BD Physioject™ Disposable Autoinjector

Track record at a glance

10+ Chronic illnesses treated with biologics administered using the BD Physioject™ Disposable Autoinjector

15+ Pharmaceutical companies using the BD Physioject™ Disposable Autoinjector for the development and commercialization of combination products

9+ Drugs launched by pharmaceutical companies in the BD Physioject™ Disposable Autoinjector

9 Human factors studies conducted (7 Formative, 2 Summative) [3,4,5]

8 regions where the BD Physioject™ Disposable Autoinjector is used with approved medications**

118M+

BD Physioject™ Disposable Autoinjectors sold since launch for commercial use [1]*

600+ Individuals participated in the BD Physioject™ Disposable Autoinjector human factor studies [3,4,5]

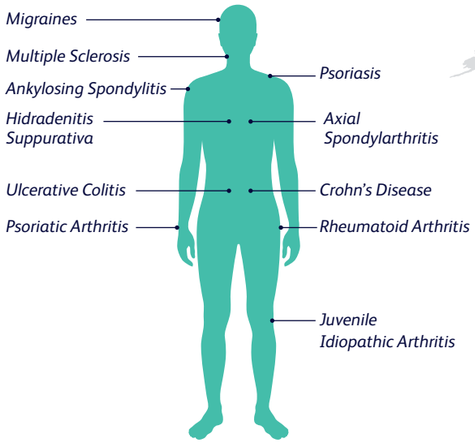
10+ Years since first regulatory approval and supporting the delivery of medications in global markets [6]

* Since 2010. ** Includes regions such as the EU, United States, Russia, Canada, Japan, Argentina, and India.

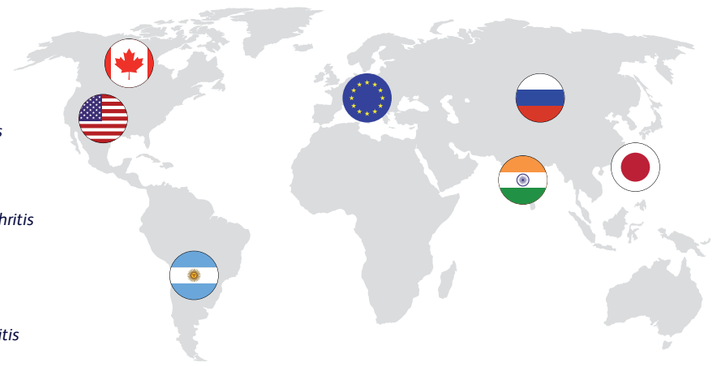
BD

Helping patients manage their chronic diseases around the world

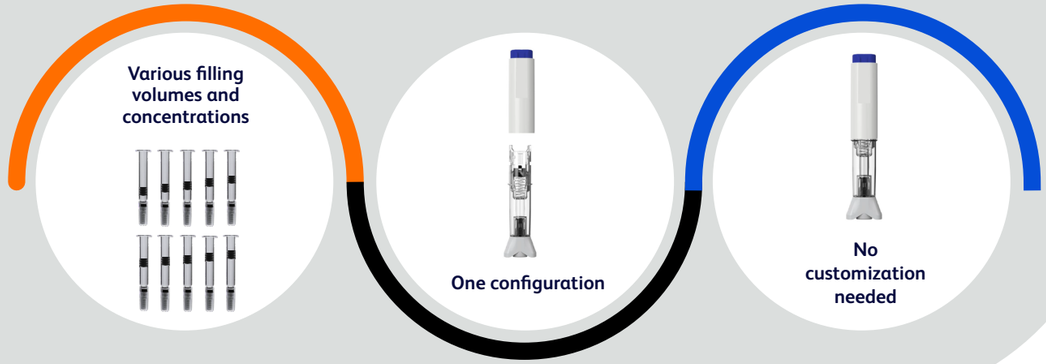
Chronic illnesses treated with medications delivered using the BD Physioject™ Disposable Autoinjector



BD Physioject™ Disposable Autoinjector usage in approved combination products



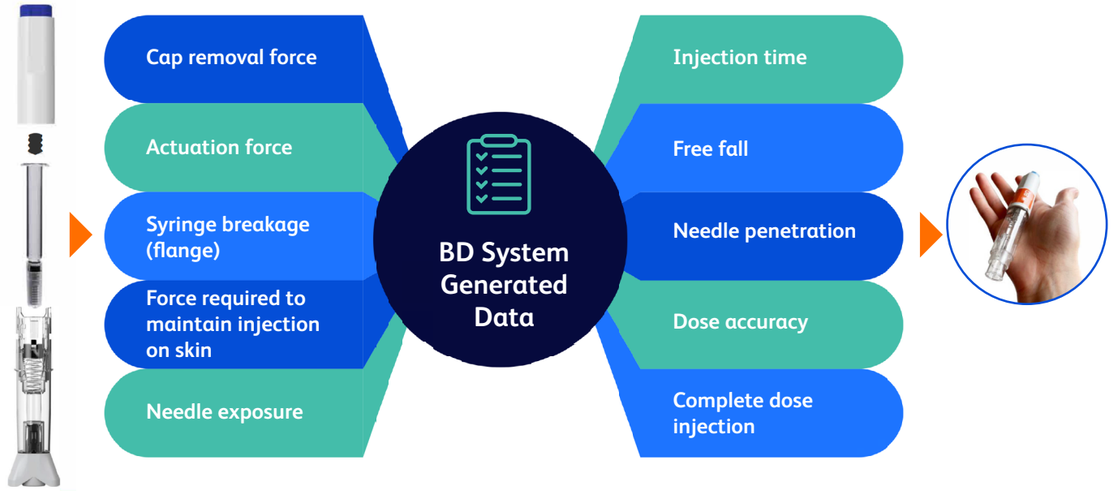
Platform solution capable of meeting the needs of your diverse pipeline



Clinically validated design[3] and demonstrated patient usability

- **90.8% of patients** with rheumatoid arthritis in a human factors study found the **force** required to press the button was **acceptable.***,[4]
- **90% of participants** in a human factors study were **willing to accept** self-injection with the BD Physioject™ Disposable Autoinjector when prescribed by a doctor. **,[4]
- **40 healthy volunteers** in a clinical study reported **significantly less pain** when injections were self-administered by the BD Physioject™ Disposable Autoinjector than when given by nurses with a prefilled syringe (P<0.0001). ‡,[3]
- Patients with rheumatoid arthritis found it useful to be able to check if the injection was complete by viewing the drug through the **360˚ drug viewing window** in the BD Physioject™ Disposable Autoinjector during a human factors study. §,[4,7,8]
- **All patients** at the end of a clinical study **preferred** to self-inject with the BD Physioject™ Disposable Autoinjector in comparison to an injection given by a nurse using a prefilled syringe.¶,[3]
- **Integrated needle covering system** was automatically deployed and locked in **100%** of cases during human factors# and clinical studies. ‖,[3,4]

BD Physioject™ is designed for full integration with BD pre-fillable solutions to drive performance reliability and help mitigate risk



Extensive documentation and regulatory support is available to help streamline your combination product development timeline

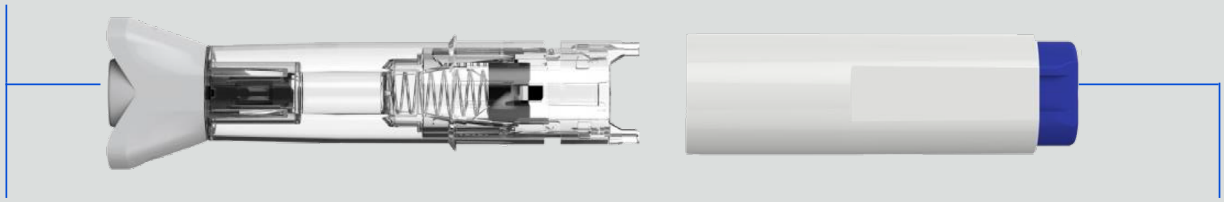
- Customer Product Specifications
- Customer Drawings
- BD Design Verification Summary Report
- Biocompatibility Statement
- Materials of Concern and Safety information
- Intended Use and Residual Risk Information
- BD Physioject™ Validated Directions for Use (DFU)
- Human Factors Engineering Summary Report
- List of Machine Manufacturers for Final Assembly
- Summary of Test Methods for Incoming Inspection
- Letter of Authorization (LOA)/Technical Dossier (TD)
- Final Assembly Recommendation

***** In a human factors study with 65 patients with rheumatoid arthritis, 59/65 participants (90.8%) gave a score ≥6 on a 0-10 Likert scale for acceptance of required force to press the button and trigger the injection. ****** In a human factors study with 65 patients with rheumatoid arthritis, after 6 simulated injections, n=59/65 (90.8%) of patients with rheumatoid arthritis gave a score ≥6 on a 0-10 Likert scale for acceptance of further self-injections with BD Physioject™ Disposable Autoinjector. **‡** This was a randomized, single-center, crossover study comparing SC self-injection using an autoinjector with SC nurse-administered injection using a syringe. Two volumes (0.2 mL and 1 mL) were injected into 40 healthy volunteers. Immediately after each of the 960 injections, Pain was measured using a 100mm Visual Analogic Scale (VAS), ranging from 'no pain' to 'very painful'.

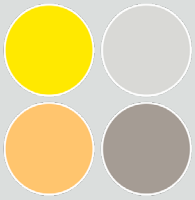
§ In a human factor study with 65 patients with rheumatoid arthritis, the mean score on a 0-10 Likert scale on the usefulness for the end user to be able to check the injection completeness was 9. **¶** In clinical study with 40 healthy volunteers, at the end of the last session, subjects were told they will have an unscheduled additional injection. The results showed that all the 40 subjects (100%) preferred the BD Physioject™ Disposable Autoinjector for that injection (which was not done, the question was just for informational purposes).**#** In a human factors study with 65 patients with rheumatoid arthritis, 100% (n=390/390 injections) of passive sharp injury prevention feature activation was recorded. **‖** In a clinical study with 40 healthy volunteers, the passive sharp injury prevention feature activation was recorded 100% (n=480/480 injections) of the time.

Customizable features to support your brand strategy and drug delivery needs

Needle cover ◯ Clear ◯ Frosted



Lower sub assembly - Cap



Exposed needle length* 6mm or 8mm

Top sub assembly - button

* 'Illustration only. Not representative of actual injection depth.

1. BD WW Demand Database, 2012-2021

2. BD Quality System complaint data - Complaint extract for reported user complaints related to system integration

3. Berteau, Cecile, et al. "Evaluation of performance, safety, subject acceptance, and compliance of a disposable autoinjector for subcutaneous injections in healthy volunteers." Patient Preference and Adherence. 2010:4 379-388

4. Schwarzenbach, Florence, et al. "Results of a human factors experiment of the usability and patient acceptance of a new autoinjector in patients with rheumatoid arthritis." Patient Preference and Adherence. 2014:8 199-209

5. Summary Report - BD Physioject Formative Evaluations (CHFIN 21-31)

6. Press Release: October, 2010

7. Physioject™ external R&D document. Design Control Evidence of BD Physioject™ with Hypak™ for BTH 1mL Long Size [external report]. Pont-de-Claix, FR: Becton, Dickinson and company; 2021

8. Physioject™ design verification report [internal report]. Pont-de-Claix, FR: Becton, Dickinson and company; 2014

bd.com