

Instructions for Use of Carrying Accessory for VYAFUSER™ Pump

VYAFUSER™ is a trademark of AbbVie AB.



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These Instructions for Use are
to be used exclusively with the
VYAFUSER™ Pump.



This Instruction for use is available on Phillips-Medisize website
<https://www.phillipsmedisize.com/ifu>

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Carrying Accessory Instructions for Use (IFU) is referenced in the patient Instructions for Use of VYAFUSER™ PUMP.

Patient IFU is intended to be used by advanced Parkinson's patients, their Caregivers and HCPs. Patient Instructions for Use contains instructions on how to use the pump and accessories to deliver the drug. Specific individual component IFUs (i.e., preparing solution IFU, carrying accessory IFU, vial adapter IFU, mains adapter IFU, battery charger IFU, and infusion set IFU) are referenced in the patient IFU.

HCP IFU is only intended for HCP to program the pump. HCP IFU contains instructions on how to program the pump for a particular patient and the relevant technical specification.

Collectively, patient IFU and HCP IFU form the complete set of delivery system IFU.

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1. Carrying Accessory Parts

1.1 Intended Use

AbbVie's Parkinson's Drug Delivery System is an automated drug delivery system intended for the infusion of AbbVie's foscarnidopa and foslevodopa drug product to treat advanced Parkinson's disease.

The VYAFUSER™ Pump is an ambulatory infusion pump intended for the subcutaneous delivery of AbbVie's foscarnidopa and foslevodopa drug product. The VYAFUSER™ pump and carrying accessory are part of the AbbVie's Parkinson's Drug Delivery System. The carrying accessory facilitates ambulatory use of the pump.

1.2 Intended User

The VYAFUSER™ Pump and Carrying Accessory are intended to be used by adult patients with advanced Parkinson's disease, caregivers, and healthcare professionals.

1.3 Indication for Use

The Carrying Accessory is indicated for use by patients with advanced Parkinson's disease that are in treatment with the VYAFUSER™ pump.

1.4 Contraindication

None.

1.5 Introduction

The Carrying Accessory is qualified to carry the VYAFUSER™ Pump on the patient's body. Two belts and one strap allow it to work in different ways, as you most prefer.

The Carrying Accessory is not designed to keep the Pump dry. It doesn't protect the pump from water droplets in a shower or rain or from other liquid spills.

Two belts are included. This allows you to choose the one that fits best and they connect together for additional length.

The belt(s) allow you to wear the Carrying Accessory around your hips and to orient the Pump horizontally or vertically.

The strap allows you to wear it on your neck.

Both the strap and belt may be used to allow for a tighter fit.

The Carrying Accessory includes (see *Figure A*):

- Carrying Case (called “Case” in these instructions)
- Removable Flap
 - Used to cover the Pump buttons.
 - Can be removed entirely.
- 2 Belts (wider than strap and with buckle)
 - Used to secure the Case on the hip.
 - 2 belts can be connected to create a longer belt.
 - The belts are marked with “S” for short and “L” for long.
- Strap (thinner strap with snap hooks and neck pad)
 - Used to secure the Case on the neck or across the body.
 - Packaged inside the Case when shipped.

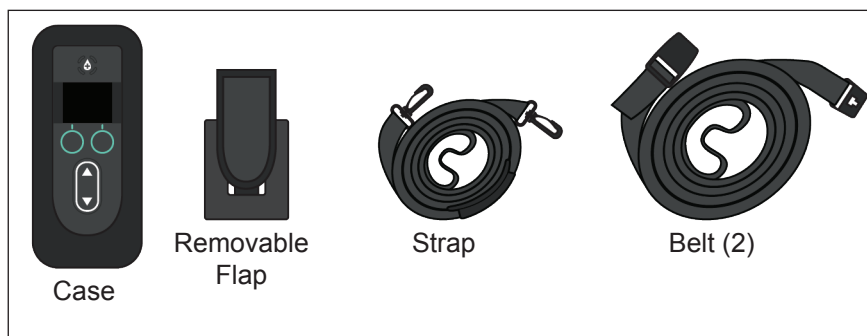


Figure A

2. How to Carry the Pump

Wear the Carrying Accessory in a way that is comfortable for you and that gives you easy access to interact with the Pump.

Caution: To minimize the risk of strangulation, **do NOT** use the Carrying Accessory in a way such that the strap or belts could wrap around your neck.

Note: When the Syringe is in the pump and the infusion set tubing is connected to the body, no portion of the Syringe can be higher than 7 3/4 inches (20 cm) above the infusion site or lower than 21 1/2 inches (55 cm) below the infusion site. Placing it higher or lower than indicated could impact delivery accuracy.

Note: **Do NOT** use the Carrying Accessory if it is damaged.

Note: **Do NOT** let the Pump fall when positioning the Carrying Accessory.

Note: Recycle/dispose the Carrying Accessory according to local regulations.

Note: Any serious incidents that occur in relation to the device should be reported to the device manufacturer and the competent authority.

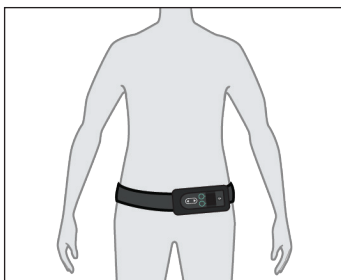


Figure B

To **Carry the Pump on Your Hip** (see Figure B), go to section **Prepare the Case to Carry on Your Hip**.



Figure C

To **Carry the Pump Across Your Body** (see Figure C), go to section **Prepare the Case to Carry Across Your Body**.



Figure D

To **Carry the Pump on Your Neck** (see *Figure D*), go to section ***Prepare the Case to Carry on Your Neck***.



Figure E

Optional: To **Carry the Pump Across Your Body** (see *Figure E*), go to section ***Prepare the Case to Carry Across Your Body***.

2.1 Prepare the Case to Carry on Your Hip

1. Inspect both belts and choose one or both, depending on your preferred belt size.

Note: The 2 belts allow you to use either one or you may connect them together to add length.

Note: When carrying the Case on your hip, it is recommended that you strap the belt around your waist while seated and before inserting the Pump. This will help to prevent accidentally dropping the Pump.

Note: **Do NOT** let the Pump fall when positioning the Carrying Accessory.

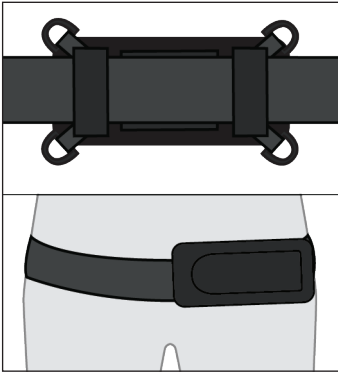


Figure F

2. Slide the Belt through the loops on the back of the Case.

Note: When the Syringe is in the pump and the infusion set tubing is connected to the body, no portion of the Syringe can be higher than 7 3/4 inches (20 cm) above the infusion site or lower than 21 1/2 inches (55 cm) below the infusion site. Placing it higher or lower than indicated could impact delivery accuracy.

- **Horizontal Orientation:** To wear the Pump in a horizontal orientation, slide the Belt through the loops on the back of the case as shown in *Figure F*
- **Vertical Orientation:** To wear the Pump in a vertical orientation, slide the Belt through the loops on the back of the case as shown in *Figure G*

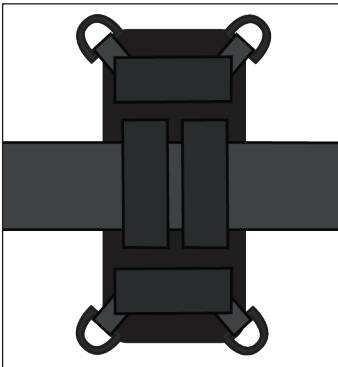


Figure G

Note: When wearing the Pump vertically on your hip, if the Display is closer to the ground, when you tilt it up to read it, the Display will be oriented correctly for reading.

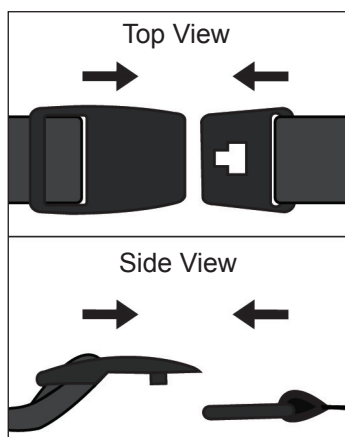


Figure H

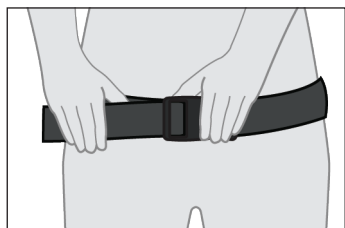


Figure I

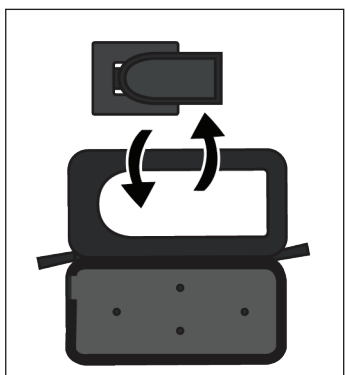


Figure J

3. Put on the Belt.

- a. Attach the Belt with the buckle (see *Figure H*).

- b. Loosen or tighten the Belt so that it fits securely around the hips.
- c. While holding the buckle in one hand and the belt in the other hand, slide the belt to the desired length (see *Figure I*).

4. Remove or insert the (optional) removable flap (see *Figure J*).

Note: The flap can be partially detached to allow access to the Pump buttons or removed permanently. While partially detached it remains tethered to the carrying case.

- a. Unzip the Case

Note: Either or both zippers may be used to open the Case.

- b. Attach or detach the removable flap.

Note: You may need to experiment with the flap to get it positioned in a way that covers the buttons while not covering the display.

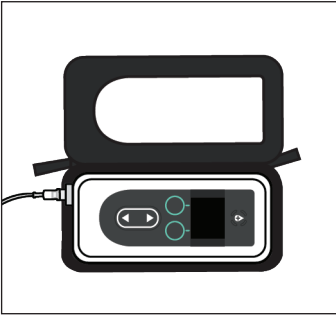


Figure K

5. Insert the Pump.

- a. Insert the Pump into the Carrying Accessory with the buttons and display facing out and with the Syringe opening aligned with the Pump Syringe (see *Figure K*).

6. Zip the Case closed to secure the Pump.

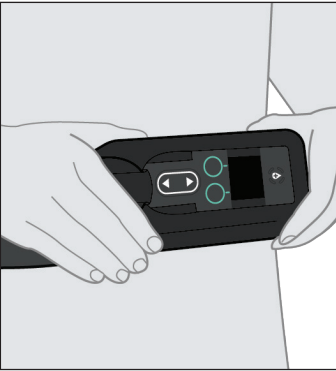


Figure L

7. Tilt the Pump to ensure you can read the display (see *Figure L*).

2.2 Prepare the Case to Carry Across Your Body

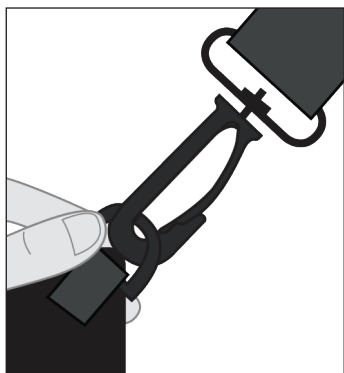


Figure M

1. Attach the Strap to the Case.

- Clip one end of the Strap to one ring on the Case and the other end to another ring so that the Case is conveniently oriented (see *Figure M*).

Note: Hold the ring between your fingers in one hand to stabilize it when attaching the snap hook.

Note: **Do NOT** let the Pump fall when positioning the Carrying Accessory.

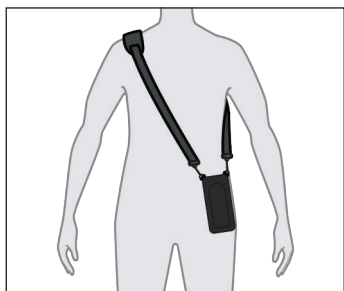


Figure N

2. Place the Strap over your head so that it is resting on one shoulder (see *Figure N*).

- Adjust the Strap by loosening or tightening it so that the Pump is close to your body.

Note: When the Syringe is in the pump and the infusion set tubing is connected to the body, no portion of the Syringe can be higher than 7 3/4 inches (20 cm) above the infusion site or lower than 21 1/2 inches (55 cm) below the infusion site. Placing it higher or lower than indicated could impact delivery accuracy.

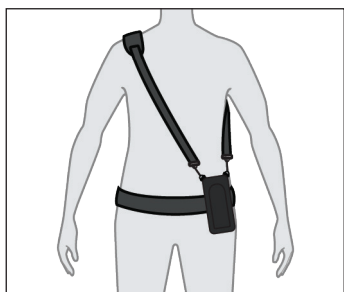


Figure O

- Optional: Add the belt by sliding it through the back of the case, adjust the length for a tight fit, and attach the belt buckle for a comfortable fit (see *Figure O*) (refer to **Prepare the Case to Carry Across Your Body**).

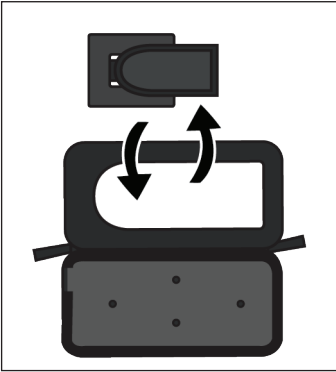


Figure P

3. Remove or insert the (optional) removable flap (see Figure P).

Note: The flap can be partially detached to allow access to the Pump buttons or removed permanently. While partially detached it remains tethered to the carrying case.

- a. Unzip the Case

Note: For your convenience, either or both zippers may be used.

- b. Attach or detach the removable flap.

Note: You may need to experiment with the flap to get it positioned in a way that covers the buttons while not covering the display.



Figure Q

4. Insert the Pump.

- a. Insert the Pump into the Carrying Accessory with the buttons and display facing out and with the Syringe opening aligned with the Pump Syringe (see Figure Q).

5. Zip the Case closed to secure the Pump.

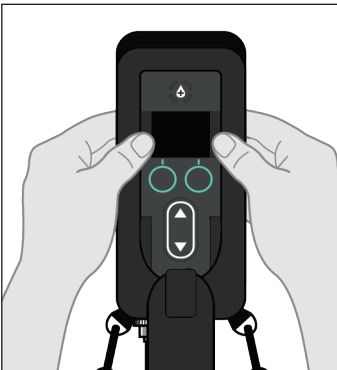


Figure R

6. Tilt the Pump to ensure you can read the display (see Figure R).

2.3 Prepare the Case to Carry on Your Neck

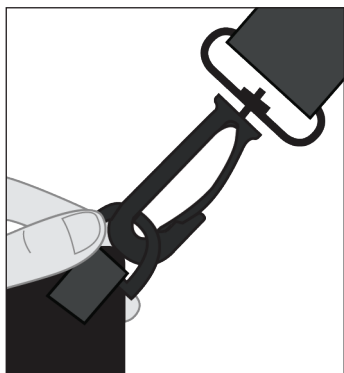


Figure S

1. Attach the Strap to the Case.

- Clip one end of the Strap to one ring on the Case and the other end to an adjacent ring so that the Case is conveniently oriented (see *Figure S*).

Note: Hold the ring between your fingers in one hand to stabilize it when attaching the snap hook.

Note: **Do NOT** let the Pump fall when positioning the Carrying Accessory.

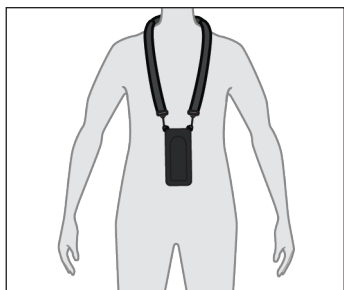


Figure T

2. Place the Strap over your head (see *Figure T*).

- Tighten or loosen the Strap so that the Pump is at a comfortable height and close to your body in a comfortable position.

Note: When the Syringe is in the pump and the infusion set tubing is connected to the body, no portion of the Syringe can be higher than 7 3/4 inches (20 cm) above the infusion site or lower than 21 1/2 inches (55 cm) below the infusion site. Placing it higher or lower than indicated could impact delivery accuracy.

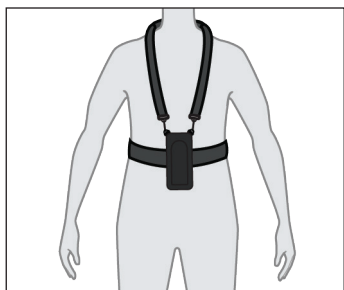


Figure U

- Optional: Add the belt by sliding it through the back of the case, adjust the length for a tight fit, and attach the belt buckle for a comfortable fit (see *Figure U*) (refer to **Prepare the Case to Carry on Your Neck**).

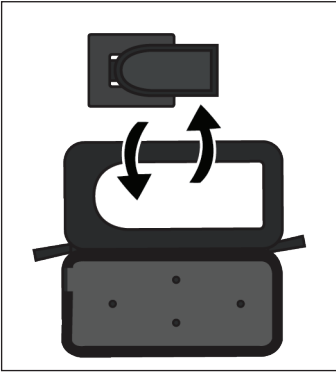


Figure V

3. Remove or insert the (optional) removable flap (see Figure V).

Note: The flap can be partially detached to allow access to the Pump buttons or removed permanently. While partially detached it remains tethered to the carrying case.

a. Unzip the Case

Note: For your convenience, either or both zippers may be used.

b. Attach or detach the removable flap.

Note: You may need to experiment with the flap to get it positioned in a way that covers the buttons while not covering the display.



Figure W

4. Insert the Pump.

a. Insert the Pump into the Carrying Accessory with the buttons and display facing out and with the Syringe opening aligned with the Pump Syringe (see Figure W).

5. Zip the Case closed to secure the Pump.

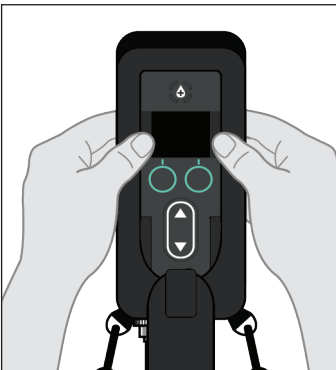


Figure X

6. Tilt the Pump to ensure you can read the display (see Figure X).

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3. Removing the Carrying Accessory

1. Remove the Pump from the Case.

- a. Unzip the Case to open.

Note: Be careful when unzipping the Case to ensure the Pump does not fall out. It is good practice to perform this task when you are by a table top.

- b. Remove the Pump from the Case.
- c. Place the Pump on a flat surface.

2. Remove the Carrying Accessory.

- a. Remove the Carrying Accessory from your hip, shoulder or neck.

Note: When removing the Carrying Accessory, take special care to prevent the Pump from falling and pulling on the Infusion Set Tubing.

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4. Cleaning the Carrying Accessory

You should clean the Carrying Accessory as needed.

It is acceptable to wipe the Carrying Accessory with a damp cloth while the Pump is inside but if you need to clean it thoroughly, you should remove the Pump first.

Do NOT pour water or cleaning solutions directly onto the Carrying Accessory or Pump. Protect your Carrying Accessory and Pump from running water and fluid spills.

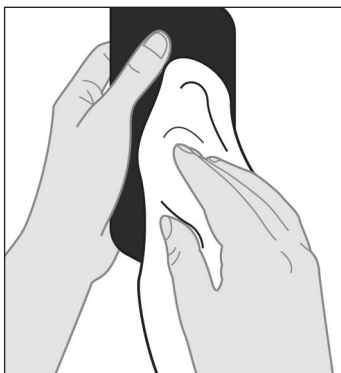


Figure Y

1. Clean the Carrying Accessory.

- a. Lightly dampen a soft cloth with clean water and mild detergent.
- b. Gently wipe the surface that requires cleaning (see *Figure Y*).

Note: Allow Carrying Accessory to dry completely before inserting Pump.

Note: **Do NOT** machine wash the Carrying Accessory.

Note: **Do NOT** tumble dry the Carrying Accessory.

Note: **Do NOT** clean the Carrying Accessory with harsh chemicals (acetone, solvents, abrasive detergents, etc.) or abrasive materials (stiff brushes) as damage may occur.

Note: Leaving the Carrying Accessory in direct sunlight for extended periods is likely to result in fading.

Note: The Carrying Accessory should not be stored at temperatures above 60° C (140° F).

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5. Explanation of Symbols

Symbol	Title and Designation Number of Standard Regulation or Guidance	Reference Number	Title/Meaning of Symbol
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.1.1	Manufacturer
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.1.3	Date of Manufacture
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.1.5	Batch Code
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.1.6	Catalog Number
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.1.10	Model Number
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.3.7	Temperature Limits
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.3.8	Humidity Limits
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.4.12	The medical device can be used multiple times by a single patient
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.7.7	Medical Device
	EU Directive 94/62/ EC of 20 December 1994 on Packaging and Packaging Waste & EU Commission Decision 97/129/EC	04 is reserved for Low Density Polyethylene	Recycling

Symbol	Title and Designation Number of Standard Regulation or Guidance	Reference Number	Title/Meaning of Symbol
	EN ISO 7010:2020 ISO 7010: 2019	ISO 7010- M002	Refer to instruction manual/booklet
	Regulation (EU) 2017/745	Annex V	CE mark, indicates that this device is in conformity with the applicable requirements set out in (EU) 2017/745 and other applicable directives and regulations.
	The Medical Devices Regulations 2002 (UK MDR) as amended	Part II 10	UK Conformity Assessed (UKCA) marking is a conformity mark that indicates this device is in conformity with the applicable requirements as set out in the Medical Devices Regulations 2002 as amended, for devices sold within Great Britain.
 devices.abbvie.com	EN ISO 15223-1:2021 ISO 15223-1:2021	5.4.3	Consult <i>instructions for use or electronic instructions for use</i>

Symbol	Title and Designation Number of Standard Regulation or Guidance	Reference Number	Title/Meaning of Symbol
	Law No 2020-105 Antiwaste law for a circular economy (AGEC)	Article 17	The Triman Logo contains important sorting information for end users

References

EN ISO 15223-1:2021 Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General Requirements

ISO 15223-1:2021 Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General Requirement

EN ISO 7010:2020 Graphical symbols — Safety colors and safety signs — Registered safety signs

ISO 7010: 2019 Graphical symbols — Safety colors and safety signs — Registered safety signs

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