Case Study

Towards automation of stent manufacture

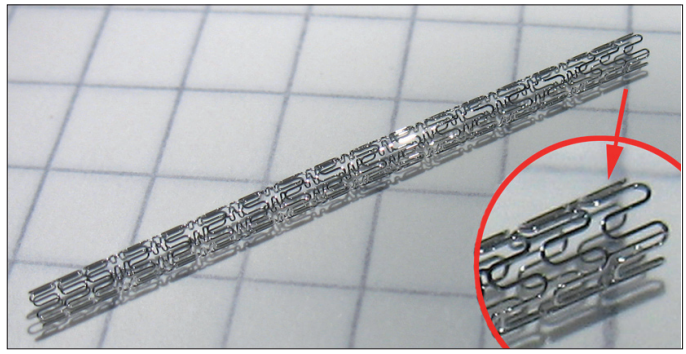
Current process chains for the manufacture of stents are characterized by multiple manual operations and open loop, batch-oriented quality assurance procedures. New developments call for more uniform stent characteristics and thus for a significantly higher degree of process control. A key element for achieving these aims is a state of the art diode-pumped fibre laser cutting system excelling by 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 in 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 stabilize weakened blood vessels e.g. after removal of clogging coagulations. Standard procedure for their application is the introduction using a specialized catheter and a subsequent expansion by a ballooning tip section. Alternative technologies using memory effect alloys have become available as well. 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 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”, said Dr Giese. New developments thus include stents with drug-eluting coatings consisting of a biodegradable matrix releasing suited drugs such as Paclitaxel over a period of 8-10 weeks after insertion. But this improvement also generates higher requirements to be met by manufacturing processes since 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 latter 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%. Together with the trend to further reduce strut dimensions from about 110 µm to 60-85 µm.



To meet these more exacting requirements, eucatech upgraded their laser cutting systems and reassessed the whole process chain layout. "In the long term, the current semi-industrial approach involving multiple manual operations and open loop, batch-oriented (=“post mortem”) quality assurance procedures will have to be replaced by a monolithic, IT-based total quality management system involving fully automated and controlled process chains “from tube to stent” without any manual interference," said Dr Giese.

Improved laser technology

Eucatech chose Swiss Tec AG to supply the high precision micro laser machining system. “The laser cutting process marks the very start of the whole process chain – and is crucial for its ultimate result”, said Eduard Fassbind, CEO of Swiss Tec.

The unit selected was the micro-T15, a specialized tube cutting, drilling and welding plant equipped with a 50W diode-pumped “redPower” fibre laser from SPI. To meet the requirements 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) are designed for virtually maintenance-free 24/7 production service. A laser focus spot size of 10-12 µm achieves a cutting speed of 500-600 mm/min, expected to rise to >1.000 mm/min if additionally internal liquid cooling of the workpiece is employed.

“Among the features we welcome most with the new plant is the transition from lamp pumping to diode pumping technology”, says Dr Giese. "Apart from their rather limited service life of some 2000 hours, lamp drift influenced the characteristics of the laser beam resulting in unstable processing results. All too often we were producing batches with substandard or even out of tolerance products after only a few hundred hours of service. Production then had to be halted and the laser system thoroughly readjusted, a task that could involve considerable time and cost in the use of a highly qualified specialist.

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

Process automation

“The new laser cutting system is just the first step to a completely automated production chain”, explains Dr Giese. Another key component is a fully automated optical inspection station that is capable to performing unmanned 100% optical quality assessment of the inside and outside geometry of stents with a resolution of just 1 µm. 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 three of the decisive plant types of its future fully automated stent production chain. Their current arrangement in a common lab will be complemented by further plants as well as by robot handling and conveying systems.

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

Contact: Eduard Fassbind, CEO
Swiss Tec AG
T: +41 41 790 3385
E: e.fassbind@swisstecag.com
W: www. swisstecag.com

UK representative: John Cocker
T: 01246 267714 E: johnc@lasertrader.co.uk