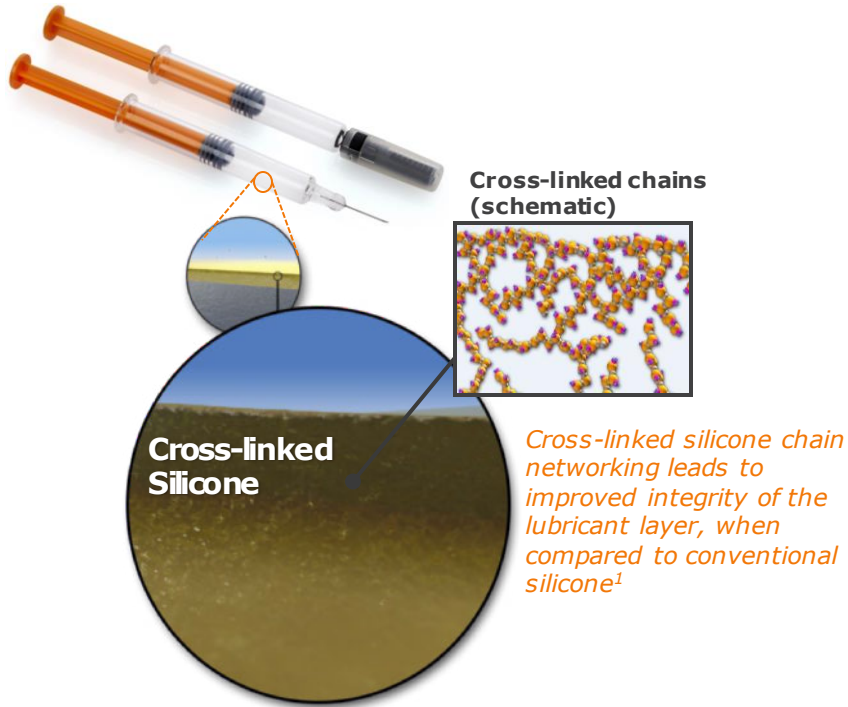


# BD tools for enabling delivery of complex biologics

## BD Neopak™ XSi™ Glass Prefillable Syringe

### Product



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**.<sup>1</sup>

### Key benefits

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

- ✓ **Minimizes sub-visible particle generation**<sup>1,2,3,4\*</sup>  
Helping you achieve **compliance** with standards<sup>10,11,12</sup> for particulates, even when using formulations reactive to conventional silicone and/or higher drug concentrations  
*\*As compared to conventional liquid silicone lubrication.*
- ✓ **Stabilizes the silicone lubricant layer & mechanical properties**<sup>1,2,5,6,7</sup>  
Helping you to increase confidence in **full drug delivery**
- ✓ **Does not introduce new chemistry**<sup>μ</sup>  
Designed to have **no impact on manufacturing and fill & finish lines**, avoiding additional costs associated with PFS switch.

### Experience

- BD partnering in combination product development with the biopharmaceutical industry for 30 years<sup>8</sup>
- Glass used as reference material for vast majority of biologic drugs prefillable syringes<sup>9</sup>

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

- Compatible with existing manufacturing and inspection technologies and practices
- Supports single PFS platform<sup>†</sup> approach

<sup>†</sup> PFS platform: Serving a range of requirements (silicone reactivity, drug fill volume, viscosity, device integration, etc.) with a minimal number of SKUs and little to no change in core materials (glass, silicone, rubber, etc.)

### Availability

2 configurations of BD Neopak™ XSi™ are available for testing through the BD PartnerPath™ program:

- **1mL 29G Thin Wall**
- **2.25mL 27G Special Thin Wall**

*\*Additional product configurations may be available on demand.*

<sup>μ</sup> 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.  
<sup>1</sup> Depaz et al. Cross-Linked Silicone Coating: A Novel Prefilled Syringe Technology That Reduces Subvisible Particles and Maintains Compatibility with Biologics. JOURNAL OF PHARMACEUTICAL SCIENCES 103:1384-1393, 2014  
<sup>2</sup> BD Neopak™ XSi™ 1 mL - Competitive Benchmark [Internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company; 2020.  
<sup>3</sup> Neopak™ XSi™ 2.25ml - Subvisible particles quantification by MFI / pipetting & HIAC / flushing [Internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company. 2019  
<sup>4</sup> Neopak™ XSi™ 1 mL 29 G TW & 27STW ½" RNS BD260 - Subvisible particles [Internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company. 2019  
<sup>5</sup> Neopak™ XSi™ 2.25ml 27G STW ½" - Empty AGF. [Internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company. 2019  
<sup>6</sup> Neopak™ XSi™ 1mL 29G TW ½" - Empty gliding force at 1ml. [Internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company. 2018  
<sup>7</sup> Neopak™ XSi™ 2.25ml 27G STW ½" - Injection time. [Internal Study]. Pont-de-Claix, FR: Becton Dickinson and Company. 2019

<sup>8</sup> BD Medical Pharmaceutical systems BD Hypak™ Glass Prefillable Syringe since 1975 BD Website.  
<sup>9</sup> BD Situation analysis extract [Internal document]. Pont-de-Claix, FR: Becton Dickinson and Company; 2020  
<sup>10</sup>: <788> PARTICULATE MATTER IN INJECTIONS - The United States Pharmacopeial Convention, current edition.  
<sup>11</sup>: <787> SUBVISIBLE PARTICULATE MATTER IN THERAPEUTIC PROTEIN INJECTIONS - The United States Pharmacopeial Convention, current edition.  
<sup>12</sup>: EP 2.9.19 Particulate contamination: Sub-Visible Particles - The European - Pharmacopoeia, current edition

