

Top trends impacting medical device design and products finishing

Smaller devices mean bigger parts cleaning challenges

Ongoing advances in medical device design are meeting patients' demands for more portable and wearable medical devices. External health devices, or those worn outside the body, are getting smaller and lighter. Bulky devices like ECG monitors, spinal stimulators and insulin pumps are now tiny and discrete. The patient benefits of these advances can be life-changing with improved physical comfort and mental well-being. However, for manufacturers, building these new miniature, complex devices can be a challenge.

Smaller devices require thorough cleaning

Medical devices must be cleaned and dried to the highest standards and to ensure their readiness for the next step in the manufacturing process. Production debris like machining, stamping or cooling oils, dust, metal filings, marking inks, fingerprints and other soils must be removed prior to assembly, packaging, sterilisation or coating. Any remaining particulate or residue can lead to inconsistent outcomes and have an impact on the devices' performance.

Smaller medical devices have smaller spaces that can be more difficult to clean

and dry during manufacturing. They often include intricate shapes and tight crevices, all of which makes cleaning particularly difficult. In addition, modern devices are made with more delicate parts and varied materials. Softer plastics and lightweight metals can be easily damaged, so cleaning and drying must be done carefully to prevent harm. As a result, medical device manufacturers require newer, better cleaning fluids and methods to get the devices clean and dry. The cleaning fluids must penetrate all areas of the complex geometries, awkward shapes, and blind holes. Plus, they cannot leave residue or damage sensitive materials such as polycarbonate and acrylic.

What's old is new again

Vapour degreasing meets that demand and continues to grow in popularity for medical device cleaning and drying. A few decades ago, vapour degreasing was the preferred method for cleaning medical devices. It was easy to use and provided highly reliable cleaning performance. However, in the late 1990s, environmental concerns fuelled an industry-wide trend to switch from this process, which at that time used chemicals harmful to the environment, to aqueous-based cleaning systems. Although there

were disadvantages to using the water cleaning systems, like energy and water consumption, the environmental issues linked to many of the cleaning solvents at that time outweighed the benefits of vapour degreasing.

However, major advancements in solvent technology have generated more environmentally friendly fluids which have led to renewed interest in cleaning through vapour degreasing.

Modern vapour degreasing fluids feature excellent materials compatibility, making them well-suited for cleaning delicate plastic parts or mixed-material devices. They also have low surface tensions and high liquid densities, meaning they penetrate parts to clean them thoroughly. Even more importantly, the cleaning fluids dry quickly without leaving any moisture inside the devices that can cause corrosion or lead to bioburden issues. Medical device designers find this benefit of modern fluid cleaning to be of utmost importance because it doesn't limit the complexity of the product design. Also, vapour degreasing systems are not geometry-sensitive, meaning if the component will fit in the machine, the machine will clean it. This is beneficial because it reduces the need for expensive fixtures and it's an extremely forgiving process even when cleaning large quantities of parts.

The vapour degreasing process

A typical vapour degreasing system consists of two chambers, both filled with a modern cleaning fluid. In one chamber, the cleaning fluid is heated to a boil, which then generates a vapour cloud that rises to meet cooling coils. These cooling coils cause the vapours to condense and return to their liquid state. This liquid is then channelled back to the second chamber, the rinse chamber.

Soiled parts are immersed in the continuously filtered and distilled cleaning fluid inside the vapour degreaser to dissolve or lift the soils from the parts surface. In some instances, ultrasonic agitation is added for additional cleaning power. As the parts are lifted from the cleaning fluid, they undergo a brief vapour rinse and drying



Man checking ECG: portable medical devices are getting smaller and more discreet

process. The cleaning fluid condenses and drips back into the vapour degreaser to be reused. The vapour degreaser recycles and reuses the cleaning fluid for hundreds of times before it needs to be refreshed or replaced. This helps reduce the cost of hazardous waste removal. After a typical cleaning cycle of about 6-20 minutes, the parts come out clean, rinsed, dried and ready for the next stage of production.

Vapour degreasing - it's more than just cleaning

Using a vapour degreaser not only cleans effectively but also creates the opportunity for manufacturing efficiencies. For example, it is possible to combine the vapour degreasing cleaning process with a second-step surface treatment for the application of medical-grade lubrication or a specialty film. The versatility of the vapour degreasing cleaning process means parts are cleaned and coated in seconds, streamlining the overall process significantly.



Vapour degreaser overview: vapour degreasing meets that demand and continues to grow in popularity for medical device cleaning and drying

Future trends in cleaning fluid technology

Nearly all the recent advances in cleaning fluid technology are centred around developing safe chemistries that meet both cleanliness standards and environmental regulations, meaning they do not contribute to global warming and are not an ozone depleting substance. In the past, high-performing cleaning solvents such as trichlorethylene (TCE), Perchloroethylene (Perc) and n-Propyl bromide (nPB) presented air and ground water quality issues as well as health and safety concerns. That resulted in layers of regulations established to discourage their use. Early efforts to develop cleaning solvent alternatives initially resulted in mild cleaning that did not meet cleaning standards, especially those needed in the medical device space.

Next generation cleaning fluids

Today, there are a number of modern cleaning fluids available that are both very effective and environmentally progressive. They offer excellent cleaning performance combined with a low GWP (Global Warming Potential) and low ODP (Ozone Depleting Potential) profile. They are formulated using a mixture of compounds that can include hydrocarbons like mineral spirits, isopropanol and ethanol. Depending on how the compounds are combined determines the cleaning fluid's effectiveness and its material compatibility. The vapour degreaser can use just one type of cleaning fluid or it can be mixed, blended or custom formulated to remove a specific soil from a specific device, maximising its cleaning effectiveness.

Due to their improved environmental and safety profiles, these modern vapour degreasing fluids make ideal long-term replacements for the less planet-friendly solvents like nPB, Perc and TCE, plus the new cleaning fluids are sustainable. This means they not only meet today's environmental regulatory demands but are also equipped to meet emerging "green" rules in the future.

Going greener to clean

These next generation fluids maintain or even increase cleaning consistency. This reduces scrap and rework which lessens the amount of raw materials used to complete an order, plus fewer scrapped parts get sent to the landfill. Many of the modern cleaning fluids have a lower boiling point than the older solvents. This reduces the amount of energy needed to heat the cleaner inside the vapour degreaser. The result is less fossil fuel consumption, a lower total carbon emission and less greenhouse gas output. In addition, the vapour degreasing process uses zero water, helping ensure future populations will have enough of this vital non-renewable resource.

Conclusion

As the trend toward miniature external medical devices continues, manufacturing them becomes more challenging. Devices continue to shrink in size and weight while growing in complexity. Intricate geometries, awkward shapes, and internal blind holes are now common features of the designs. Efficiently cleaning the devices without



Thread polishing: production debris like machining, stamping or cooling oils, dust, metal filings, marking inks, fingerprints and other soils must be removed

damage is also more difficult. Therefore, medical device manufacturers are opting for new methods and tools to properly clean them. Modern cleaning fluids and vapour degreasing equipment offer better cleaning and coating flexibility. They provide effective and consistent cleaning to meet cleanliness standards and strict performance guidelines, both now and in the future.

Companies looking for information about the vapour degreasing process and modern cleaning fluids should consult with a partner that has medical device cleaning and vapour degreasing expertise. A cleaning partner can help conduct on-site audits or perform in-lab tests with sample parts to ensure cleaning success. Based on specific parts make-up and the contamination encountered, they can recommend or formulate the fluids and device cleaning methods that will work best.

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