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ARTICLE REPRINT

Reducing Particle Contamination and Risk by Using Ionization in Medical Plastics Manufacturing

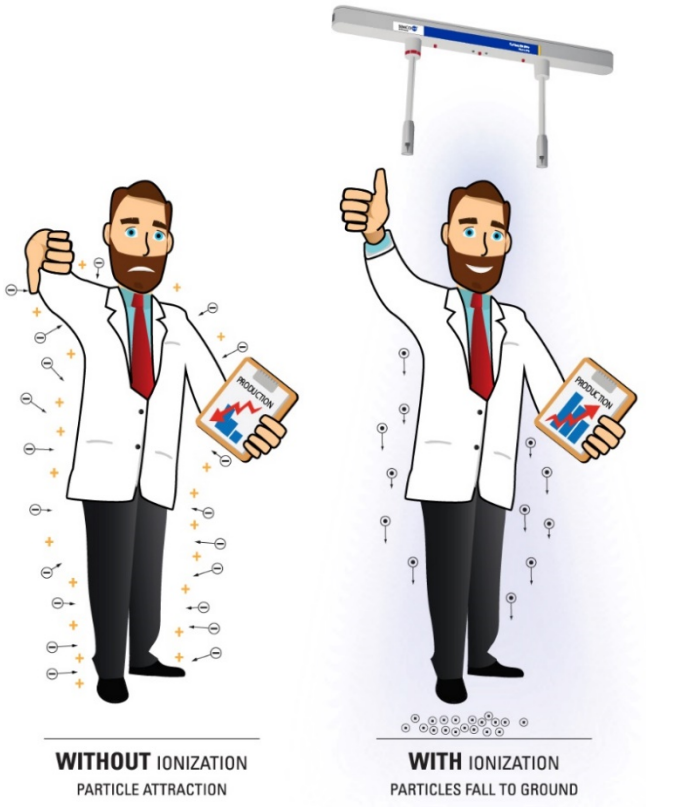
Static attraction, as a root cause, is responsible for the vast majority of particle contamination yield losses experienced in many medical device manufacturing operations and, in a recent FDA concern, a voluntary recall of products used to address aortic stenosis with patients. The medical devices include catheters, stents, heart valves, optical lenses, IVs, syringes, hip/knee replacements, pacemakers, blood filters and vials, breast implants and other implantable devices, etc., etc. – essentially all plastic or insulative devices in medical applications. Recent studies across many companies manufacturing these types of plastic medical devices had shown that substantial yield improvements result when the electrostatic attraction (ESA) problems were eliminated via ionization technology.

These studies clearly point to the fact that static attraction is usually the overwhelming major contributor in contamination yield losses during the manufacturing of these devices. In many cases, the contamination yield losses were determined to be virtually 100% caused by static attraction. Addressing particle contamination losses by implementing a "cleaner" cleanroom (a much costlier approach) did not provide anywhere near the level of yield improvement provided by eliminating the static attraction contribution.

The basic issue we are frequently observing in the medical plastics manufacturing industry is simple in nature. When the plastic devices are contacted, rubbed, handled, etc. they generate tremendous static charges. It is common to have plastic materials charge into the tens of thousands of volts (10-20 kV is typical) during such "triboelectric" charging (i.e., charging resulting from friction). In the case of stents and catheters, for example, in addition to handling and contact with operating personnel, charge generating operations include heating/cooling of the tubes, stretching or ballooning, and laser welding, to name only a few. When these products are charged to those thousands of volts levels, they attract more particles to their surface than their non-charged counterparts. When charges were removed from the plastic devices and the surrounding particles (via ionization) - in the manufacturing areas in these facilities - the vast majority of their contamination yield losses were removed with them, and the resulting positive financial impact was invariably substantial.

What is Ionization? Air ionization is the most effective method of eliminating static charges on nonconductive materials and isolated conductors. Air ionizers generate large quantities of positive and negative ions in the surrounding atmosphere, which serve as mobile carriers of charge into the air. As ions flow through the air, they are attracted to oppositely charged particles and surfaces. The neutralization of electrostatically charged surfaces can be rapidly achieved through the process. Air ionization may be performed using electrical ionizers, which generate ions in a process known as corona discharge. Electrical ionizers generate air ions through this process by intensifying an electric field around a sharp point until it overcomes the dielectric strength of the surrounding air. Negative corona occurs when electrons are flowing from the electrode into the surrounding air. Positive corona occurs as a result of the flow of electrons from the air molecules into the electrode. It is noted here that insulative materials such as plastics, glass, rubber, ceramic, etc. will not dissipate their charge when grounded. Only bringing air ions close to their surface via ionization equipment removes the charge (which resides on the surface of the insulator).

Ionization in Gowning Rooms: Ionization equipment, when employed in a gown-up room, "loosens" the particles on personnel by eliminating the attraction force. Consequently, a great majority of the previously adhered particles will literally fall off of the person and their clothes due to gravity, even in the absence of any additional airflow. Incorporating additional ionized air flows (ionizing air showers, ionizing blowers, etc.) can be an additional benefit to eliminate even more of the unwanted particles from entering the cleanroom.



Typical Ceiling-Based Ionization System in Gowning Room

Similar Issues in Transfer Rooms: In typical medical device cleanroom manufacturing facilities, there are dedicated "transfer rooms" where product is staged before entering the cleanroom. These transfer areas are not typically a part of the cleanroom and can be less than clean. If this area is not ionized as well, substantial amounts of particles once again find their way into the cleanroom. The basic issues are reviewed below in a typical example of transfer room process steps that don't include ionization:

Most manufacturers use a "double bag" packaging technique to keep the incoming product clean. In principle, this is the correct approach. However, care must be taken to avoid static attraction issues. Widely across the industry, no precautions are taken (unfortunately). First, the double-bagged product typically comes from a warehouse area into a transfer room for staging. There are typically enormous amounts of particles on the outside of the outer bag due to it being highly charged in the warehouse, attracting particles continuously while charged. The outer bag is then removed and discarded. Without ionization in place here, the inner bag is highly charged as well and attracts particles found in the transfer room and also from the outside bag that is removed.

Then, the "single bagged" product is transferred into the cleanroom with substantial particle contamination on the outside of that inner bag, due to its highly charged exposure in the less than clean transfer room. Thus, all sorts of unwanted particles enter the cleanroom on the outside of these single bagged products. It can be common for the single bagged product to sit in the transfer room for hours and hours, continually attracting particles to the outside of the bag the entire time that it remains charged.

Inside the cleanroom, the single bag is opened, and the product inside is then exposed. Charge redistribution can take place, and particles on the outside of the bag can rush inside the bag and end up all over the product (and also throughout the cleanroom). To avoid these issues, ionization should be in place in the transfer room to bathe and blow off the double bag first before its removal and also to bathe the inner bag as soon as it is exposed so that it does not attract massive amounts of particles while it sits in the transfer room. Ceiling based room ionization, overhead ionizing blowers, and ionizing guns (or a combination of all of them) can all be used effectively here. The bottom line for particle control is to ensure the static charges are always removed during the bag removal processes and to keep the single bag free of charge during the entire length of time it sits in the transfer room

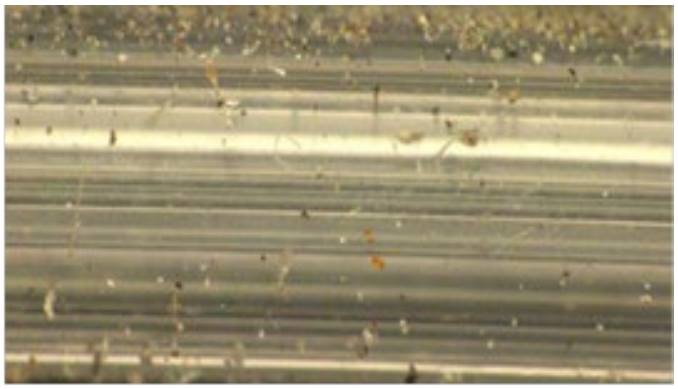
Cleanroom Production Area Ionization: The attraction of particles to charged products also is a worry in the cleanroom production areas. Ionizing the gown up and transfer rooms is only a piece of the puzzle. Ionizing the cleanroom as well is needed for the full elimination of static-related contamination issues (which are historically the biggest root cause of particle contamination in the medical plastics industry). However, the cost for addressing the gown-up room and the transfer area is relatively very small while providing a huge benefit, both in terms of reducing

particle counts overall in the cleanroom and also reducing subsequent yield losses and rework attributed to particle contamination. Also, by implementing these small first easily affordable steps, the facility can acquire in-house data immediately on the effectiveness of ionization for particle control. Good future decisions on the expansion of ionization into other areas in the facility, without risk, can be made based on the documented internal improvements observed with these initial small implementations.

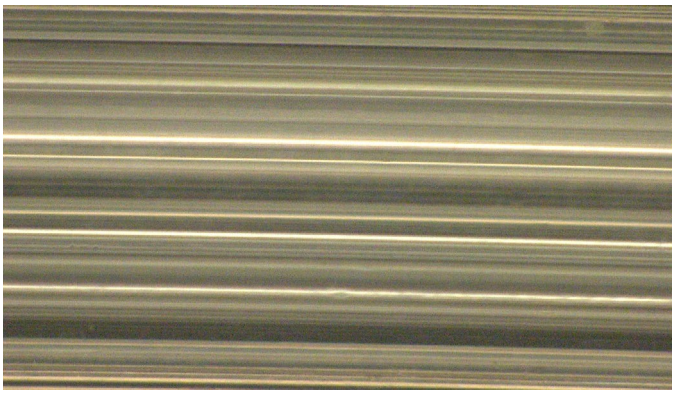
Ionizing the gowning and transfer areas will cut down significantly on "people" particles such as skin, hair, eyelashes, makeup, clothing fibers, etc. In addition to the people generated contamination, there are process generated particles such as metal filings, plastic insulation slivers, etc. that add to the contamination issues. Process related particulates are generated by machines and dynamic process operations in the cleanroom assembly areas.

In summarization, ionizing the gown up rooms and transfer areas will significantly reduce people generated particle contamination. In contrast, ionizing critical production areas inside the cleanroom will reduce process generated airborne particulate generated by machines, manual assembly, and packaging.

Substantial particle contamination reduction is typical when the static component is eliminated. Many studies have been published on this. An example of the difference in particle contamination on a catheter during manufacturing is illustrated in the photos below. The photo on the left is the particle contamination that occurred without ionization during manufacturing at a major catheter manufacturer. The photo on the right is the reduced contamination that occurred with ionization in place.



Catheter Manufactured Without Ionization



Catheter Manufactured With Ionization

Yield Loss Reductions: Simco-Ion has worked with hundreds of medical device manufacturers. As non-disclosure agreements prevent the publishing of their data and results, we summarize here anecdotally:

- Every facility (100%) that has done the testing has measured substantially reduced particle counts in the cleanroom when ionization has been implemented in the gown-up room. Many facilities conducted experiments where they would turn the ionization systems on and off in the gown up room and observe the correlated rise and fall of their cleanroom particle counts. Almost all facilities in this industry have particle count measurement equipment, so this is an easily verifiable experiment to conduct.
- Yield improvements were observed in ALL cases when only gown up room ionization was implemented. The typical reduction in yield losses due to particle contamination was 25%. That reduction was totally due to just the gown-up room ionization. That is a huge return on a very small investment!
- When room ionization is implemented throughout all areas in the facility (i.e., the gown up rooms, transfer areas, and cleanrooms), a very large majority of the contamination losses previously experienced on an ongoing basis were eliminated (80-90% typically). To date, the lowest reduction in losses observed in any of the facilities was 50%. The highest reduction was over 95%.

Summary: Static attraction, as a root cause, is responsible for the vast majority of particle contamination yield losses experienced in many medical device manufacturing facilities. The medical devices include all plastic or insulative devices in medical applications essentially. Recent studies across many companies manufacturing these types of plastic medical devices had shown that substantial yield improvements result when the electrostatic attraction (ESA) problems were eliminated via ionization technology.

(Plastic medical devices such as catheters, stents, heart valves, optical lenses, IVs, syringes, hip/knee replacements, pacemakers, blood filters and vials, breast implants and other implantable devices, etc.)

About the Author

Roger J. Peirce has been Manager of Technical Services since 2006 for Simco-Ion, Technology Group, an ITW Company. Previously, he provided ESD/ESA consulting services for 20 years to the semiconductor, medical device, and electronics manufacturing communities for ESD Technical Services – a consulting company he founded in 1986. He co-founded Voyager Technologies in 1983 to design innovative ESD test equipment and started his 13-year career at Bell Labs in Murray Hill, NJ in 1970. He holds 10 US patents and has authored and published more than 20 technical papers on ESD/ESA. Mr. Peirce is a graduate of Fairleigh Dickinson University.

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