10th CIRP Conference on
Photonic Technologies [LANE 2018]

Industrial Paper

Corrosion-free non-cytotoxic marking of medical metal surfaces by ultrashort pulsed laser – ready for Industry 4.0 applications

Susanna Friedel[a,*], Klaus Stolberg[a], Ewa Hild[a]

[a]*JENOPTIK Laser GmbH, Göschwitzer Strasse 29, 07745 Jena; Germany*

Abstract

In 2017 the new Medical Device Regulation (MDR) has been approved of by the European Parliament. Like the Unique Device Identification (UDI) System in the US it states to mark all medical devices unforgeable for retraceability. Manufacturers are increasingly faced with requests for complex subsystems that include laser marking as well as and optical quality proof of the marking. For medical surgery equipment and medical implants the marking has to withstand also the various sterilization processes and also must be non-cytotoxic. Cytotoxic markings would forbid direct contact e.g. with blood and body tissue.
This paper will highlight on high contrast marking of metal surfaces for medical use and compare standard laser marking done by nanosecond laser with the new black marking done by picosecond laser.
Also a plug-and-play micromachining module is introduced, which contains all components required for laser beam delivery and laser marking readout, which supports Industry 4.0 concepts.

Keywords: Medical Technologies; Industry 4.0; USP laser; laser marking

1. Introduction

Quality control becomes more important with higher automation grade of our production facilities. Especially in a very sensitive industry like Medical Device Manufacturing it is important to be able to identify each device individually and unforgeable for retracing. The importance of this is so high that even Governments like in the US and the European Parliament find it necessary to install regulation systems for it.

This identification markings need to be machine readable and have to have fixed and variable data segments. Additionally they have to be permanent and durable to withstand not only the usual cleaning processes but also the environment conditions for example in the human body. For use in contact with body fluids it is also necessary to proof the non-cytotoxicity of such a mark. Variable data content require a flexible solution like a laser marking system which can be included into a cyber physical system.

In this paper we will detail on the opportunities given for medical marking as requested by the UDI and MDR by using black marking done by picosecond laser in comparison to standard laser marking done by nanosecond laser. We will also introduce a plug-and-play micromachining module which supports the Industry 4.0 concepts.

* Corresponding author. Tel.: +49-3641-65-3467.
E-mail address: susanna.friedel@jenoptik.com

2. Experimental Details

2.1. Experimental Setup

As seen in Fig. **1** we investigated 2 typical materials for medical devices (Titanium Grade 5 and Stainless Steel) for investigation. We tested standard marking with a JenLas®fiber ns laser (JENOPTIK) and the more sophisticated black marking with a JenLas®pico laser.

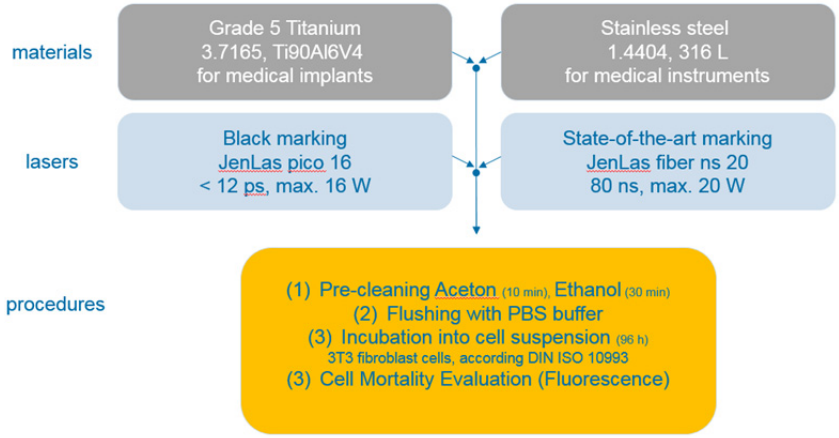


Fig. 1. Experimental setup and cytotoxic test procedure

To generate our test structure (Fig. **2**) for the following cleaning and cytotoxic tests we used the JENOPTIK MMT (Micro Machining Tool; Figure 4), which is a compact smart micromachining and marking tool. The test structure consists mainly of filled squares which simulate typical branding marks. To show real world examples a Data Matrix Code, a logo and a plain text have been added.

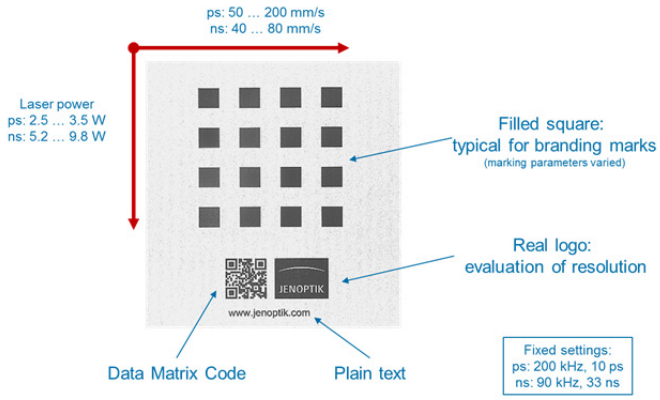


Fig. 2. Test structure and process parameters

2.2. Incubation, Cleaning and Cytotoxic Test

To analyze the durability of the mark when used in the human body we tested incubation in water and isotonic NaCl solution. Afterwards the parts were steam sterilized, which is a typical cleaning procedure for medical devices. If the laser marking damages or changes the surface of the metal material we expect oxidation to happen in these areas.

For in-body-use it is necessary to ensure that the laser marking is not cytotoxic and therefore encourages no body reaction. For this test we pre-cleaned the samples with acetone and ethanol and flushed it with a PBS

buffer. Afterwards they got incubated into a cell suspension for 96 hours (3T3 fibroblast cells according to DIN ISO 10993). The cell mortality was evaluated with fluorescence. We doped the cells with commonly used Fluorescein Diacetate (FDA) and GelRed fluorescence dyes.

3. Results

3.1. Incubation Test

On titanium alloy nanosecond as well as picosecond laser marks show no significant effect caused by the cleaning procedure (see Table **1**). This means that both lasers are acceptable for the application and no further post treatment is needed.

On stainless steel the standard marking done by ns-laser for some parameters oxidation effects can be observed. An even stronger reaction can be observed for nearly all parameter combinations in case of isotonic NaCl incubation, which simulates a chemical environment found in the human body. This effect is accelerated by steam sterilization. Multi-colored ferric oxides at different oxidation stages can be observed. The damaged surfaces changes color or flakes off, which makes the marking unreadable and indicates unpredictable chemical reaction with body fluids or tissue. This is not acceptable for an identification marking. To prevent this, stainless steel parts get an additional surface passivation after laser marking. The black marking done by picosecond laser does not show this reaction on stainless steel. We could observe no oxidation. The marking behaves similar to the one on titanium. Therefore it is acceptable without additional passivation step.

Table 1. Results after steam sterilization

	Stainless steel	Titanium alloy
Nanosecond laser		
Picosecond laser		

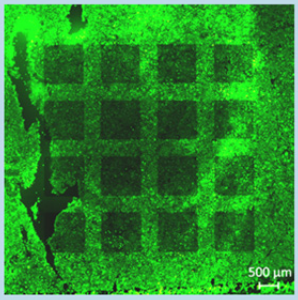
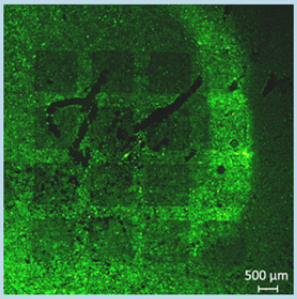
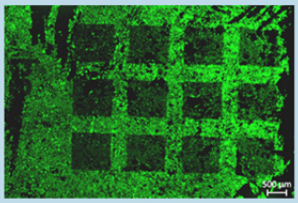
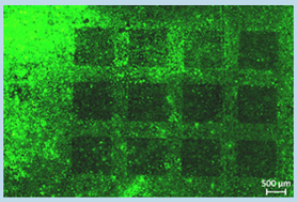
A detail of oxidation effects in given in Figure 3. Multicolored iron oxides can easily be observed:

Fig. 3. Oxidation effects in nanosecond lasermarking after steam sterilization

3.2. Non-Cytotoxic Test

As described above, fluorescence dyes are used as an indicator of cell vitality: Red fluorescence would indicate dead cells and green shows living cells. From Table **2** the cell mortality can be derived with less than 5%. Black marking as well as conventional marking do not show remarkable cytotoxic effect within a 4-day trial. The material performance with respect to cytotoxicity is not influenced.

Table 2. Results of cytotox investigation

	Stainless steel	Titanium alloy
Nanosecond laser		
Picosecond laser		

4. Conclusion

Both kinds of laser marking showed a good performance on titanium base material. On stainless steel the standard ns-marking showed significant failures on the readability, durability and chemical inertness, which requires an additional passivation step in real production. This can be prevented by “black marking” the parts with a picosecond laser. These high quality marks are corrosion free, permanent and non-cytotoxic. The properties of certified materials for medical instruments and implants are unaffected using a “cold” laser process. Together with the MMT it enables UDI and MDR compliant marks.

The MMT shown in Figure 4 consists of a process channel (laser marking components) and an additional camera channel. Furtheron the embedded software enables image recognition, evaluation of optical features and network communication. The laser submodule gets the information on the part structure and orientation, recognizes the target position for the ID label and draws the ID data for the marking label content from an external database or by a local algorithm. It allows not only to align a variable marking on the right labelling position, but also allows inline quality control right after marking process. If the evaluation algorithm for contrast and readability delivers a positive result, the ID number and can be sent to an external database. This enables the integration of black marking laser module to Industry 4.0 concepts.

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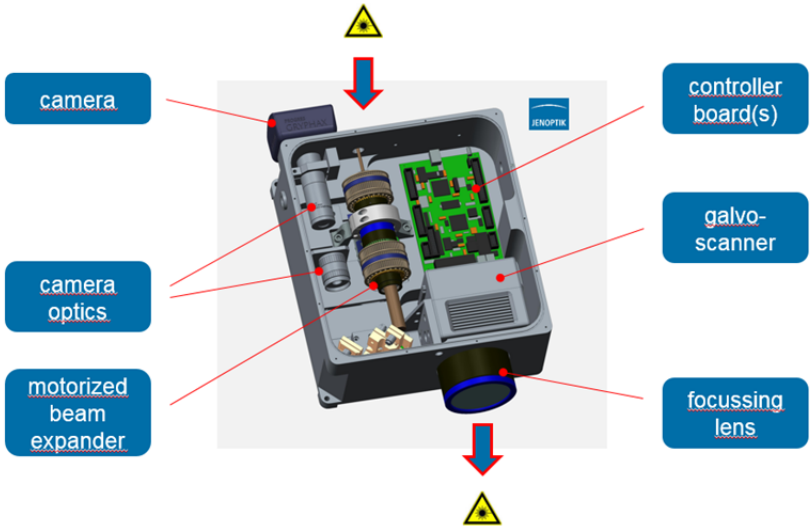

Fig. 4. JENOPTIK Micro Machining Tool

Acknowledgements

Our cordial acknowledgements are to the biomaterials team of Innovent GmbH for consulting and support relating biology.