TRUMPF

White paper

Reprocessing laser-marked medical devices

Contents

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Summary

According to the EU Medical Device Regulation (MDR) and regulatory requirements set by the US Food and Drug Administration (FDA), medical devices must be clearly labeled with a mark that remains legible during their entire service life. In this paper, we present the results of a study into the reprocessing of laser-marked medical-grade stainless steel 1.4301. Conducted under realistic reprocessing conditions, the study was designed to evaluate how the contrast and legibility of laser marks vary depending on which laser technology is used. The marks examined in the study were applied using nanosecond, picosecond and femtosecond lasers. The results show that annealing with nanosecond lasers and black marking with ultrashort-pulsed lasers from TRUMPF are both ideally suited to the task of marking reprocessable medical devices. Even after 50 reprocessing cycles of alkaline cleaning and steam sterilization, the marks remained as corrosion-free and legible as they were when they were applied.

Introduction

New requirements introduced by European and US regulatory authorities state that medical devices must be labeled with unique device identification (UDI) codes in order to ensure seamless traceability. The guidelines specify that all laser-marked UDI codes – apart from a few exceptions – must be marked directly on the device itself and remain clearly legible over a long period of time. Particular emphasis is placed on surgical instruments and other medical devices that may be reprocessed up to several hundred times during their lifetime. Both the machine-readable UDI code and its human-readable equivalent, the human-readable interpretation (HRI), must meet these legibility requirements. This poses a significant challenge to the marking procedures used by modern reprocessing plants, which typically carry out reprocessing using strongly alkaline detergents and high-temperature steam sterilization. The requirements can only be met by meticulously validating the laser parameters in each case. Marks must not fade or corrode even after multiple cleaning cycles. They must remain clear enough to ensure that the medical device can be put to practical use for as long as possible.

This is the first systematic study of how such harsh, real-world reprocessing conditions affect the legibility and contrast of laser marks applied using TRUMPF laser technologies such as annealing and black marking.

Laser marking technology for medical devices

Pulsed laser sources offer an excellent method of applying UDI codes because they meet the requirements for durable, high-contrast and corrosion-free marks specified in the European MDR and US FDA regulations. Laser marking systems make it easy to add serial numbers for track-and-trace solutions that ensure maximum product safety and protection against counterfeiting.

TRUMPF offers a broad range of laser technologies that are ideally suited to the task of marking medical devices, including, in particular, reprocessable medical devices made of steel. UDI-compliant markings can be applied by short-pulsed lasers in the nanosecond regime (TruMark 6030-G2) as well as by ultrashort-pulsed fiber lasers in the femtosecond (fs) and picosecond (ps) regimes (TruMicro Mark 2000). These systems include sophisticated power regulation features which guarantee reproducibility of the energy applied to the workpiece throughout the laser's entire service life. To ensure the consistency of the marking process, the energy input must remain constant and meet the specifications at all times. This is the only way to guarantee reliable and homogeneous labeling while also preventing the formation of nanocracks on the lasered surface which could potentially cause corrosion.

To achieve optimum contrast and prevent corrosion, the selected laser parameters must be perfectly matched to the material being marked. Key factors to take into account include surface finish, device geometry and the steel alloy, as well as the secondary passivation performed after marking. TRUMPF has carried out comprehensive studies to determine the optimum marking parameters for each laser technology.

Reprocessing cycles

The reprocessing study was carried out under realistic conditions using a two-step process of alkaline cleaning followed by steam sterilization. The sample parts were cleaned with an alkaline detergent in a medical washer-disinfector from Miele (PG8582), which is used to reprocess medical instruments in physicians' offices and hospitals (fig. 1). This step was based on the cleaning and disinfection strategy described in EN ISO 15883 for reprocessing instruments without hollow sections or lumina. The alkaline detergent employed in the study was Neodisher (MediClean forte, Dr. Weigert).

Source: Miele

Figure 1: Alkaline cleaning system and steam sterilizer for reprocessing medical devices.

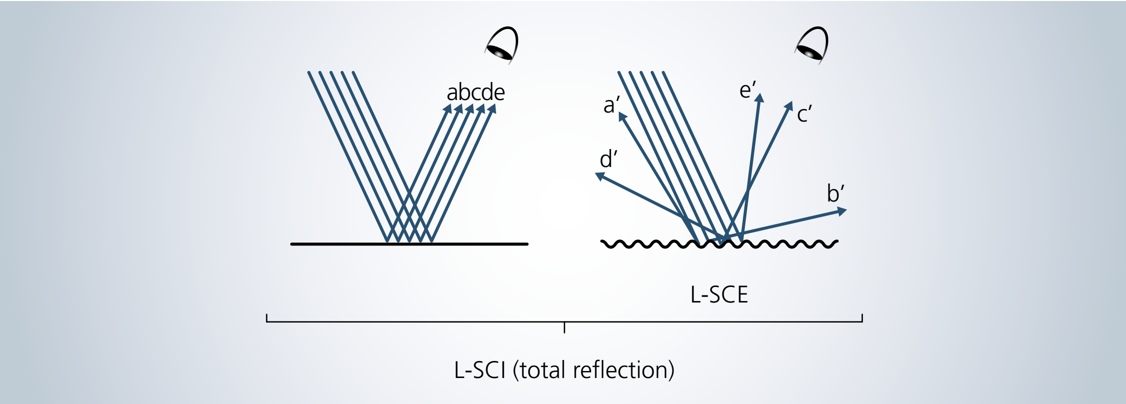
Following alkaline cleaning and disinfection, the steel plates were autoclaved in a steam sterilizer (Miele Cube) at steam temperatures of up to 134°C in line with standard everyday practice. With an A0 value of 3,000, this reprocessing method closely replicates real-world conditions and destroys any thermoresistant viruses that may be present on surgical instruments. In this study, the sample parts were cooled to room temperature after each reprocessing step before entering the next alkaline cleaning cycle. Up to three cycles were run per day, once again in line with real-world conditions.

Material

The sample parts used in the marking and reprocessing study were austenitic chromium-nickel 1.4301 stainless steel plates (X5CrNi18-10) with six different surface finishes ranging from a roughness of Ra ~ 1.2 (barrel finishing, corundum blasting) to a highly reflective surface with a roughness of Ra ~ 0.12 (barrel finishing, electropolishing). Before being marked with the laser, the steel plates underwent primary passivation and cleaning in accordance with the Nitric 2 method specified in ASTM A967. Secondary passivation was carried out after laser marking and the sample parts were stored for at least 24 hours before reprocessing began.

Quantitatively assessing the quality of marks made by annealing and black marking

Spectrophotometric methods were used to provide a quantitative assessment of mark contrast (fig. 2). Measurements were made of the total radiation reflected from the surface (sum of specular plus diffuse reflectance) and a normalized scale was used to compare contrast values over a range from 0 (absolute black) to 100 (absolute white).



Source: https://www.konicaminolta.com/instruments/knowledge/color/part3/02.html, last accessed on May 20, 2021

Figure 2: Using spectrophotometry to measure contrast.

Marking processes

The steel plates were marked using one of three different types of laser combined with either an annealing or a black-marking process.

- Annealing (ns) with the TruMark 6030-G2 nanosecond laser
- Black marking (fs) with the TruMicro Mark 2000 and a pulse duration of 900 fs
- Black marking (ps) with the TruMicro Mark 2000 and a pulse duration of 20 ps

Effects of reprocessing on the marks

To enable a quantitative comparison, the study measured and compared the contrast of marks made by the various marking methods both before and after the 50 reprocessing cycles. The results in figure 3 show that alkaline cleaning and steam sterilization did not cause any changes in mark contrast for any of the marking methods or laser types.

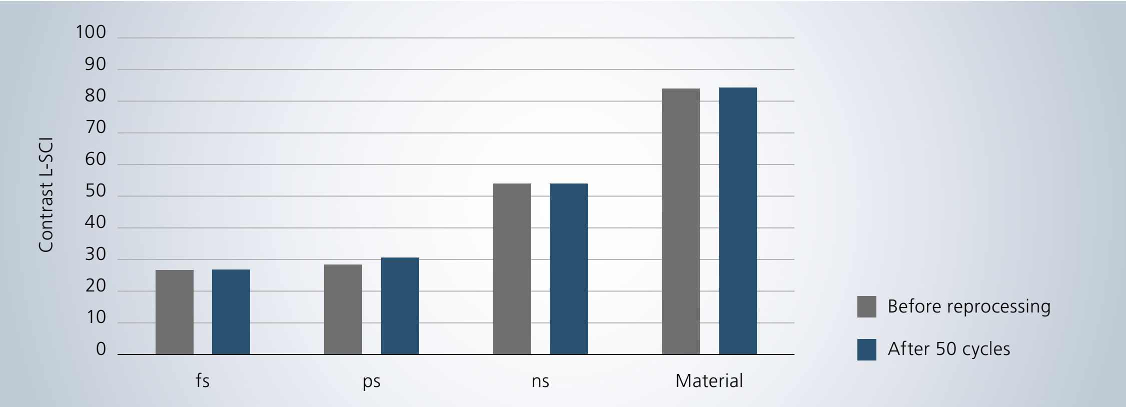


Figure 3: Contrast measurements before and after reprocessing.

Even after reprocessing, marks applied with a femtosecond laser (fs) using the black marking method remain the highest-contrast marks of all current technologies, closely followed by marks applied with a picosecond laser (ps). Marks made with the solid-state laser (ns) generally have a somewhat lighter contrast, but maintain their contrast equally well after the rigors of reprocessing.

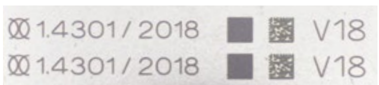
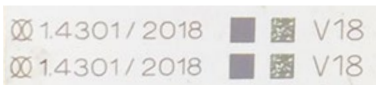
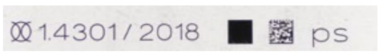
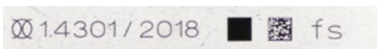
Before reprocessing	After 50 reprocessing cycles	Technology
		Annealing (ns)
		Black marking (ps)
		Black marking (fs)

Figure 4: Marks made by annealing and black-marking methods before and after 50 reprocessing cycles.

After undergoing 50 reprocessing cycles, mark quality was still very high for both the machine-readable Data Matrix Code (DMC) and the human-readable lettering and logos (fig. 4). The study results show that UDI laser marks produced by various technologies in the nanosecond, picosecond and femtosecond regimes are sufficiently durable to consistently withstand highly alkaline sterilization and cleaning processes. The corrosion characteristics of our sample parts were not affected by the reprocessing cycles. The surfaces remained in pristine condition with no visible traces of corrosion even after the harsh series of reprocessing cycles was completed.

Which laser technology offers the most benefits for reprocessable medical devices?

Durable, corrosion-free UDI marks can be applied to metal surfaces using both ultrashort-pulsed lasers and nanosecond lasers. TRUMPF has developed, tested and validated suitable marking parameters for common medical-grade steels and surface finishes for the laser types that are suitable for use in medical technology applications.

So what are the advantages and disadvantages of each marking technology for reprocessable medical devices?

Black marking

One of the advantages of black marking with ultra-short-pulsed lasers is the very high contrast of the marks it produces and the legibility of these marks from any angle. This high contrast and ability to read marks from any angle are maintained even after reprocessing (fig. 3 and 4). This has made black marking a popular marking method for surgical instruments, for example, because the marks are easily readable even under the harsh, bright lighting used in operating rooms.

It should also be noted, however, that the contrast-enhancing oxide film produced by black marking is relatively thin compared to that produced by annealing, since the laser only acts on the material for a very short time. The advantage of this thin film is that it is very resistant to corrosion, since the short duration of laser action leaves the chromium-to-iron ratio largely unchanged and maintains the protective passivation layer. The disadvantage, however, is that black markings are more sensitive to mechanical stresses such as abrasion and impact due to the thinner oxide film and the microstructuring of the surface. This may be detrimental in the context of reprocessing since surgical instruments are frequently damaged by mechanical shocks in the course of day-to-day use. To solve this problem, TRUMPF and its med-tech industry partners are already deploying a method in which the labeling applied by black marking is situated slightly beneath the surface of the instrument thanks to a process of high-precision engraving. This creates a mark that is well protected against mechanical damage.

Annealing

Marks made by nanosecond lasers are much less susceptible to diminished legibility or reduced corrosion resistance as a result of mechanical shocks. The relatively long duration of the laser action on the metal surface forms a distinctively thick and dark oxide film. The correspondingly greater resistance of these marks to mechanical stresses was confirmed in this study, in which we observed no wear or deterioration due to mechanical shocks during reprocessing. Another advantage of annealing is that it does not alter the surface properties (roughness) of the medical-grade steel.

To produce corrosion-free markings with nanosecond lasers, it is important to control the heat input of the laser on the surface in such a way as to prevent any networks of cracks from forming in the oxide film. This is because cracks – even those smaller than one micron in size – could set in motion localized corrosion processes during the numerous reprocessing cycles. To achieve shallow heat gradients, annealing marking typically employs a defocused laser beam and longer pulse durations. This greatly increases the reliability of the process for producing corrosion-resistant UDI marks. However, the annealing process with nanosecond lasers reaches its limits when it comes to applying tiny, delicate lettering or very small 2D codes to the workpiece. These latter applications can be better tackled by marking with ultrashort-pulsed lasers, since the black marking process works with the smallest possible laser spot.

Conclusion

Our study shows that the legibility and contrast of marks made by ultrashort-pulsed and short-pulsed lasers from TRUMPF remain unchanged even after 50 reprocessing cycles. What's more, the realistic reprocessing cycles carried out in this study (with alkaline cleaning and subsequent steam sterilization) show that sample parts made of 1.4301 medical-grade steel do not exhibit any corrosion. This means that cost-effective annealing and high-quality black-marking procedures with TRUMPF femtosecond and picosecond lasers are ideally suited to the task of applying UDI marks to medical devices.

Learn more about solutions from TRUMPF:
www.trumpf.com/s/medical-technology

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