BD Sterifill Advance™

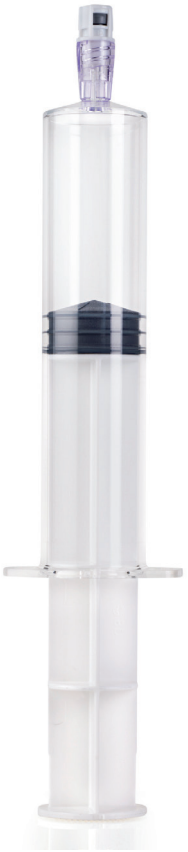
Make it a part of your drug launch strategy

Polymer Pre-fillable Syringe
for Intravenous Drugs

BD

Integrate the BD Sterifill Advance™ Polymer Pre-fillable Syringe into your drug launch or Life Cycle Management strategy

Do you know, approximately **92% of hospital stakeholders*** in a study were willing to use pre-filled syringes for multiple drugs?[1] In fact, transitioning a fixed dose drug from its vial or ampule format to a prefilled syringe (PFS) can serve as a differentiation strategy in a market dominated by vials and ampules.[2,3]



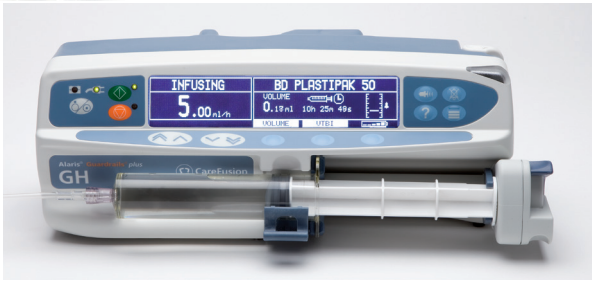
Differentiate

your drug-prefilled device combination with BD Sterifill Advance™ features and benefits:

- Cyclo Olefin Polymer
- **Screw-on tip cap** that is preferred by healthcare professionals over conventional push-on rubber tip cap[4**]
- **Time associated with drug preparation** can be reduced in comparison to conventional, immediate use syringes and vials/ampules[5†]
- Available in sizes 5, 10, 20 and 50 ml
- **Compatibility demonstrated** with different syringe pumps[6‡]

Keep your **First-to-Market** advantage on track

- BD Sterifill Advance™ supports your **"First-Mover"** strategy with usability data from human factors and reports on compatibility with syringe pumps.[8††]
- **This data can help you streamline your drug filing process** and address relevant questions from regulatory bodies on combination product usability.[††]
- BD Sterifill Advance™ polymer pre-fillable syringe has been validated for intravenous manual infusions for 5,10, and 20ml and syringe pump based infusions for 20 and 50ml in human factors studies.[6‡,7§]



Footnotes:

* Stakeholder respondents include risk managers & infection control nurses, intensive care nurses, business/ department managers, pharmacists, and anesthesiologists according to a quantitative survey (n=147) on "Drivers of use of prefilled syringes" conducted in UK, France and Germany. Types of drugs covered were from categories cardiac, anesthetics, pain etc. in the survey.

** The simulated study was a single session, randomized with n=60 HCWs experienced with a daily practice of 50mL. During this study, HCWs performed 8 simulated infusions on BD Sterifill Advance™ 50mL syringes. Tip cap satisfaction levels of HCWs were done through a scoring of 0 (very dissatisfied) to 10 (very satisfied) wherein 90% of HCWs gave S-Lok a score of 8.

† An observational study n=28 comparing preparation using BD Sterifill Advance™ with conventional, immediate use syringe was conducted. On average, preparation time for 5mL BD Sterifill Advance™ was 1:50min whereas for the 5mL immediate use syringe it was 2:56min. Similarly, for 20mL BD Sterifill Advance™ it was 1:09min whereas for the 20mL immediate use syringe, it was 2:23min.

‡ A 2013 clinical study was designed to demonstrate the compatibility (flow characteristics) of BD Sterifill™ 50mL (renamed to BD Sterifill Advance™ 50mL prior to commercial launch) with a panel of electric syringe pumps available on the market for 4 flow rates (1, 5, 25 and 100mL/h) through a total of n=150 simulated Water for Injection (WFI) infusions as per ISO 7886-2. Tested syringe pumps were Perfusor space (B Braun), Module DPS (Fresenius Kabi), Poliot A2 (Fresenius Kabi), Injectomat (Fresenius Kabi) and GH+ Alaris (Becton Dickinson).

§ Human factor results from intravenous, subcutaneous and intra-articular manual injections performed by 15 experienced nurses indicates no technical incident or adverse event was recorded for manual use (5,10 and 20ml) and for pump use (20ml). The difficulty encountered by nurses to select the correct program on the syringe pump highlights importance to provide training to end-users on the use of pump. BD Sterifill Advance™ barrel is not intended to be filled with drugs containing metabisulfite preservatives.

††First-Mover' refers to being first-to-market in a geography with a drug-prefilled syringe combination. Reports referred are for BD Sterifill Advance™ polymer prefillable syringe summary data on compatibility with syringe pumps. Summary of results can be provided; more information is available on request. Human factor studies for BD Sterifill Advance™ are conducted with Water-for-Injection.

References:
1. Drivers of use of prefilled syringes [Internal study, n=147], Le Pont-de-Claix, France; Becton, Dickinson and Company, 2018.
2. Considerations and Options for Prefilled Syringes [External study - White paper], Illinois, USA; Baxter Healthcare Corporation, 2019.
3. Based on extracted IQVIA database - 2019.
4. A simulated study of usability of a new plastic syringe for infusion with electric pump [Internal Document, n=60]. Pont-de-Claix, Becton, Dickinson and Company, 2014.
5. BD Sterifill Advance 5,10 and 20mL Human factor Executive Summary [Human factor study, n=28]. Pont-de-Claix, FR: Becton Dickinson and Company; 2016.
6. A simulated study of performance and acceptance of a new plastic syringe for infusion with electric pump. [Internal Document, n=150]. Pont-de-Claix, Becton, Dickinson and Company, 2013.
7. Summary of Human Factor Validation Study for BD Sterifill Advance™ 5,10 and 20mL syringes [Human factor study, n=28. Pont-de-Claix, FR: Becton Dickinson and Company; 2016.
8. System Integration Challenges in Combination Products for Injectable Drugs [Internal study], Le Pont-de-Claix, France; Becton Dickinson and Company, 2019.

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