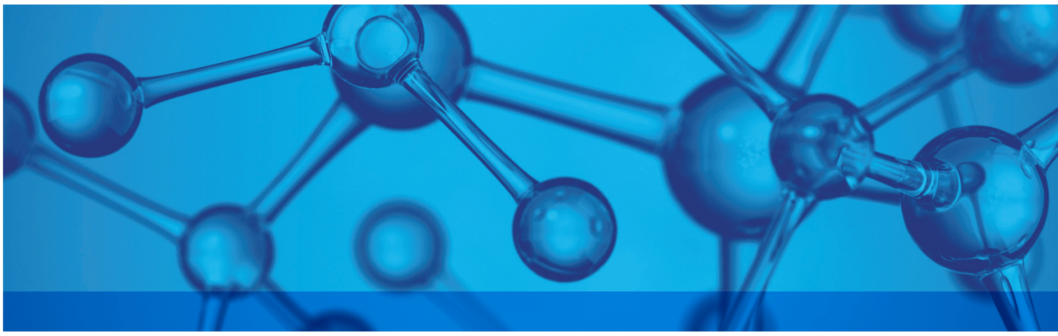


Comparison Steam Sterilization Study of Radel® PPSU and Celcon® POM

Solvay conducted an internal study to aid customers in their evaluation of Radel® PPSU as a replacement for Celcon® POM in reusable surgical instruments and sizing trials. The study provided a head-to-head comparison of the effects of steam sterilization on Radel® PPSU and Celcon® POM. Basic properties such as mechanical strength, flexibility and impact strength were evaluated throughout the study. Attributes such as color retention and dimensional stability were examined before and after steam sterilization.

Since surgical instruments and sizing trials are machined from rod stock, standard test specimens were machined from 3-inch rod stock. Parts machined from rod stock can produce slightly different test values than injection molded samples; therefore, results reported from this study may be slightly different than published data sheet values.

Radel® PPSU in Reusable Medical Devices

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, using pressurized steam at 121 to 134 °C (250 to 273 °F) for up to 25 minutes. As with all sterilization techniques, reusable medical devices are chemically washed and disinfected prior to autoclaving. They may also be exposed to other chemicals, such as morpholine, which are often added to central steam sterilization systems to inhibit corrosion in the lines. This process is one of the most severe sterilization environments for materials.

Engineered for especially harsh environments, Radel® PPSU can be steam sterilized more than a thousand cycles without significant loss of properties. For over 25 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 key performance attributes that are inherent to the polymer:

- High heat resistance
- Long-term thermal stability
- Resistance to prolonged hot water exposure
- Broad range of chemical compatibility
- Exceptional toughness and durability

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.

Materials and Sample Preparation

Starting material: nominal 3 inch diameter extruded rod stock, rod stock was extruded using nominal material process conditions.

- Radel® R5500 GY1037 (medium grey)
- Celcon® M25 CC34031 (grey)

Machining: both materials were prepared by the using the following conditions:

- Turning feeds F.008
- Turning speeds: 350 SFPM
- Milling RPM: 10,000 (3/32-inch endmill)
- Milling feeds: 20 IPM

Test specimens

- Tensile properties – ASTM Type I tensile bars (7-inch length, 0.125-inch thickness)
- Flexural properties – ASTM Flexural bars (5-inch length, 0.125-inch thickness)
- Color and drop impact properties –

3-inch diameter × 0.125-inch thickness disc

- Dimensional properties –
  2-inch diameter × 1.125-inch deep grooved cup

No post machining conditioning or annealing steps were conducted on parts before sterilization exposure.

Steam Sterilization Conditions

Samples were staged on flat open pans 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 – 4 pulses
- Target sterilization temperature: 135 °C (275 °F)
- Typical chamber pressure: 31 to 33 psig
- Typical chamber vacuum: 27 inHg
- Times: 15-minute sterilization
  30-minute dry
  50-minute total cycle (typical)

These conditions are taken from AAMI ST79:2010 guidance document, section 8.6.1, Tables 4 and 5, and represent a worse case scenario for wrapped non-porous instruments in a gravity-displacement sterilization.

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® software. Tensile tests were conducted per ASTM D638 for tensile at 2.0 in/min.

Impact testing was conducted on a Instron® Ceast 9350 system per ASTM D3763. Impact drop weight was 143 lbs with an impact velocity of ~8 ft/sec using a 0.5" diameter impactor tip.

Color change was measured on one side of the 3-inch diameter disc using a BYK Gardner® colorsphere instrument; reflectance mode, CIE L*a*b* scale with a D65 – 10° illuminant and observer.

Test Results

Results show that machined Radel® R-5500 does not exhibit any significant differences in tensile, flex and drop impact properties after 1,000 sterilization cycles. Tensile strength, modulus and elongation to yield show as expected results. Tensile elongation to break is typically a highly variable number and a drop in value beyond the yield point is not un-expected. Materials are subject to earlier rupture due to minor defects on the surface of the machined specimens under this high strain scenario. Although tensile elongation to break results show an initial drop at 50 cycles, the value was stable afterward and showed no continuing decline in ductility.

Drop impact results are again consistent over 1,000 cycles showing no significant negative trends in toughness of the Radel® PPSU. All materials showed extremely high impact loads of between 1,200 to 1,400 ft-lbs. All Radel® PPSU samples yielded in a typical ductile impact that consisted of a punctured plaque with no crack propagation past the point of impact.

Radel® PPSU's dimensional stability was excellent after 1,000 sterilization cycles, with an average change of only 0.003 % over a 2-inch span.

In comparison, the Celcon® POM samples showed a continuous loss in most properties over the duration of the study and significant change in visual appearance.

Data Graphs and Sample Images

Results for the mechanical properties are presented in Figures 1 – 7. Except for color change, all values are reported as percent change from nominal values. Nominal machined baseline values are presented in Table 1. Dimensional changes and representative images of samples during the study are presented in Figures 8 – 11.

Table 1: Starting property values

Properties	Unit	Radel® R-5500	Celcon® M25	Test Method
Tensile strength	MPa (psi)	83.0 (12,040)	65.6 (9,521)	ASTM D638
Tensile elongation at yield	%	7.4	14.8	ASTM D638
Tensile elongation at break	%	26	25	ASTM D638
Tensile modulus	MPa (psi)	2,280 (331,000)	2,790 (405,000)	ASTM D638
Flexural strength	MPa (psi)	104 (15,023)	84 (12,219)	ASTM D790
Flexural modulus	GPa (psi)	2,420 (351,000)	2,760 (400,000)	ASTM D790
Impact – max. load	kg_f (lbf)	606 (1,336)	287 (633)	ASTM D3763

We would like to thank Röchling for their experienced production and handling of the rod stock for this study and Perryman Company for their knowledge and assistance in the proper machining of these materials.

Figure 1: Tensile strength at yield

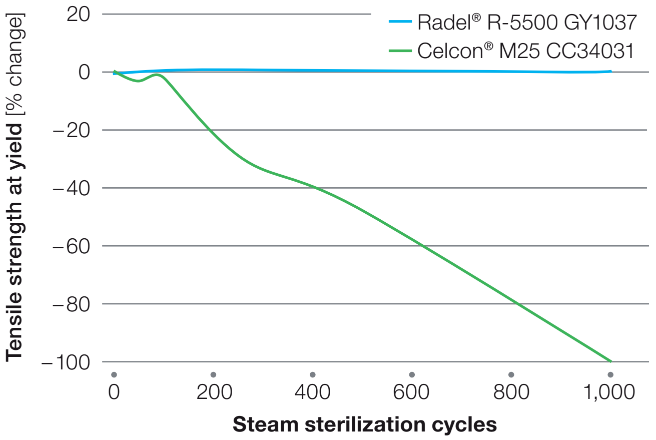


Figure 4: Tensile elongation at break

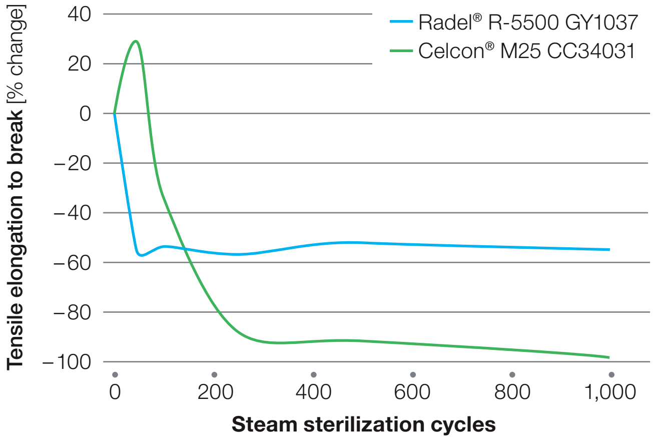


Figure 2: Tensile elongation at yield

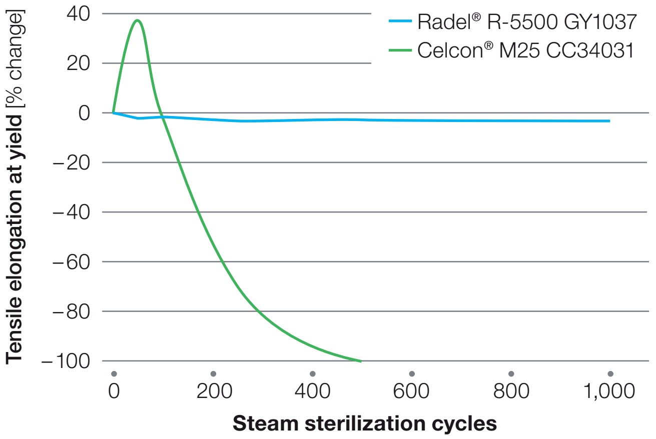


Figure 5: Flexural strength

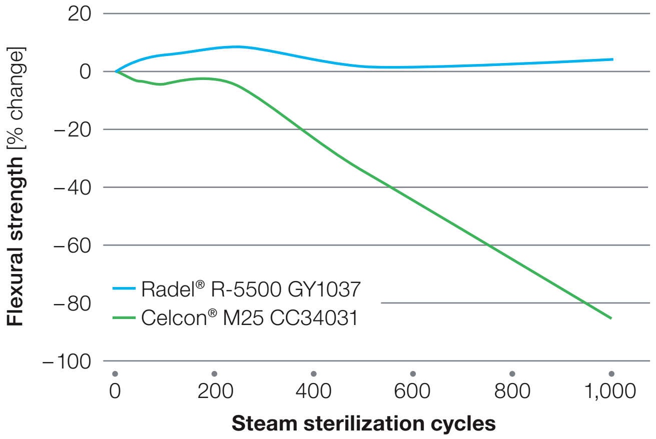


Figure 3: Tensile modulus

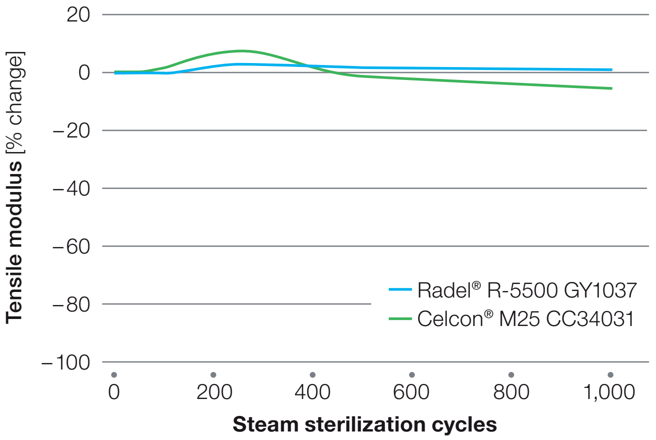
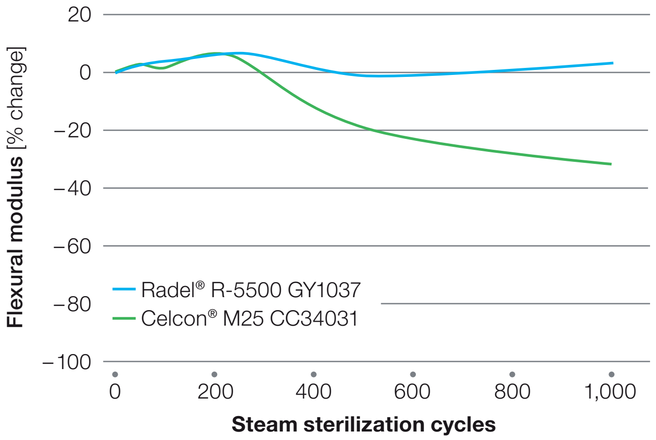


Figure 6: Flexural modulus



Test conditions for Figures 1 through 8 are 15 min at 135 °C (275 °F), 30 min dry time pre-vac cycle

Figure 7: Instrumented drop impact – maximum load

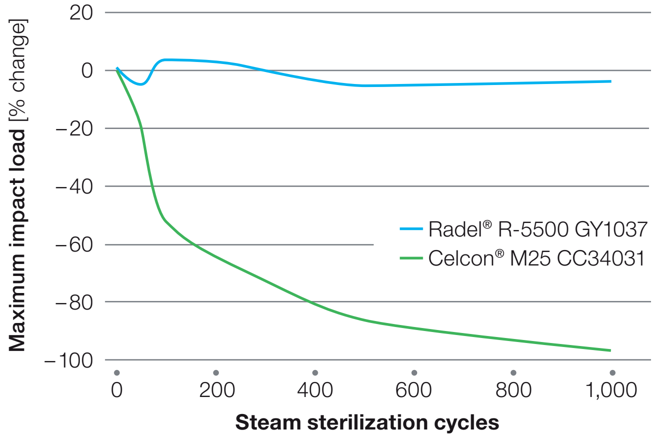


Figure 8: Color change

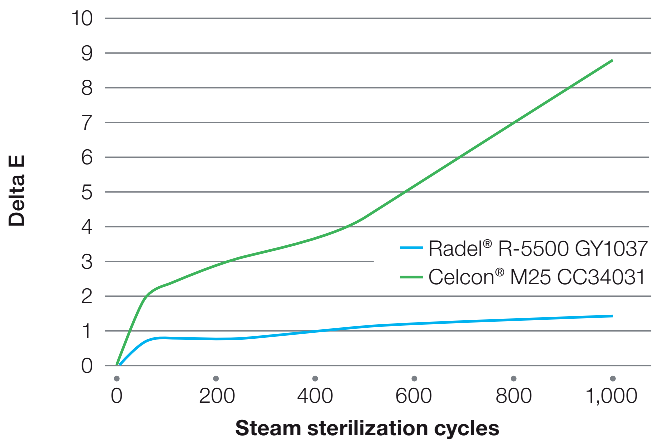
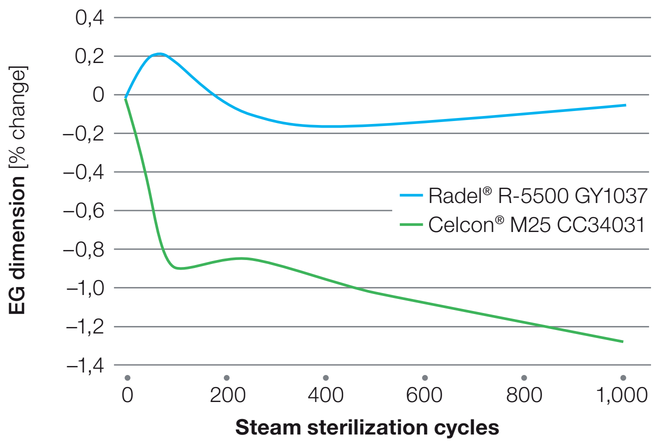


Figure 9: Dimensional change across part



Test conditions for Figures 1 through 8 are 15 min at 135 °C (275 °F), 30 min dry time pre-vac cycle

Figure 10: Dimensional cup sample used in study

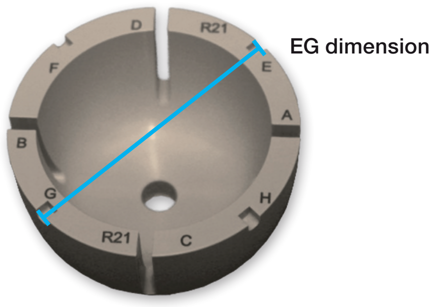
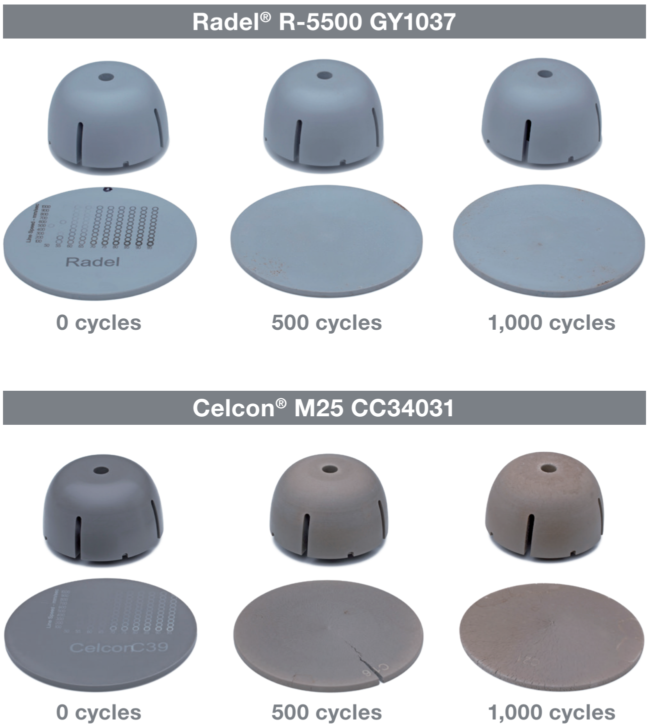


Figure 11: Appearance of steam sterilized test samples



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