EASTMAN

Eastman TRITAN™
copolyester

The clear choice
for next-generation blood contact devices

Higher-yield workflow

Until now, processing bottlenecks have been the unfortunate trade-offs for producing clear blood contact surgical devices from polycarbonate (PC) resin.

Eastman Tritan™ copolyester can eliminate the secondary annealing step required to reduce potential stress cracking issues in PC—and virtually eliminate the extra time and energy required by this costly bottleneck. Because parts made with Tritan can be molded with insignificant inherent stress, there is less risk of environmental stress cracking (ESC) during production or final use.

In addition to eliminating annealing from your workflow, Eastman Tritan™ copolyester offers additional benefits to improve yield while reducing overall system cost:

- Good resin flow
- Best-in-class chemical resistance to improve yield during secondary operations, such as solvent bonding of polyvinyl chloride (PVC) tubes with device connectors
- Toughness to withstand the demand of common secondary operations
- Reduced scrap rate due to black specs, flow marks, cracking, and breakage

The processability and tooling for Eastman Tritan™ copolyester are similar to PC but with no sacrifice of chemical resistance, durability, clarity, and sustainability.

It's hard to resist the bottom-line benefits of Eastman Tritan™ copolyester.

Clearer view of blood flow

In addition to clear advantages in processability, final products molded from Eastman Tritan™ copolyester also provide functional advantages related to chemical resistance and clarity:

- Chemical resistance helps devices retain aesthetic and functional integrity after exposure to blood, lipids, and aggressive disinfectants.
- Toughness of Tritan provides durability during shipping and handling—especially valuable for devices with multiple ports.
- Glasslike transparency before and after gamma or electron beam (e-beam) radiation and ethylene oxide (EtO) gas (see next page).
- Superior clarity after sterilization allows improved performance from optical sensors and easier detection of entrapped air, thrombogenesis, and blood leakage.

All this, plus freedom from bisphenol A (BPA), makes Eastman Tritan™ copolyester ideal for many blood contact and blood management devices, including:

- ***Surgical devices,*** such as oxygenators, bubble traps, hematological reservoirs, and housings for hematological filters and cardioplegia filters.
- ***Blood management devices,*** including centrifuge bowls, blood separation cassettes, and blood microfilters.

It’s easy to see the advantages of chemical resistance and clarity

Eastman Tritan™ copolyester creates value advantages over PC and other materials by reducing total system cost without sacrificing performance and aesthetics.

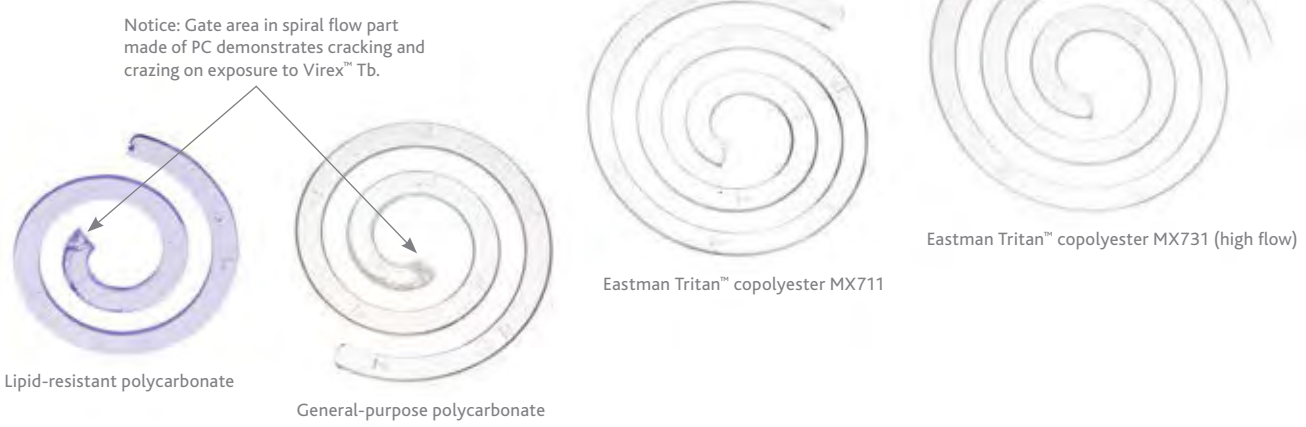
Clearly exceptional chemical resistance

Blood contact devices molded from Eastman Tritan™ copolyester offer best-in-class resistance to blood, lipids, and a wide range of aggressive disinfectants. The improved chemical resistance of Tritan also means improved ESC resistance during solvent bonding that uses cyclohexanone, as well as other solvents.

The following spiral flow pictures highlight the combination of chemical resistance and good flow properties. All test spirals were dipped in Virex™ Tb, a common medical disinfectant, demonstrating how residual stress can cause cracking in molded parts on exposure to chemicals and disinfectants.

Comparison of flowability and chemical resistance

Notice: The medical grade polycarbonate flow length (linear distance in spiral flow part) is significantly less than Tritan copolyester resin flow length.



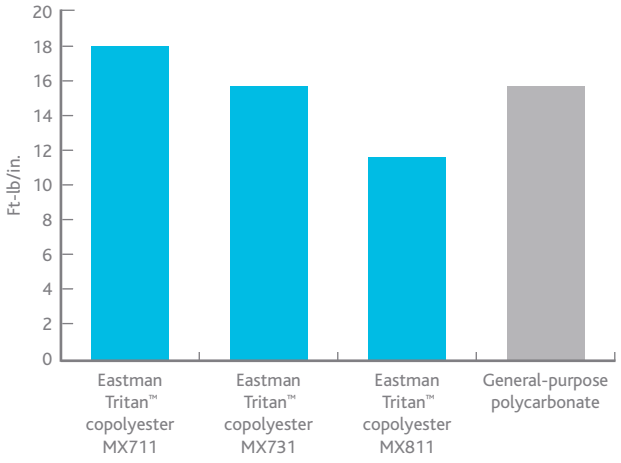
Chemical resistance with externally applied stress

The photo on the left demonstrates the excellent ESC resistance of Eastman Tritan™ copolyester. An external stress was applied to the plaques pictured, and then each plaque was exposed to Virex™ Tb. You can see that Tritan resists craze and crack initiation and propagation, maintaining the physical integrity of the molded part.

Outstanding impact strength and toughness

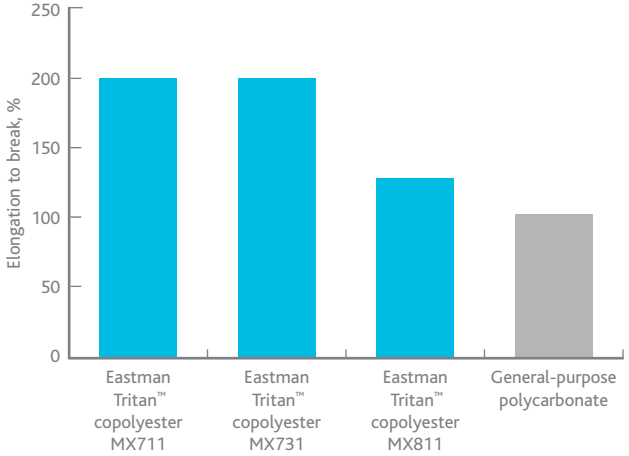
Eastman Tritan™ copolyester compares favorably with PC for both major toughness metrics—and offers significantly greater impact strength than other common thermoplastics, such as acrylics, styrenic copolymers, and polyolefins.

Notched izod impact* (compared with PC)



*Izod impact strength, notched @ 23°C (73°F) ASTM D256

Elongation to break* (compared with PC)



*Tensile elongation to break @ 23°C (73°F) ASTM D638

Retains clarity, color, and strength after sterilization

Compared with polymers that shift color significantly after sterilization—or become opaque and hazy—Eastman Tritan™ copolyester provides superior retention of color and clarity. See the following photo for an actual comparison of Tritan with lipid-resistant polycarbonate and general-purpose PC after sterilization.

Less color shift—better aesthetics and patient confidence

Eastman Tritan™ copolyester shows minimal color shift and returns to original color in 14 days. Acrylic and PC have significant color shifts after exposure to gamma radiation.

Black specks

Eastman Tritan™ copolyester processes with less risk of black speck formation when compared to PC. The presence of black specks in medical devices is considered undesirable.

Resulting black specks can be expensive for device manufacturers, particularly when devices are rejected by hospitals or clinics due to this defect.

Internal testing demonstrates that PC has an increased propensity to char, resulting in black specks in molded parts. Tritan does not have this propensity to char, resulting in significantly fewer defects.

Improving products while improving sustainability

Eastman understands many brand owners and manufacturers of blood contact devices are working toward sustainability goals.

Many health care facilities have likewise implemented Environmentally Preferable Purchasing (EPP) guidelines to reduce their overall environmental impact and improve patient safety.

Eastman Tritan™ copolyester provides a material that can be molded into parts with sustainability advantages:

- Durability allows the potential for less packaging.
- Made without BPA or halogens and is not manufactured with *ortho*-phthalates
- Free of chlorine—reduces a potential generation of hazardous pollutants during incineration
- Lower specific gravity—2% less weight than PC
- Toughness of devices made from Tritan results in less breakage during shipping and handling—potentially reducing protective packaging requirements and waste.

Helping you shape what's next

Eastman Chemical Company has a tradition of innovation. For more than 70 years, Eastman has been helping customers develop innovative products—then bring them to market efficiently.

Today, as always, Eastman is committed to the long-term needs of the medical industry. Eastman is a reliable supplier of technical support and a robust portfolio of Eastman medical polymers for medical devices and rigid medical packaging.

Eastman is always prepared to leverage its industry understanding, design capability, and engineering and manufacturing expertise to help customers shape what's next.

This may include investigating design potentials that are simply not possible with PC or other less-forgiving resins. Or it may include collaboration and support with 501(k) submissions or other compliance issues.

Less is definitely more. Eastman Tritan™ copolyester offers you more ways to enhance your "green" image.

Learn more

See how Eastman Tritan™ copolyester and Eastman can help you manufacture superior blood contact devices. **Visit www.eastman.com/medical or call 1-800-EASTMAN (1-800-327-8626).**

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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.