Thermoplastic Material Solutions with High Heat Sterilization Capability

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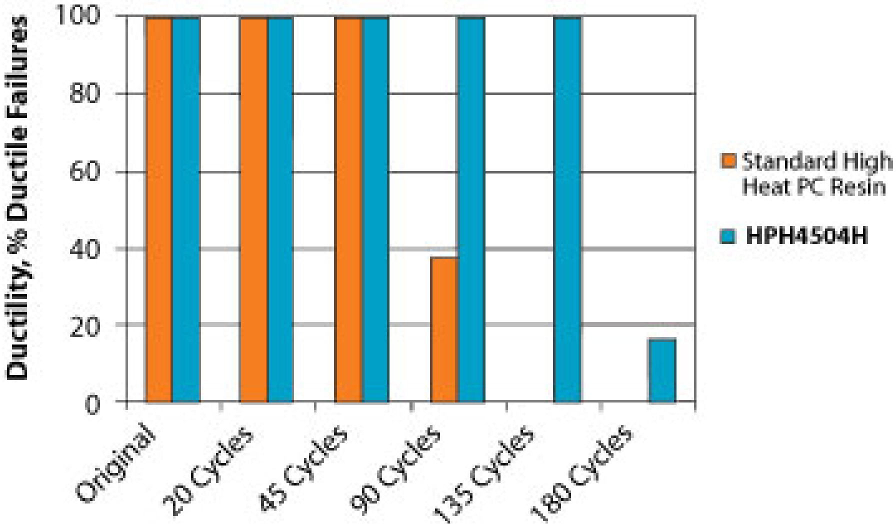
This article presents innovative material solutions supporting multi-use medical device applications. Respective materials support a broad range of application requirements, like transparency, property retention after autoclaving, colorability, and chemical resistance against commonly used disinfectants/cleaning agents.

Multi-use electrosurgical pen, by Megadyne Medical Products [1], made with PS/PPE blend and polyetherimide resin.

Trends within and outside the hospital and clinic institutes are related to achieving overall better care, maintaining a high level of patient and staff safety, and facilitating a lower care cost structure without comprising critical quality standards. These trends are directly reflected in the continuous evolution of medical devices. Medical devices are reengineered and redesigned to meet criteria concerning integrated functionality, efficient and comfortable use in different point-of-care situations, aesthetics, and changes driven by the regulatory/legislative framework.

The increased use of engineering thermoplastics in medical devices has resulted in material solutions that have the capability of efficient sterilization and/or disinfection while meeting stringent overall property performance requirements. Sterilization can be defined as the removal and/or destruction of microbial organisms, including spores of bacterial or fungal nature. Disinfection is a lower grade of sterilization and only destructs pathogenic organisms. Disinfection is less expensive compared to typical sterilization methods. A medical device should be appropriately disinfected or sterilized based on its intended use. Sterilization methods typically used for thermoplastics involve autoclaving, irradiation (gamma or e-beam/beta rays), or gaseous chemicals [e.g., ethylene oxide (EtO)].



Graph 1: Retention of ductility in a multi-axial impact experiment upon autoclaving (20 min/cycle) of Lexan HPH4504H resin compared to standard high heat polycarbonate resin.

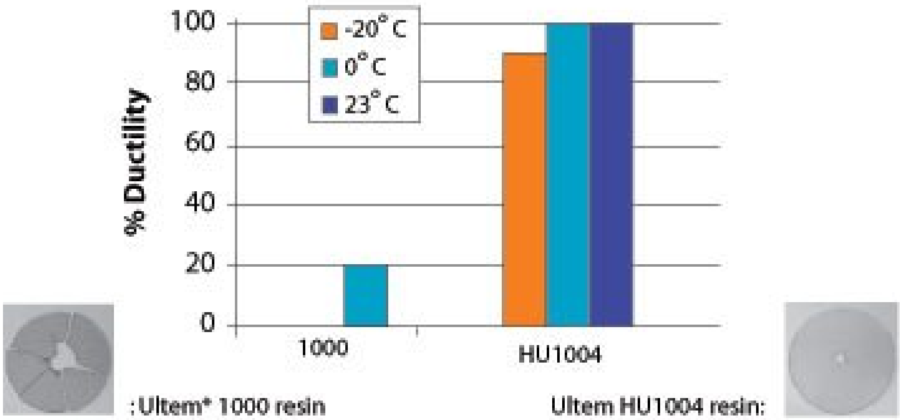
Many medical devices are routinely cleaned and sterilized via the previously mentioned methods. During these processes, the medical devices are repeatedly exposed to high temperatures (typically 121-134°C), gamma or beta radiation, or gases like EtO. Additionally, a disinfection cycle with disinfection chemicals is typically part of the autoclave process. A shift in autoclaving temperatures ranging from 121 to 134°C and higher is seen as a consequence of stricter requirements for cleanliness of multi-use medical devices. Institutes, like the Robert Koch Institute in Germany [2], issue revised guidelines to meet new standards of cleanliness to avoid any hospital-borne infections. The capability to raise autoclaving temperature from 121 to 134°C also provides a significant productivity opportunity in terms of autoclave cycle time.

Exposure at elevated temperatures during the autoclave cycle may contribute to deterioration of the thermoplastic used in the medical device. Therefore, it is critical for designers to have knowledge on the effect of the autoclave cycle on the retention of overall material properties, including the potential effect of used disinfectants.

Material Solutions
SABIC's Innovative Plastics business [3] has introduced a range of products to support the need for efficient autoclaving at elevated temperatures in view of client and clinician safety. In addition, these products demonstrate good chemical resistance against disinfectants and other chemical agents that are commonly used in the healthcare industry. Respective products are potential candidates for use in multi-use medical devices. Three of these products will be discussed in more detail: Lexan HPH4504H resin (HPH PC), Ultem HU1004 resin (PEI), and Noryl HNA055 resin (PS/PPE). All three products are included in the healthcare product portfolio, food

contact compliant, assessed and compliant according ISO10993, and developed for steam sterilization at 134°C.

Lexan HPH4504H (HPH PC) is a clear transparent, high heat resistant polycarbonate resin providing good impact retention at autoclaving at 134°C (Graph 1). HPH PC resin shows a significant improvement in terms of retention of ductility upon autoclaving compared to standard high heat polycarbonate resins. HPH PC resin is suited for cleaning in an acidic environment; exposure to extreme alkaline environments should be avoided with polycarbonate-based resins. Another benefit of HPH PC resin is the good retention of its original transparent color following autoclaving compared to polysulphone resins that are more prone to yellowing.



Graph 2: Initial multi-axial impact strength of Ultem HU1004 resin compared to standard polyetherimide resin.

Ultem HU1004 resin (PEI) has been a recent addition to the healthcare product portfolio as an improvement over existing high heat resins that are targeted for medical devices requiring high heat steam sterilization. The improved PEI resin maintains its high performance and amber transparent appearance even after numerous cycles of chemical cleaning in a strong alkaline environment (pH range 12-13) and over 1,000 cycles of autoclaving at temperatures of 134°C. A strong alkaline environment and elevated temperatures are applied to obtain quality cleanliness in line with regulatory guidelines. Graph 2 shows a comparison of initial multi-axial impact performance—clearly demonstrating the improvement in impact strength of PEI even at sub-ambient temperatures. In addition, PEI demonstrates the typical polyetherimide performance profile—a unique balance of excellent processing, dimensional stability, high strength, and stiffness at elevated temperatures.

Noryl HNA055 resin (PS/PPE) is an excellent material candidate for medical device applications too. This opaque PS/PPE resin is biocompatible according to ISO10993, and can withstand repeated steam autoclaving and other types of sterilization without significant change of properties. PS/PPE samples in a laboratory experiment maintained mechanical performance for up to 2,500 autoclave sterilization cycles at 134°C (20 min/cycle). PS/PPE resin has a good chemical resistance and can be cleaned in both acidic and strong alkaline environments. Other key performance attributes of PS/PPE are impact resistance, dimensional stability, hydrolytic stability, and high performance under high and low temperature conditions. Additionally, PS/PPE resins provide a benefit in terms of specific gravity in comparison to other engineering thermoplastic resins.

Conclusion
The trends for multi-use medical devices call for innovative material solutions that have a good retention of mechanical performance upon autoclaving at elevated temperatures(e.g., 134°C).The table summarizes key material attributes of the three healthcare grades developed at SABIC’s Innovative Plastics business that are targeted to support more stringent requirements in multi-use medical devices.

Table

Key Considerations	Lexan* HPH resin	Ultem* HU Resin	Noryl*HNA Resin
Biocompatibility[++]	yes	yes	yes
Food Contact Compliance[1] (FDA and EU)	yes	yes	yes
134 °C Autoclave (test data available)	yes	yes	yes
Instrument Disinfection (General guidance is provided; however, due to the large range of chemicals available, testing is strongly recommended; SABIC IP test data available)	Generally resistant to commonly used hospital disinfectants including solvents, strong acids & avoid mild/strong bases.	Generally resistant to commonly used hospital disinfectants including solvents, strong acids & mild bases; avoid strong bases.	Generally resistant to commonly used hospital disinfectants including solvents, strong acids & bases
Color Capability	Clear transparent & Opaque colors	Amber transparent & Opaque colors	Opaque colors only
Specific Gravity (ASTM D792)	1.20	1.28	1.08
Processing	Injection Moldable	Injection Moldable & Machinable	Injection Moldable & Machinable

[1] Confirm status specific grade-color with SABIC IP Product Stewardship
[++]Biocompatibility: A representative lot of material tested either by ISO 10993 or USP VI protocol. Test data available via Type I or Type II letter. Type I Letter: Issued for products that have been specifically tested for biocompatibility. Type II Letter: Issued when specific product has not been tested but similar products have been tested for biocompatibility.

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