

Eastman™ Plastics for Medical Applications

Combining Medical and Polymer Science to Deliver the Material Difference™

Medical science is also material science. Eastman Chemical Company supplies high-quality products for numerous applications within the medical industry, ranging from plastics for non-implantable medical devices and packaging used in the operating room to coatings for familiar household pharmaceuticals.

For more than 65 years, OEMs have benefited from using Eastman's portfolio of plastics in a wide range of medical device and packaging applications that meet performance demands and regulatory requirements. Additionally, our copolyester and cellulosic resins are environmentally responsible materials that are free of ortho-phthalate plasticizers, bisphenol-A, and halogens. The absence of chlorine in copolyesters and cellulose avoids the potential for generation of polychlorinated pollutants during incineration.

Eastman has enjoyed the trust of the industry's foremost innovators. We continually collaborate with customers throughout the value chain to develop medical devices and packaging on the cutting edge of science.

Eastman understands the needs of the medical industry. Our products are used in devices as well as protective/functional packaging, giving us the ability to deliver a total solution to our customers. For medical grade resins, we can provide ISO 10993 biocompatibility and USP Class VI test reports. Technical data and U.S. drug or device master file authorizations are available for some resins. OEMs can speed development time and bring applications to market quickly with Eastman's comprehensive applications development and technical support.

Medical Devices

Eastman™ plastics are key components used in numerous medical nonimplantable devices, including syringes, minimally invasive surgical instruments, blood therapy systems, rigid and flexible tubing, and IV components. We offer a diverse product line of DuraStar™ and Eastar™ copolyesters, Eastalloy™ copolyester/polycarbonate blends, and Tenite™ cellulose. These products provide a broad range of properties to deliver application performance and flexibility. For instance, color stability and mechanical properties are not affected by sterilization techniques, including gamma and e-beam.



Eastman™ copolyesters have excellent chemical resistance to lipids, isopropanol, and most cleaning solutions. Eastman™ plastics also perform well in secondary operations such as solvent bonding and laser and ultrasonic welding.

Rigid Medical Packaging

Sheet of Eastar™ copolyester 6763 is the industry standard in rigid medical trays, delivering functionality with performance that has withstood the test of time. It maintains long-term clarity and does not yellow or stress-whiten over time. Due to its inherent toughness, it provides puncture resistance, critical to maintaining a superior sterile barrier. It has excellent thermoformability and cuts cleanly, eliminating the possibility of particle generation which can lead to contamination.



Flexible Medical Packaging

From Ecdel™ thermoplastic elastomers to Eastar™ copolyester plastics, Eastman™ resins can be used to produce high-quality monolayer or multilayer films for highly demanding flexible packaging applications. The unique attributes of Eastman™ resins enable cost-effective packaging for fluids like IV solutions and blood, as well as form-fill-seal packaging for bulk pharmaceuticals and medical devices. Ecdel™ elastomers provide several advantages: autoclavability, toughness, clarity, flexibility without plasticizers, outstanding heat resistance, improved package heat sealability, and long-term integrity.



Healthcare Supplies

Eastman™ copolyesters can be molded into thick-walled bottles with glass-like appearance that have improved toughness and reduced weight. They can also enable the production of cost-effective, thin-walled containers that provide the safety and performance characteristics necessary to withstand the rigors of usage. Eastman™ copolyesters maintain good clarity after sterilization and have excellent chemical resistance.



About Eastman Chemical Company

Founded in 1920 and headquartered in Kingsport, Tenn., Eastman Chemical Company manufactures and markets plastics, chemicals, and fibers worldwide. Eastman is a FORTUNE 500 company with 2007 sales of \$6.8 billion and approximately 11,000 employees.

EASTMAN

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Material Safety Data Sheets providing safety precautions, that should be observed when handling and storing Eastman products, are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product in order to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (sub-acute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available upon request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

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