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Static Attraction in Medical Plastics Manufacturing

The Primary Cause of Particle Contamination

Overview

Static attraction, as a root cause, is responsible for the vast majority of particle contamination yield losses experienced in many medical device manufacturing operations. The medical devices include catheters, stents, 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. This article summarizes recent studies across a number of companies manufacturing these types of plastic medical devices – that have led to substantial yield improvements when the electrostatic attraction (ESA) problems were eliminated.

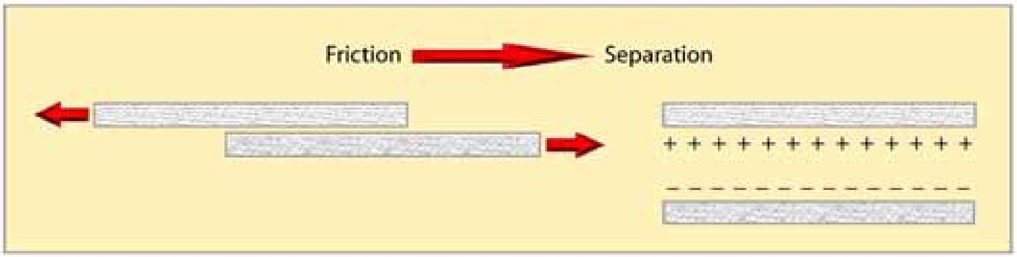
These studies clearly point to the fact that static attraction is usually the overwhelming major contributor in contamination yield losses during manufacturing of these devices – in many cases, the contamination yield losses were determined to be virtually 100% caused by static attraction. Addressing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

(In the semiconductor manufacturing industry, yield losses resulting from increased particle contamination on semiconductor wafers due to the effects of ESA are well documented[1-8]. If ionization techniques are not implemented properly, yield losses are quite common[9].)

The Generation of Static Charge

Static charge generation can occur when two different materials slide against each other and then separate.

As shown above, after the separation has occurred, one side has charged positively and the other side has charged negatively. (These two oppositely-charged sides will now tend to attract each other – and this is how “*static cling*” originates.) Charged ***conductive*** materials (such as metals) can be grounded to remove their charge, however, ***insulative*** materials such as plastics, glass, ceramics, etc. (good electrical insulators) cannot be grounded to eliminate their charge buildup. For these insulators, the charge resides on the surface and can only be eliminated by bringing the opposite polarity charge to its surface through the air via ionization, which will be reviewed later in this article.



Charging of Plastic Devices during Manufacturing

The basic issue we are observing frequently 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. All of that is common knowledge. However, the studies we have concluded recently clearly point to the fact that static attraction is usually the ***overwhelming major contributor*** in contamination yield losses during manufacturing of these devices. 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.

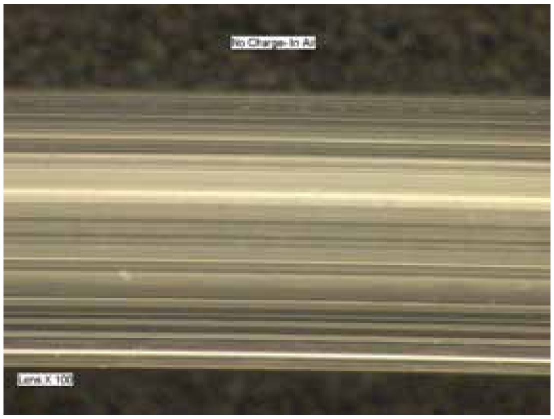
Case Studies – The Effect of Static Charge on Particle Contamination

In this section, we guide the reader through one of our typical engineering studies that we have performed repeatedly at facilities to determine the correlation between their particle contamination yield losses and the charging of their devices through the manufacturing process steps. Initially, we worked with local staff to standardize how we would quantify the number of particles on the product (visual determination, optical equipment determination, etc.). Then, a series of technical experiments were conducted to determine the percentage of their current particle contamination to the effects of static attraction. In our case study here (catheter manufacturer), we determined the following:

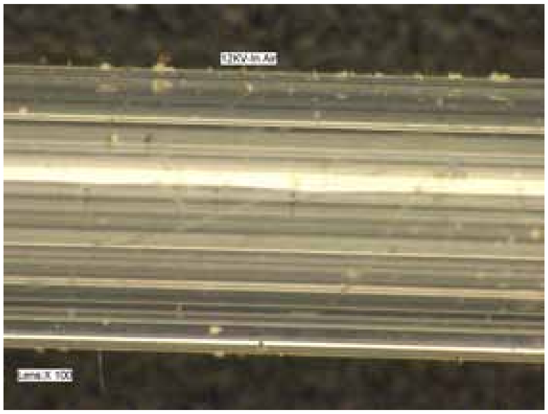
1. We first methodically measured the static charge levels on the catheters as they moved through all the various process steps – observing the tubes routinely charging from 5-20 kV all along the way. The average charge on the catheters was 12 kV.
2. The number of "killer" particles (i.e., particles that are larger than the allowable size and result in the scrapping of the product) on the surface of the unformed catheter tubing material as it came out of its initial packaging were observed and recorded (There was no static charge on the tube.)
3. We placed the uncharged tubes into the local air environment (Class 100,000 clean

room) and waited for 30 minutes (typical start to finish time for the entire manufacturing process to take place for the devices) to determine how many killer particles landed on the tubes naturally.

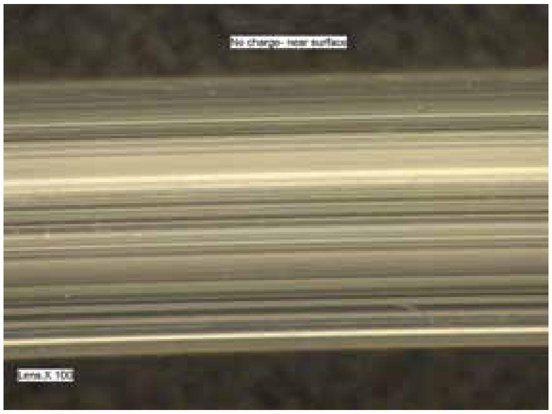
4. We placed the uncharged tubes in moving airflows (near fans, etc.) to see if increased particle contamination would take place.
5. We placed the uncharged tubes 1/2 inch away from typical work surfaces throughout the facility for a 5 second timeframe.
6. Summarizing the results described in #2-5 above, we observed absolutely ***negligible particle contamination on the tubes if they were uncharged***. However, as is the case in all of the facilities we have been into along this front, dramatically different results are observed when we allowed the plastic device to become statically charged, as detailed in our continuing case study below.
7. When we charged the tube to 12 kV (i.e., the typical charge on the catheters during routine manufacturing processes) and suspended it similarly as before with the uncharged tube in the same local air environment (waiting 30 minutes) we observed approximately ***10 times*** the number of killer particles. (Incidentally, this number is quite consistent with published studies in the semiconductor industry.) In this case, the charged tube accumulated particles at a ten times rate versus the uncharged tube – just sitting there in mid air.
8. We placed the charged tube (12 kV) similarly as before 1/2 inch away from typical surfaces throughout the facility for 5 seconds – and observed approximately ***30 times*** the number of killer particles.
9. Our conclusions at this facility were quite similar to all of the facilities where we have done these studies – virtually 100% of the ***particle contamination yield losses are coming from static attraction root causes***! Photos of some of the catheters used in the study above are shown below – underscoring the difference in particle contamination between charged and uncharged catheters.



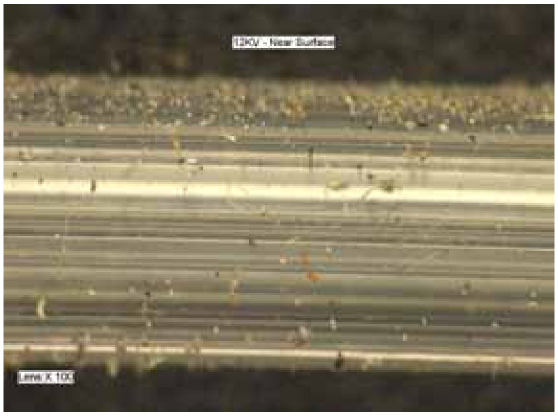
Uncharged Catheter – 30 min in air



Charged Catheter – 30 min in air



Uncharged Catheter – ***½" from surface***



Charged Catheter – ½” from surface

As predicted by the studies above, facilities that implemented ionization systems to maintain constant low charge levels on both their plastic devices and (just as importantly) the surrounding airborne and surface particles, realized substantial yield improvements. Summing up the results of the many studies we have done in the medical industry over the past few years, we have noticed that their particle contamination yield losses (initially without ionization) ranged between 3-15% typically. *In all those facilities where ionization was implemented to remove the charging issues, we observed those yield losses reduced virtually to 0% to 1.5%.* (Before reviewing which type of ionization systems work best in these environments, an ionization overview is given below.)

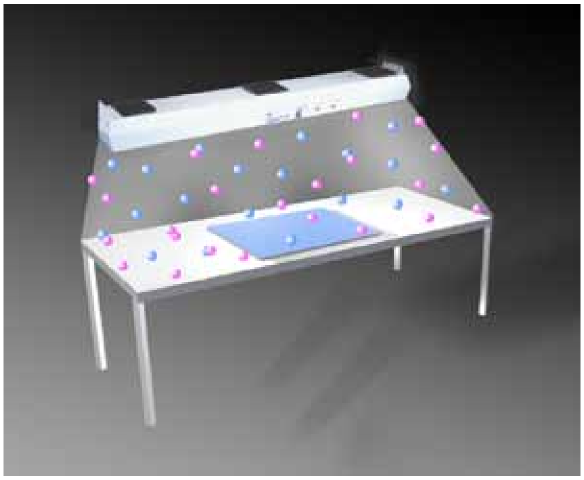
Ionization Overview

Air ionization is the most effective method of eliminating static charges on non-conductive 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. Neutralization of 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.

Ionization Systems

Armed with results in the *“Case Studies”* section earlier – where clearly the majority of particles on the plastic catheters were caused by ESA, the next logical step to eliminate or reduce particle contamination was to insure the plastic devices did not become charged during handling and processing. We have found that local ionizers (overhead fans, ionizing bars, etc.) – although effective in *reducing* yield losses substantially -only keep the plastic devices at zero charge at those local places – and we find the devices are routinely highly charged elsewhere in the facility (consequently attracting particles in those unprotected locations).



Local Ionization

We have found that many times the best coverage can be provided by complete room ionization systems for many applications.

Room System Ionization (Ceiling Grid)

Room System Ionization (100% Coverage)

With the room system in place, the ***devices*** (catheters, etc.) stay uncharged in ***all*** locations in the room. In our case studies, we have found that substantial local ionization can still result in charged devices (in between local ionizers) up to 70% of the time during manufacturing! Room systems reduced that 70% to virtually zero.

Perhaps even more importantly, the ceiling grid room system approach eliminates charges on ***all*** the ***particles*** in the room – even particles in the environment up to the ceiling and work surfaces in general. This has a major impact on reducing the particle attraction force to the devices – and subsequently can result in even less particle contamination than local ionization alone.

Summary

Static attraction, as a root cause, is responsible for the *vast majority* of particle contamination yield losses experienced in many medical device manufacturing operations. We have found that most medical product manufacturers have not been aware of the huge extent that static attraction contributes to their contamination-based yield losses. Typical particle counts on these plastic products increase at least ***10-30 times*** *when the product is charged* during routine processing. Room ionization systems have been proven to be great implementations to eliminate these yield losses caused by electrostatic attraction, providing eye-opening, immediate returns on investment (ROI).

References

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