STERILIZATION

Part inspiration. Part insight.

TOUGHNESS

Take a closer look at how Eastman Tritan[™] copolyester helps create successful medical devices.

Breakthrough technology. Go-to-market solutions.

Taking medical devices and packaging from concept to care.

Property demonstration key

These parts demonstrate how Eastman Tritan[™] copolyester can add value to medical device designs—especially in these four key areas:



Sterilization stability

Patient confidence and safety are closely tied to attributes that make parts look clear and glossy as new devices, as well as after sterilization methods, including irradiation and EtO.

Secondary operations

Complex medical devices often require secondary operations to complete the assembly or fabrication process of molded or otherwise formed parts, including bonding, welding, and joining methods.

Toughness

Much more than impact strength and shatter resistance, "toughness" also adds value through the many benefits tied to durability and long service life demanded by medical applications.

Chemical resistance

Eastman Tritan[™] copolyester offers excellent resistance to the damaging effects of exposure to blood, lipid, and chemical solvents, cleansers, and disinfectants.

Easy-to-process pellets



Medical grade Eastman Tritan[™] copolyester delivers peace of mind without sacrificing performance in medical device applications. Its high-flow viscosity also results in greater ease of processing, such as:

- Faster injection molding cycles
- Fast drying times
- Desirable melt flowability
- Higher heat resistance
- Excellent clarity
- Excellent hydrolytic stability

For more information about medical devices and packaging, visit www.eastman.com/medical.

Cradle-to-pellet energy demand



4EMN LCA TR-2011-09958

These charts are pending a third party review.

Sterilized step chips comparison

- Compare clarity pre- and post-sterilization
- Thick and thin transitions
- Clarity through different thicknesses

For more information on sterilization of medical devices and packaging, visit www.eastman.com/medical.

General-purpose acrylic

General-purpose polycarbonate

Lipid-resistant polycarbonate

Eastman Tritan[™] copolyester MX711

Black specks comparison



Eastman Tritan[™] copolyester can be processed similar to polycarbonate (PC) but with less risk of undesirable—and unsightly—black speck formation.

A stagnant area in an injection molding barrel can cause PC to char, resulting in black specks in molded parts. Tritan, however, does not have this propensity to char.

Black specks can be expensive for device manufacturers, particularly when hospitals or clinics reject entire lots of devices because of defects.



Eastman Tritan[™] copolyester MX711



General-purpose polycarbonate

Chemical resistance with externally applied stress



- Stressed plaque submerged in Virex[®] Tb.
- External stress applied.
- Eastman Tritan[™] copolyester retains clarity and integrity.
- Tritan demonstrates excellent environmental stress crack (ESC) resistance.
- Tritan demonstrates exceptional toughness.

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General-purpose polycarbonate

General-purpose acrylic

Flowability and chemical resistance comparison

- Flowability for easy processing
- All test spirals dipped in Virex[®] Tb
- Demonstrates the effect of residual stress in molded part exposed to chemicals/disinfectants

Notice: Gate area in spiral flow part made of PC demonstrates cracking and crazing on exposure to Virex[®] Tb.

Notice: The medical grade polycarbonate flow length (linear distance in spiral flow part) is significantly less than the resin flow length of Eastman Tritan[™] copolyester.

Eastman Tritan[™] copolyester MX711

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Eastman Tritan[™] copolyester MX731 (high flow)

Lipid-resistant polycarbonate

General-purpose polycarbonate

Double-dosing cup

Prototype by DD Studio

- Impact resistance
- Vibrant colors and clarity
- Variety of wall thicknesses
- Stiction—coefficient of friction used in assembly
- Result of collaboration between Eastman and DD Studio



Suitability for ultrasonic weld design methods

- Eastman Tritan[™] copolyester is suitable for ultrasonic welding.
- Optimum weld designs—energy director, crisscross shear joints shown here.
- Tests to pull apart welded pieces reveal strength nearly equal to unwelded molded part.





Needle hub

- Intricate design and long flow lengths
- Retains color and clarity if irradiated
- Retains properties after solvent bonding
- Staked needle is typically held by adhesive bonding.
- Processability

The needle hub is used to create the pathway for the catheter inserted into the patient for fluid administration purposes.



Luers with tubing

- Color/clarity retention if irradiated
- Retains properties after solvent bonding or laser welding
- Withstands exposure to lipids and disinfectants



Tensile bars

- Tough enough to bend and strike
- Vivid colors and clarity—before and after sterilization
- Acoustic quality
- Better machinability
- If exposed, resistant to disinfectants and cleansers



Safe and sustainable alternatives for the health care industry

- Bisphenol A (BPA) free
- Doesn't require the use of plasticizers
- Low energy consumption
- Low greenhouse gas (GHG) emissions
- Improved durability for harsh environments

Helping shape what's next.

- Eastman Tritan[™] copolyester
- DuraStar[™] polymers
- Eastar[™] copolyesters
- Tenite[™] cellulosics



ΕΛSTΜΛΝ

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#05-04 Winsland House 3 Killiney Road Singapore 239519 Telephone: (65) 6831-3100 Fax: (65) 6732-4930 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-01993, 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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The results of **insight**