

## Application Note

### → Laser Marking Dental Products

Technologically advanced,  
small in size, greatly effective

*Direct marking is required for reusable, reprocessed dental devices (such as instruments)\*; however, many manufacturers of single-use or general-use dental products – ranging from implants to complete practice equipment – highly value the many production, product and treatment related benefits as well as the competitive advantages permanent laser marking of their products provides.*

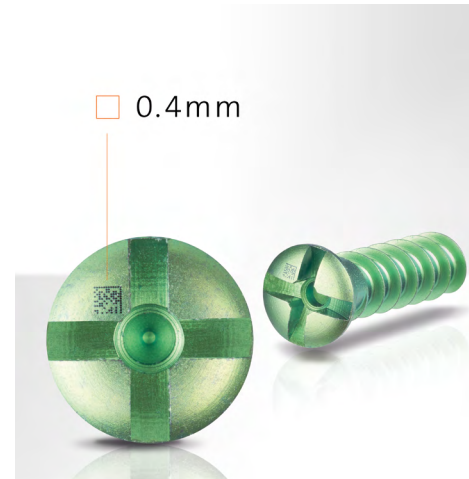
## Products and Applications

Dental products are marked for various reasons with various content. The **UDI labelling regulation\*** applies to **multi-use instruments that have to be reprocessed** (e.g. autoclave) before each use. These include endodontic and parodontic instruments, various curettes and sinus lift instruments, implant drills, osteotomes and condensers. Instruments like these also have to be marked with permanent CE signs or – as in the case of drills – with depth gauges.

**Direct marking does not apply to sterile packed dental implants and screws.** However, for many reasons, it makes good sense to apply a direct laser mark on such dental products, and many manufacturers already do so: Brand logos, trademark signs and the CE sign ensure protection against counterfeiting; laser marked depth gauges provide treatment safety; and reliably machine-readable 2D codes guarantee full traceability throughout the entire product lifecycle.

## Challenges

Besides the various **regulations** – such as the UDI directive – **hospital logistics related requirements** are increasingly gaining importance. Clinics benefit from standardized, consistently marked and reliably traceable dental products. Manufacturers providing products in accordance with these demands enjoy distinct competitive advantages. Additionally, also **functional markings** such as depth gauges or optical markings for the purpose of **brand and counterfeit protection** are required. **High quality standards, patient safety and traceability** have to be ensured as well as an **efficient and almost error-free production with as little scrap as possible**.



Why it's beneficial to laser mark dental products

- regulatory labelling requirements (e.g. UDI)
- functional requirements (e.g. depth gauges)
- quality assurance
- patient safety
- brand/forgery protection
- traceability
- lean manufacturing

*\* Reprocessed/reused class II devices for US-distribution have to carry a directly-marked UDI since 2018. The same is mandatory as of 2022 for corresponding class I products, both according to FDA regulations. In Europe, multi-use/reprocessable class IIa/IIb products have to carry the UDI as of 2025, corresponding class I products as of 2027, both according to the European MDR.*

Furthermore, next to the **materials** – ranging from Titanium nitride through stainless to Titan-oxidized surfaces as well as some plastic compounds –, it's the direct marking of the **tiny devices** that challenges the industry. **The smallest markings** have to be applied in minimal spaces with the **highest resolution and contrast**. **All marks must be biocompatible** and **reliably readable**. In the case of reusable reprocessed instruments, all marks have to survive multiple **autoclave cycles**.

## The Solution

### Cost-effective dental device marking thanks to integrated vision

FOBA's laser marking solutions are ideally suited for the reliable, permanent and economic identification of dental devices. Vision systems that are directly integrated in the scan head of the marking laser help to bring costly scrap down by 80%. Validation and verification steps before and immediately after marking directly in the laser system ensure lean and stable marking processes and repeatable results. This is especially critical for manufacturers that have to meet strict quality standards: Marking contents are read, validated and verified immediately after marking while the device is still in the laser station.

### Tiny marks perfectly traceable

Our system and machine solutions are particularly suitable for **marking even the tiniest micro 2D codes with high contrast**. Despite their small size, even these small parts are **reliably traceable even after repeated cleaning and processing**.

FOBA marking lasers easily and flexibly integrate into production environments, and mark dental devices with all required content. Brand logos, trademarks and graphics are applied as reliably, permanently and forgery-proof as serial and batch numbers, manufacturing dates and (UDI) codes (2D, etc.).

Our **Y-Series, Yb:fiber lasers** are perfect for clean, high-contrast and efficient laser marking of various metals and plastics. The **UV marking laser V.0020-uv** is ideal for high-contrast marking of sensitive plastics. Equipped with **integrated vision** and integrated in the high-precision **M-Series\*** range of laser workstations, supremely precise laser marking and a stable and repeatable marking process are ensured.

## Added Value

The expert knowledge of our application engineers guarantees an optimal laser and parameter setup. Our optional **service care packages** and **equipment qualification** offerings additionally support our customers with their IQ/OQ and long-term PQ/MQ requirements.



### Laser integrated validation:

- automatic part validation
- automatic mark alignment
- Autofocus
- Optical Character Verification OCV
- code reading and validation
- mark verification

### Advantages of laser marking

- economical process with up to 80% less scrap when utilizing laser-integrated vision
- simple, flexible integration
- clean marking without consumables
- reliable legibility and traceability even of the smallest marking contents

### Marking characteristics

- high-contrast, high-resolution markings
- durable, resistant markings
- forgery-proof
- biocompatible

\*construction with polymer concrete

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