EASTMAN

The effect of electron beam sterilization on transparent polymers used in medical devices

The Material Difference™
in medical applications

The effect of electron beam sterilization on transparent polymers used in medical devices

The objective of sterilizing medical devices is to reduce the bioburden to a safe level with minimal effects on physical and optical properties. The most widely used sterilization methods in the medical industry today are electron beam (e-beam), gamma radiation, ethylene oxide (EtO), autoclave, and low-temperature hydrogen peroxide gas plasma. Recent technology advances have improved operating efficiency, making e-beam radiation a safe, efficient, reliable source of energy that is gaining in popularity. E-beam radiation typically costs less compared to gamma radiation mainly due to higher dose rates which reduce the time of exposure at the same target dose. The shorter exposure time to e-beam radiation minimizes the oxidation reactions that can occur at the surface of polymers and consequently has less effect on the physical and optical properties of most resins when compared to gamma radiation.

Eastman conducted studies to determine the effects of e-beam radiation on the physical and optical properties of Eastman™ specialty plastics and various other transparent polymers used in the medical industry. Specific products tested are shown in Table 1.

Optical properties

Color measurements were made 3, 7, 14, and 42 days after e-beam radiation using a HunterLab UltraScan™ Sphere 8000 and the CIE L*, a*, b* color scale. Samples were concealed in dark enclosures throughout testing and were only exposed to light for measurement of color. The b* value measures the blue to yellow scale which Figure 1 shows as the most prevalent color change after exposure to ionization energy.

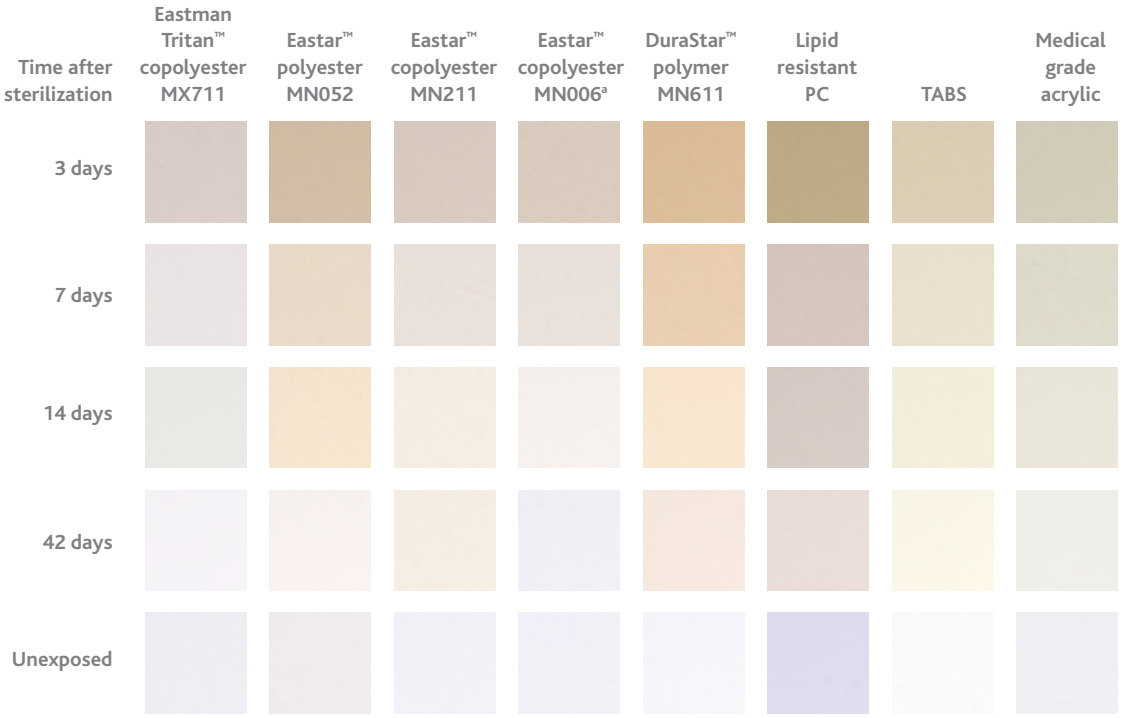
Table 1

Formula and resin type used in e-beam testing

Formula	Resin type
Eastar™ polyester MN052	polyester
Eastar™ copolyester MN211	copolyester
Eastar™ copolyester MN006	copolyester
DuraStar™ polymer MN611	copolyester
Eastman Tritan™ copolyester MX711	copolyester
Tenite™ propionate 360A40012	cellulose acetate propionate (CAP)
Lipid resistant PC	polycarbonate
TABS	transparent ABS
Medical grade acrylic	acrylic (PMMA)

Figure 1

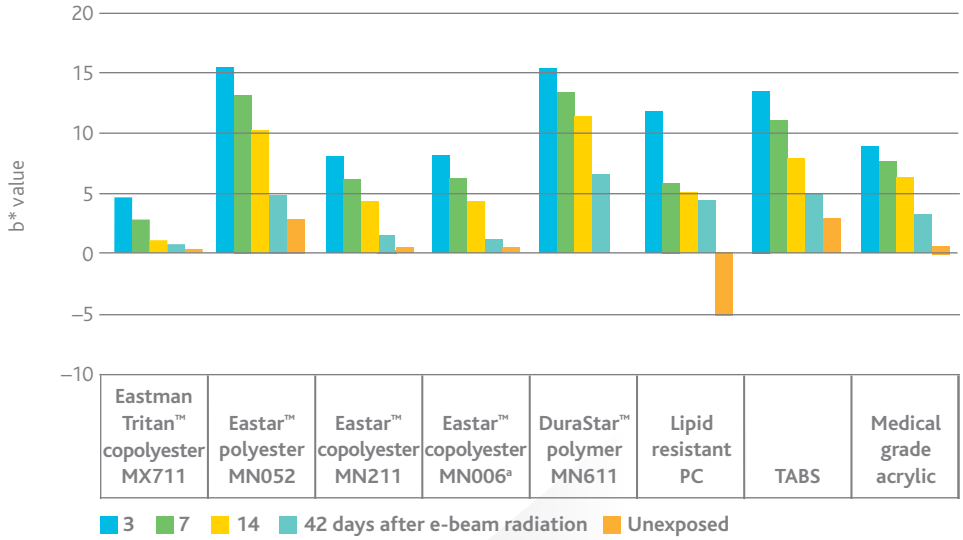
Photographs of molded resins before and after e-beam radiation at 50 kGy



[a]*Next-generation Eastar™ DN004*

Figure 2

Eastman™ specialty plastics and competitive resins after e-beam radiation at 50 kGy—b* color measurements



[a]*Next generation Eastar™ DN004*

Of the resins tested, Eastar™ copolyesters MN211 and MN006 showed the smallest change in b* values immediately after sterilization compared to the competitive resins.

Figure 3

Change in b* 42 days after e-beam radiation

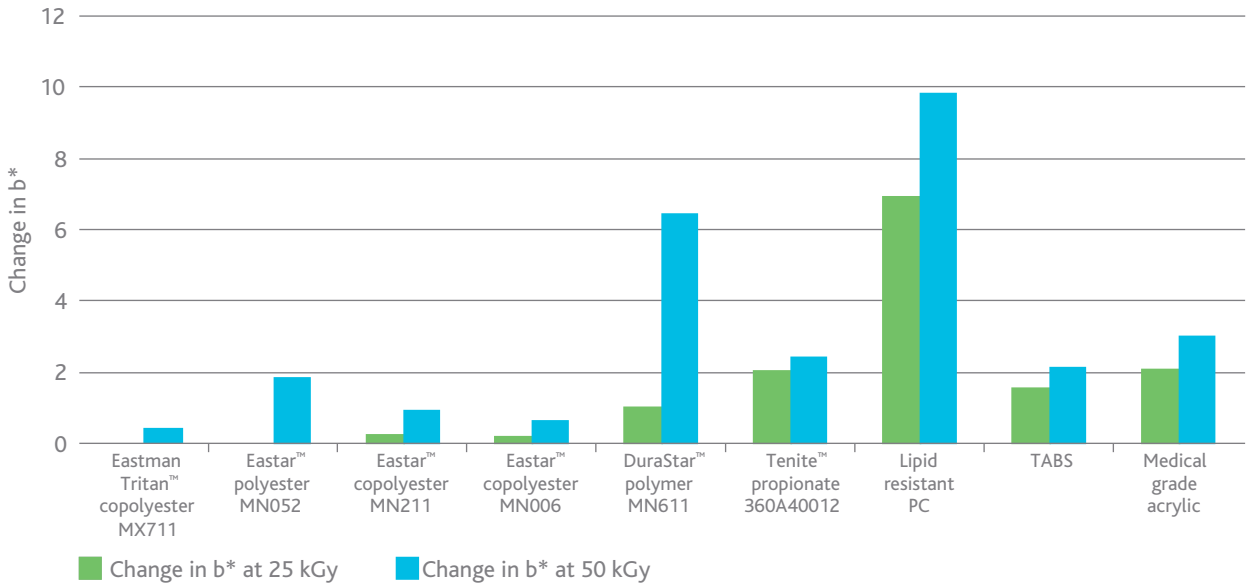


Figure 3 shows the difference in values between the unexposed samples and the sterilized samples 42 days after exposure at 25 and 50 kGy.

Eastar™ copolyester resins show the smallest color shift 42 days after exposure compared to the other resins tested and were very close to their initial color, especially at the lower dosage.

Physical properties

Physical properties were measured before and after e-beam sterilization at 25 and 50 kGy. No physical property degradation was noted for any resin tested. Tables 2 and 3 show the test results.

Table 2

Physical properties before and after e-beam radiation of Eastman™ specialty plastics and competitive resins

	E-beam energy, Mrad	Eastman Tritan™ copolyester MX711	Eastar™ polyester MN052	Eastar™ copolyester MN211	Eastar™ copolyester MN006	DuraStar™ polymer MN611	Tenite™ propionate 360A40012	Lipid resistant PC	TABS	Medical grade acrylic
Tensile yield strength, MPa	Unexposed	43.9	59	52	47	51	28	64	49	44
	25	NA	61	52	47	51	28	63	48	44
	50	42.9	62	54	47	52	28	62	48	45
Tensile break strain, %	Unexposed	196.2	117	71	312	271	37	146	14	6.2
	25	NA	73	64	330	272	31	134	15	7.8
	50	184.3	99	38	340	288	23	147	17	8.7
Flatwise impact @ 23°C; total energy, J	Unexposed	NA	66	59	62	65	36	89	4.5	14
	25	NA	63	57	62	66	36	95	3.8	11
	50	NA	63	57	64	61	36	85	3.2	17

Molecular weight was determined by Gel Permeation Chromatography for Eastman™ specialty plastics before and after e-beam radiation. Table 3 shows molecular weight of the sterilized resins as a percentage of the original molecular weight of unexposed resins.

Table 3

Percent retained molecular weight after e-beam radiation of Eastman™ specialty plastics

E-beam, energy, kGy	Eastman Tritan™ copolyester MX711	Eastar™ polyester MN052	Eastar™ copolyester MN211	Eastar™ copolyester MN006	DuraStar™ polymer MN611	Tenite™ propionate 360A40012
25	NA	99	100	100	99	88
50	93	99	99	100	99	77

The polyesters and copolyesters showed no statistical change in molecular weight after exposure to e-beam radiation. Tenite™ propionate 360 showed significant change in molecular weight. Aliphatic polymers such as Tenite 360 are more prone to chain scission when exposed to ionization energy than aromatic polymers.

Eastman's specialty medical grades for devices deliver a wide range of processing and performance attributes, including:

- Brilliant clarity before and after e-beam radiation, gamma radiation, EtO, and low-temperature hydrogen peroxide gas plasma sterilization
- Chemical resistance to most medical solvents and most medical and household cleaners
- Good balance of mechanical properties, including excellent toughness
- Flexibility to use in various processes, including injection molding, injection blow molding, extrusion blow molding, and extrusion
- Ability to undergo numerous secondary operations, including solvent bonding, swaging (cold forming), laser welding, ultrasonic welding, adhesive bonding, and hot-plate welding

If e-beam sterilization is a key material selection criterion, Eastman™ specialty plastics can provide The Material Difference™ in your application. Contact Eastman today for more information on compatibility of Eastman™ resins with e-beam sterilization.

EASTMAN

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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.