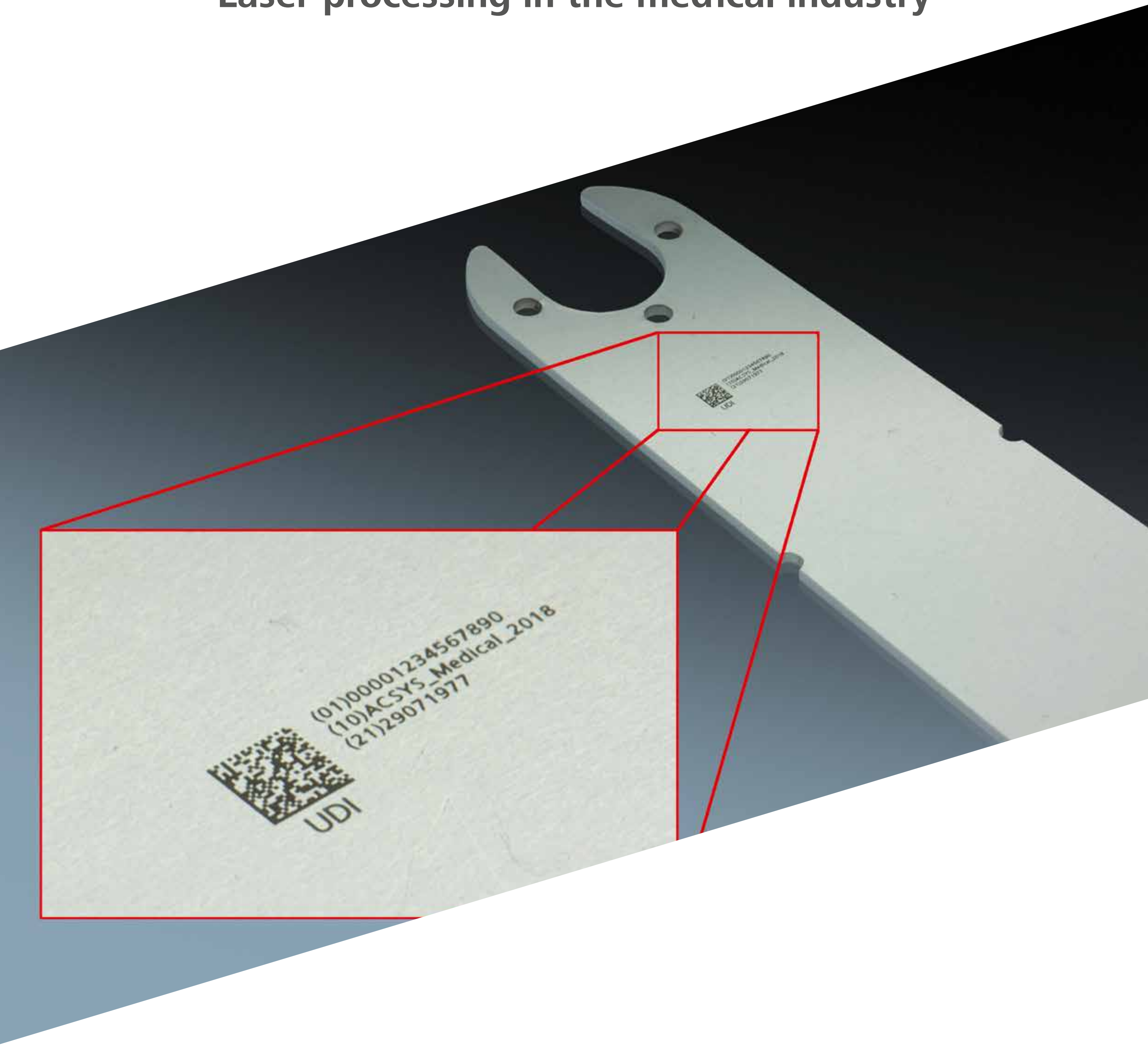
Laser processing in the medical industry



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

UDI – We make your medical devices unique.

(01)00001234567890
(10)ACSYS_Medical_2018
(21)29071977

UDI

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

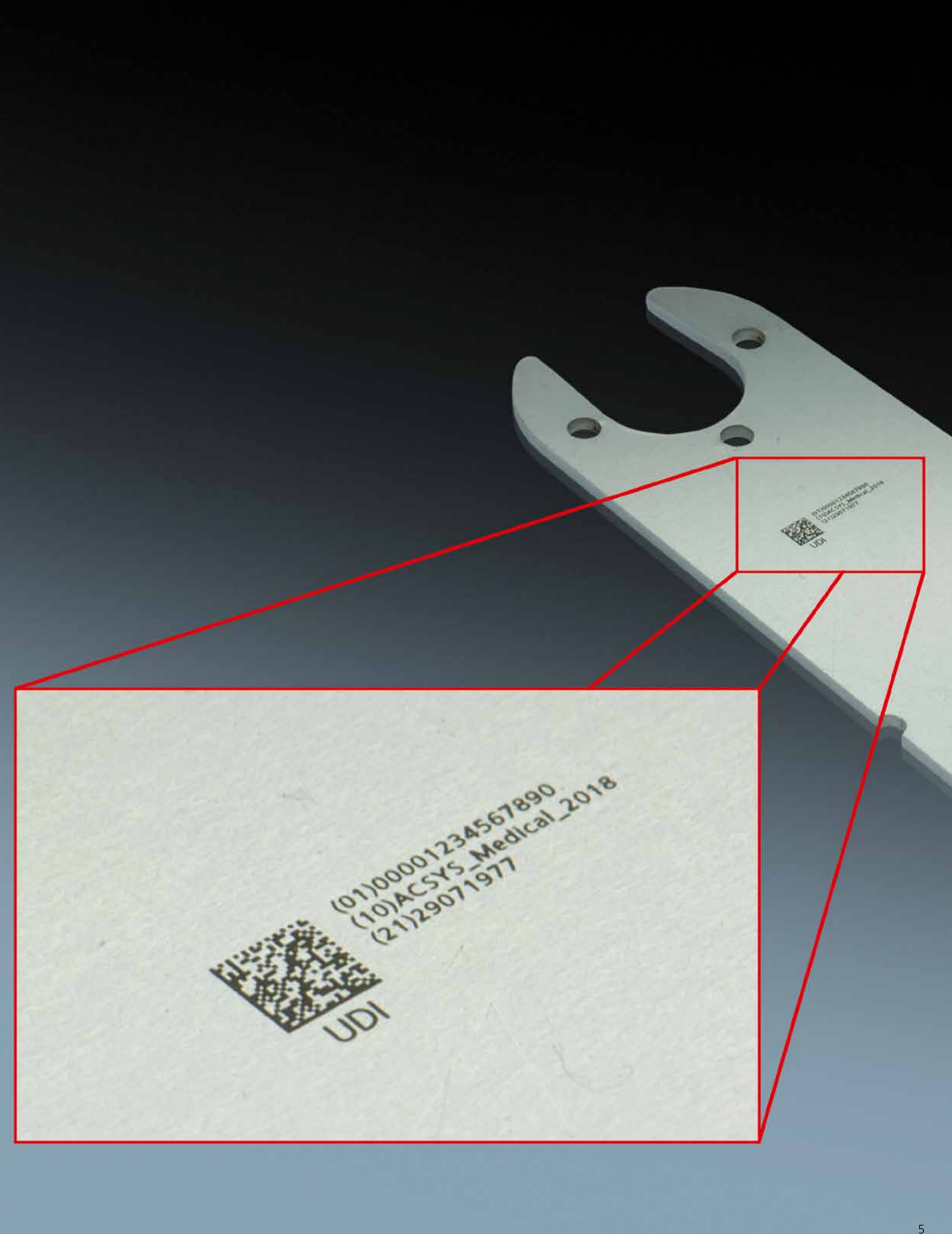
Whether you are involved in annealed marking, ablative laser marking or carbonizing and foaming of plastics and technical ceramics, the advantages of laser machining over conventional marking techniques such as needle embossing or printing are significant.

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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Collaboration based on partnership makes us unique.

Laser processing 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.

Eclipse.

Black marking

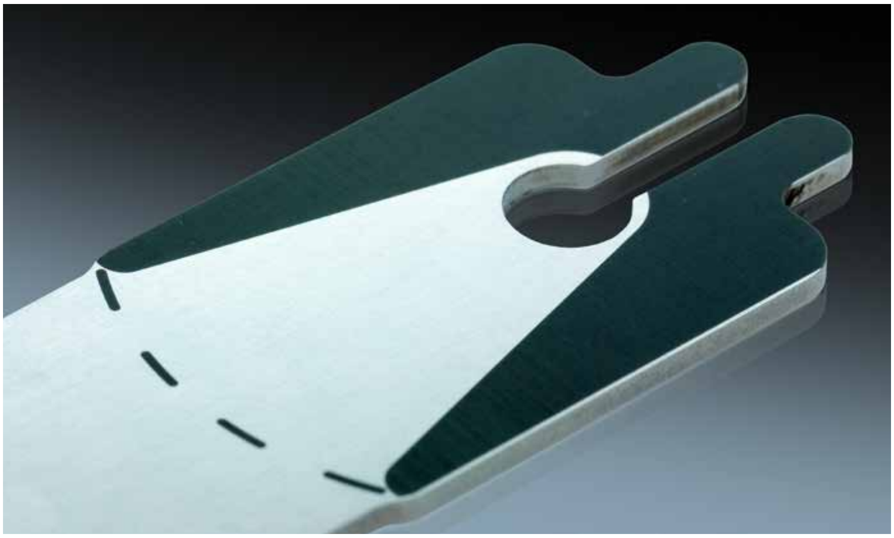
The corrosion-resistant and non-angle-dependent black marking is a newly developed process, which only works with the use of a picosecond laser.

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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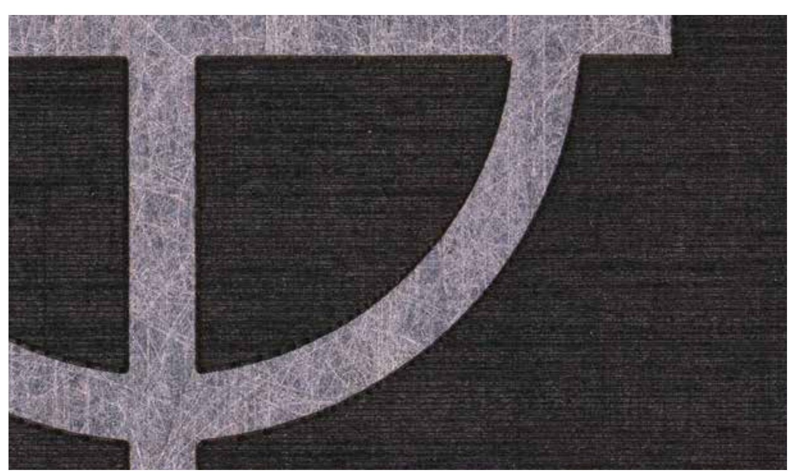
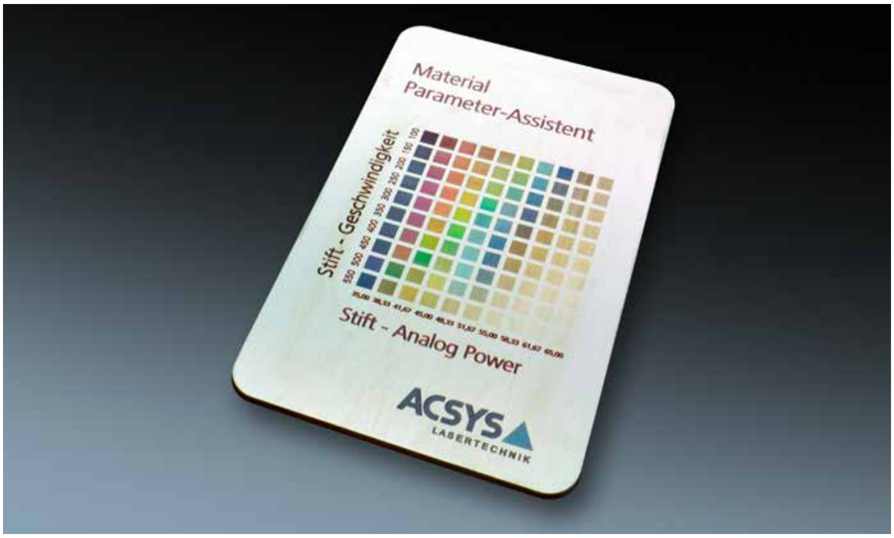


1. Black marking of a picosecond laser on a sawblade.
2. Black marking on a prosthetic hip shank.
3. Black marking of a picosecond laser on a sawblade.

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



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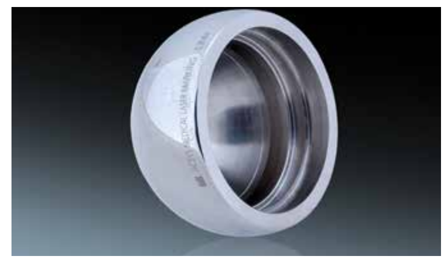

3.

		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.

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

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.

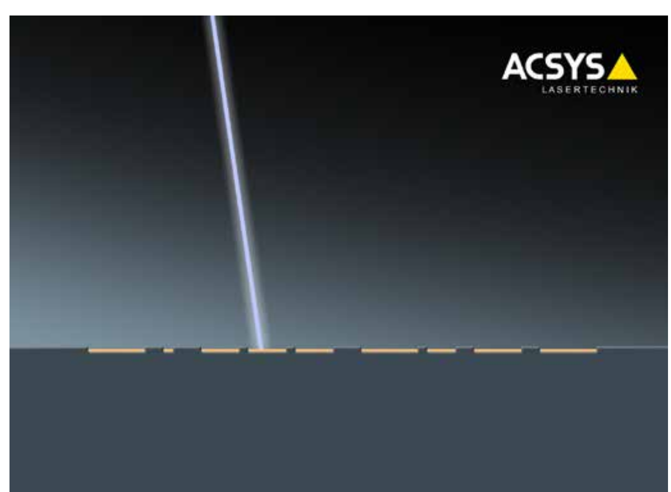

Illustration of laser engraving marking.


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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).

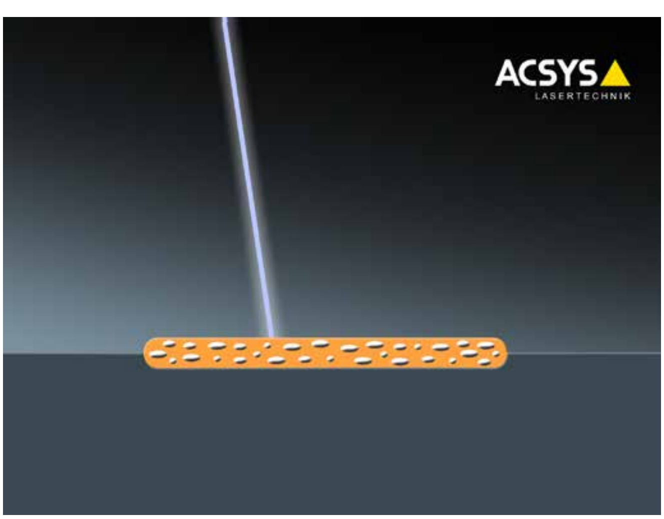


Illustration of the laser foaming process.

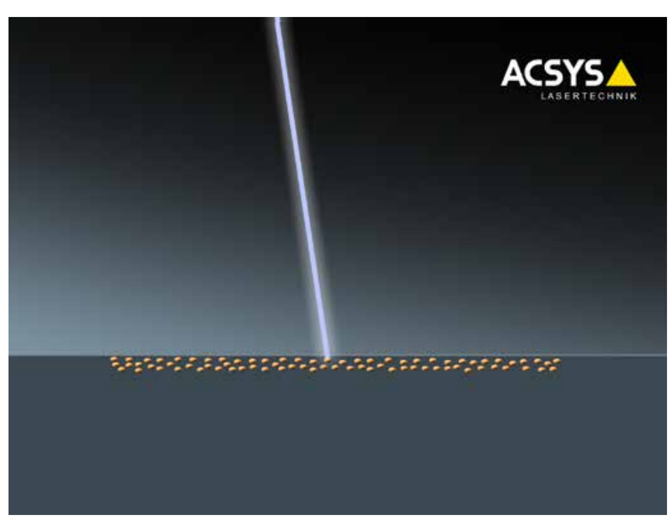


Illustration of laser carbonizing.

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.

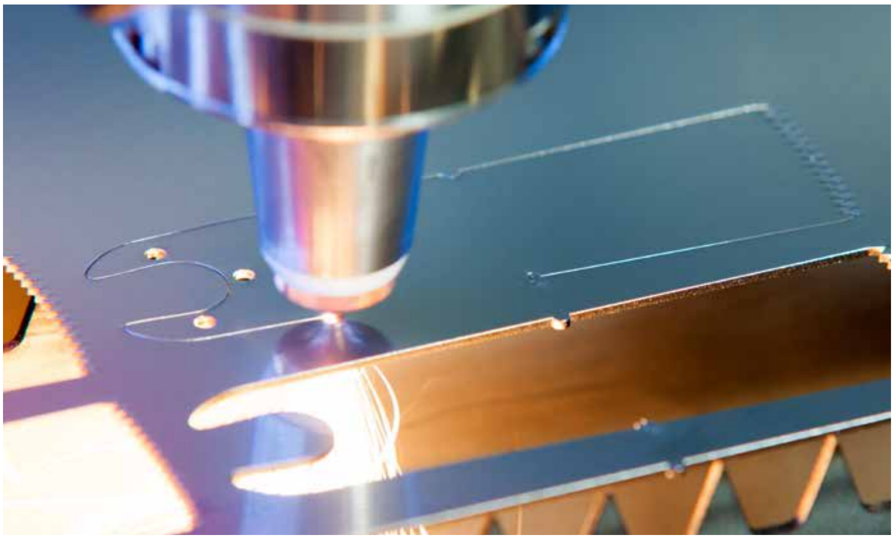
Advantages:

- 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.


1.

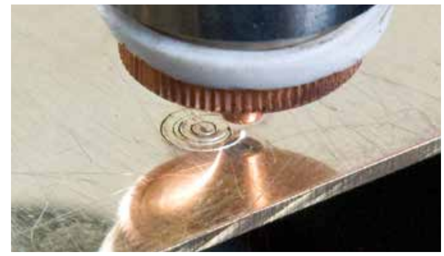
1. Laser fusion cutting of 1 mm stainless steel. 2. High-precision laser fusion cutting of 1 mm brass plate.

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.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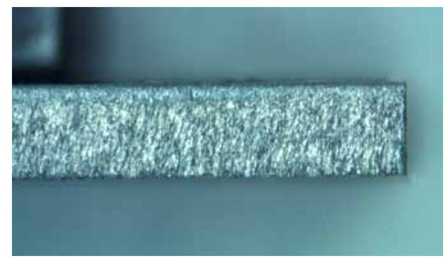
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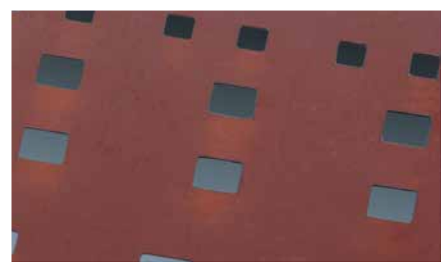
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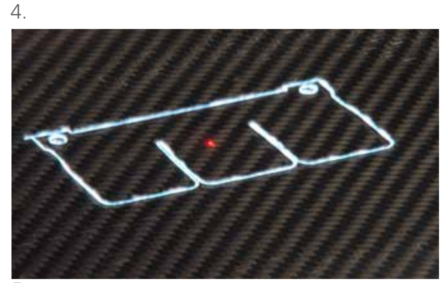
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6.

Always one „cut“ above the rest.

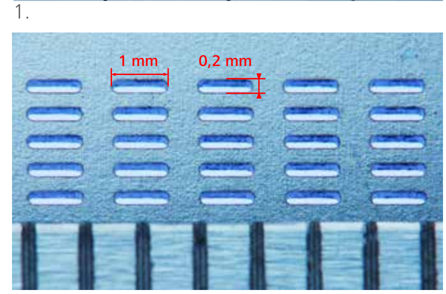
Laser fine-cutting

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.

1.

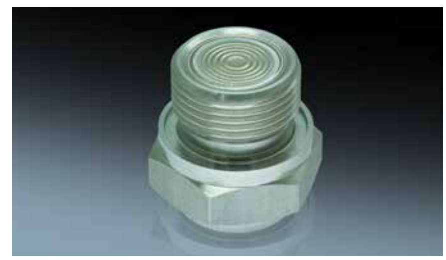


2.

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.

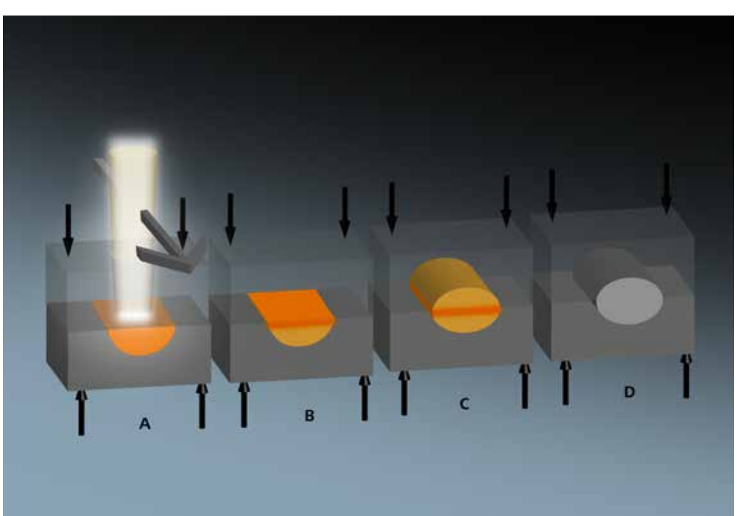

2.


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.

ACSYS LASERTECHNIK

ACSYS Lasertechnik GmbH
Leibnizstrasse 9
70806 Kornwestheim · GERMANY

Phone: +49 7154 807 75 0
Fax: +49 7154 808 75 19
E-Mail: info@acsys.de

www.acsys.de/en

ACSYS Lasertechnik US Inc.
8224 Nieman Road
Building 5, Lenexa, KS 66214 · USA

Phone: +1 847 246 2394
Fax: +1 847 844 0519
E-Mail: info@acsyslaser.com

www.acsyslaser.com

ACSYS Lasertechnik UK Ltd.
Unit 6, Silver Birches Business Park, Aston Road
Bromsgrove, Worcestershire B60 3EU · UNITED KINGDOM

Phone: +44 152 787 0820
E-Mail: info@acsyslaser.co.uk

www.acsyslaser.co.uk