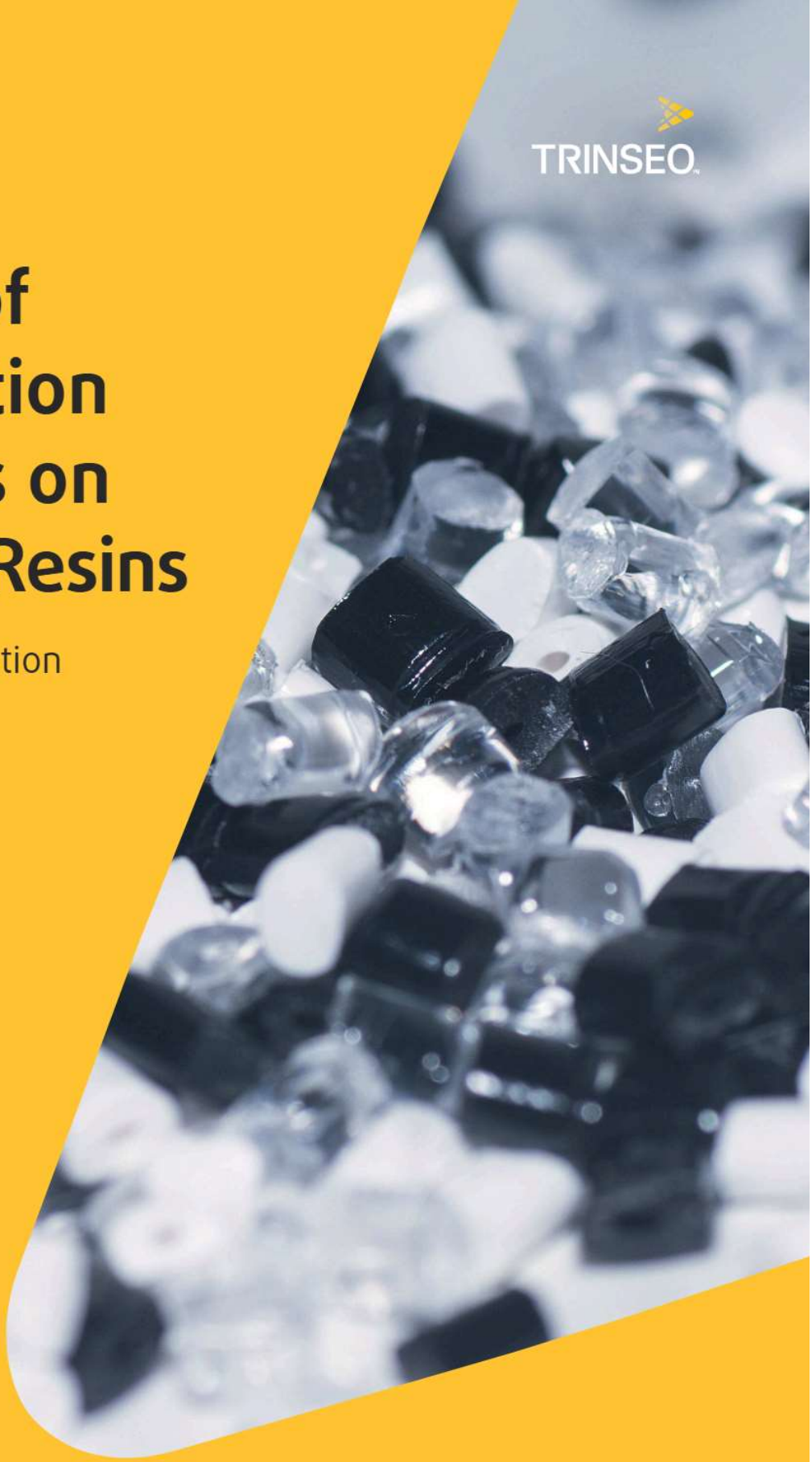
TRINSEO

Effects of Sterilization Methods on Medical Resins

Technical Information



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Introduction

General Types of Sterilization Methods

Single-use medical devices (SUDs) and multiple-use medical devices (MUDs) that come in contact with human tissue or bodily fluids must be sterilized for patient safety. Determining a material's compatibility with the different methods of sterilization that are used for medical devices can be involved and complex. One must consider the effects of the sterilization process on both the physical integrity and the optical characteristics of the material. This document is a collection of data based on studies performed on Trinseo medical resins. It serves as a reference for those interested in the effects of various sterilization methods on the performance of Trinseo's polymer materials.

Disposable or SUDs are commonly sterilized one time prior to being used. This sterilization is often done by the manufacturer on the fully assembled and packaged device prior to delivery to the customer. The typical methods are ethylene oxide (EtO) and irradiation sterilization. Irradiation may be done by gamma radiation (cobalt-60) or electron beam (e-beam) radiation. A common method of sterilization for reusable or MUDs is steam autoclave. The performance of the CALIBRE™ Polycarbonate, MAGNUM™ ABS, MEGOL™ TPS-SEBS and RAPLAN™ TPS-SBC Resin family under various sterilization methods is summarized in **Table 1**.

More detailed analysis of the effects of sterilization on CALIBRE™ and CALIBRE™ MEGARAD™ Polycarbonate Resins is provided in this report. These studies look at the effects of sterilization on the physical properties and appearance of the resins.

Table 1: Guidelines for Sterilization of Transparent CALIBRE™ Polycarbonate Resins[1]

Grade	Sterilization Technique			
	Steam Autoclave (Cycles)	Gamma Radiation	Electron Beam (e-beam) Radiation	Ethylene Oxide (EtO) (Cycles)
CALIBRE™ 2060, 2061 Transparent Series				
CALIBRE™ 2061 030003	1–5	Not Recommended	Not Recommended	1–5
CALIBRE™ 2061 030004	1–5	Not Recommended	Not Recommended	1–5
CALIBRE™ 2060 030003	1–5	Not Recommended	Not Recommended	1–5
CALIBRE™ 2061 (all colors)	1–5	Opaque only	Opaque only	1–5
CALIBRE™ MEGARAD™ 2081 Transparent Series				
CALIBRE™ MEGARAD™ 2081 030006	1–5	2.5 Mrad (25 kGy)	2.5 Mrad (25 kGy)	1–5
CALIBRE™ MEGARAD™ 2081 030116	1–5	5.0 Mrad (50 kGy)	5.0 Mrad (50 kGy)	1–5
CALIBRE™ MEGARAD™ 2081 030105	1–5	7.5 Mrad (75 kGy)	7.5 Mrad (75 kGy)	1–5
MAGNUM™ ABS Series				
MAGNUM™ 8391 MED	Not Recommended	10 Mrad (100 kGy)	10 Mrad (100 kGy)	1–3
MEGOL™ TPS-SEBS Series				
MEGOL™ MED	Yes*	2.5 Mrad–5.0 Mrad (25–50 kGy)	Not Recommended	Yes*
MEGOL™ SK	Yes*	2.5 Mrad–5.0 Mrad (25–50 kGy)	Not Recommended	Yes*
RAPLAN™ TPS-SBC Series				
RAPLAN™ MED	No	2.5 Mrad–5.0 Mrad (25–50 kGy)	Not Recommended	Yes*
STYRON™				
STYRON™ 2678 MED	Not Recommended	5.0 Mrad (50 kGy)	Yes*	Yes*
STYRON™ 2686 MED	Not Recommended	5.0 Mrad (50 kGy)	Yes*	Yes*

* Contact Trinseo representative for variances in cycles

[1] Trinseo testing. Complete protocols and results are available upon request.

Sterilization Methods/ General Information

Gamma Sterilization

Gamma radiation, which involves exposure to photons from a cobalt-60 source, is widely used for the sterilization of medical devices. Gamma rays have no mass and are thus able to penetrate deeply into the material. As a result, they can easily penetrate most packaging materials, enabling the sterilization of devices in assembled and packaged form. A common gamma dosage for sterilization is 2.5 Mrad (25 kGy), although higher doses of 5.0 and 7.5 Mrad (50 and 75 kGy) are also used depending on application requirements. The process temperature is low, usually between 30 and 40 °C (86 and 104 °F). Sterilization cycle time is dependent on the level of gamma radiation required.

Polycarbonate Resins

One of the advantages of gamma sterilization is that it has almost no effect on the physical performance of polycarbonate, as shown in **Figures 1 and 2**. Samples of CALIBRE™ MEGARAD™ 2081 Polycarbonate Resin were exposed to gamma sterilization at 2.5 and 10 Mrad, in order to simulate a "worst case" type of exposure. Physical property data is summarized in **Figure 1**, which shows excellent retention of physical properties, even at radiation doses up to 10 Mrad (100 kGy). While there is a small reduction in the dart impact performance, all other physical properties are nearly identical to the control prior to sterilization.

The physical integrity of the material over time is important because of the delay between the time of manufacture/sterilization and the time the device is actually used. It is essential that the materials selected maintain their properties over the expected shelf-life of the product. A study was performed to evaluate the physical properties of CALIBRE™ MEGARAD™ 2081 after sterilization and storage up to one year. The retention of key properties is shown in **Figure 2**, which indicates that time after sterilization does not significantly affect the material's performance. In fact, all properties were retained at more than 95 percent of their pre-sterilization values.

Figure 1: Effects of Gamma Sterilization on Property Retention of CALIBRE™ MEGARAD™ 2081-15 030105[1]

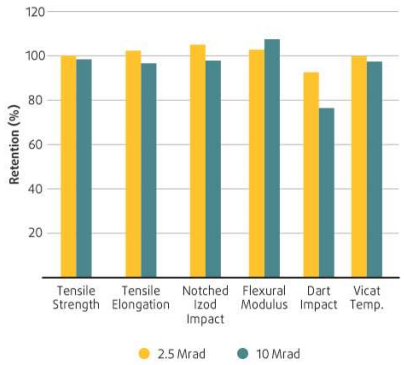
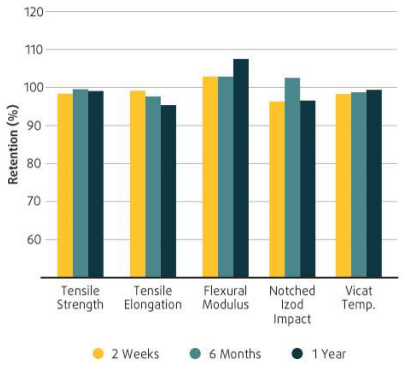


Figure 2: Long-term Effects of Gamma Sterilization (2.5 Mrad) on CALIBRE™ MEGARAD™ 2081-15 030006[1]



Gamma radiation is known to cause discolorration of polycarbonate (PC) resin. CALIBRE™ MEGARAD™ 2081 Polycarbonate Resins are designed to reduce post-sterilization color shift primarily for transparent products. Three standard tints have been developed to help compensate for color changes after sterilization at various radiation doses **(see Table 2)**.

Table 2: Standard CALIBRE™ MEGARAD™ Tints and Recommendations

Grade and Tint	Recommended Gamma Radiation Level[1]
CALIBRE™ MEGARAD™ 2081 030006	2.5 Mrad (25 kGy)
CALIBRE™ MEGARAD™ 2081 030116	5.0 Mrad (50 kGy)
CALIBRE™ MEGARAD™ 2081 030105	7.5 Mrad (75 kGy)

[1] Trinseo testing. Complete protocols and results are available upon request.

To study changes in color over time, standard color tint offerings of CALIBRE™ MEGARAD™ 2081 were exposed to 2.5 Mrad of gamma radiation. The color of each sample was then measured after one and eight weeks for comparison. The resulting data is provided in **Figure 3**, with yellowness prior to sterilization shown as time zero.

While an increase in yellowness index is observed in all three samples initially, the yellowness of the materials diminishes with time. This phenomenon is known as photo-bleaching. After exposure to gamma radiation, the transparent PC samples equilibrate back toward their original color prior to irradiation. The resin's color package must be adjusted to compensate for the required radiation dosage so that the desired final color is achieved in the time specified by the customer's requirements. Trinseo offers the standard tints listed in **Table 2** (vide supra) as starting points to enable customers to select the CALIBRE™ MEGARAD™ Polycarbonate Resin and color compensation package best suited to their applications and radiation levels.

Storage conditions can also play a role in photo-bleaching. To determine the effect of storage lighting conditions, irradiated CALIBRE™ MEGARAD™ 2081 resin samples were stored in fluorescent light and dark conditions and the yellowness index was measured every week for six weeks. The results of this study are summarized in **Figure 4**, with samples exposed to fluorescent light noted as "Light" and those stored in darkness noted as "Dark." It was observed that the color recovery is accelerated if the samples are stored in lighted conditions. No differences in physical properties were observed based on storage conditions.

Opaque colored polycarbonate resins can also be suitable for gamma sterilization. As previously shown, the physical property retention is excellent up to at least 10 Mrad. CALIBRE™ 2061 is offered in various opaque colors that can be used with gamma sterilization. There can be a minor change in appearance after sterilization and this will depend on the specific color and radiation dosage. As with the MEGARAD™ resins, opaque CALIBRE™ resins will also have some color recovery with time.

In summary, all PC discolors from exposure to radiation and the discoloration increases along with the dosage. The physical properties of CALIBRE™ MEGARAD™ Polycarbonate Resins remain very stable when exposed to gamma radiation, with the ability to withstand levels up to 10 Mrad (100 kGy). The color compensation technology of CALIBRE™ MEGARAD™ Polycarbonate Resins helps minimize the initial discoloration and accelerate the return to near-initial color. Exposure to fluorescent or mild ultraviolet (UV) light can also help accelerate color recovery.

Figure 3: Effects of Gamma Sterilization (2.5 Mrad) on CALIBRE™ MEGARAD™ 2081 Resin[1]

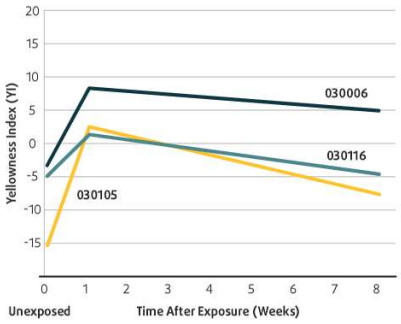
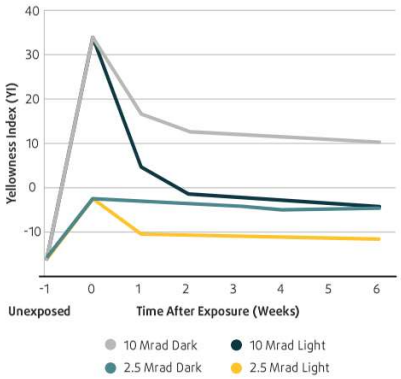


Figure 4: Effects of Storage Conditions on Color Recovery of CALIBRE™ MEGARAD™ 2081 Resin[1]



ABS Resins

In contrast to polycarbonate, the retention in impact strength of gamma sterilized polymers modified with butadiene rubber is dependent on the degree of cross-linking of the butadiene phase. As gamma irradiation can induce cross-linking the energy dosage and exposure time will determine the level of additional cross-links of the impact modifier in ABS and thus the level of decrease in impact properties. The higher the radiation dosage, the greater the cross-linking, and the lower the ultimate impact strength. At the sterilization exposure level of 10 Mrads, ABS shows losses in impact strength accompanied by a slight increase in tensile strength and a decrease in tensile elongation-at-break. This change is attributed to the crosslinking of the butadiene rubber matrix, **see Table 3**.

Table 3: Physical properties of MAGNUM™ 8391 MED after gamma sterilization

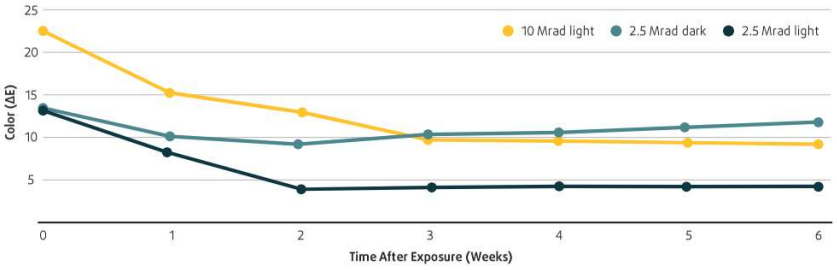
	MAGNUM™ 8391 MED 0 Mrad	MAGNUM™ 8391 MED 5 Mrad	MAGNUM™ 8391 MED 10 Mrad
Notched Izod (ftlb/in)	4.1	3.5	3.1
Tensile Strength (psi)	6890	6500	7020
Tensile Break (psi)	5290	5370	5520
Elongation at Yield (%)	2.5	2.9	2.6
Elongation at Break (%)	7.2	8.8	4.8
Tensile Modulus (psi)	344000	331000	349000

If the rubber content is high enough, crosslinking becomes the dominating factor in determining the physical property characteristics of the polymer upon irradiation.

Crosslinked butadiene rubber loses its impact strength, thus, at dosages sufficient to crosslink all the rubber, the enhanced impact properties originally provided by the rubber modifier are lost. The remaining impact strength of the material will be no better than that of the unmodified polymer. Comparing the notched Izod impact strength at 2.5 Mrads and 10 Mrads, one can see the loss in properties with the increase in radiation dosage. In general a decrease in Izod impact of 10–20 % after exposure to 2.5 Mrad and a 30 % reduction after exposure to 10 Mrad are to be expected.

Besides changes in physical properties gamma irradiation of ABS will further lead to discoloration. While exposure to 2.5 Mrad in light colors leads to retention of the original color within 2 weeks, exposure to 10 Mrad results in permanent discoloration, **Figure 5**.

Figure 5: Graph 2-01 in "Color change (ΔE) of natural ABS resin after gamma sterilization"



[1] Trinseo testing. Complete protocols and results are available upon request.

Polymethyl Methacrylate Resins

Trinseo PMMA resins — PLEXIGLAS® in the Americas and ALTUGLAS™ in EMEA/APAC — are designed to provide outstanding transmission and water-white clarity. These resins also exhibit excellent resistance to discoloration after high-energy sterilization methods as demonstrated in **Figure 6**. Medical devices molded from these resins start and stay clearer, compared to other transparent resins tested, after 4 Mrad of gamma radiation, with minimal yellowing and discoloration.

This results in shorter waiting periods for device shipment and can translate into lower safety stock inventory requirements.

Figure 7 provides a comparative look at impact strength for the Trinseo PMMA medical resins. These impact modified acrylic resins continue to provide impact strength, tensile strength and high modulus, even after high energy sterilization.

Figure 6: Yellowness Index (E313) after 5 Mrad Gamma Irradiation

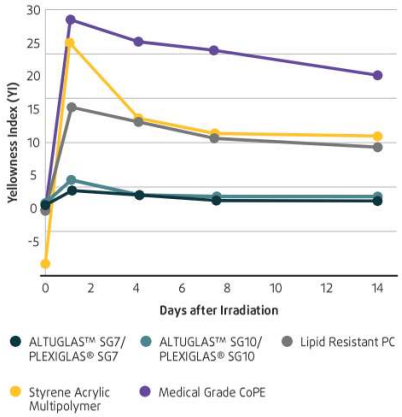
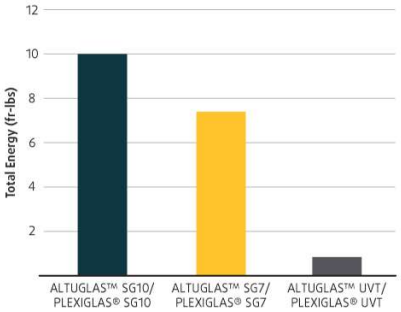


Figure 7: Impact Strength (Falling Dart) at 3.2 mm Thickness



Thermoplastic Elastomer Resins

Like impact modified styrenics, thermoplastic elastomers can show a slight loss in properties upon sterilization with gamma radiation. Yet, using 2.5 Mrad and 5 Mrad radiation on MEGOL™ MED 25 IP and MEGOL™ MED 80 IP results in excellent retention in tensile strength 100 % and 300 %. Smaller loss in tensile strength can be observed for the tensile strength at break **(Figure 8 and 9)**.

Even after 6 months, the properties remain fairly stable as shown in **Figure 10**. While the mechanical properties remain intact the natural (uncolored) base material shows yellowing when exposed to 2.5 Mrad and 5 Mrad **(Figure 11 and 12)**. Color recovery is rather slow and reaches 40 % after 6 months.

Figure 10: Long term effect of Gamma sterilization on property retention of MEGOL™ MED 80 IP. T0: tested immediately after sterilization, T6 tested 6 months after sterilization.

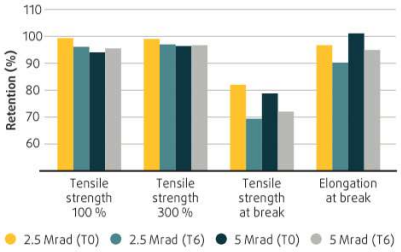


Figure 8: Effect of Gamma sterilization, 2.5 Mrad and 5 Mrad, on property retention of MEGOL™ MED IP grades

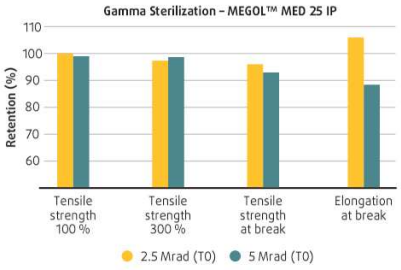


Figure 11: Yellowness Index variation after gamma sterilization on natural MEGOL™ MED IP grades.

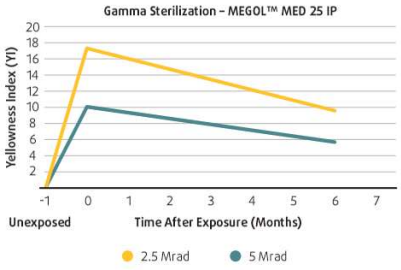


Figure 9: Effect of Gamma sterilization, 2.5 Mrad and 5 Mrad, on property retention of MEGOL™ MED IP grades

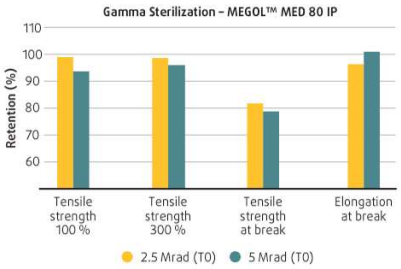
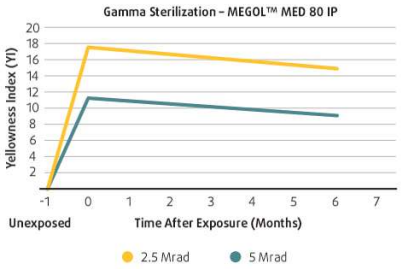


Figure 12: Yellowness Index variation after gamma sterilization on natural MEGOL™ MED IP grades.



(1) Trinseo testing. Complete protocols and results are available upon request.

Similar results were obtained for MEGOL™ MED AD grades, thermoplastic elastomers specially designed for strong adhesion to polar substrates such as polycarbonate, ABS or PC/ABS. Both MEGOL™ MED 50 AD and MEGOL™ MED 80 AD showed excellent property retention when radiated with 2.5 Mrad and 5 Mrad **(Figure 13 and 14)**. The properties are unchanged after storage at 23 °C and 50 % R.H. for 6 months **(Figure 14)**.

Figure 13 and 14: Effect of Gamma sterilization, 2.5 Mrad and 5 Mrad, on property retention of MEGOL™ MED AD grades.

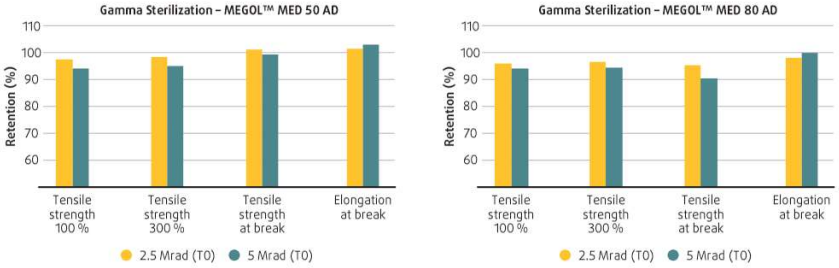
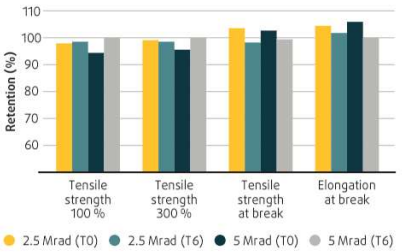


Figure 15: Long term effect of Gamma sterilization on property retention of MEGOL™ MED 80 AD. T0: tested immediately after sterilization, T6 tested 6 months after sterilization.



In contrast to MEGOL™ MED IP grades the adhesion optimized AD series shows less yellowing in natural (uncolored) grades.

The significantly stiffer RAPLAN™ MED 52D, designed and optimized for drip chamber applications, does not show any significant changes in properties at both 2.5 Mrad and 5 Mrad exposure. Also, the yellowing is moderate and does not increase with increasing radiation energy.

Figure 16 and 17: Yellowness Index variation after gamma sterilization on natural MEGOL™ MED AD grades.

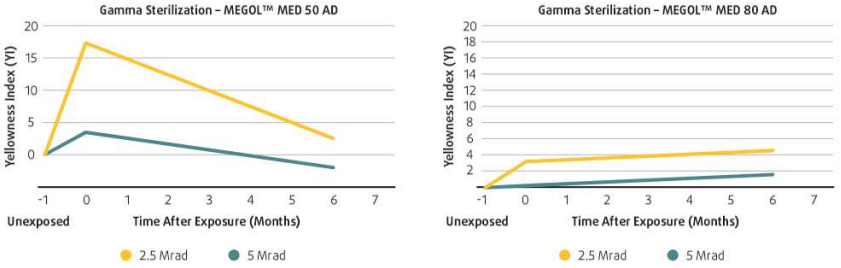
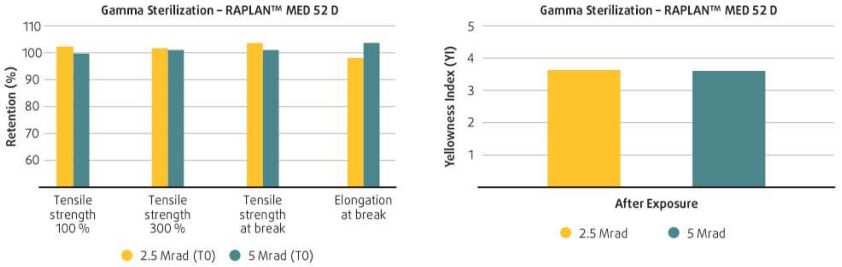


Figure 18 and 19: Effect of Gamma sterilization, 2.5 Mrad and 5 Mrad, on property retention and yellowness index variation of RAPLAN™ MED 52D immediately after sterilization.



(1) Trinseo testing. Complete protocols and results are available upon request.

Electron Beam Sterilization

Polycarbonate Resins

Electron beam (e-beam) irradiation is the penetration of high-energy electrons throughout the material. Typical doses are in the 1–6 Mrad (10–60 kGy) range. The e-beam sterilization process is significantly faster than gamma sterilization. Parts need to be exposed only for minutes rather than hours. It should be noted, however, that the penetrating capability of e-beam radiation is not as good as that of gamma radiation and articles may need to be treated from multiple directions to achieve complete sterilization.

A study was performed to determine the effects of e-beam sterilization on CALIBRE™ MEGARAD™ 2081 Polycarbonate Resins. As shown in **Figure 20**, the physical property retention is very good. These results are similar to those for gamma sterilization **(Figure 1, page 5)**.

The effects of e-beam radiation on color change were evaluated in comparison to gamma sterilization. **Figure 21** shows that the color change and recovery of CALIBRE™ MEGARAD™ 2081 resins exposed to e-beam and gamma irradiation are similar. The initial color change for e-beam was slightly lower compared to gamma, but over time the resulting color is virtually the same.

Figure 20: Effects of E-Beam Sterilization on Property Retention of CALIBRE™ MEGARAD™ 2081-15 030105[1]

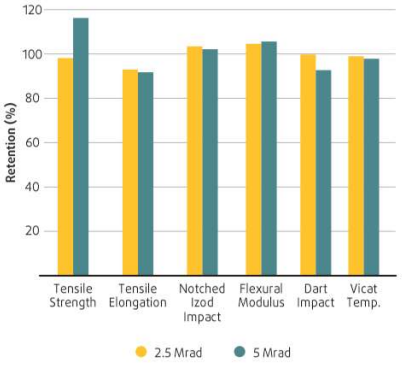
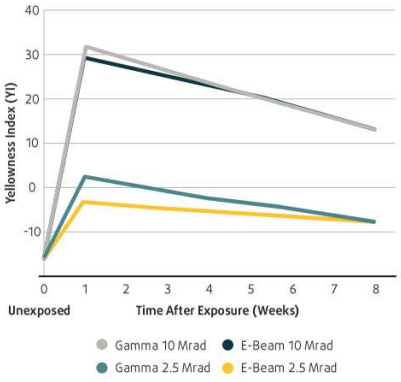


Figure 21: Effects of E-Beam and Gamma Sterilization on Yellowness Index of CALIBRE™ MEGARAD™ 2081-15 030105[1]



Ethylene Oxide Sterilization

Polycarbonate Resins

Ethylene Oxide (EtO) is another common form of sterilization for disposable medical devices or SUDs. The advantage of EtO sterilization is that compared to other sterilization methods, it is the least aggressive toward many thermoplastic materials. EtO can be used with materials that are sensitive to the heat of steam sterilization or significantly degrade under irradiation.

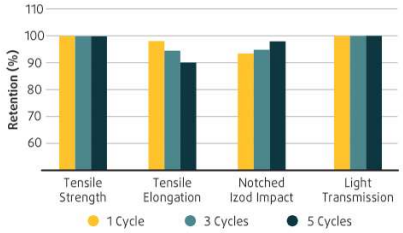
EtO sterilization is normally done at temperatures in the 50–60 °C (122–140 °F) range. Pure EtO is very flammable, toxic and explosive, so it is usually mixed with inert gas, such as carbon dioxide and some types of fluorocarbon gas. There are several variables for effective sterilization, including the exposure time, temperature, humidity and gas concentration. Other important considerations are the compatibility of the material with EtO gas and the permeability of the packaging material.

Figure 22 shows that CALIBRE™ 2061 Polycarbonate Resin maintains its strength, toughness and appearance for up to as many as 5 cycles of EtO sterilization. Samples of CALIBRE™ 2061 were sterilized with EtO using a HCFC-124 carrier gas for 1, 3 and 5 cycles. Tensile and Izod properties are maintained at over 90 percent of the original values. A slight reduction in tensile elongation is observed with each exposure cycle. The appearance, however, is unchanged, as indicated by the light transmission data.

As with gamma sterilization, the delay between manufacturing/EtO sterilization and use of the device makes it essential that the materials selected maintain their performance throughout the product's expected shelf-life. For this reason, a study was conducted to evaluate the physical properties of CALIBRE™ 2060 and CALIBRE™ MEGARAD™ 2081 Polycarbonate Resins after EtO sterilization and storage up to one year.

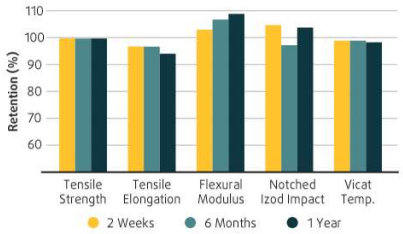
As shown in **Figure 23**, time after sterilization does not significantly affect the long-term performance of CALIBRE™ 2060, with all properties retained at more than 94 percent of their pre-sterilization values throughout the one-year testing period. The results for CALIBRE™ MEGARAD™ 2081 **(Figure 24)** also reveal excellent retention of all properties.

Figure 22: Effects of EtO Sterilization on Property Retention of CALIBRE™ 2061 Resin[1]



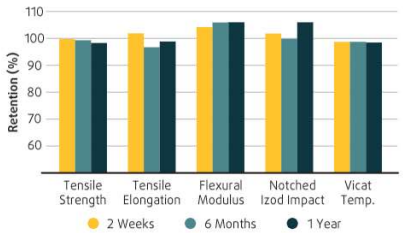
Sterilization Cycle: Condition at 38 °C (100 °F), 50% relative humidity (RH) for 8 hrs. Expose to 600 mg/l constant gas for 3.5 hrs. at 49 °C (120 °F), 50% RH. Aerate at 49 °C (120 °F) for 16 hrs.

Figure 23: Long-term Effects of EtO Sterilization on CALIBRE™ 2060-22 030004[1]



Sterilization Cycle: Condition at 38 °C (100 °F), 60% RH for 8 hrs. Expose to 660 mg/l constant gas for 6 hrs. at 49 °C (120 °F), 60% RH. Aerate at 32 °C (90 °F) for 16 hrs. Samples aged up to 1 year at 21 °C (70 °F), 50% RH.

Figure 24: Long-term Effects of EtO Sterilization on CALIBRE™ MEGARAD™ 2081-15 030006[1]



Sterilization Cycle: Condition at 38 °C (100 °F), 60% RH for 8 hrs. Expose to 660 mg/l constant gas for 6 hrs. at 49 °C (120 °F), 60% RH. Aerate at 32 °C (90 °F) for 16 hrs. Samples aged up to 1 year at 21 °C (70 °F), 50% RH.

[1] Trinseo testing. Complete protocols and results are available upon request.

Thermoplastic Elastomer Resins

Ethylene Oxide sterilization of MEGOL™ MED thermoplastic elastomers for 120 min shows good property retention directly after sterilization. Even after 6 months of storage all samples showed a minimum of 70 percent of their initial properties **(Figure 25–26)**. In addition, discoloration of natural samples without a special additive package is very low **(Figure 27)** and almost complete recovery is obtained after 6 months.

Figure 25–26: Effect of ethylene oxide sterilization on property retention and yellowness index variation of MEGOL™ MED immediately after sterilization (T0) and after 6 months storage (T6).

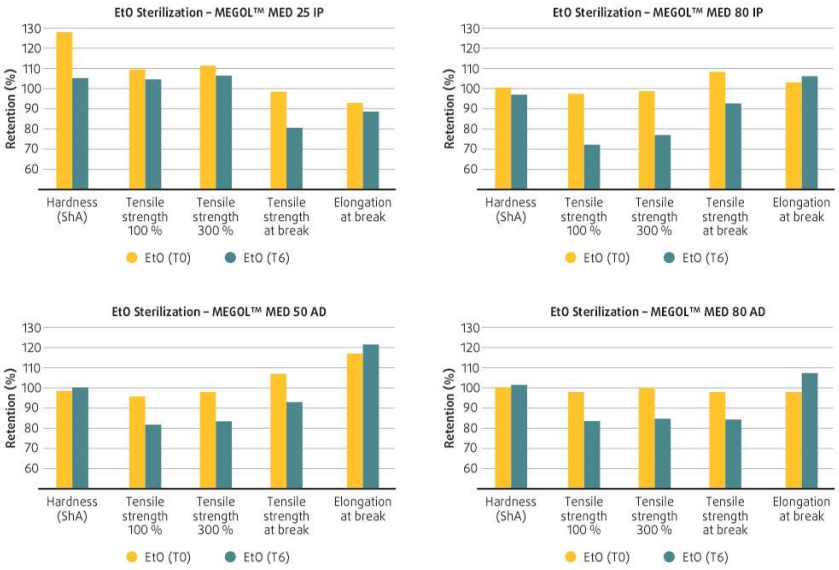
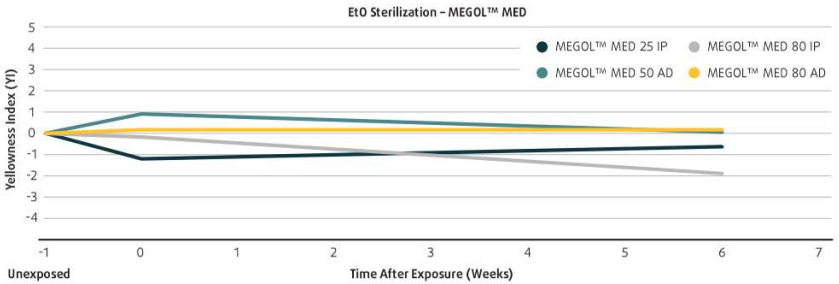


Figure 27: Yellowness index of MEGOL™ MED after ethylene oxide sterilization over a time period of 6 months.



Steam Autoclave Sterilization

Polycarbonate Resins

A steam autoclave process is typically used to sterilize reusable or multiple-use medical devices (MUDs). However, single-use medical devices (SUDs) are also normally engineered to withstand 1–2 autoclave cycles in case a previously sterile package is believed to be compromised during shipping or handling. A steam autoclave unit uses high-pressure saturated steam in order to create an environment that effectively inactivates most bacteria, viruses, spores and fungi. Standard conditions for autoclave sterilization are 3–10 minutes at 132–134 °C (270–273 °F) and 3–30 minutes at 121 °C (250 °F). The high humidity and temperature create a harsh environment for plastics. Therefore, the polymer selected needs to have a glass transition temperature that exceeds the autoclave operating temperature in order to survive. CALIBRE™ 2061 Polycarbonate Resin is suitable for reusable medical equipment requiring autoclave sterilization.

A study was performed on CALIBRE™ 2061 in order to determine the effects of autoclave exposure on the retention of physical properties. Using typical exposure conditions of 134 °C/8 minutes and 121 °C/30 minutes, the molecular weight of CALIBRE™ 2061 samples exposed to 3 and 5 autoclave cycles was measured. As shown in **Figure 28**, the molecular weight of this material remains very consistent up to 5 cycles. This demonstrates that the polymer is hydrolytically stable and there is no significant degradation that would cause a loss of material performance.

The appearance of the device after sterilization can also be of great importance, especially for transparent parts. Since repeated autoclave cycles can cause increases in the haze and yellowness of the material, tests were conducted to evaluate the effects of up to 5 cycles on CALIBRE™ 2061 Polycarbonate Resin. As shown in **Figure 29**, haze is relatively unaffected after 5 cycles at high temperature for short time periods of 8 minutes per cycle. With longer cycle times, however, the haze begins to slightly increase up to 1 percent. The yellowness of the material, as shown in **Figure 30**, remains relatively stable under all conditions tested. In order to maintain an excellent appearance in the final part, it is recommended that the autoclave exposure time be limited to a cumulative duration of 2 hours.

A second study was performed to evaluate the effect of extreme conditions. Autoclave sterilization was performed at 132 °C (270 °F) and up to 100 cycles at 13 minutes per cycle. **Figure 31** shows the retention of key physical properties after exposure to 10, 50 and 100 cycles. The tensile yield strength and tensile modulus are maintained over multiple cycles of exposure. After 10 cycles, the instrumented dart impact begins to decrease and the tensile elongation is significantly affected.

The durability of the resin will depend on the autoclave time and temperature. The acceptable number of cycles also depends on the functional requirements for the part or device. General recommended conditions for steam autoclave sterilization of CALIBRE™ Polycarbonate Resins are 1–5 cycles at 134 °C (273 °F).

NOTE: All testing performed in this report was done according to standard ASTM methods as shown in Table 4.

Table 4: ASTM Test Methods

Tensile Properties	ASTM D 638
Flexural Properties	ASTM D 790
Notched Izod Impact	ASTM D 256
Instrumented Dart Temperature	ASTM D 3763
Vicat Softening Temperature	ASTM D 1525
Light Transmission & Haze	ASTM D 1003
Yellowness Index (YI)	ASTM D 1925
Molecular Weight (Mw)	ASTM D 3536

(1) Trinseo testing. Complete protocols and results are available upon request.

Figure 28: Effects of Steam Autoclave Sterilization on Molecular Weight of CALIBRE™ 2061 Resin[1]

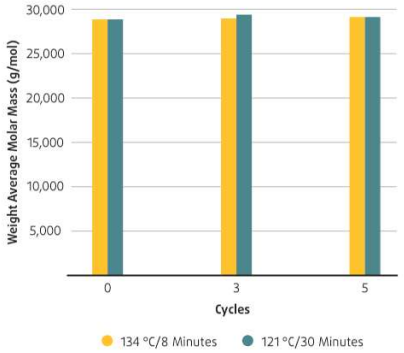


Figure 29: Effects of Steam Autoclave Sterilization on Haze of CALIBRE™ 2061 Resin[1]

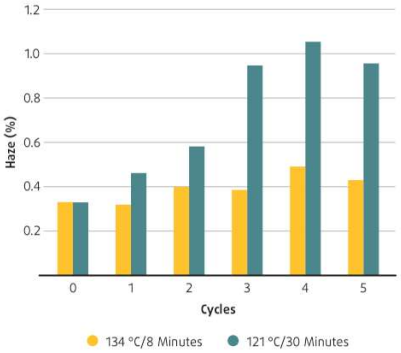


Figure 30: Effects of Steam Autoclave Sterilization on Yellowness Index of CALIBRE™ 2061 Resin[1]

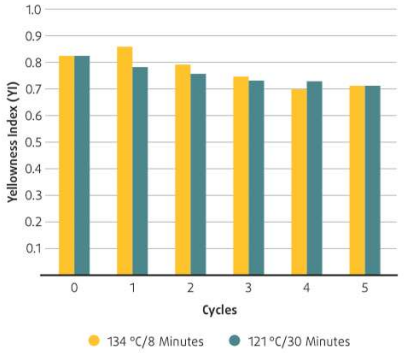
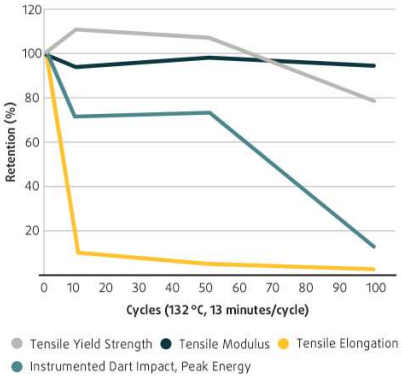


Figure 31: Effects of Steam Autoclave Sterilization on Physical Properties of CALIBRE™ 2061-15 Resin[1]

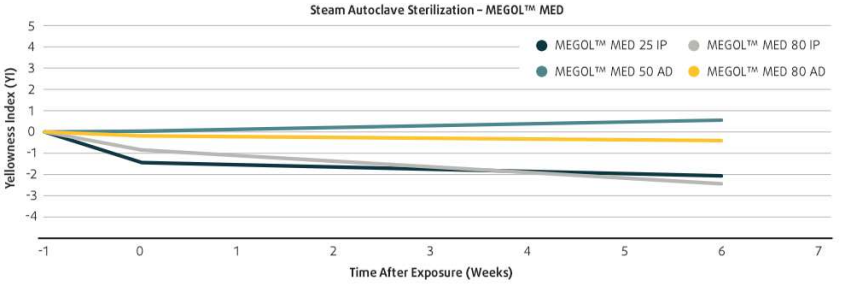


Thermoplastic Elastomer Resins

Steam autoclave sterilization at 121°C on MEGOL™ MED samples showed very good property retention directly after sterilization and more than 70 percent property retention after 6 months. Discoloration of natural samples show slight yellowing.

Figure 32–35: Effect of steam autoclave sterilization on property retention and yellowness index variation of MEGOL™ MED immediately after sterilization (T0) and after 6 months storage (T6).

Figure 36: Yellowness index of MEGOL MED after ethylene oxide sterilization over a time period of 6 months.



[1] Trinseo testing. Complete protocols and results are available upon request.

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