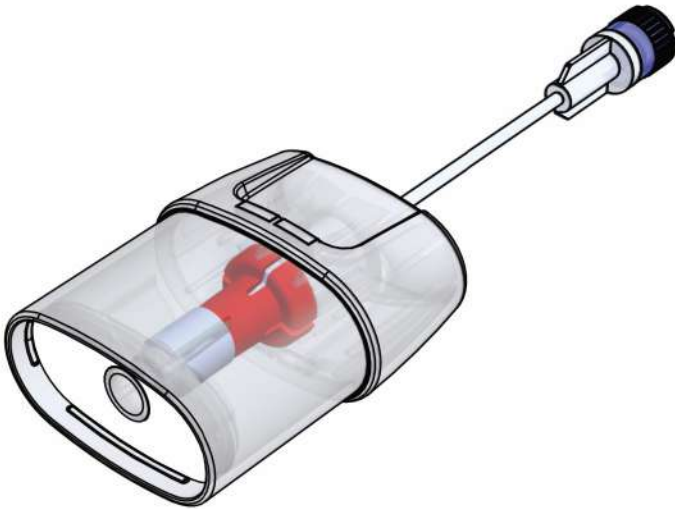


P P

Soft mist inhaler



Intended Use

Medical purpose: Pulmospray™ is a single-use, non-active soft-mist inhaler for administration of single doses of inhalation solution to the lower respiratory airways. The device is intended for use in combination with the Respi Lever Drive actuation device and a Luer-Lock Syringe (1mL) manufactured from BD or other syringes specified by the manufacturer.

Conditions to be treated: The Pulmospray™ inhaler can be used for medication therapy of infectious diseases as COVID-19 (ICD-10: U07.1) with medicinal products (inhalation solutions) intended for inhalation with a soft-mist inhaler.

Intended user(s): The Pulmospray™ can be used by adult patients for self-administration under supervision of a health care professional or administrated by the health care professional to the adult patient.

Environment: The device is suitable for use at hospital and general practice.

Portability: Pulmospray™ is a portable, handheld device.

Single use: The Pulmospray™ is for single patient use and single-use applications.

Use duration/contact: Pulmospray™ is in contact with intact skin, mucous membrane and in indirect blood contact (inhalation of liquid in contact with syringe, spray nozzle unit, tubing).

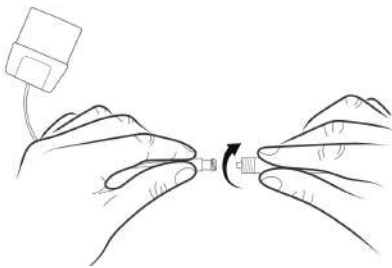
Contra indications: There are no contra indications known related to Pulmospray™. There may be contra indications defined for the inhalation solution.



1 Fill

Take the Luer-lock 1 ml syringe and fill it with the prescribed medication in appropriate dose.

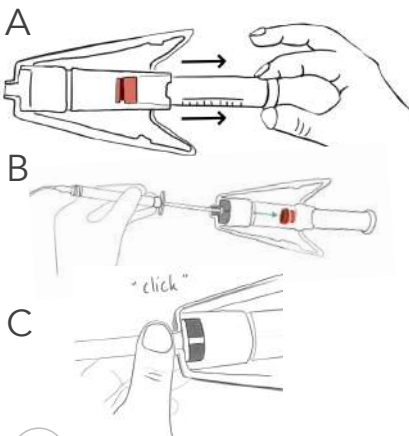
Make sure the correct syringe is used.



2 Connect

Unpack a Pulmospray™ device from an undamaged pouch. When not in use keep the device on a clean, flat surface.

Connect the Pulmospray™ to the prefilled syringe by turning the syringe clockwise (see arrow image).

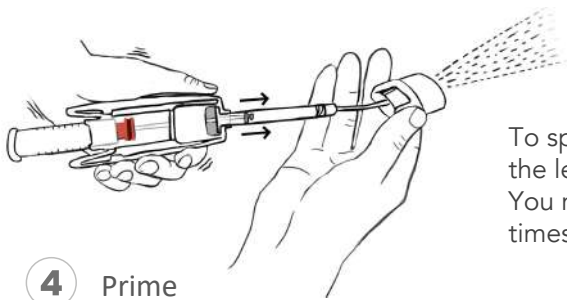


3 Insert into Respi Lever Drive

Prepare the Respi Lever Drive by pulling out the pusher until it reaches the end stop, see Respi Lever Drive IFU.

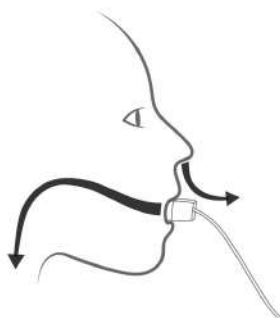
Insert the syringe plunger into the Respi Lever Drive carefully and click the syringe in place.

Make sure you „click“ the syringe in place at its flanges (bottom picture).



To spray: Fully **compress** and **hold** the levers.
You may need to do this several times before you see the first spray.

4 Prime



During inhalation, sit upright and tilt your head slightly upwards. Place the mouthpiece on top of the front of your tongue and close lips around it. Inhale slow and deeply.

Before administration, practise inhaling through the mouth and exhaling through the nose. If this is not possible, exhale through the mouth with mouthpiece removed.

5 Patient practice

Never exhale through the mouthpiece!

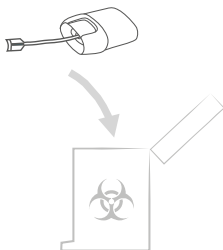


When subject inhales, compress the levers of the Respi Lever Drive™ quickly and completely.

Hold the levers compressed for up to 3 sec. Then quickly release the levers. Never keep levers compressed when subject exhales.

6 Dose Administration

Watch the syringe to see how much medication has been dispensed. Repeat actuations until the syringe is empty and the full dose is administered.



7 Discard

Pull the empty syringe from its holder in the Respi Lever Drive™

Dispose the used Pulmospray™ and syringe according to standard clinical procedure.

Information for safety

Warnings

- Single use device. Dispose after procedure.
- For use by trained medical professionals only.
- Only use with approved prescribed substances for inhalation with a soft mist inhaler.
- Using a contaminated device introduces risk of respiratory tract infection.
- Do not use device if device is damaged. Using a damaged device introduces risk of choking.
- Not following IFU inhalation instructions may lead to dyspnea.
- Not following IFU dosing instructions may lead to dyspnea.

Cautions

- Do not use passed expiry date.
- Do not use device if packaging is damaged.
- Not following IFU assembly instructions may lead to dyspnea.
- Exhaling through the Pulmospray may reduce treatment efficacy and lead to dyspnea.
- Leakage of the device may indicate a malfunction or improper assembly, which leads to a reduced treatment effect. A new dose and device may be required.

Product information

Product name Pulmospray

Article No. (REF) 5913

Performance specifications

Compatible inhalation solutions Solutions approved for inhalation with soft mist inhalers.

Max fill volume 1 ml

Min fill volume 0.3 ml

Residual volume 0.15 ml

Device mass 10 grams

Dimensions 41 x 50 x 23 mm

Tube length 55 mm

Connector Luer-Lock

Shelf life 1 year

For aerosol data please contact Medspray B.V.

Parts necessary for correct use

Actuation aid 5915 Respi Lever Drive

Liquid container - BD 1mL Luer Lock (PC)
Article REF: 309628
- Or other syringes specified by the manufacturer



Medspray B.V.
Colosseum 23, Enschede
The Netherlands