


Instructions for Use of Carrying Accessory for VYAFUSER™ Pump

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This Instructions for Use describes how to use the carrying accessory for the VYAFUSER pump (see the Patient Instructions for Use of VYAFUSER Pump) to deliver VYALEV (foscarnidopa and foslevodopa).

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TABLE OF CONTENTS

1. Carrying Accessory Parts	5
1.1 Intended Use	5
2. How to Carry the Pump	7
2.1 Prepare the Case to Carry on Your Hip	9
2.2 Prepare the Case to Carry Across Your Body	12
2.3 Prepare the Case to Carry on Your Neck	14
3. Removing the Carrying Accessory	17
4. Cleaning the Carrying Accessory	19
5. Explanation of Symbols	21

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1. Carrying Accessory Parts

1.1 Intended Use

The carrying accessory is used to carry the pump on your 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 does not 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. The belts can connect together for additional length, if needed.

The belt(s) allow you to wear the carrying accessory around your hips. On a belt, the pump can be placed side to side (horizontally) or up and down (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 the strap and with buckle)
 - Used to secure the case on the hip.
 - 2 belts can be connected to create longer belt.
 - The belts are marked with “S” for short and “L” for long.
- Strap (thinner than the belts with snap hooks and neck pad)
 - Used to secure the case on the neck or across the body.
 - Packaged inside the case when shipped.

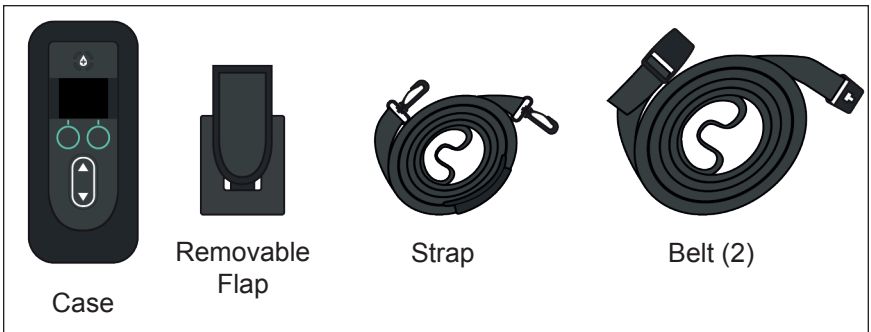


Figure A

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2. How to Carry the Pump

Wear the carrying accessory in a way that is comfortable for you. Also, wear the carrying case so that gives you easy access to interact with the pump.

Caution: Do NOT use the carrying accessory in a way that the strap or belts could wrap around your neck. If the strap or belts wrap around your neck, there is a risk of being strangled.

Note: When the syringe is in the pump and the infusion set tubing is attached to the body, make sure the syringe is in the correct placement. The whole syringe must be within 7 3/4 inches (20 cm) above and 21 1/2 inches (55 cm) below the infusion site. Placing it higher or lower than this could impact delivery accuracy.

Note: Do NOT use the carrying accessory if it is damaged.

Note: Do NOT let the pump fall when putting the carrying accessory in place.

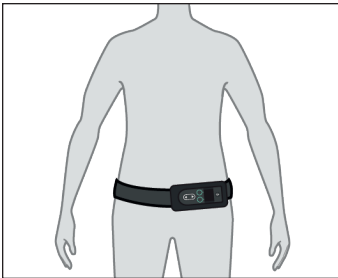


Figure B

To carry the pump on your hip (see Figure B), go to the section **Prepare the Case to Carry on Your Hip**.



Figure C

To carry the pump across your body (see Figure C), go to the section **Prepare the Case to Carry Across Your Body**.



Figure D

To carry the pump on your neck (see *Figure D*), go to the section ***Prepare the Case to Carry on Your Neck.***



Figure E

Optional: To carry the pump across your body (see *Figure E*), go to the 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, you should 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 putting the carrying accessory in place.

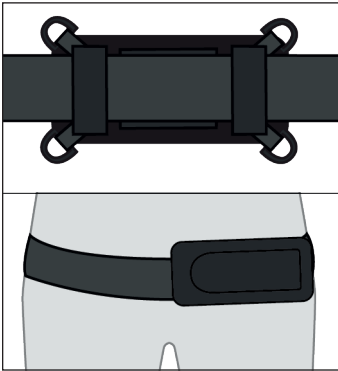


Figure F

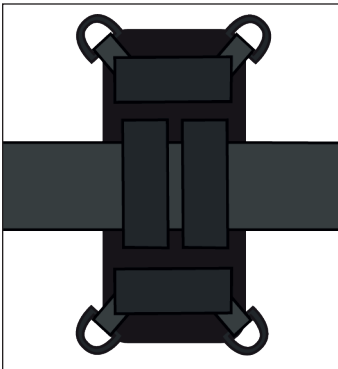


Figure G

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 attached to the body, make sure the syringe is in the correct placement. The whole syringe must be within 7 3/4 inches (20 cm) above and 21 1/2 inches (55 cm) below the infusion site. Placing it higher or lower than this could impact delivery accuracy.

- Side to side (horizontal) placement: To wear the pump in a side to side placement, slide the belt through the loops on the back of the case as shown in *Figure F*.
- Up and down (vertical) placement: To wear the pump in an up and down placement, slide the belt through the loops on the back of the case as shown in *Figure G*.

Note: When wearing the pump in an up and down placement on your hip, the display part of the pump should be closer to the ground. In this placement, when you tilt the pump up to read it, the display will be in the correct placement for reading.

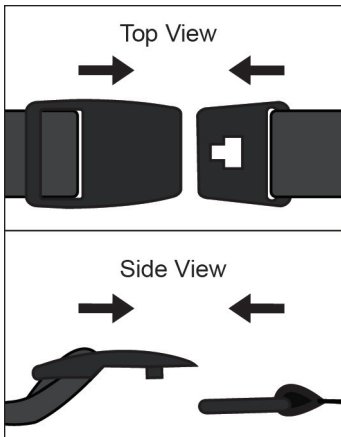


Figure H

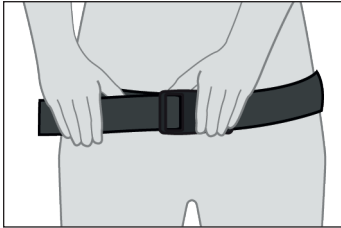


Figure I

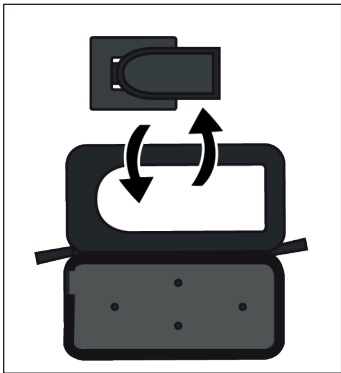


Figure J

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 partly detached to allow access to the pump buttons or permanently removed. While partly 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 try different placements for the flap to get it to cover the buttons but not the display.



Figure K

5. Insert the pump.

- a. Insert the pump into the carrying accessory with the buttons and display facing outwards. Align the syringe opening with the pump syringe (see *Figure K*).

6. Zip the case closed to secure the pump.

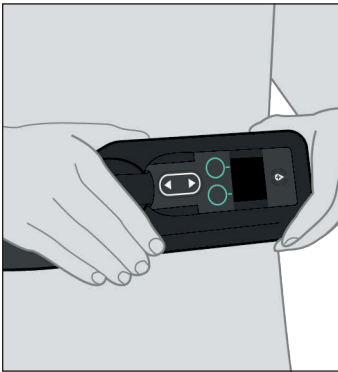


Figure L

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

2.2 Prepare the Case to Carry Across Your Body

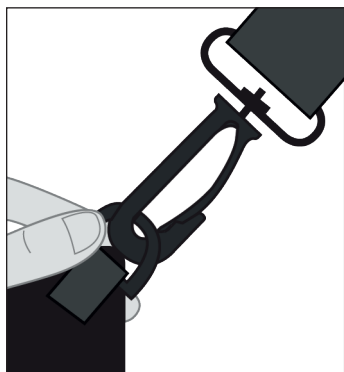


Figure M

1. Attach the strap to the case.

- The case has four rings to attach the strap. Clip one end of the strap to one ring on the case and the other end to an adjacent ring so that the case has a convenient placement (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 putting the carrying accessory in place.

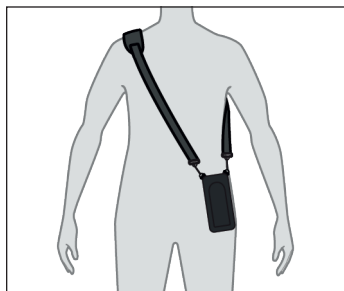


Figure N

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 attached to the body, make sure the syringe is in the correct placement. The whole syringe must be within 7 3/4 inches (20 cm) above and 21 1/2 inches (55 cm) below the infusion site. Placing it higher or lower than this could impact delivery accuracy.

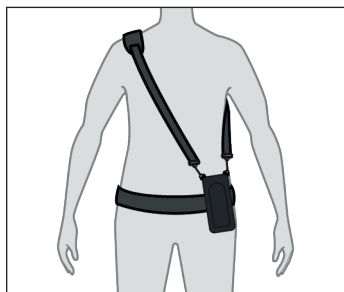


Figure O

- Optional: Optional: Add the belt by sliding it through the loops on the back of the case. You can adjust the length of the belt 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**).

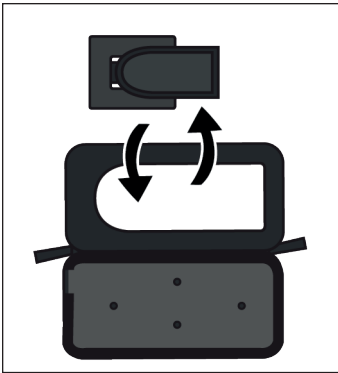


Figure P

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

Note: The flap can be partly detached to allow access to the pump buttons or permanently removed. While partly 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 try different placements for the flap to get it to cover the buttons but not the display.



Figure Q

4. Insert the Pump.

- a. Insert the pump into the carrying accessory with the buttons and display facing outwards. Align the syringe opening with the pump syringe (see *Figure Q*).

5. Zip the case closed to secure the pump.

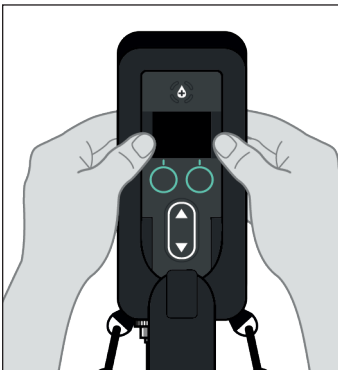


Figure R

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

2.3 Prepare the Case to Carry on Your Neck

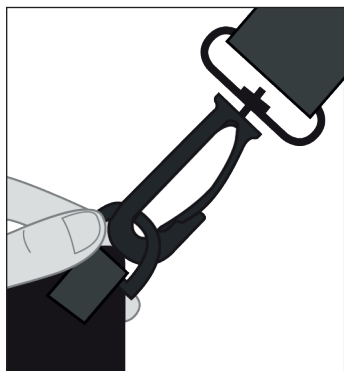


Figure S

1. Attach the Strap to the Case.

- The case has four rings to attach the strap. Clip one end of the strap to one ring on the case and the other end to an adjacent ring so that the case has a convenient placement (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 putting the carrying accessory in place.

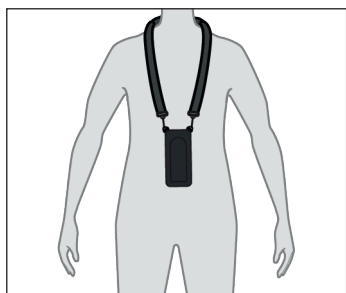


Figure T

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

- You can tighten or loosen the strap so that the pump is at a comfortable position. Adjusting the strap can change the height of the pump and how close it is to your body.

Note: When the syringe is in the pump and the infusion set tubing is attached to the body, make sure the syringe is in the correct placement. The whole syringe must be within 7 3/4 inches (20 cm) above and 21 1/2 inches (55 cm) below the infusion site. Placing it higher or lower than this could impact delivery accuracy.

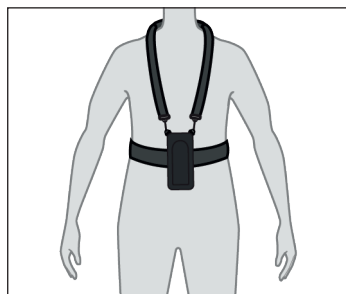


Figure U

- Optional: Add the belt by sliding it through the loops on the back of the case. You can adjust the length of the belt 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**).

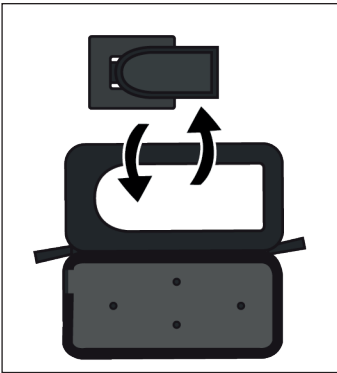


Figure V

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

Note: The flap can be partly detached to allow access to the pump buttons or permanently removed. While partly 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 try different placements for the flap to get it to cover the buttons but not the display.



Figure W

4. Insert the pump.

- a. Insert the pump into the carrying accessory with the buttons and display facing outwards. Align the syringe opening with the pump syringe (see *Figure W*).

5. Zip the case closed to secure the pump.

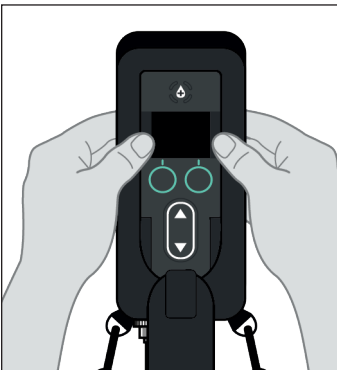


Figure X

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 you unzip the case to ensure the pump does not fall out. It is good practice to perform this task when the case is over a tabletop.

- 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: Be careful when you remove the carrying accessory. Take special care to not let the pump fall and pull on the infusion set tubing.

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4. Cleaning the Carrying Accessory

You should clean the carrying accessory as needed.

You can wipe the carrying accessory with a damp cloth while the pump is inside. If you need to clean the carrying accessory thoroughly, you should remove the pump first.

Do NOT pour water or cleaning fluids onto the carrying accessory or the pump. Protect your carrying accessory and pump from running water and fluid spills.

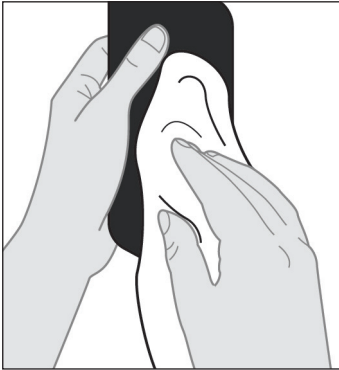


Figure Y

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: Let the carrying accessory dry fully before putting in the 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). These may cause damage to occur.



Note: If the carrying accessory is left in direct sunlight for a long time, it may fade.

Note: **Do NOT** store the carrying accessory at temperatures above 140° F (60° C).

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5. Explanation of Symbols

Symbol	Title and Designation Number of Standard	Reference Number	Title/Meaning of Symbol
	ANSI/AAMI/ISO 15223-1:2021	5.1.5	Batch Code
	ANSI/AAMI/ISO 15223-1:2021	5.1.6	Catalog Number
	ISO 7010:2019	ISO 7010-M002	Consult Instructions for Use
	ANSI/AAMI/ISO 15223-1:2021	5.1.3	Date of Manufacture
	ANSI/AAMI/ISO 15223-1:2021	5.3.8	Humidity Limitation
	ANSI/AAMI/ISO 15223-1:2021	5.1.1	Manufacturer
	ANSI/AAMI/ISO 15223-1:2021	5.7.7	Medical Device
	EN ISO 15223-1:2021 ISO 15223-1:2021	5.4.12	The medical device can be used multiple times by a single patient.
	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
	EU Directive 94/62/EC of 20 December 1994 on Packaging and Packaging Waste & EU Commission Decision 97/129/EC	20 is reserved for corrugated fiberboard (PAP- paper)	Recycling
	ANSI/AAMI/ISO 15223-1:2021	5.1.7	Serial Number
	ANSI/AAMI/ISO 15223-1:2021	5.3.7	Temperature Limits

Symbol	Title and Designation Number of Standard	Reference Number	Title/Meaning of Symbol
	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.

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 or Graphical symbols — Safety colors and safety signs — Registered safety signs

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Approved: 10/2024