Particle Contamination on Medical Devices Caused by Static Attraction

Roger Peirce – Simco an ITW Company

Overview:

In the semiconductor manufacturing industry, yield losses resulting from increased particle contamination on wafers due to the effects of static charging are well documented[1-8]. If ionization techniques are not implemented properly, yield losses are quite common. Similarly, medical devices (such as catheters, stints, optical lenses, etc., etc. – *essentially all plastic or insulative devices in medical applications*) have been identified as having very similar yield loss mechanisms during manufacturing operations. This white paper summarizes our recent studies across a number of companies manufacturing these types of medical devices – that have led to substantial yield improvements when the electrostatic attraction (ESA) problems were eliminated.

Charging of Plastic Devices During Manufacturing:

The basic issue we are observing frequently in the medical device 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 during such “triboelectric” charging (i.e., charging resulting from friction). In the case of stints and catheters, for example, charge generating operations include simple handling, heating of the tubes, stretching or ballooning, laser welding, etc., etc.

When these products are charged to those levels, they attract more particles to their surface than their non-charged counterparts. All 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 – in many cases, the contamination yield losses were determined to be almost 100% caused by static attraction. When charges were removed from the plastic devices (via ionization) - in all 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.

Recent Case Studies:

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

1. “Killer” particles (particles that are larger than the allowable size and result in the scrapping of the product) were essentially ***zero*** on the surface of the unformed stint tubing material as it came out of its initial packaging (if there was no charge on the tube).
2. We placed the uncharged tube into the local air environment 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 tube naturally. Again, we saw ***zero*** particles at the end of that timeframe.
3. We placed the uncharged tube in moving airflows (near fans, etc.) to see if increased particle contamination would take place. It did not; ***zero*** particles were observed again.
4. We placed the uncharged tubes 1/4 inch away from typical surfaces throughout the facility for 5 seconds at a time – again, ***zero*** particles were observed.
5. Summarizing the results described in #1-4 above then, we observed absolutely ***no 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.
6. When we charged the tube to 2Kv (which is a very modest level – most operations charged the tubes between 10Kv and 20 Kv) and suspended it similarly as before with the uncharged tube in

the same local air environment (waiting 30 minutes) we observed ***10 times*** the number of particles. (Incidentally, this number is quite consistent with published studies in the semiconductor industry.) In this case, the charged tube attracted particles at a ten times rate versus the uncharged tube – just sitting there in mid air.

7. We placed the charged tube similarly as before 1/4 inch away from typical surfaces throughout the facility for 5 seconds – and observed ***30 times*** the number of particles.
8. We then methodically measured the static charge levels on the tubes as they moved through all the various process steps – observing the tubes routinely charging from 5-20Kv all along the way (well above the 2Kv level we used in the experiments above!)
9. Our conclusions at this facility are quite similar to all of the facilities where we have done these studies – almost 100% of the ***particle contamination yield losses are coming from static attraction root causes***!

Ionization Considerations:

Armed with the data above, the next logical step is to insure the plastic devices do not become charged during handling and processing. We have found that local ionizers (overhead fans, ionizing bars, etc.) only keep the plastic devices at zero charge at those local places – and we find the devices are routinely highly charged everywhere else in the facility (consequently attracting particles in those uncovered locations). We have found that the best coverage by far is provided by complete room ionization systems for this application, as the devices stay uncharged in ***all locations***. Yield improvements have been observed and documented with room systems versus local ionization implementations.

Summary:

Static attraction root causes are responsible for the *vast majority* of the particle contamination yield losses experienced in many medical products 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 ESA, providing eye-opening, immediate returns on investment (ROI).

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About the Author:

Roger J. Peirce is Director of Technical Services for Simco Ionization for Electronics Manufacture, an ITW Company. Previously, he provided ESD consulting services for the prior 20 years to the semiconductor and electronics manufacturing community for ESD Technical Services – a consulting company he founded in 1986. Over that timeframe he provided consulting services in over 2,000 facilities. 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. (rpeirce@esimco.com)

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