Combating Infections with the Right Materials (A Roundtable Q&A)

Gopal Saraiya, Global Segment Leader—Medical Devices, Eastman Chemical Company

Eastman's Gopal Saraiya, global segment leader of medical devices at Eastman Chemical Company [1], took time to address a number of questions related to the use of materials in medical device development. 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?*

Saraiya: Hospitals are looking to combat healthcare associated infections (HAIs) to increase patient safety and peace of mind. In addition, financial incentives and public perception benefits for reducing HAIs are increasing dramatically. The highly aggressive disinfectants and powerful cleaners needed to prevent HAIs are harsh on devices and can cause them to crack, craze, and discolor, which comprises patient safety and public peace of mind.

Because of the increased use of these disinfectants, original equipment manufacturers (OEMs) and device designers need to turn to materials that are not compromised by these cleaners. Copolyesters are tough and durable, and they offer excellent chemical resistance against cleaners and disinfectants. They resist cracking and discoloring, improving device functional and aesthetic integrity and resulting in fewer part failures.

Q: *How are materials answering the challenges posed by newer, aggressive sterilization systems?*
Saraiya: With an increased use of aggressive sterilization methods and harsh chemical cleaners, OEMs are turning to materials that are less affected by these disinfectants and sterilization methods. In turn, health facilities are turning to devices made with these materials. Material suppliers need to offer a product that withstands these aggressive systems, and OEMs need to understand the affect sterilization methods and chemicals will have on devices early in the development process in order to select the most appropriate material for the application and environment in which it will be used.

Eastman Tritan copolyester is well-recognized in the marketplace as being a chemical resistant, tough, durable material that retains clarity and integrity. Tritan also demonstrates excellent environmental stress crack resistance after exposure to aggressive chemicals and sterilization methods used to help reduce HAIs. Healthcare personnel and patients associate a device's clarity with cleanliness and patient safety. Clear devices provide personnel with unobstructed views to more easily and quickly see foreign substances, bubbles, clots, and fluid levels.

Q: *In what types of devices are sterile/antimicrobial materials being implemented where they weren't previously?*
Saraiya: Eastman Chemical Company is always exploring new opportunities and areas in which sterile and antimicrobial materials can be used for medical devices. Currently, the company is exploring applications that come in direct contact with patients' skin. Skin-contact applications made with sterile and/or antimicrobial materials can help reduce the flow of pathogens during fluid transfers, during which there is the potential to develop infections.

Q: *How are sterile materials impacting medical device design?*
Saraiya: Understanding how a material used for a medical device functions and responds to harsh chemicals and disinfectants and other sterilization methods helps manufacturers make educated material choices from the onset for successful device design and development.

Manufacturers can then work closely with suppliers to select a material that offers minimal color shift after sterilization and the best chemical resistance to disinfectants. Color stability is extremely important because healthcare personnel often rely on the color-coded attributes of devices to determine their size, type, and function. Healthcare personnel and patients associate devices that have excellent clarity with cleanliness, as they look new, clean, and safe.

Q: *In what direction are material advances headed to address critical needs in*

medical device design/manufacturing?
Saraiya: Suppliers will need to continue to develop materials that have resistance to harsh chemicals and disinfectants that are necessary to combat HAIs. Additionally, one area in which there is ongoing development and innovation to address these critical needs is with antimicrobial material.

Q: *How are materials aiding with the development of devices used directly by the patients in their homes and on their person?*
Saraiya: Home use of devices for preventative care is a growing trend. Patients spend less time in hospitals than they used to, and people want to be able to perform diagnoses at home. Therefore, portable, wireless medical devices are being developed.

Materials that exhibit processability and design flexibility should be considered for portable device development. These materials provide good ergonomics and aesthetics to devices, making them user friendly and ideal for in-home use. Additionally, by using materials with high chemical resistance, home healthcare personnel and even patients can use disinfectants and chemicals readily available at home so as not to affect the functionality of the device.

An example of this is the ViSi Mobile System, a continuous vital signs monitoring device produced by Sotera Wireless that uses Eastman Tritan copolyester for its lens, housing, and connectors. The monitoring system is small, worn on the wrist, and measures and displays all core vital signs. When small devices are developed, design is highly critical. Designers need to be sure the material they use can meet stringent design requirements and offers design flexibility to develop aesthetically pleasing and user friendly device.

Q: *Any additional thoughts or comments on materials for medical devices?*
Saraiya: Keeping infections at bay is an extremely important consideration in the development and use of medical devices. For healthcare facilities, increasing patient safety as well as the financial incentives and public perception benefits for reducing HAIs are increasing dramatically. For OEMs, the aggressive disinfectants and cleaners and other sterilization methods needed to help combat HAIs are harsh on devices and can cause them to discolor, crack, and haze, comprising patient safety and public peace of mind.

Materials that provide high resistance to harsh chemicals and disinfectants need to be considered in the device development process. Using these types of materials will help keep a device from cracking, crazing, and discoloring, as well as keep the device functioning as intended.

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