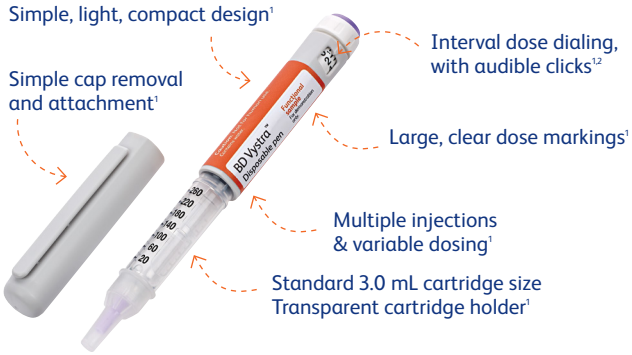
BD solutions for enabling delivery of complex biologics

BD Vystra™ Disposable Pen for the self-injection of chronic disease medications

Compatible with standard pen needles[1]



- Disposable, variable dose pen injector for the self-injection of medications
- Configured to integrate into a reliable system with standard drug cartridges
- Dose delivery: up to 0.8 mL total dose
- Compliant with ISO 11608, US 21 CFR 820.30, and ISO 13485 certifications (for Design Center and Assembly Plant) to verify that product and processes meet regulatory agency expectations[3-7]

Key benefits

Designed for use with a **wide range** of drug therapies that require **variable dosing:**[10]

- **Adjustable features** and **clear dose markings** to support self-injection and **ease of use**[10]
- **Patient Centric Design**
  Over 100^ Patients, HCPs & Experts informed the BD Vystra™ Disposable Pen injector design[1,2,10]
- Comes with regulatory and technical documentation including but not limited to:
  - **Human Factors Engineering Report**[1,2]
  - Validated platform **Instructions for Use** (IFU) available for reference[11]
  - Technical information to support Regulatory Submissions: **Master File (MAF)** for US Market and **Technical Dossier (TD)** for Key Global Markets[11,12]
  - R&D documentation to support development activities**

Experience

- Used globally in marketed drug combination products in markets such as but not limited to Europe, Australia, India, Japan and the United States[18, 21]
- Launched to pharmaceutical organizations for development in 2012[19]
- Protected by >100 patents worldwide on pen injection technology and supported by thorough freedom to operate analysis[22,23]

Availability

- Samples readily available
- Available in pre-configured combinations through the BD PartnerPath™ Program*

^ 103 participants

* BD Vystra™ is not offered off the shelf and requires a services agreement

** R&D documentation such as - Design Verification Summary Report[13] Cartridge Specification Recommendation,[14] Final Assembly Recommendations[15,16] BD Vystra™ ISO 10993 Compliance statement[8] Materials of Concern/Technical Data Sheet[9]

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