

BD tools for enabling subcutaneous injection delivery of complex biologics

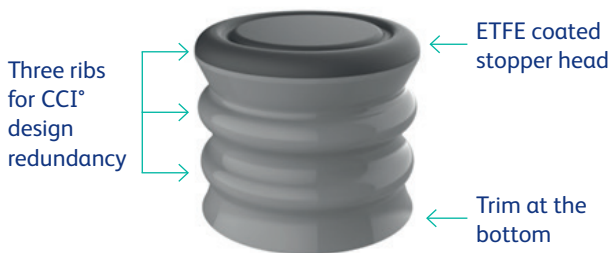
# BD SCF™ PremiumCoat® 1-3mL Plunger Stopper



BD SCF™ PremiumCoat® 1-3mL Plunger Stopper is intended to support the subcutaneous injection of complex biologics and viscous solutions with a 1-3mL prefilled syringe-based combination product.<sup>1,2</sup>

## Product Features:

- 1-3mL plunger stopper
  - Leverages BD's end processing expertise in washing, siliconization, vision inspection and packaging
  - Utilizes Aptar's commercialized PremiumCoat® vial stopper formulation and coating
- Bromobutyl formulation (6720GC)<sup>3</sup>
- Fluoropolymer coating - ethylene tetrafluoroethylene (ETFE)<sup>3</sup>
- Flexibility in processing: compatible with both vented and vacuum stoppering methods<sup>4</sup>



## System Integration Experience:

- BD offers a robust system data package<sup>9</sup> to support integration of the BD SCF™ PremiumCoat® into combination products, such as with a prefillable syringe and/or autoinjector or safety device

## Availability:

- Commercially available\*\*\*\* in TSCF and BSCF packaging configurations without BD Visioguard™ 100% camera inspection
- BD Visioguard™ 100% camera inspection planned for release in 2025

## Performance & Safety Benefits:

- BD SCF™ PremiumCoat® supports a **higher predictable system injection performance** in combination with autoinjector due to **reduced glide force and glide force variability** by up to **51% and 73% respectively**<sup>\*5</sup>
- With BD SCF™ PremiumCoat®, BD guarantees\*\* that **all stopper ribs touch** inside of the prefilled syringe barrel to enable **improved container closure integrity**<sup>\*5,6</sup>
- BD SCF™ PremiumCoat® coating **prevents migration** of certain elements<sup>7\*\*\*</sup>
- **Minimizes the risk of contamination** from foreign matter using BD Visioguard™ 100% camera inspection once available in 2025<sup>8</sup>



- ° CCI = Container Closure Integrity
- \* When compared to the BD SCF™ FluroTec® Plunger Stopper. Results are based on a sample of 100 pieces of BD Flurotec® and BD SCF™ PremiumCoat®. Variables compared were Mean (glide force reduction) and standard deviation (glide force variability)
- \*\* Becton, Dickinson and Company. BD SCF™ PremiumCoat® Plunger Stopper 1-3mL Customer quality specification
- \*\*\* Extractables analysis with glass cane and by immersion showed that the coating provides a barrier effect for a number of potential extractables in the 6720 formulation, for elemental impurities and semi-volatile and non-volatile organic molecules.
- \*\*\*\* As of March 2024, For Human Use samples are available without vision inspection
- ¥ Gliding test performed at nominal design space, in BD Neopak™ Glass Prefillable Syringe 2,25mL 27G filled with WFI

TSCF Transfer door Sterile Clean Fill – 15,000 stopper units per package

BSCF Bagged Sterile Clean Fill – 4,600 stopper units per package

#### References:

1. Becton, Dickinson and Company. Prefilled Syringe Customer Requirements Research, Voice of the Customer [internal study]. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2018.
2. Becton, Dickinson and Company. TPP20190717 (v0.1)\_BD SCF™ PremiumCoat® Target Product Profile [internal study]. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2020.
3. Becton, Dickinson and Company. DIS20184181\_BD Design Input Specification, Le Pont-de-Claix, France; Becton, Dickinson and Company; 2021 .
4. Becton, Dickinson and Company. Bausch + Ströbel SCF™ PremiumCoat® Plunger Stopper: Proof of processability. BD Medical – Pharmaceutical Systems; 2024.
5. Becton, Dickinson and Company. TR20234488 Le Pont-de-Claix, France; Becton, Dickinson and Company; 2024.
6. Becton, Dickinson and Company. BD SCF™ PremiumCoat® 1-3mL Plunger stopper finite element analysis simulating contact pressure [internal study], Pont-de-Claix, FR: Becton Dickinson and Company; 2022.
7. Becton, Dickinson and Company. TR20233592 Extractable study of BD SCF™ PremiumCoat® 1-3mL.
8. Becton, Dickinson and Company. BD SCF™ PremiumCoat® 1mL R&D data\_[internal study]. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2020. Similar results expected for 1-3mL.
9. Becton, Dickinson and Company. BD R&D System Integration data generation plan road map.