Addressing HAIs and Antimicrobial Materials (A Roundtable Q&A)

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Scott Fallon, formerly the general manager of Global Specialty Products for SABIC'S Innovative Plastics business [1], was a part of the staff written article, "Materials Impact Medical Device Design Trends [2]." He took time to present a full array of responses that were not able to be included in the article, so they are presented here.

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

Fallon: Material solutions to the problem with HAIs are based on addressing two key needs: creating materials that have greater chemical resistance and creating materials that have antimicrobial properties. The use of more aggressive cleaning agents is becoming prevalent in hospitals and other healthcare facilities in an effort to combat the spread of HAIs. These cleaning agents are often detrimental to the materials used in medical devices, which can cause them to degrade or perform poorly. There is an opportunity to develop materials that are better able to withstand harsh chemicals. A second approach to reducing HAIs involves the use of antimicrobial materials, such as the new line of antimicrobial engineered resins from SABIC's Innovative Plastics business. These new products are available in a variety of resins, including LEXAN resin and various blends, to target a wide range of medical applications where it is important to reduce the potential spread of

germs. These include high touch surfaces, such as bed rails; medical carts; in-dwelling items such as catheters, drains, and IV components; and fluid delivery applications such as tubing.

Q: How are materials answering the challenges posed by newer, aggressive sterilization systems?

Fallon: SABIC recently announced third-party test results that validate the multiple sterilization capabilities of its remarkably tough ULTEM HU1004 polyetherimide (PEI) resin. This high-performance resin—previously utilized with other sterilization techniques and now tested for use with the STERRAD NX low-temperature hydrogen peroxide gas plasma sterilization—gives healthcare providers the flexibility to choose any major method for sterilizing trays, electronic medical devices, and other applications. The data revealed that ULTEM HU1004 resin has significant performance and aesthetic advantages—in particular, ductility and color stability—over competitive materials such as polyphenylsulfone (PPSU) that are used with STERRAD NX sterilization. ULTEM HU1004 resin's validation underscores SABIC's commitment to providing its healthcare customers with the highest quality materials to meet their needs for process simplification and performance.

Q: *In what types of devices are sterile/antimicrobial materials being implemented where they weren't previously?*

Fallon: Antimicrobial materials and/or coating have been used in catheters, wound dressings, and other likely infection routes (such as implantable devices) for many years. However, medical device makers are considering the merit of these high performance materials in many more devices today, such as high touch surfaces like bed rails and electronic touch pads due to heightened awareness of the problem of HAIs.

Q: *How are sterile materials impacting medical device design?*

Fallon: Current generations of antimicrobial materials typically focus on migrating an active species (such as silver ions) to the surface in order to achieve desired performance, but next generations of materials will likely contain better engineered surfaces and/or inherently antimicrobial materials and/or coatings. Also, newer methods of sterilization will impact these efforts, likely creating a need for more specialized, high performance solutions. Finally, the trend of achieving cost reductions through sustainability efforts by validating sterilization and reuse procedures will likely create more demand for these same types of materials.

Q: *In what direction are material advances headed to address critical needs in medical device design/manufacturing?*

Fallon: Material advances are needed to support inherent antimicrobial resistance; safe and effective multiple re-use of devices; bio-inert compositions, and improved performance while enabling lower system costs.

Q: How are materials aiding with the development of devices used directly by the patients in their homes and on their person?

Fallon: The increase in home health care and patient-directed care has created trends for greater portability, miniaturization and greater aesthetics, all of which combine to support patient acceptance and compliance with treatment protocols.

These trends, in turn, are driving a strong need for high performance engineered thermoplastics that can provide ease of processing and assembly, and superior mechanical properties to address these trends. For instance, PWB Health Ltd. from Dumbarton, Scotland developed the award-winning Breastlight, a home-use device that makes it easier to perform self-examinations by literally shining a light on breast tissue to illuminate internal changes. PWB Health had a number of application requirements, beginning with the device's housing. Because the product is typically used in the bathroom where it might drop onto a hard tile floor, the company wanted a tough, impact-resistant resin. A bright white color was specified, but at the same time this light colored resin needed to minimize light seepage from high-power red LED bulbs. For ease of use, PWB Health wanted relatively thin walls (2 mm) to make the housing lightweight, which required a high-flow resin. Also, the material had to be a medical grade. For the Breastlight lens, the company wanted a crystal-clear material with excellent impact resistance and the ability to be ultrasonically welded. To optimize the performance and durability of the Breastlight, PWB Health Ltd. Selected SABIC's LEXAN and CYCOLOY healthcare resins for use in the housing and lens of the device. CYCOLOY resin, which is assessed to ISO10993 standard for biocompatibility, offers excellent impact resistance for durability and a high flow for thin-wall molding. It also offers the ability to incorporate special opacifiers without deteriorating mechanical properties. SABIC's Innovative Plastics business color-matched the desired white shade at its COLORXPRESS facility in Bergen op Zoom, The Netherlands. For the lens, LEXAN polycarbonate resin was selected for its optical clarity, impact resistance and the ability to be ultrasonically welded to the housing. This grade is also assessed to ISO10993 standard for biocompatibility.

Q: *Any additional thoughts or comments on materials that you'd like to share with the medical device design/manufacturing industry?*

Fallon: Yes. Because we see our role as helping our global healthcare customers achieve their goals, we have invested in developing one of the industry's broadest healthcare product portfolios, differentiated by our Healthcare Product Policy. SABIC developed its Healthcare Product Policy to provide OEMs with the security of knowing that the materials used in development of their devices would:

- Meet global standards for safety
- Be available in a consistently formulated supply
- Be pre-assessed for biocompatibility

The Healthcare Product Policy provides:

- Easily identifiable product nomenclature ("H" or "PCG" series resins)
- Biocompatibility assessment according to ISO 10993 or USP Class VI
- Food contact compliance for most healthcare products
- FDA Drug Master File and/or Device Master File listing (letter of authorization provided as needed)
- A "formula lock" and stringent management of change process to protect surety of supply for up to 18 months in the event changes need to be made

to existing grades of materials

And, because SABIC has both unique copolymer technologies and unmatched compounding expertise, we are able to deliver specialty materials with desired effects that are superior to those developed through a masterbatch process. Some of the effects required for healthcare include:

Shielding against radiation and electromagnetic/radio-frequency interference (EMI/RFI): SABIC's Thermocomp HSG (high specific gravity) compound can replace lead in radiation shielding applications, enabling medical imaging device manufacturers to meet the European Union's (EU) Restriction of Hazardous Substances (RoHS) directive. Faradex compound combines SABIC's LEXAN EXL resin with proprietary fillers and additives to provide EMI/RFI shielding solutions with superior toughness, flame retardance and processability.

Detecting lost device parts: Thermocomp compound can help to make a surgical device detectable via X-ray imaging. This safeguard allows the fragments to be located and retrieved before concluding the procedure.

Decreasing "slip-stick": Lubricomp and Lubriloy compounds help to decrease the chance that a surgical device will slip or stick due to wear and friction. The inherent lubrication properties of these materials help ensure that the device performs consistently, thus avoiding errors and accidents.

Avoiding fire hazards: Stat-Kon compound combines base resins with electrically conductive fillers or reinforcing agents to produce conductive and dissipative materials. STAT-KON compound helps protect devices and components against static build-up and electrostatic discharge (ESD), which present potential fire hazards in operating rooms and other locations where oxygen is used.

Ensuring consistent drug delivery: Stat-Loy compound provides permanent anti-static properties. This is important in drug delivery systems to prevent the medication from adhering to device walls and resulting in inconsistent dosages.

At the end of the day, though, it's more than a materials discussion—innovative designs can be enhanced by collaboration among the materials provider, the designer and the molder to achieve optimal, differentiated results. SABIC has deep experience in working with designers and molders to advise on material selection, assess molding issues, and help designers understand material characteristics in a way that may spark future product innovations.

Links:
[1] http://www.sabic-ip.com/

[2] http://www.mdtmag.com/articles/2013/06/materials-impact-medical-device-design-trends