

## Bright Future Ahead for Medical Molding

Stephen Lee, Business Development Manager, Pelham Plastics Corp.



Stephen Lee, business development manager at [Pelham Plastics Corp.](#) [1], was a part of the staff written article, "[Molders Address Biggest Device Issues](#) [2]." He took time to present a full array of responses that were not able to be included in the article, so they are presented here.

**Q:** *How can medical molders help device designers achieve compliance with the upcoming UDI rule?*

**Lee:** In 2007 Congress passed legislation directing the FDA to develop regulations establishing a unique device identification (UDI) system for medical devices. According to the FDA, UDI is a unique numeric or alphanumeric code that includes a device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date.

Pelham Plastics provides customer molding and assembly of components used exclusively for medical devices. We supply to a wide range of medical device manufacturers. To date, we have not yet experienced the impact of UDI legislation. That said, when such opportunities arise we are prepared to provide unique component identifications with-in the molds design or through printing operations after molding.

**Q:** *What features are most important to device designers to achieve through molding material selection?*

**Lee:** Biocompatibility of materials has long been a top priority for material selection in medical devices. Today, however, we are also seeing a significant trend in selection of 'like' materials. Materials that can be bonded together by heat or over-molded allow for device engineers to eliminate solvents or adhesives in assembly and can improve efficiencies in manufacturing. One example is the selection of materials for a catheter shaft and luer. If the materials of these components are melt compatible, the luer can be over-molded onto the shaft and create a bond without the use of adhesives.

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**Q:** *How are the capabilities realized through micro molding changing medical device design?*

**Lee:** The formal definition of micro molding often suggests molded parts that are the size of a single pellet or smaller. A broader definition of micro molding may include molding of increasingly smaller parts. This definition is very applicable in the medical device industry. Medical device companies are increasingly reducing part sizes, often to provide greater patient comfort. The suture wing on a catheter end today is roughly 30% smaller than the same product we were molding 5 years ago.

Provided molds are designed appropriately and the right materials are selected, design engineers can achieve tremendous benefits packaging, shipping, functionality and patient comfort through further reduction of medical device components.

**Q:** *What type of molding technique is gaining more interest with medical device engineers?*

**Lee:** Over-molding is growing rapidly as a way to eliminate adhesives as well as manufacturing steps. This results in significant cost savings. In addition, over-molding can produce higher quality bonds between components than those joined with adhesives.

**Q:** *How are molders addressing the movement to more patient-based devices?*

**Lee:** As a custom molder and component assembly company we are focused on providing capabilities that meet the shifting needs of our customers. We expect the move towards home healthcare and patient-based devices will result in new aesthetic and functionality requirements of devices, and the molded components from which they are comprised. Versatility and flexibility to serve medical device companies is the key to success in today's marketplace.

**Q:** *How are material advances impacting the capabilities offered with implantable devices?*

**Lee:** The rapid growth in implantable devices in recent years has been heavily supported by innovations in polymers, particularly bioresorbables and polyketones (PEEK). Many of these materials are substantially more expensive than polymers used in non-implantable devices. Our equipment and mold designs have to be accurately matched to the component size and production quantity to ensure we achieve maximum utilization of the raw material. Bioresorbable implants require careful handling prior to and after molding to ensure moisture does not prematurely degrade the finished product.

Compounding of additives into these polymers is also adding a new level of functionality in the final product. Bone growth additives are commonly added to bioresorbable polymers for orthopedic implants.

**Q:** *Where is medical molding headed over the next five to ten years?*

**Lee:** We see no sign of medical molding slowing down. In fact, we see the increasing need and benefit for more comprehensive collaboration with our customers. Demand for greater product performance, such as burst pressure in a catheter device, with decreasing part sizes and wall thickness requires that we work

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with product designers earlier in the process to ensure parts are designed for manufacturing. Our engineers are increasing working with OEM device designers months or even years before molding the first prototype to ensure what is designed can be produced and meets the functional requirements.

More demanding product requirements demand greater focus on sub-assemblies, and not just the individual molded components. In most cases, we are assembling multiple components into sub-systems that meet the desired specifications.

**Q:** *Any thoughts/comments on molding or another related area that you would like to share with medical device manufacturers to aid them?*

**Lee:** Medical device companies will benefit a great deal through collaboration with their molder as early in the design process as possible. An experienced medical molder can bring a great deal of knowledge to the table that can minimize costs and improve product development cycles.

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[1] <http://www.pelhamplastics.com/>

[2] [http://www.mdtmag.com/articles/2013/07/molders-address-biggest-device-issues#.Umq\\_VJzAaQw](http://www.mdtmag.com/articles/2013/07/molders-address-biggest-device-issues#.Umq_VJzAaQw)