Roundtable Q & A: Molding

John Schmitz, Shu Peng, and Dave Pool

Question 1: How are innovative molding techniques enhancing the design capabilities of medical device manufacturers?

John Schmitz
President, Aberdeen Technologies, Inc.

Because Aberdeen deals predominantly with insert molding, we see numerous opportunities where components can be incorporated into the device without the need for a secondary operation. This opens the door for design considerations not previously available, such as molding around filter membranes, extremely delicate wires, and even glass. Sometimes the insert itself is a core pin with a unique shape or profile which is removed by hand after molding, leaving an internal passageway in the device. This is especially helpful when designing certain catheters or implantables.

Shu Peng
Engineering Manager, Parker's Medical Systems Division

The following advancements in elastomeric molding techniques have improved the overall design capabilities of medical device manufacturers, allowing for designing

more complex parts and assemblies while maintaining tool efficiencies and improving product ivy:

- Enhanced over-molding to numerous substrates with self-bonding silicones
- High cavitation liquid injection molding with vision system & automation
- Innovative tool design capabilities employing cold runner technology allows for better flow characteristics needed for complex parts
- Use of inserted cavity stacks allow for maintaining tool efficiencies

Dave Pool
Vice President of Engineering, Sil-Pro

The molding machines have become extremely accurate, allowing for precise control on a number of process parameters. This accuracy is critical on very small shot sizes.

Question 2: What issues must be addressed with a molded component that will need to be sterilized as part of a finished medical device?

JS: Again, dealing with insert molded devices, it can become tricky because the method of sterilization could be dictated not so much by the molded plastic itself, but by the other components which are molded into the part and may be more unstable against some sterilization methods.

SP: The key elements to keep in mind whenever a molded elastomeric component is sterilized are the following:

- Loss of physical properties (hardness, elongation, tensile)of the elastomer

- Potential discoloration of the molded component
- Thus the choice of the material is critical.

DP: Materials need to be selected based on the type of sterilization, and performance requirements of the component. Multiple sterilization cycles may also need to be considered, based on sterilized sub-assembly kits, going into final packaged assemblies that will see an additional exposure. Part performance needs to be characterized after the maximum number of sterilization cycles.

Question 3: How have material advances helped to make molding a preferred component fabrication process?

JS: A perfect example is the new bio materials that can be absorbed into the body through enzyme breakdown. We once molded an orthopedic screw which was able to remain in the body instead of having to be removed at a later stage. This actually spared the patient from having to undergo a second invasive procedure for the same wound.

SP: Improved physical properties and ease of moldability of elastomeric materials such as liquid silicons have made molding a very attractive and cost effective option for component fabrication. Decreases in material cure times allow for higher throughput production

Question 4: Any thoughts/comments on molding or another related area that you would like to share with medical device manufacturers to aid them

JS: I would suggest that R&D and design engineers work closely with the manufacturing team at the very outset of new projects to get their input and feedback. I believe it is especially important to consult with the mold tooling engineers because many times it is their perspective which opens new avenues of thinking and possibilities when determining if a part can be manufactured in a consistent manner while still meeting the quality standards. We utilize this total team approach at our company and it has not only fostered innovation but also saved us from much heartache when it comes time to ramp up for production.

SP: The effective usage of FEA has made material selection and product design far more efficient and cost effective for medical component device designers. Computer aided flow and thermal analysis have also become effective aids in production tool design.

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