Innovations in IV components

Exceptional clarity, durability, and chemical resistance deliver superior devices and patient safety.
Taking to heart the clear need for chemical resistance.

In an environment that encourages the use of aggressive cleaners and disinfectants to prevent hospital acquired infections (HAIs), Eastman Tritan™ copolyester provides a welcome alternative. Tritan is a tough, clear polymer that delivers best-in-class chemical resistance. It helps manufacturers of intravenous (IV) components differentiate their products in the marketplace while improving user satisfaction and confidence.

See a consistent difference in clarity.

Components made with Eastman Tritan™ copolyester experience little or no stress cracking or haziness from contact with cleaners and disinfectants, or from lipids, isopropyl alcohol, or bonding solvents. Limited testing with oncology drugs also shows little or no stress cracking or haziness.

• Unlike many other polymers, Tritan does not suffer color shifting or loss of properties following nonautoclave sterilization methods such as gamma or electron beam (e-beam) radiation.
• Tritan can offer significant advantages in components such as Y-sites, stopcocks, or manifolds where stress cracking is more prevalent on exposure to aggressive solvents, disinfectants, and cleaners.
• Improved visibility of IV fluids and pharmaceuticals by the health care team can result in improved patient safety.

Eastman Tritan™ copolyester has been rigorously tested by reputable third-party labs and shown to be free of estrogenic activity.

See clear advantages over polycarbonate (PC).

Eastman Tritan™ copolyester provides toughness that is comparable with polycarbonate (PC) with minimal changes to tool design or molding process parameters. In addition, Tritan delivers greater color stability after sterilization and is manufactured without bisphenol A (BPA).

Eastman Tritan™ copolyester offers performance and processing advantages over PC.

• Tritan does not require annealing to relieve inherent residual stress, which can reduce cycle time and energy costs. Low residual stresses offer significant chemical resistance advantages.
• Tritan is significantly more solvent compatible, allowing greater freedom in secondary operations and bonding with PVC tubing.
• Tritan provides superior chemical resistance in applications that encourage the use of aggressive cleansers and disinfectants.
Clearing the way for improved sustainability.

Eastman Tritan™ copolyester provides several advantages that can help manufacturers achieve sustainability goals, including:

- Inherent toughness helps reduce waste:
  - Less breakage in shipping and handling
  - IV components can be designed with thinner walls.
  - Components may require less packaging.

- Made without BPA or halogens and is not manufactured using ortho-phthalate plasticizers

- Free of chlorine

- Meets hospital Environmentally Preferable Purchasing (EPP) guidelines
  - Bisphenol A (BPA) free
  - No halogens (chlorine, bromine, etc.)
  - Free of ortho-phthalate plasticizers

Helping you shape what’s next.

Eastman Tritan™ copolyester is an important part of the robust portfolio of Eastman medical polymers for medical devices and rigid medical packaging. For more information on the entire portfolio and how Eastman can help you find the best solutions for developing IV components, visit www.eastman.com/medical or call 800-EASTMAN (800-327-8626).
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 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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