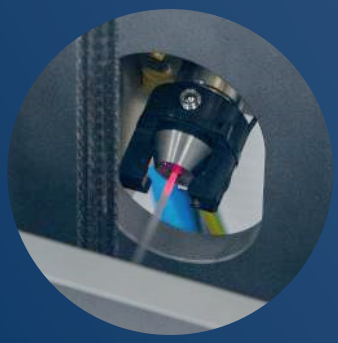

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Case study

Dry-cleaning of medical Stents for Bentley InnoMed GmbH

acp systems AG -
technology leader for advanced clean production

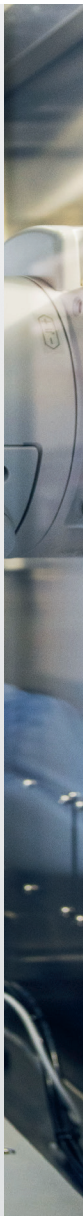
Subject of the case study

Bentley InnoMed GmbH are a medical technology company with a product portfolio of stents, in different matrix sizes, for minimally invasive treatment of vascular afflictions. In stent technology, Bentley is represented in more than 70 countries and is the market leader in some of them. Complex geometries and high cleanliness requirements make the cleaning of stents a particularly demanding task in the medical industry (healthcare sector). acp systems AG has solved this problem with a new product featuring quattroClean® snow jet technology.

Requirement

A new development of a stent system made of superelastic Nitinol, requires laser structuring, heat treatment and electropolishing. To comply with quality control, these processes need to be completed with a cleaning process on the both the interior and exterior surfaces to remove particles and chemical contaminants from the implant. Due to a complex filigree structure and tight radii of the new implant geometry, existing cleaning methods were not possible. Therefore, an alternative, reliable, repeatable method of cleaning, with minimal manual intervention was required.

quattroClean
technology



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CO_2 snow-jet cleaning

Objectives in manufacturing
Dry, particle and film free products

Features & benefits
- Dry, chemical-free cleaning
- Fast & efficient (no drying cycle required)
- Residue free
- Selective
- No chemicals or wastewater
- Kind on the environment (recaptured CO_2)
- Manual or automated

Solution

The solution was found with acp 'quattroClean®' technology from cleaning trials completed at the acp technical center in Germany, which needed to satisfy Bentley that the challenging cleaning requirement could be achieved – consistently. The cleaning medium, from recaptured sources, is liquid phase, non-corrosive, inert, carbon dioxide (CO_2) which has practically unlimited shelf life with both a bacteriostatic and fungistatic effect. This is supplied to the process from a maintenance-free, two-component nozzle from a high purity media system to meet high product cleanliness requirements. Liquid phase CO_2 expands on exiting the nozzle to form fine CO_2 snow, which is then accelerated by a contained jacket of compressed air to supersonic speed. This focused jet of snow and compressed air impacts the surface to be cleaned, triggering a quattroClean® combination of thermal, mechanical, sublimation and solvent effects. The interaction of these four effects removes particulate and filmic contamination in a reliable and reproducible process, whist being gentle enough not to damage delicate and finely structured surfaces.

Automation

acp configured a standard cleanroom compatible, mini-environment cleaning cell (acp JetStation®) with the required tooling, automation, and extraction to repeatably clean the stents with parameters that were validated from the cleaning trials. These parameters included the media flow rates, timing, temperature, contact angle, movement sequences, and number of process nozzles to achieve the cleaning specification in the required cycle time.

Stents are manually loaded into the cleaning cell on trays, each with a capacity of 30 product-specific carriers.
A cleanroom robot pick-and-places one stent at a time from a custom mount and inserts it into the process chamber. There, two diametrically opposed nozzles apply jets to the rotating implant. Forces of the jet and a powerful extraction unit continuously removes the detached contaminants from the stent from within the process chamber. Since frozen crystalline CO_2 sublimes completely to gas during the cleaning process, the implants dry immediately, without any residues.After the cleaning process, the stents are removed and packaged into the catheter for sterilization.

Monitoring

To ensure the high quality of the process, the consistency of the jet from each nozzle is monitored continuously with an optical sensor. The supply of CO_2 and compressed air to the nozzles is monitored, as is the length of time the jet is applied. This production data is recorded automatically and uploaded to a higher-level quality control system for subsequent validation and quality tracking.

Summary and Testimonial

Medical engineers at Bentley were able to work together with engineers at acp to develop a reliable automated dry-cleaning solution for stents.

"Together with acp, we have developed a cleaning solution that consistently meets our requirements and is easy to use," summarizes Hansjörg Haller, Bentley InnoMed GmbH.

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