EASTMAN

Improving through innovation

Eastman and Minntech Corporation enhance performance in the renal market.

Minntech Corporation, a leading manufacturer of medical devices, sterilants, and water purification devices, was the first to take advantage of the cutting-edge attributes of Eastman Tritan™ copolyester in the renal market. Minntech needed a material for its Hemocor HPH hemoconcentrators and Renaflo II hemofilters that could protect these devices' internal membranes as well as reduce waste from product failure. The material also had to be chemically resistant to avoid stress cracking and be able to withstand exposure to blood, lipids, and chemical agents. Tritan meets all these needs and is manufactured without bisphenol A (BPA), *ortho*-phthalate plasticizers, or halogens. In addition, the higher glass transition temperature of Tritan allowed the company to utilize existing molds and improve processing capabilities.

For more information on Eastman Tritan™ copolyester, visit www.eastman.com/tritan.

Eastman Tritan™ copolyester enhances application performance by providing toughness, chemical resistance, and color stability after sterilization.

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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.

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