Medical Industry White Paper
Medical Device Marking: Challenges and Solutions

Marking medical devices can be challenging for medical device manufacturers. Identification tasks become increasingly demanding and the industry's regulations are getting stricter, such as currently shown by the FDA’s (Food and Drug Association) UDI (Unique Device Identification) directive. However, manufacturers of marking systems and identification solutions take up the various challenges and multifaceted requirements and develop reliable solutions for medical device marking. Solutions that not only ensure the proper marking of all medical products but are also capable of improving medical device producers' process reliability and efficiency.
Medical products have to be marked for...

Manufacturers of medical products have to follow rigorous standards in their production lines. It starts with choosing the right material and ends with marking the product properly. Taking into account only this last step, there is a lot to comply with.

Many medical devices have to be marked...
- Devices used in the operating room/invasive surgical tools
- General surgical devices, instruments and tools
- Cannulas, catheters, tubes, wires, etc.
- Implants/implantable devices

... with contents, information and codes like these...
- Alphanumeric contents such as simple serial numbers or date and lot codes
- Complex codes such as 1D and 2D Datamatrix codes and bar codes (i.e. GS1, EAN 128, etc.)
- Company or trademark logos
- International fonts

Medical products have to be marked with information that is...
- Permanent and traceable
- Legible and readable
- High in contrast
- Counterfeit-proof
- Sterilization-resistant
- Hygienic and smooth

Medical products have to be marked for...
- Product identification (manufacturer ID, production ID, device ID)
- Traceability (improve patient safety, simplify product recalls)
- Regulatory and industry compliance (i.e. Unique Device Identification Marking, UDI)
- Product liability
- Product safety (trademark protection, protection against product piracy)
- Quality assurance.

When it comes to materials, the preconditions for marking metal (high-alloy stainless steel, titanium, silver, cobalt-chrome), plastic (polyamides and silicones) and ceramic components, used in a medical context include the need for...
- Resistance to high alkaline cleaning methods
- Acids
- Water
- Corrosion

Furthermore it is indispensable to ensure that the marking does not affect the invasive products: product surfaces have to stay smooth in order to hinder bacterial growth.

For various reasons laser marking has become the first choice for marking medical devices. Marking lasers handle nearly every marking task on nearly every material. The contact-free marking process does not affect the product surface, and guarantees high-quality and high-precision marks that are permanent and clearly legible.

Laser marking offers...
- Process reliability, efficient and lean production: high-precision and repeatable marking, reproducible results, flexible products for short process/cooling times
- Zero defect marking: high-quality processing, reduction of scrap, rework and mismarked devices; assurance that only the correct information is marked on the correct position on the correct part.

Medical device marking:
A critical part in the production process

Usually, medical devices are marked at the end of the production process; sometimes marking is the final step in the process chain. At this late stage of manufacture, product scrap caused by mis-marking, incomplete markings or incorrect markings is extremely costly. If mark errors can be corrected, they are very costly to correct; if they can’t be corrected, the device itself is scrap.

Most often, medical devices come in many shapes and sizes. Some parts require very small marking contents, others very large marks. Also, the information contained can vary from part to part, batch to batch or lot to lot. Medical device manufacturers are trying to achieve zero defect marking in order to eliminate mark defects due to fixturing problems, operator errors, and other random defects. That is why it is essential to control the marking process at the work cell level to prevent bad marks from being placed on the part, correct marks from being placed on the wrong part, or making marks that do not survive the manufacturing process (cleaning, sterilization, post mark passivation, for instance).

Advanced laser marking technology, like FOBA’s HELP (Holistic Enhanced Laser Process), is ready to solve these marking challenges and even to contribute to improved product quality and increased production efficiency.

FOBA White Paper
Medical device marking: challenges and solutions

Recalls will be simpler and more effective.

Medical device manufacturers mark for their customers. That means that they also have to guarantee that the marks on their parts are permanent in order to be completely readable and traceable all along their life-cycle: from the manufacturing site where the device was produced to the operating room where the device is used or implanted on a patient. Medical manufacturers have to ensure that the correct information is marked on the correct part in the right location and that this identifying information is legible at any time. All marks have to meet accuracy specifications, badly marked parts must never make their way to the patient.

UDI: Unique Device Identification

UDI has already been issued by the FDA and requires that most medical devices distributed in (and imported to) the US carry a unique device identifier (UDI) to identify devices through distribution and use. Also device labels and packages have to include a UDI. Repeatedly used equipment (i.e. surgical tools, instruments) has to be marked directly.

UDI uses a unique numeric code consisting of a device identifier (DI), specific to a device model and a production identifier (PI) (i.e. lot/batch number, serial number, expiry date, manufacturing date, etc.).

The goal is to have one standardized labeling and barcoding system for medical products, in order to better track their usage and facilitate product recalls. UDI will provide more information on how products are performing. Patient confidence and safety will improve. Manufacturers will have deeper insight into how their products are being used and access to information that can help them advance their technologies.

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A closed-loop process for the identification of medical products:
HELP – a Holistic Enhanced Laser Process

Medical device manufacturers are typically high mix, low to medium volume. They often face the challenge of processing small, single use devices in high demand with ever-increasing reliability requirements. Not only for these reasons they value systems that are flexible and make changeover from part to part and batch to batch a convenient and easy process.

Many suppliers offer different solutions, however, only a few provide real turnkey and closed-loop solutions. FOBA’s HELP is such a comprehensive process that offers additional value.

HELP (Holistic Enhanced Laser Process) is a three-stage closed-loop medical device marking process that ensures process reliability before and after laser marking and easy compliance with regulations. Parts are validated prior to marking and with the help of the TTL (Through-The-Lens) vision system IMP (Intelligent Mark Positioning), only the correct mark is applied at the correct position on the correct part. Marking contents can then be verified (i.e. Optical Character Verification OCV) and 2D codes can be read back while the part is still in the machine – everything with just one laser and its built-in vision system.

HELP benefits at a glance:
+ seamless traceability
+ increase in product quality
+ compliance with regulations
+ more flexible production
+ cost reduction through increased yield and less scrap
+ more economic production through repeatable process and increase in process reliability

The core of this closed-loop marking process is a reliable high-precision marking laser system combined with the vision alignment system IMP, capable of OCV and 2D code reading.

HELP in three stages:
Laser marking with pre- and post-mark validation eliminates potential marking errors

Apart from the marking of the medical product itself, HELP offers pre-mark verification prior to marking and post-mark validation right after marking. Particularly important for medical device manufacturers: During the unique post-mark verification process, the content of 1D and 2D codes (e.g. Datamatrix [ECC200], GS1 compliant and graded) can be directly read which is indispensable for compliance with the new Unique Device Identifier set by the FDA.

1: Pre-mark verification
2: Laser marking (product identification)
3: Post-mark verification

Part validation: Validates that the correct part is in place and prevents from marking wrong parts or defective products.

Mark verification: Validates that marks are placed where they are expected (checks for positioning, alignment, size).

Optical Character Verification (OCV): Validates that every character marked by the laser matches the expected content.

2D code validation and code reading:
Reads the contents of 1D and 2D codes (Datamatrix [ECC 200, GS1], QR) and compares the results to the expected content. A classification of the code into quality classes is possible.
Laser technology for medical device marking: Example applications

**Application case:**
**Banding marks for depth measurement**

Many manufacturers request banding marks for depth measurements during surgery. Line marks that function as depth indicators have to be applied around the circumference of cylindrical tube shaped parts such as minimally invasive tools or catheters. These marks show surgeons how far the respective device is inserted into the patient’s body.

Procedure: The cylindrical devices are marked while they are rotating at a constant speed. The marking is applied by moving the laser along the length of the part while the rotating part generates the equivalent of the cross motion.

→ Catheters, tubes, wires, needles, etc.

**Application case:**
**2D codes on surgical instruments**

High-quality laser marks are ideal for ensuring quality assurance and traceability in many ways. For instance, individual 2D codes are marked on surgical instruments and individually manufactured implants such as pacemakers or cardioverter defibrillators. Prior to implanting, these 2D codes can be used to check if the one and only implant for the respective patient is used. After the surgery, the 2D codes on the instruments and tools used can be scanned to ensure that all equipment that went into the operating room is also there after the surgery and not left inside the patient’s body.

Laser marked 2D codes last a lifetime and can additionally be used for tracing devices and distinguishing them from illegal copies.

**Application case:**
**Marking of sensitive medical plastics**

Hygienically laser marking of medical plastics with the help of UV laser markers: The product’s surface is colored photochemically. The marking process produces such a low local heating (‘cold’ marking) that delicate and sensitive products remain largely unscathed. The surface remains smooth, making it impossible for germs to take root.

With a typical pulse duration of 20 ns and a beam diameter of 10 µm, the UV marking laser (355 nm) colors the surface without damaging it. This process can be used to mark medical products such as cannulas or insulin pumps, and it ensures that the marks are long-lasting and sterilization-proof.

→ **Safe**: Cold and damage-free marking of critical plastics.
→ **Hygienic & sterile**: Photo-chemical surface coloration on medical plastics instead of foaming.
→ **Pioneering**: Previously unmarkable materials (i.e. silicones, white polyamides) can be processed.
→ **Down to the last detail**: High resolution for extra fine and high contrast marks.
→ **No solvents or material additives** required for marking plastics.

**Application case:**
**Marking of bone screws**

Laser marking bone screws presents many challenges, including the positioning of small characters (i.e. 0.2 mm high) in a very limited area (i.e. a 3 mm diameter screw head) and the ability to do this repeatedly without having the operator adjusting the laser parameters. Bone screws are manufactured in many sizes that, at first glance, can look the same, so it is critical to confirm the bone screw type to ensure that the correct information is marked for that particular part. Failure to do so can result in costly consequences.

The code positioning and quality of marks on screw heads must be reproducible to eliminate any procedural adjustment. Precise positioning of the mark in the target area without expensive fixtures can also reduce overall production costs. Vision alignment, like FOBA’s IMP (Intelligent Mark Positioning) tool, can be used here. A vision model is used to locate a screw head location and mark it accurately. This achievement has allowed operators to reduce the revalidation and marking procedures, which can take up to 80 percent of their production time. Product throughput is improved, waste is practically eliminated, and simple fixtures have reduced the cost of tooling. Another benefit is a significant reduction in setup time. Marking repeatability on bone screws can be as accurate as 25 µm, therefore allowing manufacturers to mark contents into tight spaces.

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Banding process using laser technology.
Laser marking medical devices and products: Identification, compliance, traceability, product safety, liability and quality

There is much more to marking medical devices than just complying with regulations. Whether manufacturers have to comply with global standards and apply all ID marks reliably with repeat accuracy or whether they have to ensure product quality – all medical products have to be marked properly in the first place. To ensure correct part identification, absolutely traceable marks are indispensable. Laser marking is the ideal method to create these marks and at the same time offers an increase in production efficiency and decrease in costly product scrap.

Laser-based medical product identification with the system, process, vision and verification solutions offered by FOBA provides numerous advantages over alternative processes. We will be happy to tell you more in a face-to-face meeting or a live demonstration in one of our application laboratories or at your site. Just get in contact with us at: info@fobalaser.com