Roundtable Q&A: Materials

This month, insights on materials topics—desirable benefits, development focus, and influence on design—are shared.

Question 1: Beyond the physical characteristics, what benefits are medical device manufacturers most interested in when selecting a material?

Stephen Freeman
Vice President, International Business Development, Materion Corp.

After answering the absolutely non-negotiable, essential requirements of biocompatibility, functionality, and reliability, medical device manufacturers need manufacturability, availability, and of course, cost effectiveness.

Dr. Mary Krenceski
Elastomers Process Chemist, Momentive Performance Materials

Materials used in medical devices tend to be of high quality and purity and can be expensive. Our medical device customers demand products that are consistent in processing so they can minimize waste during molding. Of course, they need documented assurance about the quality of their raw materials to comply with FDA regulations. Many device manufacturers also look for versatility in a material so that they can use it for multiple applications or parts. They build on their experience and know in advance a material will perform both in fabrication and in their testing protocols.

Tilak Shah
CEO, Polyzen Inc.

There are several key parameters to consider when selecting materials for medical device applications:

- Mechanical properties needed to meet functional requirements
- Chemical structure and additive packages for its bio-toxicity
- Chemical resistance to various solvents, disinfectant, and bio-fluids used

during the assembly, or end use, of the device
- Material stability when exposed to selected sterilization process
- Material compatibility with other materials or components used during the assembly process
- Ease of processing to achieve desired shape, size, or thickness requirements for the device
- Long-term availability; re-qualifying alternate materials and suppliers is costly and time consuming

Question 2: What is the primary focus in the development of materials for future medical device applications?

SF: More and more, we see medical device manufacturers coming to us for out-of-the-box solutions to solve complex demands upon materials. There are just a finite number of combinations of biocompatible, functional, and reliable natural elements that can be put into alloys or polymers. The smart manufacturers are open to custom hybrid solutions, where we combine materials to take advantage of the combination of properties that individual components bring.

MK: More of our applications are focused on devices requiring additional levels of complexity. Momentive is developing innovative new platforms to address those applications. We are also focused on coupling the exceptional properties of silicone with other functionality, like microbe and fungus resistance or drug release. Some of those applications require new and sophisticated synthetic chemistry solutions.

TS: When developing any new material, one needs to look at current unmet needs or future trends in the medical device industry. Many devices are becoming smaller as less invasive therapeutic and diagnostic approaches are becoming more popular and growing. Improvements that result in materials with a higher modulus, increased elongation, and/or other mechanical properties that may allow a reduction in either device wall thickness or overall size of the device should not sacrifice its performance and reliability.

Question 3: How are materials influencing the development and design of medical devices?

SF: By advancing the frontiers of what is possible with existing materials of commerce, materials engineers are putting solutions into the hands of the medical device design community that were not possible even a few years ago. Solutions like: Bi- or tri-metallic hybrid strip materials that can be used to manufacture a combined battery electrode; through post and biocompatible terminals in one piece, thereby reducing part counts and increasing reliability; and continuous thin film deposition onto a wide range of substrates of multiple layers of conducting and dielectric coatings, possibly overcoated in-line with polymeric biocompatible protective coatings.

MK: Silicone properties can mimic many of the body’s natural materials. For instance, like human cartilage, silicone can provide soft cushioning combined with tough tear resistance. As a result, silicones are an excellent choice for small joint

restoration in the hands and feet. Where designs call for the ability to flex repeatedly and avoid fatigue resistance, silicones excel. The inherent low surface energy of a silicone part also allows it to be resistant to microbe and fungal growth, which are both key drivers for <I>in vivo medical devices.

TS: Consideration should be given to materials creep phenomena and melt shrinkage factor during processing prior to finalizing on all wall thickness tolerances and other design parameters along with its limitation(s) with respect to any secondary melt or adhesive/solvent bonding process with other components. This would include looking at the total assembly, functionality, and life of the device prior to the selection of materials/resins for each of the components to ensure its suitability/compatibility with all components during the secondary assembly process, packaging, sterilization, and shelf-life of the device.

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

SF: Never assume that the limits have been reached in materials engineering development. Keep asking the questions like, "Can we just have the formability and biocompatibility of stainless steel combined with the conductivity of copper, but also include the non-friction properties of Parylene? Like Merlin the alchemist, materials engineers today can achieve what was impossible yesterday, and the miracles take just a bit longer.

MK: Momentive works with each of our medical device customers on an individual basis. We assemble a strong team that fully utilizes the skill sets of our technical experts, application engineers, and market specialists. When our customers learn the broad range of silicone properties and products, they are very creative in ways to use our products. Silicone chemistry is extremely versatile; we can add functionality to our molecules in ways that generally are not available to other polymers. Building on inherent silicone properties and using creative chemistry gives us the opportunity to meet many performance demands simultaneously.

TS: When selecting specific resins or materials, consideration should be given to the inherent lot-to-lot variability of the raw materials. In particular, the molecular weight and melt viscosity are critical in processing the resin into components.

It is necessary to be aware of the manufacturer’s specification range for the material’s melt flow index value and/or intrinsic melt viscosity value. During process validation, enough tolerance should be built into the process parameter window(s) to accommodate for lot-to-lot variability and maintain acceptable yields.

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