

BD solutions for enabling delivery of complex biologics

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



Compatible with standard pen needles¹

Simple, light, compact design¹

Simple cap removal and attachment¹

Interval dose dialing, with audible clicks¹²

Large, clear dose markings¹

Multiple injections & variable dosing¹

Standard 3.0 mL cartridge size
Transparent cartridge holder¹

- 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}

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 2012¹⁹
- 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 Report¹⁹ Cartridge Specification Recommendation,⁶ Final Assembly Recommendations^{5,8} BD Vystra™ ISO 10993 Compliance statement⁴ Materials of Concern/Technical Data Sheet⁹

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^{12,10}
- Comes with regulatory and technical documentation including but not limited to:
 - **Human Factors Engineering Report**¹²
 - Validated platform **Instructions for Use (IFU)** available for reference¹¹
 - 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**



References

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