GORE ImproJect Plunger
A new silicone-free plunger for bare-glass (non-siliconized) barrels

SILICONE-FREE PLUNGERS TO ENABLE DELIVERY OF COMPLEX, SENSITIVE BIOLOGICS

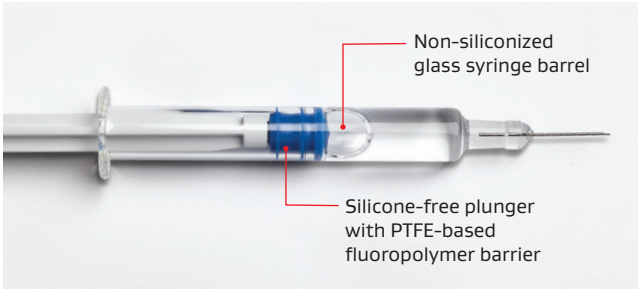
Background

Conventional pre-filled syringe systems use silicone to help provide a seal and to act as a lubricant between the barrel and the plunger. However, there can be problems associated with silicone that impact broader drug stability. Estimates indicate that between 10–15% of large molecules may have decreased drug stability due to potential interaction with silicone.[1] In addition, silicone migration over time can impact consistency of delivery as break loose/glide force (BLGF) and injection time can change with aging. Silicone oil has been shown to cause aggregation and particle formation in therapeutic proteins.[2,3]

Product Description

GORE ImproJect Plungers are intended for use in bare glass (non-siliconized), pre-filled syringe barrels. These plungers eliminate the need for silicone as a lubricant on the plunger and in the barrel, eliminating silicone-induced aggregation and particulation while enabling consistent injection time with aging. The proprietary ePTFE fluoropolymer barrier supports compatibility with drug product as demonstrated in biocompatibility and extractables testing results.

GORE ImproJect Plungers are silicone-free. Silicone oil is not a raw material and is not used in the manufacture of the plungers.



Common Applications

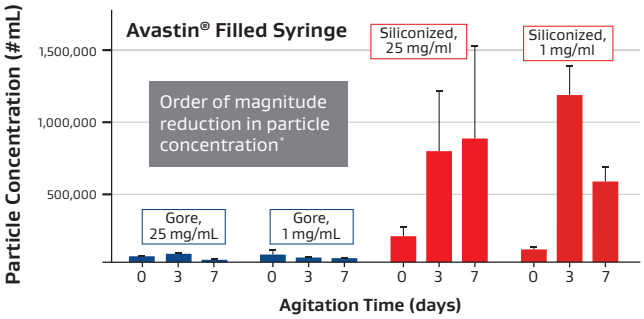
- For silicone-sensitive biologics and conjugate vaccines
  - Enables low particulation, eliminating the risk of silicone-induced aggregation
  - Maintains consistent injection time with aging
- Compatible with auto-injectors

References

1. "Pre-Filled Syringes West Coast 2016." Pharmaceuticals: All, smi-online.co.uk/pharmaceuticals/archive/6-2016/conference/Pre-Filled-Syringes-West-Coast Terumo, SMi Pre-Filled Syringes West Coast, June 2016.
2. Basu P, Blake-Haskins AW, O'Berry KB, Randolph TW, Carpenter JF. "Albinter-feron a2b adsorption to silicone oil-water interfaces: effects on protein conformation, aggregation, and subvisible particle formation." *J Pharm Sci.* 2014;103(2):427-436.
3. Gerhardt A, Bonam K, Bee JS, Carpenter JF, Randolph TW. "Ionic strength affects tertiary structure and aggregation propensity of a monoclonal antibody adsorbed to silicone oilewater interfaces." *J Pharm Sci.* 2013;102(2):429-440.

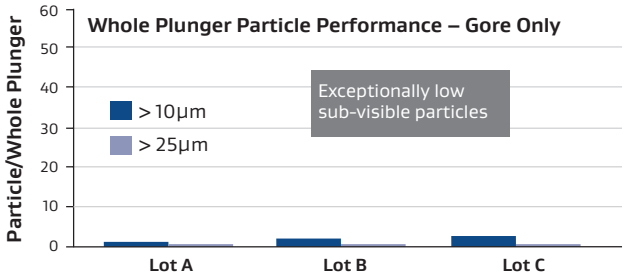
Together, improving life

Sub-visible Particulates Performance



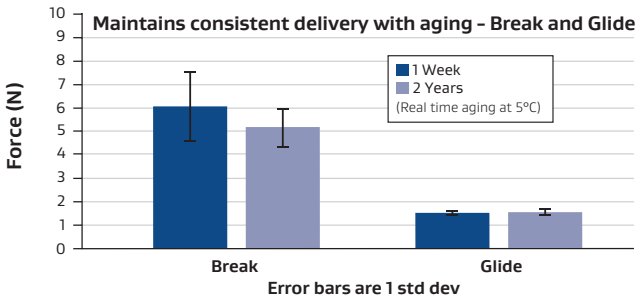
Avastin® Filled Syringe with Agitation. Particle and soluble protein levels in samples of Avastin agitated in syringes in contact with the fluoropolymer-surfaced plunger in a bare-glass syringe (blue bars) and a traditional siliconized plunger in a siliconized glass syringe (red bars) as measured by MFI.

* "Avastin® Filled Syringe": Teska et al., J Pharm Sci. 2016, 105 (7), 2053-2065.



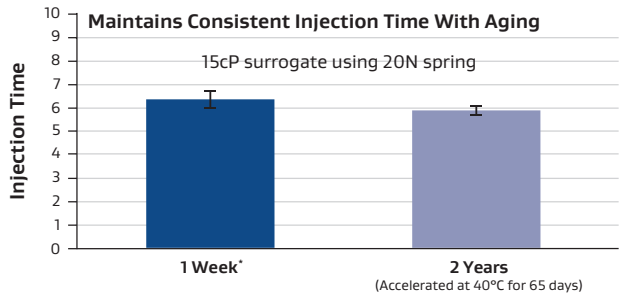
Whole plunger particle performance was tested by NAMSA per USP <788> Particulate Matter in Injections for Large Volume Parenterals using the Light Obscuration Method.

Functional Testing



Fill: ~1 mL Water-for-injection (WFI). Error bars are 1 std dev.

BLGF: Tested at 250 mm / minute. Schott non-siliconized syriQ® 1 mL Long 27G TW staked needle. Real time aging conditions = 5 ˚C, 2 years. 1 week: After filling and vent tube insertion, these samples were stored needle up for 1 week at ambient conditions prior to testing.



Fill: ~1mL, 15cP Glycerol/WFI. Error bars are 1 std dev.

Injection Time: Gore developed a benchtop R&D test simulating common off-the-shelf autoinjectors. Schott non-siliconized syriQ® 1 mL Long 27G TW staked needle (~0.25mm needle inner diameter), flat plunger rod. 1 week: After filling and vent tube insertion, these samples were stored needle up for 1 week at ambient conditions prior to testing. Accelerated aging conditions = 40 ˚C, 65 days.

Conclusions

- Using a commercially available drug, there was an order of magnitude reduction in particle concentration with the GORE ImproJect Plunger in bare glass (non-siliconized) barrel compared to conventional siliconized PFS
- In WFI filled syringes, the GORE ImproJect Plunger had exceptionally low sub-visible particles
- Functional testing showed the GORE ImproJect Plunger maintains consistent injection time with aging

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. GORE ImproJect Plungers, like all products in the Gore PharmBIO Products' portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

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