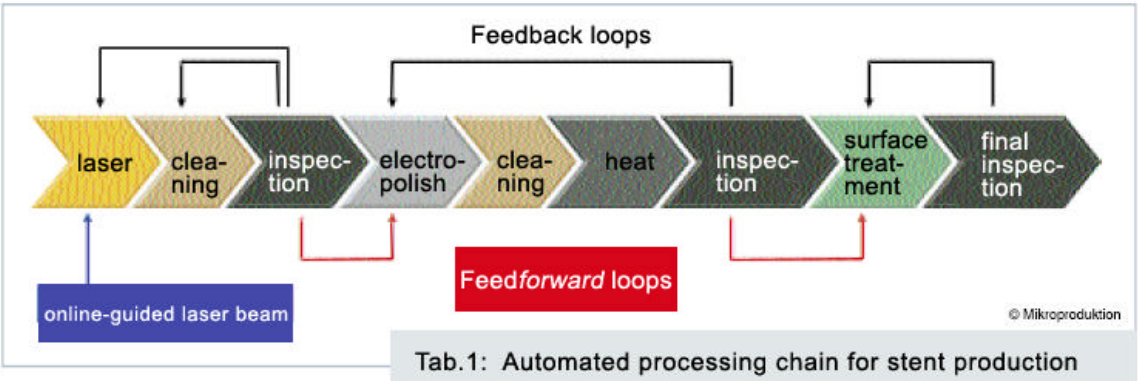
Process management in stent manufacturing

Getting More Through-Put with Automated Inspection



Tab.1: Automated processing chain for stent production

Supply chain processes involving cardiovascular implants commonly include as many control stops as there are machining steps. Several manual inspections are necessary to keep the geometry consistent and to establish a reliable account of surface properties.

As medication eluting stents are becoming the industry standard, and the reproductibility of medicational dosage is becoming an important requirement, the ability to perform highly accurate dimensional measurements is very high on the priority list of manufacturers. Also, surface properties of implants play a major role in minimizing irritations of the vascular system, once the medication tapers off.

To live up to these challenges and to be able to secure the efficiency and reliability of the machining process, eucatech, a company in Rheinfelden, Germany, developed an application standard for a new concept of automation.

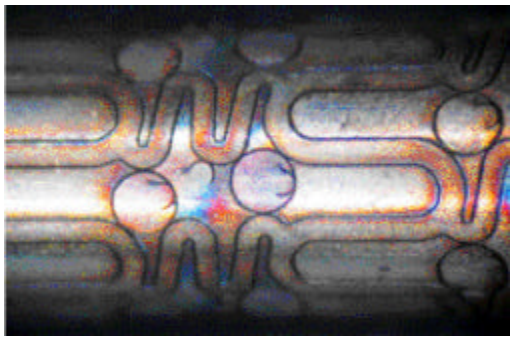
Automated Process Monitoring	*vs.*	**Manual Process Monitoring**
- total quality management with electronic, 100% traceability		- 100% traceability of process with printed documents (protocol)
- automated, user-independent inspection		- manual inspection by user
- integrated monitoring process		- single step monitoring process

The advantages of Automated Process Monitoring are obvious: Higher productivity, higher through-put, significantly lower production cost. But there is more: The inspections are user-independent and all processing steps are intricately interwoven. Thanks to automatic feed back and feed *forward* data within the supply chain, great economics of scale as possible.

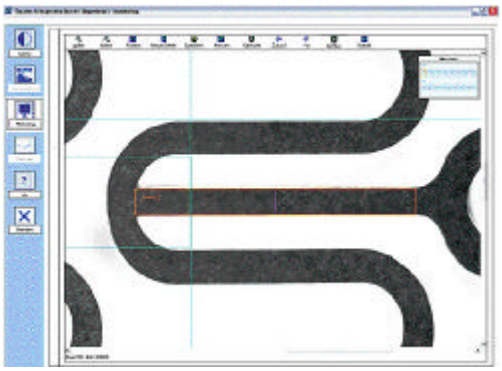
The processing chain shown in tab 1 is entirely controlled by feed*back* and feed*forward* loops. In this case, a fully automatic processing chain for stent production has been created, including laser cutting, automated inspection after laser cutting, automated heat treatment and automated final inspection (geometric consistency, surface analysis inside and outside).

Fiber Laser with a Kerf Width of 10 Microns

In order to achieve top results with laser cutting, the plants in this processing chain are equipped with fiber lasers by *SPI Lasers*, Southampton. Fiber lasers provide a highly consistent light source and a kerf width of 10 µm (microns). This makes for an accuracy of outline of +/- 3 µm and a cutting speed of between 500 and 700 mm/min.



The automatic inspection of geometry works with a resolution of 1 µm, which means that on an industrial production scale for stents, reliable monitoring of accuracy of outline is possible. In addition, the statistical analysis of the stent production is made possible, which describes the process of laser cutting in great detail. For example, potential thermal variances are analyzed, so that NC programs may be optimized still in the prototype stage. During the final inspection after heat treatment, surface deficiencies are detected and analyzed with individually defined 'defect modules' in the software. The analysis provides feedback about possible damages occurring during electro-polishing or heat treatment (tab 3).



The experience gained so far with this project is a good indicator for the feasibility of fully automated inspections and for an enormous potential of cost reduction. The time for the final surface inspection for stents between 8 and 38 mm long is between 1.0 and 1.25 minutes respectively. The process of electro-polishing may be individually re-adjusted according to the insights gained from the inspection after laser cutting, and the analysis of the final inspection after heat treatment provides important data to improve the following process of surface coating, e.g. geometric consistency and exact weight.

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