

Medical Implants



Branson's Benchmark sets the standard for precision cleaning of medical implants.

Background

The health needs of an aging population, combined with ongoing advances in materials, manufacturing, and technology, have dramatically increased the use of medical implants.

Replacement knee, hip, and shoulder joints, plates, rods, screws, staples, and mesh are being used more than ever to repair and replace injured or deteriorated joints and other orthopedic structures.

Implants are being manufactured with an increasing variety of materials, including specialty plastics, stainless steel, ceramics, and high-strength metals such as titanium, zirconium and cobalt-chrome.

And in addition to being made from materials that are compatible with human physiology, implants must be completely bioburden- and contaminant-free. There is no margin for error, as the cost of ineffective cleaning can be staggering.

Challenge

Effective implant cleaning can be challenging. The variety of materials in use, complex graft-surface geometries, and multi-metals of medical implants make them uniquely difficult to clean.

The wide variety of soils – from machining coolants, to polishing and buffing compounds, to oils from handling, and microscopic environmental contaminants – must be eliminated before an implant can be considered ready for use. And cleaning processes need to meet the challenges of economy, efficiency, and automation to minimize the potential for operator error.

Implant materials of construction, the complexity and preciseness of their design, and the types of contaminants an implant may be exposed to are all key factors in choosing the proper precision-cleaning process.

In addition, both the equipment used and the chemistry of the cleaning solution must meet FDA guidelines. And the final results of cleaning must satisfy various industry quality standards.

(continued on back)

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Solution

Branson's breadth of experience and expertise in precision cleaning can provide the ideal solution for the intricate cleaning demands of medical implants. The Benchmark cleaning system offers state-of-the-art quality and engineering flexibility capable of delivering a fully automated, computer-controlled system employing up to 14 tanks.

There are five important considerations with precision-cleaning implants to meet the quality standards of manufacturers, the performance needs of users and strict guidelines of the FDA.

- **Ultrasonic Cleaning:** Precision cleaning can be aqueous or solvent-based or a combination of the two. Various cleaning chemistries can be used to comply with FDA guidelines.
- **Ultrasonic Rinsing:** Overflowing rinsing with de-ionized (DI) water is provided at all appropriate points in the process.
- **Passivation:** Nitric or (more recently) citric acid chemistries can provide maximum corrosion resistance of passive oxide film to meet ASTM A 967 or A 380 standards.
- **Drying:** Re-circulating hot-air drying is typically required.
- **Data Acquisition:** A control system can be incorporated to capture key operating parameters and provide an audit trail to ensure that each part or batch went through the process properly.

Plus, the Benchmark system offers a variety of options to customize the installation to any application:

- Ability to automate all or part of the cleaning process.
- Custom tank sizes.
- Optional methods for monitoring and maintaining proper liquid levels and chemical detergent concentrations.
- Sanitary plumbing.
- HEPA filtering for hot-air drying.
- Pilot-scale process development for testing prior to full-scale implementation.
- On-site water de-ionization capabilities.
- Clean-room compatibility.

Results

With Branson's Benchmark system, you can be assured that your precision-cleaning process will meet your requirements, those of your customers, and the FDA.

Branson has pioneered many of the processes that have become industry standards. And with numerous precision-cleaning systems installed worldwide, you are working with experts who have the knowledge, experience, and creativity to help you customize just the right cleaning system for your application.