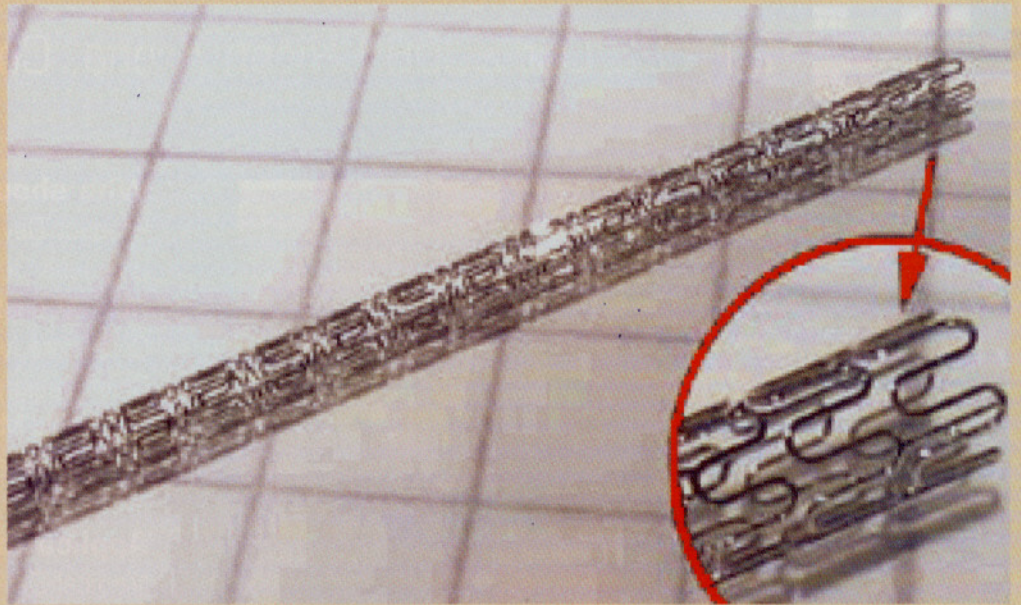


RIGHT  
A Stent and Close Up Detail



In the medical field, a wide range of new and intricate micro structures are in use. The most commonly known implant that uses laser cutting to manufacture an intricate microstructure is the medical stent.

The current manufacturing process for the manufacture of stents is characterised by batch manufacturing, with the added value operations linked by multiple manual operations. By definition, the batch-oriented quality assurance procedures are also batch and end of line inspection related and can lead to high rejection rates when a problem is identified.

In the medical market, the materials used are expensive, the processes demanding, and the time lost in the added value operations results in significant cost loading to the final manufacturing cost.

New developments in medical applications are calling for consistent quality and cost-effectiveness. The automotive industry has already developed the Six Sigma methodology DMAIC (Define, Measure, Analyse, Improve, Control) to enable high-speed, repeatable manufacturing, maintained accuracy, consistent quality, and traceability of automotive parts.

Six Sigma production levels are achieved by maintaining the process capability, and is a measureable property of a process to the specification, expressed as a process capability index ( $C_{pk}$  or  $C_{pm}$ ) or as a process performance index ( $P_{pk}$  or  $P_{pm}$ ).

The output of this measurement is usually illustrated by a histogram and calculations

that predict how many parts will be produced out of specification. For a Six Sigma process, the  $C_{pk}$  has to be  $\geq 2.0$ . So the Six-Sigma design process translates into a manufacturing process wherein 99.99966 % of the products made are defect free.

Six Sigma manufacturing requires a significantly higher degree of process control, accuracy, and repeatability. A key element for achieving these aims is a state-of-the-art, diode pumped fibre laser cutting system exhibiting speed, accuracy, and an outstanding level of process control capability.

"The emergence of new generations of stents creates the need for an in-depth redesign of the manufacturing process chain as a whole," claims Michael Giese, CEO of Eucatech AG, Rheinfelden, Germany, an innovative manufacturer of medical technology for interventional cardiology and radiology with a specific focus on stent systems and related application equipment.

### Stent Manufacturing Requirements

Stents are expandable metal grid structures used to stabilise weakened blood vessels, for example after the removal of clogging coagulations. Standard procedure for their application is introduction using a specialised catheter and a subsequent expansion by a ballooning tip section. Alternative technologies using memory effect alloys have also become available.

Stents are produced from thin-walled tubes

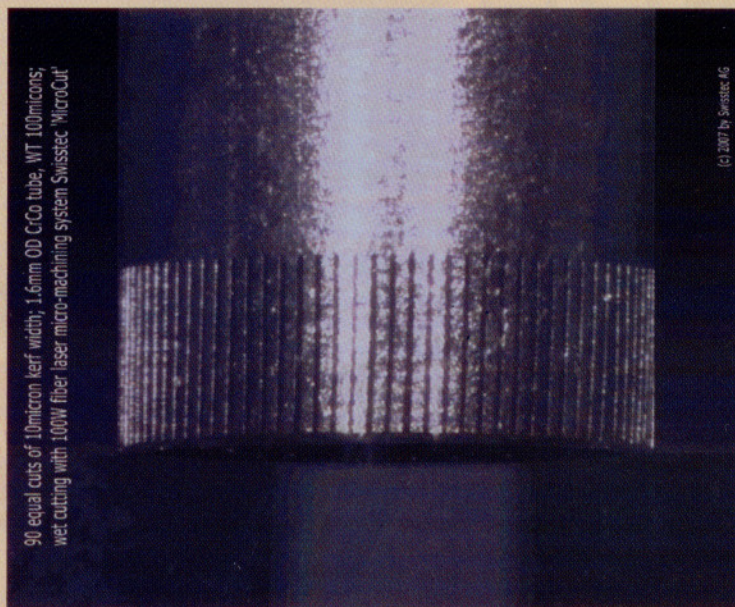
made of high quality metal alloys such as stainless steel, cobalt chromium alloys, or memory effect alloys such as Nitinol. The filigree, intricate grid structures that are the prerequisite for achieving their impressive diameter expansion ratios are produced using precision laser cutting micro machining technology. With the challenges resulting from new developments, manufacturers have to focus on the stability and uniformity of cutting process results.

As with any foreign material inserted into the body, a stent will interact with its environment, creating an irritation that might interfere with the healing process. New developments thus include stents with drug-eluting coatings consisting of a biodegradable matrix releasing suitable drugs such as Paclitaxel over a period of 8–10 weeks after insertion.

But this improvement also generates increased requirements that need to be met by manufacturing processes, as this automatically implies additional validations and approvals by bodies such as the US Food and Drug Administration (FDA). In order to ensure appropriate drug dosing, the FDA prescribes a very restricted scatter bandwidth for the total surface area of the stent, thus significantly narrowing manufacturing allowances from formerly some 15% to a mere 6–8 %. This is combined with the trend to further reduce strut dimensions from about 110  $\mu\text{m}$  to 60–85  $\mu\text{m}$ .

To meet these more exacting requirements, Eucatech upgraded its laser micro machining cutting systems (*define*) and

**RIGHT:**  
100W fibre laser micro-machining system



reassessed (*analyse*) the whole process chain layout. "In the long term, the current semi-industrial approach involving multiple manual operations and open loop, batch-oriented (*measure*) quality assurance procedures will have to be replaced (*improve*) by a monolithic, IT-based total quality management system involving fully automated and controlled process chains 'from tube to stent' without any manual interference," says Giese.

### Improved Laser Technology

Eucatech chose SwissTec AG to supply the high precision, laser micro machining system. "The laser cutting process marks the very start of the whole process chain — and is crucial for its ultimate success," says Eduard Fassbind, CEO of SwissTec.

To achieve a Six Sigma process capability of  $C_{pk} > 2.0$  in the laser cutting process, and using Six Sigma design methodology (DMAIC), SwissTec selected the Micro-T15, a specialised tube cutting, drilling and welding plant equipped with a 50W diode-pumped "red Power" fibre laser, from SPI.

To meet the customer's requirements (*define*) for high precision stent production on an industrial scale, all components (granite base structure, linear drive x-axis, laser forming/ focusing system, IT control system) in the Micro-T15 (*control*) are designed for high reliability, repeatability, accuracy and virtually maintenance-free 24/7 production service.

Using a laser that can be focused to a spot size of 10–12  $\mu\text{m}$  achieves a cutting speed of

800–1200 mm/min, and maintains the required process capability. If internal liquid cooling of the work piece is employed, the cutting speed can rise to  $> 2.000$  mm/min.

"Among the features we welcome most with the new plant is the transition (*improve*) from lamp pumping to diode pumping technology," says Giese. "Apart from their rather limited service life of some 2000 hours, lamp drift influences the characteristics of the laser beam resulting in unstable processing results. All too often, we were producing batches with substandard products or even out of tolerance products after only a few hundred hours of service. Production then had to be halted and could only be resumed after the laser system had been thoroughly readjusted, a task that could easily take more than a full shift's time span and required the involvement of highly qualified — and accordingly highly paid — specialists."

Using the fibre laser, downtimes (*measure*) have been halved, machine usability has jumped to well above 90%, and the share of out of tolerance (*analyse*) products has dropped significantly. On top of this comes the superior processing speed of the new system, producing stents in just half the time of the old plant. The overall result is a substantial rise in the output of marketable products per unit and per day (*control*).

### Process Capability in the Process Automation

"The new laser cutting system is just the first step to a completely automated production chain," explains Giese. Another key

component is a fully automated optical inspection station that is capable of performing — unmanned — 100% optical quality assessments of the inside and outside geometry of stents with a resolution of just 1  $\mu\text{m}$ . This unit is used twice, first for an assessment of the stent geometry immediately after laser cutting, and again after the stent has passed further production steps including electro polishing and heat treatment.

The results of the inspection provide feedback to the laser cutting and electro-polishing units enabling them to continually optimise production parameters. Eucatech already operates five fully automated stent production chains together in a laboratory environment, which will soon be complemented by further plants as well as by robot handling and conveying systems.

Of course, realising full automation may bring unexpected difficulties. Under such circumstances, all parties involved are called to team up in an ongoing innovation process. "This aspect played a key role when we selected SwissTec as the supplier for our laser equipment," reveals Giese, adding that "this decision was founded on mutual confidence resulting from the experience of six years of close cooperation."

#### SwissTec

Contact: Alan Boor

T: +44 (0)1491 57 91 18

F: +44 (0)1491 41 22 11

E: [sales.uk@swisstecag.com](mailto:sales.uk@swisstecag.com)

W: [www.swisstecag.com](http://www.swisstecag.com)