EASTMAN

Redefining the balance between processability and chemical resistance

The new go-to copolyester

Eastman **TRITAN**™
copolyester

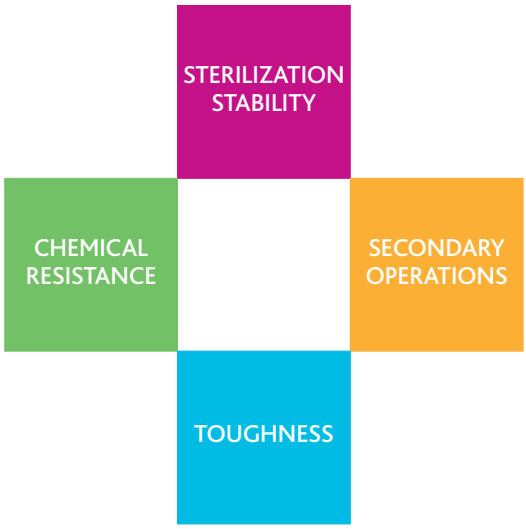
Transforming the potential for medical grade polymers

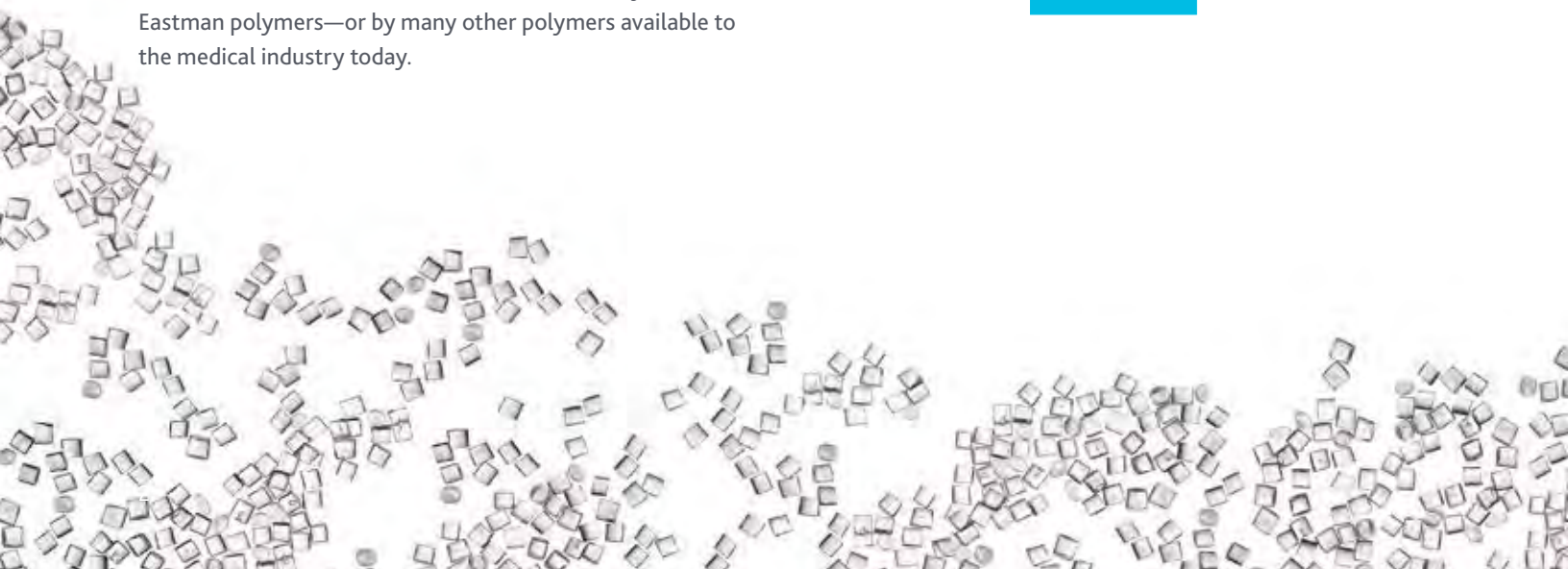
Eastman has supplied a wide range of materials for the medical market for more than 65 years. Today, the company is committed to the long-term needs of the medical industry and is a reliable supplier of innovative medical grade polymers and technical support for a variety of applications, including molded medical devices.

Now, we're even better prepared to provide a "total solutions" approach to the needs of the medical industry because of the addition of Eastman Tritan™ copolyester to our polymers portfolio.

Tritan builds on the rich heritage of other successful Eastman brands, including DuraStar™ polymers, Eastar™ copolyesters, and Tenite™ cellulosics. Like our traditional polymers, Tritan provides outstanding lipid and chemical resistance and is free of bisphenol A (BPA) and halogens. It also offers greater toughness, heat resistance, and processability than heritage copolyesters.

This unique combination of properties allows Tritan to satisfy a set of customer needs that have not been met by other Eastman polymers—or by many other polymers available to the medical industry today.





When innovation exceeds expectations

Eastman Tritan™ copolyester MX711 is an innovative, clear medical grade polymer that delivers a unique balance of design, processing, and physical properties for medical devices.

- For applications that demand superior chemical resistance, clarity, and hydrolytic stability, Tritan provides the advantages of a copolyester.
- For clear applications that demand easier processability and greater durability, Tritan offers performance that is comparable or, in many cases, superior to other medical grade polymers.

Expect a balance of important advantages

Tritan MX711 combines design, processing, and physical properties that are most important in medical devices.

Processability

The innovative chemistry of Tritan provides enhanced heat resistance as well as:

- Improved processability over traditional copolyesters
- Faster cycle times in optimal molding conditions/design
- No need for annealing
- Molded part shrinkage similar to polycarbonate (PC)

For medical grade applications requiring thin walls or intricate design, Tritan is available in a high-flow product, Eastman Tritan™ copolyester MX731 (see page 9).

For additional information on molding medical polymers, visit www.TritanMoldIt.com.

Chemical resistance

Tritan offers excellent resistance to the effects of exposure to common substances found in the medical environment that can lead to environmental stress cracking and functional deterioration:

- Blood and lipids
- Chemical agents like isopropyl alcohol (IPA), disinfectants, and bonding solvents

Toughness

Risk is reduced for manufacturers through:

- Excellent toughness
- Fewer broken parts, reduced part failure, and less waste
- Greater customer satisfaction

Hydrolytic stability

Tritan has outstanding hydrolytic stability, so parts made from this innovative polymer are unlikely to deteriorate when exposed to heat, humidity, and chemical agents.

Compatibility with sterilization methods

Reliable long-term clarity, color stability, and retention of functional integrity following sterilization by:

- Gamma irradiation
- Electron beam (e-beam) irradiation
- Ethylene oxide (EtO) gas

Clarity

Tritan MX711 provides glasslike transparency that conveys safety, quality, and peace of mind for both health care professionals and patients.

BPA free

Like all Eastman copolyesters and cellulosics, Tritan is made without BPA or halogens.

Secondary operations and assembly

Tritan MX711 is compatible with a wide variety of manufacturing operations and techniques, including:

- Solvent and adhesive bonding
- Ultrasonic welding
- Laser welding
- Cold swaging

Heat resistance

Enhanced heat resistance relative to heritage copolyesters:

- Slower physical aging
- Reduced creep

Explore a wide range of applications

Tritan is well-suited for medical device applications that demand superior chemical resistance, clarity, and hydrolytic stability, including:

- IV system components
- Blood contact devices

The following pages show how Tritan's advantages have been validated. Let us show you how this innovative polymer can deliver performance and peace of mind in your medical device applications.

- Single-use bioprocessing equipment
- Minimally invasive surgical devices such as cannulas and trocar systems
- Drug delivery devices including syringes, insulin pens, and inhalers
- Connectors, manifolds, luers, and catheters for fluid administration
- Fluid and respiratory canisters
- Nonimplantable medical devices

When innovation meets validation

Eastman is committed to providing information about its medical grade polymers. The Eastman Medical Applications Development Team has tested Eastman Tritan™ copolyester MX711 under rigorous conditions against other popular polymers for the properties that are most important for high quality medical devices. More trial results for this innovative polymer are available on request.

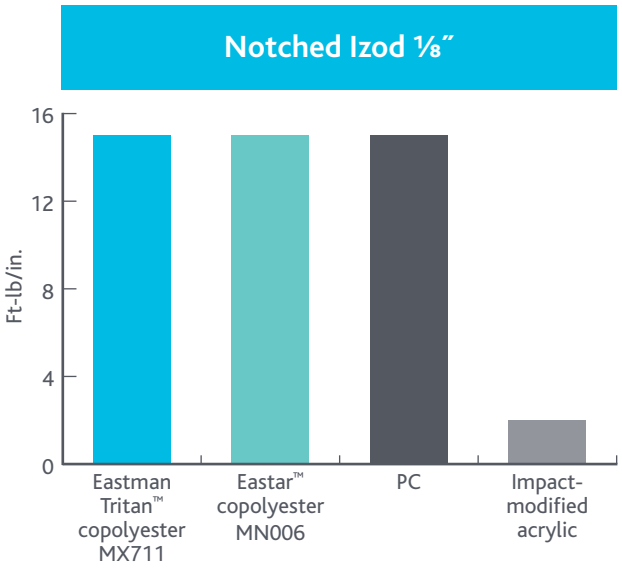
Chemical resistance

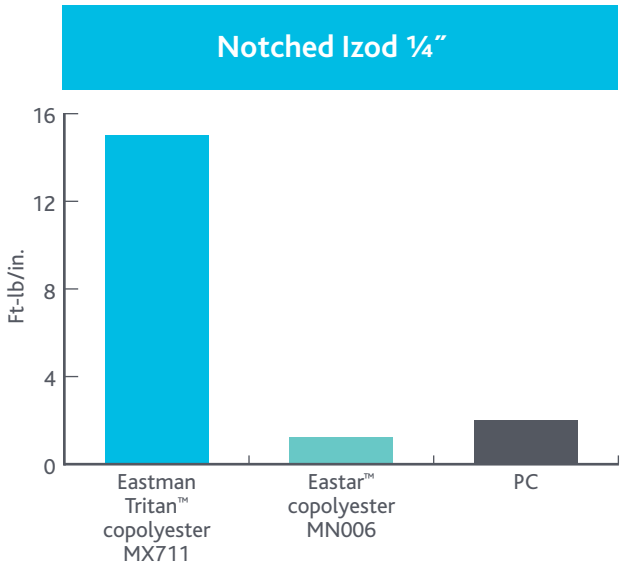
Excellent resistance against lipids, IPA, disinfecting agents, and bonding solvents is a respected legacy for Eastman copolyesters; Tritan MX711 continues this tradition. In this trial, the chemical resistance of Tritan MX711 was compared with high-flow PC, lipid-resistant PC, and impact-modified acrylic. Eastar copolyester MN006 natural also was compared as a benchmark.

Toughness

Tritan MX711 delivers exceptional toughness. It offers impact and shatter resistance that is comparable to PC. In this trial, Tritan MX711 was tested according to ASTM D256 Notched Izod Impact at 23°C.

Eastar copolyester MN006 natural as well as a medical grade acrylic and PC were tested for comparison. Two thicknesses were evaluated: the standard ⅛″ as well as ¼″. Tritan MX711 maintains high-impact strength at both thicknesses.

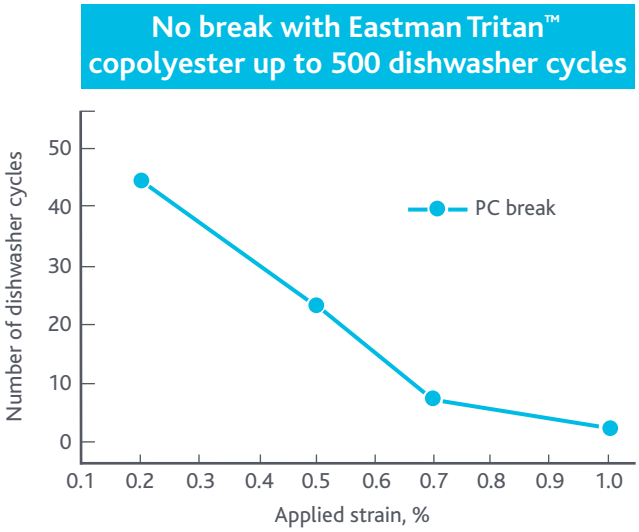




Hydrolytic stability

Tritan demonstrates excellent stability against high humidity, moderate heat, and aggressive chemical environments.

Samples were strained to varying degrees and exposed to typical residential dishwasher conditions. Tritan shows no cracking or crazing even after hundreds of wash cycles; PC fails quickly when exposed to this environment.

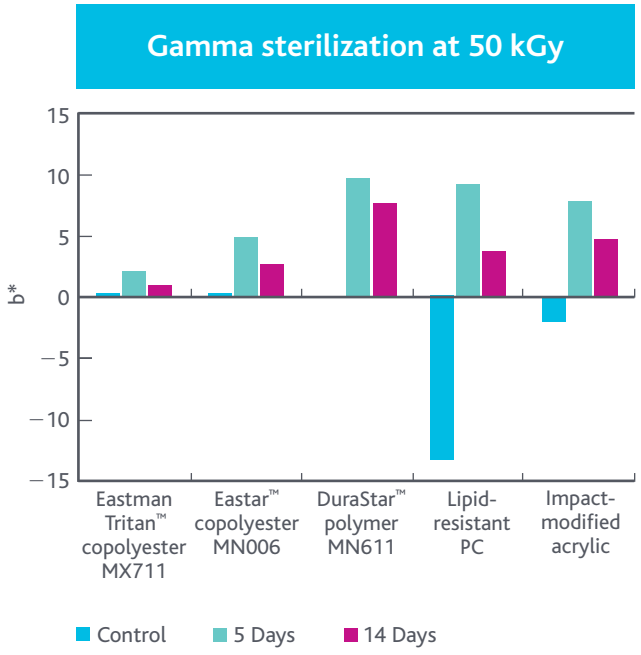


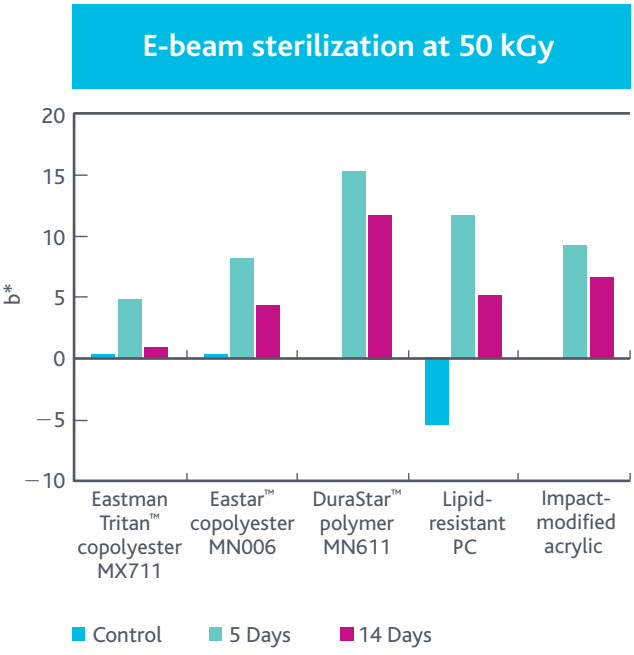
Sterilization

Both e-beam and gamma irradiation are known to change polymers subjected to these processes—changes which can impact color and overall aesthetics, color-coding options, and even functional integrity. Tritan MX711 was compared with PC, acrylic, DuraStar MN611 natural, and Eastar MN006.

For applications involving e-beam, gamma, EtO, or other low-temperature sterilization processes, Tritan MX711 gives outstanding, reliable performance.

Eastman provides a "total solutions" approach for medical device manufacturers, leveraging years of experience with innovative materials, such as Tritan, to deliver the best solution for your needs.





Committed to making a material difference

As a committed medical polymer solutions provider, Eastman can leverage its industry understanding—along with extensive design, engineering, and manufacturing expertise—to help customers develop products, bring them to market quickly, and follow through with strong technical support.

Eastman provides a wide variety of polymer solutions through its family of product offerings. Let our experienced professionals help select the right balance of properties for your applications.

Comparison of medical grade polymers

Material	Desired property					
	Higher heat resistance	Toughness	Lipid resistance	Solvent bonding	Faster injection molding cycles	Comments
Eastman Tritan™ copolyester MX711	◕	●	◕	◕	●	Superior clarity after sterilization; BPA free; hydrolytic stability
DuraStar™ polymers	◑	◔	●	◑	◑	BPA free
Eastar™ copolyesters	◔	●	◕	●	◔	Superior clarity after sterilization; BPA free
Tenite™ cellulosics	◑	◕	●	●	●	BPA free
PC[a]	●	●	◑	◑	●	PC typically requires annealing at faster mold cycles to improve chemical resistance
Impact-modified acrylic[b]	◕	○	◑	◕	◕	BPA free

● Best ◕ Good ◑ Average ◔ Fair ○ Poor

[a] *PC represents high-flow PC.*

[b] *Toughened acrylic represents impact-modified acrylic.*

Eastman Tritan™ copolyester MX731, a high-flow, medical grade product

For molding parts such as cannulae, with long thin walls or deep cavitation sections, Tritan MX731 provides a practical solution.

Tritan MX731 provides the benefits of high-flow lengths while maintaining the polymer's other important benefits:

- Chemical resistance
- Toughness
- Clarity
- Color stability

Eastman Tritan™ copolyester MXF121, excellent chemical resistant in a flame-retardant polymer

Eastman Tritan™ copolyester MXF121 is an opaque polymer that offers excellent chemical resistance and toughness, plus an Underwriters Laboratories (UL) 94 V2 flame rating.

Key advantages:

- Flame-retardant properties
- Chemical resistance with aggressive disinfectants
- High impact resistance and excellent durability
- Made without bisphenol A (BPA), halogens, or *ortho*-phthalate plasticizers
- Reliable color matching

When innovation matches application

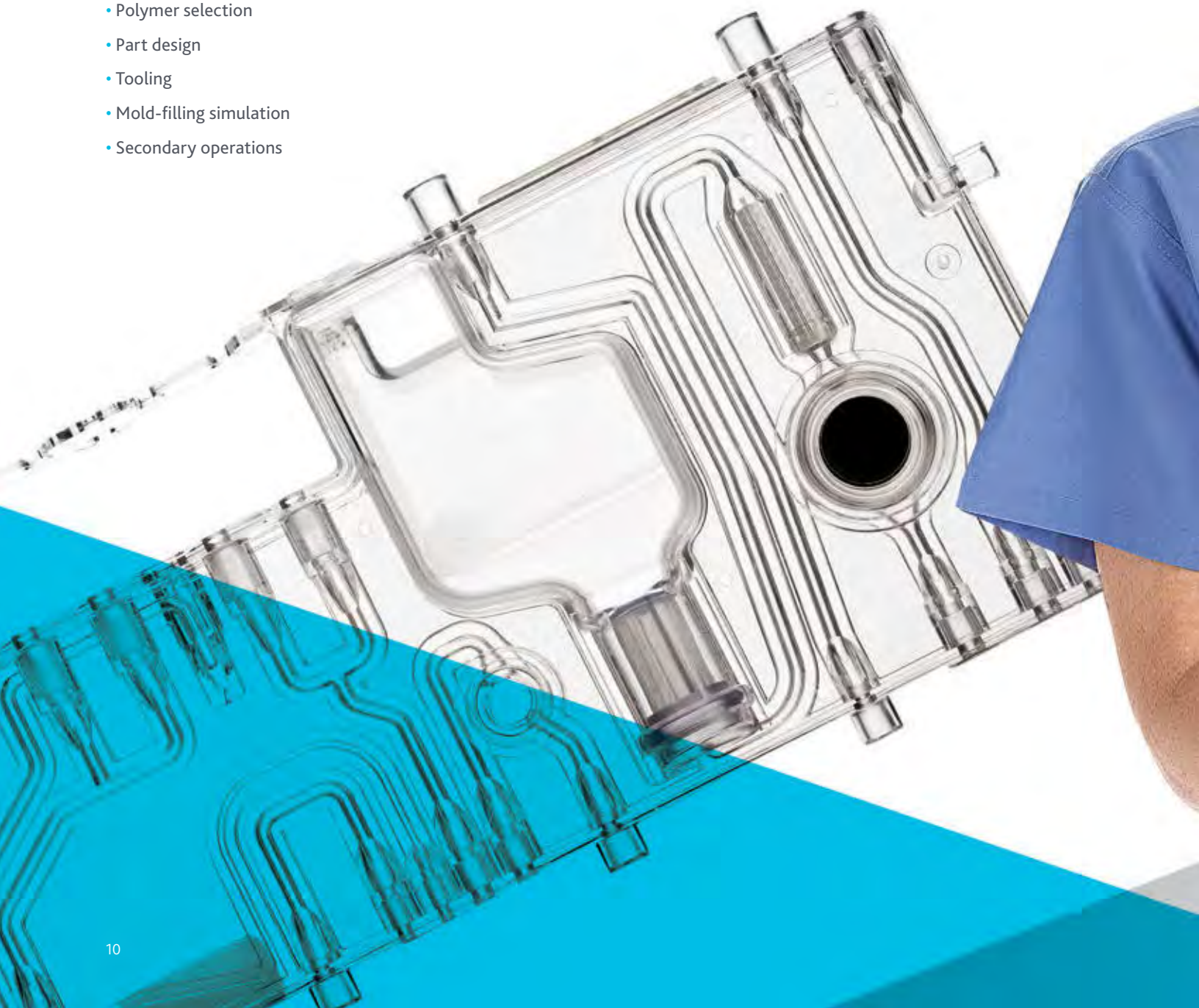
With current trends driving an increased need for simple, robust, and reliable medical devices, a partner with Eastman's experience can be invaluable for matching technology to your needs.

With more than 20 years of experience, the Eastman Medical Applications Development Team has assisted customers in the development of component medical parts that meet the functional and aesthetic requirements of the medical industry.

From mold design to end-use performance, medical device manufacturers can count on Eastman for extensive technical support, including:

- Polymer selection
- Part design
- Tooling
- Mold-filling simulation
- Secondary operations

The Eastman Medical Applications Development Team works with customers at all stages of the process—beginning early in the design and specification stage to optimize development of the medical device. With the assurance that Tritan MX711 and high-flow MX731 are matched with the proper part design, suitable mold design, and recommended processing parameters, designers and molders can achieve the most efficient manufacturing of high-performance, reliable medical devices.



For more information about Eastman Tritan™ copolyester and how Eastman helps you find the best solutions for your medical devices, visit www.eastman.com/medical or call 1-800-EASTMAN (1-800-327-8626), Ext. 5408.

EASTMAN

The results of **insight**™

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Eastman Tritan™ copolyester is not approved for implantable devices.

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.