and of
1D and 2D codes.

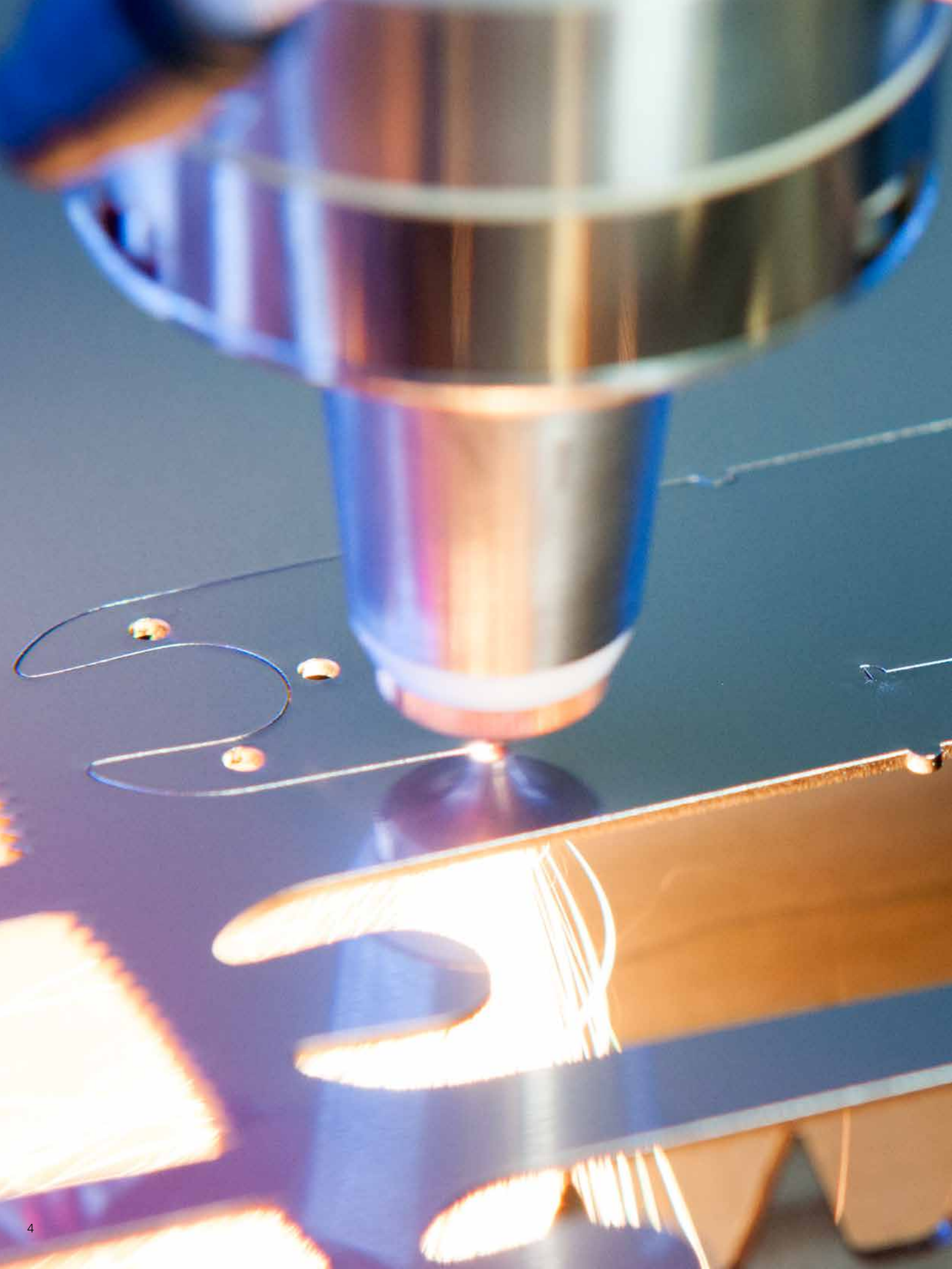
More on page 22

Solutions for you from a single source.

Our claim: To exceed expectations.

Know-how is our passion, and your requirements are our source of motivation. We here at ACSYS Lasertechnik GmbH see ourselves as a totally customer-oriented partner for laser unit solutions in the medical industry. This personal commitment enables us to set new standards in terms of quality and reliability. From marking and engraving to fine-blanking and micro-machining, and the structuring of different materials. Wherever precision laser systems are used, we are committed not only to meeting your expectations, but to surpassing them.

Our customers benefit from the expert knowledge of a team of experienced specialists who tackle every task with dynamics and a powerful vision - all in the service of maximum customer benefit. With a passion that can be sensed at every single step in a project. See for yourself: From advice to planning and production and to implementation in your production sequences, we are uncompromisingly committed to improving your efficiency and to extending your competitive edge.



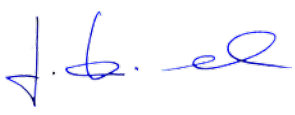
ACSYS – Your partner for the perfect laser process in medical technology

Preface

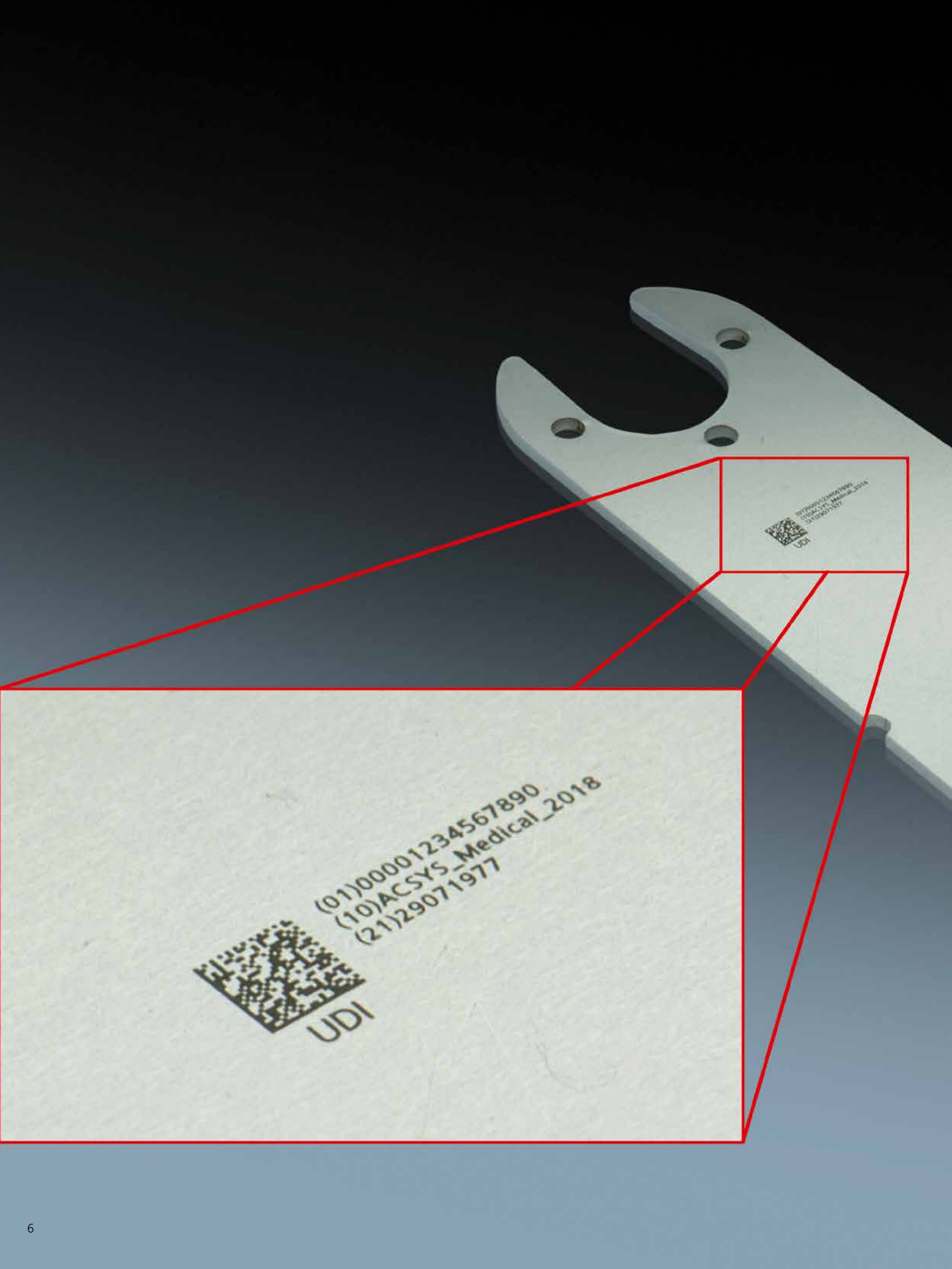
Through many years of experience and partnership-based collaboration with our customers in the medical industry, ACSYS has grown into a technology leader, and a supplier in worldwide demand for its ultra-modern laser machining units. Unique patented solutions deliver the requisite added value in the manufacture of its high-quality medical products.

As the managing director and owner of this internationally successful company, I am proud of our team of highly motivated specialists.

In my functions as a team player and coach, I work on continuous, strategic further development with an awareness of my responsibilities toward co-workers and their families, and toward customers and business partners. We define objectives and strategies founded upon sustainable corporate development, and a long partnership based on confidence. We focus on production methods that conserve resources and that are environmentally friendly. For this, we develop the very latest, advanced laser and system technologies. In this way, we have succeeded in improving the efficiency of our laser units continuously, and have also made them vastly more effective.



Gerhard Kimmel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UDI

Inhalt

Know-how is passion.

Process validation

and qualification of laser system solutions

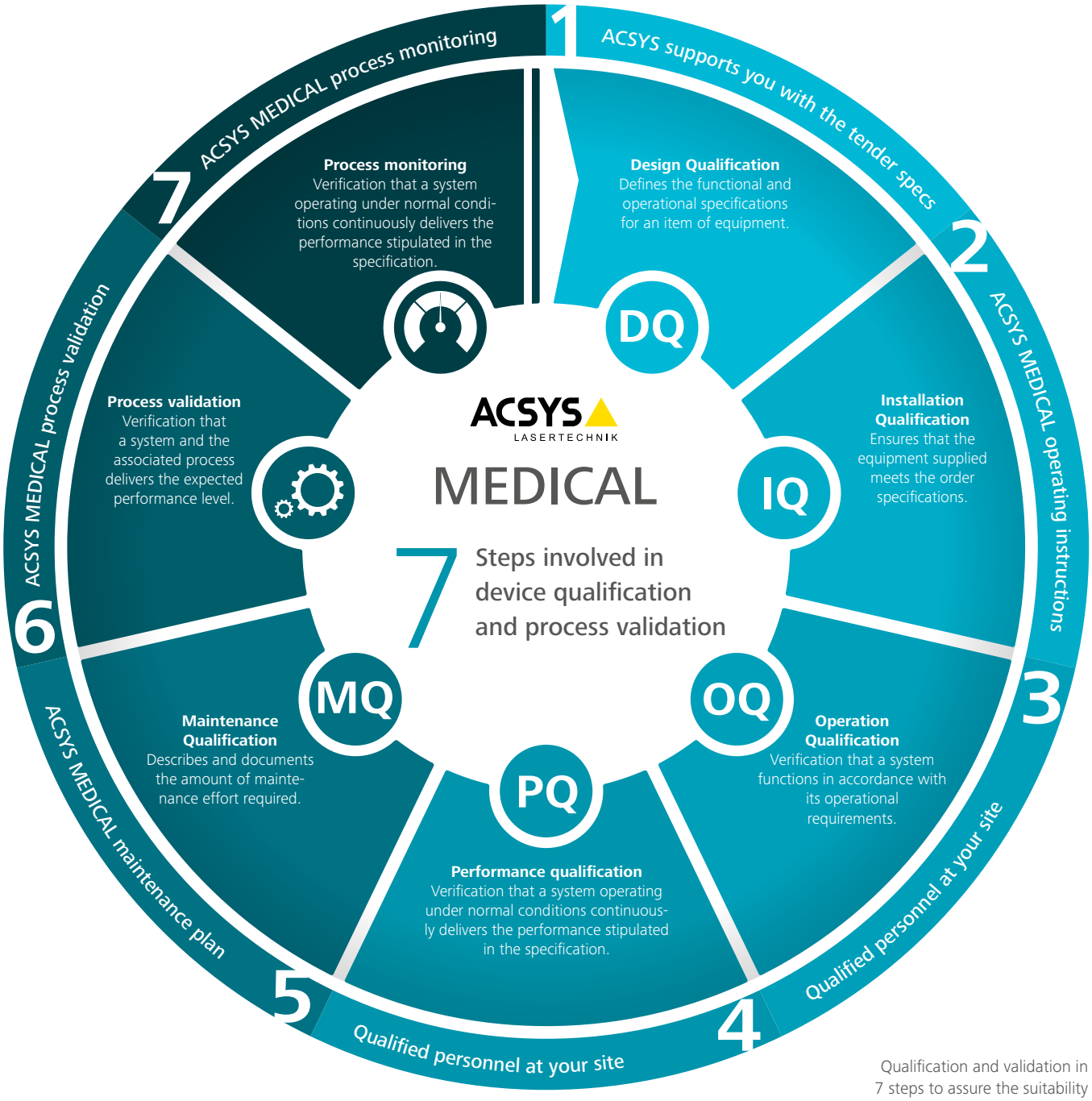
The basic concept underlying process validation is that quality requirements for the product must be satisfied reliably and to one hundred percent in the production process. To this end, every step in the manufacturing process is viewed and tested in advance.

Process validation therefore is a form of documented verification to show that a product can be manufactured within the context of a defined process sequence, and that it possesses the required characteristics, provided that certain parameters are observed during production.

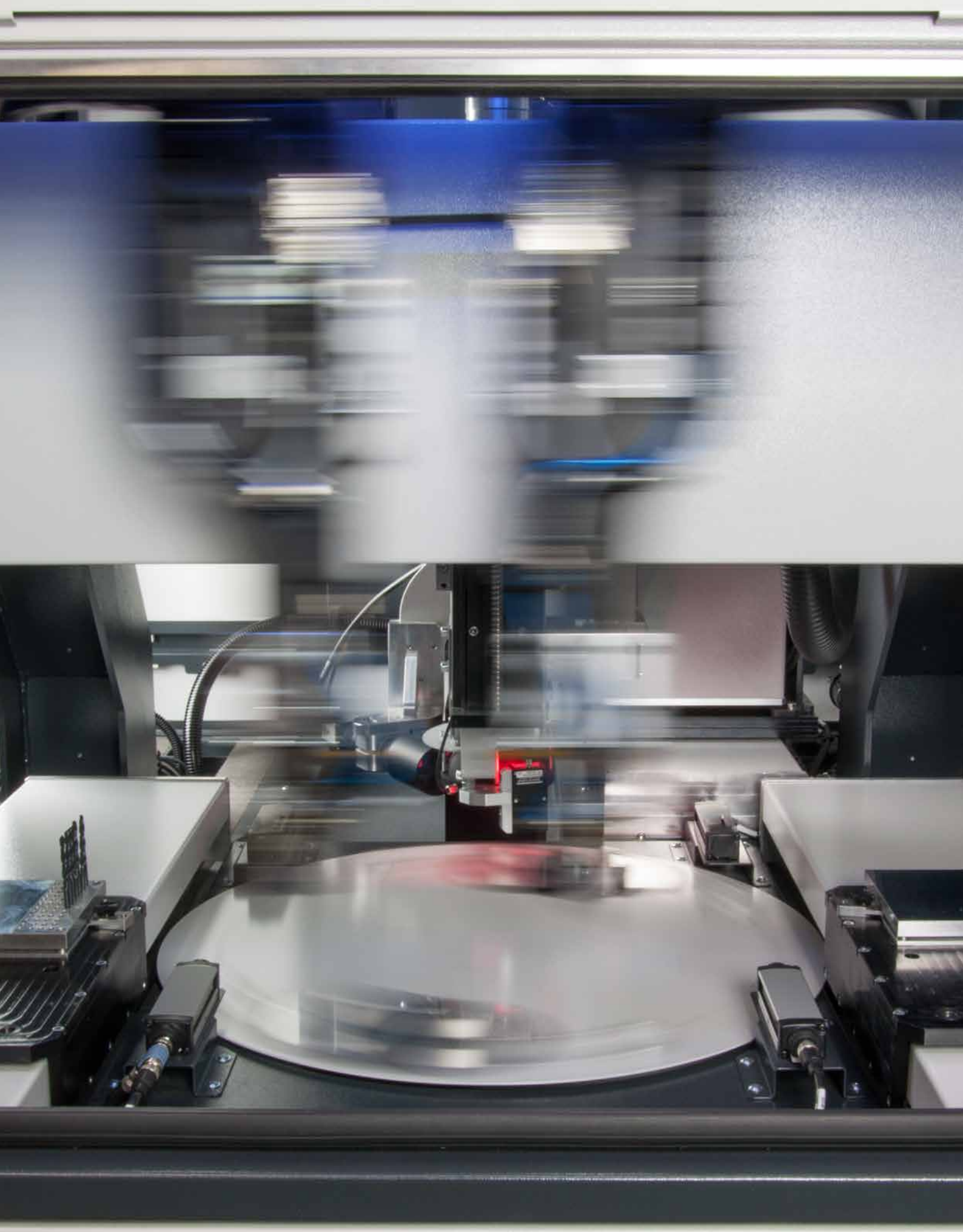
The qualification of laser machining systems for the manufacture of medical products is a clearly defined requirement from the “Rules of Good Manufacturing Practice - GMP”, and is therefore an indispensable element of the quality assurance process. This guide provides an overview of the specifics governing how we should proceed with the qualification process – in particular with respect to the inclusion of individual activities in the planning and building of complex laser systems.

Right from the outset, ACSYS is there to provide you with detailed technical knowledge in relation to the FDA-compliant qualification (US Food and Drug Administration) of laser units in the medical industry.

Solutions for you from a single source.



Qualification and validation in 7 steps to assure the suitability of a laser machining system in the medical industry for an intended application.



1. Design Qualification

Design Qualification is a form of documented verification to show that due account has been taken of quality-relevant, GMP-related requirements for the design of a laser machining system and its optional accessories, including buildings, premises and auxiliary equipment items. ACSYS actively supports you in the production of the tender specifications.
DQ is an examination of the **requirements** relating to:

Hardware specifications
- Materials
- Condition
- Dimensioning

Software specifications
- Functional characteristics
- Performance characteristics

System documentation
- Completeness
- Thoroughness

2. Installation Qualification

Installation Qualification (IQ) is a form of documented verification to show that critical items of equipment and systems have been supplied and installed in accordance with the requirements stipulated, and with legislative requirements. The operating instructions are part of the ACSYS MEDICAL package, specifically designed to meet the requirements of the medical industry.
IQ is an examination of **execution** relating to:

- Documentation
- Scope of delivery / completeness
- Specifications / marking
- Installation
- Supply and disposal connections
- Safety devices
- Overall condition
- Accessibility for maintenance and cleaning

3. Operation Qualification

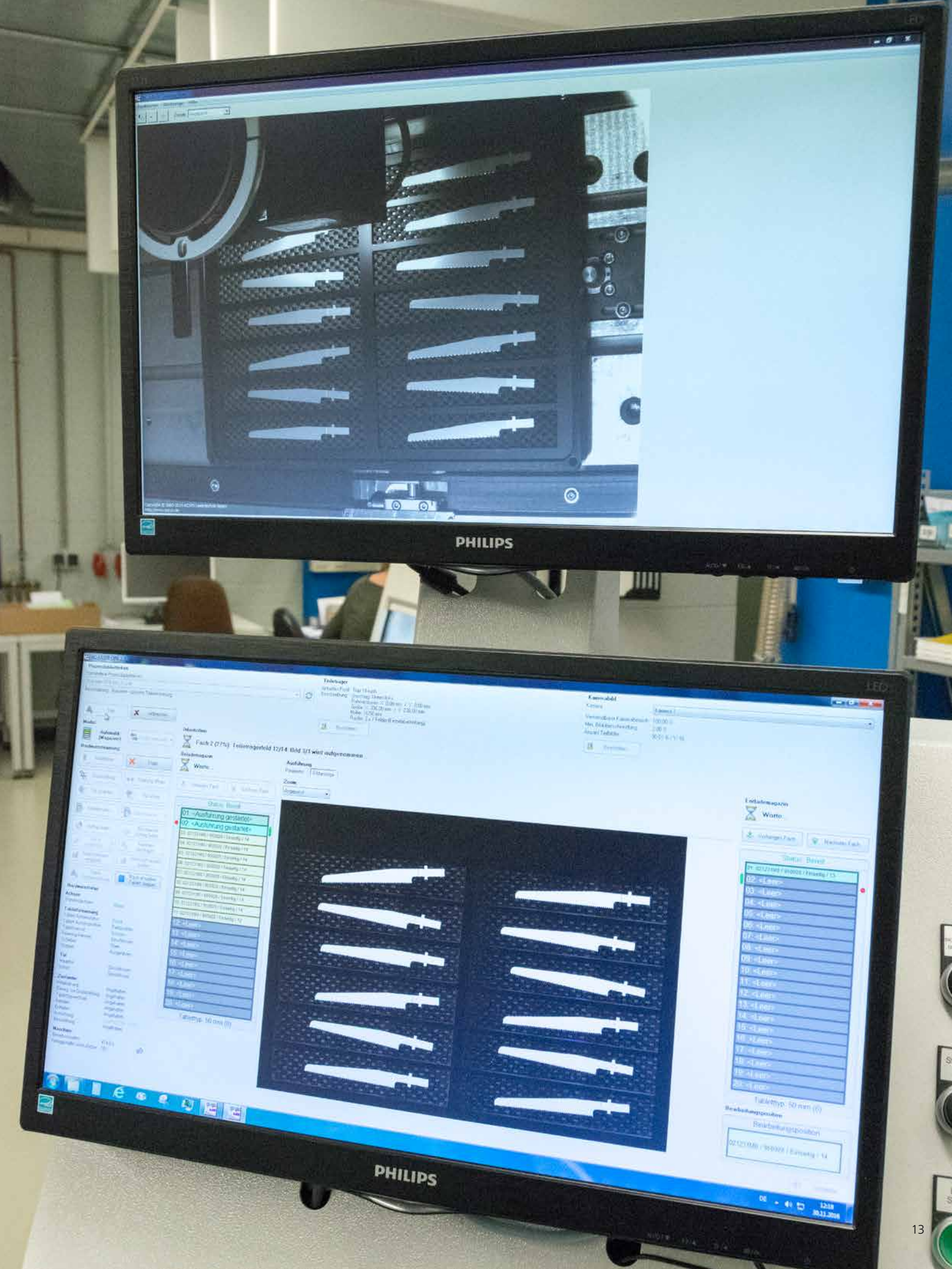
Operation Qualification is a form of documented verification to show that critical items of equipment and systems operate in the intended manner, in compliance with the requirements stipulated throughout their operational range and within specified limits. ACSYS accompanies you with qualified personnel on site, i.e., on your premises.
The OQ checks **Operation** in relation to:

- Tightness
- Mechanically moved parts
- Manually moved parts
- Switching and control circuits
- Step sequence and program sequence controls
- Safety devices
- Measurement, display and recording equipment
- Working conditions

4. Performance Qualification

Performance Qualification (PQ) is a documented form of verification to show that critical equipment items and systems operate in accordance with stipulated requirements across the entire working area under prevailing workplace conditions (with product) and deliver the required levels of performance. ACSYS accompanies you with qualified personnel on site, i.e., on your premises.
PQ checks **performance** in relation to:

- Measurement of critical performance criteria
- Definition of requirements (working conditions)
- Definition of the test method
- Definition of the test aids
- Definition of the acceptance criteria (limits)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PHILIPS

5. Maintenance Qualification

Maintenance Qualification (MQ) describes and documents the required maintenance and servicing work, including the documentation of repairs. A maintenance program is an essential requirement to ensure that a system - including premises and auxiliary items - remains in its qualified condition and is therefore also an FDA requirement. ACSYS supports you with an ACSYS MEDICAL maintenance schedule.
MQ is a **definition** of:

- Maintenance and inspection points
- Maintenance cycles
- Responsibilities
- Procedure
- Documentation and evaluation of the execution process

6. Process validation:

Process validation is a documented form of verification to show that a product can be manufactured within the context of a defined process sequence, and that it possesses the required properties, provided that defined parameters are observed during production. The FDA Quality System Regulations, specifically in 21 CFR 820.75, describe the requirements for process validation: Process validation involves the collection and assessment of data, starting with the design phase and extending through to production, delivering scientific evidence that a process delivers quality products on a continuous basis.

The basic concept underlying process validation is that quality requirements for a product must be satisfied reliably and in full, i.e., to 100%, in a production process. To this end, every step in the manufacturing process is viewed and tested in advance.

7. Process monitoring:

Process monitoring is a documented form of verification to show that critical items of measuring equipment operate reliably under prevailing operating conditions within the intended range of values and that they comply with specified tolerances.

The ACSYS MEDICAL program supports you in the selection of measuring methods, the testing, aptitude inspection of measuring equipment and the corresponding validation of that measuring equipment.

Calibration checks the **definition** of:

- Value ranges
- Operating conditions
- Error limits
- Tolerances
- Calibration values
- Calibration cycles


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UDI – We make your medical devices unique.

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Schedule for the introduction of UDI (USA):

- September 2013: Decision taken to roll out UDI (final rules)
- September 2014: UDI binding for all medical products in Class III
- September 2015: UDI binding for implantable and life-preserving medical products
- September 2016: UDI binding for medical products in Class II
- September 2018: UDI binding for medical products in Class I

Safe, clean and sterile: Medical devices Mark as UDI-compliant.

Introduction

For unique identification of medical products and their packaging, you are obliged as a manufacturer to mark all classes of medical device for your customers with the Unique Device Identification (UDI). UDI is the globally valid system for uniform marking of medical devices. In addition, the requirements for UDI marking on medical devices are high: They must be long-lasting, clearly legible and feature strong visual contrast. The marked surfaces must be clean and hygienic, and must be resistant right across their life cycle to sterilization and cleaning operations. Scalpels, canules or X-ray devices - it is possible with the ACSYS laser units and the ACSYS PRO-MED laser system to mark all shapes, sizes and materials of medical devices.

To assure worldwide traceability and to protect against counterfeiting, a great deal of information must be attached to surfaces made of different materials, some of which may be very small and/or round or oval. This includes a UDI-compliant code - a barcode or a 2D code with encrypted data contents for traceability purposes - as well as information about the manufacturer and the production process. For the manufacturer - i.e., the party bringing the product into circulation and/or the labeler - the UDI system provides a clear framework that defines the form in which information should be encoded on the medical product in accordance with its classification. However, this still leaves an unsolved problem for the manufacturer, namely how to satisfy the high requirements for marking, for example, on a hip joint implant.

UDI. Laser. Binding.

UDI – close to series

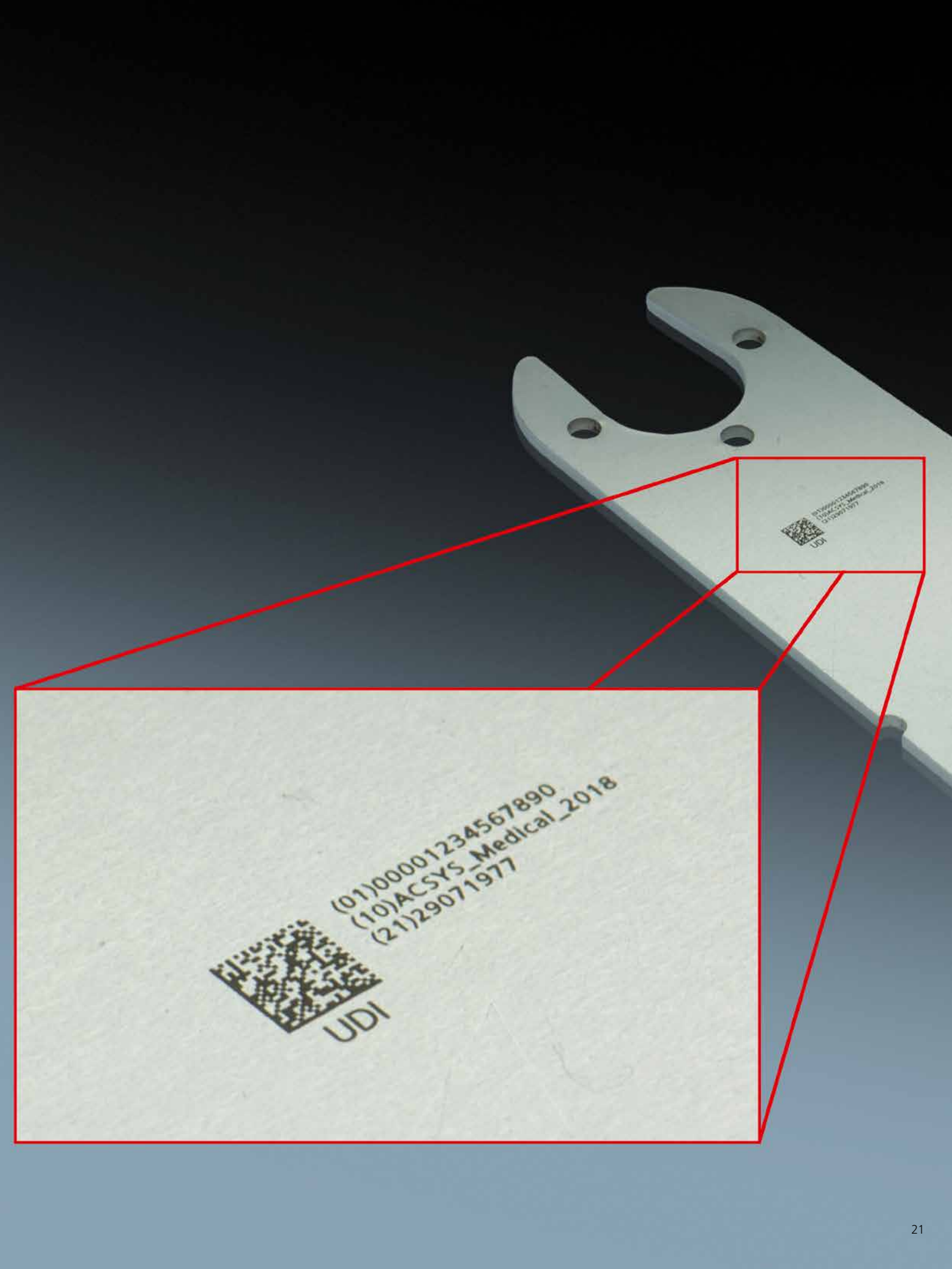
Whether you are involved in annealed marking, ablative laser marking or carbonizing and foaming of plastics and technical ceramics, the advantages of laser machining over conventional marking techniques such as needle embossing or printing are significant.

Laser markers are ideal for the long-lasting marking of products - for short production runs with variable data and for high-volume production runs. The contactless laser marking process guarantees high-quality markings on almost all materials, down to tiny sizes and always very precisely.

When using a laser, layers of the surface are vaporized. This does not affect the properties of the surrounding material, nor does it affect the deeper layers. This makes it possible to achieve low-melt, burr-free marking at a high level of precision - even on the tiniest contours of very hard material surfaces. This makes even the minutest of 2D code layout easily legible and surrounded by clear outlines. Furthermore, thermal influences of the kind that can cause metals to decompose, degrading the material properties, play no role here whatsoever.

Advantages of the laser:

- High speed
- Stability
- Maximum precision
- High process stability
- Contactless operation
- Short retooling times
- Low maintenance requirement
- No additional costs for drills or turning tools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(21)29071977
UDI

More precise, more economical, better - that is our claim.

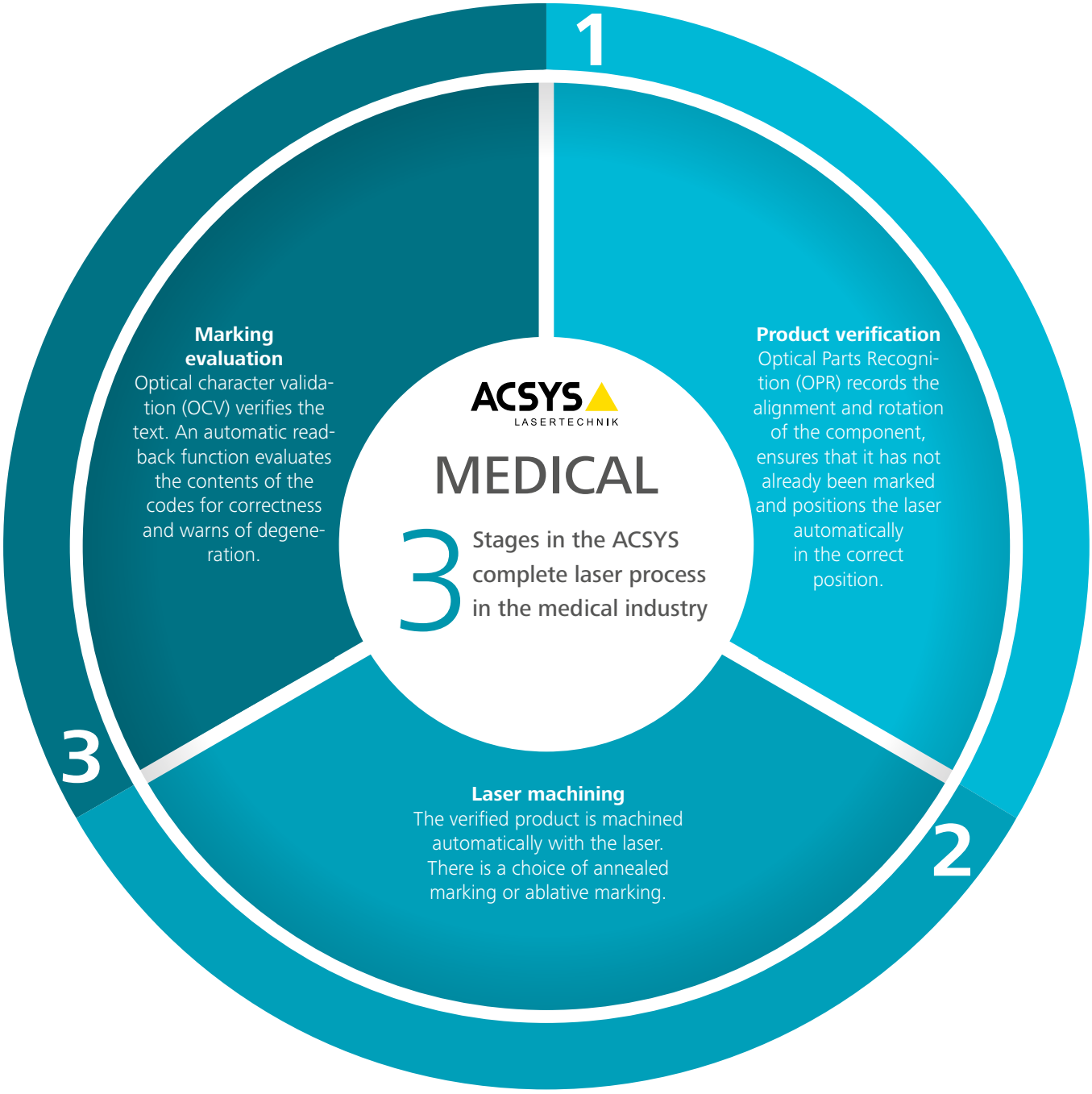
ACSYS MEDICAL laser process in medical technology

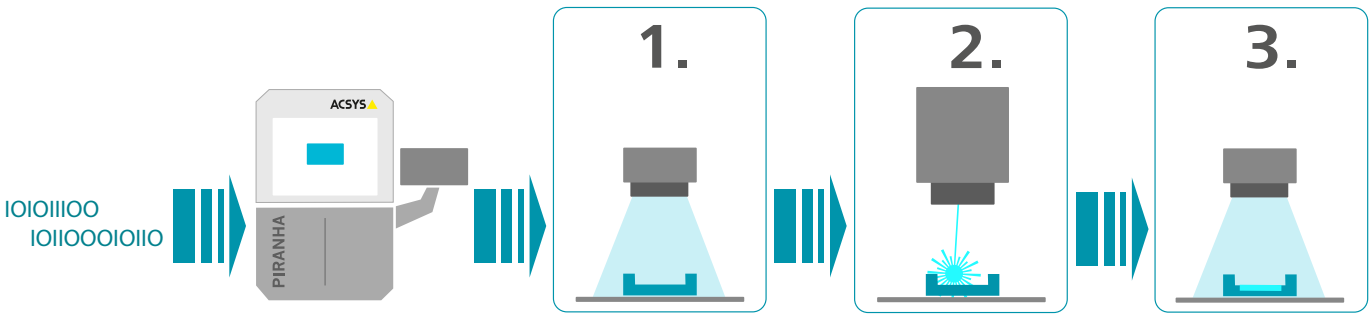
Laser marking and laser engraving are just one part of the overall process that ACSYS can display in medical technology. Our holistic approach and close collaboration with customers enables ACSYS to offer modular and customer-specific solutions. Our in-house software development department produces the appropriate software with database connections, component recognition, the corresponding protocol functions and concluding read-back functions of barcodes and DataMatrix codes as well as plain text entries.

On the following pages, you will learn all you need about the decisive themes:

1. Product verification
2. Laser machining
3. Marking evaluation

ACSYS laser systems are manufactured in accordance with GMP recommendations. A high level of vertically integrated production means that all necessary hardware requirements can be taken into account, required for subsequent operation in the manufacture of medical products.





The in-house data connection provides ACSYS MEDICAL with the machining data

ACSYS MEDICAL
Product verification

ACSYS MEDICAL
Laser machining

ACSYS MEDICAL
Marking evaluation

1.

2.

3.

1. Product verification: Optical Parts Recognition (OPR) enables fully automatic processing of palletized and non-palletized components. The high-resolution camera system ensures that only the correct component is machined.
2. Product verification: Component as seen by the AC-LASER software from ACSYS. The software detects the position and rotation of the component and then marks or engraves it at the previously taught-in location. The software also ensures that a component that has already been machined does not pass through the process once again.
3. The interaction of high-resolution camera systems with precision optics in combination with optimum illumination (in this photo, white light ring luminaires with additional infra-red lighting) provide the required level of process reliability during the product validation process.

Visible know-how in image acquisition.

1. Product Verification

The manufacture of a medical product to the required high standards is resource-intensive and requires the most careful of attention at every stage of production. As a rule, medical products receive their customer-specific marking as the last step in an extended sequence of processes. Manufacturers of medical products must ensure that the correct information is positioned precisely on the right component.

We are the pioneers here, with a unique camera-based setting system – The LAS-Live Adjust System®. With more than ten years of experience in optical part recognition followed by the fully automated processing of palletized and non-palletized workpieces, we are able to provide our customers with a large „modular range“ of options to implement optical product validation. Totally reliable recognition of parts is a process based on a combination of precision camera systems, appropriate lenses and optimum lighting, together with tried-and-tested software.

Advantages:

Optical Parts Recognition from ACSYS

- verifies the product and ensures that only the correct components are machined,
- checks to ensure that the product has not already been marked,
- automatically detects the alignment and rotation of the product,
- and positions the laser for precise laser machining.

Greater process reliability in series.

2. Laser Machining

More precise, better, more economical - that is our claim. Machine solutions from ACSYS impress with their ultimate standards of accuracy, precision and repeatability. A holistic view of machine and workpiece processing allows us to achieve highly precise, uncompromisingly tailor-made solutions for processes and products.

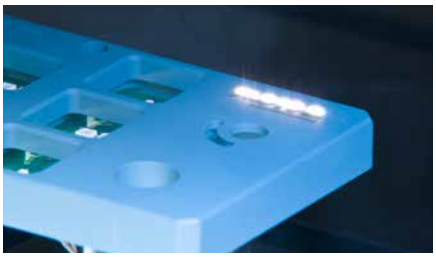
Our systems are reliable service providers in automated production processes, in 3-shift operation and for just-in-time logistics. At the exciting interface where high-performance technology encounters cutting-edge applications, we can provide you with production tools precisely designed to suit your processes.

For us, reliability is not just a quality argument. Instead, it is a fundamental tenet of our corporate and product philosophy.

Advantages of the laser:

- High speed
- Stability
- Ultimate precision
- High process stability
- Contactless operation
- Short retooling times
- Low maintenance requirement
- No additional costs for drills or turning tools

1.



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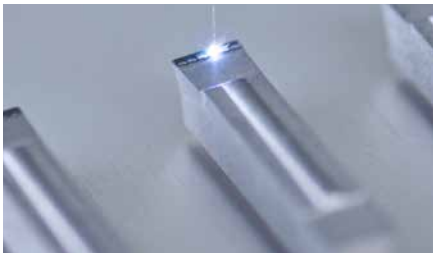
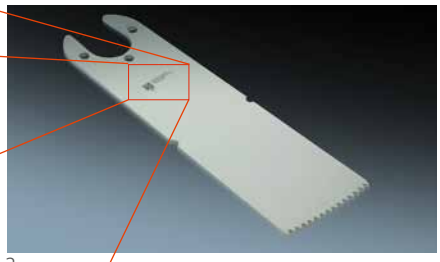


3.

1. Laser process of a micro-engraving.
2. Marking of plastics.
3. Precision laser removal

1.



2.

3.

1. + 2. UDI marking (2D DataMatrix code [ECC200] GS1-compliant) on an orthopedic sawblade. The entire marking measures only 2 x 1 mm in size.
3. The interaction of high-resolution camera systems with precision optics in combination with optimum illumination (in this photo, white light ring luminaires with additional infra-red lighting) provide the required level of process reliability during the marking evaluation process.

Seeing and recognizing are not the same ...

3. Marking evaluation

Evaluation of laser marking is yet another challenge for the overlapping laser machining process in the medical industry. Once a component has been marked, the marking, the barcode or the DataMatrix code (DMC) must be checked.

The precision camera system (LAS) from ACSYS ensures that the position, alignment and size of the marking comply with what was intended. Optical Character Verification (OCV) in the AC-LASER software from ACSYS verifies that every marked character matches the intended content.

In the same step, the integrated code verification and read-back facility of the AC-LASER checks the contents of the lasered 1D and 2D codes (DataMatrix [ECC 200, GS1], QR). It also allows classifying codes in quality levels. The system warns of any degeneration in marking (grading), thereby assuring a reliable process. The direct read-back of 1D and 2D codes (e.g. DataMatrix [ECC200] GS1-compliant) is a central component of the UDI directive.

Advantages:

- Maximum efficiency: Product verification, laser marking and marking evaluation in one process and one system.
- Seamless traceability and compliance with regulations.
- Very high product quality and low levels of rejects.

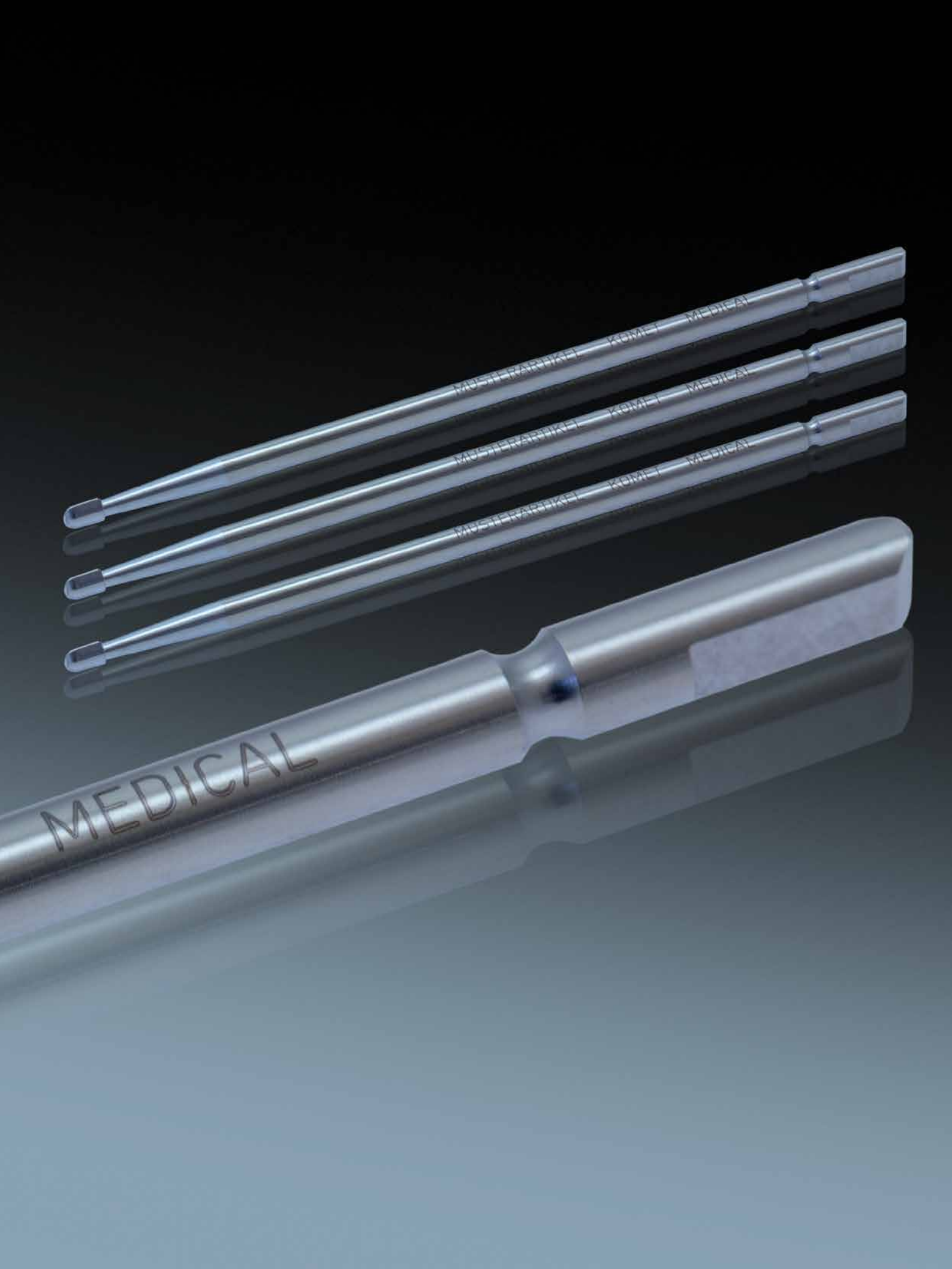
Collaboration based on partnership makes us unique.

Laser machining in the medical industry

For demanding marking processes, we develop and produce the corresponding laser technologies, laser systems and the appropriate software.

This does not involve just ONE standard solution that can provide all customers with an optimum laser system for the wide-ranging and entirely diverse medical products in their various sizes, materials and production volumes. This is why our specialists talk at length to each customer about the ACSYS MEDICAL laser machining systems, and test process-relevant factors. As a consequence, we develop the total laser concept with you in a partnership-based form of collaboration.

At all times, we are able to offer the very latest technologies for fiber lasers, nanosecond, picosecond and femtosecond lasers with different wavelengths for many materials, all at the cutting edge of technology. We develop these technologies in our research laboratory and work closely with various laser institutes and test laboratories in Germany.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Eclipse.

Black marking

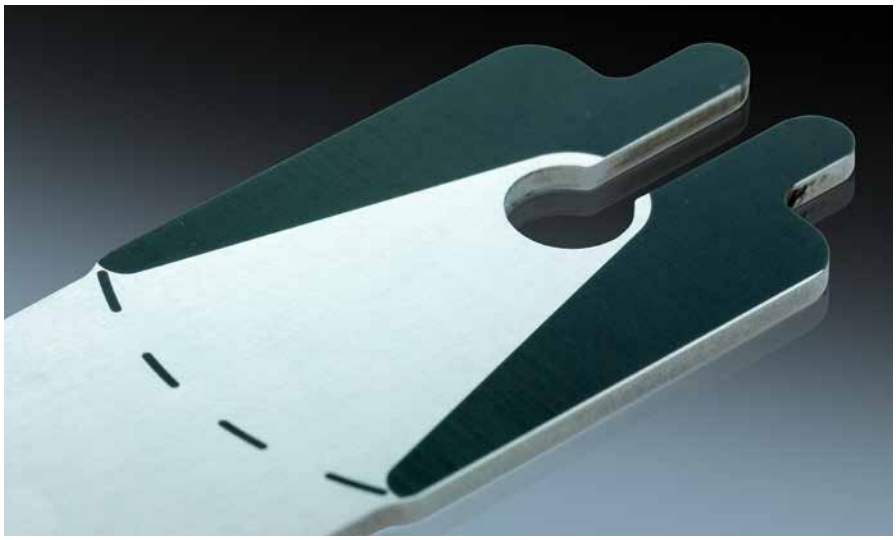
The corrosion-resistant black marking is a newly developed process, which only works with the use of a picosecond laser.

Compared to the nanosecond laser, the picosecond laser offers the advantage that its high-energy laser pulses are significantly shorter in duration, which means that thermal transfer to the surrounding material is close to zero. The phrase used here is „cold marking“. The picosecond laser generates a functional microstructure entirely without a melted burr.

Blackening is not the result of an oxide layer forming (annealing marking), but is instead due to optical effects caused by the microstructure created on the material. Black marking is not dependent on the angle of view.

Advantages:

- No thermal transfer to the material.
- Black marking is not dependent on the angle of view.
- Corrosion-resistant
- No subsequent passivization is required
- The surface of the material remains almost undamaged



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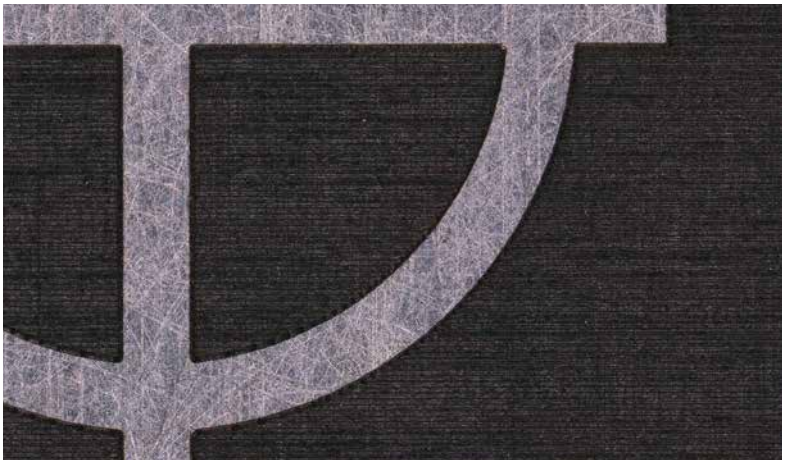
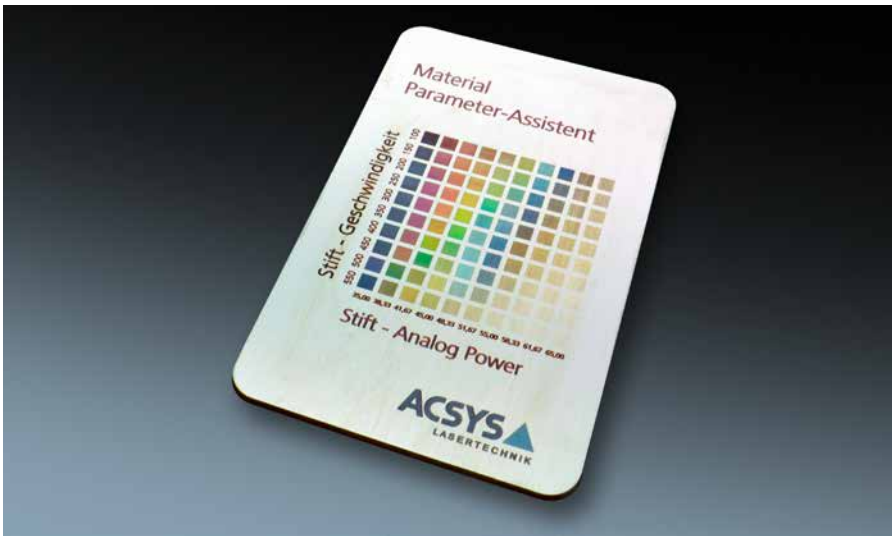


High-precision, cold-marked black surface structure on stainless steel with the picosecond laser.

1. Black marking of a picosecond laser on a sawblade.
2. Black marking on a prosthetic hip shank.
3. Black marking of a picosecond laser on a sawblade.



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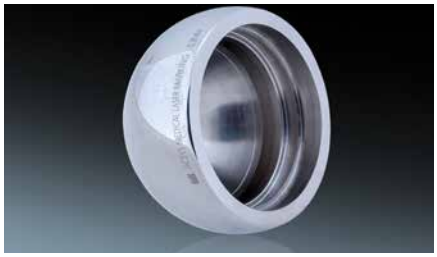
2.


3.

1. Multi-colored annealing marking on stainless steel.
2. Colored annealing marking on dental drills.
3. Annealing marking on a titanium prosthetic hip joint.

	Annealing temp. °C
Whitish yellow	200
Straw yellow	220
Golden yellow	230
Yellowish brown	240
Brownish red	250
Red	260
Purple red	270
Violet	280
Dark blue	290
Cornflower blue	300
Light blue	320
Bluish gray	340
Grey	660

Annealing colors for stainless steel.

Striking.

Annealing marking

Annealing marking applied by laser brings color into play. The laser makes it possible to apply scripts, structures and surface textures to the workpiece surface in different colors - without the use of additives. This annealing marking process is completely abrasion-resistant and watertight, and the only way to remove it is by reheating the component (to at least 700°C in the case of iron compounds). The natural passive layer on stainless steel products can withstand repeated heating provided that we set up the laser parameters accordingly. Annealing marking does not attack the surface because no material is removed in the process. All that happens is that a high-contrast color change takes place on the outer surface of the material.

Advantages:

- High visual quality with filigree markings
- No material burr
- No damage to the surface
- Passive layer remains intact on stainless steels
- Various metals: Stainless steel, titanium, coated materials (TiN and others).
- Low machining depth: 30 - 50 µm
- Several colors are possible
- Long-lasting and reproducible

Engraving.

Ablative laser marking

When marking medical products, we focus on long-lasting, clean and easy-to-clean marking - even down to the micron range. For all processes associated with laser engraving and marking, we use the energy of the laser beam to vaporize material selectively, creating slightly recessed marking. This engraving effect occurs when the surface is removed, or when a surface layer is applied, such as Eloxal, paint or chrome. This happens because a color contrast is created by „free lasering" of the surface material. Assuming that the laser is used properly, the surface of the actual component remains undamaged, and no microcracks appear in the material.

The following processes are involved in engraving marking:

- Laser marking involving material removal
- Coating removal
- Plastic engraving
- White marking

Advantages:

- Possibilities for fast marking
- Although the coating is removed, the surface of the component remains undamaged
- Long-lasting marking - falsification-proof and durable, also toward aggressive media

1.

2.


3.

1. Rapid engraving marking on medical implements.
2. Plastic engraving on a hearing aid component.
3. Layer removal from coated titanium implants.

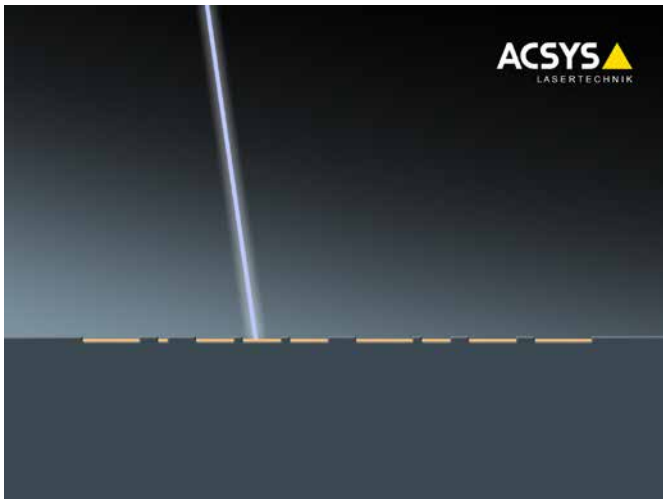


Illustration of laser engraving marking.

1.

2.

3.

1. Laser marking of plastic pushbuttons (ABS) using the carbonizing process.
2. Laser marking by foaming of thick PVC films.
3. Carbonizing of identification rings (PSU).

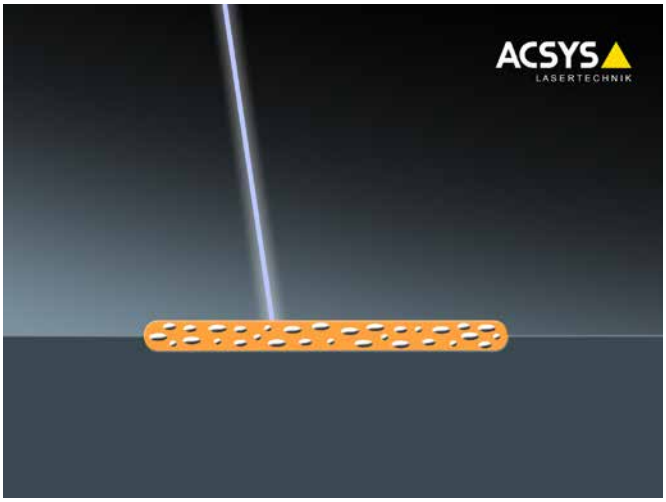


Illustration of the laser foaming process.

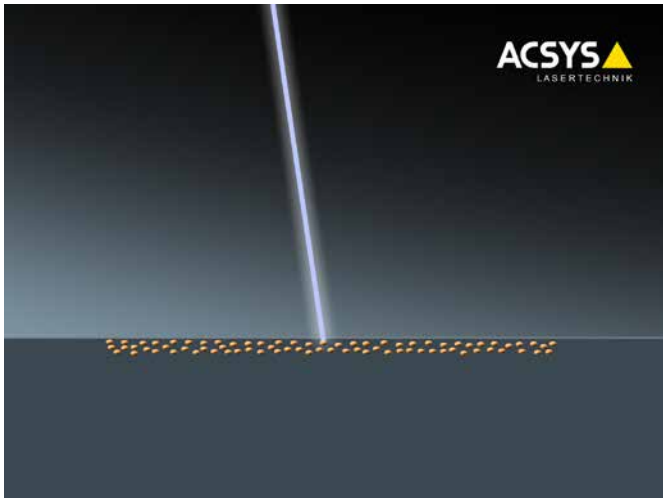


Illustration of laser carbonizing.

Raised.

Carbonizing and foaming of plastics and technical ceramics

For medical products made of plastics, we recommend either foaming or carbonizing for marking purposes. In the case of foaming, we use the laser beam selectively for gentle melting of the surface of the plastic. During the laser process, gas bubbles form in the plastic. These increase the volume of the material. The surfaces contacted by the laser beam have a raised structure after they have cooled.

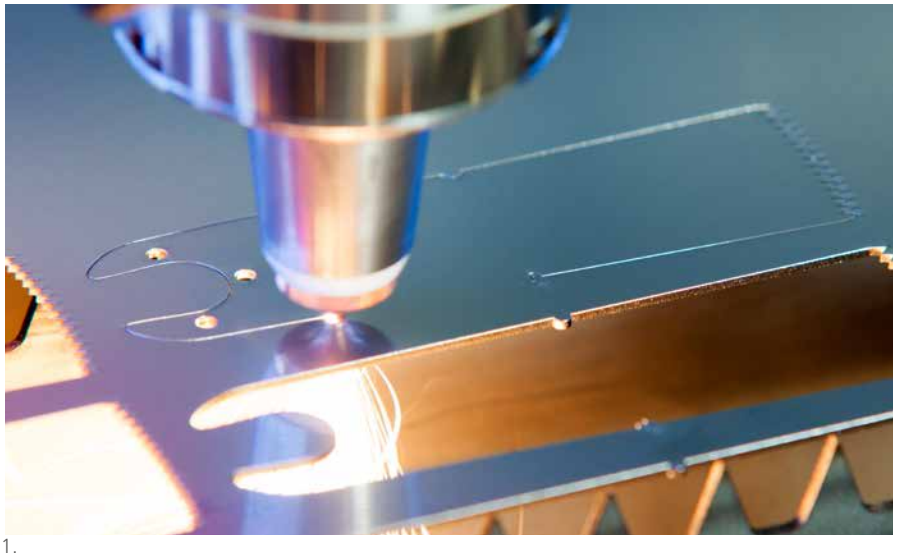
Advantages:

- Raised and tangible marking
- Surface of material remains almost undamaged
- Long-lasting marking that can only be removed destructively.

During carbonization, a color change and bleaching are achieved by the laser. This effect can be applied to certain plastics, for example, to materials combined with defined additives and to certain coatings and technical ceramics. The laser penetrates the material at a specific wavelength and is absorbed by colored pigments. If the pigments change chemically, this causes the material to discolor. Since the laser radiation penetrates the plastic, the surface remains almost undamaged. The color change depends on the pigment and on the base material.

Advantages:

- The surface of the material remains almost undamaged
- Long-lasting marking that can only be removed destructively.



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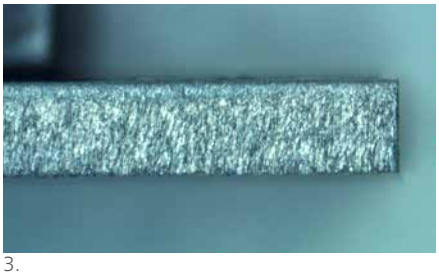

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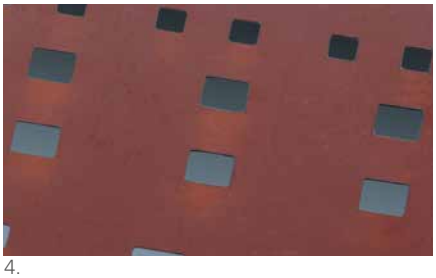

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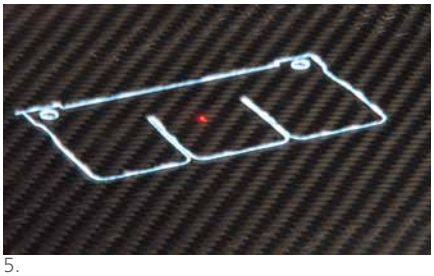


5.

6.

1. Laser fusion cutting of 1 mm stainless steel. 2. High-precision laser fusion cutting of 1 mm brass plate.

3. Micrograph, cutting edge 2 mm steel.

4. Laser cutting of Kapton film (polyimide) in the electronics and medical sectors.

5. Laser remote cutting of carbon mats. (long-term exposure: This enables you to view the laser plasma during a cut).

6. High-precision laser fine-cutting of stainless steel sheets. The sheet is secured to the machine table by means of a vacuum system.

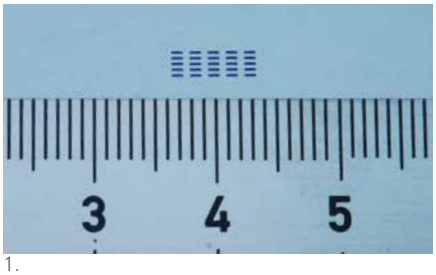
Always one „cut“ above the rest.

Laser fine-cutting

In medical technology, there are two basic laser cutting processes: Laser fusion cutting using the protective gases argon or nitrogen and laser remote cutting using a scanner for cutting very thin materials.

The advantage of the **laser fusion cutting process** is that its cutting edge is virtually free of oxides. An inert gas is used as the cutting gas. This blows the melt out of the mold parting line and also cools the cutting edge. This process is ideal if parts are required to satisfy high aesthetic standards without further processing. Further to this, hygienic and technical laboratory aspects need to be taken into account if further material changes are to be avoided.

Laser remote cutting (sublimation cutting) is defined as laser cutting of very thin and fragile materials that are cut without cutting gases. Instead, it is the laser alone that evaporates the material and generates a very fine cutting gap through layer-by-layer material removal. This process offers unique solutions for the processing of a wide range of composite materials.



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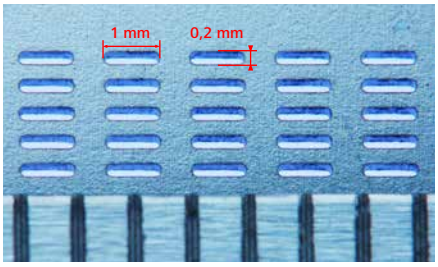


2.

1. & 2. High-precision laser fine-cutting of metal. Aperture size 0.9 x 0.2 mm at a material thickness of 0.3 mm compared to a working scale defined in DIN 866. (for an enlarged picture, see photo 2).

1.

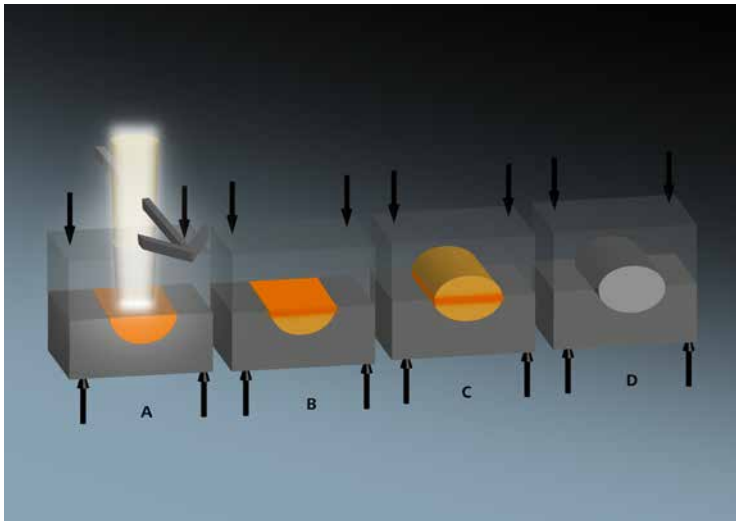
2.

3.

1. Laser welding of threaded heads on micro valves.

2. Laser marking and welding of plastic containers for medical technology (material: PP).

3. Laser welding of metal membranes of pressure sensors.



Working principle of laser absorption welding in plastics.

The laser light penetrates the upper layers and is absorbed by the lower piece to be joined (A). As the lower piece heats up (B), heat is conducted to the upper piece (C). The shared molten area solidifies under pressure applied externally, thereby creating a high-quality weld joint (D).

Binding.

Laser welding

ACSYS laser processing systems are suitable in particular for extremely fine and precise welding processes.

Depending on the material, different processes are used. ACSYS welding systems work without addition of filler metal. Their flexible performance and pulse design allows special pulse shapes and pulse trains to be created for special effects.

The **metal laser welding** process is basically sub-divided into two processes: Melt welding/fusion welding and keyhole welding.

The basic process of **laser plastic weldin**g is seam welding. During this process, the laser beam penetrates the upper piece to be joined and is absorbed by the lower piece.

Laser welding of temperature sensor housings.

Made in Germany.

Simplicity made by ACSYS – Solutions for you from a single source.

ACSYS laser systems

In every specific requirement, we see an active challenge. In meeting that challenge, we broaden the scope of our technological expertise – to your benefit.

Our solution-oriented wealth of innovativeness and our reliability are consistently harnessed to meeting your individual requirements. We take due account of economic aspects to help guide your company toward corporate success - with our process reliability and our systems, all designed for high productivity.

We master all disciplines of laser machining on a vast array of different materials. Through continuous investigation and development of new as well as extended solutions and customer applications, we can offer our target markets state-of-the-art technologies from a single source. Your application is our challenge – whether it involves marking, engraving, cutting, or welding. Challenge us with your application!

High-strength, vibration-free construction made of granite for the ACSYS PIRANHAμ.

Heavy Metal and Hard Rock

A holistic view of machine and workpiece processing allows us to achieve highly precise, uncompromisingly tailor-made solutions for processes and products. Our high level of vertically integrated in-house production provides the basis for a highest level of flexibility in our laser systems.

Furthermore, for us, reliability is more than just a quality argument, it is instead a basic tenet of our corporate and product philosophy.

Our wide range of available machines allows us to accommodate product-specific and production-specific requirements in a flexible manner, with customized system solutions.
The intelligent networking of the individual modules results in a highly efficient and flexible operation of the system. Our systems communicate with cutting-edge bus systems and peripheral devices.

More efficiency in production and service – we are pace-setters for your laser processing.

Options

For every need.

LAS – Live Adjust System®

The camera-based Live Adjust System (LAS) significantly simplifies the setup process and allows precise positioning of even the smallest of workpieces. A high-resolution camera with coordinated precision optics, including field illumination, is complemented by the continuous digital zoom function, revealing the detailed features of the workpiece. In this way, layouts can be placed with high precision. An exact preview shows the target result on the screen. New layouts can be created directly on the workpiece without having to take additional measurements.

ACSYS offers a two-camera solution for maximum precision. The first camera shows the entire working area and provides the operator with an overview of the workpieces that are to be machined.

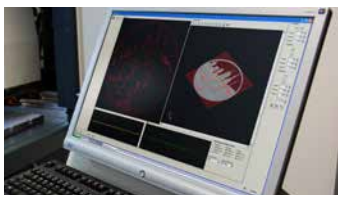
LAS – Live Adjust System®

LAS – Live Adjust System.
Dual camera (external + internal with beam track of the laser).

Efficiency with ACSYS:
Precise and direct.
The Live Adjust System from ACSYS – provides our customers with the fastest and simplest way to set up a machine.

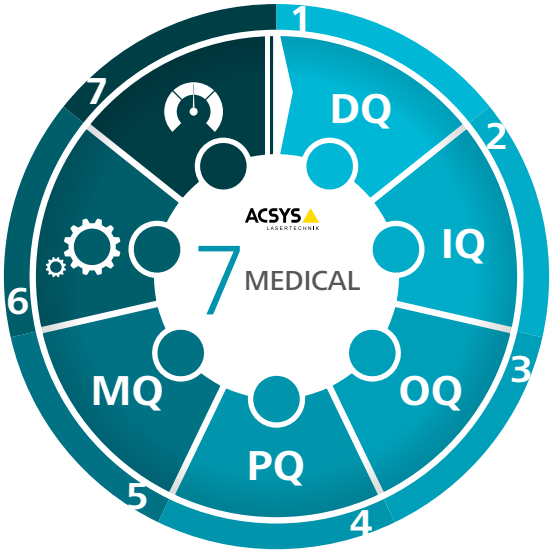
It features comprehensive and intuitive zoom, contrast and other image-processing functions.

The camera set-up module Live Adjust System at a glance.
Phase 1: Insert the part to be machined.
Phase 2: Zoom and align texts, graphics and 3D models directly on the workpiece on screen.
Phase 3: Start laser machining.
Phase 4: Remove the perfect result and continue with the next project.



ACSYS MEDICAL package

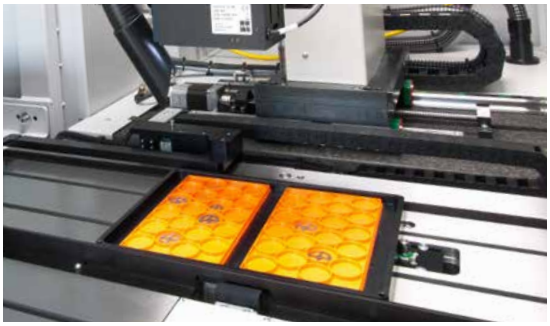
Right from the outset, ACSYS is there to provide you with detailed technical knowledge in relation to the FDA-compliant qualification of laser units in the medical industry. From advice to planning and production, and on to implementation in your operational facilities, we are uncompromisingly committed to your efficiency and to helping you maintain your competitive edge.



OPR – Optical Part Recognition (product validation)

Optical Parts Recognition enables fully automatic processing of non-palletized loose parts. The software detects the position and rotation of the workpieces and then processes them at the previously taught-in location.

QR-Code for Film



OCR/OCV – Optical Character Recognition/Verification (marking evaluation)

The Optical Character Verification (OCV) component of the AC-LASER software from ACSYS evaluates whether every marked character complies with the intended contents.

Seeing and recognizing are not the same ... The ACSYS wizard systems.

Automatic DMC evaluation

In the same step, integrated code evaluation and reading back by AC-LASER check the contents of lasered 1D and 2D codes (DataMatrix [ECC 200, GS1], QR). It also allows classifying codes in quality levels. The direct read-back of 1D and 2D codes (e.g. DataMatrix [ECC200] GS1-compliant) is a central component of the UDI directive.

Robotics

Robot handling with integrated control. Flexibility in conjunction with ultimate precision: The systems and products from ACSYS are based on a completely modular system and can be adapted very effectively indeed to suit the wishes of our customers. Robotic grippers, automation solutions in conjunction with robot handling systems or Robot Pick & Place solutions are just one part from the portfolio of possible robot solutions.

Pallet processing

To enable several workpieces to be processed in a stack, ACSYS offers customized and made-to-measure pallet systems for its laser system.

AC-LASER in OPR mode.
The high-resolution camera detects the position and rotation of loose parts. The automatic processing operation that follows can also be extended with a pallet conveyor, roller feeder system or a conveyor belt, or can be integrated into an existing production line.

AC-LASER
Laser Software Suite.

ACSYS Software – The intelligent interface between you and the laser.

Software made by ACSYS

Discover the new dimensions of laser processing. The AC-LASER software is the ideal software package for laser material machining. In a homogeneous, intuitive environment, the AC-LASER provides you with all the important tools for your work – from the production of simple markings up to the manufacture of complex 3D engravings for one-off or volume production operations.

Achieve excellent results with our AC-LASER high-performance software modules. Thanks to the graphic user interface, you can implement every requirement within a very short period of time, without having to make compromises in terms of design or quality. Intelligent image processing functions minimize set-up times.

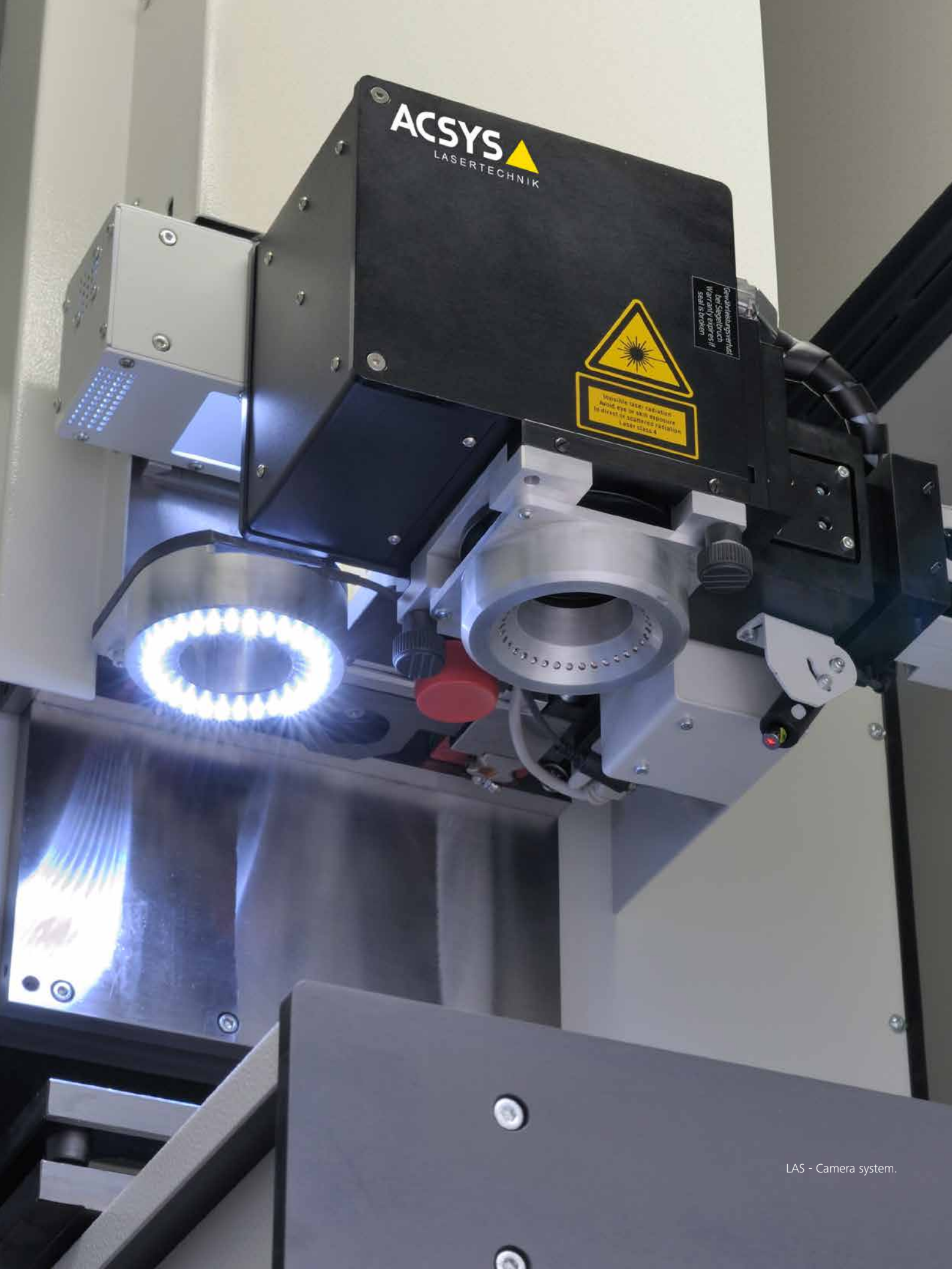
The AC-LASER software enables productivity without compromises. The close integration and uniform functionality of the different modules enables you to implement your ideas and requirements in a consistent manner.

Visible know-how in image acquisition.

High-precision laser marking (UDI Code) on a laser-cut orthopedic sawblade.

Keyfeatures

- **Industry 4.0**
  AC-LASER and ACSYS laser systems are equipped with the latest technology in every respect. A variety of intelligent networking option interlinks the production with information and communication technology.
- **Camera image**
  The LAS – Live Adjust System – allows precise positioning of even the smallest of workpieces.
- **Multi-axis functions**
  A large number of controlled axes can be traversed simply by clicking a mouse or fully automatically.
- **3D functionality**
  Extensive processing options for 3D engraving operations with integral depth control and digitalization functions.
- **Custom programming**
  Customized layout and process programming as well as database connectivity are possible.
- **Professional text layout tools**
  Line spacing, changes in tracking and record type can be programmed and modified for any font installed on Windows.
- **Intuitive user interface**
  Different user interface standards are available. AC-LASER offers an intuitive layout for fast and creative working, ranging from the „easy mode“ setting to the customer-programmable user interface.
- **Material Parameter Wizard**
  A wizard simplifies the search for suitable laser parameters for different materials, and automatically produces a parameter scale from a comprehensive database of parameters.
- **Barcode and DataMatrix Code**
  Extensive editing module for barcodes and DataMatrix codes.
- **Dual laser control**
  The software is capable of managing and controlling two laser sources simultaneously.
- **Split Layout**
  For intelligent segmentation, large-area engravings are „intelligently“ segmented on flat or round parts and seamlessly executed.
- **Multiple Execution**
  Intelligent stack processing. The laser system is capable of controlling tasks fully automatically, and processing multiple blanks automatically overnight or on weekends.



LAS - Camera system.

ACSYS *MEDICAL*
Sector-specific expertise in the medical industry.

OYSTER® Tabletop laser machine

BARRACUDA® Laser processing system

PEARL Laser table system

SHARK® cut Laser cutting center

PIRANHA® Laser processing system

ORCA® Laser machining center

Medical solutions based on standards

The portfolio of solutions from ACSYS provides the evidence: Through the application of new technological solutions, no boundaries are set in stone for ever. We have been enhancing our laser machining system with automation and robotics for some considerable time already. For this, we use the skills of our team of specialist development engineers and ultra-modern 3D design tools and many years of expertise. This enables us to can bring to bear a unique technological creative potential on task profiles, and to do so in a way that no-one has previously dared to venture.

- Robotics
- Automation
- Multiple laser and multi-head systems
- Conveyor belt and roller supply
- Palletizing and Pick & Place
- Rotary indexing table and cross table
- Film and rating plate handling

From the planning phase to the testing of products under production conditions, we work closely with our customers to devise tailor-made special solutions and software applications. Over the last few years, we have developed and built hundreds of customized solutions that perfectly meet prevailing requirements.

On the following pages, we present you a selection of solutions specifically developed and built for the most demanding of requirements in the medical sector.

Technical Data

Laser digitalization, laser marking, laser engraving, laser cutting, laser welding

Max. workpiece weight
Variable

Max. workpiece size (WHD)
Variable

Materials
Metals, plastics, composites, organic substances

MEDICAL

PIRANHA®µ PICO
The definition of precision.

Technical Data

Laser digitalization, laser marking, laser engraving

Max. workpiece weight
20 kg

Max. workpiece size (WHD)
410 x 400 x 410 mm

Materials
Metals, plastics, composites

PIRANHA®

1.

2.

3.

1. Dual camera system for the high-precision laser system

2. Vibration-free cross table made of granite.

3. Dividing head for rotational machining on all sides.

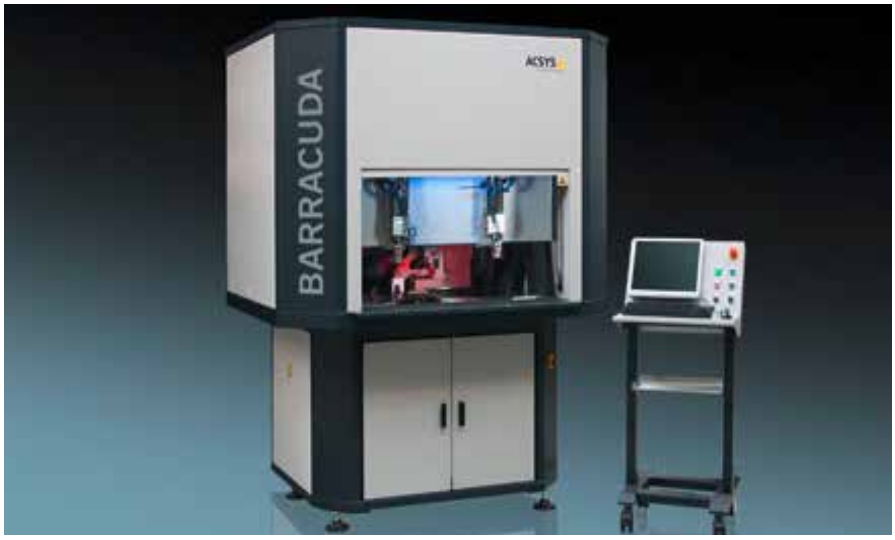
PIRANHA®µ PICO – Laser processing system

The new PIRANHA®µ PICO is the flagship of the PIRANHA family. It is equipped with a pico-second laser of the latest generation. Optionally, the modular design of this system also permits a configuration with a femtosecond laser or a current fiber laser system.

The PIRANHA®µ PICO can also be equipped with a second laser source, to operate as a dual laser system. With an area of less than 2.5 sqm, the PIRANHA®µ PICO is extremely compact and flexible.

The ultra-strong, temperature-stable and vibration-free granite structure of the PIRANHA®µ PICO ensures that the laser system has the required level of precision and satisfies the highest requirements for repeatability in micro-processing.

BARRACUDA®
Seeing, recognizing and machining precisely.



Technical Data

Laser marking, laser engraving

Max. workpiece weight
300 kg

Max. workpiece size (WHD)
950 x 450 x 520 mm

Materials
Metal, plastic, composites

BARRACUDA®

QR-Code for Film

BARRACUDA – Automation, OPR and robotics gripper

This BARRACUDA masters full automation for palletized tasks. The left gripper places the components from the left pallet in the integrated dividing head of the rotary indexing table. The rotary table moves the component automatically in front of the laser lens and the adjacent camera lens. The high-resolution camera system detects rotation and position and the component, and the system rotates the component automatically into the correct position.

The laser then applies micro-engraving to the cutting edge. The rotary table automatically rotates the machined workpiece back into its starting position while at the same time a second table dividing head rotates an unmachined workpiece in front of the lenses of the camera and the laser. The right gripper removes the machined component from the integrated dividing head and places it automatically in the right pallet. The left robot gripper loads the dividing head in parallel fashion with a new and unmachined workpiece.

PIRANHA® Multishift 24/7 – Compact design for series production.

Technical Data

Laser digitalization, laser marking, laser engraving

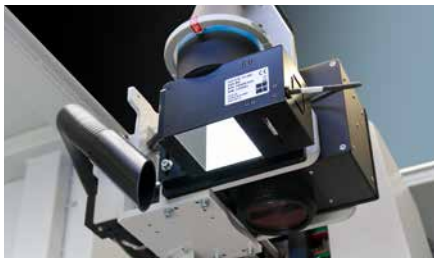
Max. workpiece weight
3 kg per pallet

Max. workpiece size (WHD)
530 x 450 x 440 mm

Materials
Metals, plastics, composites

PIRANHA®

QR-Code for Film



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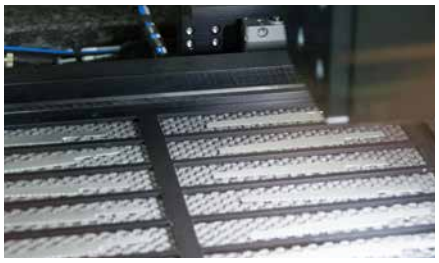

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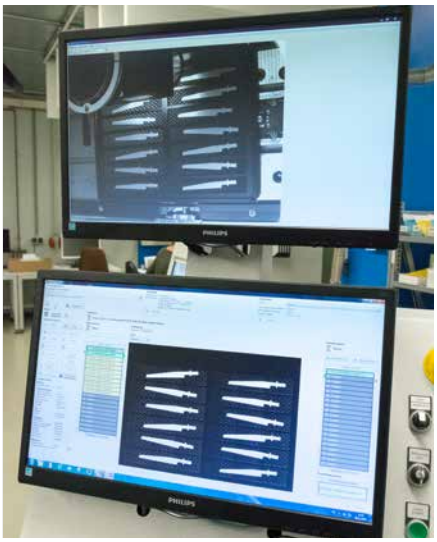


3.

1. Precision camera system for the LAS - Live Adjust System and the OPR - Optical Parts Recognition.

2. Automatic recognition of saw blades by the OPR of ACSYS.

3. PIRANHA® Multishift. High-precision pallet processing with optical part recognition.

PIRANHA® Multishift – Laser processing system

PIRANHA Multishift is a symbiosis of fully-automatic processing and high-precision laser machining. This platform is based on the PIRANHA whose platform was extended by a loading and unloading lift station.

Depending on configuration, the magazine can hold up to 20 panels that are loaded into the system automatically. The heights of the pallet inserts are variable, and can be adjusted to suit different component heights. The range of parts for individual panels is machined in specific grades. If the inserts are assigned differently, the PIRANHA Multishift still carries out the orders reliably, and optionally even during operation in a chaotic sequence, using DMC encoding.

Another option is to equip the laser system with OPR (Optical Part Recognition) from ACSYS. The workpieces are then inserted loose into the panels, the system detects the position and rotational angle of the workpieces, and then processes these parameters automatically at the previously taught-in position.

The high-strength, temperature-stable and vibration-free granite table on the PIRANHA Multishift ensures that the laser system has the required level of precision and satisfies the highest requirements for repeatability in micro-processing.

BARRACUDA®
Automated flexibility.

Technical Data

Laser marking, laser engraving

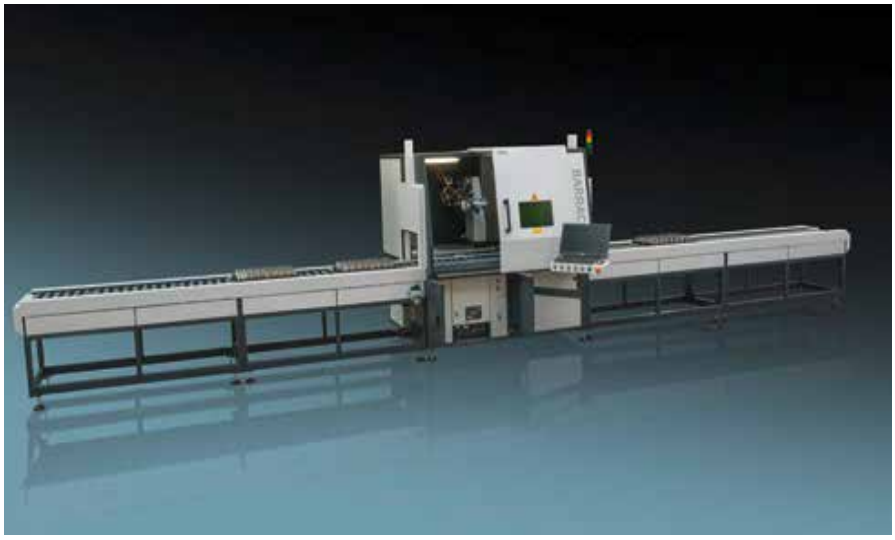
Max. workpiece weight
300 kg

Max. workpiece size (WHD)
950 x 450 x 520 mm

Materials
Metals, plastics, composites

BARRACUDA®

QR-Code for Film



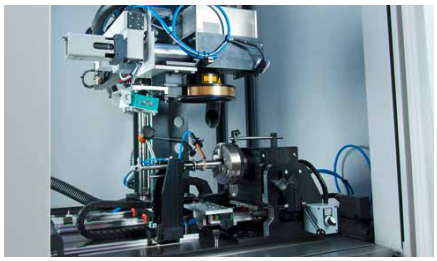
BARRACUDA® automation with robotics

This BARRACUDA can be integrated superbly into a fully automated value-adding chain. The workpieces are palletized and are placed on the left roller track. The laser system transports the pallets into the system where the workpieces are then processed in a fully automatic operation.

Inside the laser machine, the robot arm removes the workpieces from the pallet one at a time. In doingso, the robot arm detects the diameter of each component automatically and adjusts its settings automatically to suit it. The robot arm moves the component precisely into the focus of the laser galvanizing head and rotates it during the marking or engraving process in accordance with its programming. After the laser machining, the robot arm places the workpiece back in the pallet and removes the next unlabelled component, which it then places under the laser machining head.

Once the pallet has been processed completely, it it ejected to the roller conveyor on the right-hand side. At the same time, the laser system guides the next pallet into the system from the left-hand side for processing. The machining process inside the laser unit starts over again.

PIRANHA®
High-precision laser welding of stainless steel.



Technical Data

Laser digitalization, laser marking, laser engraving

Max. workpiece weight
3 kg per pallet

Max. workpiece size (WHD)
530 x 450 x 440 mm

Materials
Metals, plastics, composites

PIRANHA®

QR-Code to Film

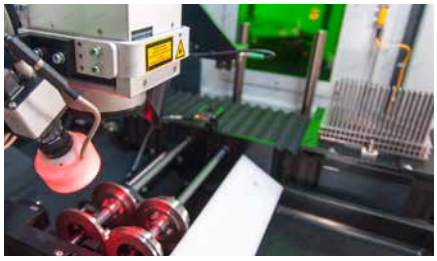
PIRANHA® laser welding

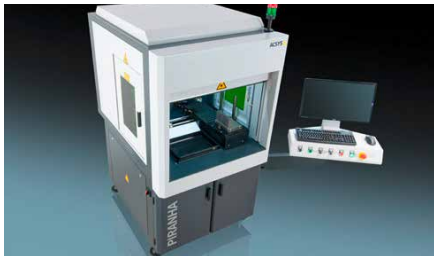
The PIRANHA with dividing head has been optimised for fast and precise laser welding of stainless steels. The generously proportioned working area of the PIRANHA and the precision dividing head offer the user great flexibility in terms of the size and scope of the various components to be welded.

LAS – the Live Adjust System - first displays a high-resolution camera image of the component to be welded and enables the weld seam to be aligned precisely. The compact laser system, based on the PIRANHA III, is equipped with a very precise CNC-controlled dividing head that can be swiveled through 90 degrees. This enables rotational machining to be performed on all sides of various different workpieces. An integrated collision detector prevents damage to the laser system caused by accidental operator error.

The integrated clamping system features flexible adjustment and functions pneumatically. The workpieces to be welded are held safely in position by pneumatic clamping action. Some of these components are fragile, and to avoid damaging them, the clamping pressure can be adjusted individually. The protective gas supply is also freely selectable. The protective gas nozzles can be adjusted quickly and precisely to suit the component being welded, and do not require any resource-intensive conversion work.

PIRANHA®
Robot gripper and automation.





Technical Data

Laser marking, laser engraving

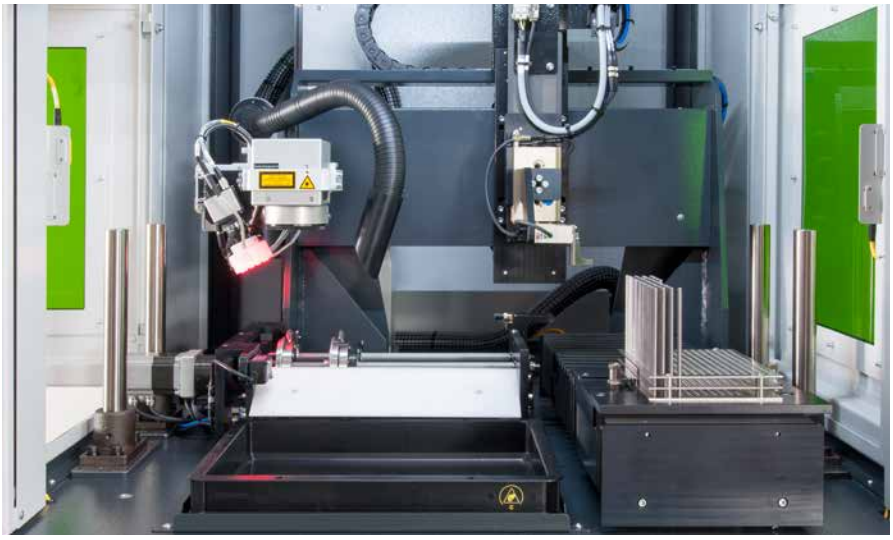
Max. workpiece weight
100 kg

Max. workpiece size (WHD)
730 x 450 x 440 mm

Materials
Metals, plastics, composites

PIRANHA®

QR-Code for Film



PIRANHA® – with robot gripper and automation

This PIRANHA is a customer-specific solution for the medical industry, and is equipped with a robot gripper and optical position detection. It processes the palletized workpieces automatically.

The workpieces are placed on a Rollomatic pallet inside the machine on the right. The robot gripper removes one workpiece from the pallet and moves it in front of the position detection module. Depending on the alignment of the workpiece, it is placed under the laser galvanizing head and machined automatically. In the laser machining process, the workpieces are machined on one or more sides.

The roller support is configured as a dividing head. The layout of the ACSYS AC-LASER software contains details of the location and angle by which the workpiece should be rotated. After machining with the laser, the workpiece is unloaded with the help of a „driver". The robot gripper then places the next workpiece on the roller support, and the machining process recommences from the beginning.

Our laser systems are reliable performance platforms that form the basis for a dependable and long-lasting business relationship.

Quality Management

The ACSYS quality management system is subject to continuous supervision by the German Technical Control Board (TÜV) to assure compliance with the globally recognized certification standards ISO 9001 and ISO 14001, and guarantees consistent quality of our production sequences and of the technical components of our suppliers.

In numerous tests, the laser system is subjected to a grueling set of trials and is then calibrated to perfection by our project engineers, with the help of state-of-the-art test equipment.

The acceptance test conducted by our customers usually takes place at ACSYS in the Mittweida production facility. Here, customers are introduced to the functions and technical features of the system, which are explained to them in detail. Possible adjustments and extensions can therefore be discussed and implemented directly in the production premises. Goods are packaged and dispatched once the system has been acceptance-tested by the customer.

Management System

ISO 9001:2008

ISO 14001:2004

www.tuv.com
ID 9105031461

Technical Data ACSYS Laser Machines

	OYSTER (with X axis)	PEARL	PIRANHA I	PIRANHA II	PIRANHA III	PIRANHA II Multi	PIRANHA III Multi
Housing	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser
Dimensions W/D/H (mm)	850 x 700 x 950	1500 x 1600 x 1000	690 x 1600 x 990	870 x 1860 x 1450	1080 x 1860 x 1450	870 x 1860 x 1450	1080 x 1860 x 1450
Approx. weight (kg)	140	430	550	650	930	800	980
Max. workpiece weight (kg)	30	5	100	100	100	100	100
Inner surface (mm)	500 x 350	290 x 220 175 x 100 (cross table)	520 x 375	750 x 600	950 x 550	750 x 550	950 x 550
Working range							
Traverses x/y/z (mm)	250 x 0 x 225	0 x 0 x 140 25 x 25 x 140 (cross table)	0 x 0 x 390	0 x 0 x 390	0 x 0 x 390	360 x 275 x 390	560 x 275 x 390
Axis positioning x/y (µm)	50	50	-	-	-	25	25
Usable range x/y/z (mm) with 25 x 25 mm (f=56) optics Machining area	-	25 x 25 x 250 50 x 50 x 250 (KT)	-	-	-	-	-
Usable range x/y/z (mm) with 70 x 70 mm (f=100) optics Machining area	320 x 70 x 210	70 x 70 x 220 95 x 95 x 220 (KT)	70 x 70 x 390	70 x 70 x 390	70 x 70 x 390	430 x 345 x 450	630 x 345 x 450
Usable range x/y/z (mm) with 110 x 110 mm (f=160) optics Machining area	360 x 110 x 220	110 x 110 x 145 135 x 100 x 145 (cross table)	110 x 110 x 315	110 x 110 x 315	110 x 110 x 315	470 x 385 x 375	670 x 385 x 375
Usable range x/y/z (mm) at optics with 170 x 170 mm (f=254) machining area	420 x 170 x 50		170 x 170 x 160	170 x 170 x 160	170 x 170 x 160	530 x 445 x 220	730 x 445 x 220

PIRANHA II Rotary table	PIRANHA III Rotary table	PIRANHA Multishift	PIRANHA II µ	PIRANHA III µ	PIRANHA µ PICO	BARRACUDA Multi	ORCA	ORCA µ
Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser
870 x 1860 x 1990	1080 x 1860 x 1990	2540 x 2120 x 2020	870 x 1970 x 1430	1070 x 1970 x 1630	1060 x 1980 x 2350	1320 x 1890 x 1880	3100 x 2300 x 2750	2800 x 2300 x 2050
930	1200	3500	1300	1600	2700	1600	6000	6500
20 (pro Tischseite)	20 (pro Tischseite)	3 (pro Palette)	40	40	20	300	1500	750
360 x 120	560 x 150	750 x 500	750 x 400	950 x 600	300 x 300	1100 x 600	1800 x 1000	1200 x 1000
360 x 275 x 390	560 x 275 x 390	360 x 275 x 390	400 x 400 x 275	600 x 600 x 275	300 x 300 x 400	780 x 350 x 390	1600 x 800 x 800	600 x 600 x 600
25	25	25	10	10	10	25	25	10
-	-	-	425 x 425 x 270	625 x 625 x 270	325 x 325 x 400	850 x 420 x 450	1625 x 825 x 930	625 x 625 x 630
430 x 345 x 450	630 x 345 x 450	430 x 345 x 450	470 x 470 x 220	670 x 670 x 220	370 x 370 x 350	890 x 460 x 375	1670 x 870 x 880	670 x 670 x 580
470 x 385 x 375	670 x 385 x 375	470 x 385 x 375	510 x 510 x 140	710 x 710 x 140	410 x 410 x 270	950 x 520 x 220	1710 x 910 x 800	710 x 710 x 500
530 x 445 x 220	730 x 445 x 220	530 x 445 x 220	-	-	-	-	1770 x 970 x 640	770 x 770 x 340

▲ All details reflect the current definition at the time of printing of this magazine (as of March 2017). Binding details can be obtained at any time by contacting us!

Technical Data Machine

	PIRANHA II cut	PIRANHA III cut	PIRANHA II cut µ	PIRANHA III cut µ	SHARK cut	SHARK II cut
Housing	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser	Class 1 laser
Dimensions W/D/H (mm)	900 x 1900 x 1500	1070 x 1900 x 1500	870 x 1970 x 1430	1070 x 1970 x 1780	2100 x 2300 x 3100	2450 x 2400 x 3400
Approx. weight (kg)	900	930	1400	1420	5500	7000
Max. workpiece weight (kg)	30	30	30	30	50	50
Inner surface (mm)	750 x 400	950 x 600	750 x 400	950 x 600	1000 x 1000	1250 x 1250
Working range						
Traverses x/y/z (mm)	400 x 400 x 120	600 x 600 x 120	400 x 400 x 250	600 x 600 x 250	1000 x 1000 x 80	1250 x 1250 x 80
Axis positioning x/y (µm)	25	25	10	10	25	25
Usable range x/y/z (mm) with f=50 cutting optics	400 x 400 x 100	600 x 600 x 100	400 x 400 x 100	600 x 600 x 100	1000 x 1000 x 70	1250 x 1250 x 70
Usable range x/y/z (mm) with f=80 cutting optics	400 x 400 x 70	600 x 600 x 70	400 x 400 x 70	600 x 600 x 70	1000 x 1000 x 50	1250 x 1250 x 50
Usable range x/y/z (mm) with f=125 cutting optics	400 x 400 x 30	600 x 600 x 30	400 x 400 x 30	600 x 600 x 30	-	-

EAGLE EYE	EAGLE EYE specifications
Vertical axis Z	
Precision (µm)	0.5 - 100
Reproducibility 1 σ **(µm)**	0.1 - 35
Working area (mm):	0.2 - 180
Working distance (mm)	9.5 - 245
Max. measuring range (°)	150 - 170
Transverse axis X	
Transverse resolution **(µm)**	2 - 90
Laser dot size **(µm)**	3.5 - 100
Data processing	
Data rate **(pps)**	up to 3000

LASER	
ACSYS offers various laser sources for a wide range of different materials. Whether nanosecond or picosecond lasers – power ratings from 0.5 to 1000 watts ensure that we will have the optimum configuration for all your applications.	*Ideal* Laser source powered by ACSYS • Fiber lasers • Picosecond lasers • Femtosecond lasers • UV lasers • CO_2 lasers • Solid-state lasers

Technical Data Software

	AC-LASER
Language versions	German, English, French, Italian
Safety/Security	The software is protected by a product-specific dongle.
Interfaces	Profibus, RS232, TCP/IP, Digital IO (PLC), additional project-specific interfaces possible
File import	STL, DXF, DWG, PLT, JPEG, BMP, HP-GL, HP-GL/2, SVG
Text processing	Line spacing, changes in tracking and record type to professional standards are possible with any font installed in Windows.
3D functionality	Extensive 3D editing module for a wide range of formats.
Database connection	For automation, AC-LASER offers the option of customized connection to databases and external data sources, such as Excel or text files.
Barcode and DataMatrix code	Extensive editing module for barcodes and DataMatrix codes. QR code, Aztec, and GS-1 Datamatrix are optional.
Batch processing	Multiple Execution. The laser system is capable of controlling tasks fully automatically, and processing multiple blanks automatically overnight or on weekends.
LAS – Live Adjust System	Camera-based processing of graphics and text directly on the workpiece.
OPR – Optical Parts Recognition	Full automatic detection and machining of palletized and unpalletized parts.
DFC – Dynamic Focus Control	Dynamic Focus Control allows modification of the focal point during the laser machining process. The basis is the projection of the "real" 3D model on the workpiece.
ODC – Online Depth Control	µ-precise material removal for deep and 3D engraving ensures high-precision results. Free-form surfaces can also be sampled and digitalized with the ODC module, making them easy to process.
OCR/OCV – Optical Parts Recognition	Text recognition and automatic verification of laser-printed texts on a wide range of components.
Automatic DMC verification	Process-integrated reading back of DataMatrix code with verification of contents and, if necessary, evaluation of the reading results (dependent on the reader that is used).
Remote control	The online connection "ACSYS – Direct Access Line" for service, support or training allows us to assist you directly on your system with complex tasks, to support you with training on new technical software features, or to offer you, in the event of a malfunction, the fastest possible remote maintenance service.
Custom programming	Customized layout and process programming as well as database connectivity.
Intuitive user interface	Different user interface standards are available. AC-LASER offers an intuitive layout for fast and creative working, ranging from the "easy mode" setting to the customer-programmable user interface.
Material Parameter Wizard	Easy searching for suitable laser parameters for a wide range of materials. Automatic creation of a parameter scale from an extensive parameter database.
Automatic splitting "Split Layout"	Intelligent segmentation. Large-area engravings are "intelligently" segmented on flat or round parts and seamlessly executed.
Dual laser control	The software is capable of managing and controlling two laser sources simultaneously.

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