SiO2 MATERIALS SCIENCE℠

Dimensional Stability of a Multicavity Injection Molded Article

Technical Bulletin Series 2017-008

Keywords: dimensions, syringe, blood tube, vacutainer, cavity, injection, molding, diameter, variation, glass

INTRODUCTION

SiO2 Materials Science, Inc.'s (SiO2) containers for parenteral medications stand out from all other polymer and glass containers for parenteral solutions on the market today for many reasons.

1. The polymeric material's viscoelastic properties lend itself to break resistance.
2. The inner surface of the polymeric material is internally coated using plasma enhanced chemical vapor deposition (PECVD) with three layers of silicon-based material that provides pH resistance, oxygen barrier properties, and leachable resistance. In addition, due to the materials of construction, the vial is metals free.
3. Injection molding processing produces primary containers with high dimensional consistency not attainable by borosilicate glass processing.
4. The SiO2 container incorporates a unique unit dose identification. Traceability can be shown down to the unit level.

PURPOSE

This study was designed to determine relative dimensional stability of SiO2 injection molded articles over glass.

BACKGROUND

Both glass and plastic primary containers for parenteral dosage forms are available to the pharmaceutical industry. There are many factors in making the decision to use one over the other. One of the most important factors that pharmaceutical packaging professionals need to consider when choosing container material is variation. As Dr. W. Edwards Deming proclaimed in the early 1960's "Understanding variation is the key to success in quality and business." By understanding inherent variation and its ramifications, pharmaceutical professionals can make decisions that not only save time, money, and opportunity cost but also lives. This study looks at peer processes used to manufacture articles from glass and plastic, in this case cyclic olefin polymer (COP).

METHODOLOGY

A Renishaw Equator 300 Coordinate Measuring Machine (CMM) was used to take the measurements of the components.

RESULTS AND DISCUSSION

To illustrate the differences between glass and injection molded syringes, three key dimensions of the syringe were selected:

This study looks at two conditions that test the upper limits of storage conditions to accelerate any potential impact on stability to the coating quality of the vial.

Figure 1. Barrel Inner Diameter

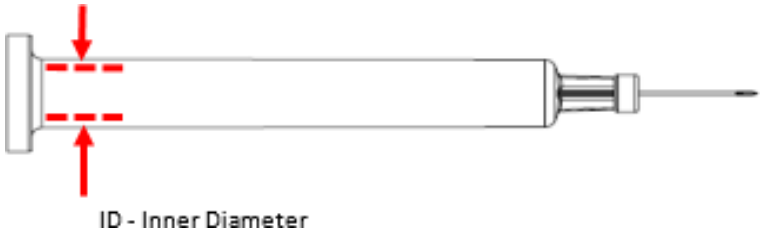


Figure 2. Flange Outer Diameter

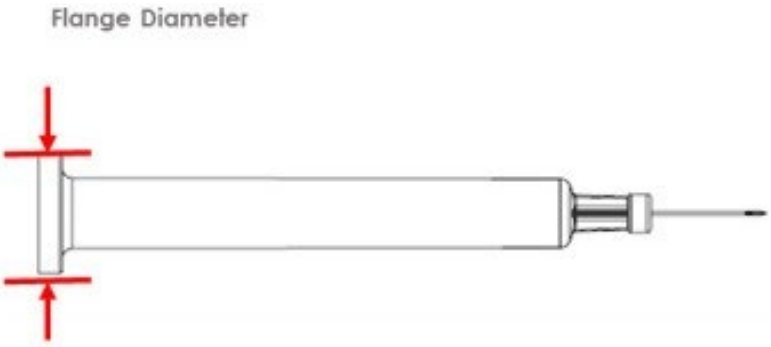
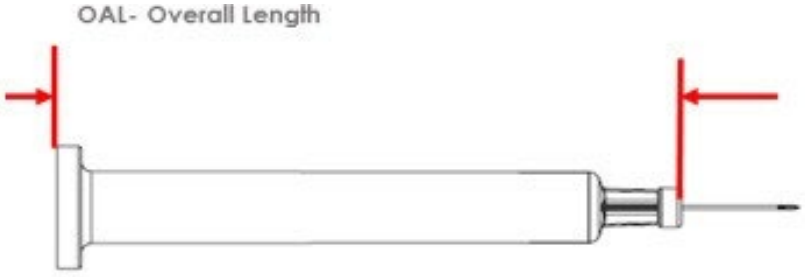


Figure 3. Syringe Length



The following Figures 4-6 show the reduced variability of the SiO2 injection molded syringe as compared to a glass syringe with the SiO2 Limits delineated.

Single cavity syringe pilot mold, n = 30 samples

Commercial glass 1 mL syringes, n = 30 samples

Glass syringe data is normalized to SiO2 syringe nominal dimensions for comparison purposes. Overall, the SiO2 injection molded syringes exhibit less variability with tighter tolerances than glass syringes.

Figure 4.

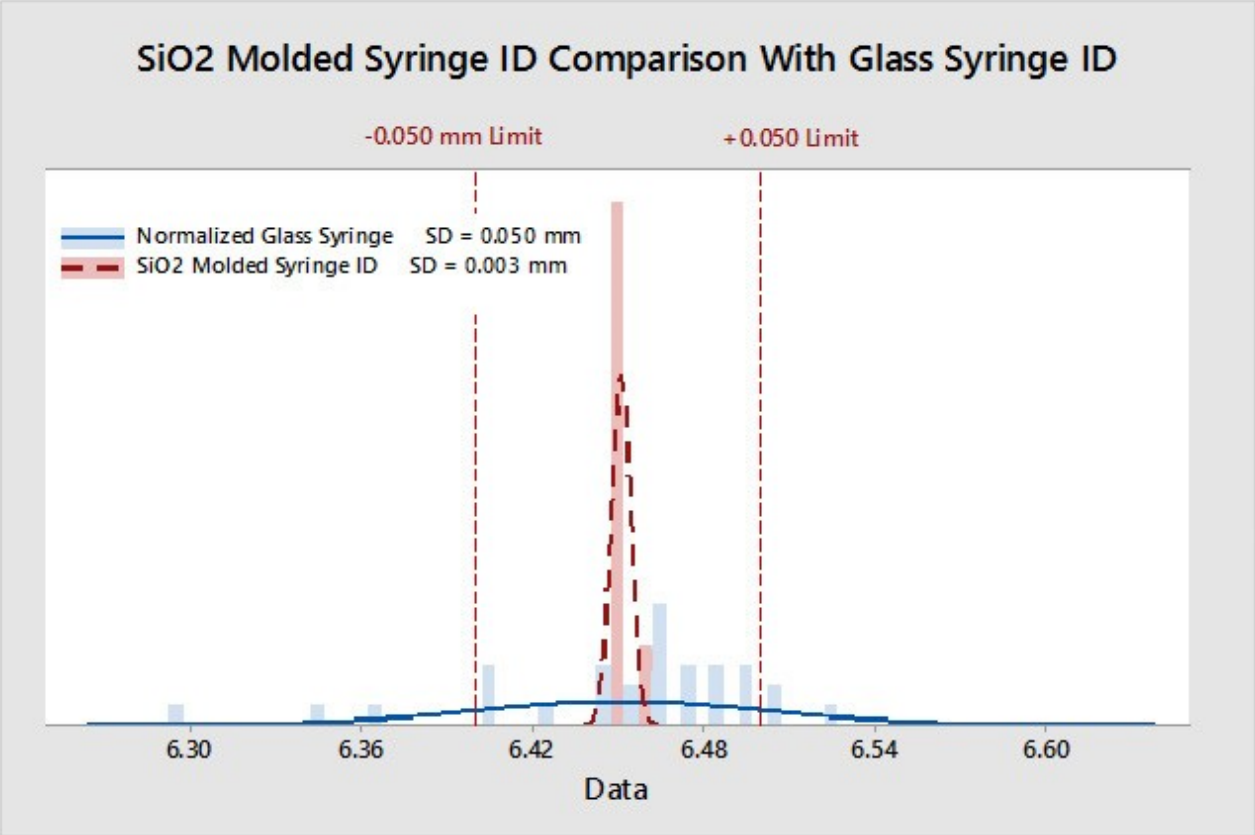


Figure 5.

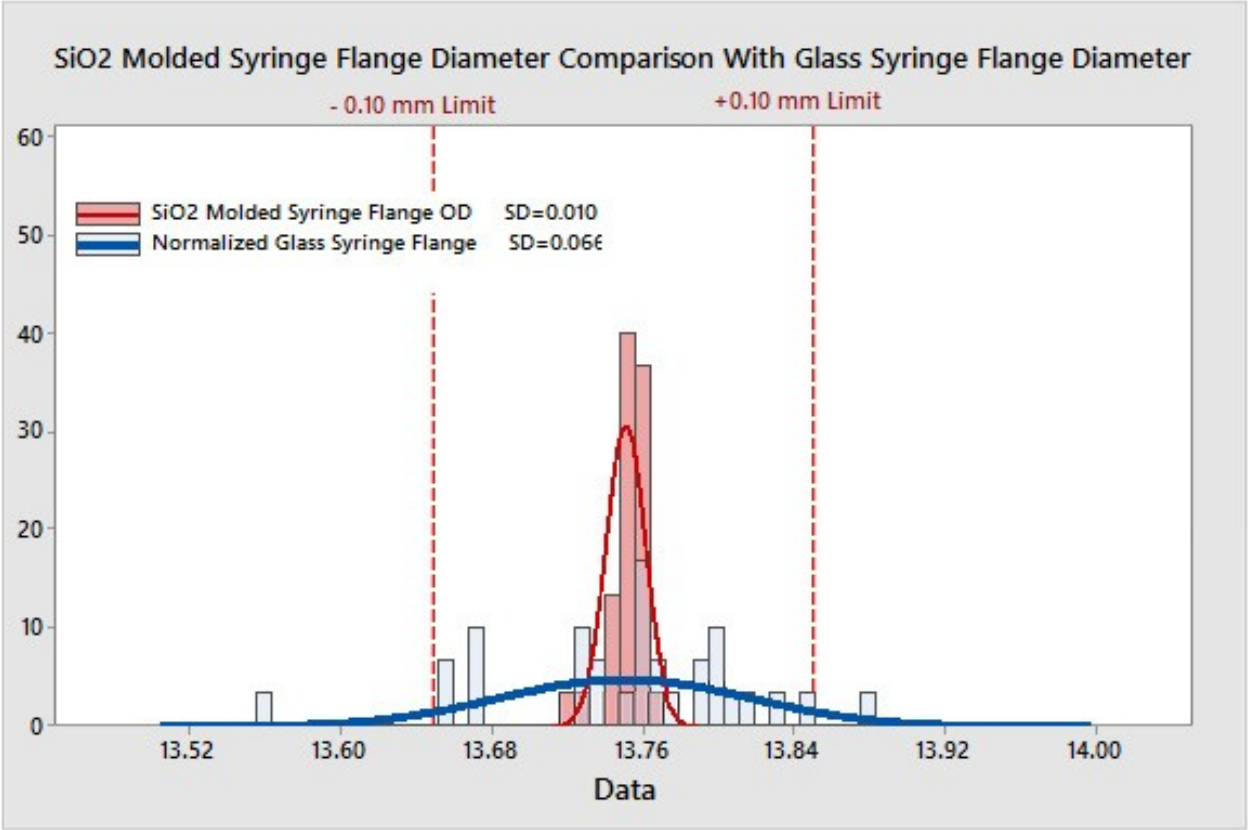
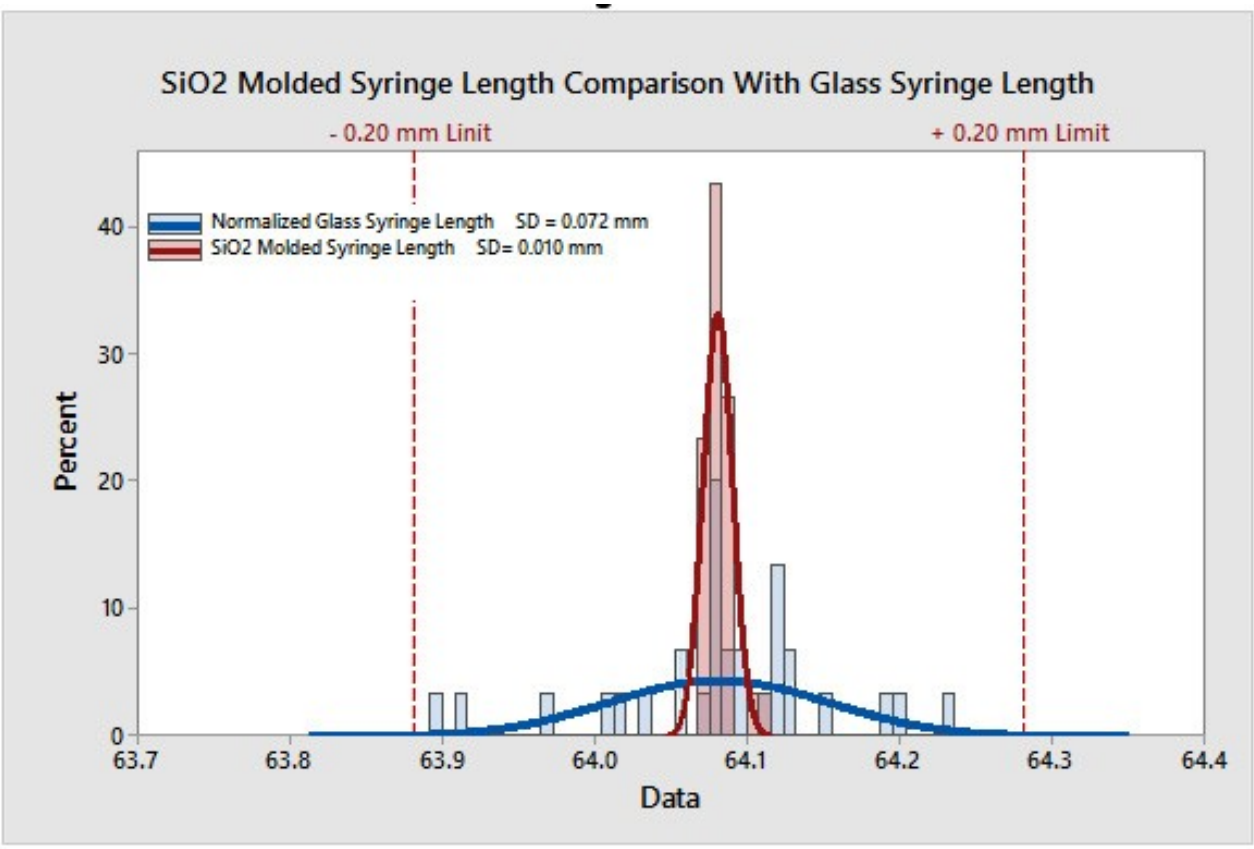
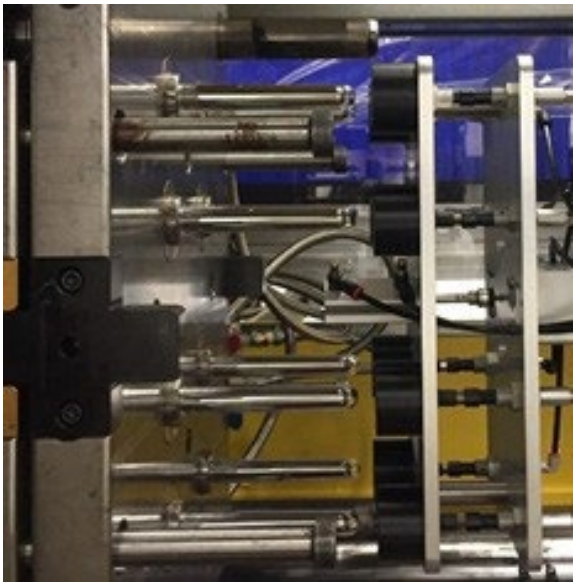


Figure 6.



MULTIPLE CAVITY PRODUCTION VARIABILITY

A typical production injection mold will have several cavities that make the same part to maximize productivity. To account for this additional source of variability, data was generated from an existing 8 cavity production mold of a 4 mL blood tube. A blood tube or vacutainer is a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube facilitating the draw of a predetermined volume of liquid. Most commonly used to collect blood samples in venipuncture. SiO2 manufactures millions of these products using the same material and injection molding technology as used on syringes having the same inherent dimensional consistency. The blood tube is illustrative of a multiple cavity tool so the cavity to cavity and process variation can be observed and compared to glass.



The following charts offer a dimensional comparison of the relative variability of three container systems:

- SiO2 Single Cavity Pilot 1 mL Long Syringe Mold (same data as shown on initial figures)
- Glass 1 mL Long Glass Syringe (same normalized data as shown on initial figures)
- SiO2 8 cavity production mold of 4 mL COP Blood Tube (331 Samples distributed across all 8 cavities normalized to SiO2 syringe dimensions for comparison)

Figure 7.

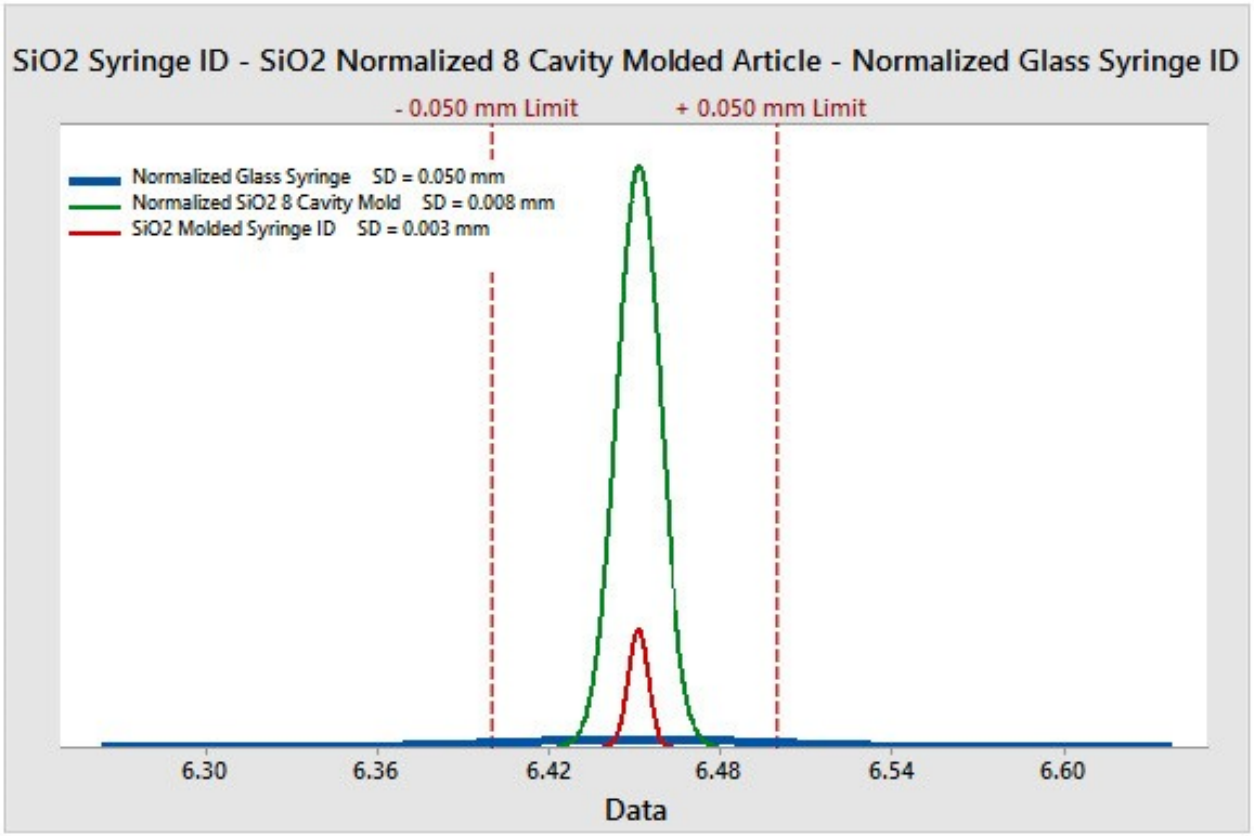


Figure 8.

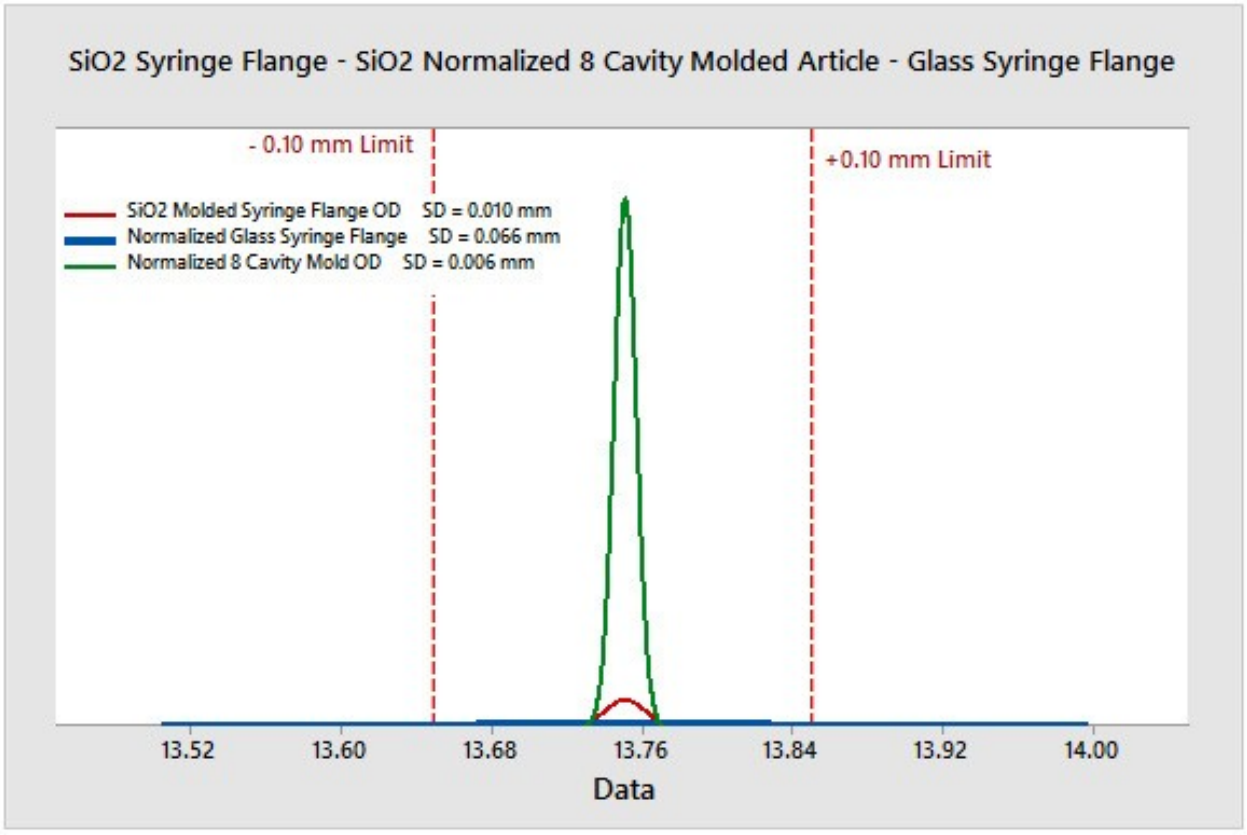
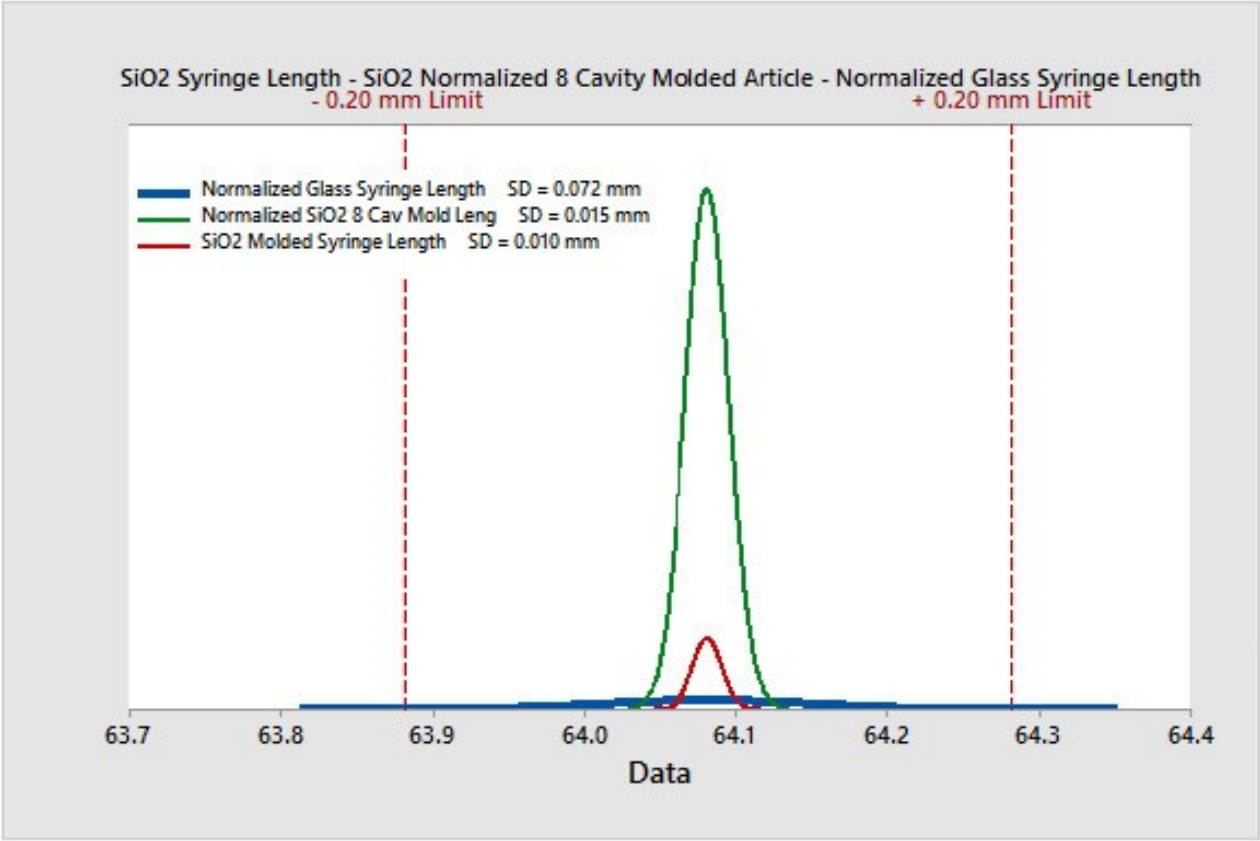


Figure 9.



CONCLUSIONS

- Both process variation and cavity-to-cavity variation of all COP containers are smaller (as much as an order of magnitude) compared to glass.
    - Glass has 11 times the variation as compared to multiple cavity injection tool for Flange Outer Diameter.
    - Glass has 6 times the variation as compared to multiple cavity injection tool for Internal Diameter.
    - Glass has 5 times the variation as compared to multiple cavity injection tool for Overall Length.
- Reducing dimensional variation improves component integration, such as with autoinjectors, whichreduces field failures.

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