Emphasis On Automated Inspection

Achieving Greater Through-Put Utilizing Automated Inspection

Implementing inspection procedures into the medical device manufacturing cycle helps to ensure a successful outcome through enhanced quality control and effective oversight of delicate processes. By automating these, companies take advantage of additional benefits. This article looks at the gains involved with automating inspection processes, specifically in the example of stent fabrication.

By Dr. Gregory Flinn

Supply chain processes involving cardiovascular implants commonly include as many control steps 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 stent cutting geometry is becoming more and more complex, and the reproducibility of precision cuts an important requirement, the ability to perform highly accurate dimensional measurements is very high on the priority list for manufacturers. Also, reliable machining capabilities translate into cost effective manufacturing standards.

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.

> Reliable machining capabilities translate into cost effective manufacturing standards.

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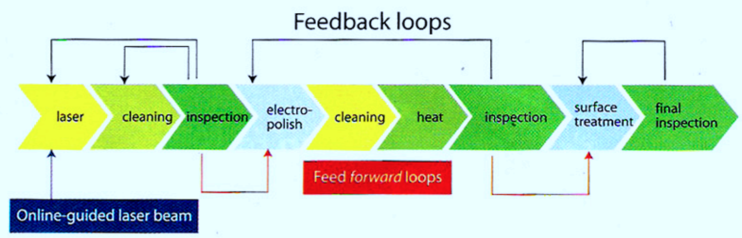
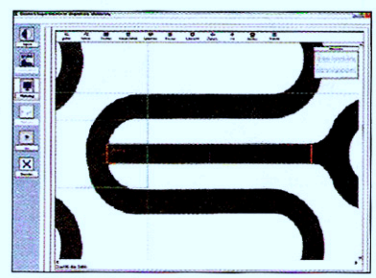


Automated processing chain for stent production

The advantages of automated process monitoring are obvious—higher productivity, higher throughput, and significantly lower production cost. But there are additional benefits. The inspections are user-independent and all processing steps are intricately interwoven. Thanks to automatic feedback and feedforward data within the supply chain, economics of scale are able to be observed.

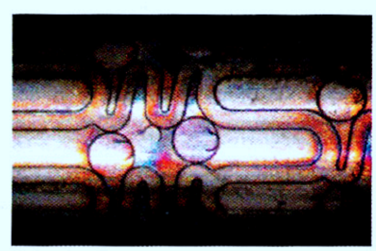
The processing chain shown in the illustration is entirely controlled by feedback and feedforward loops. In this case, a fully automatic processing chain for stent production has been created, including laser cutting, automated inspection after laser cutting, automated heat treatment, and automated final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



Sophisticated analysis provides feedback about possible damages occurring during electropolishing or heat treatment.

Fiber Laser Cutting Capability

In order to achieve the desired level of results with laser cutting, the plants in this processing chain use state-of-the-art machining equipment by Swiss Tec, an emerging Swiss manufacturer of high performance micro-machining workstations. The stations are equipped with fiber lasers providing a highly consistent light source and a kerf width of



Actual cutting result on chrome cobalt tube with a 1-micron-tolerance (contour fidelity)

Automated Process Monitoring	vs.	Manual Process Monitoring
• Total quality management with 100% traceability for electronic data	vs.	100% traceability of process with printed documents (protocol)
• Automated, user-independent inspection	vs.	Manual inspection by user
• Integrated monitoring process	vs.	Single step monitoring process

10 µm. This enables an accuracy of outline (contour fidelity) of ±3.0 µm and cutting speeds of between 600 and 1,200 mm/min., depending upon the materials used.

The automatic inspection of geometry works with a resolution of 1.0 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.

The experience gained so far with this project is a good indicator as to the feasibility of fully automated inspections and for an enormous potential in cost reduction.

Conclusion

The experience gained so far with this project is a good indicator as to the feasibility of fully automated inspections and for an enormous potential in 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 readjusted 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 final process of surface coating (e.g., geometric consistency and exact weight).

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- www.eucatech.de
- www.swisstecag.com