INSTRUCTIONS FOR USE EN

enFuse® 20 mL ST System

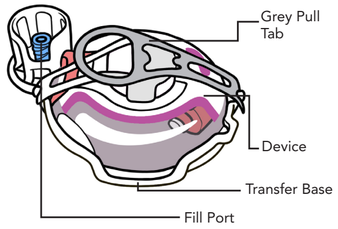
For abdominal subcutaneous delivery of medicinal products

Single-Use On-Body Delivery Device

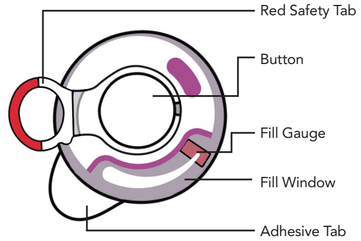
Read these Instructions for Use before you start using the device and each time you get a new device as there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. The patient or caregiver will be instructed by a qualified healthcare professional in the use of the On-Body Delivery System in accordance with the Medicinal Product Package Leaflet. The decision of a possibility of self-administration and home infusions should be made after evaluation and recommendation from the treating physician. Ask your healthcare provider about any instructions you do not understand. If you have questions, concerns, or need of help, please call Enable Injections at 1-513-326-2800.

The Intended Purpose – For abdominal subcutaneous delivery of medicinal products
Indications for Use – The on-body delivery device system is intended for subcutaneous abdominal bolus administration of drug or biologic products with a viscosity between 8.5 cP - 16 cP in accordance with the drug product requirements.
Patient Target Group(s) – Age 12+ and ≥ 30 kg.
Intended Users – Healthcare Providers (HCPs), Caregivers, & Patients (age 12+).

Parts of enFuse System



Device in Syringe Transfer Base



Device

Product Description:

The enFuse System is a sterile, non-pyrogenic, user-filled, single-use, fixed-dose subcutaneous dose delivery system. The enFuse System consists of the device and Syringe Transfer (ST) base. The device utilizes an elastomeric balloon to deliver medicinal product, and contains an integrated needle that is inserted into the subcutaneous space once the Button is depressed. The device design is "constant pressure" rather than a pre-set constant flow rate; target in vitro flow rates are achieved by customized needle sizes. An adhesive backing on the device, exposed upon removal of the device from the Transfer Base, allows for direct attachment to the skin during subcutaneous administration. The Transfer Base is intended for one (1) single-use syringe insertion and transfer of medicinal product upon attachment of a pre-filled, pre-measured syringe with a luer fitting (compatible with ISO 80369-7 compliant syringes). The Enable enFuse System is fully mechanical and does not contain any electronics or software.

Clinical Benefit:

A large volume, hands-free dose administration of a medicinal product to the abdominal subcutaneous space which improves patient management by reducing the burden on the user.

Selecting Correct enFuse System Configuration:

Note: This information is provided to assist the prescribing health care provider. The needle inner diameter can be found on the product labeling.

The flow rate from the device is determined by a number of variables both internal to the device design (i.e., needle inner diameter) and external (patient backpressure, medicinal product viscosity). The anticipated flow rates from each 20 mL enFuse System configuration (containing a needle with an inner diameter of 0.165 mm and 0.198 mm, respectively) for a given range of medicinal product viscosities are provided in Flow Rate Table.

Determination of the appropriate enFuse System configuration can be made by comparing the high and low flow rate ranges anticipated for the nominal viscosity of the medicinal product with the medicinal product labeling requirements. If the potential medicinal product viscosity is known to vary outside of 30% from the listed value, the full potential flow rate range can be determined by the highest flow rate of the low end of the viscosity and the lowest flow rate of the high end of the viscosity. For example, if a medicinal product viscosity may vary between 8 and 12 cP (such as from manufacturing/concentration variation), the resulting flow rate range from the device may vary from 9 - 53 mL/hr for the 0.165 mm needle. This flow rate range can then be compared to the medicinal product labeling to ensure safe and effective delivery with the enFuse System.

Flow Rate Table

Viscosity (cP)	Needle ID - 0.165 mm		Needle ID - 0.198 mm	
	Flow Rate Range (mL/hr)	20 mL Dose Time Range (minutes)*	Flow Rate Range (mL/hr)	20 mL Dose Time Range (minutes)*
8	53 - 14	22 - 85	108 - 29	11- 41
10	43 - 11	28 - 106	87 - 23	13 - 51
12	36 - 9	33 - 128	73 - 20	16 - 60
14	31 - 8	39 - 147	63 - 17	19 - 71
16	27 - 7	45 - 172	55 - 14	22 - 82

* Time Range is an estimation that will vary based on the patient's unique subcutaneous anatomy. The Flow Rate Range was estimated using ambient conditions and may vary based on environmental changes.

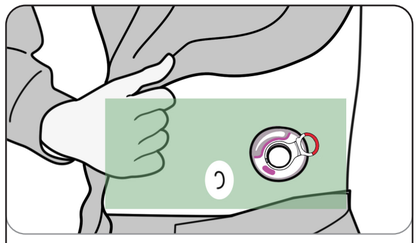
If it is unclear whether a medicinal product is compatible with the enFuse System, contact Enable Injections: email medinfo@enableinjections.com or call 1-513-326-2800.

Warnings:

- **Warning!** Keep away from children 3 years and younger. Contains small parts.
- **Do not** use enFuse System if tamper-proof label has been broken
- **Do not** use if you dropped enFuse System or if it appears damaged
- **Do not** use if sealed plastic tray is open or damaged
- **Do not** use if expiration date on the box has passed
- **Do not** reuse enFuse System
- **Do not** store filled device
- **Do not** touch the white adhesive on bottom of device before attaching to abdomen
- **Do not** let clothes touch the clean site
- **Do not** remove device from skin until Button pops out
- **Do not** throw away (dispose of) device into trash
- **Do not** remove device from skin during dose delivery
- **Do not** use materials to hold device in place that could compress device against skin
- **Do not** put any objects in the fill port other than the filled syringe

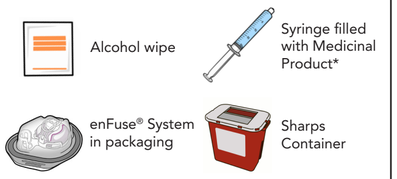
Precautions:

- **Do not** use enFuse System if patient has a skin condition on their abdomen (delivery site)
- Ensure the patient is wearing loose clothes so that they do not get in the way of the device
- **Do not** store enFuse System outside of storage conditions
- **Do not** use enFuse System outside of use conditions
- **Do not** apply device along the belt line or on areas where the device will be affected by folds in the skin
- **Do not** remove Red Safety Tab until device is attached to body
- Choose dose delivery site at least 2.5 cm from the edge of patient's belly button and the edge of device, and 2.5 cm from last dose delivery site. Use the device on abdomen only.
- **Do not** bathe, shower, exercise, use hot tubs, whirlpools, or saunas. Avoid getting abdomen wet. Device is not waterproof. Water or sweat may loosen Device from skin
- **Do not** sleep during dose delivery
- Avoid engaging in intense physical activity
- **Do not** bump or knock device
- **Do not** bump the device Button



Once you complete steps 1-9, the **result** is to attach the device to the abdomen.

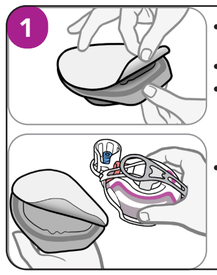
Supplies required for Dose Delivery



*Refer to the Medicinal Product Package Leaflet for the instructions to prepare and fill syringe. The On-Body Delivery device will administer the transferred volume. The volume cannot be changed once filled.

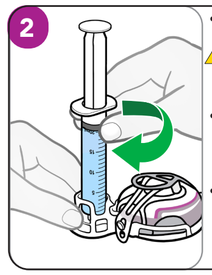
Fill Device with Medicinal Product

1



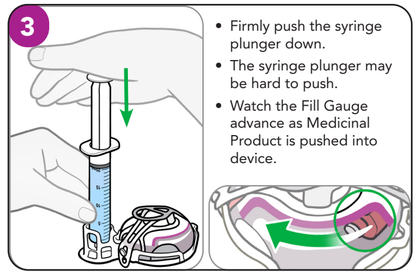
- Wash your hands well with soap and water.
- Dry your hands.
- Peel back the cover and remove the clear packaging insert.
- Remove device and the surrounding Transfer Base from the packaging. Place it on a clean, flat surface.

2



- Pick up the syringe filled with Medicinal Product.
- ⚠ Double check that you have withdrawn your prescribed dose.
- The filled syringe may have a luer cap; if so, twist to the left (counter-clockwise) to remove the cap.
- **Twist** the filled syringe tip to the right (clockwise) into the Fill Port until it is tight.

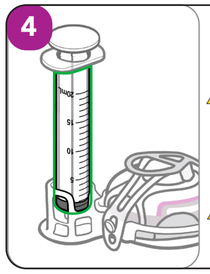
3



- Firmly push the syringe plunger down.
- The syringe plunger may be hard to push.
- Watch the Fill Gauge advance as Medicinal Product is pushed into device.

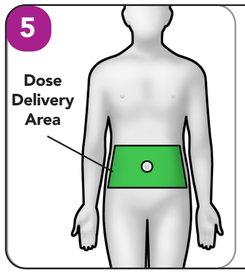
Identify and Clean the Delivery Site

4



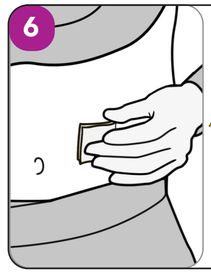
- Make sure the syringe is empty. If needed, press firmly down on the syringe plunger again.
- ⚠ **Do not** remove empty syringe from Transfer Base.
- After the device is filled, continue with the preparation and dose delivery.
- ⚠ **Do not** store filled device.

5



- Determine where to place the device on the bare abdomen.
- ⚠ Use the device on abdomen only.
- Choose a site:
  - At least 2.5 cm from the edge of patient's belly button and the edge of the device.
  AND
  - At least 2.5 cm from the last site.
- ⚠ Avoid site that is tender, bruised, red, hard, irritated, scarred, tattooed, or has stretch marks.
- ⚠ **Do not** apply the device along the belt line or on areas where the device will be affected by folds in the skin.
- ⚠ Ensure the patient is wearing loose clothes so that they do not get in the way of the device.

6



- Clean site with an alcohol wipe.
- Allow the site to dry for at least 30 seconds.
- ⚠ **Do not** touch, fan, blow, or let clothes touch the clean site.

Symbol	Symbol Title	Symbol Definition
	Manufacturer	Indicates the medical device manufacturer
USA	Country and Date of Manufacture	Indicates the country where the medical device was manufactured and the date of manufacture
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Use by date	Indicates the date after which the medical device is not to be used
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed
	Keep dry	Indicates a medical device that needs to be protected from moisture
UDI	Unique device identifier	Indicates the manufacturer's device identifier so that a specific medical device can be identified
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
STERILIZE	Do not resterilize	Indicates a medical device that is not to be resterilized
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
Cobalt, CAS No. 7440-48-4	Hazardous substance symbol for Cobalt material	Indicates that material is a hazardous substance on labeling
MD	Medical Device	Indicates that the item is a Medical Device
EU REP	Authorized representative in the European Union	Indicates the authorized representative in the European Union
CE 2797	CE Marking	Signifies European technical conformity
	Single Sterile Barrier System	Indicates a single sterile barrier system
QTY	Quantity	Quantity of devices contained inside the commercial packaging

EU REP Emergo Europe
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

Patent:
EnableInjections.com/patent

IFU:
EnableInjections.com/ifu

Manufactured by:
Enable Injections, Inc.
2863 E. Sharon Road
Cincinnati, OH 45241, USA

10131899 Rev. A Issued FEB2026

CE 2797

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Remove Device from Transfer Base and Attach to Abdomen

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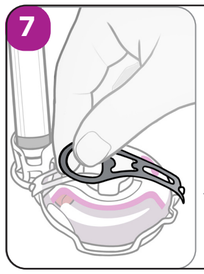
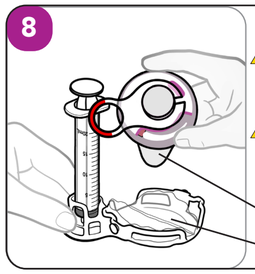


- Grasp the Grey Pull Tab and pull. Allow both the Grey and Clear Pull Tabs to fall to the side.
- The tabs may fall to the side or come off completely.

⚠ **Do not** remove the Red Safety Tab until the device is attached to body.

8



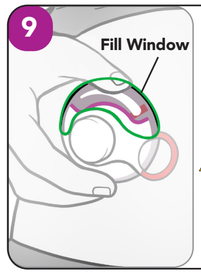
- Hold the sides of device and pull it straight up to remove it from the Transfer Base.

⚠ **Do not** touch the adhesive on the bottom of the device or fold the adhesive onto itself.

- The White Adhesive will stay attached to the device and the Clear Liner will stay attached to the Transfer Base.

⚠ Ensure site has been cleaned before attaching device.

9

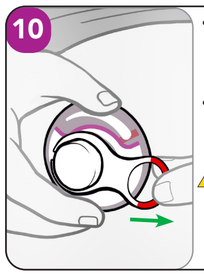


- Position the device so the Fill Window is pointed up towards the patient's face.
- Press firmly on the clear portion of the device to attach to abdomen.

⚠ **Do not** reposition device once attached to the belly. Device functions regardless of Fill Window orientation.

Start Dose Delivery

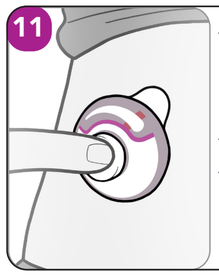
10



- Hold the device with 1 hand. Use other hand to pull Red Safety Tab off.
- The dose delivery will not start until the Red Safety Tab is removed.

⚠ **Do not** use materials to hold the device in place that could compress the device against the patient's skin.

11



⚠ Pushing the button will insert the needle into the patient's skin. The patient may feel the needle go into the skin.

- After placing the device on abdomen, immediately press the button firmly until it stays in place to start the dose delivery.

⚠ Be careful not to bump, knock, or twist the device or button during dose delivery.

⚠ **Do not** sleep or bathe during dose delivery. During dose delivery keep abdomen totally dry. Avoid intense physical activity.

- Light daily activities can be done during dose delivery.

Track Dose Delivery

12

- Dose delivery will continue as long as Button is in. Delivery time will vary based on dose volume, medication viscosity, and device needle configuration. Refer to Flow Rate Table (Page 1) for estimated delivery time ranges.
- To track progress, watch the Fill Gauge move across Fill Window towards empty. Gauge is an estimate of progress. It may take some time to move and may advance slowly.

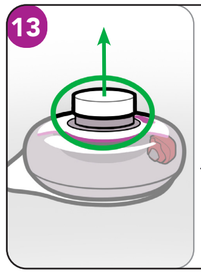
⚠ If dose delivery exceeds 2 hours and 30 minutes, refer to Questions and Answers.

⚠ **Do not** remove the device until the Button pops out.

⚠ **Caution:** Holding down the Button will pause the flow of medicine. Dose delivery will begin again when the Button is released.

⚠ If the patient has an allergic reaction to the adhesive, provide or seek immediate medical care.

13

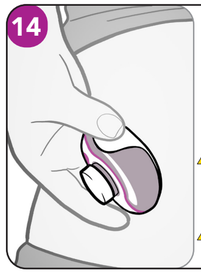


- When the Button pops out, the dose delivery is done, and needle is pulled out of the skin, back into the device, and will not stick you or the patient.

⚠ **Do not** remove the device until the Button pops out. The Button popping out is the only way to know if the dose delivery is complete.

Remove Empty Device

14



- Use thumb to lift Adhesive Tab. Hold the Adhesive Tab against the device.
- Slowly peel the device away from patient's skin.

⚠ **Do not** reuse device. Refer to Questions and Answers for more information.

⚠ **Do not** rub injection site.

Dispose of Empty Device and Supplies

15

- Put used device in a sharps disposal or puncture-resistant container or dispose according to local regulations right away after use.
- The Transfer Base with empty syringe attached, alcohol wipe, and packaging may be placed in trash.
- Refer to organizational or local disposal policies to ensure compliance.

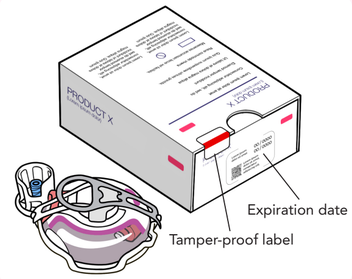
If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow community guidelines for the right way to dispose of sharps disposal container.

- Do not dispose of full sharps disposal containers in the trash unless community guidelines permit this.
- Do not recycle full sharps disposal containers.
- Keep the used device and sharps disposal container away from children.

How to Store the enFuse System

- Keep the enFuse System in unopened tray inside the original box.
- **Do not** open the tray until ready for the dose delivery.
- **Store** the enFuse System in clean, dry area away from heat and sunlight, at temperature 36°F - 86°F (2°C - 30°C).
- **Use** the enFuse System where the temperature is 41°F - 104°F (5°C - 40°C).



General Information

- The enFuse System is for abdominal subcutaneous delivery of medicinal products only.
- Device has a fill capacity of 20 mL.
- Consult pharmacy label for pump fill volume and infusion duration.

Questions and Answers

Can I use more than 1 syringe to fill the device?
No, use only 1 syringe per device.

Can I remove the device from the abdomen and put it on later to finish dose delivery?
No, device cannot be reattached. If removed, the full dosage may not be delivered.

What should I do if dose delivery takes longer than 2 hours and 30 minutes?
Press and hold the button while removing device from patient's skin. Put the device aside. Consult prescribing health care provider.
⚠ **Do not** touch the bottom of the device as the needle will be exposed.

What if I try to re-use the device?
The device has been designed to lock out after delivery of the dose and cannot be re-used. The enFuse ST System cannot be re-sterilized.

Possible Complications

What if the Button won't push in and lock?
Make sure that you have taken off the Red Safety Tab. If the Safety Tab is removed, make sure you have tried to push the Button all the way in. If you still cannot push the Button all the way in, then the device is damaged. Remove the device and set aside. Open a new enFuse System and start over.

What should I do if syringe plunger will not push down to fill the device?
You must firmly press down on the plunger to fill the device. It will feel like there is resistance.

What if the device falls off?
If the device falls off the body, pick it up carefully. Do not touch the needle or any medicine that may be on the device. Put the device aside. Consult the prescribing health care provider.

Other Potential Risks

- Local injection site reactions such as local tissue inflammation, irritation, swelling, or trauma
- Minor bruising, contusion, minor puncture injury, or laceration
- Systemic Infection due to exposure to blood borne pathogens

Serious incidents regarding the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

It is normal to see a little bleeding. You may press a cotton ball or gauze on the injection site and cover it with a small bandage.

Contraindications

- Not intended to be used with lifesaving acute medications.
- Not intended to be used with products that need a carefully controlled flow rate.
- Not intended to be used on pregnant women.
- Not intended to be used with medicinal products that may cause permanent or severe harm requiring medical intervention if it comes into contact with the skin.
- Not intended for the delivery of blood, blood products, insulin, total parenteral nutrition, and lipid emulsions.
- Not intended for patients that have an acrylic allergy.