



### SURGICAL INSTRUMENTS MARKING APPLICATION

July 24, 2017 by Johny Chen, Telesis Technologies, Inc.

#### The Customer Challenge

According to the U.S. Department of Commerce, there are more than 6,500 medical device companies in the U.S. with a total market size of \$148 billion. The most active sub-category in the industry is surgical and examination instruments (based on value of export shipments), which includes products ranging from scalpels to intricate catheters.

With strict regulations and proposed new rules (Unique Device Identification system) by the U.S. Food and Drug Administration and the European Union, Telesis can provide a wide variety of reliable and innovative solutions to often difficult and challenging marking tasks.



#### The Telesis Solution – Fiber Laser Marking

The F-Series fiber lasers are a versatile product robust enough for heavy industrial etching and delicate enough for annealed marks. Typical for medical applications are annealed marks that cause no damage to the surface or the material and maintain the corrosion resistant nature of the medical instruments.



This form of non-invasive processing is crucial in the prevention of bacterial accumulation. Whether it's banded titanium needles or high-grade stainless steel scalpels, this laser can mark them with precision, consistency and reliability.



## SURGICAL INSTRUMENTS MARKING APPLICATION (cont.)

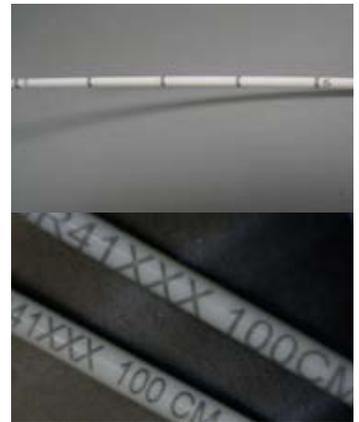
### The Telesis Solution – Green Laser EV4G

Coupled with the appropriate F-Theta lens, the EV4G laser with its 532nm wavelength can create high contrast marks with absolutely no damage to the polycarbonate or ABS plastic housing assembly of catheters (shown on the right). Whether in-focus or off-focus, the green laser can create color change in the material that achieves the annealed effect without damaging the surface.



### The Telesis Solution – UV Laser Marker

The Telesis UVC laser, with the combination of short wavelength (355nm) and excellent  $M^2$  value, produces a small spot size, which makes it an ideal choice for creating delicate marks on sensitive materials. For example, the UV laser reacts well with silicone or PVC to create fine graduated markings that denote depth of insertion on the catheter tubes below. Since the laser beam only creates color change on the surface, the material is not damaged and is free from bacteria contamination. Thus, this laser allows a safe and reliable process for medical device manufacturers.



### Unique Device Identification (UDI) Regulation

This document is not intended as an exhaustive summary of UDI regulation, but it does offer a few items to note:

- The FDA describes UDI “as a unique numeric or alphanumeric code that consists of two parts: 1) a device identifier such a manufacturer and model name; 2) a production identifier like batch number and serial number.”
- UDI is a system that includes a unique device identifier in human- and machine readable- form.
- UDI offers benefits on identification, traceability, reduction of errors, prevention of counterfeits, management of recalls, and more.



# Industry Solution Guide



## SURGICAL INSTRUMENTS MARKING APPLICATION (cont.)

- Proposed UDI regulations between the FDA and the EU are very similar as they wish to bring uniformity and consistency to global manufacturers, users and other partners.
- The system will be phased in over several years.
- Telesis lasers markers can apply GS1 compliant standard and 2D barcodes.

### GS1 Compliant 2D Code

Telesis offers a diverse lineup of marking systems to satisfy UDI marking requirements on a wide variety of materials. Customers can count on our years of experience to provide dependable and complete marking solutions.



Give us a call at 1-800-654-5696 or visit [www.telesis.com](http://www.telesis.com).



### Sources:

- [www.fda.gov](http://www.fda.gov)
- [www.selectusa.gov](http://www.selectusa.gov)
- <http://www.ghx.com>
- <https://ec.europa.eu>



*More UDI information is available on the FDA website.*



*More UDI information is available on the European Union website.*

Department of Commerce – International Trade Administration:  
2016 Top Market Report Medical Devices