

BD HylokTM
Make it a part of your
drug launch strategy

Glass Pre-fillable Syringe for Intravenous Drugs



Integrate the BD Hylok™ Glass Pre-fillable Syringe into your generic drug launch or Life Cycle Management strategy

Do you know, approximately **92% of hospital stakeholders*** in a study were willing to use prefilled 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 ampoules.²³

Differentiate your drug-PFS combination with BD Hylok™ features focused on connection performance:

by users over a standard clip-on tip $cap^{4^{**}}$

Screw-on tip cap is preferred

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

- BD Hylok™ supports your prefilled syringe "First-Mover" strategy with usability data from Human Factors and reports on compatibility with intravenous connectors.^{‡†}
- This data can help you streamline your drug filing process and address relevant questions from regulatory bodies on combination product usability.^{‡†}
- Moreover, the connection performance⁴⁵ of BD Hylok[™] for intravenous applications is validated in Human Factor studies.

Footnotes:

- * Stakeholder respondents include risk managers & infection control nurses, intensive care nurses, business/department managers, pharmacists, and anesthesiologists included in a quantitative survey (n=147) on "Drivers of use of prefilled syringes" conducted in UK, France and Germany.
- ** First use, without Instructions For Use.
- ‡ Connection with commonly used Needleless Access Devices (NLADs) in the acute care USA market were validated.
- ‡‡ "First-Mover" refers to being first-to-market in a geography with a drug-prefilled syringe combination.
 Reports referred are for BD Hylok™ glass prefillable syringe summary data on compatibility with intravenous connectors.
 Summary of results can be provided; more information is available on request.
 Human factor studies for BD Hylok™ were conducted with Water-for-Injection.
- + Comparable products indicate 3 widely used glass prefillable syringe brands with Plastic Rigid Tip Cap (PRTC) based design.
- ++ Terminal steam sterilization cycles at 121°C/2cycles/20 min. Functional tests relating to closure system and luer-lock adaptor connectivity with a minimum sample size of n=30 were conducted to validate resistance of BD Hylok™ glass prefillable syringe and stopper to steam sterilization.
- § Human factor results from 320 manual infusions performed by nurses: No luer lock adaptor rotation or disconnection and no syringe clogging was observed during infusion. For trained clinical users, intended uses and environmental conditions as defined in the Human Factor studies.

§§ 1 mlL format is available. Sizes 1.25 ml to 10 ml are currently under development.

<u>Europe</u>

References

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- 3. Based on extracted IQVIA Smart MIDAS Datapack 2019.
- 4. A simulated study of usability of BD Hylok™ [internal report]. Pont-de-Claix, FR: Becton Dickinson and Company; 2015.
- 6. BD Hylok™ and BD Hylok™ competitor syringes performance evaluation [Internal reports, n=30 for both]. Pont-de-Claix, FR: Becton Dickinson and Company; 2018.
- 7. BD Hylok™ Design verification results [Internal Report]. Pont-de-Claix, Becton Dickinson and Company, 2019.
- 8. System Integration Challenges in Combination Products for Injectable Drugs [Internal study], Le Pont-de-Claix, France; Becton Dickinson and Company, 2019.

BD Medical Pharmaceutical Systems United States 1 Becton Drive

<u>United States</u> 1 Becton Drive Franklin Lakes, NJ 07417 +1 800 225 3310 11 rue Aristide-Bergès 38800 Le Pont-de-Claix France Phone: +33 4 76 68 36 36 - Fax: +33 4 76 68 35 05 Becton Dickinson France S.A.S - Share capital: 64 719 915 € RCS Grenoble B 056 501 711



