SIMCO ION™
An ITW Company

Life Sciences Market
CASE STUDY

Reducing Contamination, Improving Efficiency

Stent Manufacturer

A Stent Manufacturer in advanced cardiovascular and peripheral stent manufacturing, successfully mitigated static and particle contamination issues, enhancing product quality, operational efficiency, and regulatory compliance. By implementing targeted contamination-control strategies aligned with rigorous ISO 14644 cleanroom standards, the manufacturer achieved a significant 30% reduction in contamination-related defects, ensuring product integrity and patient safety.

Problem

- Static-induced particle attraction causing contamination of critical components.
- Regulatory risks due to approaching contamination thresholds (ISO 13485 and FDA standards).
- High defect rates, increased waste, and reduced production yields.
- Operational inefficiencies from frequent cleaning and production rework.
- Root causes included inadequate static control, suboptimal air filtration and cleanroom design, and inconsistent operator handling practices.

Solution

- **Static Mitigation Measures**: Room ionization grids, ionizing bars within laminar flow hoods, overhead ionizing blowers, and hand-free ionizing guns were installed in final packaging areas. Conventional materials were replaced with static-dissipative alternatives.
- **Enhanced Cleanroom Protocols**: HEPA filters were upgraded for increased efficiency (capturing particles down to 0.3 microns), and airflow patterns were optimized to reduce turbulence.
- **Operator Training and Standardization**: Mandatory cleanroom behavior training was provided alongside real-time particle monitoring systems.
- **Advanced Cleaning Systems**: Ultrasonic cleaning systems and automated cleaning stations with integrated particle collectors and ionization tools were installed.

Results

- 30% reduction in contamination-related defects within six months.
- 20% improvement in production yield.
- Passed ISO 14644 audits with zero findings.
- Enhanced reputation and increased customer trust.
- Streamlined production processes, reducing downtime and manual cleaning requirements.

Key Takeaways

- Proactive adoption of static mitigation technologies.
- Comprehensive approach integrating equipment upgrades, operator training, and cleanroom enhancements.
- Continuous monitoring enabling data-driven decision-making.

By systematically addressing static and particle contamination, [Stent Manufacturer] significantly improved its manufacturing efficiency, product quality, and regulatory compliance. This case study highlights the importance of adopting advanced technologies and proactive management practices within medical device manufacturing.