

ADVANTAGES OF FULLY COATED PLUNGERS FOR PREFILLED SYRINGES AND CARTRIDGES

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With the rise of therapeutic biologics, as well as, auto-injectors and wearables that facilitate self-administration, there are more drug delivery challenges than ever before. In these prefilled syringe and cartridge applications, plungers must meet strict requirements for drug compatibility, func-

tionality, and machineability. The best way to achieve these standards is through a complete fluoropolymer coated plunger, such as Datwyler's NeoFlex™. In this poster, we will analyze the functional performance of Datwyler's NeoFlex™ plungers.

BREAK LOOSE AND GLIDING FORCE

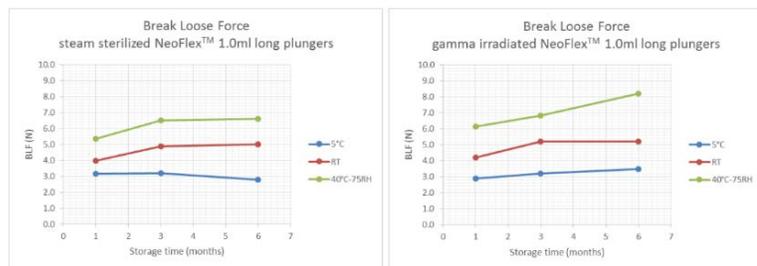


Figure 1: Break loose force on steam sterilized and gamma irradiated NeoFlex™ 1.0 ml long plungers stored in a low siliconized barrel at different temperatures during a period of 6 months.

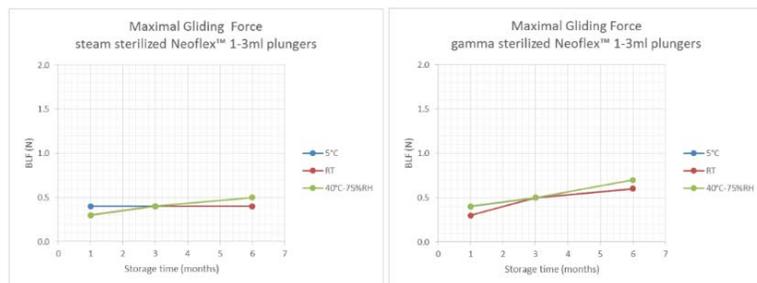


Figure 2: Maximum gliding force on steam sterilized and gamma irradiated NeoFlex™ 1-3 ml plungers stored in a standard siliconized barrel at different temperatures during a period of 6 months.

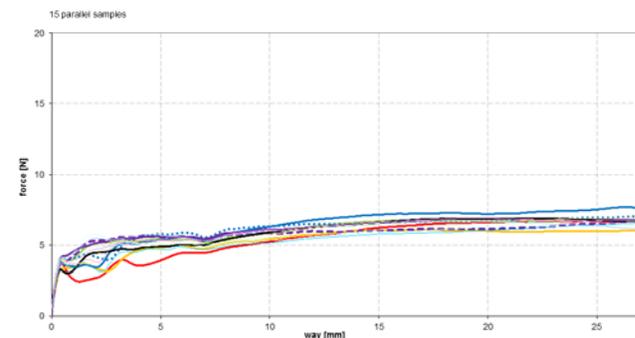


Figure 3: Break loose and gliding curve of NeoFlex™ plungers in Gerresheimer Gx RTF® 1 ml long glass syringe, baked-on siliconized, expressed with 270 mm/min, 3 months storage data, 25°C. 15 parallel samples.

SEAL INTEGRITY

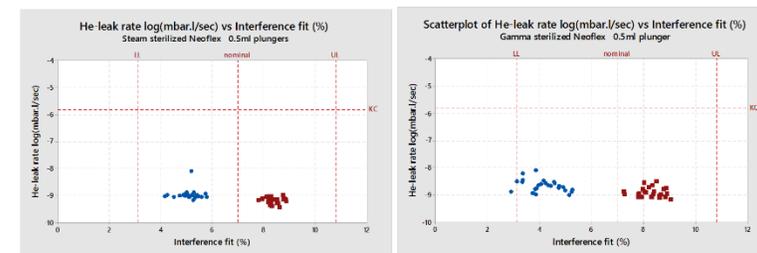


Figure 4: He leak rates of steam sterilized and gamma irradiated 0.5 ml plungers with different interference fit. All cases easily meet the Kirsch Criterion (1.6E-6mbar./sec).

PLUNGER MOVEMENT

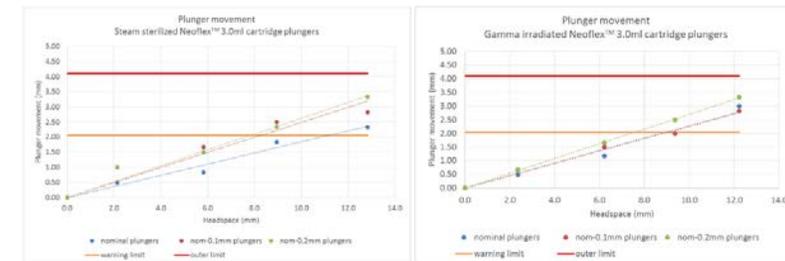


Figure 5: Plunger movement of steam sterilized and gamma irradiated NeoFlex™ plungers for 3 ml cartridges measured with different headspaces. The plunger movement is tested in a vacuum chamber at 752mbara (=8000ft) at room temperature. This condition is typically the pressure decay for a pressured cargo air jet.

NeoFlex™ plunger stoppers were tested at Gerresheimer Bünde GmbH to underline syringe system functionality by an external partner. Different GX RTF® syringe types in glass and COP as well as siliconization profiles, such as spray and baked-on siliconization, were successfully tested. This data shows the performance in silicone reduced baked-on syringes, often used in Biotech and Ophthalmics, WFI filled, after 3 months real time aging at room temperature.

CONCLUSION

Datwyler's NeoFlex™ plungers are proven to provide reliable drug compatibility, superior functionality, and excellent machineability. The fluoropolymer spray coating provides a barrier to extractables and leachables while ensuring smooth delivery in the field. NeoFlex™ plungers meet the highest demands for quality and performance for highly sensitive, large molecule drugs.