

Information about LOW DEAD-VOLUME SYRINGES AND/OR NEEDLES for Pfizer-BioNTech COVID-19 Vaccine

Pfizer-BioNTech COVID-19 Vaccine is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The use of Pfizer-BioNTech COVID-19 Vaccine is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 [Interim order \(IO\)](#)*. Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's *IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*.

*<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8>

Dead volume (also called 'dead space') is the amount of fluid remaining within the syringe and needle after an injection is completed.²

Low dead-volume (LDV) syringes and needles are designed to reduce this wastage

<p>HIGH dead-volume needle and syringe^{2,3}</p>	<p>LOW dead-volume modified syringe^{2,3}</p>	<p>LOW dead-volume detachable needle^{2,3}</p>	<p>LOW dead-volume fixed 'all in one' needle and syringe^{2,3}</p>
<p>Withdrawal of 6 doses is unlikely with standard detachable needles with standard syringe[†]</p>	<p>LDV SYRINGES have plungers molded to the luer cone, allowing fluid to be cleared from the syringe tip during injection</p>	<p>LDV NEEDLES have an extension of the needle that fits through the opening of some standard syringes, allowing for a reduction in dead space</p>	<p>FIXED-NEEDLE SYRINGES have low dead volume</p>

● = residual volume

Adapted from Kesten et al. 2017

In order to extract 6 doses from a single vial of Pfizer-BioNTech COVID-19 Vaccine, the low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres (0.035 mL).^{4†}

Process to test syringes/needles for LDV compatibility:⁴

- Assemble needle and syringe, and remove needle shield.
- Weigh empty needle and syringe combination with a high-precision balance (accurate to 1 microgram) and record weight in grams.
- Draw up water into syringe, ensuring no large air bubbles are remaining in the barrel, and then depress the plunger completely to expel the water. The water remaining within the needle and syringe is the dead volume.
- Weigh needle and syringe containing remaining water dead volume, record weight.
- Subtract weight of empty needle and syringe from the weight of the needle and syringe containing the water dead volume.
- The weight of the water in grams is equal to the milliliters of dead volume.

Repeat for 6 syringes to get the average hold-up. It should be ≤ 0.035 mL to ensure 6 doses are extractable. Results greater than 0.05 mL are not likely to achieve 6 doses.^{4†}

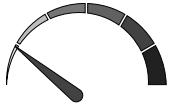
6 doses of Pfizer-BioNTech COVID-19 Vaccine in a vial[†]

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial.^{††}

[†] Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information on this document and in the Product Monograph regarding the number of doses per vial after dilution supersedes the number of doses stated on the vial labels and carton.

STEPS AND SUGGESTED TIPS ON DRAWING 6 DOSES PER PFIZER-BIONTECH VACCINE VIAL*

Refer to the STEPS Leaflet or visit CVDvaccine.ca for complete preparation and administration instructions



DO NOT RUSH


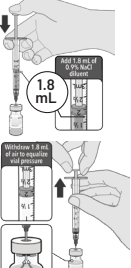


Successful extraction of all 6 doses* requires accuracy.

Taking the time to properly measure out diluent and vaccine is important.

Equilibrate and dilute

Strict adherence to aseptic technique must be followed.

STEPS

- 1**  • After thawing and prior to dilution, ensure the vial is equilibrated to room temperature. Invert gently 10 times. Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if liquid is discoloured or if other particles are observed.
- 2**  • Using aseptic technique, withdraw **1.8 mL** of 0.9% Sodium Chloride Injection, USP into a transfer syringe (21-gauge or narrower needle). Use only this as the diluent.
- Cleanse the vaccine vial stopper with a single-use antiseptic swab. **Add 1.8 mL** of 0.9% Sodium Chloride Injection, USP into the vaccine vial. You will feel pressure when adding diluent to the vaccine vial – **this is normal.**
- Ensure vial pressure is equalized by **withdrawing 1.8 mL of air** into the empty diluent syringe **before removing the needle from the vaccine vial.**
- 3**  • Gently invert the diluted vial 10 times to mix. Do not shake.
- Inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discoloured or contains particulate matter.
- 4**  • Record the date and time of dilution in the appropriate place on the Pfizer-BioNTech COVID-19 Vaccine vial label.
- Use within 6 hours from the time of dilution. If not used within 6 hours, it should be discarded. Store between 2°C to 25°C (35°F to 77°F).

The tips included in this document are based on the experience of a healthcare professional, and are provided in an informational context only. Pfizer cannot guarantee that by solely following these tips, 6 vaccine doses can be extracted from each vial.

SUGGESTED TIPS⁴

Take your time:

- Withdrawing diluent too quickly may result in bubbles.

Be precise:

- Do not add more or less than 1.8 mL of diluent.

Hold the vaccine vial firmly on a flat surface while diluting

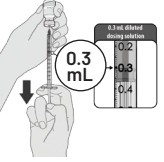
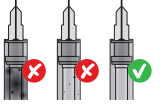
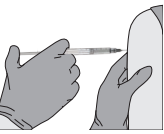
Press plunger slowly:

- Adding diluent to the vaccine vial too quickly may cause fizzing.
- The pressure in the vials is not typical of other multi-dose vials.

For air withdrawal:

1. With your thumb still pressed against the plunger, bring the needle to the part of the vial that is filled with air.
2. Release the plunger. Pressure in the vial may push some air into the syringe.
3. Withdraw 1.8 mL of air into the empty syringe, making sure no vaccine volume is drawn with it (should this happen, expel the vaccine volume from the syringe, with its needle still in the vial and ensure you return the plunger to 1.8 mL of air).
4. Pull the needle out of the vial.

Prepare and administer

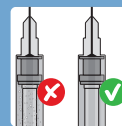
- 5**  • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and slowly withdraw 0.3 mL of Pfizer-BioNTech COVID-19 Vaccine, preferentially using low dead-volume syringes and/or needles.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Administer immediately, and no later than 6 hours after dilution.
- Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction.
- **Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of vaccine.**
- It is recommended to use the same needle to withdraw and administer the dose whenever possible. If a second needle is required for administration, pull back on the syringe plunger until a small amount of air enters the syringe prior to removing the first needle in order to avoid loss of dosing solution during the needle change. Place a new needle before releasing the plunger.
- 6**  Do a visual inspection to verify the final dosing volume of 0.3 mL and the absence of particulates and discoloration. Do not administer if vaccine is discoloured or contains particulate matter.
- 7**  Administer the vaccine intramuscularly in the deltoid muscle of the non-dominant arm immediately. Do not inject the vaccine intravascularly, subcutaneously or intradermally.

The tips included in this document are based on the experience of a healthcare professional, and are provided in an informational context only. Pfizer cannot guarantee that by solely following these tips, 6 vaccine doses can be extracted from each vial.

SUGGESTED TIPS⁴

Do not draw more than 0.3 mL of vaccine

Go slow: Withdrawing the diluted vaccine too quickly may result in fizzing.



If bubbles appear, restart if necessary by expelling the drawn volume and redrawing the dose only while still in the vial.

When drawing the 6th dose, place needle tip just inside rubber stopper; slightly tilt vial and ensure the needle bevel is facing down and close to the vial neck to collect remaining vaccine in order to draw a full dose of 0.3 mL.

Consideration for practice: Where permissible, train a few key personnel to mix and load properly

For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic and then dried before each withdrawal.

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Please consult the Product Monograph at www.pfizer.ca/pm/en/COVID-19Vaccine.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available upon request by calling 1-833-VAX-COVI (1-833-829-2684).

References: 1. Pfizer-BioNTech COVID-19 Vaccine. Product Monograph. Pfizer Canada ULC. 2. Strauss K, van Zundert A, Frid A, Costigliola V. Pandemic influenza preparedness: The critical role of the syringe. *Vaccine* 2006;24:4874–4882. 3. Kesten JM, Ayres R, Neale J *et al.* Acceptability of low dead space syringes and implications for their introduction: a qualitative study in the West of England. *Int J Drug Policy* 2017;39:99–108. 4. Pfizer Inc. Data on File. 2021.



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