

The new BD Sterifill Advance™

Polymer Pre-fillable Syringe

The next-generation,
high performance polymer syringe



BD Sterifill Advance™ delivering greater value to hospitals patients and your pharmaceutical products



BD Sterifill Advance™ is a pre-fillable syringe designed for the injection of large-volume, injectable anesthesia, pain management cardiac therapy and nutrition drugs. Being a ready-to-administer solution, it provides the following advantages:

- No dilution, standard dosage, standard labeling
- Only a few simple preparation steps, no drug transfer
- Reduced risk of microbial contamination¹

BD Sterifill Advance™ is made of CCP (Crystal Clear Polymer)

Crystal Clear Polymer is a proprietary cyclic olefin polymer (COP). While cyclic olefins are advanced plastic materials widely used in the drug packaging industry, BD's CCP material offers numerous benefits for your drug:

- High mechanical resistance, reducing breakages²
- High chemical resistance²
- Compliant with Biocompatibility requirements (ISO 10993 applicable parts)²
- Excellent barrier properties with minimal moisture vapor transmission rate²
- Tested after autoclaving during 20 min at 121°C²
- Easy filling and assembly on readily available processing equipment²
- Little pH variation²

Unlike most other polymers available on the market, BD Crystal Clear Polymer has:

- Glass-like transparency²
- Low porosity and low level of extractables²

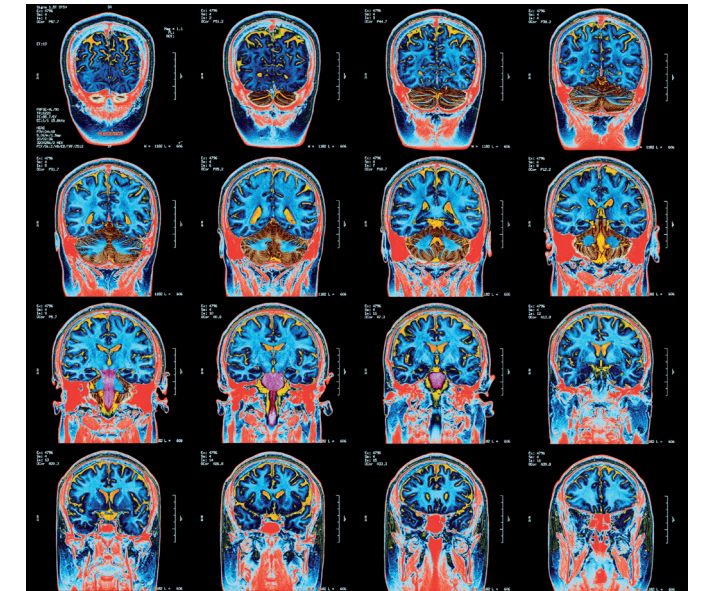
BD Sterifill Advance™ areas of application

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BD Sterifill Advance™ answers hospital needs for available, ready-to-administer solutions that reduce medication errors¹ and risk of microbial contamination¹.

BD Sterifill Advance™ can address a number of drug delivery needs, such as:

- Intravenous infusion of large volumes of intensive care and emergency drugs
- Contrast media
- Highly viscous solutions
 - Hyaluronic acid
 - Other products used in surgery
- Oncology drugs



BD Sterifill Advance™ the next-generation, high-performance polymer syringe

Reduced potential drug interaction and proven performance for a seamless introduction of ready-to-administer drugs in hospitals

Superior primary container design

- Crystal Clear Polymer, a proprietary cyclic olefin polymer (COP) for enhanced drug compatibility and transparency².
- Proven performance and integration with syringe pumps to ensure accuracy and consistency, and to achieve appropriate delivery of the medication¹.
- Designed to mimic the dimensions and behavior of BD Plastipak™ disposable syringes¹, widely used around the world.
- No need to change syringe pump programming practices, reducing the risk of administration errors¹.

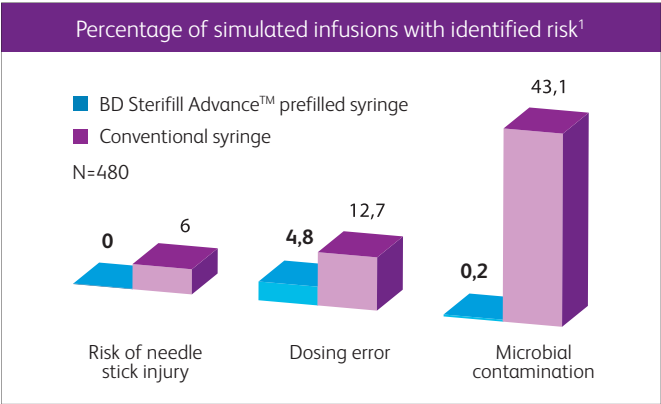


Tested after autoclaving during 20 minutes at 121°C
proprietary BD™ CCP²

Reduces medication delivery errors & contamination

When compared to conventional systems⁴ prepared at time of use, BD Sterifill Advance™ delivers:

- Fast preparation³
- Reduced risk of administration error¹
- Reduced risk of microbial contamination¹



Reliable connection with extension lines thanks to the **specific Luer Lok design**¹

Intuitive, ergonomic and robust screw-on tip closure for enhanced drug integrity **BD S-Lok™**³

New coating for accurate and consistent gliding performances **BD GSi™**¹

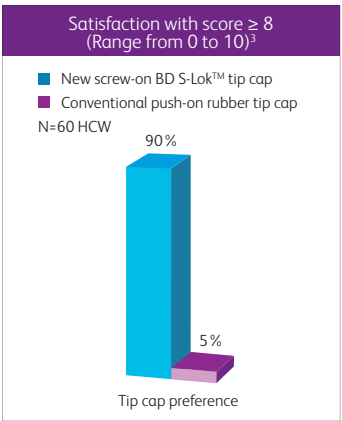
Minimized potential drug interaction thanks to the **low extractable stopper**²



Promotes user preference & safety

After using it for the first time, 95 % of medical practitioners in hospitals would continue to use the prefilled BD Sterifill Advance™ 50 mL syringe¹.

- BD's exclusive screw-on BD S-Lok™ tip cap highly satisfies HCWs when compared to conventional push-on rubber tip caps³.
- The screw-on BD S-Lok™ tip cap eliminates the risk of drug projection during its removal from container, therefore, reducing potential toxic and chemical contamination³.



BD Sterifill Advance™ product line

A wide portfolio to address your evolving needs

Main features

- BD™ CCP: proprietary polymer tested after autoclaving for 20 minutes at 121°C
- Integrated Luer Lok
- BD S-Lok™: screw-on tip cap
- BD GSi™: coating for accurate and consistent gliding performances
- Pump compatible for the 20 mL and 50 mL format
- Low extractable stopper



SIZES	5 mL	10 mL	20 mL	50 mL
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BD Medical – Pharmaceutical Systems

Supporting your drug development with a full range of services

Establishing and maintaining our customer’s trust is at the forefront of our collaboration effort. Decades of experience working closely with you has provided us with expertise and proven track records regarding:

- Drug/container/device integration
- Product quality and quality-control efficiency
- Supply assurance
- Registration requirements
- Problem resolution

When you partner with BD Medical - Pharmaceutical Systems, you also have access to following benefits:

Consultative services on drug delivery options

With deep, skills in human factor engineering and worldwide expertise in developing solutions, BD offers an intimate knowledge of the many issues affecting your product. To support our customers, we ensure the functionality of the drug delivery system, providing consultative expertise to help customers quickly and easily choose the most suitable delivery system.

Regulatory support to optimize time-to-market

BD Medical - Pharmaceutical Systems Regulatory Affairs team offers regulatory expertise on worldwide registration of pre-fillable delivery systems to support customers with their applications and optimize time-to-market. Depending on the targeted region(s) for registration, the BD Medical - Pharmaceutical Systems Regulatory Affairs team provides:

- A Letter Of Authorization (LOA) for applications in the United States (CDER, CBER, CDRH, CVM), Canada and Australia.
- A Technical Dossier (TD) of BD container closure system under a signed Confidentiality Disclosure Agreement (CDA), for enabling the preparation of your applications.
- A case-by-case customized regulatory support based on your specific needs

Request your LOA and TD online in just a few clicks on: <http://www.bd.com/pharmaceuticals/regulatory>.

Compatibility testing to mitigate risk

BD provides rigorous compatibility testing of container packaging components well in advance in their marketing. If required, BD can also propose tailored extractables & leachables (E&L) studies, mechanical data, and functional data for regulatory or registration purposes.

Global reach and capacity to ensure business continuity

With offices in more than 50 countries, BD has both the familiarity of the global marketplace and the manufacturing capabilities to ensure supply continuity. Our global reach enables us to minimize the impact of unexpected events. Our global management network and high-level quality-assurance system ensure consistent processes to meet product specifications.

(Pre)Clinical and Usability assessment Data to support registrations

The Medical Affairs Department is responsible for the safety of our products. We can support your registration efforts by sharing summaries of preclinical (including toxicology) clinical and Human Factor data generated to assess efficiency and safety of our products. Our Medical Affairs team can also work with you to integrate this evidence in your regulatory strategy and, when needed support you in the development of studies tailored to your combination product development strategy.

BD Sterifill Advance™

The right choice for your pharmaceuticals

Compared to a disposable syringe filled at time of use, BD Sterifill Advance™:

- Delivers improved patient safety and treatment¹³
- Is designed to become the container and injection device of choice for healthcare workers and hospital management

References and notes:

1. STP01 BD Clinical Study on performance, safety and acceptance of BD Sterifill™ 50 mL for infusion with electric pump.
2. Extractables on components [design verification tests]. 2009. Leachables on system [design verification tests]. 2013.
BD CCP and Topas 6015 COC visual properties: coloration, microvoids and transparency by Mark Quinto [comparative assessment]. 2003.
3. STP02 BD Clinical Study on usability of BD Sterifill Advance™ 50 mL.
4. "Conventional system" defined as vial, diluent, needle and disposable syringe.

BD Medical

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