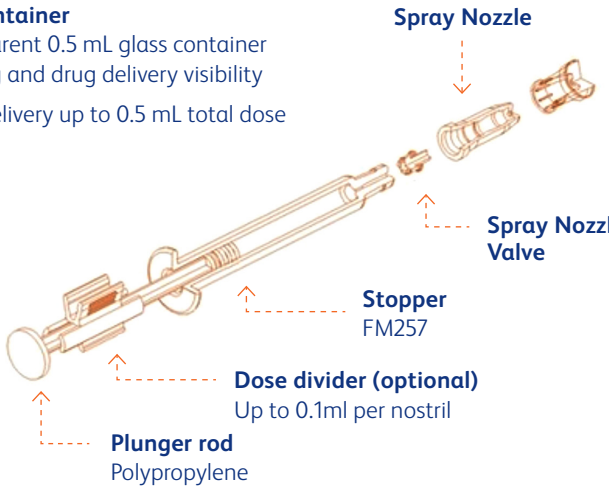
BD tools for vaccine combination product developers

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.

BD

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

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