EASTMAN

Applications for Eastman medical polymers

When medical science meets polymer science

Eastman Chemical Company has been a trusted supplier to the medical market for more than 70 years and has consistently raised standards for quality, reliability, patient safety and comfort, customer service, and sustainability.*

Eastman brings customers a "total-solutions" approach, combining our collaborative philosophy and industry expertise with our growing portfolio of Eastman medical polymers. This marriage of application and material knowledge can advance innovation in market-changing ways.

Medical devices

(including syringes, instruments, blood contact devices, rigid and flexible tubing, IV components)

Eastman Tritan™ copolyester MX711 has transformed how the industry looks at clear medical grade polymers. Its combination of processability, chemical resistance, toughness, and compatibility with sterilization methods (gamma, e-beam, and EtO) helps Tritan deliver advantages over heritage copolyesters, polycarbonates, and acrylics. Tritan MX731 is also available for thin-walled applications requiring high flow.

The portfolio of Eastman medical polymers also includes DuraStar™ polymers, Eastar™ copolyesters, Eastman Provista™ copolymer, and Tenite™ cellulosics. All retain color and mechanical integrity following sterilization, and all Eastman copolyesters provide excellent chemical resistance to lipids, isopropanol, disinfectants like Virex™ Tb, oncology drugs, and cleaning agents. In fact, Tenite is recognized as the industry leader in chemical resistance.

Flexible medical packaging

(including blood and IV bags and form-fill-seal packaging for pharmaceuticals and devices)

Ecdel™ elastomers and Eastar™ copolyesters can be used to produce high quality monolayer or multilayer films for highly demanding flexible-packaging applications. In addition to toughness, clarity, and flexibility without plasticizers, Ecdel is autoclavable and provides outstanding heat sealability and long-term integrity.

Rigid medical packaging

Eastar 6763 sheet has been the industry standard in rigid medical packaging for more than 20 years. It maintains long-term clarity without yellowing or stress-whitening. Its inherent toughness and puncture resistance help maintain a superior sterile barrier. Processing advantages include excellent thermoformability and clean cutting without generating particles that can lead to contamination.

Eastman Tritan™ copolyester MP100 provides many of the same benefits, including best-in-class toughness. Tritan also has high-heat resistance, allowing for more rapid accelerated aging protocols and increased package shelf life.

Health care supplies

Eastman copolyesters can be molded into thick-walled applications with glass-like appearance, improved toughness, and reduced weight. Excellent toughness also allows cost-effective, thin-walled containers with proven performance and safety. All maintain good clarity after sterilization and have excellent chemical resistance.

For more information about Eastman medical polymers or how Eastman can work with you to bring innovation to market efficiently, visit www.eastman.com/medical or call 1-800-EASTMAN (1-800-327-8626, Ext. 5408).

**For more information about the progress of Eastman's sustainability efforts, visit http://www.eastman.com/Company/Sustainability.*

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The results of **insight**™

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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 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 (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on 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 on 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.