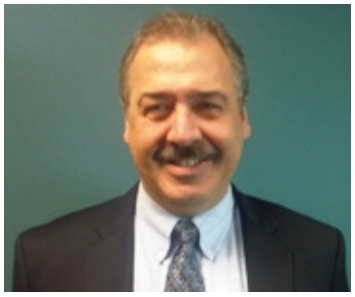
Perspectives on Battling HAIs

What impact does the effort to reduce the incidence of hospital acquired infections have on the development of new medical devices?

Tony Samurkas
Director, Plastics, R&D, Styron LLC



In an effort to reduce hospital acquired Infections, the Center for Disease Control in the U.S. issued guidelines for disinfection and sterilization in healthcare facilities. These guidelines include disinfectants and cleaners for sanitizing various types of medical devices, including passive and powered medical equipment.

Disinfecting solutions contain ingredients ranging from alcohol and bleach to more aggressive solvents like butyl cellosolve. These chemicals pose a challenge to the equipment because they have a tendency to attack the surface materials. In the case of plastic, constant cleaning can cause cracking, crazing, and embrittlement, and eventually, shorten equipment life.

Today’s plastics need to withstand the conditions in healthcare settings. They need to have chemical resistant properties, as well as other properties needed by manufacturers such as ignition resistance, durability, and aesthetic appeal. The challenge—and where innovation really occurs—is to manage these properties to ensure that one property isn’t compromised in favor of another.

Since material choice often impacts product design, developers of medical equipment need to know what materials are available and possible to produce, and work collaboratively with a knowledgeable material supplier early in the development process. This not only controls cost but ensures that final products meet needs and expectations.

Julee Barrett
Hospital Reprocessing Department Manager, Nelson Laboratories Inc.

Although not a new problem, hospital-acquired infections have certainly received increased attention over the past few years. As a result, there is concern that this attention will result in burdensome validations of sterility, packaging, and reuse instructions. However, the reality is that the current standards and testing requirements should already assure an adequate level of rigor. It is my expectation that the biggest impact will be on the time frame and test plan prior to submission. Allotting ample time for generation, performance, and acceptance of the validation is a necessity. Having the test plan preapproved, although time-consuming initially, can save significant time on the backend. Additionally, anticipating potential questions, regarding the test plan, can make all the difference in the world. Without solid preparation, an endless loop of questions and justifications can occur and without thorough knowledge of the device itself, such as materials and actual use, these justifications are impossible. The end result being that the next innovation in medical technology may not go to fruition.

The past six months have been a difficult time for medical device manufacturers attempting a new device launch. In years past, general test requirements were followed, which resulted in vague, difficult to perform instructions for use (IFU) for the end user. In order to stay in line with the competitive landscape and keep technology in medical care advancing, there are important trends to be mindful of when developing a timeline for this type of event.

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

To combat hospital acquired infections (HAIs), material selection at the onset of product development is increasingly important to ensure that devices meet marketplace demands. The aggressive chemical disinfectants and cleaners being used to combat HAIs are harsh on devices and can cause them to crack, potentially comprising patient safety and peace of mind. Medical device manufacturers therefore need to ensure their devices can maintain functional integrity and aesthetics after interaction with these disinfectants and cleaners as well as after sterilization. To develop a robust device, it is pertinent that brand owners understand the effect these chemicals and sterilization methods have from the start of the development process.

Eastman Chemical Company has an innovative material, Eastman Tritan copolyester, that offers the superior chemical resistance that devices need to stand up to harsh disinfectants and strong antibiotics, oncology drugs, and other medications. The toughness and durability of Tritan allows devices to resist cracking after exposure to these chemicals. This results in fewer part failures, thereby reducing waste and saving money.

Eastman Tritan copolyester retains its superior clarity even after undergoing disinfection and sterilization. Doctors, nurses, and patients associate clarity of a device with cleanliness and patient safety. Devices with excellent clarity provide healthcare personnel unobstructed views that allow them to more easily and quickly see foreign substances, bubbles, clots, and fluid levels. Clear devices look new, clean, and safe. When a device has become discolored as a result of chemical disinfectants or sterilization, its function, sterility, and safety can become questionable.

Steve Kennelly
Senior Manager, Medical Products Group, Microchip Technology Inc.

We’re seeing a lot of new medical devices being designed as single-use items, in part to minimize HAI. In many of these devices, the designers are taking advantage of small, low-power, and cost-effective microcontrollers (MCUs) to ensure usage that’s in accordance with the labeling. In the case of a device with a disposable portion, the MCU can perform an encrypted authentication operation when it is connected to the non-disposable part of the device (or console). After the first use, the encryption key can be changed in such a way that the console will not allow reuse.

There are also new medical devices being designed with HAI control as their primary purpose. A number of companies are working on hospital-wide monitoring systems that track hand washing and other sanitization activities. Some of these systems use badges or tags to “watch” hospital staff as they move from room to room. Besides serving as a reminder to maintain hygiene, the data collected could also be used by the hospital to provide documentation that good practices are being followed.

Chris Mertens
VP, Healthcare, Personal Systems Group, HP

Healthcare-associated infections (HAIs) strike an estimated 1.7 million hospital

patients in the U.S. each year, and our infection control strategies have to account for any number of locations where infections can be passed on.

As a top provider of computing solutions to hospitals, we recognize that shared keyboards in hospitals are a prime spot for cross contamination. That's why we recently reached an agreement with Vioguard to add their FDA-approved self-sanitizing keyboard to HP's healthcare technology portfolio. The Vioguard keyboard uses the germicidal properties of ultraviolet light to completely disinfect the keyboard and touchpad, automatically destroying more than 99% of harmful bacteria and viruses within seconds. Users can initiate a disinfection cycle or the keyboard will clean itself after a period of inactivity.

Vioguard and HP are working closely with hospitals to integrate the self-sanitizing keyboards into their busiest environments, such as shared computer stations that are highly susceptible to spreading harmful organisms that could result in an HAI.

We expect that an increased focus on preventing HAIs will lead to the development of medical devices like Vioguard's self-sanitizing keyboard that automate cleaning procedures in hospitals and reduce the need for manually cleaning and disinfecting shared surfaces.

Bradley Michael Stroka
Product and Process Engineer, Precision Manufacturing Group

Nosocomial infections, better known as hospital-acquired infections, are estimated to impact nearly 10% of hospital patients every year, and are a major source of concern for both patients and health care facilities. In 2007, the CDC issued a report where the costs of these infections were listed at $28.4 to $33.8 billion annually. In an effort to minimize the risk of these infections and mitigate the associated costs, medical device manufacturers are looking at new product development in a different light.

One major step is an effort to design medical devices which are practicably disposable. These single-use devices must strike a balance between meeting the final customer specifications, while simultaneously meeting cost requirements. Since these devices will be disposed of after use, the disposal method must be considered during the development cycle to meet any waste

regulations. Not only must devices effectively complete their required function, they must also be able to meet these additional demands.

Manufacturers who can successfully leverage these developments have the potential to gain a competitive advantage in the market as an ever-increasing focus is placed on reducing healthcare-associated infections.