SOLVAY
asking more from chemistry®

Effects of Hydrogen Peroxide Gas Plasma Sterilization

High-Performance Medical-Grade Plastics

Solvay's high-performance plastics continue to find a wide variety of opportunities in the healthcare market. The demand for alternatives to metal continues to grow for instruments and devices, in addition to the tray systems that support them. Solvay offers the largest selection of high-performance polymers for the healthcare industry, which includes five unique chemistries. These medical-grade plastics give design engineers the ability to create medical instruments devices that provide metal-like performance in a lightweight design, with the ease and flexibility of plastics manufacturing.

Healthcare products often require some form of sterilization prior to use. For single-use devices, the common methods are radiation and ethylene oxide. Historically, the standard for reusable devices has been steam autoclave sterilization. Yet, with the growing use of electronics and endoscopes, which are not compatible with the high-temperature environment of the steam autoclave, the need for low-temperature sterilization such as hydrogen peroxide gas plasma has become prevalent in the industry. In order to support medical customers and their design engineers, Solvay continues to evaluate its medical-grade polymers in many current and new sterilization environments.

Hydrogen peroxide gas plasma sterilization units operate at a lower temperature and can safely sterilize a much broader range of polymers than can be sterilized with steam. Compatibility of any material, metal or plastic, should be thoroughly tested in the proposed sterilization environment. Solvay has conducted an extensive study to support the growing use of our polymers in sterilization environments using hydrogen peroxide gas plasma.

The following information and data is intended to present the designer with confidence in a material's long-term properties or potential limitations in repeated exposure to the indicated environment. Solvay is not making any judgments as to the suitability of a specific instrument's design compatibility with the sterilization environment or any conclusions on suitability of using any specific manufacturer's sterilization equipment with any materials. This information is only presenting the effects of the sterilization environment on the properties and characteristics of typical production lots of various Solvay medical-grade plastics.

Study Program Overview

The study consisted of three major phases: sample preparation, sample sterilization and conditioning, and sample testing.

Sample Preparation

All materials used in this study were standard commercial products currently offered by Solvay Specialty Polymers. A list of products tested are presented in Table 1. All samples were prepared by standard injection molding techniques using Solvay's published recommendations for processing conditions of each of the polymer families. Test specimens consisted of standard ASTM Type I tensile bars, ASTM flexural bars measuring 12.7 cm x 1.27 cm x 0.32 cm (5 in. x 0.5 in. x 0.125 in.) and plaques measuring 10.2 cm x 10.2 cm (4 in. x 4 in.).

Specimens were then packaged for shipment. No post-molding conditioning or annealing steps were conducted on test samples.

Table 1: Solvay medical-grade plastics tested

Product Grade
Ixef® GS-1022 GY02
Ixef® 1022/0006
Udel® P-1700 NT11
Udel® GF-120 NT
Radel® R-5000 NT
Radel® RG-5010 BU323
AvaSpire® AV-651 BG15
AvaSpire® AV-651 GF30 BG20
KetaSpire® KT-880 NT
KetaSpire® KT-880 GF30 BG20
KetaSpire® KT-880 CF30

Sample Sterilization and Conditioning

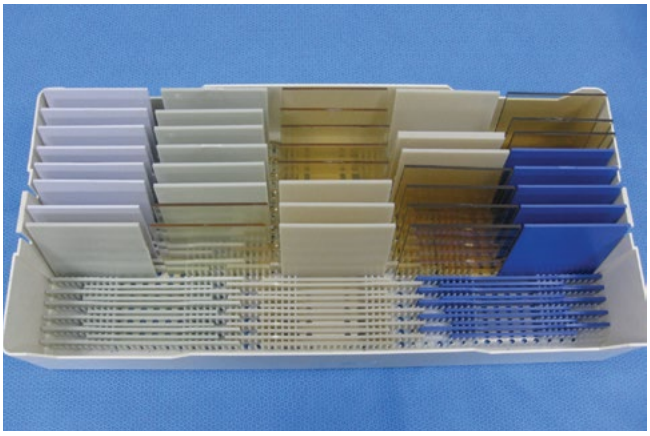
Three identical sets of the materials listed in Table 1 were prepared by Solvay and each set was separately processed to 25, 100, or 200 cycles. Seven tensile bars, seven flex bars, and seven 10.2 cm x 10.2 cm (4 in. x 4 in.) plaques of each material were sent to the ASP® facility in Irvine, CA. ASP® handled staging and conducted the cycling as outlined below. All samples were then packaged and sealed and returned to Solvay for testing.

Test Procedure

Sterilization unit and cycle: Sterrad® 100NX® using the standard cycle.

Testing was performed in accordance with ASP® standard test procedures for the Sterrad® 100NX® sterilization systems in healthcare facilities.

Figure 1: Sample arrangement



The load consisted of the Solvay test samples divided into two Sterrad® Aptimax® tray systems with mats. The samples were placed on edge and separated to maximize sterilant exposure around each sample (see Figure 1). The prepared trays were then double wrapped with polypropylene CSR wrap. The trays were placed on both shelves of the Sterrad® 100NX® sterilization chamber and processed using the standard cycle. Hydrogen peroxide (sterilant) was supplied to the sterilizer by a Sterrad® 100NX® cassette. The test samples were processed for 25, 100 and 200 cycles with approximately 30 minutes or longer rest between cycles. Every 10 cycles the samples were wiped down with a lint free wipe moistened with DI water and allowed to dry before continuing. These minimal washing conditions created a “worst case” scenario for material and functional compatibility testing.

Sample Testing

Returned samples were tested in Solvay labs in Alpharetta, GA, which have ISO 9001 and A2LA certification.

Tensile and flexural testing was conducted using Instron® 5569 Load Frames using Bluehill® v2.2 software. Tensile tests were conducted per ASTM D638 and D790 standards for tensile and flex. Tensile testing was conducted at 5.1 mm/minute (0.2 in./minute) for filled materials and 51 mm/minute (2.0 in./minute) for unfilled grades.

Impact testing was conducted on a Dynatup® 8000 System using Impulse® v2.2.1 software.

Impact drop weight was 70 kg (155 pounds) with an impact velocity of ~ 2.4 m/sec (~8 ft/sec) using a 12.7 mm (0.5 in.) diameter impactor tip.

Molecular weight was determined by Size Exclusion Chromatography using a Waters Alliance 2695 Separation Module and 2487 Detector.

Color change was measured on both sides of the 10.2 cm x 10.2 cm (4 in. x 4 in.) plaques using a BYK Gardner® Colorsphere Instrument set on Reflectance mode, using CIE L*a*b* scale with a D65 – 10° illuminant and observer. Gloss was measured using a BYK Gardner® Micro-TRI-gloss Model 4525.

Test Results

A graphical summary of the test results are presented in Figures 2 through 13.

Tensile results show no significant change in any of the materials, except for the Ixef® 1022/0006; however, the gamma-stabilized Ixef® GS-1022 GY02 grade showed improved resistance to mechanical property changes. This drop in properties was not unexpected for Ixef® PARA as polyamide-based polymers can be affected by oxidation-based sterilization. Tensile elongation to break results for the unfilled grades show high variability, but this is not unexpected as the samples were well beyond their yield elongation and therefore subject to rupture due to minor imperfections in the test samples at the high strain levels.

Flexural results showed no significant changes except in the Ixef® PARA which was expected, as mentioned above.

Instrumented impact results show no changes in load to failure or total energy absorbed. This is most significant in the unfilled grades as the materials showed all ductile impacts even after 200 cycles.

Appearance properties showed the most change in all the materials, with Delta E color shifts from one to six units, excluding Ixef® PARA. The glass-filled products showed more of a shift on average, which likely is due to the effects of the glass on the surface appearance.

Color shifts in an oxidizing environment will typically tend to shift most polymers to a more "yellow" tint, although there was not a significant change in the yellowness index in most samples.

The change in gloss was most apparent in the Ixef® PARA test samples due to the affects of the sterilization on the polymer and especially the surface of the parts.

Finally, minor changes were seen in the molecular weight of these polymers, excluding the Ixef® PARA. The differences were likely more related to the fact the analysis was conducted over several weeks and results will shift over time due to testing variably in the columns. There was no indication of significant change in the polymer structure, which is also supported by the lack of change in mechanical properties.

Conclusions

Test results from in-depth study of Solvay's medical-grade plastics indicate that all but Ixef® PARA retain their excellent mechanical properties and good appearance after 200 cycles of the Sterrad® 100NX® Standard Cycle.

Figure 2: Tensile strength after Sterrad® 100NX® sterilization

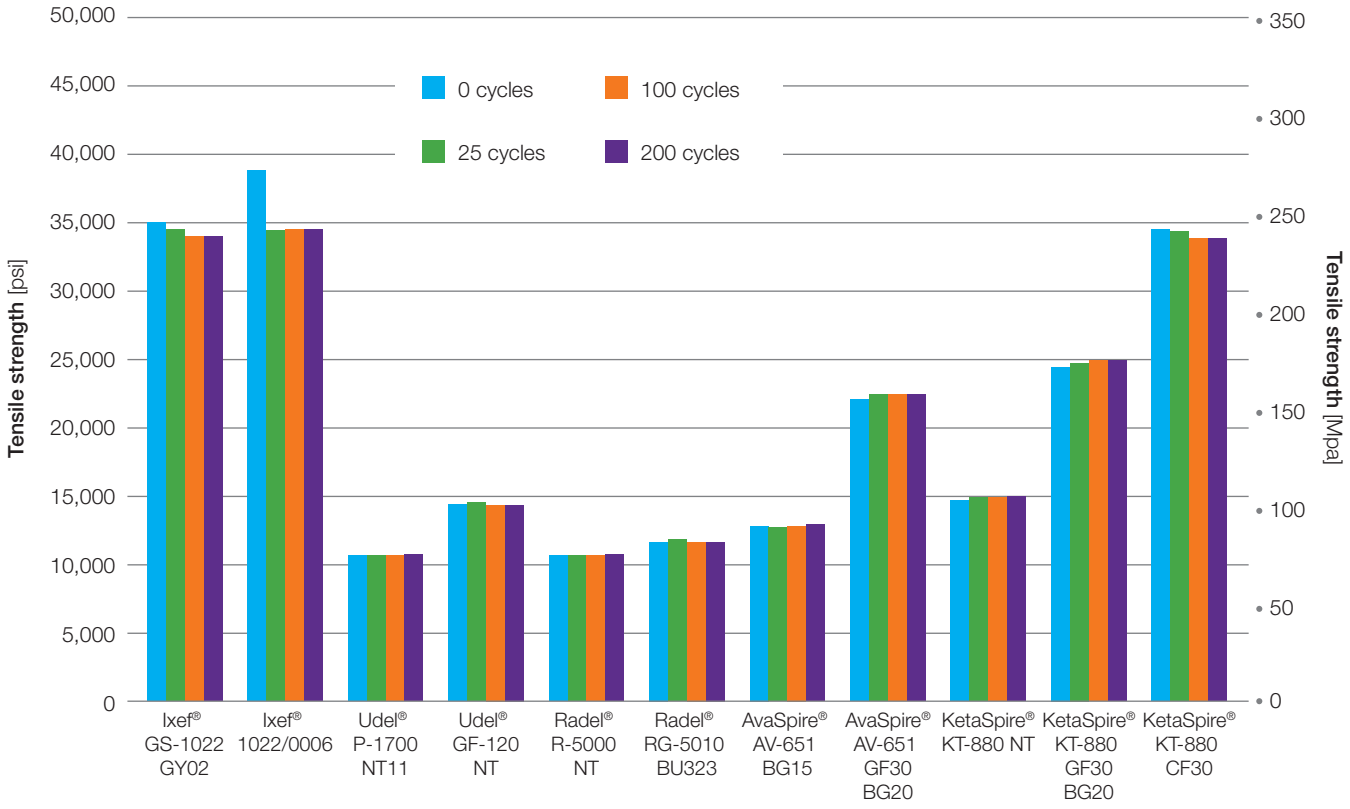


Figure 3: Tensile modulus after Sterrad® 100NX® sterilization

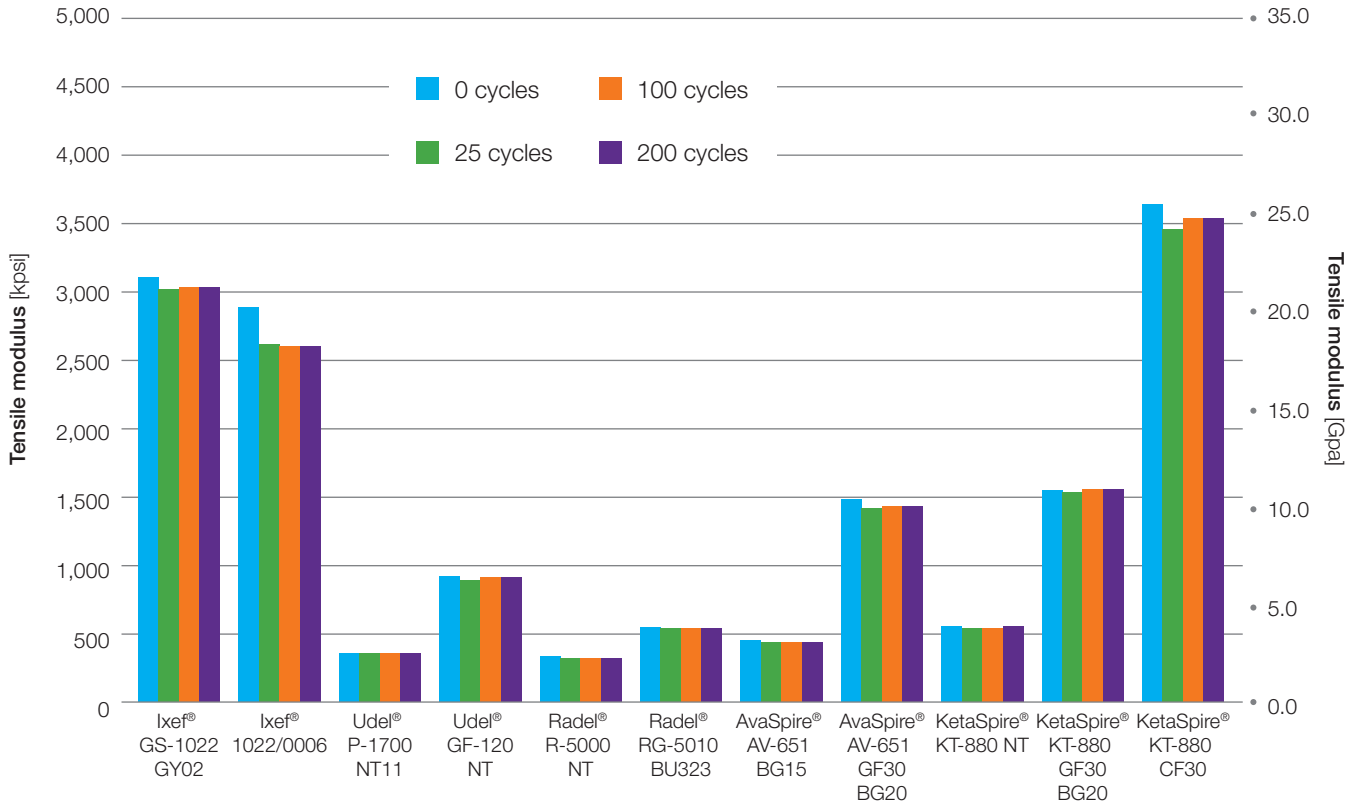


Figure 4: Tensile elongation to break after Sterrad® 100NX® sterilization

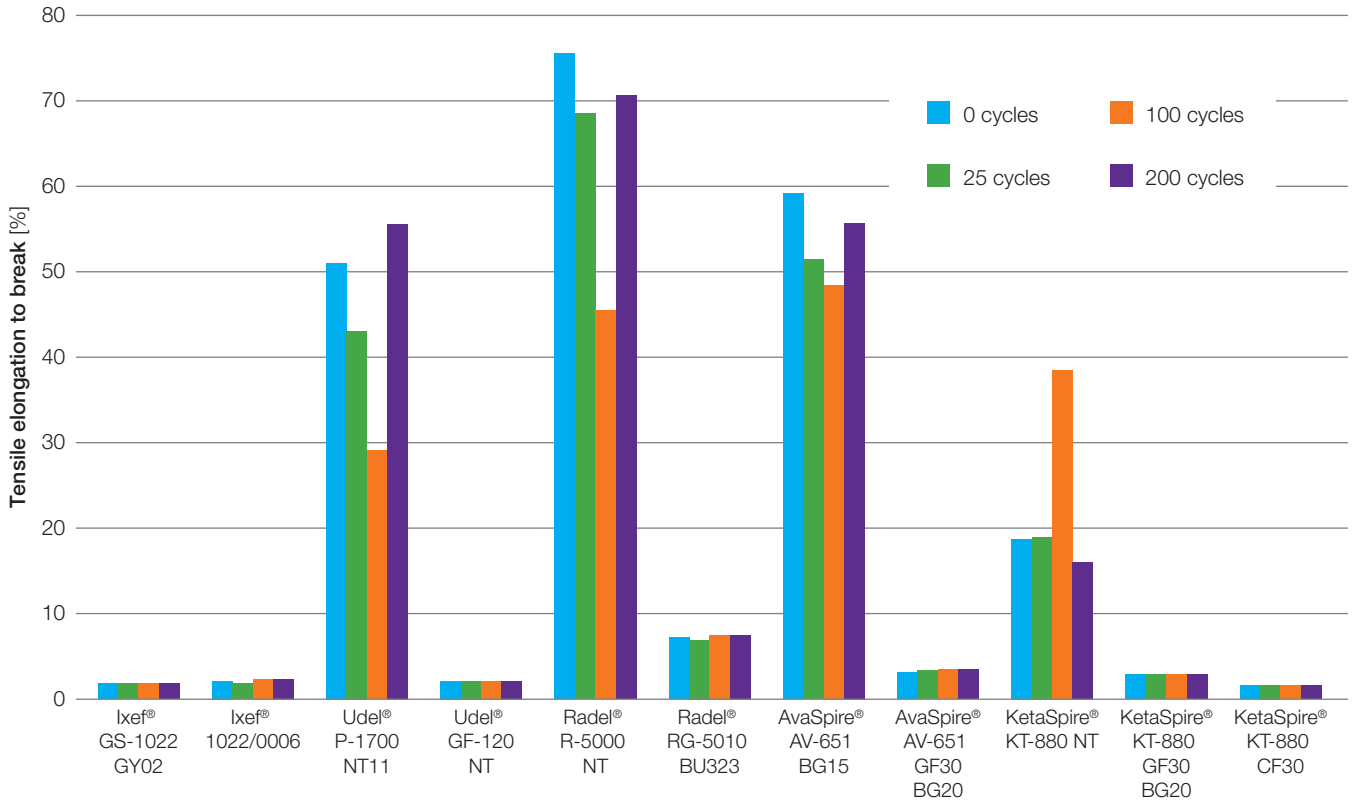


Figure 5: Flexural strength after Sterrad® 100NX® sterilization

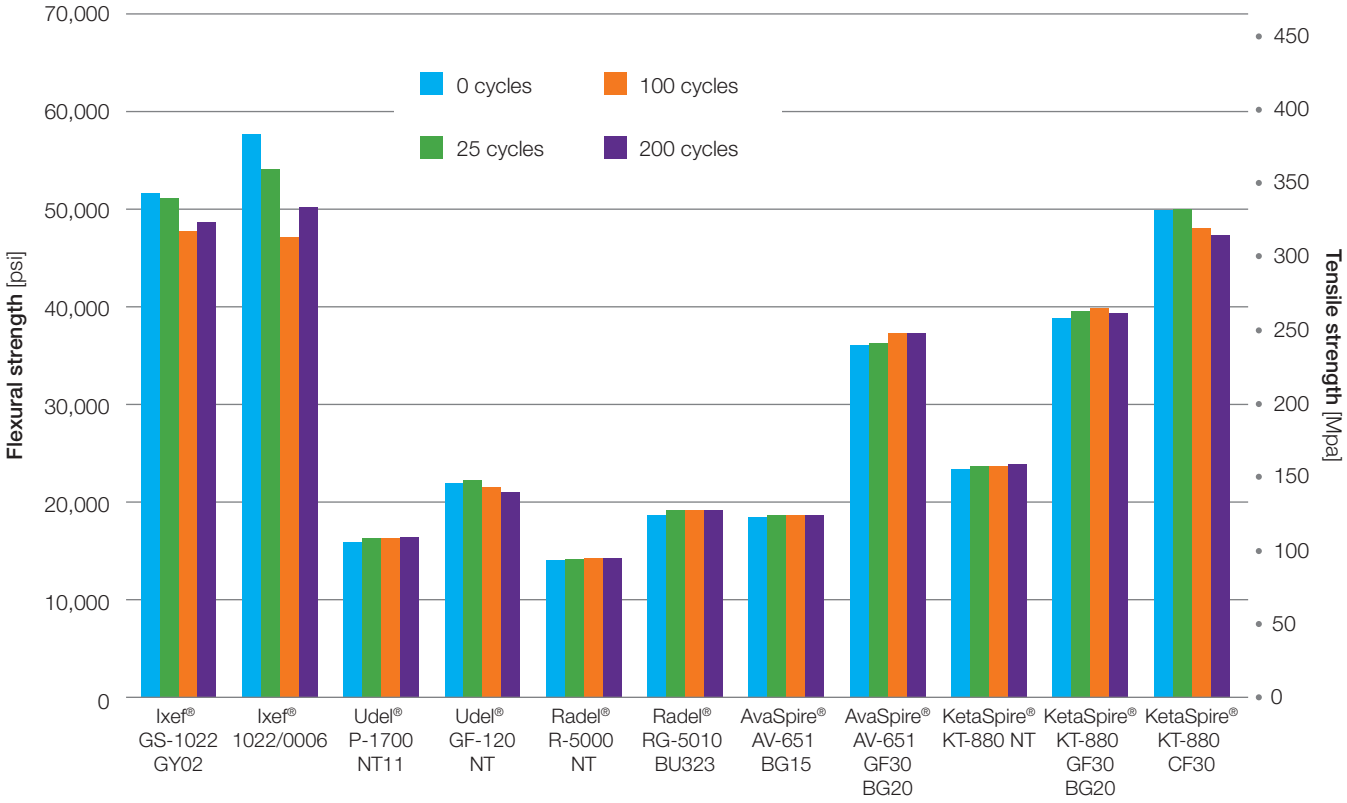


Figure 6: Flexural modulus after Sterrad® 100NX® sterilization

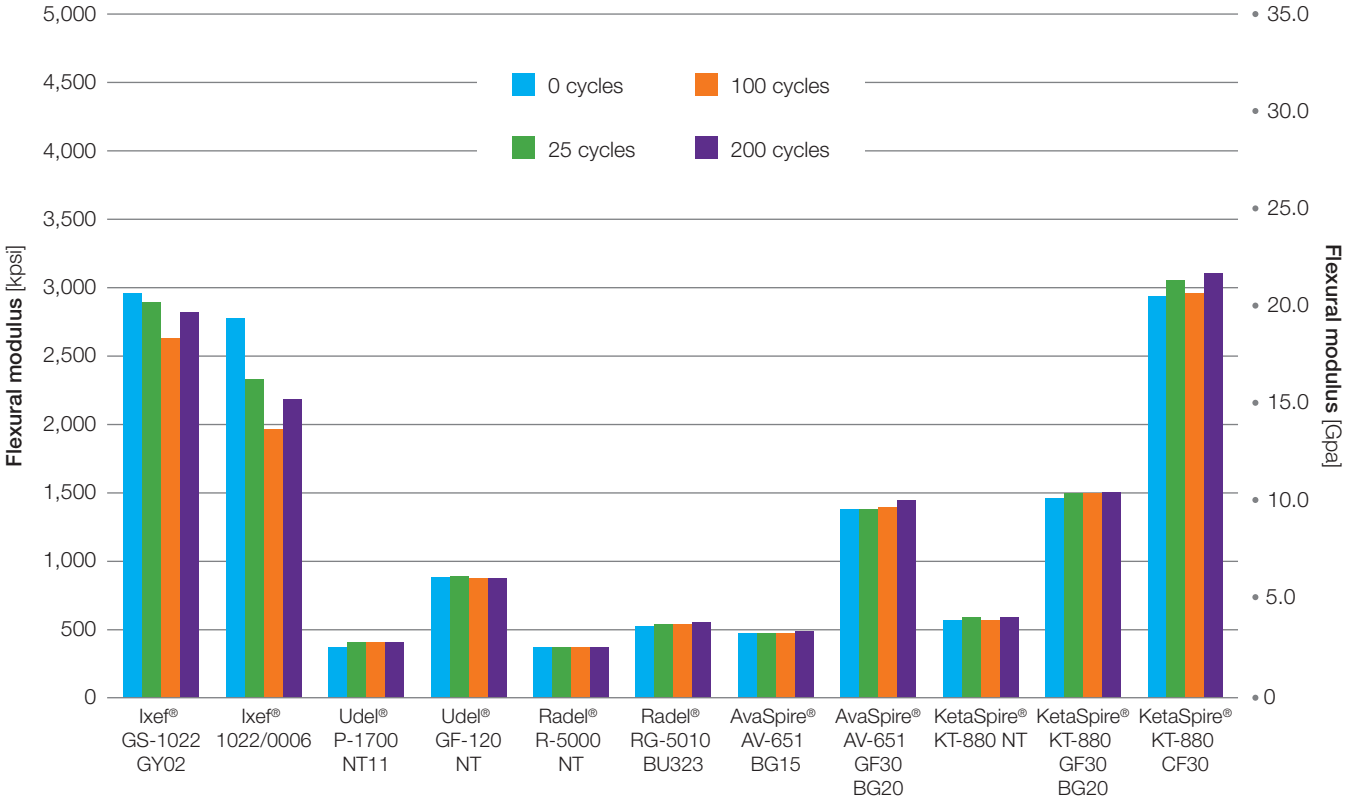


Figure 7: Instrumented impact load after Sterrad® 100NX® sterilization

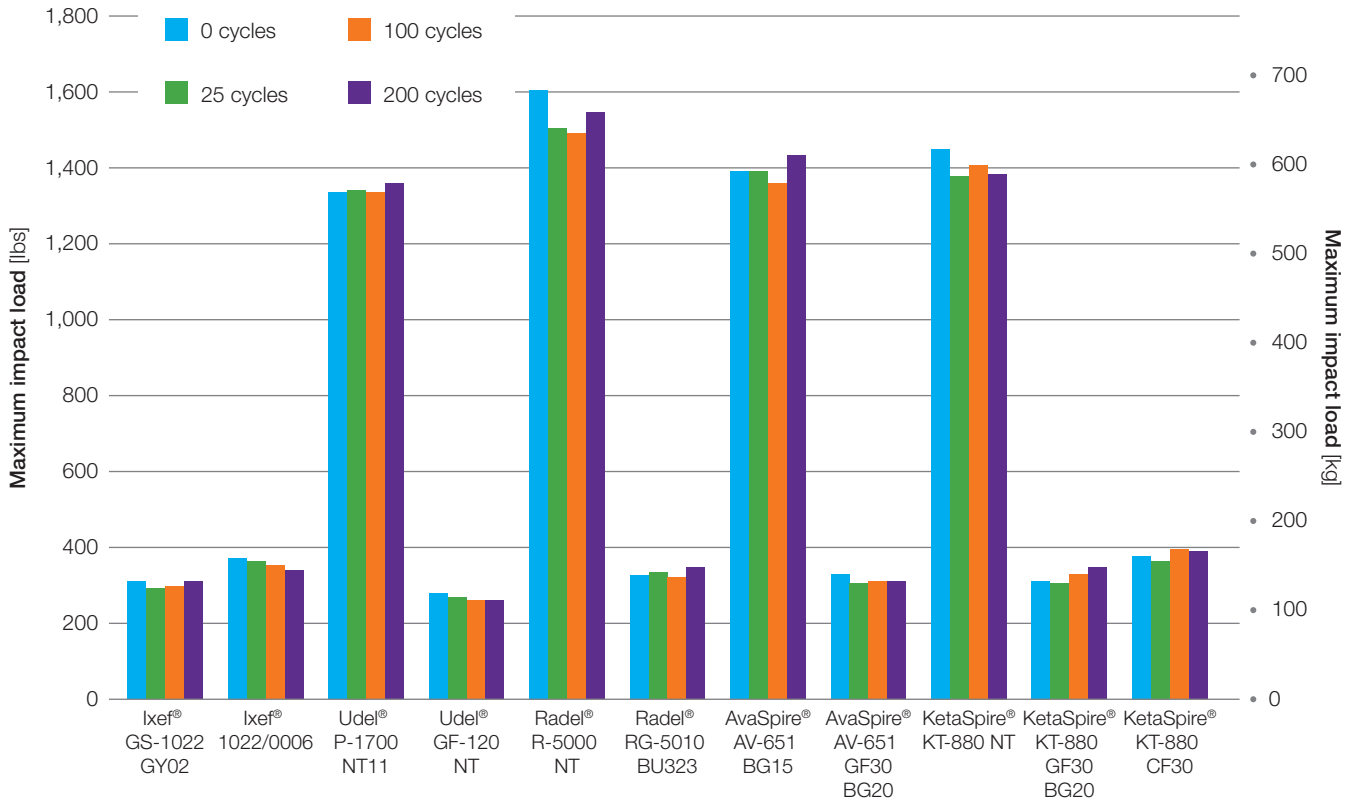


Figure 8: Instrumented impact engergy after Sterrad® 100NX® sterilization

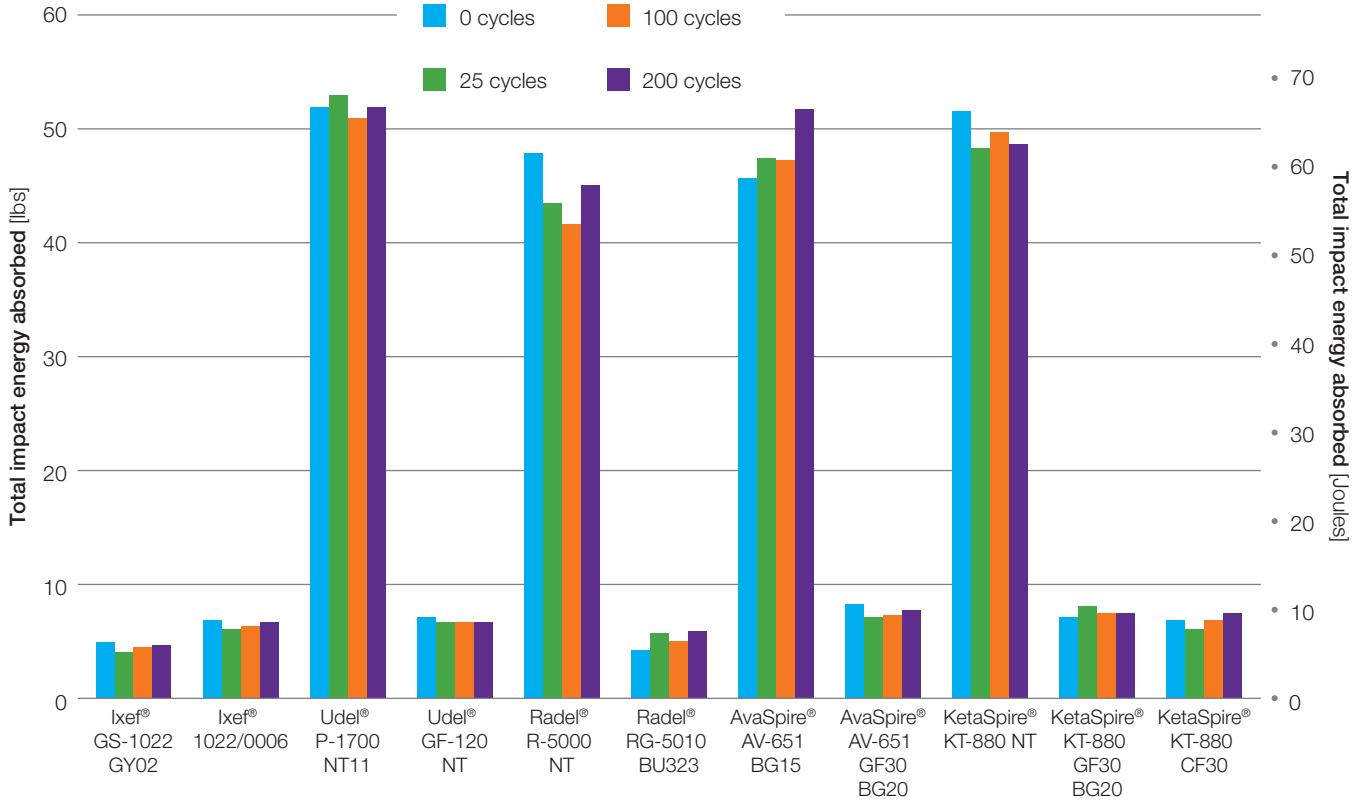


Figure 9: Color change after Sterrad® 100NX® sterilization

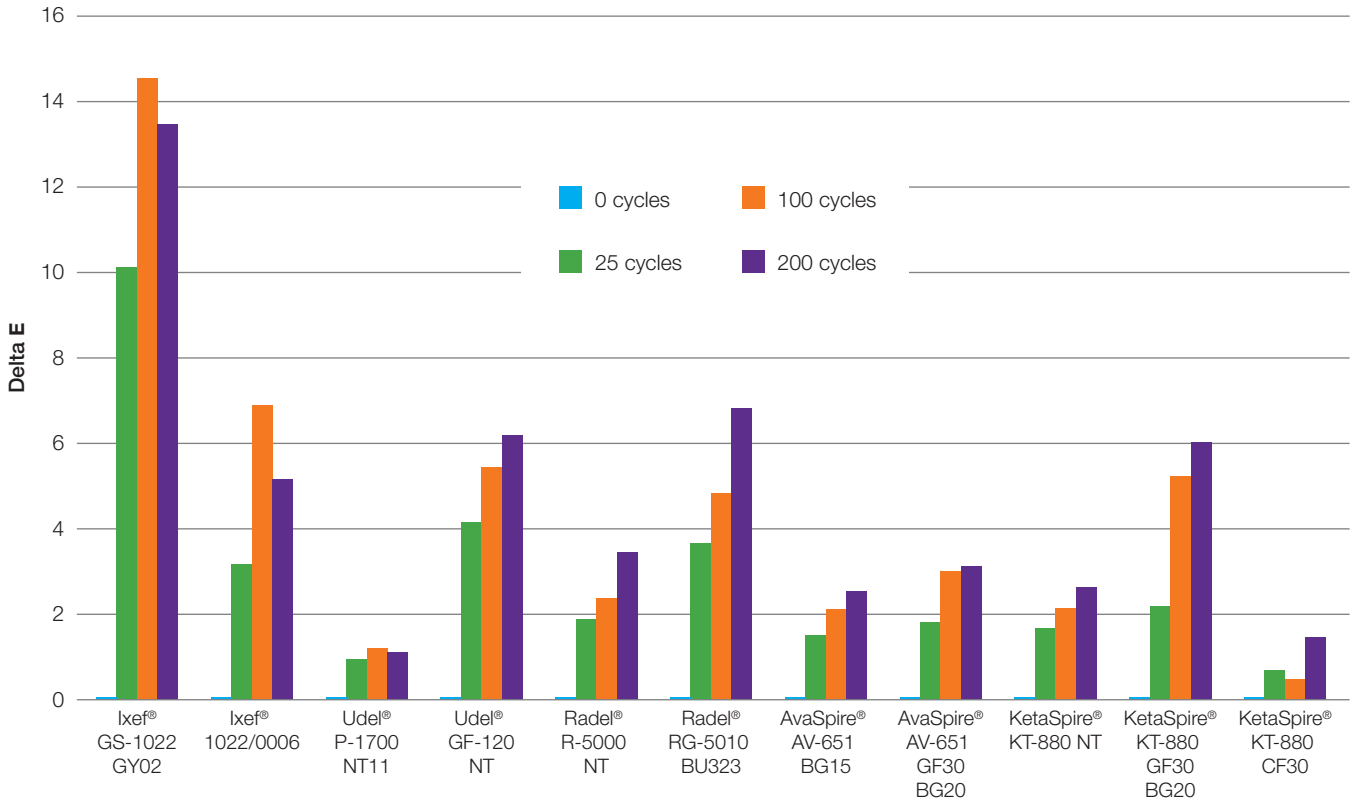


Figure 10: Yellowness index after Sterrad® 100NX® sterilization

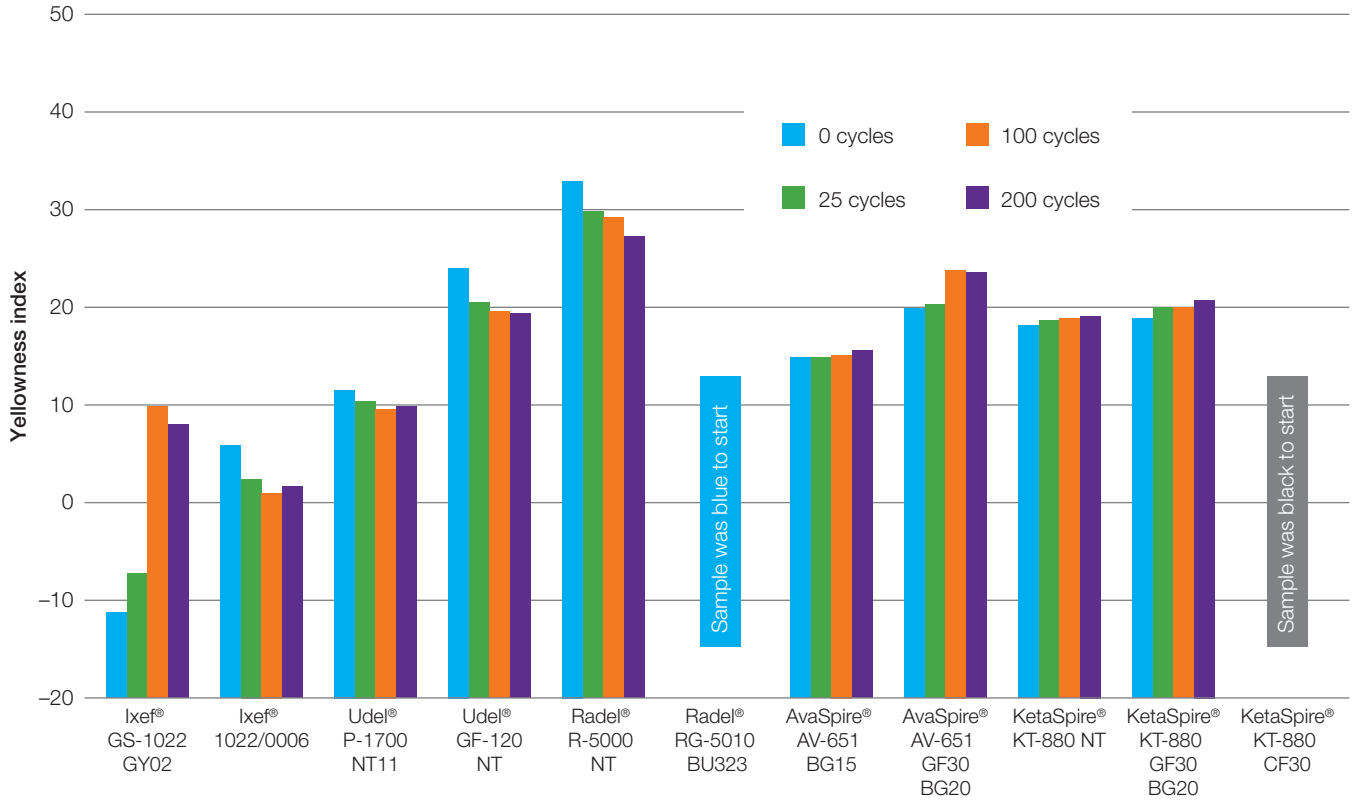


Figure 11: 60° gloss measurement after Sterrad® 100NX® sterilization

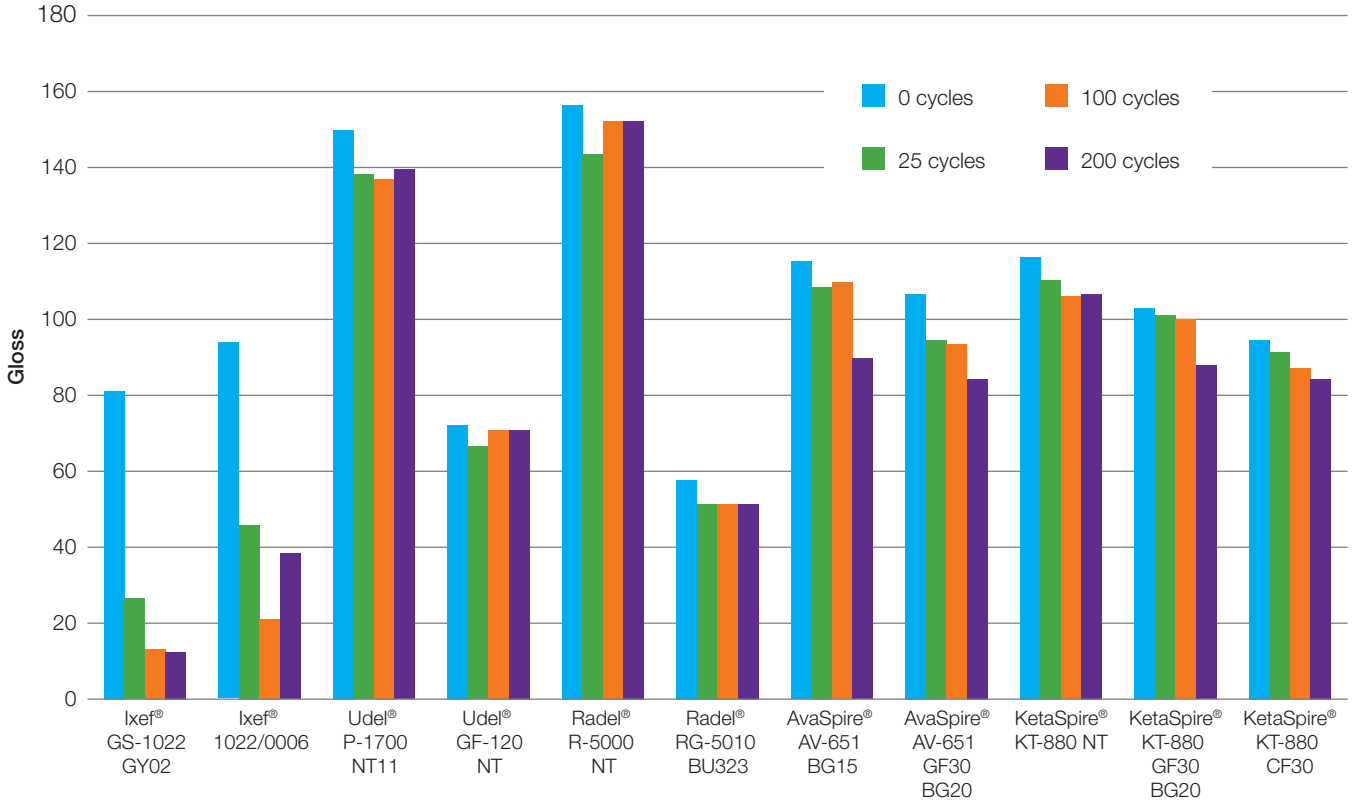


Figure 12: Number Average Molecular Weight after Sterrad® 100NX® sterilization

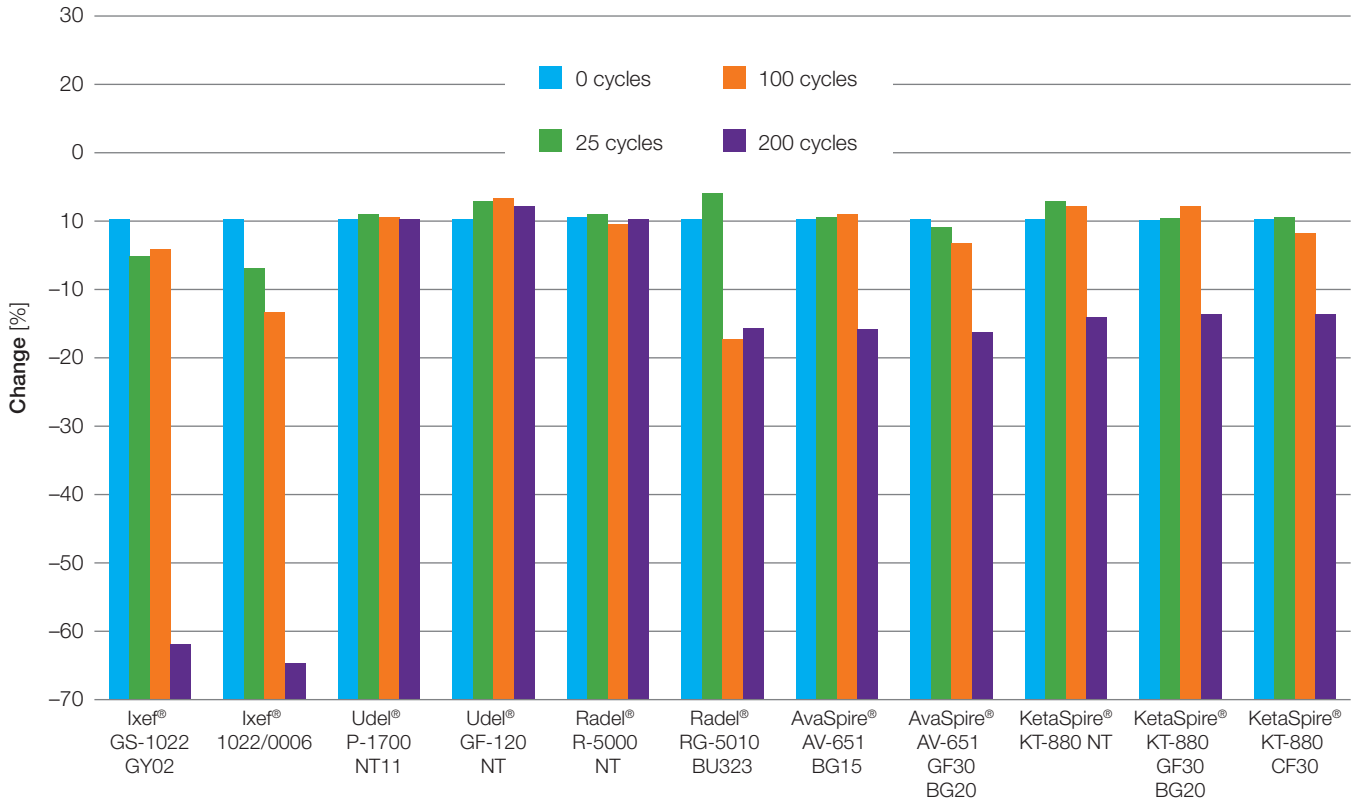
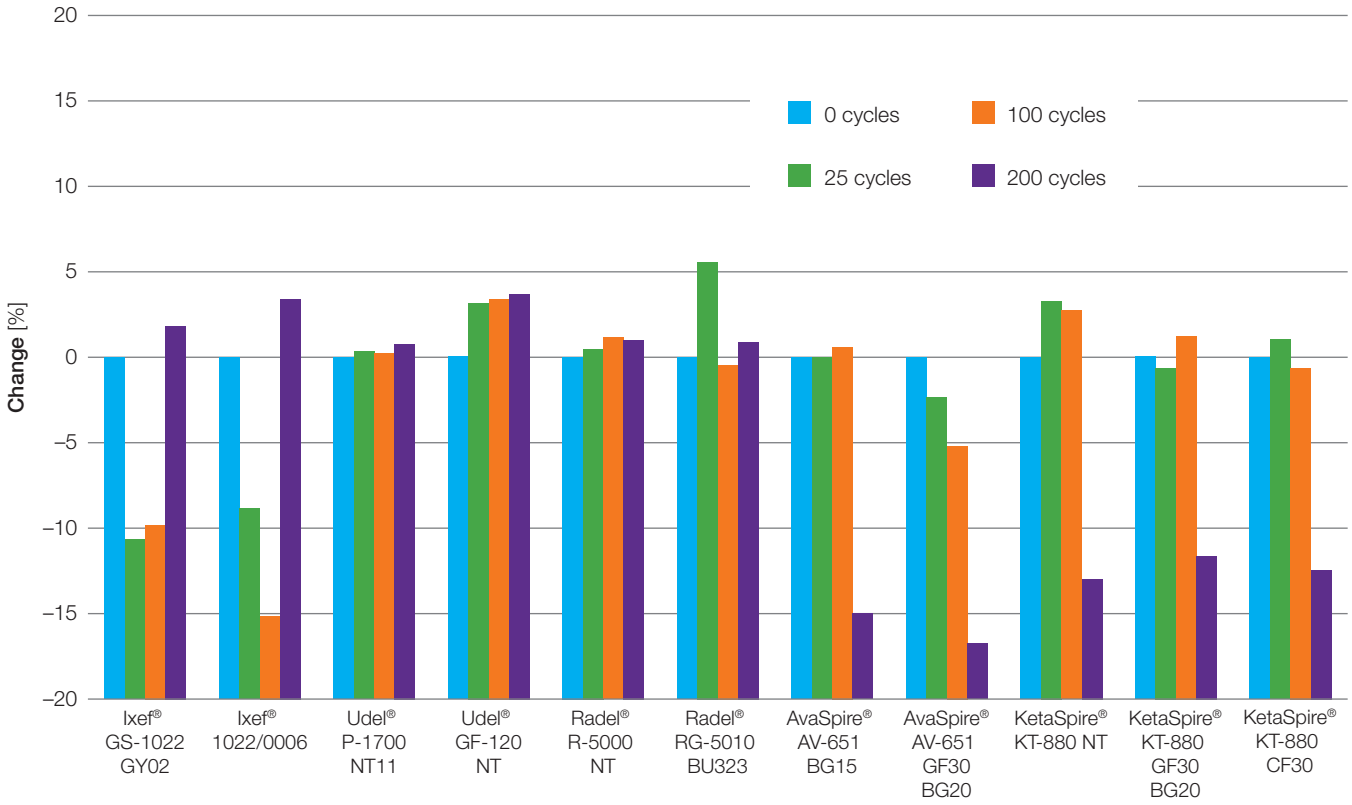


Figure 13: Weight Average Molecular Weight after Sterrad® 100NX® sterilization



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