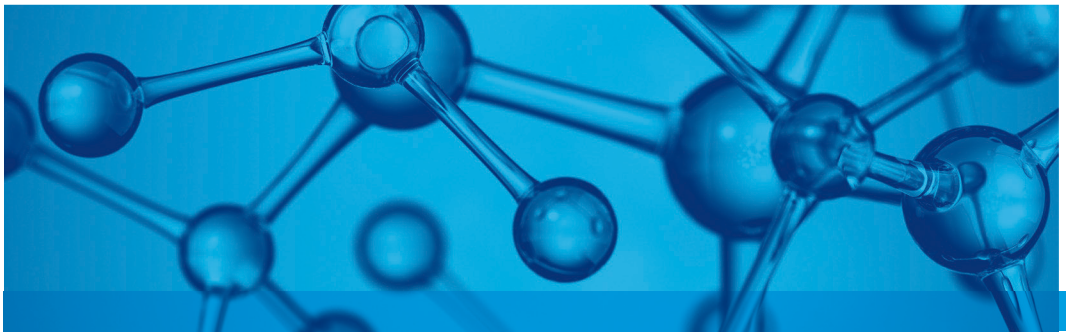


SOLVAY
asking more from chemistry®

Sterilization Compatibility Overview

High-Performance Medical-Grade Plastics

Plastics continue to find more uses in medical and dental applications by replacing metal, glass and other traditional materials in single-use and reusable medical devices. They offer strong, lightweight performance along with design flexibility, ease of fabrication, and the ability to differentiate products and brands using color.

Sterilization is a standard procedure used to prevent the spread of pathogens by destroying or removing living organisms. These living organisms are typically in the form of bacterial or fungal spores. The sterilization technique used depends on the device, its intended use and the type of healthcare facility. The most commonly used methods include steam autoclave, ethylene oxide, vaporized hydrogen peroxide and radiation.

Solvay has conducted extensive testing to study the compatibility of its healthcare plastics with these methods. The results are reported in this bulletin.

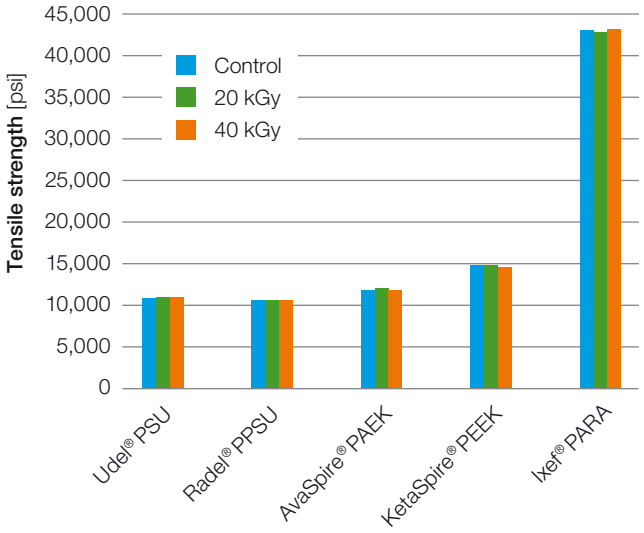
High-Performance Polyamides		Single-Use Applications	Reusable Applications
Ixef® PARA Polyarylamide	Combines outstanding strength and stiffness with exceptional surface appearance and high flow for enhanced design flexibility; excellent for metal replacement applications. Gamma-stabilized colors are available.	●	
Sulfone Polymers			
Radel® PPSU Polyphenylsulfone	Incredibly tough, transparent plastic with a heat deflection temperature (HDT) of 207 °C (405 °F) and excellent chemical resistance. Withstands more than 1,000 cycles of steam sterilization without any significant loss of properties. Glass fiber reinforced grades as well as opaque and transparent colors are available.	●	●
Udel® PSU Polysulfone	A high-strength transparent plastic with an HDT of 174 °C (345 °F) and good chemical resistance; excellent dimensional stability when exposed to steam and oxidizing agents. Glass fiber reinforced grades as well as opaque and transparent colors are available.	●	●
Spire® Ultra Polymers			
KetaSpire® PEEK Polyetheretherketone	One of the most chemically resistant plastics available with excellent strength, stiffness, fatigue resistance, and HDT up to 315 °C (599 °F) for filled grades. Glass fiber and carbon fiber reinforced grades are available.	●	●
AvaSpire® PAEK Polyaryletherketone	Tailored to provide new and unique combinations of performance and value. AV-600 Series products deliver a range of distinctive performance attributes with some grades offering more attractive economics when compared to PEEK.	●	●

Radiation

Radiation generated by either electron beam (E-beam) or gamma rays is used to sterilize bulk quantities of disposable healthcare devices. Dosage amounts typically range between 2 to 4 Megarads (Mrad) or 20 to 40 kiloGrays (kGy). Because the dosage can vary depending on packaging density within the sterilization chamber, some items may be exposed to higher levels.

Color and mechanical properties can be affected by radiation. Color change is a very common issue and most plastics can be stabilized to address this.

Figure 1: Tensile strength after gamma sterilization



Loss of mechanical properties is a more serious concern and must be taken into account during the assessment of any polymer.

During the study, several Solvay healthcare plastics were exposed to 20 and 40 kGy of gamma radiation. Tensile properties and color were measured before and after exposure. As shown in the tables below, all of the polymers tested retained their mechanical properties. The most noticeable color change occurred in the natural grade of Ixef® PARA, which showed significant yellowing. Ixef® PARA gamma-stabilized grades appreciably minimize this effect.

Figure 2: Tensile modulus after gamma sterilization

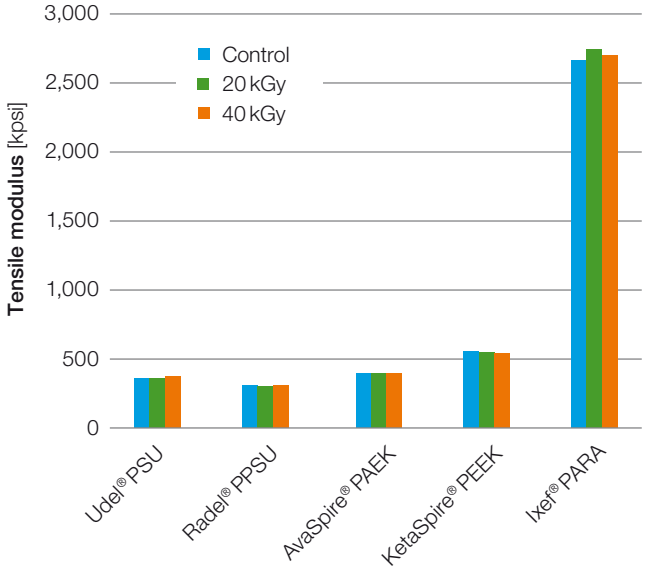
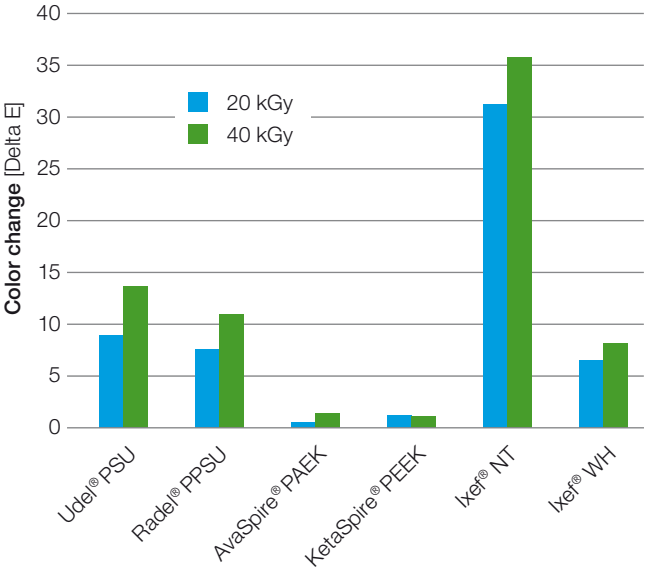


Figure 3: Color change after gamma sterilization



Ethylene Oxide

Devices that are sensitive to heat or moisture are often sterilized using ethylene oxide (ETO), a toxic gas that acts as a strong alkylating agent. Items must be completely dry before sterilizing as water can inhibit the effectiveness of the gas. Gas concentration, temperature, humidity and exposure time must be precisely controlled to ensure proper sterilization.

Plastics sterilized by this method must withstand exposure to ETO gas as well as the moisture generated during the process. ETO sterilization can require up to 12 hours of aeration to remove residual gas from the sterilized devices. Test results reported below show that Solvay healthcare plastics are compatible with ETO sterilization.

Test Conditions

- Concentration: 883 mg/L of 100 % EtO
- Temperature: 55 °C (131 °F)
- Exposure time: 60 minutes
- Relative humidity: 70 %
- Aeration time: 60 minutes

Figure 4: Tensile strength after ETO sterilization

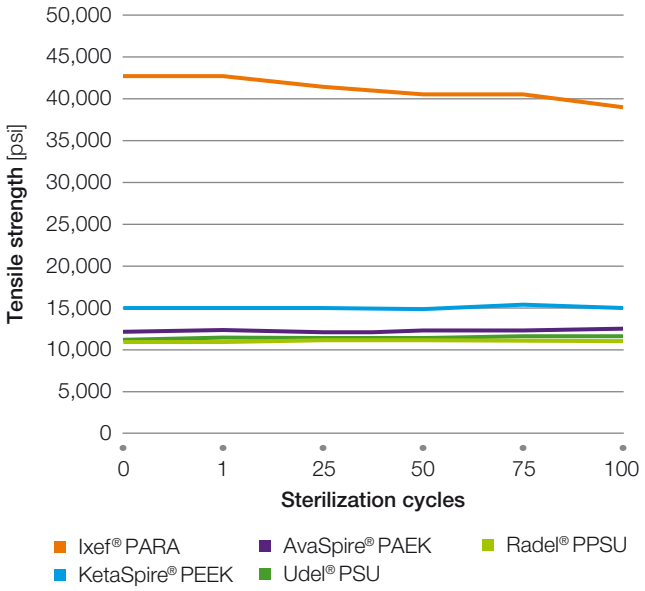


Figure 5: Tensile modulus after ETO sterilization

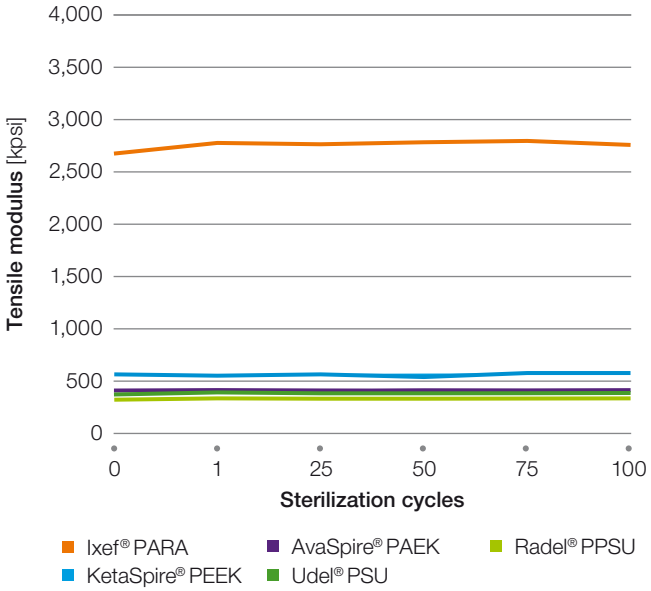
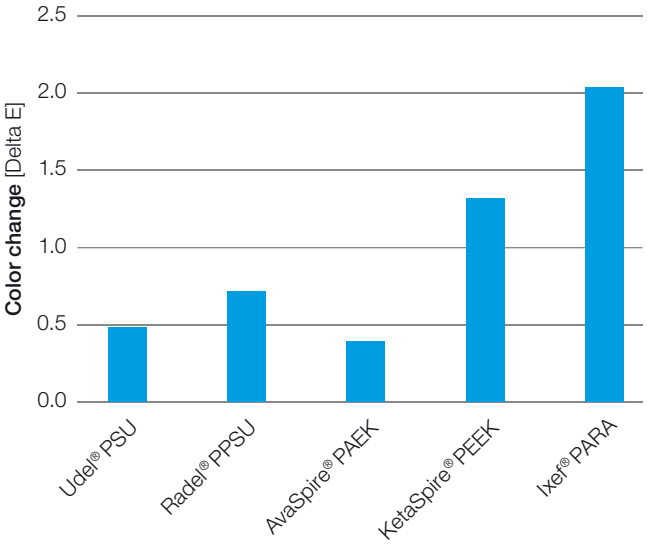


Figure 6: Color change after 100 cycles ETO Sterilization



Vaporized Hydrogen Peroxide

Another alternative for low-temperature sterilization is Vaporized Hydrogen Peroxide (VHP) gas plasma. Today's VHP gas plasma systems use a concentrated solution of hydrogen peroxide (H_2O_2) that is injected into a vacuum chamber. The VHP gas is allowed to diffuse through the chamber, and then an electromagnetic field is initiated to create a gas plasma.

The gas plasma breaks down hydrogen peroxide, creating UV energy and free radicals. As the plasma loses energy, oxygen and water are formed as by-products. These steps are repeated for added efficacy. After the final venting step, the devices are ready to use as no aeration is needed. This system is limited by the use of certain metals, smaller diameter lumens and the need for items to be completely dry. Materials that absorb moisture, such as paper and cotton, cannot be sterilized using this technique.

The test results summarized below show that Solvay healthcare plastics had no significant loss in properties over the course of 25 cycles.

Test Conditions

- Equipment: Sterrad® 100S
- Concentration: 58 % of H_2O_2
- Temperature: 45 °C (113 °F)
- Pre-plasma time: 10 minutes
- Exposure time: 12 minutes
- Diffusion time: 4 minutes

Figure 7: Tensile strength after VHP sterilization

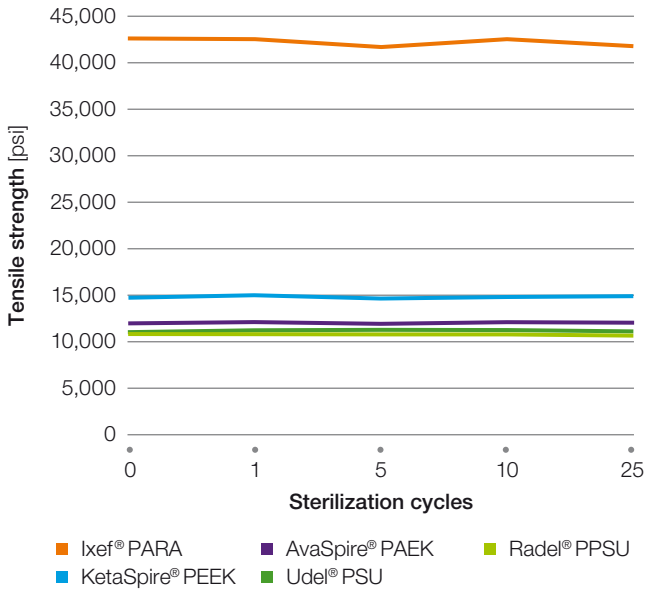


Figure 8: Tensile modulus after VHP sterilization

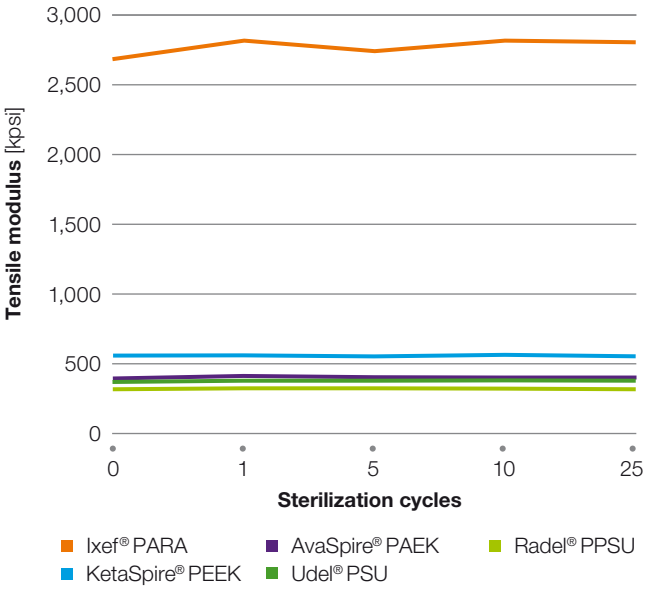
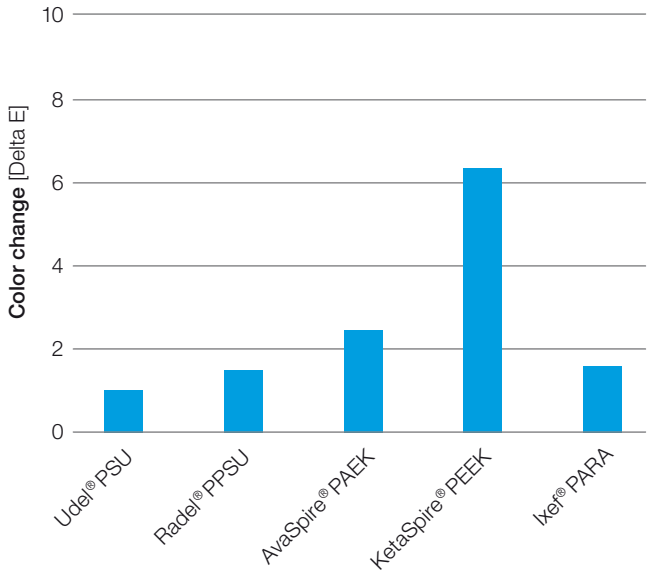


Figure 9: Color change after 25 cycles VHP sterilization



Steam Autoclaving

All healthcare agencies recommend using steam autoclaving whenever possible. It is a fast, reliable and inexpensive technique used to sterilize reusable instruments and devices. This technique uses a combination of heat and moisture to kill microorganisms. Actual cycle times and temperatures depend on the items being sterilized. Typical cycles are 15 to 30 minutes with temperatures ranging from 121 °C to 134 °C (250 °F to 273 °F).

Plastics used for reusable medical devices must be chosen carefully as many of them cannot withstand prolonged, repeated exposure to high temperature and steam. For example, polypropylene (PP), polyamide (PA) and polycarbonate (PC) are suitable for only a limited number of cycles (<100 cycles). Higher performing plastics like Radel® PPSU, KetaSpire® PEEK and AvaSpire® PAEK can withstand over 1,000 steam sterilization cycles without significant loss of mechanical properties and are well-suited for more demanding applications.

Udel® PSU offers an intermediate level of performance and is suitable for several hundred steam sterilization cycles (<500 cycles). Ixef® PARA is not recommended for steam autoclaving for more then a few cycles as the material quickly loses tensile strength.

Test Conditions

- Equipment: Amsco® Century® Sterilizer SV-136H
- Cycle: Pre-vac
- Temperature: 135.5 °C (275.9 °F)
- Pressure: 31 to 33 psig
- Vacuum: 27 inHg
- Sterilization time: 18 minutes
- Drying time: 10 minutes
- Total time: 33 minutes

Figure 10: Tensile strength after steam sterilization

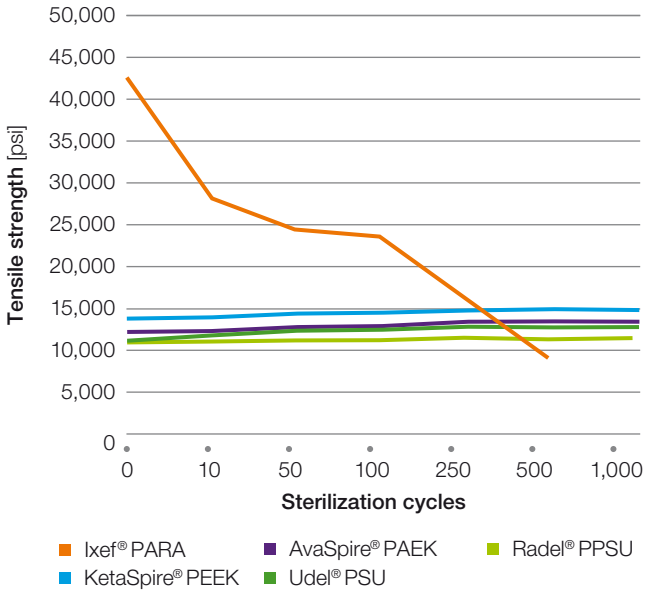


Figure 11: Tensile modulus after steam sterilization

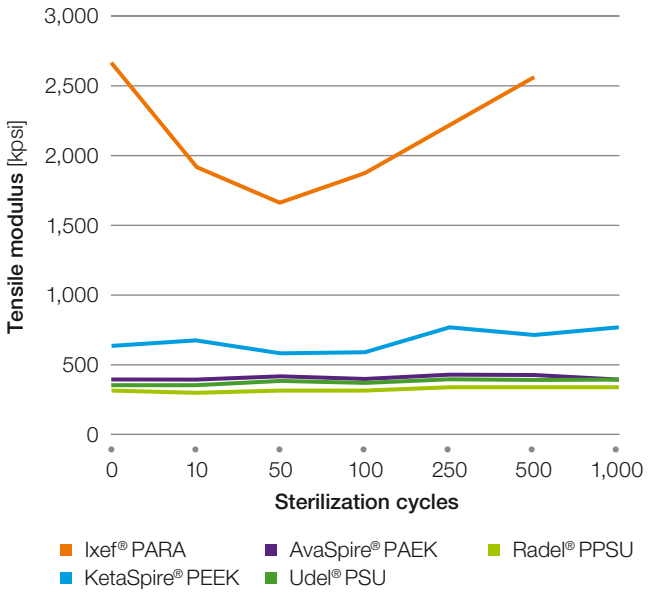
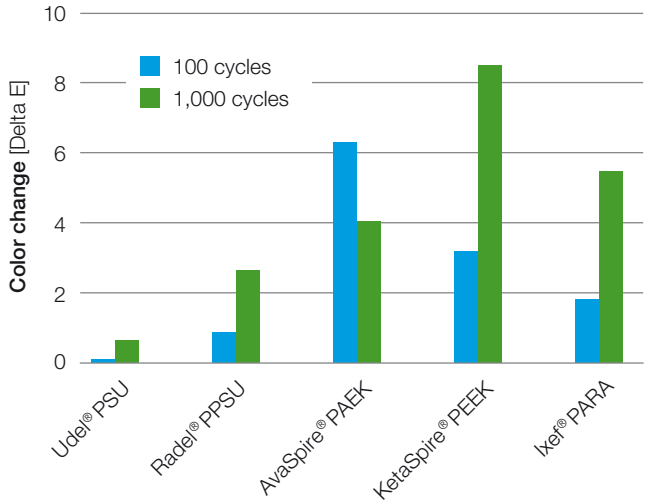


Figure 12: Color change after steam sterilization



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