Medical Device Contamination

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SUMMARY

This technical brief describes the types of contaminants that can be found on medical devices during manufacturing. Optimal methods of contaminant removal are provided. The increasing importance of minimizing particulate contamination on medical devices is discussed.

INTRODUCTION

Medical devices have extended lifetimes and improved the quality of life for millions of people worldwide. We normally think of replacement knees and hips, vascular stents and pacemakers as representative of these engineering marvels. Endoscopes and catheters, used for diagnostic and therapeutic procedures, are also categorized as medical devices since they are placed into the body and retain their original form. To clarify, a needle that is inserted into the body is classed as a medical device (since it enters the body and retains its original form), but the solution injected through that needle is specifically classed as a pharmaceutical. Given that medical devices enter the body, the need to be free of contamination is paramount for patient safety.

CONTAMINANTS AND CONTAMINANT REMOVAL

Prior to the introduction of the device into the body (whether temporarily for diagnostic purposes or permanently for therapeutic purposes), we want it to be as free of contaminants as possible. Medical device contaminants can include traces of lubricants, oils, and other processing residues (e.g. polymers, adhesives), viables (microorganisms), and non-viables, such as particles and fibers.

In the manufacturing process, medical devices are packaged and then terminally sterilized as the last step. The sterilization procedure does not remove contaminants; it only ensures that any viables left on the device cannot proliferate further—any residual surface contamination left on the device before sterilization remains after the process and can pose a risk to patient safety. Fortunately, simple wiping techniques employed with proper wipers and solvents prior to packaging and sterilization can produce a clean medical device.

OPTIMAL CONTAMINANT REMOVAL TECHNIQUES

The contaminants described previously—processing residues, viables, particles, and fibers—are best removed using pre-wetted polyester knit wipers dampened with a solution of 70% isopropyl alcohol (IPA) and 30% deionized water. These pre-wetted wipers are convenient to use and contain the right amount of wetting liquid (Visit Berkshire.com for the Berkshire Technical Brief “Pre-Wetted Wipers Optimized for Application-Specific Cleaning”).

The optimal procedure for cleaning:

1. Wipe gloved hands with a pre-wetted wiper to remove any contaminants on the gloves. Discard this wiper.
2. Use a fresh pre-wetted wiper to grasp the medical device to be cleaned. Take another pre-wetted wiper to clean the medical device using linear overlapping strokes, if necessary, to cover the entire surface of the device.
3. View the device after cleaning. If there is any visible surface residue remaining, wipe again (if necessary, with a fresh wiper). High intensity lighting or, if needed, black light (with necessary eye protection) can be used to visualize remaining contamination. Wipe until there is an absence of visible residue. Discard the used wipers.
4. Place the cleaned device on a known clean surface or in the packaging used for terminal sterilization. The cleaned device should be protected against further contamination. The cleaned device should not be handled again. If it is handled, it should be re-cleaned as outlined above.

REMOVAL OF PARTICLES FROM MEDICAL DEVICES

As patient safety concerns mount, global government regulation and the US Food and Drug Administration (FDA) attention to the topic of particle contamination are increasing.

For example, Addressing Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, an FDA guidance document recommends measurement of the
total quantity and size(s) of the particulates generated during the simulated use of the device. This recommendation is based on the premise that “if particles are introduced in the bloodstream during an angioplasty procedure, they may present an embolic risk to the patient”.

The FDA document further states, “measurement of the total quantity and size of particulates a device may generate is an indication of embolic risk”. In addition, J. Simon writes in his article, Medical Device Coating Particulate, “particulate escaping into the vasculature can ultimately accumulate in the brain, occluding small vessels and leading to ischemic stroke”. Lastly, Reynolds and Lunceford in Analyzing Particulate Matter on Medical Devices address similar concerns and describe various methods of analyzing particulate matter on medical devices.

Particulate contamination will take on even more significance as technological advancements occur with the use of robotics and nanotechnology which focus on the reduction of scale and particulate size. It will be incumbent on manufacturers to understand particles and develop the proper procedures to minimize contamination on the devices they create.

FREQUENTLY ASKED QUESTIONS

1. **Why wipe rather than use alternate cleaning methods?** Wiping provides the necessary surface energy for the most effective removal of surface contaminants. The wiper traps the contaminants into its fabric.

2. **Why are polyester knit wipers specified?** Polyester knit wipers contain lower levels of particles, fibers and non-volatile residues compared to other types of wipers. They will be most effective at removing surface contaminants and will leave the surface as clean as possible.

3. **Why is a wetting solution of 70% IPA, 30% DIW specified?** This solution provides proper sanitizing capability for killing surface microorganisms, and it evaporates clean. The high concentration of IPA also provides effective cleaning capability for the removal of trace amounts of lubricants, oils, adhesives, and polymers as well as surface soils.

4. **Is it necessary to remove surface microorganisms when a terminal sterilization step is used?** If surface microorganisms are not removed by wiping, the device may contain elevated levels of endotoxin substances on its surface after sterilization. These endotoxins, which consist of the outer membrane of dead gram-negative bacteria on the medical device, can be introduced into the body and cause fevers or even death. The wiping step not only kills the bacteria, but physically removes it from the surface of the medical device before sterilization (the dead bacteria are trapped within the interstices of the wiper). Thus, it minimizes the possibility of endotoxin formation.

5. **Is particle removal from the medical device important?** Particles are indeed very important and are removed by the wiping process. Particles remaining on a medical device could have disastrous consequences when it is used. Patient health and safety being of the highest concern.

6. **What is an example of a non-human generated particle?** Manufacturers are cautioned against the use of powdered gloves in medical device cleanrooms since these can be a significant source of particles and may end up contaminating the very devices they are trying to clean.

CONCLUSION

As more products come to market, global demand climbs, and new technology develops, it is no surprise that contaminant and particle removal from medical devices is an area of increased importance. Fortunately, the solution is still straightforward. Proper surface cleaning with wipers is effective and it is the preferred method of particulate contamination control for improving patient safety. As outlined, performing the proper procedures, working with the correct wiper, and selecting the suitable chemistry for wipe downs are essential components in the effective removal of contaminants.

REFERENCES

2. J. Simon bog. info.biocoat.com/bid/63121/Medical-Device-Coating-Particulate