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Medical Applications of Polycarbonate

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Polycarbonate fills an important niche as one of the most popular engineering resins in the medical device market. Bisphenol-A polycarbonate has been commercially available since the 1960s, and its use in medical devices dates from approximately that time. Possessing a broad range of physical properties that enable it to replace glass or metal in many products, polycarbonate offers an unusual combination of strength, rigidity, and toughness that helps prevent potentially life-threatening material failures. In addition, it provides glasslike clarity, a critical characteristic for clinical and diagnostic settings in which visibility of tissues, blood, and other fluids is required. Because biocompatibility is essential for any material used in direct or indirect contact with patients, polycarbonate grades are available that comply with biocompatibility testing standards such as ISO 10993-1 and USP Class VI.

A recently developed lipid-resistant polycarbonate formulation (Makrolon DP1-1805, Bayer Corp., Pittsburgh, PA) was used to manufacture components of a needle-free IV system (Safsite, from B. Braun Medical, Inc., Bethlehem, PA).

PROCESSING

Polycarbonate can be processed with standard injection molding equipment. It can also be blow-molded into hollow containers or extruded into film, sheet, and thick- or thin-walled tubing. Polycarbonate sheet and film can be thermoformed into various complex shapes. For short-run devices or prototypes, polycarbonate rod and slabs can be cut, milled, and machined to the desired configuration.

STERILIZATION

In the medical market, sterilization is a crucial factor in the development of devices that have direct contact with patients. A key attribute for polycarbonate is that it can be sterilized using all major methods: ethylene oxide (EtO), irradiation (both gamma and electron-beam), and steam autoclaving. Polycarbonate can also be disinfected with common clinical disinfectants, such as isopropyl alcohol. This range of techniques offers the device designer broad flexibility in determining the most cost-effective method for a particular product. Polycarbonate is not suitable for devices that will be autoclaved repeatedly.

TYPICAL APPLICATIONS

The major properties of polycarbonate—clarity, high strength and impact resistance, good heat resistance, low water absorption, and biocompatibility—have led to its use in a wide range of critical medical devices.

Renal Dialysis. Patients with end-stage renal disease often require external treatment of their blood (hemodialysis) to remove excess water and toxins that cannot be removed by their failing kidneys. Hemodialysis is most often accomplished by passing the patient's blood through a semipermeable membrane cartridge. Filter cartridges engineered from polycarbonate provide a rigid housing that supports and protects the fragile hemodialysis membrane. The polycarbonate material resists shattering during manufacture, shipping, and use, and its thermal stability allows for single-pass steam sterilization or processing via EtO or gamma. Clarity of the housing is vital, enabling the dialysis technician to observe the blood throughout the procedure.

Cardiac Surgery Products. During invasive cardiac surgery, such as coronary-artery bypass and valve replacement, the heart is stopped and a blood oxygenator takes over the function of the heart and lungs. Polycarbonate has been used in blood oxygenators, blood reservoirs, and blood filters used in the bypass circuit for more than 20 years. Glasslike clarity is required to allow for visual evaluation of blood flow and condition during the procedure, while the toughness of the material provides an optimal level of safety.

In the course of many surgical procedures, blood is recovered, filtered, and reinfused into the patient, minimizing the need for donated blood. Various blood-management products feature polycarbonate filters and centrifuge filter bowls to clean and separate blood components for reuse. Because the filter bowls spin at high rates, generating intense forces, the bowl material must be strong enough to maintain its integrity throughout the process in order to prevent fracture and spilling of the contents.

Surgical Instruments. Surgical instruments used in minimally invasive procedures have also benefited from polycarbonate in their design and use. Taking advantage of the polymer's rigidity and toughness, instrument designers specify polycarbonate as a replacement for metal. Products such as trocars—essentially long tubes that act as a pathway for inserting surgical instruments into the body cavity—must be able to avoid bending and possible fracture as they are positioned by the surgeon, and should be transparent to facilitate inspection of instruments inside the tube. Trocars are typically sterilized by radiation, to which polycarbonate is stable. Additional products well suited for fabrication with polycarbonate include inflators, which are syringelike instruments used to pressurize flexible catheters during angioplasty procedures. The transparent inflation chambers of these devices must be dimensionally stable and able to resist shattering under pressure.

IV Connection Components. Connectors used in intravenous (IV) fluid lines and other fluid-transfer systems are ubiquitous in the medical device industry, comprising components such as stopcocks, y-injection sites, cannulae, check valves, filter housings, and male and female luer fittings. These products are typically bonded to flexible PVC tubing to create preassembled sets that are stripped sterile for clinical use. For such components, polycarbonate gives the device manufacturer valuable flexibility in choosing the sterilization mode. For example, preassembled kits are most often sterilized with radiation or EtO; however, if a prepackaged pharmaceutical is included in the kit, it can be steam autoclaved to avoid potential interactions of these methods with the drug. Once again, clarity and toughness are the important characteristics for polycarbonate connectors. Transparent components permit the user to monitor fluid flow or see obstructions in an IV line, while toughness and dimensional stability allow for tight connections with minimal risk of leaking.

POLYCARBONATE DEVELOPMENTS FOR THE MEDICAL MARKET

The success of standard polycarbonate formulations in medical components has led to the development over time of specialized resin grades specifically designed to meet certain processing or end-use conditions of the device market.

Radiation Grades. High-energy irradiation has grown rapidly as a sterilization method for polymer-based devices. Unlike EtO, irradiation leaves behind no residue, and it can be used for thermally sensitive components when steam autoclaving is inappropriate. Products can be sterilized while sealed in their packaging, and the fully penetrating irradiation places fewer constraints on device configuration compared with other methods.

Radiation-grade polycarbonates are a relatively new development for the medical product market. Polycarbonate is inherently stable to gamma radiation at doses up to approximately 100 kGy, and resists embrittlement or other degradation of its physical properties. However, clear polycarbonate grades undergo considerable yellowing after irradiation, which is aesthetically undesirable. Early attempts to counteract this color change included adding a dye to alter the color after irradiation. While this helped mask the discoloration, products often looked dark and gray. The ability for device users to see through the polycarbonate was also diminished by this approach.

More recent developments have led to polycarbonate grades with special additives that actually prevent discoloration by chemically inhibiting the processes that lead to formation of colored species during the irradiation process. This has resulted in polycarbonate grades with a 60–90% reduction in yellowness after irradiation (see Figure 1). These products maintain high transparency while remaining aesthetically pleasing.

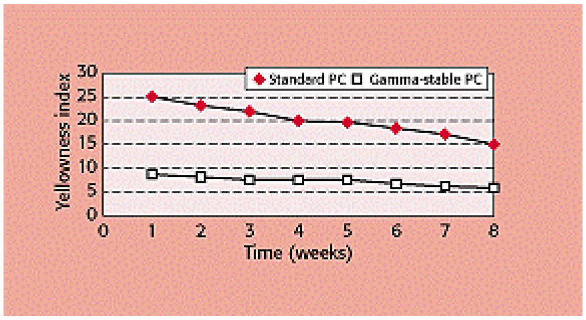
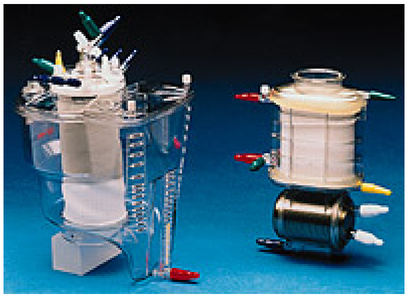


Figure 1. Yellowness index of standard and gamma-stable polycarbonate following gamma radiation sterilization (35-kGy dose, 2.5-mm sample thickness).

High-Temperature Grades. With a service temperature of approximately 250°F, polycarbonate medical devices can be steam autoclaved. Recently, high-heat or "flash" autoclaving, which operates at temperatures of about 270°F, has been introduced to help shorten the autoclave cycle. Because standard polycarbonate can distort at temperatures above 250°F, it cannot be used in these high-temperature autoclaving processes. Multiple autoclaving cycles can also degrade the polymer's physical properties.

To address the need for a polycarbonate that can withstand flash autoclaving or limited multiple autoclave cycles, manufacturers have developed high-temperature grades. These products are typically copolymers that impart higher heat resistance to the resin with little effect on the overall property profile. Applications include dental or surgical devices that must be autoclaved in the clinic prior to use and clinical labware that may be autoclaved repeatedly.



Polycarbonates with internal mold-release agents can eliminate the need for external mold-release sprays in the fabrication of complex parts.

Polycarbonate Blends. Polycarbonate can be blended with other polymers to provide an alloy with enhanced properties compared with the nonblended resins. Common examples include blends with acrylonitrile-butadiene-styrene (ABS) terpolymers and blends with polyester.

Polycarbonate/ABS blends combine the strength and rigidity of polycarbonate with the easy flow and toughness of ABS. The result is a blend with polycarbonate-like properties that can be injection molded into large, rigid equipment housings or other structural components. Examples are rigid housings for medical equipment and diagnostic instruments. These blends can be combined with flame-retardant technology to provide an appropriate housing for medical electronic equipment and other diagnostic instruments.

Polycarbonate/polyester blends demonstrate many of the same properties as those of polycarbonate/ABS. In addition, the polyester content provides for optimum chemical resistance for equipment that will be used in challenging chemical environments. Among the products manufactured from polycarbonate/polyester blends are portable diagnostic equipment, therapeutic equipment such as portable respiratory therapy devices, in-home dialysis equipment, and portable defibrillators.

Gamma radiation–stable polycarbonate formulations include slightly tinted grades that revert to clear following gamma sterilization.

Polycarbonate Film. Polycarbonate can be extruded into film that offers high gloss and clarity, and that can be thermoformed into strong, clear packaging for critical medical devices. Polycarbonate films provide superior impact resistance, and will not stress-whiten when hit or otherwise damaged. The polycarbonate package and its contents can be sterilized by radiation or EtO. Alternatively, the heat resistance of polycarbonate packaging allows the device to be steam autoclaved by the end-user inside the package prior to use.

Enhanced-Productivity Grades for Cleanroom Molding. New medical-grade polycarbonate resins are commercially available that incorporate recently developed technology for easy release of molded components from tooling (see Figure 2). These formulations help eliminate the need for external mold sprays that can contaminate the part and lead to extra costs for subsequent cleaning. In addition, component molding can be consolidated into cleanroom areas where aerosol sprays cannot be used.

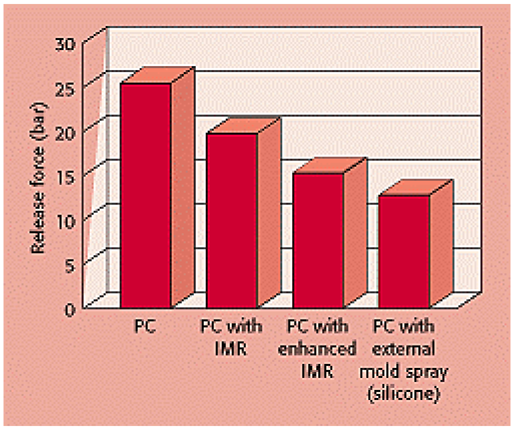


Figure 2. Comparative mold-ejection force (hydraulic ejection force) of standard polycarbonate and formulations incorporating internal mold release (IMR) agents.

Typical applications include blood reservoirs and other critical components used in cardiac surgery—which would otherwise require cleaning before being assembled—or any molded product that is difficult to remove from the tool.

Lipid-Resistant Grades. In the past few years, the use of lipid or fat emulsions for IV therapy has grown in popularity. The reason is that lipid emulsions are better suited than are aqueous solutions for administering certain drugs that may not be water soluble. Although polycarbonate has long been used safely and effectively for IV connector components, fatty solutions can attack the polymer while it is under stress load, causing anything from minor crazing to cracks and leaks. Female luer fittings are particularly susceptible to stress cracking. Compounding the problem is that, as part of a drive to reduce costs, IV sets may be left in place from 48 to 96 hours rather than changed out every 24 hours. The longer the exposure, the greater the chance for stress-related attack of the component. Polycarbonate can be replaced with other expensive and often exotic resins, but the cost can prohibit widespread use. In addition, many bonding, joining, and other secondary operations must be retooled to account for the different properties of the new material.

Recently, lipid-resistant polycarbonate grades have been developed for the IV component market. These products have many of the attributes of standard polycarbonate grades but with dramatically improved resistance to stress-related failure when exposed to typical lipid emulsions.

CONCLUSION

Polycarbonate occupies a unique niche in the medical device market. Engineers have tapped its key characteristics of toughness, rigidity, and strength for critical device applications in which safety and performance are vital. The ease of sterilizability of polycarbonate gives designers wide latitude in developing products that are not dependent on a single sterilization method. These features are further complemented by polycarbonate's high clarity, a key benefit when visual assessment of patients and their prescribed therapies is indispensable.

Polycarbonate suppliers have responded to the specific needs of device companies by developing medical grades with specially tailored features: for example, radiation grades for minimal color change, high-heat grades for faster autoclaving, easy-release grades for lubricant-free cleanroom molding, and lipid-resistant grades for lipid-based IV therapies. Polycarbonate alloys with ABS or polyester further advance the performance of polycarbonate in a variety of medical equipment and diagnostic instruments.

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