

Image courtesy: Trumpf

LASER MARKING

Laser Marking in Medical: The Dark Arts of Dark Marks

*An endoscopic device
that has been marked with a
Trumpf fiber-laser marking system.*

Laser marking is growing in popularity, driven by FDA regulations, the low cost of the mature technology and innovations from builders aiming to make their products stand out

Michael C. Anderson

Senior Editor

There's been strong motivation for medical device manufacturers to embrace laser marking in recent years. First, of course, there is the FDA, which has been phasing in regulations for medical devices to have a unique device identifier—a UDI—that is permanent and can be read by machine as well as the human eye. But mature marking technologies are also growing more affordable, even as laser machine builders find creative ways to further develop the process and make their brands stand out. What's more, we're now in a manufacturing era where everyone wants traceability for more parts than ever—just about everything, really—which makes laser marking technology a good investment for most anybody in manufacturing. "Not only medical but all industries are seeing the value of traceability. The current trend is toward direct part marking whether the part is plastic or metal or ceramic," said Mark L. Boyle, laser product engineer at Amada Miyachi America (Monrovia, CA).

LASER MARKING



Image courtesy Epilog Laser

The FiberMark Fusion laser marking system from Epilog Laser.

Specifically in medical, though, the UDI requirement is pushing new innovations into the marking marketplace by demanding machine-readable marks, such as a 2D data matrix.

"The FDA has required some marking all along for traceability. But what is in the implementation stage now is an increase on the number of parts," explained Thomas Burdel, national sales manager for laser marking at Trumpf Inc. (Farmington, CT). "So where in the past maybe an entire assembly needed to be identified, now all of its parts need to be identified as well."

Robert Henry, product manager of fiber lasers at Epilog Laser (Golden CO), said the new regulations are driving more interest in marking technologies, even beyond requirements.

"It's becoming more and more popular for medical device manufacturers to mark components—whether it's strictly required yet or not," he said.

"Some of it has to do with branding—they want

their logo on the device. They want a doctor to see 'Stryker' or whichever."

"The main reason people like the fiber laser—and I've heard this time and again—is we ship them out to the customer, they plug them in, push the button, and it works."

Dave Noonan, product manager at Schmidt Marking Systems (Niles, IL), concurred. "We're seeing a lot more interest based on regulations," he said. "Part of the FDA regulation is that there must be identifying marking that is readable by people, usually as a serial number, but also marking that's machine-readable like a 2D data matrix. That is pushing a lot of medical components into the marking arena where there may have been resistance before."

Affordability Improves

Current laser marking technology, in particular fiber lasers used for marking metals, are much less expensive than the CO₂ and YAG lasers that preceded them in the market.

"Over the past 10 years or so we've seen price reductions—through efficiencies and through the price point of the laser sources—probably in the range of 30–40%," said

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Noonan of Schmidt. "And fiber lasers have really pushed the price point down. It's become more affordable for your smaller manufacturers to get in and enjoy the benefits of having that traceability. It makes these companies more competitive because now they can offer this capability the way their larger rivals can."

Henry of Epilog believes that the lower price point is a contributing factor to the increased interest. "Prices are not terribly high these days, the ease of use is better, all of these things contribute to systems like ours becoming more desirable," he said. "Add to that the traceability expectations and I think more and more companies are moving toward laser marking because it has become inexpensive and fairly easy to do."

Just how low has the price gone? Boyle of Amada Miyachi America said that "now you can get an entry-level fiber-laser marker for \$20, 25K, maybe \$30K with an enclosure."

"Laser marking itself is at this point a commodity," Boyle said. "People know what it is, they know what it does—it's just a matter of getting set up and going."

That said, there is still plenty of innovation that's being introduced in this area.

The Dark Arts of Metal Marking

Because medical products pose a danger of spreading contaminants, which can hide in even tiny indentations in a device, they need to be marked in a way that retains the surface integrity of the metal. The preferred method of marking metal in the medical industry—and what the fiber laser is well suited for—is often called "annealing." Purists say that this term is a misnomer, however, as it implies—at least for them—softening of metal. Tony Hoult, applications manager for

IPG Photonics Corp. (Santa Clara, CA) prefers the term "dark marking."

"With dark marking you are growing an oxide layer and making it thick enough that it appears dark to the eye—but



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without melting the metal," Hoult said. "You don't want a rough surface that will hold contaminants. A really good mark can barely be felt, while a poorly done one will feel rough from a bit of melting, particularly at the stop/start positions."

Burdel at Trumpf compares this kind of mark to the dark corrosion that can be found on well-used exhaust pipes. "That dark color is oxidation brought up to the surface of the exhaust by heat," he said. "The difference with laser marking is that the beam is narrow enough and fast enough that you can get a clean mark with no melting."

"The challenge is that it's a slow process," IPG's Hoult explained. "If



Photo courtesy Amada Miyachi America

The Amada Miyachi Laser Marking Work Station or LMWS.

you hit it too hard or use too high a pulse energy, it becomes uneven. You want to enhance the oxide, chromium oxide layer, that's native to stainless. If you do overheat it too much you get chromium diffusion that depletes the subsurface area of chromium and you can get corrosion. Of course, the subcontract laser marking guys want to bang it through as quickly as possible through their shop—and that's caused problems in the past," Hoult remembered.

"Some materials are more difficult to dark-mark without corrosion than others," Hoult noted. "The basic stainlesses, the 304s, are fairly easy; 316 is marginally more difficult. The most challenging one is 17-4PH steel. It's a low-temperature precipitation

hardening [PH] steel. It's a high-strength steel but with a low-temperature heat treatment to bring up the full strength. To get a good dark mark on it that doesn't corrode takes a slow process to allow the oxide to grow."

This dark mark needs not only to be legible without deforming the surface of the metal but also able to stand up to the passivation, or sterilization, processes used with multi-use medical products.

"We'll test the mark with a bath of nitric acid that cleans off all of the germs and debris on the part."

"What we've seen in the past is a situation where a device is marked successfully and has resisted corrosion and all is well—and then some new variable is introduced," Hoult said. "In one case the passivation bath conditions changed, leading to a reduction in the corrosion resistance of the laser marks—and flaking occurred."

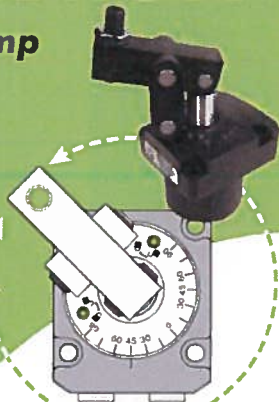
Boyle at Amada Miyachi America is familiar with this challenge as well. "Recently we've been developing passivation-resistant marks with our fiber laser markers. It's a newer, very sensitive technique," he said. "We'll test the mark with a bath of nitric acid that cleans off all of the germs and debris on the part, and see that the mark

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survives intact. It's a very aggressive test because the acid is basically eating away at the metal at some levels. We've proven that we can keep the mark on and now we're implementing the technique at a couple of customer sites. It's a recent development."

Fiber Laser Advantages

The industry-wide acceptance of the fiber laser goes beyond its having a lower price point. It has numerous advantages over earlier systems such as CO₂ and YAG (yttrium aluminum garnet) sourced lasers because a lot of complexities have been removed. YAG lasers, for example, used to be driven with a flash lamp in order to get the high-intensity light needed to get the energy propagated through the YAG crystal. Flash lamps were water-cooled, required a lot of service, and were very expensive, explained Epilog's Henry. Enter fiber.

"Fiber lasers were born out of fiber optics use in the communications industry. Some very smart scientists and

engineers discovered that they could dope these optical cables with different rare elements and get different wavelengths of light to propagate through and off of them. Instead of using flash lamp light, they use diode light," Henry said. "The fiber lasers are air-cooled—you don't need a watercooling device; they're very compact, so they're very easy to integrate into our systems; and they're incredibly robust. They just work."



Photo courtesy Schmidt Marking Systems

The Schmidt Alpha Laser Enclosure.

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IPG's Hoult added, "To say that fiber lasers have turned the industry upside down—that wouldn't be overstating it. IPG introduced the first nanosecond-pulsed low-power laser for marking. And I think now everybody who manufactures laser marking systems has a fiber laser version in their inventory.

"The main reason people like the fiber laser—and I've heard this time and again—is we ship them out to the customer, they plug them in, clamp up the optic, push the button, and it works," Hoult continued.

Fiber lasers are also simpler overall.

"With fiber laser, there's no free-space optics anywhere in the device—no flash lamp. Your energy source, a diode laser, is fiber-coupled. Instead of a bunch of optic components arranged and tweaked, you simply have to splice fibers

together. That means the whole thing is far more rugged and maintenance-free. The diodes last for many tens of thousands of hours. The diodes we use are called single-emitter diodes—they're pretty much telecom diodes on steroids, with a lifetime in the six-figure range," he said, noting that IPG makes "all our own diodes and all our own fibers."

Improving the System

While using diode-powered fiber lasers to anneal or 'dark-mark' medical metals is a mature technology in many ways, the providers of these systems are active in finding ways to make improvements for their customers.

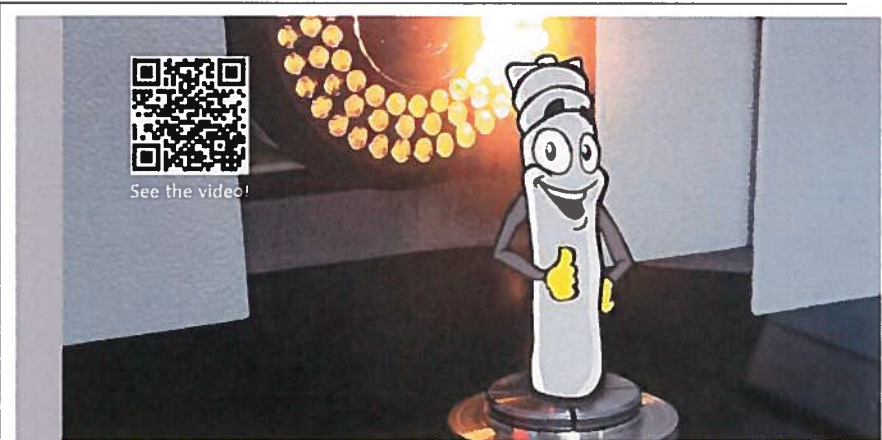
Schmidt Marking Systems, for example, offers the Alpha laser system enclosure—a cabinet with a 22" (559-mm) wide pneumatic stainless steel door, according to Schmidt's Dave Noonan. The enclosure has a powered Z-axis for automatic height variance and a removable side panel for access to the laser head and lens. It can be equipped with rotary devices, vision systems or part feeders and can be fully customized for larger part configurations.

"We do custom cabinets and custom automation as well," Noonan said. "One customer recently needed us to make an enclosure that was large enough to hold a hospital bed. The most requested bit of automation we're asked for is a door that opens automatically when the marking cycle is done so the operator doesn't have to wonder if the process is finished. It also alleviates repetitive motion concerns."

At Amada Miyachi America, they've moved from working in two dimensions to three. "The basic configuration has always been a 2D marking field. Now, as technology has improved, we're able to look at multiple levels, incorporating motion with that, marking

around curved surfaces," Boyle said. "Let's use a trocar as an example."

The trocar is a hollow rod that is used in surgeries, with laser-marked guidelines that show how far the surgeons are



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sticking this rod into the patient, Boyle explained. They then feed in a camera or a surgical instrument into the patient through the trocar.

"The trocar has those cylindrical marks plus a mark at the tip and identification marking maybe further down the shaft. So the software and fixturing needs to work in three or four axes," he said. "One of the unique things about our systems is that we have the possibility of incorporating motion within our power supply unit for the laser. So we have up to four axes of control. 'Marker Motion'—that's our trademarked name for it. With that power supply and with the software we supply, customers have full functionality—they don't have to have a preexisting external XYZ stages; it's all part of our system.

"Our latest development is a laser marking workstation—our LMWS. It's an individual, manual-door system that sits on the job floor, where operators would be manually loading and unloading parts, usually in small batches," he said. "The other approach we use to take our LMWS marker—the same marker as in the workstation—and hook it up to be part of a

production line. It has full networking capabilities and can be completely integrated into the customer's process."

Epilog Laser customers are benefitting from a larger work area. Robert Henry explained: "Historically, YAG lasers were used in combination with a galvo, a galvanometer. These are high-speed motors with mirrors attached, that were used to direct the laser beam from the laser via the mirrors to the work surface. These galvo systems are fast but they have a very small work area—typically 4 in.² [101 mm²]. With our systems we use a gantry, or 'flying optics' style laser beam delivery. The gantry has a lens assembly attached, with which we deliver the beam to a work area of either a 24 × 12" [610 × 305-mm] work area or our larger one, which is a 32 × 20" [813 × 508-mm] work area. Medical customers like it because they can load up as many parts in the machine as possible, then have the laser do the work while they step away and do other things in the shop.

"To say that fiber lasers have turned the industry upside down—that wouldn't be overstating it."

"We've also recently released what we call a Job Manager—it's essentially a software program our customers can use that communicates directly with the laser and allows for job storage, recall of a job, reprinting of a job, and updating information about a job. These aren't major laser-technology breakthroughs," Henry acknowledged, but they "create better functionality and management of the existing laser technology for our customers."

Trumpf sees, and is part of, a movement to make the laser systems themselves ever smaller, and therefore easier to move. "The trend is to make the systems smaller and smaller," said Burdel. "These are air-cooled systems, so the bulk, and complications, of chiller systems are gone. The latest laser system we've introduced—the TruMark 5010—has a modular design that is only as big as a shoebox, and that's including everything—the scanner, the power supply—everything is in that shoebox." The scanner, laser head and power supply unit are connected with plug-in connectors so the laser can be easily integrated into existing production systems, he noted, and "you can take that unit and plug it into a 110-V outlet, add a computer with our software, and you can make marks anywhere you want. You can put it on a robot, put it on automation equipment—it's that compact. This is a one-box system." ➤

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