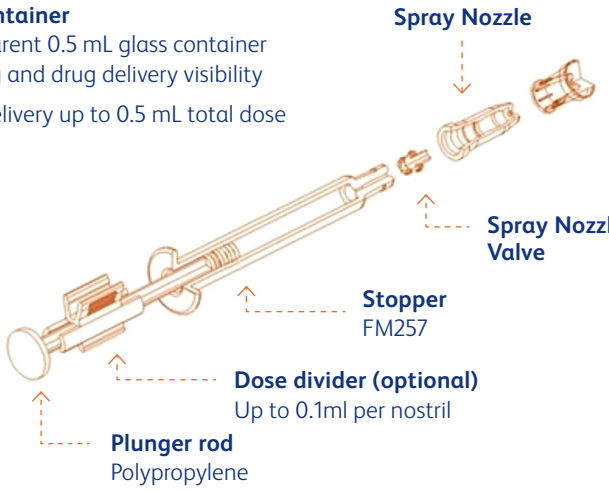
BD tools for vaccine combination product developers

# BD Accuspray™ Nasal Spray System

## Monodose or bidose nasal prefillable delivery system

**Glass container**
- Transparent 0.5 mL glass container for drug and drug delivery visibility
- Drug delivery up to 0.5 mL total dose




### BD Accuspray™

- Disposable system for nasal administration of vaccines
- Non-reusable, single use nasal sprayer for monodose or bidose administration
- BD Accuspray™ complies with ISO 10993-1[1]; USP <381>[2], <660>[3,6], <661>[4]; Ph Eur 3.1.8[5], 3.2.1[6], 3.2.9[2]

### Key benefits

- **Intranasal delivery is preferred** (88,3%) if given the option between intranasal or injectable vaccination[7]
- **Easy to vaccinate**[8]
- **Suitable for high quantities and cold chain**[9] **when space is critical:** small size barrel contributes to reduce storage space
- **Suitable for deep cold storage** conditions (-20°C and -40°C)[9]
- **Based on BD Hypak™ for Vaccines Glass Prefillable Syringe for easy implementation on filling lines**
  - Product can be filled on standard PFS filling line worldwide
  - Leverage internal/external filling infrastructure
  - Products are provided Sterile, Clean and ready to Fill* (BD SCF™)
- Broad range of **value added services***
  - Functional tests in c-GMP compliant labs
  - Regulatory expertise in combination product

### Experience

- More than 100 million[10] units of FluMist® and Fluenz™ sold with BD Accuspray™ since 2003 – the only EMA[11] and FDA[12] intranasally-delivered vaccine

### Availability

- Samples available on demand
- Commercial availability to be evaluated against requirements

* Barrel and spray nozzle are delivered assembled, to be further assembled with stopper and plunger rod.

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**References**


1. Materials Of Concern And Safety Information, 442.MOCASI.28, valid from April 2021
2. USP <381> “Elastomeric Components in Injectable Pharmaceutical Product Packaging/Delivery Systems” (Dec. 2020) and EP 3.2.9 “Rubber Closures for Containers for Aqueous Parental Preparations, for powders and for freeze-dried powders” (Jul 2018) compliance statement for W7028/ 55, STMT-QE20213696, Sept. 2021
3. USP <660> “Containers-Glass” (May 2015), STMT-20161598, April 2021
4. USP <661> “Plastic packaging systems and their materials of construction”, STMT-QE20213531, Sept. 2021
5. Ph Eur 3.1.8 "Silicone oil used as a lubricant“, STMT-QE20170709, Dec 2020
6. Hydrolytic resistance conformity of glass canes to the new version of EP 3.2.1.“Glass containers for pharmaceutical use”, STMT-QE20191153, April 2019
7. Sheldon et al. (2013) Immunogenicity of a quadrivalent Ann Arbor strain live attenuated influenza vaccine delivered using a blow-fill-seal device in adults: a randomized, active-controlled study. Influenza and Other Respiratory Viruses 7(6), 1142–1150
8. Dubé et al., April 2015, Acceptability of live attenuated influenza vaccine by vaccine providers in Quebec, Canada, Human Vaccines & Immunotherapeutics. Survey conducted to explore knowledge, attitudes and practices of 314 vaccine providers regarding use of LAIV. During the vaccination campaign, 71% of responded having used LAIV
   Almost all of these respondents indicated that it was easy to vaccinate children with the vaccine (57% strongly agreed)
9. BD internal references, EF20202208, EF20202618, EF20203052,TP20211855, TR20213724, EF20213171 BD-01-SR-01, BD-02-SR-01, BD-03-SR-01, BD Medical – Pharmaceutical Systems Le Pont de Claix, France
10. BD sales analysis [internal analysis]. Pont-de-Claix, FR: Becton, Dickinson and Company; 2021.
11. Article 57 product data, EMA, https://www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/public-data-article-57-database, Access 04/04/2022
12. Vaccines Licensed for Use in the United States, FDA, https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states, Access 04/04/2022



**BD Medical**
Pharmaceutical Systems
United States
1 Becton Drive
Franklin Lakes, NJ 07417
+1 800 225 3310
Europe
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


bd.com