

Validation of Automated Passivation and Final Cleaning for Medical Implants

As an industry leader in the contract manufacturing of medical implants and devices, Norman Noble has the most advanced technologies, including fully automated and validated Passivation and Final Cleaning processes. These advanced systems improve productivity, product quality, product consistency, operational safety and reduction of environmental waste.

FDA part cleanliness specifications frequently require devices ship with the final clean operation performed in a fully-validated (IQ, OQ, PQ) cleaning process. Norman Noble customers benefit from knowing their products can be cleaned in a fully- validated process to established acceptance testing limits. The validation for final cleaning was performed in accordance with newly-released ASTM specification F3127. The scope of testing completed for passivation and the final clean validations included residual materials, particulate size analysis, cytotoxicity, total organic carbon, endotoxins, corrosion resistance and more. The ASTM cleaning validation specification includes the requirement to complete a risk analysis of all upstream process variables that may affect the final cleanliness of a product. We completed this risk assessment and performed the validation activities using various material types common in Norman Noble manufactured components, such as stainless steel, titanium, PEEK, cobalt chrome and nitinol.

BENEFITS FOR MEDICAL OEMS: Norman Noble's cleaning validation documentation (Strategy, IQ, OQ and PQ) have been completed in a format that can be shared with customers and includes a matrix of small to large part sizes, shapes and geometric complexities produced from many medical implant material grades. This allows customers to review the validation process, documentation and test results in detail. Norman Noble's customers can compare this information to their current or proposed cleanliness specifications. In many cases this gap analysis will show *the Norman Noble cleaning validation process fully satisfies customer requirements for specification and regulatory compliance.*

AUTOMATED PASSIVATION: Our nine tank system includes the following operations: alkaline clean, nitric passivation (per ASTM A967, ASTM F86 and AMS 2700), citric passivation (per ASTM A967), deionized water rinses and HEPA-filtered downdraft drying.

AUTOMATED FINAL CLEANING: Our five tank system includes the following operations: alkaline clean, deionized water rinses and HEPA filtered down draft drying. This technology includes automated control of the passivation and cleaning system operation with real-time process monitoring, scanning of product documentation for each manufacturing lot processed, and manufacturing lot specific process records. The fully-automated systems monitor cleaning and rinse tank temperatures, conductivity, and pH during system operation to verify each manufacturing lot meets the criteria established for cleaning of the specific product. The systems are recipe-based with global cleaning recipes locked per validated parameters.

ENVIRONMENTALLY CONSCIOUS: In addition, Norman Noble has invested in an FDA 510(k)-approved deionized water treatment system to support the automated passivation and final clean systems and other process bath makeups. The deionized water treatment system is maintained and disinfected on a regular maintenance schedule and the water quality is tested to ASTM water quality standards. The deionized water treatment system also includes real-time process monitoring of outgoing and return deionized water flowing through the continuous flow loop within Norman Noble's operations.

Norman Noble remains committed to manufacturing the highest quality products using cutting-edge, advanced technology. Our automated systems provide our customers a fully-validated final clean process required for next-gen medtech devices and implants.

ABOUT NORMAN NOBLE, INC.

Established over 70 years ago, Norman Noble, Inc. remains a family-owned and -operated company offering the most advanced processes for ultra-precision micromachining. The company is known for its exceptional quality, production capacity and ability to fabricate medical implants and devices beyond the reach of most manufacturers. Norman Noble, Inc. is a strategic partner with most of the largest OEM's and well-known names in the medical device industry.

Norman Noble manufactures medical implants and devices to customer specifications in compliance with FDA regulations and ISO 13485. We offer validated manufacturing processes for Vascular Implants and Orthopedic Implants. State-of-the-art processes include laser machining and welding, Swiss turning, CNC milling, conventional and wire EDM, high-speed 7-axis contour milling, Nitinol shape setting and clean room assembly and packaging. Prototype services are available in separate and fully dedicated process development centers. FDA Registration #1531050. For more information, please call **1.800.474.4322** or visit **www.nnoble.com**.

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