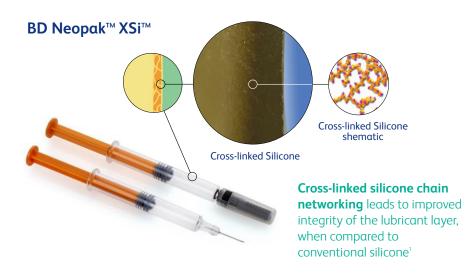
BD solutions for enabling delivery of complex biologics

BD NeopakTM XSiTM Glass Prefillable Syringe



BD Neopak™ XSi™ Glass Prefillable Syringes have been designed for improved integrity of the lubricant layer reducing subvisible particle level of biologic formulation in PFSs, particularly for drugs that may be very sensitive to silicone oil

Experience

- BD partnering in combination product development with the biopharmaceutical industry for 30 years⁸
- Glass used as reference material for vast majority of biologic drugs prefillable syringes⁹

BD XSi™is built on BD Neopak™ Glass Prefillable Syringe

- Compatible with existing manufacturing and inspection technologies and practices
- Supports single PFS platform[†] approach

Availability

- 2 configurations of BD Neopak™XSi™ are available for testing through the BD PartnerPath™ program:
 - 1 mlL 29G Thin Wall
 - 2.25 mL 27G Special Thin Wall Additional product configurations may be available on demand

Key benefits

Helping you to address silicone-related concerns in delivering biologics:

- Minimizes sub-visible particle generation^{12,3,47}
 Helping you achieve compliance with
 standards^{10,11,12} for particulates, even when using
 formulations reactive to conventional silicone
 and/or higher drug concentrations
- Stabilizes the silicone lubricant layer
 & mechanical properties^{125,67}
 Helping you to increase confidence in full drug delivery
- Does not introduce new chemistry^a
 Designed to have no impact on manufacturing and fill and finish lines, avoiding additional costs associated with PFS switch



^{*} As compared to conventional liquid silicone lubrication.

References

- µ. XSi[™] does not introduce new chemical substances or molecule entity and only modifies the distribution of chemical functions which already exists in PDMS (Polydimethylsiloxane) silicone
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- 3. Neopak™ XSi™ 2.25 mL Subvisible particles quantification by MFI / pipetting & HIAC / flushing [internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company. 2019
- 4. Neopak™ XSi™ 1 mlL 29 G TW & 27STW ½" RNS BD260 Subvisible particles [internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company. 2019
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- 11. <787> SUBVISIBLE PARTICULATE MATTER IN THERAPEUTIC PROTEIN INJECTIONS The United States Pharmacopeial Convention, current edition
- 12. EP 2.9.19 Particulate contamination: Sub-Visible Particles The European Pharmacopoeia, current edition

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