EASTMAN

Eastman **TRITAN**™
copolyester

Renal treatment device applications

Hemodialyzers, hemoconcentrators, and hemofilter housings

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Microcracks in renal devices are not only an economic challenge for hospitals, clinics, and device manufacturers but also a quality and safety issue for the patient.

Typically, renal device housings can be compromised by tapping the device to remove air, mishandling or dropping the device, or applying aggressive chemical disinfectants. A tough, clear, and chemically resistant material that offers enhanced environmental stress cracking (ESC) resistance can help reduce microcracks and breakage.

For renal device brand owners and manufacturers, a material that does not require annealing and has excellent chemical resistance with good processability can help reduce overall system costs.

Clarity of the renal device housing is crucial for the patient's peace of mind. High-energy irradiation sterilization can significantly impact device clarity.

Choosing the right material

Tough and clear Eastman Tritan™ copolyester is a superior alternative to polycarbonate (PC) for acute and chronic renal device housing applications. Tritan offers excellent resistance to common substances found in the renal treatment environment.

The glasslike transparency of Tritan delivers quality and provides peace of mind for health care professionals and patients. The clarity, color, and functional integrity of Tritan are not compromised after sterilization by gamma irradiation or e-beam radiation.

Striking the balance

Tritan is an innovative, next-generation copolyester that offers a balance of properties for renal device housing applications, including:

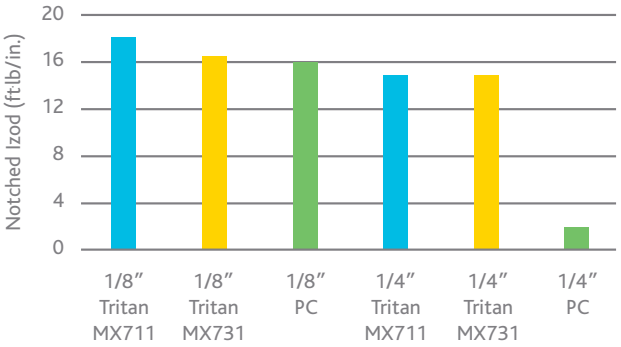
- Excellent resistance to aggressive chemicals and disinfectants
- Reduced cracking from contact with solvents, adhesives, and plasticized tubing during the assembly process
- Color and property retention after gamma and e-beam sterilization
- Sustainable—BPA, BPS, halogen, and phthalate free
- No annealing required—low residual stress and excellent chemical resistance provide chemical resistance without annealing.

Chemical resistance based on break elongation values

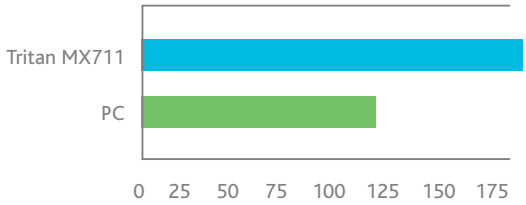
Disinfectant	Tritan MX711 copolyester	Tritan MX731 copolyester	General-purpose medical grade PC	High-flow medical grade PC
Formaldehyde 4%	4	3	2	2
Glutaraldehyde 0.8%	4	3	2	2
Peracetic acid 3%	4	3	2	2
Bleach	4	3	2	2
Virex® TB	4	3	2	2
IPA	4	2	3	1
Phenol	4 (0, 0.5%) 3 (≥ 1.0%)	3 (0, 0.5%) 3 (≥ 1.0%)	2 (0, 0.5%) 4 (≥ 1.0%)	2 (0, 0.5%) 3 (≥ 1.0%)
Lipid	4	3	3	2
Renalin	4	3	2	1

4 = highest
1 = lowest

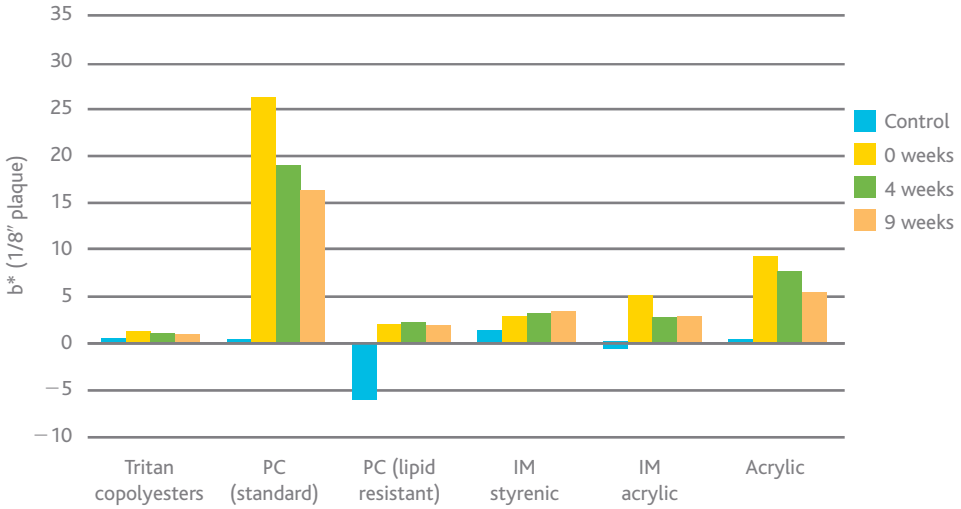
Better impact and toughness—Notched Izod impact



Elongation to break (%)



Excellent color stability—Gamma sterilization



Heat aging—Tritan MX711 copolyester

Tensile properties				1/8″ Izod	
				20-mil notch radius	
Test condition	Yield (MPa)	Break (MPa)	% Elongation	J/m	% Ductile
Initial	41.9	50.0	162	1,117	100
2 h, 60°C	43.1	50.7	159	1,102	100
20 h, 60°C	44.5	48.7	144	1,099	100
200 h, 60°C	46.7	50.5	148	1,087	100

The higher T_g of Tritan allows better stability during cure of potting compound and drying of fiber bundles as well as stability during shipping and storage.

Contact Eastman today for more information about Tritan and how Eastman can help you find the best solutions for your medical devices.

EASTMAN

The results of **insight**™

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Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman Chemical Company ("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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