



## **The Impact of Gamma and Autoclave Sterilization on Silicone Tubing**

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### **Abstract**

Gamma and autoclave sterilization on silicone tubing is studied using two different Saint-Gobain silicone tubing formulations that were extruded and sterilized by both methods. Physical properties are compared both pre and post sterilization. Gamma sterilization was found to increase hardness and modulus while autoclaving proved to have less impact. The sterilization impact on both burst pressure and pump life were also studied. For both of those properties, moderately increased pump life and increased burst pressure were observed post-sterilization.

## **1 Introduction**

Silicone tubing is widely used for medical or pharmaceutical applications for fluid handling due to its elasticity and inertness. For these markets and applications, these products need to be sterilized prior to end use. A few studies were reported on various sterilization method such as gamma irradiation, electron beam (E-beam), ethylene oxide (ETO) and autoclave including their impact on mechanical and dimensional properties <sup>(1,2,3)</sup>. However, few were focused specifically on silicone tubings and the sterilization impact on application performance such as burst pressure and pump life for peristaltic pumps. A Saint-Gobain white paper by Oh, et.al <sup>(1)</sup> focused on gamma irradiation, E-beam and ETO impact on platinum cured high consistency rubber (HCR), peroxide cured HCR and liquid silicone rubber. It systematically studied their impact on silicone slabs under various level of dosage/exposure. This paper studied two of Saint-Gobain's tubing grades and added autoclave sterilization. The impact on tubing performance was addressed via studying physical properties, burst pressure and pump life.

## 2 Material and Testing Method

### 2.1 Material: Silicone Tubing

Two Saint-Gobain silicone tubing grades, Sani-Tech® Ultra C and Sani-Tech® STHT-C, were selected for this study. All of the tubing was obtained with the same size 1/4" inner diameter and 3/8" outer diameter for direct comparison.

Sterilization Conditions:

**Autoclave condition:** 1-hour cycle at 121 °C, at Saint-Gobain Life Science, 50 W Watkins Mill Rd, Gaithersburg, MD 20878

**Gamma radiation condition:** 25-40kGy, at STERIGENICS, 502 Prairie Mine Road Mulberry FL 33860 United States

### 2.2 Test Method: Tensile/Elongation/Modulus Testing/Tear

Tubing samples were pulled on an Instron Model 4411, using an internal method MSTM M335. A pull rate of 20 inches per minute was used for both tensile and tear testing. Tear B method was used consisting of an un-notched sample.

### 2.3 Test Method: Burst Pressure Testing

Tubing burst pressure testing was performed at Saint-Gobain Life Sciences per ASTM 1599.

### 2.4 Test Method: Pump Life testing

Pump life testing of the silicone tubing was performed at ambient temperature, with purified water as media. The backpressure was 10PSI. For each tubing type, six different tubes were tested on 6 pumps. Their average pump life was calculated and reported. The time the tubing started leaking was recorded as its pump life. Pumps utilized were Cole-Parmer® MasterFlex® L/S Digital Drive (model 07523-80, 600 RPM Max) with a standard pump head (model 07017-20) which consists of 3 rollers.

## 3 Results & Analysis

### 3.1 Gamma Sterilization

#### 3.1.1 Tensile/Elongation/Modulus/Hardness

As shown in Figure 1, for both Sani-Tech® Ultra C and Sani-Tech® STHT-C tubing, gamma sterilization had no statistical impact to their ultimate tensile strength. However, as Figure 2 showed, for both tubes, elongation decreases, modulus increased and hardness increased (as shown in Figure 3-4). Those were attributed to further crosslinking of the silicone polymer due to the gamma irradiation. Free radicals were generated from the high energy radiation which in turn would crosslink <sup>(1,2)</sup>.

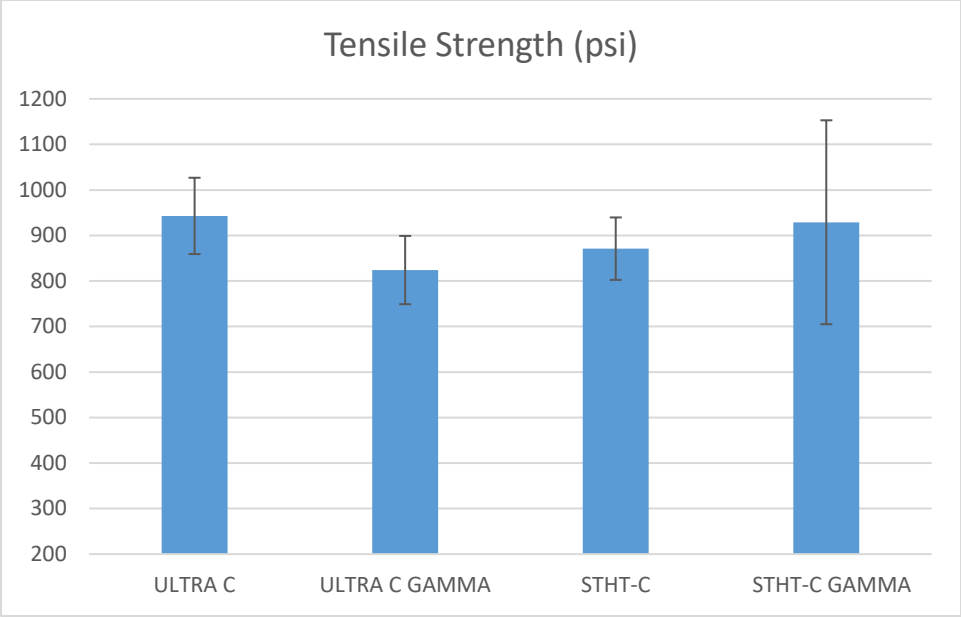


Figure 1: Tensile strength of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post gamma sterilization

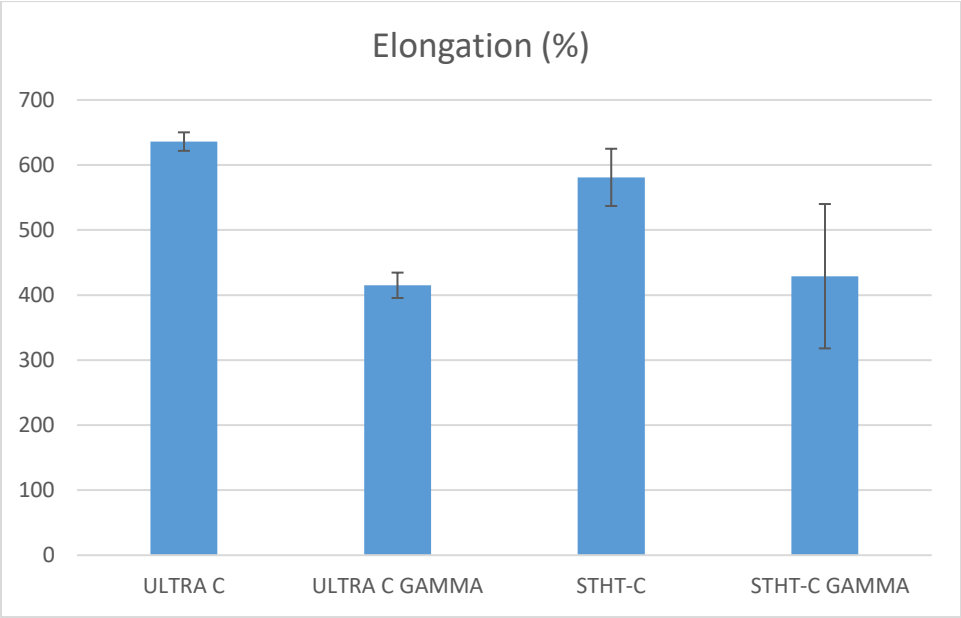


Figure 2: Elongation of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post gamma sterilization

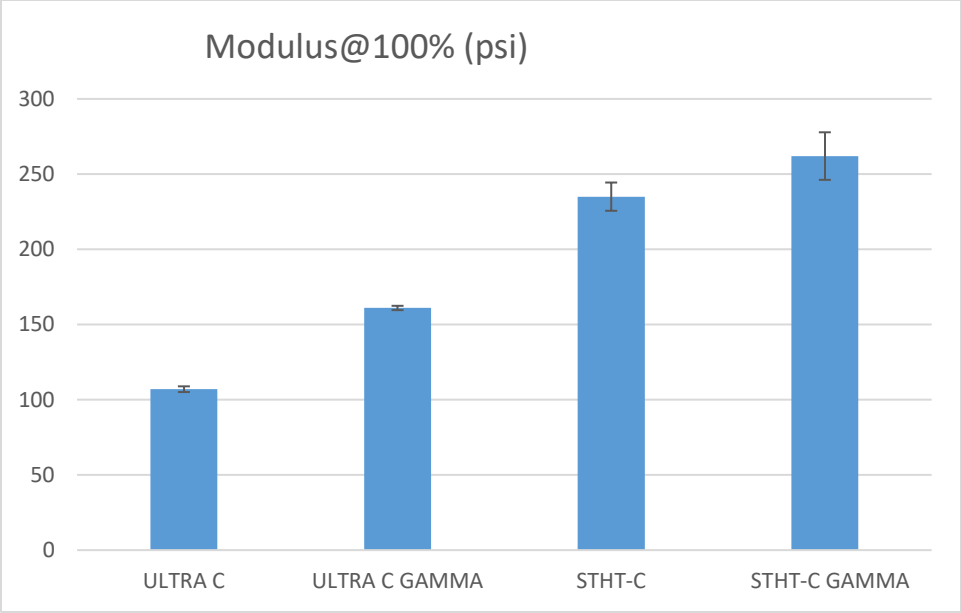


Figure 3: Modulus @100% elongation of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post gamma sterilization

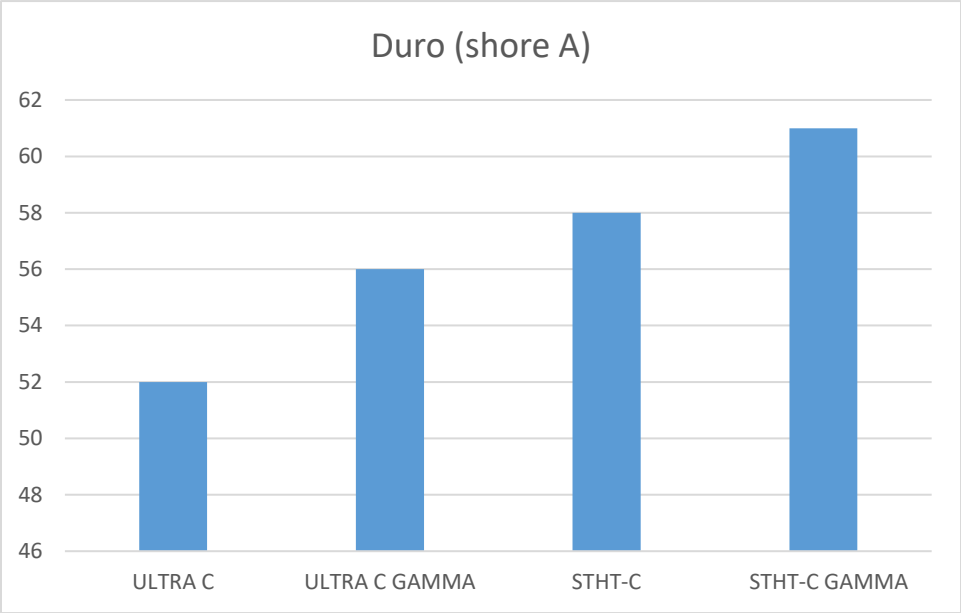


Figure 4: Hardness of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post gamma sterilization

### 3.1.2 Tubing Tear Strength

As shown in Figure 5, gamma irradiation seems to reduce Sani-Tech® Ultra C's tear strength, but has no statistical impact on Sani-Tech® STHT-C.

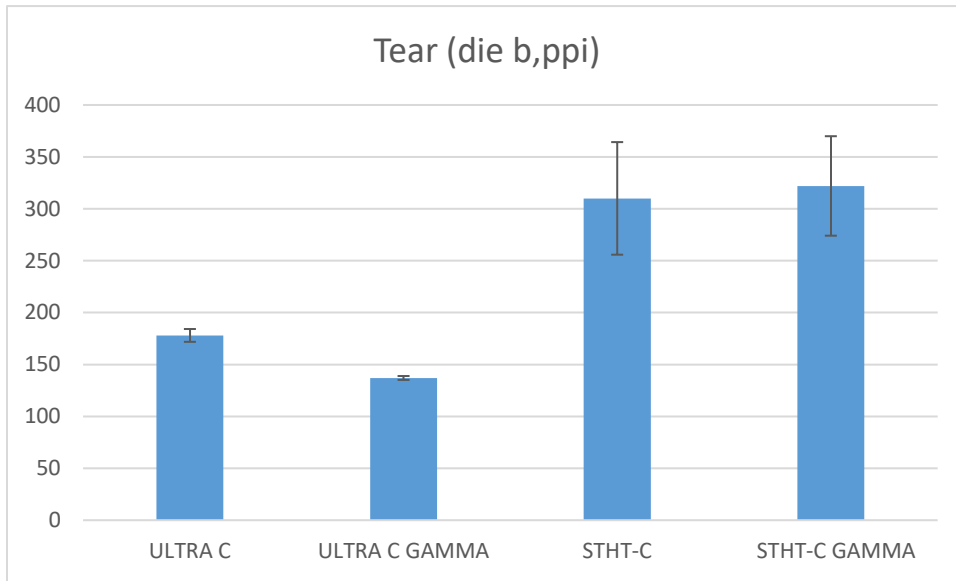


Figure 5: Tear resistance of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post gamma sterilization

### 3.1.3 Tubing Burst Pressure

As one can see, gamma sterilization increased slightly the burst pressure for both Sani-Tech® Ultra C and Sani-Tech® STHT-C tubing (Figure 6).

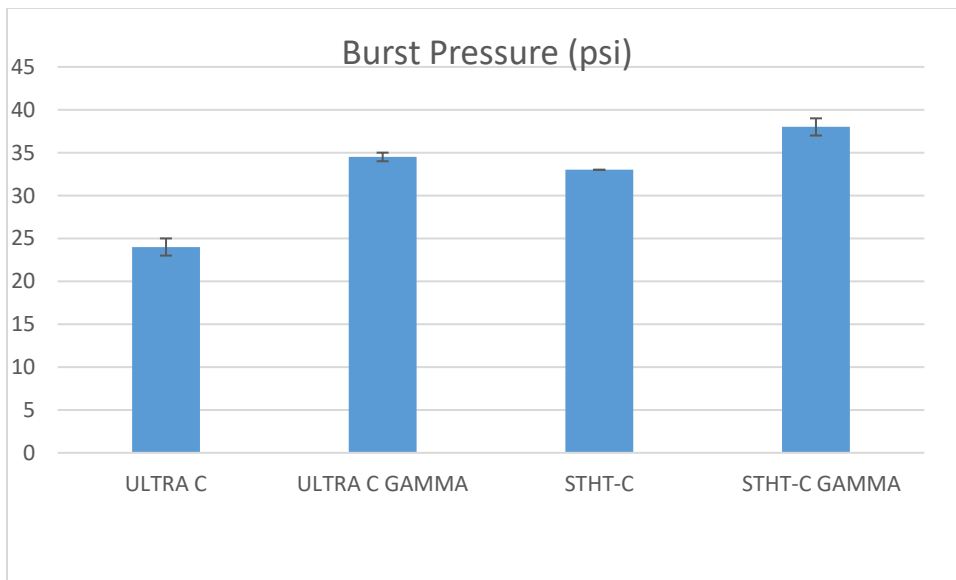


Figure 6: Burst pressure of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post gamma sterilization

### 3.1.4 Pump Life

As shown in Figure 7, gamma sterilization increases the average pump life. A number of complex factors play into the life of a peristaltic pump tube, including the intrinsic tubing physical properties and the pump life testing method variation involving many variables such as operator error and variability, tubing defect, tubing size uniformity, and backpressure oscillation and creep. Isolating each variable that plays a role in pump life of the tubing and studying their independent impacts is outside the scope of this study. Some aspects have been studied by others in Saint-Gobain and reported empirically that pump life correlates with resilience (hysteresis) of rubbers. It is understood that gamma irradiation can increase crosslinking density, thus increase resilience of rubbers.

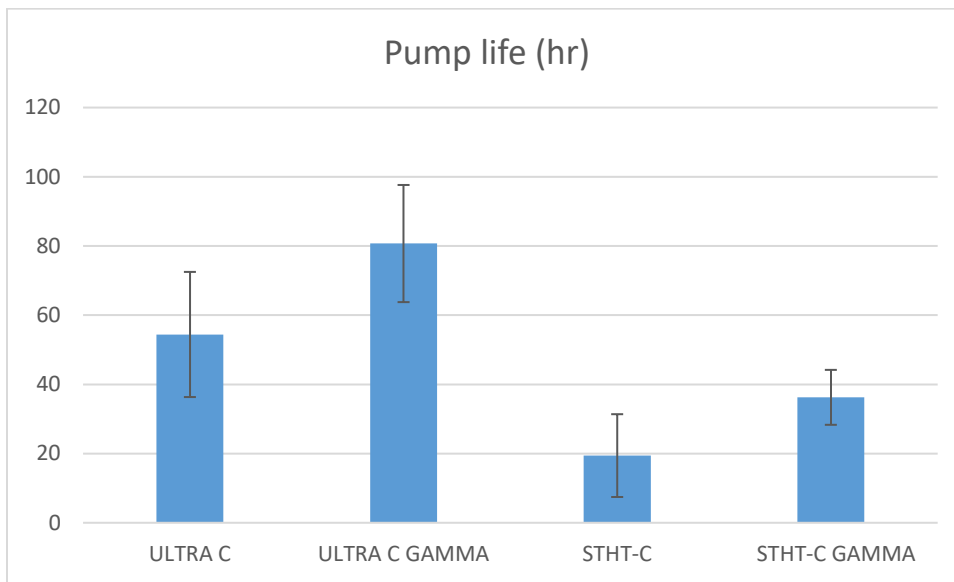


Figure 7: Pump life of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post gamma sterilization

## 3.2 Autoclave sterilization

### 3.2.1 Tensile/Elongation/Modulus/Hardness

As compared to the impact of gamma sterilization on silicone tubing, autoclave demonstrates less of an impact. As shown in Figures 8-11, the tensile strength, elongation, modulus and hardness each have little change. This is consistent with reports that typical autoclave has minimal detrimental impact on silicone rubber properties and silicone rubber can withstand hundreds of autoclave cycles <sup>(3,4)</sup>.

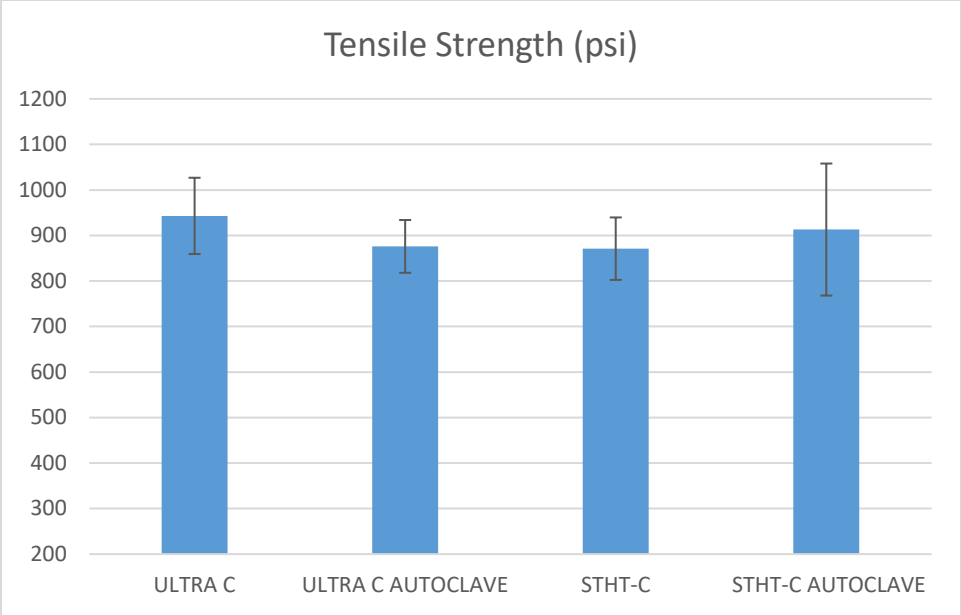


Figure 8: Tensile strength of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post autoclave sterilization

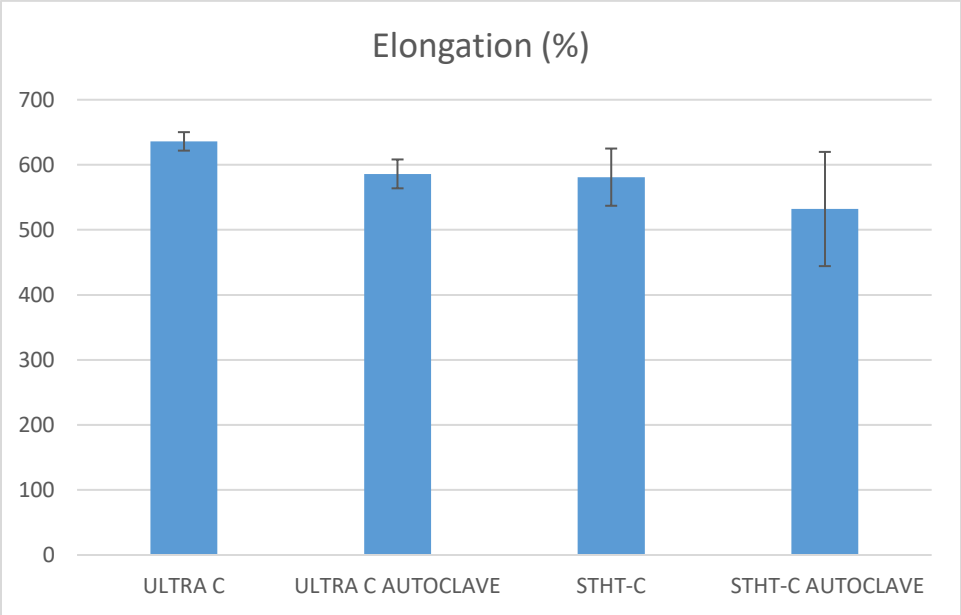


Figure 9: Elongation of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post autoclave sterilization

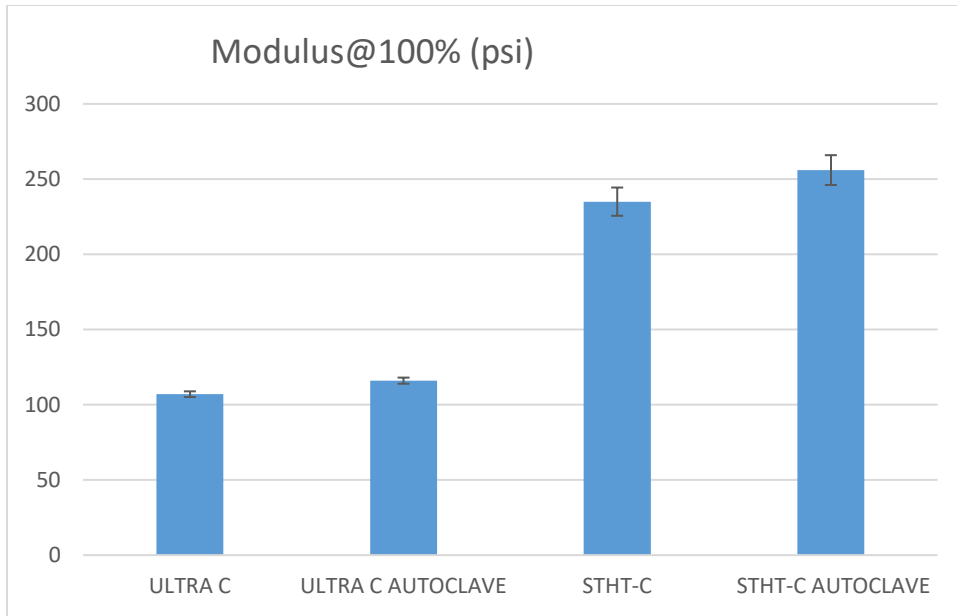


Figure 10: Modulus @100% elongation of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post autoclave sterilization

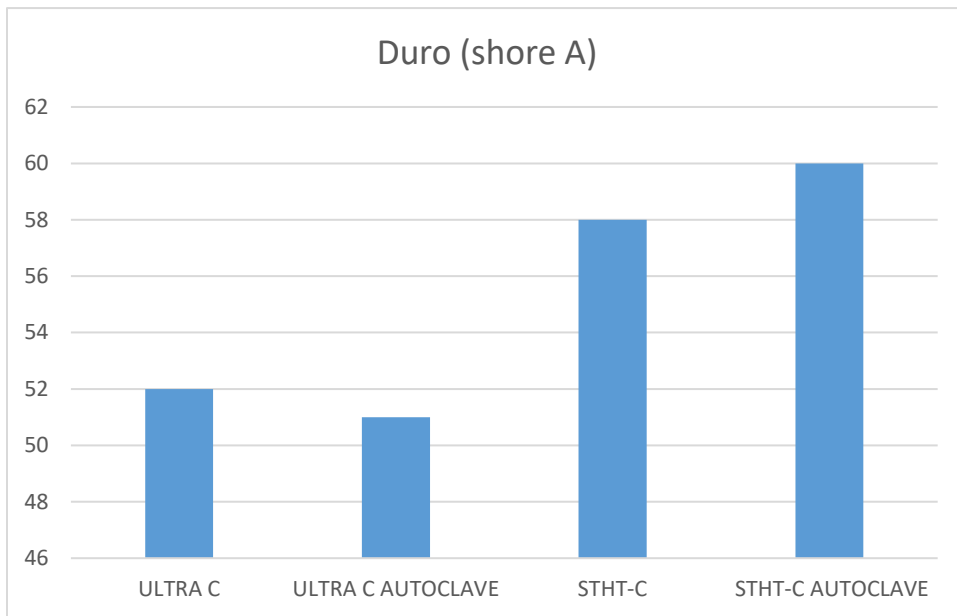


Figure 11: Hardness of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post autoclave sterilization

### 3.2.2 Tubing Tear Strength

The average tubing tear resistance strength increases from autoclave sterilization for both Sani-Tech® Ultra C and Sani-Tech® STHT-C, but it does not demonstrate a statistically significant difference.



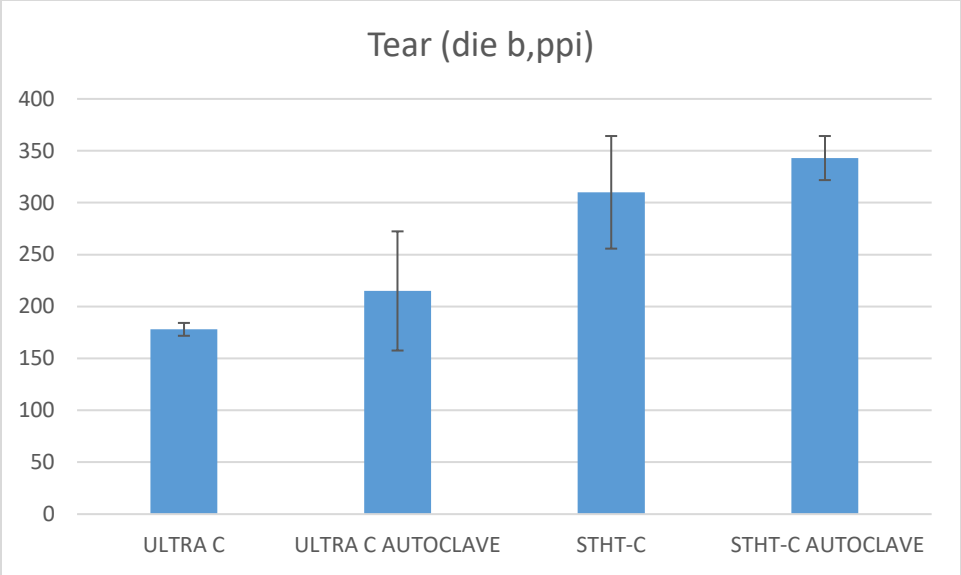


Figure 12: Tear resistance of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post autoclave sterilization

3.2.3 Tubing Burst Pressure

Consistent with autoclave's impact on modulus, hardness, and tear where a moderate increase in properties are noted; autoclave slightly increases burst pressure. Sani-Tech® STHT-C shows a larger increase in burst than the Sani-Tech® Ultra C.

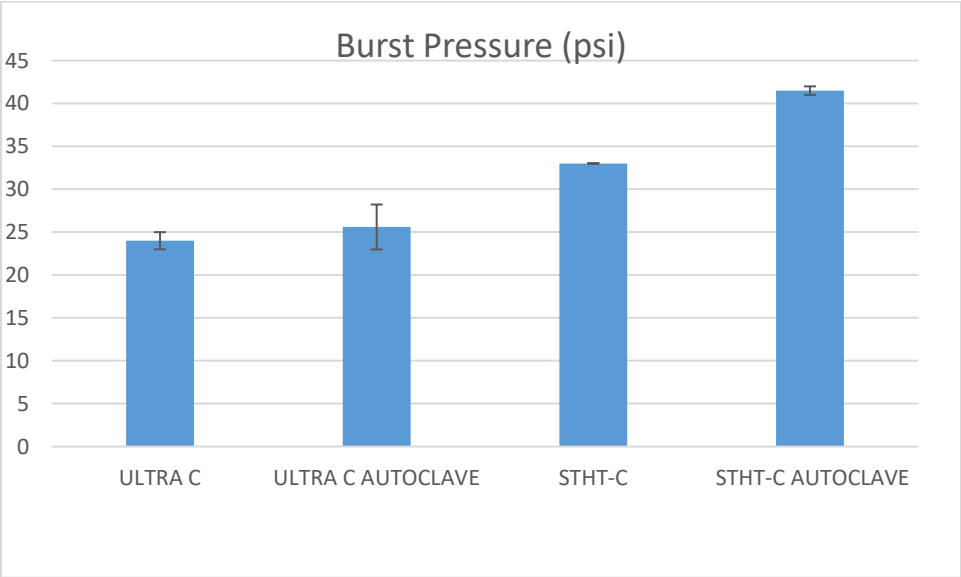


Figure 13: Burst pressure of Sani-Tech® Ultra C and Sani-Tech® STHT-C pre and post autoclave sterilization

### 3.2.4 Pump Life

As shown in Figure 14, there is no statistically significant change to pump life to either tube after autoclave sterilization.

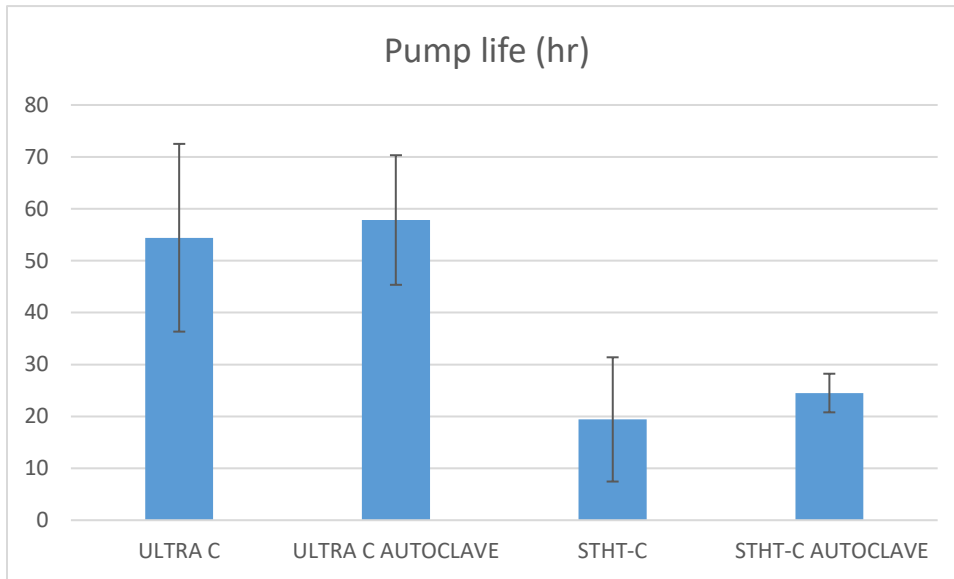


Figure 14: Pump life of Sani-Tech® Ultra C and Sani-Tech® STHT-C prior to and after autoclave sterilization

## 4 Conclusions / Summary

The effects of gamma irradiation and autoclave sterilization methods on Saint-Gobain's Sani-Tech® Ultra C and Sani-Tech® STHT-C were studied.

Gamma sterilization increased hardness, modulus and burst pressure of both tubing products. It also slightly increases their pump life.

Autoclave sterilization had less of an impact on the mechanical properties (tensile, elongation, modulus, tear resistance and hardness) of the tubes than gamma irradiation. Burst pressure was slightly increased and the pump life was not changed.

In summary, those silicone tubing products are compatible with both gamma irradiation and autoclave sterilization. No adverse effects were observed with regards to physical and mechanical properties. Additionally, application properties such as burst pressure resistance and pump life with peristaltic pumps were not negatively impacted.

## 5 Acknowledgements

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