



## APPLICATION NOTE

### Evaluation of Inflatable Seal Cycle Life Using S60121 UPS Class VI Certified Silicone

#### Introduction

For pharmaceutical equipment manufacturers, using components certified to USP Class VI is rapidly becoming a necessary “check in the box” even if the component doesn’t have direct contact with the end product. In response to this need, we have developed, tested, and validated a representative article consisting of silicone compound S60121 and S60021RTV which meets Biological Test for Plastics, USP Class VI 121°C. This particular combination of materials can be used to make either inflatable or compression seals, although in this test, the material was evaluated for use as an inflatable seal.

The profile, PR6119, was selected because it is commonly used in pharmaceutical applications.

#### Experimental

**Department:** Silicone

**Materials:**

1. 75” long (approximately 23.875” ID) PR6119 (S60121) material with proper valve and cone fittings

**Equipment:**

1. Air Supply
2. Regulator that allows up to 40 psi
3. Valve fittings
4. Cycle counter
5. Prototype chromatography fixture with modified valve connector
6. Hose assembly (attaches to PRV16377.329)



**Prototype Chromatography  
Fixture**

**Procedure:**

1. Leak test the assembly before cycling in water tub at 20 psi
2. Set up cycle test assembly to prepare for 100,000 cycles at 2.2 bar (32 psi)
3. Insert seal into fixture with approximate channel dimensions of 34.5 mm wide X 29 mm deep
4. Start the cycle test and verify the seal is operational



5. Periodically inspect seal for noticeable failure
6. Perform a final leak test before passing seal.



**PR6119**

**Results:** After 300,000 cycles, the seals passed the final leak test. No leaks or deformations were found. The seals had to reach a gap of .093 (2.36 mm) during the cycle test.

**Summary:** With these successful test results, S60121, our USP Class VI certified material is validated for use for pharmaceutical inflatable seal applications.

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