



Sterilization of Transparent CALIBRE™ Polycarbonate Resins

Single- and multiple-use medical devices that come in contact with human tissue or bodily fluids must be sterilized for patient safety. CALIBRE™ Polycarbonate Resins have been specifically developed to handle a variety of sterilization processes and application requirements. The most common forms of sterilization and the performance of transparent CALIBRE™ Polycarbonate Resins are detailed in Table 1.

Steam Autoclaving: CALIBRE™ 2061 and CALIBRE™ MEGARAD™ Polycarbonate Resins typically withstand one to five autoclave cycles (depending on cycle parameters). Polycarbonate begins to exhibit molecular weight loss, impact reduction and haze after two hours of cumulative autoclave exposure.⁽¹⁾

Gamma or Electron Beam (e-beam) Radiation: CALIBRE™ MEGARAD™ 2081 Polycarbonate Resins are designed to reduce post-sterilization color shift associated with these types of sterilization. Grades are available for three common irradiation intensities. The product has been designed to maintain mechanical properties up to 10 Mrad (100 kGy) of radiation exposure.⁽²⁾

NOTE: CALIBRE™ Polycarbonate Resins for gamma and e-beam sterilization are available in opaque colors upon request.

Ethylene Oxide (EtO): CALIBRE™ 2061 and CALIBRE™ MEGARAD™ Polycarbonate Resins withstand ethylene oxide sterilization for up to five cycles at normal conditions. Physical properties and color are maintained but multiple exposures can reduce the tensile elongation properties of the polymer.⁽³⁾

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

CALIBRE™ Polycarbonate Resin Family	Sterilization Technique			
	Steam Autoclave	Gamma Radiation	Electron Beam (e-beam) Radiation	Ethylene Oxide (EtO)
CALIBRE™ 2061 Transparent Series				
CALIBRE™ 2061 FC030003	1-5 cycles	Not Applicable	Not Applicable	1-5 cycles
CALIBRE™ 2061 FC030004				
CALIBRE™ MEGARAD™ 2081 Transparent Series				
CALIBRE™ MEGARAD™ 2081 FC030006	1-5 cycles	2.5 Mrad (25 kGy)	2.5 Mrad (25 kGy)	1-5 cycles
CALIBRE™ MEGARAD™ 2081 FC030116	1-5 cycles	5.0 Mrad (50 kGy)	5.0 Mrad (50 kGy)	1-5 cycles
CALIBRE™ MEGARAD™ 2081 FC030105	1-5 cycles	7.5 Mrad (75 kGy)	7.5 Mrad (75 kGy)	1-5 cycles

NOTE: 1 megarad (Mrad) = 10 kilogray (kGy)

Committed to the medical industry. In addition to the CALIBRE™ and CALIBRE™ MEGARAD™ Polycarbonate Resins discussed here, Trinseo offers a full portfolio of CALIBRE™ products for use in single- and multiple-use medical devices, as well as EMERGE™ Advanced Resins and STYRON™ Polystyrene Resins for medical equipment housings. Trinseo collaborates with customers so that the materials selected meet the specific needs of each application, including property performance, part design/manufacturing and regulatory requirements.

For more information on CALIBRE™ Polycarbonate Resins or other materials for medical applications, contact us at 1-855-TRINSEO, or visit us online at <http://www.trinseo.com/na/en/industries/medical/>

⁽¹⁾ Data available for steam autoclave performed at 132°C.
⁽²⁾ Data available for gamma and e-beam sterilization levels of 2.5 and 10 Mrad (25 and 100 kGy).
⁽³⁾ Data available for ethylene oxide sterilization up to five cycles at 60% relative humidity, 49°C, six hours dwell time.



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