Reusable medical products that require multiple processing cycles – such as surgical instruments – must bear a direct mark*. To permanently ensure the complete identification and tracking of the instruments, the American and European UDI Directives** require a directly applied unique UDI code (Unique Device Identifier). Considering the extensive or repeated processing in practice, these requirements place especially high demands on the lasting stability and reliable machine readability of the direct mark. Over a long period, ideally over the complete product lifecycle, the laser marking must be reliably resistant against corrosion and fading.


**regulated through the FDA and in the EU’s MDR

Many Challenges

Directly applied UDI marks should meet many criteria. They must not affect the surface finish of the device negatively, and must by no means corrode. Additionally, they must ensure counterfeit protection, must be marked in high contrast and be reliably legible and readable – this, to ensure the permanent device traceability over its lifetime. With emphasis on reusable medical devices and instruments, the reliable stability of the direct mark against high alkaline sterilization and cleaning procedures is of crucial importance. These multi-use devices must be reprocessed several hundred times in everyday clinical operations where a reliable, machine-readable direct mark is the prerequisite for traceability.

The European and American UDI Directives make no specific statements about the stability of laser markings. However, in general they require long-term stability to guarantee complete traceability.¹ Consequently, manufacturers are challenged to ensure sustainable and stable directly marked codes. Laser markings are subject to fading or even corrosion if all steps in the process have not been well aligned to each other, or if the optimal laser and marking parameters have not been thoroughly defined.
Until recently, it was unknown how often laser marked surgical instruments can be reprocessed without a negative impact on the mark quality. Moreover, the parameters and process steps that ensure stable results in the long were unknown. Various stainless steels react differently. Different surface qualities must be considered for each steel type. The optimal laser parameters will vary in each application.

The Solution

Extensive study on reprocessing verifies that short pulse lasers apply stable marks

During their own process validation, “add’n solutions”, a EU laser marking service provider, created a comprehensive study on the reprocessing of surgical instruments, laser marked with a FOBA short pulse fiber laser. The study validated and offered empirical data on the reliable resistance of the laser mark even after 500 sterilization and cleaning cycles.

→ add’n solutions, a service provider to the medical technology industry for the laser marking and subsequent cleaning, passivation, packaging and labeling of medical devices, has run a comprehensive long-term study that resulted in valid answers.

Application Case Study

The validation samples have been cleaned and autoclaved 500 times. The marks did not fade and are still reliably readable. After further sterilization cycles these results are not likely not change. The instruments themselves show the usual signs of use.

“add’n solutions” has documented the extensive representative test results in detailed progress reports.
A validated process provides valuable data

With a precisely matched process, "add’n solutions" has marked the surgical instruments with FOBA marking laser solutions, followed by a cleaning and passivation cycle. Finally, the instruments have been sterilized and cleaned 500 times:

→ The American standard for the passivation of stainless steel, ASTM 967, was used for the passivation of the instruments. The steam sterilization was accompanied by an instrument cleaning with high alkaline cleaners (pH value of 14).
→ In over 500 cycles, "add’n solutions" verified that the cost-efficient fiber lasers apply permanent marks that survive daily clinical routines and are resistant against corrosion and fading.
→ It remains an important prerequisite that hospitals adhere to the reprocessing guidelines of manufacturers and distributors (usually delivered with the instruments, providing reprocessing and/or operation instructions).
See the „Red Brochure“ of the work group 'Reprocessing of Instruments'.

Current technology not disadvantaged: short pulse marking lasers

With this study, "add’n solutions" has also proven that ultrafast lasers and short pulse lasers can create stable and reliable marks. Additionally, the study has shown that a compulsory passivation should be performed after the marking, regardless of the laser types. Moreover, ultrafast lasers such as picosecond and femtosecond lasers, have not yet been sufficiently researched and evaluated for special use cases in medical device direct marking. The data that is currently available is still very limited.

In a recent (Spring 2017) workshop on ultrafast lasers, hosted by the Fraunhofer ILT², studies have shown that the often acclaimed "cold ablation" of ultrafast lasers is not at all cold, and that it has not yet been fully understood how much heat really remains in the material.³

Furthermore, a passivation should not only be performed after marking with a short pulse laser (i.e. nanosecond) but also after a part has been marked with an ultrafast laser (i.e. picosecond). It is crucial to protect the whole product and to ensure its reliable corrosion resistance, instead of only protecting the area where the mark has been applied.

³ Heat Accumulation during Materials Processing with Ultrafast Lasers – The Consequences of Power Scaling, Prof. Thomas Graf, Institut für Strahlwerkzeuge IFSW, Stuttgart (D) und Power-Scaling with USP: Opportunities and Limits, Prof. Beat Neuen-schwander, Berner Fachhochschule, Burgdorf (CH)
Conclusion

The current study of “add’n solutions GmbH & Co. KG” proved, by documentation of 500 reprocessing cycles, that the cost-efficient fiber laser markers are indeed able to reliably apply long lasting marks, which endure the daily hospital routine.

Laser marking and subsequent cleaning and passivation along with regular clinical sterilization and cleaning procedures must, in any case, be consistent with one another and perfectly coordinated. Only by means of a validated and coordinated process of marking parameters, cleaning and subsequent passivation, can one guarantee long lasting corrosion resistance of the mark itself, but of the complete instrument.

Nermin Duratovic and Dominik Buggle of “add’n solutions” offer their customers, mostly small and midsize medical devices suppliers, this comprehensive package, consisting of a validated final cleaning and a validated passivation. These protocols in conjunction with the appropriate laser marking parameters, can provide safe, long term resistance and reliable code readability.

add’n solutions’ validated process:

1. Laser marking with FOBA laser systems
2. Post marking cleaning and passivation
3. Verification of the marking result
4. Packaging and labeling
5. Delivery to suppliers/traders

Outsourcing the marking of medical devices secures the livelihood of small and midsize device manufacturers. “add’n solutions” is a young start-up, situated in Tuttlingen, the center of the German medical device industry, whose business approach faces one of the currently greatest challenges for medical device manufacturers: The laser marking experts for UDI marking on medical devices enable their mostly small and midsize customers to put their focus back on their core competency, the manufacturing of surgical instruments – without the need to deal with the time-consuming, non-trivial laser marking according to legal requirements, neither with the subsequent process of cleaning, passivation, verification, packaging and labeling. "add’n solutions" thus offers a feasible way of implementing the strict UDI or MDR regulations to manufacturers, who cannot or do not want to implement the UDI-marking themselves, in a safe and economic production process.

As a service provider, “add’n solutions” takes care of their customers’ direct part marking on almost 40,000 medical products of different shapes, materials and surfaces as well as the cleaning, passivation, packaging and labeling of those products.

→ http://addn-solutions.de