



Press Release

UDI compliant laser marking of medical devices

A turnkey solution from TRUMPF with laser and software module for UDI marking from a single source to create corrosion-resistant marks on highly reflective materials using ultra-short pulsed lasers

FARMINGTON, Conn., March 22, 2017 – TRUMPF has launched a turnkey solution for UDI-compliant laser marking of medical devices. By combining a marking laser with a UDI software module, TRUMPF offers both components from a single source. This helps manufacturers to comply with the current provisions set forth by the U.S. Food and Drug Administration (FDA) that require every medical device to be labeled with a unique identifier that can be checked against a centralized database as part of the global device identification system. The identifier must be in a format that is readable by both a human and machine and enabling the part to be tracked through the entire supply chain.

Software and marking laser from a single source

The UDI combines static and dynamic identifiers and is most often applied as a linear bar code or 2D Data Matrix code. The static portion is a unique code for the specific medical device while the dynamic portion changes for each batch of products. There are currently three accredited UDI labeling standards: GS1, HIBC and ISBT 128. Based on its TruTops Mark marking software, TRUMPF has developed a special module to create standard-compliant UDIs from company and production data and mark them on medical devices. Users have the freedom to choose which of the three identification systems they want to use. The process also functions in reverse, with the optional VisionLine Mark image processing module enabling the TRUMPF software to quickly scan and read UDIs on medical devices.

Marking lasers have become a well-established and trusted method to affix UDIs to medical devices. With its broad product range, TRUMPF can offer the right laser for any kind of material including stainless steel, aluminum, plastics and organic materials. The new TruMicro Mark 2000 is particularly beneficial for marking medical device applications. Its ultra-short pulsed laser features extremely short laser pulses (0.4 to 20 picoseconds) and high pulse energies of up to 20 microjoules. Since the pulses



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emitted are short enough to enable cold material processing, a completely corrosion-resistant mark appears. This is possible because the time required for the material to absorb the laser energy is shorter than the time required to heat up the surrounding material. The machining of the material is therefore complete before the thermal processes can take effect. The resulting highly durable mark will maintain its high contrast even after frequent cleaning and sterilization

When marking a medical device, the high pulse peak powers of the TruMicro Mark 2000 initially produce a nanostructure on the device's surface. This rough surface then creates a kind of light trap that significantly reduces the diffuse scattering of the light, causing the mark to take on a permanent dark black hue. A significant advantage of this method is that it allows the protective chromium oxide layer of the steel to re-form after processing, thereby preventing the onset of corrosion.



About TRUMPF

TRUMPF is a world market and technology leader in fabricating machinery and industrial lasers for flexible sheet metal processing. Products manufactured with the company's technology can be found in almost every sector of industry. TRUMPF Inc. is the largest subsidiary of the TRUMPF Group and is dedicated to serving the U.S., Canadian and Mexican markets. Additional company information is available at: www.us.trumpf.com.

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Equipping medical instruments with UDIs

All medical devices must now receive a unique identifier to be UDI compliant and remain traceable through the entire supply chain.



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TruMicro Mark 2000

The new TruMicro Mark 2000 can create corrosion-resistant marks with a permanent high contrast appearance even on highly reflective materials that are cleaned and sterilized on a daily basis.

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