



Compatibility of Radel® PPSU Color Formulations with Steam Sterilization

The ability to withstand repeated sterilization is a critical requirement for any material used in reusable medical devices. Steam sterilization is the most commonly used method and is one of the most severe sterilization environments for materials, using pressurized steam at 121 to 134 °C (250 to 273 °F) for up to 18 minutes. During steam sterilization, devices may also be exposed to morpholine, a chemical that is often added to central steam sterilization systems to inhibit corrosion in the lines. As with all sterilization techniques, medical devices are chemically washed and disinfected prior to autoclaving.

Engineered for especially harsh environments, Radel® polyphenylsulfone (PPSU) can be cleaned, disinfected and steam sterilized over 1,000 cycles without significant loss of properties. For over 15 years, this remarkably strong polymer has successfully replaced metals like stainless steel and aluminum in a wide variety of applications, including sterilization cases and trays, surgical and dental instrument handles, endoscopic devices, anesthesiology equipment, and joint replacement trials. The success of Radel® PPSU can be attributed to several performance attributes that are inherent to the polymer.

Key Features:

- High heat resistance
- Long-term thermal stability
- Resistance to repeated steam sterilization
- Broad range of chemical compatibility
- Exceptional toughness and durability

Thermal Properties

Radel® PPSU is an amorphous polymer with a glass transition temperature (T_g) of 220 °C (428 °F). This is the temperature at which the polymer transitions from a glassy state to a rubbery state and generally represents the upper temperature limit for short-term use. Radel® PPSU has a heat deflection temperature (HDT) of 207 °C (405 °F) at 1.8 MPa (264 psi) in accordance with ASTM D 638. This value is a relative measure of the polymer's ability to perform at an elevated temperature while supporting a load. In general, the maximum operating temperature for amorphous polymers is 5 to 10 °C (9 to 18 °F) below the HDT value. Radel® PPSU exhibits extreme thermal stability, as seen by the use of thermogravimetric analysis (TGA) test. TGA analysis shows a temperature of 496 °C (925 °F) causes only a 1 % weight loss of the Radel® PPSU test samples.

Steam Autoclaving

When feasible, steam autoclave is the preferred method for sterilization. Steam autoclaving is a reliable process that can be found at almost all major healthcare facilities. Steam autoclaves use a combination of heat and moisture to kill microorganisms. Temperatures are typically 121 to 134 °C (250 to 273 °F) and exposure can be 3 minutes for flash sterilization to 30 minutes depending on the temperature and articles to be sterilized.

Plastics for steam autoclave sterilization must be selected carefully, as many polymers cannot withstand the repeated exposure to the high temperature steam. Some plastics can be used for a limited number of cycles (< 100); such as polypropylene, polyamides and polycarbonate. These polymers are adversely affected by the high temperature and/or high humidity. Solvay offers a range of materials for use in the steam autoclave environment. Solvay's Radel® PPSU brand delivers long term performance over 1,000+ cycles.

Solvay offers Radel® PPSU in 12 standard opaque colors. These products are custom compounded by Solvay using Radel® PPSU (naturally transparent amber base polymer) and high temperature pigment packages. Our standard colors for healthcare have been tested to ISO 10993-1 and are supported with MAF's (Master Access Files) with the FDA. Solvay has conducted additional testing of these standard opaque colors, along with the base polymer, to demonstrate the stability and robustness of the Solvay's formulated color packages in repeat steam sterilization.

Sample Preparation

- (12) Radel® PPSU standard colors for healthcare
- Samples were prepared by standard injection molding, using Solvay's published recommendations for processing conditions for Radel® PPSU resin
- Test specimens consisted of standard ASTM Type I tensile bars and plaques 10 × 10 × 0.32 cm (4 × 4 × 0.125 inch)
- No post mold conditioning or annealing steps were conducted on sample parts

Sterilization

Samples were staged on open racks for conditioning in the sterilization chamber. No wrap was used and samples were not removed from the chamber between cycles.

Equipment and sterilization cycle utilized for the purposes of this study are:

- Unit: Amsco Century Sterilizer SV-136H
- Cycle: pre-vac
- Temperature: 135 °C (275 °F)
- Pressure: 214 to 228 kPa (31 to 33 psig)
- Vacuum: 27 inHg
- Times: 18 minute sterilization
10 minute dry
33 minute total cycle

Sample Testing

Testing was conducted in Solvay's test labs in Alpharetta, GA. These labs have ISO 9001 and A2LA certification.

Tensile testing was conducted using Instron® 5569 Load Frames using Bluehill® V2.2 software. Tensile tests were conducted per ASTM D638 for tensile at 5.0 cm/min (2.0 inch/min).

Impact testing was conducted on a Dynatup® 8000 System using Impulse® V2.2.1 software.

Impact drop weight was 70.3 kg (155 lbs) with an impact velocity of 2.4 m/sec (8 ft/sec) using a 12.7 mm (0.5 inch) diameter impactor tip.

Color Change was measured on both sides of the 10 × 10 mm (4 × 4 inch) plaques using a BYK Gardner® Colorsphere Instrument; Reflectance mode, CIE L*a*b* scale with a D65 – 10° illuminant and observer.

Conclusions

Results show that Radel® R-5100 colored products do not exhibit any significant differences in tensile and drop impact properties as compared to the natural base resin. Tensile strength, modulus and elongation to yield show as expected results. Tensile elongation to break is typically highly variable in transparent and colored grades due to the fact test specimens are in a high strain configuration and beyond the yield strength. Although tensile elongation to break results shows an initial drop after 200 cycles, there were no significant trends in any colors that indicate a continuing decline in ductility.

Drop impact results are again consistent over 1,000 cycles showing no negative trends in toughness of the Radel® PPSU colored products. All materials showed extremely high impact loads between 1,762 to 2,305 N-m (1,300 to 1,700 ft-lbs). All products yielded in a typical ductile impact that consisted of a punctured plaque with no crack propagation past the point of impact.

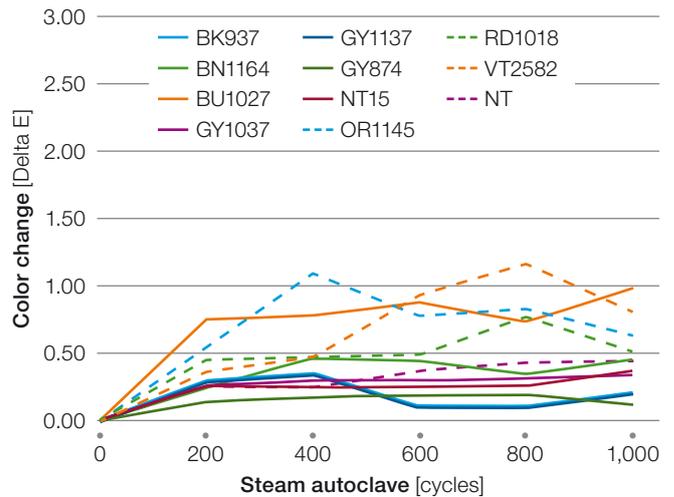
Finally, color stability was excellent with most samples below a 0.5 Delta E after 1,000 cycles and all samples finishing below 1 Delta E. Less than 1 Delta E change is considered below normal detection limits for average human observers. This is also within the normal specifications used to produce the color control the standard Radel® PPSU colors.

Testing has shown that the standard color formulations offered by Solvay are robust and stable in an aggressive steam sterilization environment. Solvay has developed these formulations to be stable in high temperature melt processing and the harsh chemical and sterilization environments seen in the healthcare market.

Solvay offers the same standard color formulations in R-5100 (injection molding grade) and the lower flow R-5500 (extrusion grade) product lines. A random sampling of R-5500 colors has shown similar behavior as seen in the R-5100 grades when conditioned and tested as outlined above. The final two graphs illustrate that the same robust behavior seen in R-5100 grades translates into the R-5500 colored products.

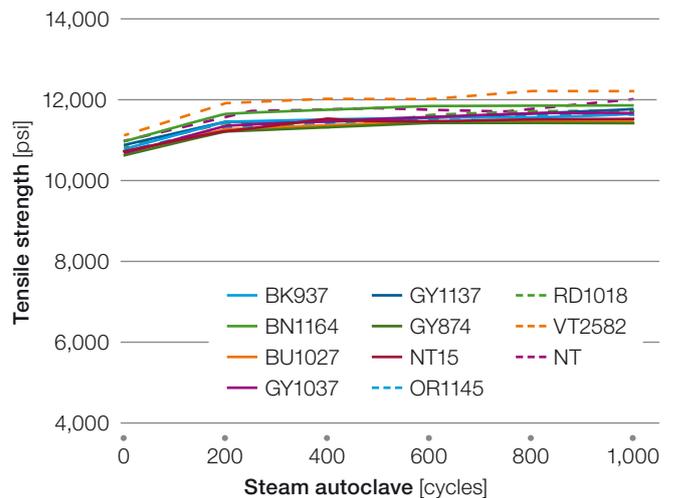
Data Graphs

Radel® R-5100: Color change after steam autoclave cycles



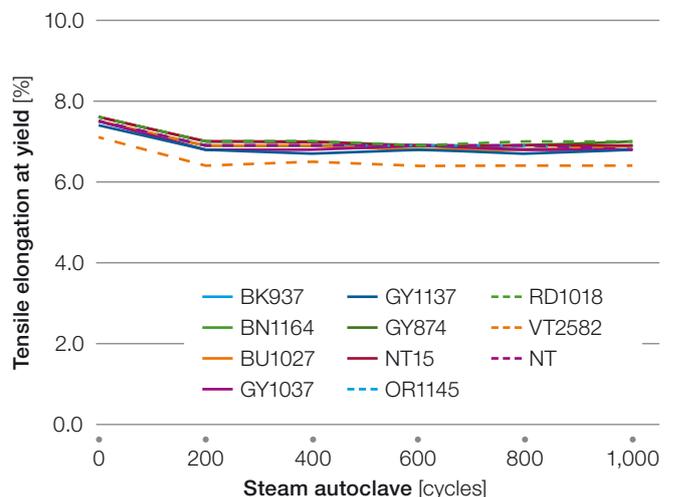
Sterilization cond.: 18 min at 135 °C (275 °F)
10 min. dry time pre-vac cycle

Radel® R-5100: Tensile strength at yield after steam autoclave cycles



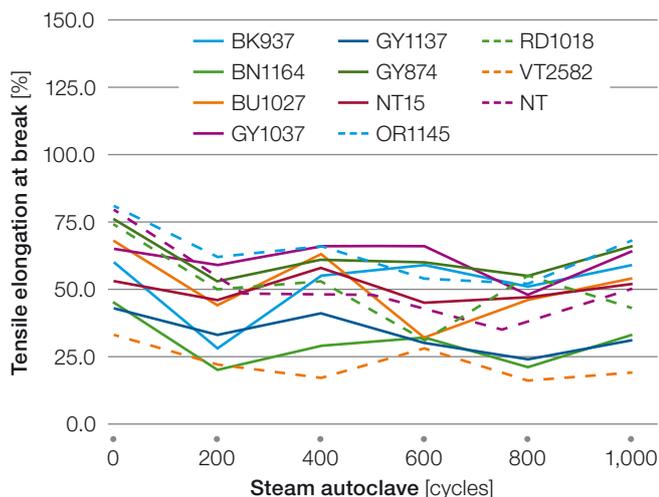
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10 min. dry time pre-vac cycle

Radel® R-5100: Tensile elongation at yield after steam autoclave cycles



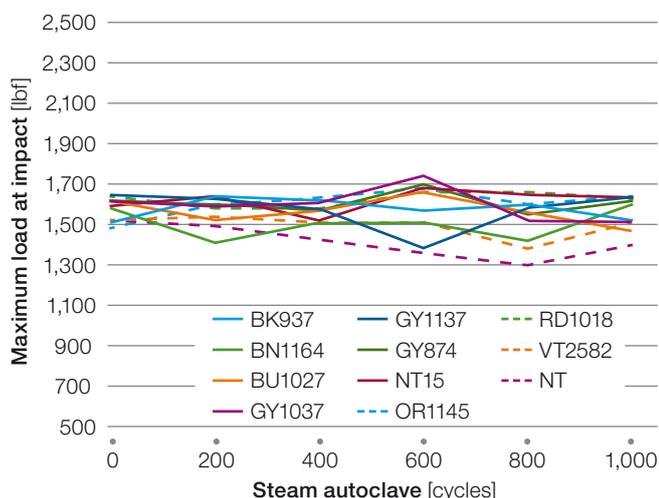
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10 min. dry time pre-vac cycle

Radel® R-5100: Tensile elongation at break after steam autoclave cycles



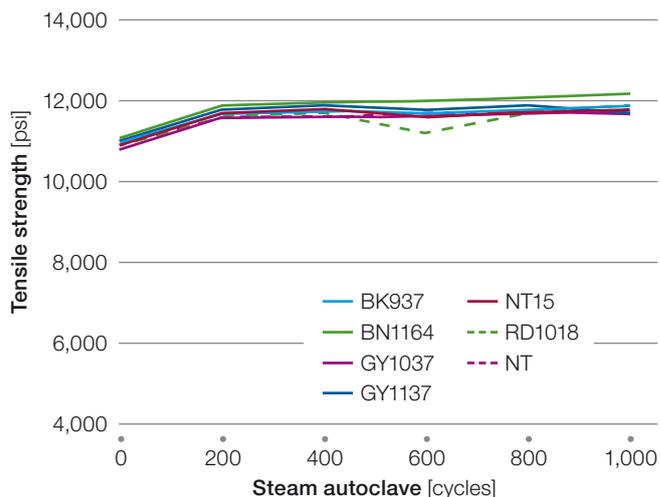
Sterilization cond.: 18 min at 135°C (275°F)
10 min. dry time pre-vac Cycle

Radel® R-5100: Instrumented drop impact after steam autoclave cycles



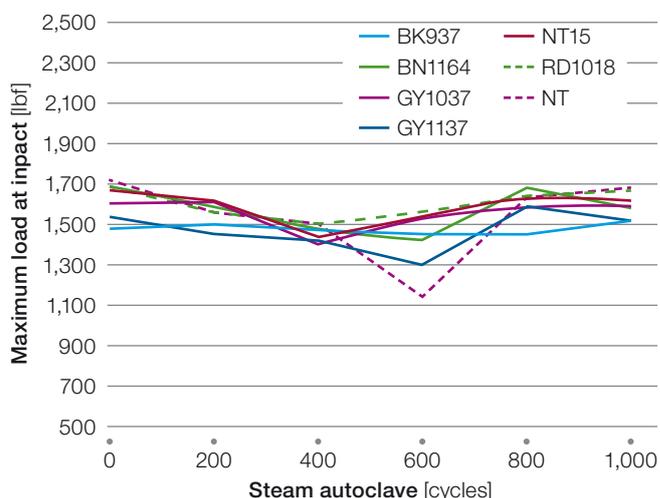
Sterilization cond.: 18 min at 135°C (275°F)
10 min. dry time pre-vac cycle

Radel® R-5500: Tensile strength at yield after steam autoclave cycles



Sterilization cond.: 18 min at 135°C (275°F)
10 min. dry time pre-vac cycle

Radel® R-5500: Instrumented drop impact after steam autoclave cycles



Sterilization cond.: 18 min at 135°C (275°F)
10 min. dry time pre-vac cycle

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