Silicone Offers Options for Medical Device Design (A Roundtable Q&A)

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Aaron Updegrove, Marketing Manager for Saint-Gobain Performance Plastics, Healthcare Markets [1], responded to questions regarding the use of materials in medical device design and manufacturing. He was included in the staff written article, "Materials Impact Medical Device Design Trends [2]." Following are all of the responses he provided.

Q: *How are materials assisting in the battle against healthcare associated infections?*

Updegrove: The materials used to manufacture medical devices ultimately have an impact on the performance of the finished device, making it critically important that raw material and component suppliers maintain a robust portfolio of pre-validated material solutions that meet global regulatory standards. One of the most important requirements for components in devices that come into direct contact with the human body or fluids is biocompatibility, meaning they will not cause a reaction with the body. USP (U. S. Pharmacopoeia) Class VI is a widely recognized

standard for biocompatibility relating to plastic materials, and it is often the minimal threshold of biocompatibility testing. Pre-testing new materials can be the first line of defense in preventing harmful patient reactions at the point of care, while helping to advance material solutions for devices.

As material science continues to advance, material manufacturers are building on their existing portfolios to ensure they meet the minimum requirements for biocompatibility but also improve performance. Silicone, for example, is a chemically inert material that is capable of meeting the USP Class VI requirement for biocompatibility. While it has been used in the medical device market for decades, recent advancements are allowing for custom compounding of the material to formulate specific properties that are tailored to the end-use device design for better precision, accuracy, and patient safety. Building upon a portfolio of pre-validated materials like silicone to improve device performance is one of the major ways that materials help prevent patient reactions and associated infections.

Q: *How are materials answering the challenges posed by newer, aggressive sterilization systems?*
Updegrove: In the medical industry, sterilization of the finished product, along with repeated sterilization of multi-use devices, such as surgical tools, is a fact of daily life with regards to ensuring patient safety. The industry relies upon three common methods for sterilization: steam, chemical, and irradiation (examples include an autoclave, ethylene oxide, or EtO, and gamma irradiation, respectively). The device manufacturing industry has also recognized that materials potentially can react differently to these sterilization methods. For example, thermoplastic components can become brittle after steam sterilization, or polymeric materials may incur a shift in physical properties after exposure to gamma sterilization. As a result, both material and device manufacturers routinely test the impact of different sterilization methods on their products and materials, determining the most appropriate sterilization methods for their devices, or conversely, manufacturing devices from materials that are compatible with commonly accepted sterilization methodologies.

However, advances in materials can help to overcome traditional limitations. Silicone valves, in particular, can be problematic for medical device designers due to their tendency to re-heal or re-knit after gamma sterilization. This issue speaks to the need for raw material and component suppliers to custom formulate materials that improve performance. For example, at Saint-Gobain Performance Plastics, we developed the Bio-Sil GR Series, which is a specially formulated platinum silicone material that prevents gamma-induced re-knitting of incised slits on check valves, duckbills, and other types of medical valves.

Q: *How are sterile materials impacting medical device design?*
Updegrove: The raw materials used to manufacture medical devices typically are not produced in sterile or clean room environments. Rather, it is often the end product itself that undergoes sterilization, such as gamma or an autoclave cycle, making it imperative to choose materials that can withstand the required processing. For medical device designers, we recommend partnering with material and component suppliers early in the development process so decisions can be

made upfront about what sterilization methods will be used during the product life. This will help define and determine the appropriate materials to be used in the manufacturing of the product. Making informed decisions from the outset of a design project will help medical device manufacturers avoid costly redesigns and delays in bringing a product to market.

Q: *In what direction are material advances headed to address critical needs in medical device design/manufacturing?*
Updegrove: A great deal of material innovation was accomplished in the 20th century, leading to major breakthroughs in polymeric materials that impacted everything from consumer goods and space travel to the automotive industry and the design of medical devices. What we are seeing today, however, is more incremental innovation in the form of custom compounding to develop material properties specific to applications. This custom approach to compounding materials allows manufacturers to target precise properties in a material that directly correlate to the performance of a system. Optimizing and controlling these critical properties helps to improve the performance of the completed product, while also minimizing performance variability. Together, this helps to improve the overall level of patient care while simultaneously increasing patient safety.

Q: *How are materials aiding with the development of devices used directly by the patients in their homes and on their person?*
Updegrove: As the level of healthcare rises, one of the major drivers of design for medical devices used directly by patients in their homes and on their persons is precision. These products must virtually eliminate the possibility for human error. As a materials expert and component supplier, we are constantly working to reduce variability in the parts we produce because they contribute to the overall precision of end-use medical devices. While materials certainly play a large role in consistent performance, the way they are processed is equally important. One way we are approaching this challenge is by closely examining our manufacturing practices, like silicone extrusion, and making the necessary changes to ensure consistent products from lot to lot. Recently, we introduced Compass Technology, a new co-development process that produces real-time manufacturing data to measure the tolerances of extruded silicone tubing used in peristaltic pump applications, like IV therapy. Combined with our custom compounding capability, Compass Technology ensures consistent performance of our materials and end products, minimizing the risks associated with devices that require precise fluid delivery.

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