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 (on the following page) shows as the most prevalent color change after exposure to ionization energy.

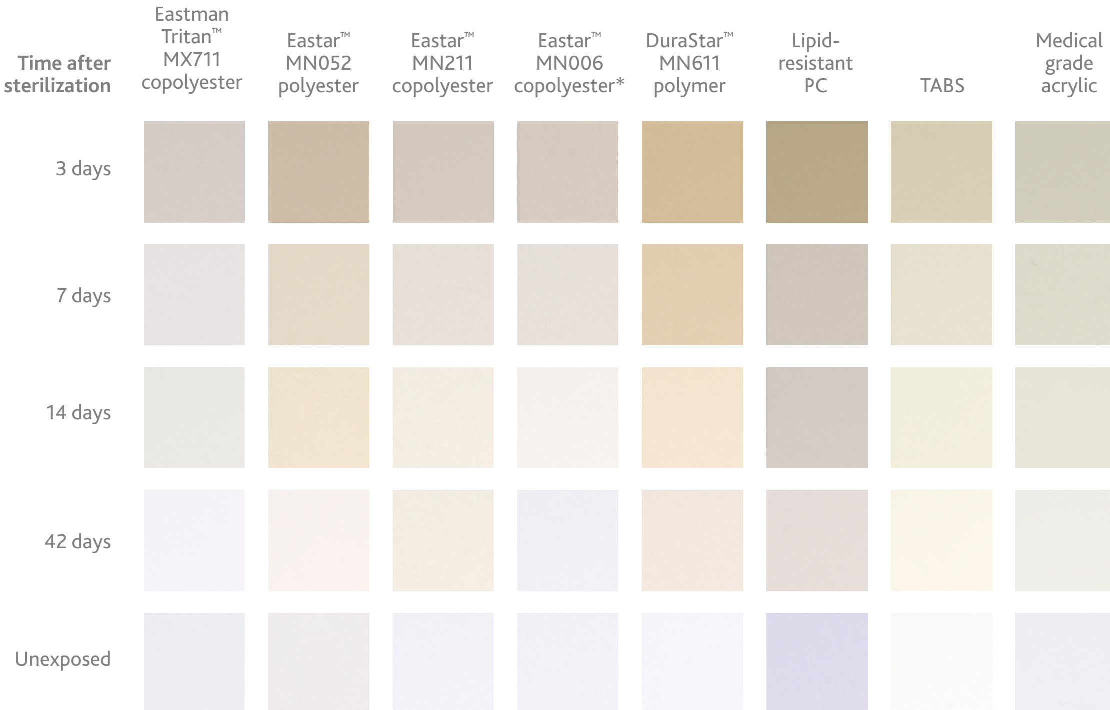
Table 1

Formula and resin type used in e-beam testing

Formula	Resin type
Eastar™ MN052 polyester	Polyester
Eastar™ MN211 copolyester	Copolyester
Eastar™ MN006 copolyester	Copolyester
DuraStar™ MN611 polymer	Copolyester
Eastman Tritan™ MX711 copolyester	Copolyester
Tenite™ 360A4000012 propionate	Cellulose acetate propionate (CAP)
Lipid-resistant PC	Polycarbonate
TABS	Transparent ABS
Medical grade acrylic	Acrylic (PMMA)

Figure 1

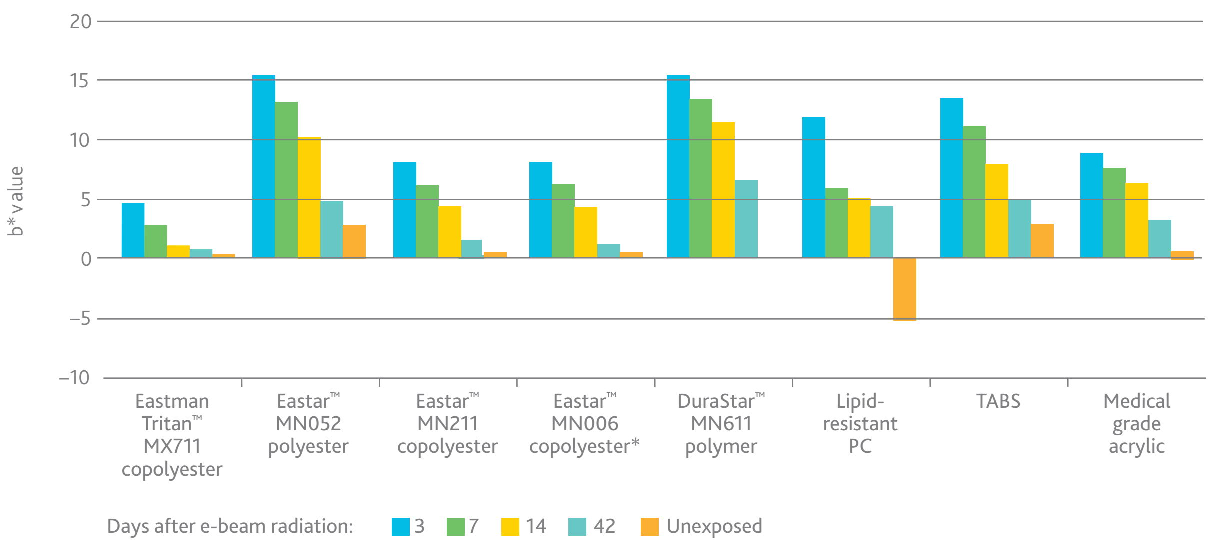
Photographs of molded resins before and after e-beam radiation at 50 kGy



**Next-generation Eastar DN004*

Figure 2

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



**Next-generation Eastar DN004*

Of the resins tested, Eastar MN211 and Eastar 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

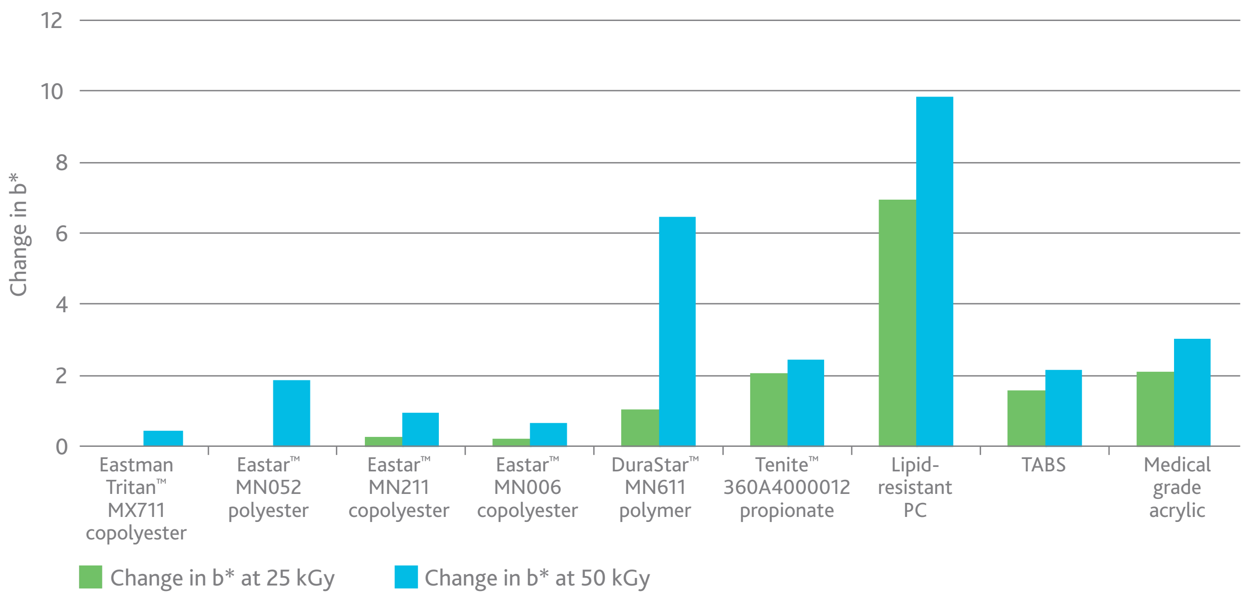


Figure 3 shows the difference in values between the unexposed samples and the sterilized samples 42 days after exposure at 25 and 50 kGy.

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™ MX711 copolyester	Eastar™ MN052 polyester	Eastar™ MN211 polyester	Eastar™ MN006 polyester	DuraStar™ MN611 polymer	Tenite™ 360A4000012 propionate	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

Table 3

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

E-beam, energy, kGy	Eastman Tritan™ MX711 copolyester	Eastar™ MN052 polyester	Eastar™ MN211 copolyester	Eastar™ MN006 copolyester	DuraStar™ MN611 polymer	Tenite™ 360A4000012 propionate
25	NA	99	100	100	99	88
50	93	99	99	100	99	77

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.

The polyesters and copolyesters showed no statistical change in molecular weight after exposure to e-beam radiation. Tenite 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.

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