Lessons Learned at the Intersection of Electronics and Medical Molding

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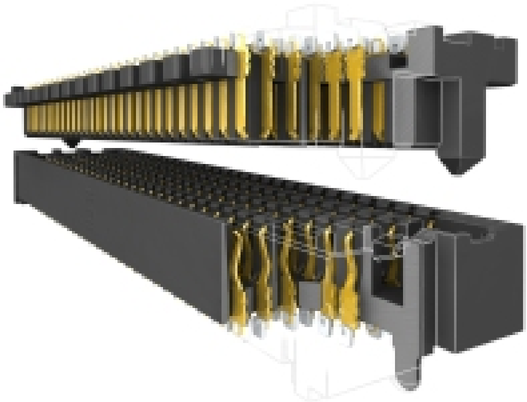
As the cross-pollination of the molded electronic and medical components industries continues, the products in each industry are becoming much smaller and much more complex. Toolmakers, molders, suppliers and the OEMs of medical components that incorporate electronics must all have a firm understanding of the ideas, processes, expectations and standards of both industries in a collaborative effort to produce the highest quality component-level parts at the lowest viable cost.



Samtec, Inc.'s, SEARAY™ is a micro pitch, high density, high speed array interconnect used in medical applications. (Photo courtesy of Samtec, Inc.)

I'd like to outline the current state as well as the future of electronic and medical molded components, exploring how these two industries overlap and looking specifically at connectors used in high-end medical devices such as MRI machines, electronic displays, and pumps.

Electronic components have often been designed, developed, and produced at a fast pace, with short turnaround times, ever-changing design revisions, and a certain degree of flexibility built directly into in the manufacturing process. These electronics OEM and their molders utilize cutting-edge, highly engineered resins to produce thin-wall and micro-features within their connector designs. Currently, as the electronics industry continues to face ever greater price pressures, many OEMs and manufacturers are now more closely evaluating the raw material resins that were originally specified on the part prints, and which play a significant role in the end component pricing. Furthermore, engineers within new product development groups continue to incorporate new materials and push the physical limits and properties of these materials with their product designs.

On the medical side of the equation, however, we’ve seen a quite different approach and industry culture related to the design and manufacturing processes. Many medical device OEMs continue to specify legacy materials that have been proven over many years within their new product designs. The high-risk aversion coupled with extensive re-qualification requirements within the medical industry strongly favor a low-risk “tried and true” approach, and with good reason. The process is much more methodical and rigorous, with little room for deviation or trial and error. There are strict qualification processes and standardization requirements in place due to regulations from the FDA, customers, etc. However, as medical device OEMs move into new markets and new geographies, they are discovering much more of a need to reassess legacy materials due to cost pressures. I have seen very expensive legacy materials that are highly over-spec’ed in terms of the required performance characteristics for certain devices and applications – cases where a much less expensive raw material can deliver the same performance and reliability in the final device. The importance of proper material selection is one reason among many that a strong partnership among the OEM, the tool maker and molder, as well as the raw materials supplier, is essential to consistently attain success in today’s global marketplace.

As the medical components industry begins to adopt some lessons learned from the electronics industry regarding materials, it is also beginning to adopt another characteristic: micro-features. The individual components that ultimately make up a medical device are becoming much smaller and much more complex as the evolution to portability, ease-of-use, and home healthcare drive demand growth of new medical devices. Micro-features have long been a key element of electronic component design, and medical molders with strong electronics molding experience are uniquely applying that knowledge to benefit their medical customers. Small features are prone to warp, bend or flex during the machining and injection molding processes, which lead to defects in the final product. These miniature mold components and finished parts can often be very hard to work with – difficult to hold, to machine or mold, and to measure. Much of the measuring and polishing requires a microscope and other advanced equipment. And of course, the smaller tolerances of these parts demand a much higher degree of precision and technical capabilities.

Advanced Scientific Molding techniques can help to approach these challenges. Through real-time production monitoring systems and advanced quality inspection equipment, many variables can be eliminated or greatly minimized. Cavity pressure sensors in the mold can help determine the exact pressure needed to consistently produce a high-quality, acceptable part. Additionally, incorporating an intricate pilot or an interlock into the top of a core will minimize movement during the injection molding process. Post production, automated detection and measurement are crucial because certain flaws on tiny parts, like short shots or flash, can often be overlooked by traditional human inspection. A high-end medical molder will be able to ensure the required precision is attained though rigorous qualification processes, advanced molding techniques and processes, fixturing, automated inspection routines, and capability and gauge R&R studies.

For this process to run smoothly, I've found that a close relationship among the moldmaker, injection molder, materials supplier and OEM is not just important, but essential. Plastikos' close working relationship with SAMTEC, an industry-leading electronics connector OEM that designs and builds a wide-range of micro, high-speed, and rugged connectors, is one example. SAMTEC designs board-to-board interconnects that are robust and reliable enough to be used in a wide variety of end-use physical environments, including within medical applications as well as within telecommunications and data processing, industrial controls, military and automotive applications. These medical applications require a demanding environment and challenging product design that is backed by rigorous discipline standards and internal processes.

In order to expand its presence within the medical industry, SAMTEC has benefited from strong relationships with their molders, toolmakers and materials suppliers. Just as importantly, they've gained many advantages by working with partners who also have experience in both the medical and the electronic components industries. A leading supplier such as SAMTEC, and in turn their partners, is a vital asset to medical OEMs who desire to incorporate electronic connectors and functionality into their devices as they proactively work to address rising health care costs, quality-of-life considerations to and the explosion of personal health care devices that are expected to dominate the market in the years to come.

Phillip Katen was formally a Senior Consultant at Deloitte. Katen is experienced at analyzing and improving strategies and operations. He understands that "continuous improvement" goes much deeper than merely buying new machines every year. It's a deep commitment to process in all aspects of business. And it enables a small company like Plastikos to succeed, despite much larger, overseas competitors. Since taking over the leadership post at Plastikos and Micro Mold in 2007, Katen has implemented strategies learned through his experience as a consultant to much larger companies. He's guiding the company to a position of sustainable industry leadership.