APP NOTE # 11 - 20200626
MAY 19

UNIQUE DEVICE IDENTIFICATION BLACK MARKING FOR THE MEDICAL INDUSTRY

The benefits of laser marking for medical devices include product traceability, product liability, quality control, distribution regulation, and counterfeit prevention. Such markings must have uncompromising durability throughout the lifetime of the device since patient safety and product quality are imperative.

Laser marking has rapidly become the preferred UDI marking process

Unique Device Identification ensures traceability

The FDA legislation[1] requires a Unique Device Identifier (UDI) marked directly onto the medical device itself to provide traceability along the entire supply chain.

It must contain plain text which is readable by humans as well as machine-readable code. Both must be permanently legible since traceability is of the utmost importance for medical implants and surgical devices.

This type of marking can be provided by an ultrafast laser which can deliver a smooth mark with very high contrast.

Marking of all kinds of material

Medical devices can range from implants and catheters to less invasive multi-use surgical tools such as scissors, forceps, and scalpels.

Logos and data matrix marked on stainless steel forceps and scissors

Typically, materials used in the manufacture of medical devices are stainless steels, aluminum, titanium, plastics (such as PEEK, HDPE, nylon), and many others. All these materials can be marked using the ultrafast laser.

Logo and barcode marked on stainless steel kidney dish

Cost-effective permanent marking

Most marks are required to remain durable after regular use and cleaning, which make laser marking ideal.

Laser marking is a very attractive and cost-effective marking solution due to the process reliability, the non-contact nature, the inherent flexibility, the capability to create intricate details, the micron precision and no need for consumables.

[1] https://www.fda.gov/medical-devices/unique-device-identification-udi-system/udi-basics

Why use ultrafast lasers?

Ultrafast lasers exhibit many advantages over nanosecond lasers. Their short pulse duration provides an exceptional peak power which enables marking of a wide range of materials without delivering heat to the material. This significantly reduces the unwanted thermal effects of traditional laser marking, which can lead to poor corrosion resistance.

Medical device markings are required to repeatedly withstand the high temperature and humidity autoclave cleaning and sterilization technique. Conventional thermal laser marking typically exhibits issues relating to fading and corrosion when subject to repeated cleaning.

Ultrafast lasers create smooth marks which have proven to survive numerous cleaning cycles. During ultrafast laser marking, no material is removed and there is no microcracking or surface damage.

The ultrashort pulses produce nanostructures on the surface of the medical device which is particularly efficient at light trapping and hence provides the high-contrast matt black "printed" appearance.

NKT Photonics' ultrafast product range can produce high-contrast black marking on stainless steel which is not sensitive to the viewing angle. These markings are smooth to the touch thus does not encourage biological trap.

The marking can be seen clearly from every angle and is completely smooth. Multi-use medical devices present a risk of spreading contaminants, so a smooth surface, free from biological traps, is essential.

Summary

The ultrashort pulses delivered by NKT Photonics' ultrafast laser range are well suited to marking in the medical industry and fulfilling the requirements for UDI-compliant marking.

The Origami XP is the first all-in-one, single-box, microjoule femtosecond laser on the market. The laser head, controller and air-cooling system are all integrated in one small and robust package, with a footprint so small it even fits into a hand-luggage!

The ORIGAMI system is based on a compact monolithic chirped pulse amplification platform capable of delivering up to 70 µJ pulse energy at 1030 nm, a 5 W average power, and a pulse duration below 400 fs.

- Air-cooled, single-box for ease of integration
- < 400 fs standard pulse width
- 5 W/70 µJ @1030 nm
- 2.5 W/35 µJ @515 nm
- 1 W/17.5 µJ @343 nm
- Single-shot and Pulse-on-Demand
- Dual-output wavelength module
- Outstanding energy and pointing stability
- Industrial, rugged design
- Mountable in any direction
- Real-time pulse energy measurement and control
- Unprecedented reliability
- Water cooling available