Tech Article

Two Ways to Boost Cleanroom Manufacturing Efficiencies

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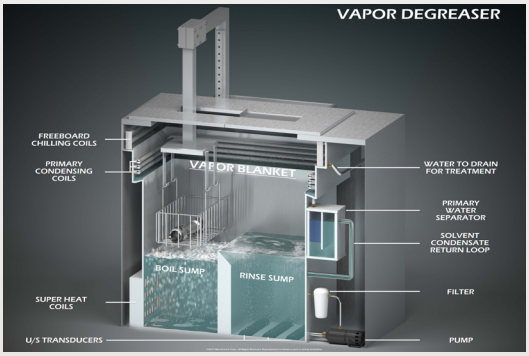
Industry: Medical Device

Published:
Cleanroom Technology



Modern cleaning fluids, when used inside a vapor degreaser, provide consistent and reliable device cleaning.

There are two ways to boost cleanroom manufacturing efficiencies. Cleaners and carrier fluids.

Many medical device manufacturers need production materials that not only work efficiently, but are also cleanroom compatible. In addition, they must stay profitable without compromising product quality or their customer's requirements. They must meet stringent quality controls and support validated cleanroom manufacturing processes all while maintaining the bottom line. Modern cleaning and carrier fluids meet all of those demands. They help cleanroom production managers produce medical devices more quickly and efficiently.

Vapor Degreasing

Nearly all medical devices require cleaning during manufacture. It is important to remove particulate, oils or inorganic contamination resulting from the manufacturing process. Most medical devices require high levels of cleanliness. This is to ensure proper sterilization of finished product and ultimately patient safety and product performance. This is especially true for those with complex assemblies, intricate shapes and delicate parts.

Modern solvent-based cleaning fluids, when used inside a vapor degreaser, provide consistent and reliable device cleaning. Another major advantage of using a vapor degreaser is the small footprint relative to the amount of production output. A small footprint means the vapor degreaser takes up less space. Yet it sustains high output, allowing for lower overall operating costs in the expensive cleanroom environment.

Modern Vapor Degreasing Fluids

The unique low-boiling cleaning fluids feature high densities, low surface tensions and low viscosities. Together with a vapor degreaser, these factors combine to completely dissolve contaminants and remove particulate. In addition to thorough cleaning, modern cleaning fluids offer these added benefits.

Fast Drying for Higher Throughput

When used with a vapor degreaser, modern cleaning fluids do not get trapped in tight spaces or deep grooves inside the devices. The parts come out of the vapor degreaser clean and dry without any residue, spots or stains. Plus, they leave the degreaser ready for the next step in the process – whether sterilizing or coating. When applying coatings or ink-based markings, it's imperative that the parts are completely clean and dry before applying. The presence of water, moisture, oils or particulate on parts after cleaning negatively impacts the coating quality. It may lead to expensive rework or scrapping of parts.

High Purity for Easier Process Control

Unlike aqueous cleaning that requires engineers to ensure the chemistry of water, detergents, and other additives are consistent and bioburden-free, modern solvent-based cleaning fluids in a vapor degreaser remain consistently pure. Plus, there is no stabilizers or acid acceptance testing as with older chlorinated solvents. Since there is no need for complicated process controls at every stage in the cleaning process, production managers get peace of mind that there is no variation in the cleaning fluid chemistry. This makes initial

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Modern cleaning fluids have excellent materials compatibility for use on a wide range of medical devices.

Universal Carrier Fluid make ISO-10993 certification easier because it dries without residue and is compatible with most sterilization processes.

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product validation, and ongoing process controls for operation of the cleanroom much simpler and less costly.

Non-Pyrogenic for Better Sterilization

Many conditions can cause bioburden, but water is the primary growth medium for bacteria. Even trace amounts of moisture can allow the growth of bacteria and create related bioburden issues. This compromises the ability to properly sterilize the medical devices prior to shipment. Modern solvent-based cleaners do not contain any water, ensuring a pyrogen-free cleaning environment. This simplifies subsequent device sterilization. It also eliminates the potential of recleaning, repackaging, or even scrapping devices affected by bioburden, ultimately reducing time and expense.

Good Materials Compatibility for Safer Cleaning

Today's sophisticated medical devices are made from a variety of materials. These include metals, ceramics, and plastics. Although metals, especially stainless steel, titanium, and nitinol are preferred materials for many device applications, device designers are also using a wide range of polymers including polypropylene, polyethylene, and polystyrene as well as nylon, polyethylene terephthalate (PET), polyimide, polycarbonate (PC), acrylonitrile butadiene, polyether ether ketone (PEEK), and polyurethane. In addition, devices constructed with mixed materials of metals and polymers is also common. Modern cleaning fluids offer high enough solvency (or Kb value) to selectively clean contaminant from the devices without damaging substrates or dislodging delicate components. Production managers can confidently choose a single cleaning fluid that effectively cleans all materials without damage, therefore streamlining processes and reducing cleaning fluid inventories.

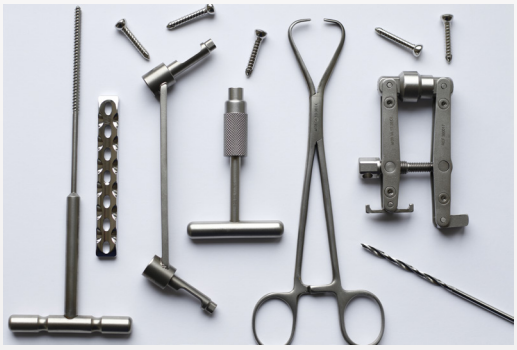
Easily Recycled for Less Waste

Lastly, modern cleaning fluids constantly recycle through the vapor degreaser. The cleaning fluid is purified, recycled and re-used hundreds or even thousands of times without fine-tuning the formulation. This ensures consistency without any unexpected variances to manage. Plus, when it is time for disposal, the vapor degreaser concentrates the soil and contaminants, minimizing the amount and frequency of waste disposal.

Modern Carrier Fluids for Coating

Vapor degreasing not only cleans effectively, it also creates opportunities for other clean room manufacturing efficiencies. For example, it is possible to design vapor degreasing cleaning equipment with a second-step surface treatment for the application of a lubricant or a specialty film. Both processes may be done in line, again saving on valuable and expensive cleanroom floor space. Vapor degreasing systems are not geometry-sensitive, meaning if the components will fit in the machine, the machine will clean or coat it. This is beneficial because it reduces the need for expensive fixtures. It is an extremely forgiving process even when cleaning and/or coating large quantities of parts.

Currently there are a number of modern fluids with formulations which multi-task in other applications beyond cleaning. The most common is a cleaner that may also serve as a carrier fluid for the application of medical-grade lubricants like PTFE, silicone or even pharmaceutical surface treatments. Such processes



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are finding common use in the manufacture of hypodermic needles and needles for sutures. These modern, advanced fluids are typically nonflammable, making them safer in the cleanroom, and much less risky for handling and storage. It's easy to see why these nonflammable fluids are a preferred choice of production managers and environmental health and safety officers alike.

Conclusion

Modern cleaning and coating fluid technologies and associated vapor degreasing equipment have brought new attention to their value in manufacturing medical devices. They are ideal for cleanroom manufacturing and assembly areas and comply with both strict bioburden and process controls.

Perfecting and validating a cleaning method that works effectively on intricate parts is vital to ensure patient safety and reliable cleaning validation. Modern vapor degreasers, when used in combination with nonpyrogenic cleaning fluids are an excellent way to clean and coat parts effectively and without introducing bioburden. They are also a safe and effective carrier fluid for deposition of silicone, PTFE lubricant and pharmaceutical coatings. Many modern cleaning and carrier fluids make required ISO-10993 certification easier and because they quickly dry from parts without any reside, are fully compatible with most sterilization processes.

However, it is important to work with a cleaning and carrier fluid supplier who has experience in the special requirements associated with manufacturing in cleanroom environments and have technical engineers who work closely with end-users at the design stage of a project to ensure they are specifying the best product for their applications. When specifying a cleaning or carrier fluid, look for a supplier that can provide expert advice. One who helps simplify the selection process, provides lab testing, and offers multiple options such as off-the-shelf and customized formulations to ensure selection of the right cleaning or carrier fluid for your specific needs.

About the author:

Jay Tourigny is Senior Vice President at MicroCare which offers precision cleaning, lubricating and debinding solutions. He has been in the industry more than 30 years and holds a BS from The Massachusetts College of Liberal Arts. Tourigny holds numerous U.S. patents for cleaning-related products that are used on a daily basis in medical, fiber optic and precision cleaning applications. For more information, visit microcare.com

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