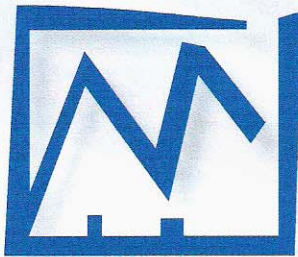


# Improving quality control in

KLAUS VOLLRATH AND WULF OPPENLAENDER

**FULLY AUTOMATED MANUFACTURING STEPS  
WITH A FOCUS ON EACH SINGLE WORKPIECE  
ARE JUST AROUND THE CORNER**



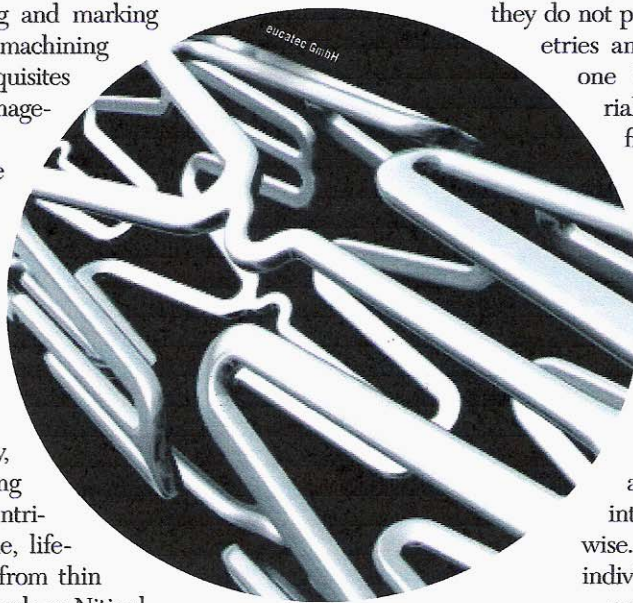
Medical device products and implants, such as stents, have to meet the highest quality requirements. As production is commonly only partially automated and traceability of individual workpieces practically nonexistent, quality-control measures generate high costs. The introduction of an integrated system for individual handling and marking of workpieces and consistent machining capabilities are therefore prerequisites for automated supply-side management on an industrial level.

“The transformation of the mostly manual production steps for cardiovascular-stent manufacturing to fully automated, high-quality industrial output is of utmost urgency,” says Eduard Fassbind, CEO of Swiss Tec AG (Zurich, Switzerland), a company that specializes in turnkey, laser-based precision machining solutions for the processing of intricate workpieces. For example, life-saving stent implants are cut from thin tubes made from superalloys such as Nitinol, with expandable metal grid structures that help to stabilize collapsed arteries after a cardiac infarction. The most common methods of stent insertion involve the use of special catheters that can be expanded like a balloon (see Fig. 1). As medical applications for stents become more diversified, their number and variety has increased significantly. Increasing production volumes and stricter quality requirements pose a great challenge

for the manufacturers. The solution—fully automated manufacturing steps with a focus on each single workpiece—is just around the corner, according to Fassbind.

## Conventional manufacturing chains

“Conventional machining processes make it difficult to obtain consistent results with regard to accuracy,” explains Swiss Tec marketing executive Armando Casanova. “Also, they do not permit varying cutting geometries and tube dimensions within one batch to optimize material and stocks.” Therefore the first steps toward improving quality and performance in the supply chain are a high degree of precision and repeatability in the machining process and flexibility in applying it. But there is more. Casanova says, “Stents are cut one by one from long tubes that are fed into the cutting area. They are then dropped into a box and collected batchwise. Any allocation of a stent to individual processing parameters and any tracing or documentation of quality determining factors within the manufacturing process are impossible. In addition, the manual removal and subsequent time-consuming handling of the fragile stents poses an obvious danger to the integrity of the parts.”



**FIGURE 1. Life saver:**  
The expandable, intricate structures of stents stabilize weakened blood vessels

# medical devices



Swiss Tec AG

**FIGURE 2.** The six-axis robot can work side by side with operational staff, with no safety cage required.

## Traceability

The integration of an automated handling system from one processing step to the next is one way of keeping an eye on the parts. But because stents are manufactured in climate-controlled environments, manufacturing real estate is costly. It makes sense to use a robot that does not require an extra safety enclosure (see Fig. 2). Also, the operator has direct access for routine manipulations, and the manufacturing process does not have to be halted.

The robot in question has a reach of 500 mm and works with an accuracy of  $\pm 0.1$  mm—sufficient for the removal and placement of stents onto batch-specific trays. The cycle time for removal is 15 s, well below even minimal cutting times for stents (that is, 60 s).

Another way of tracing workpieces is to mark the parts with serial numbers or barcodes. This is common with larger parts, but can get tricky with microstructured pieces like stents. Only the most consistently operating, high-precision cutting and marking systems permit this approach.

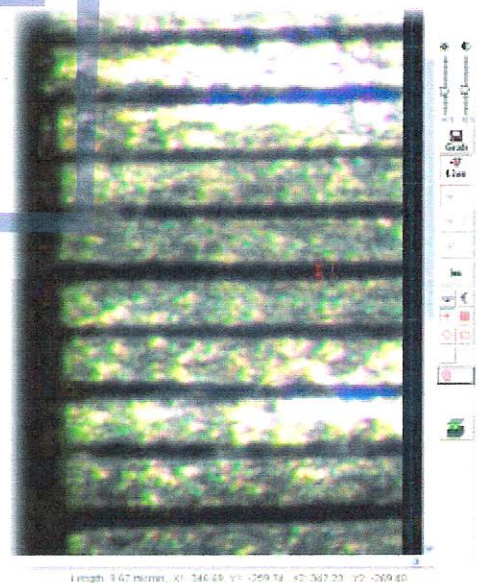
## Integration into the machining platform

To live up to the challenge, Swiss Tec's Micro-T13 and T15 tube-cutting platforms were adapted for high-performance industrial cutting and handling of small tubes (diameters of 0.2 to 8.0 mm and 1.0 to 20.0 mm, respectively). Their units

employ diode-pumped, 50W fiber lasers from SPI and state-of-the-art beam-delivery systems from Precitec, combined with their proprietary ultradynamic, upright motion systems to permit kerf widths of  $10 \mu\text{m}$  and positioning accuracies of  $2 \mu\text{m}$  (see Fig. 3). With this kind of delivery, engraving even  $200\text{-}\mu\text{m}$ -wide stent struts becomes a highly controllable process, which makes the system the tool of choice for the special manufacturing requirements of the latest stent generation.

This system, with its accuracy, repeatability, and speed ( $2000+$  mm/min), full processing data collection and interfacing ability (LAN access), advanced software for simulating and analyzing cutting geometry, wet cutting capability (to reduce heat-related issues), and fully automated ability to handle workpieces, comes closer to providing single-workpiece traceability than any

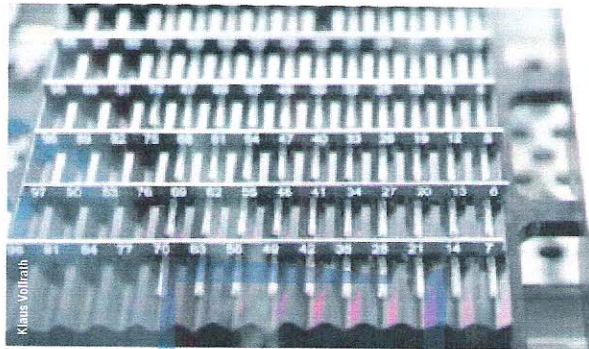
**FIGURE 3.**  $10\text{-}\mu\text{m}$  kerf width produced with a  $8\text{-}\mu\text{m}$  fiber laser spot size (tolerance/accuracy:  $2 \mu\text{m}$ )



other micromachining system. “We configured these machining platforms to work with robotic handling of individual workpieces as a standard. This way, if not already installed from the very beginning, the robotic option can always be included at a later stage, as all the interfaces are ready,” says Fassbind. The system can also be seamlessly integrated into a wider, automated manufacturing solution.

**Advantages**

The advantages of robotic handling are not limited to the quality of the product alone. The traceability of a single workpiece permits better management of tolerance variances and a reduction of waste, for example, by adjusting secondary processing parameters. Being able to identify a single workpiece allows for more flexibility in choosing the mix of individual stent types and cutting geometries, thanks to the direct allocation of the primary



**FIGURE 4.**  
Tray with cut stents.

processing parameters to a secondary processing step. The optimization of tolerances and repeatability allows for higher machining precision—a point of utmost importance for stents with pharmaceutical coatings (see Fig. 4).

“This approach to improving productivity by integrating fully automated, fully traceable manufacturing capabilities is unique,” explains Fassbind. “It will enable us to provide a complete tracking history for purposes of quality control, from the raw material to cutting, drilling, or welding processes, to polishing, heating, coating, inspecting, and so forth, and to packaging and shipping. Total quality management, already a standard in many high-tech industries like automotive or electronics, will finally also become a standard in the medical-device industry.”

*Klaus Vollrath is technical editor and Wulf Oppenlaender is a project manager for Swiss Tec, Zurich, Switzerland; www.swisstecag.com.*

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