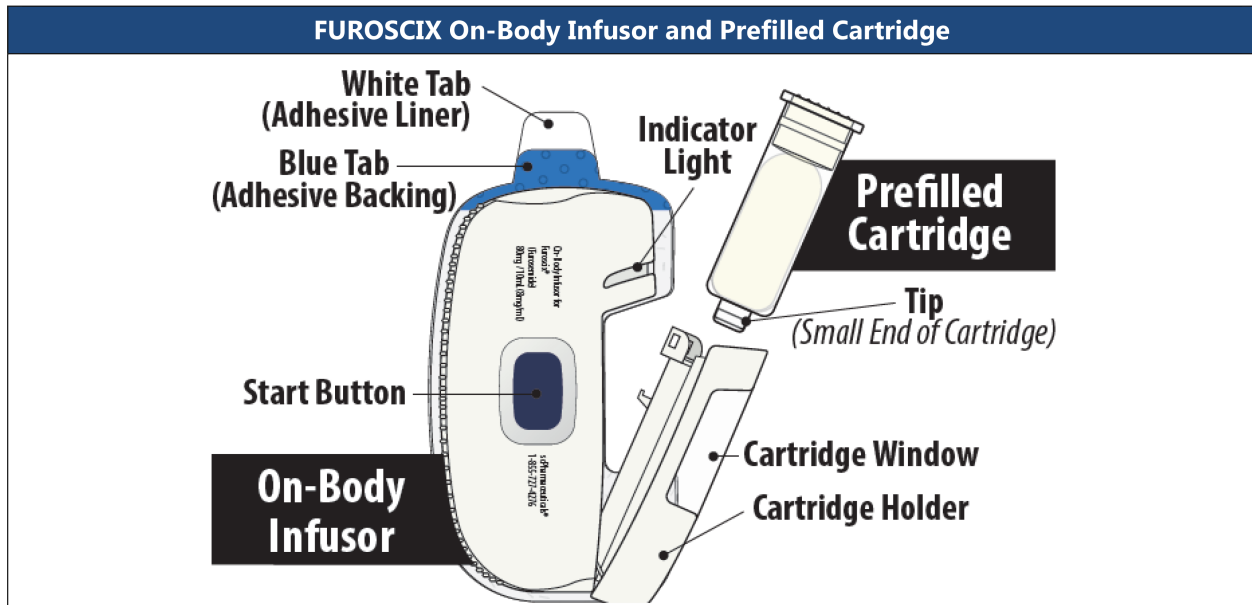


## Appendix 1. Furosemide On-Body Infusor



Interface Item	Written description of the User Interface
<b>Blue Tab</b> (Adhesive Backing)	Near the tab of the White Adhesive Liner is a blue tab to help indicate the Adhesive Backing. The user must separate the White Adhesive Liner from the Adhesive Backing before attaching the device to the site.
<b>White Tab</b> (Adhesive Liner)	Protecting the Adhesive Backing is a White Adhesive Liner. The White Adhesive Liner is removed from the Adhesive Backing to expose the adhesive. The user must do this in order to attach the device to the site.
<b>Start Button</b>	The Start Button is the dark blue button at the front of the On-Body Infusor. When pressed, the Start Button begins the infusion. The Start Button cannot be pressed prior to loading the Prefilled Cartridge in the Cartridge Holder and depressing the needle cover on the bottom of the On-Body Infusor.
<b>Indicator Light</b>	The Indicator Light is located by the Cartridge Window. This part lights up to indicate the status of the device. When users open the Cartridge Holder fully, the Indicator Light will blink blue. After loading the Prefilled Cartridge into the Cartridge Holder and applying it to the site, pressing the Start Button will cause the light to blink green. When the infusion is complete, the Indicator Light will stay solid green.
<b>Cartridge Window</b>	The Cartridge Window is the transparent part of the Cartridge Holder. The Cartridge Window allows for the Prefilled Cartridge to be seen during delivery. During delivery, the user could look through the Cartridge Window to see how much medication is left in the Prefilled Cartridge.
<b>Cartridge Holder</b>	The Cartridge Holder is the part that is partially open when removing the On-Body Infusor from the packaging. To begin infusion, the user needs to fully open the Cartridge Holder to load in the Prefilled Cartridge.
<b>Tip</b> (Small End of Prefilled Cartridge)	The small end of the Prefilled Cartridge is called the Tip. The user will need to clean tip with an Alcohol Wipe before loading the Prefilled Cartridge into the Cartridge Holder.

## Appendix 2. Instructions for Use

Model/REF # FUR-80W5

LBL-0063 R12

# Instructions For Use

## On-Body Infusor for

### FUROSCIX® [fue roe' six]

(furosemide injection) for subcutaneous use

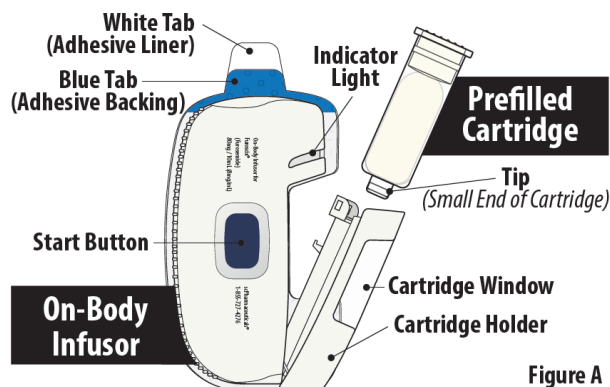
Single-Use On-Body Infusor and  
80 mg/10 mL (8 mg/mL) Prefilled Cartridge

This Instructions for Use contains information about how to prepare and use FUROSCIX On-Body Infusor.

### Before Starting

- Read this Instructions for Use before using the FUROSCIX On-Body Infusor for the first time.
- You or a caregiver should receive training before using the Furoscix On-Body Infusor.
- Always wash your hands before starting.
- The FUROSCIX On-Body Infusor will deliver a fixed dose of 80 mg of furosemide over about 5 hours.
- The FUROSCIX On-Body Infusor delivers the medicine just under the skin (subcutaneously).
- When the FUROSCIX On-Body Infusor is started, a small needle sticks into the skin to deliver the medicine. The on-body Infusor signals when all the medicine has been delivered. When the on-body Infusor is removed from the skin, a needle cover will extend over the needle to protect from an accidental needle stick.

### Parts of the FUROSCIX On-Body Infusor and Prefilled Cartridge



## Important Information

- The on-body Infusor and prefilled cartridge are not made with natural rubber latex.
- The infusion will last about 5 hours. During this time, you should limit your activity so that your bending movements are limited. Wearing the Infusor while riding in a car or flying in an airplane is not recommended.
- You should notice an increase in urine production in about an hour after the infusion is started and may need to make frequent bathroom visits. Be sure you have access to a bathroom for up to 8 hours after starting the infusion. If you do not notice the need to go to the bathroom, call your healthcare provider.
- The on-body Infusor can only be used with the prefilled FUROSCIX cartridge supplied in the kit.
- **Do not** use any other cartridges or medicines inside the on-body Infusor.
- **Do not** apply lotions, oils, or ointments to the adhesion area of the abdomen prior to applying the on-body Infusor to the abdomen.
- **Do not** use the on-body Infusor if the packaging appears to be opened, or if the on-body Infusor has been dropped or appears to be broken or damaged.
- **Do not** use the on-body Infusor within 12 inches of mobile phones, tablets, computers or wireless accessories (for example: TV remote control, Bluetooth computer keyboard or mouse).
- **Do not** use the on-body Infusor or prefilled cartridge after the expiration date on the carton.
- **Do not** use the prefilled cartridge if the liquid is discolored or cloudy. The liquid in the prefilled cartridge should be clear to slightly yellow in color.
- **Do not** use the on-body Infusor in or around an MRI machine.
- **Do not** take the on-body Infusor off your skin while it is infusing, unless there is an emergency or a device error. Removing the on-body Infusor before the infusion is done will result in a partial dose. The on-body Infusor will stop infusing and it cannot be restarted. **Do not** apply a new on-body Infusor unless instructed to do so by your healthcare provider.
- **Do not** reuse the on-body Infusor. The on-body Infusor is for single use only.
- **Do not** let the on-body Infusor get wet from water or any other liquids. **Do not** shower, bathe, swim or do activities that may make you sweat while wearing the on-body Infusor. It contains parts that should not get wet.

**Call your healthcare provider or scPharmaceuticals at  
1-855-SCPHARMA (1-855-727-4276) if you have any questions.**

## Storage Information

- The FUROSCIX On-Body Infusor and prefilled cartridge should be stored at controlled room temperature between 68°F to 77°F (20°C to 25°C) (see Figure B). Do not refrigerate or freeze.
- **Keep** the FUROSCIX prefilled cartridge in the original carton to protect from light or physical damage until you are ready to use.
- **Keep** the FUROSCIX On-Body Infusor and prefilled cartridge out of the reach of children.

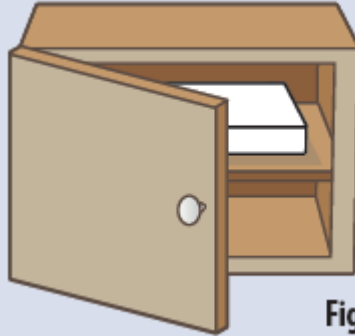


Figure B

## Prepare for the Infusion

### STEP 1 Wash Hands, Check Expiration Date and Remove Supplies from Carton

1.1 Wash your hands before using the on-body Infusor (Figure C).



Figure C

1.2 Check the expiration date on the FUROSCIX On-Body Infusor carton (see Figure D).

**Do not** use if the expiration date has passed.



Figure D

1.3 Open the carton and peel away the white paper cover. Remove the plastic cover from the clear tray. Remove supplies from the carton and packaging (see Figure E).

**Do not** use the on-body Infusor or prefilled cartridge if packaging appears to have been previously opened or damaged.

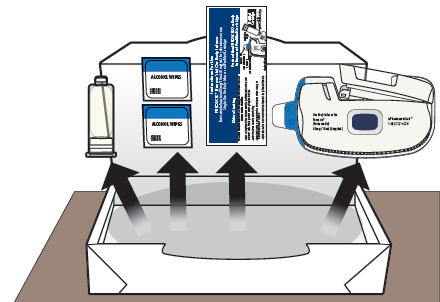


Figure E

1.4 Gather all materials needed for your injection, on a clean, well-lit work surface (Figure F):

- On-body Infusor and prefilled cartridge (Included)
- Instructions For Use (Included)
- Alcohol wipes (Included)
- Clippers (if needed) (Not included)
- Sharps disposal container (Not included)

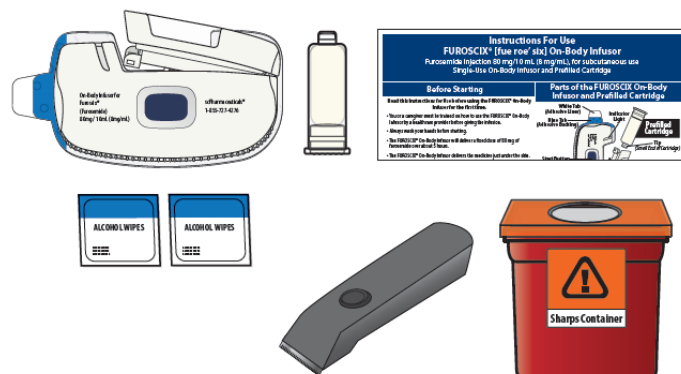


Figure F

## STEP 2

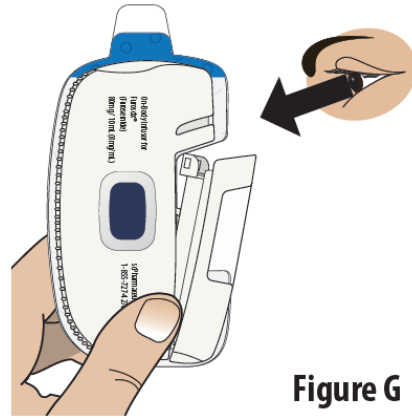
### Check On-Body Infusor and Prefilled Cartridge

**2.1** Check the on-body Infusor and prefilled cartridge for any damage (see Figure G).

**Do not** use the on-body Infusor or prefilled cartridge if either item appears to be damaged.

**Do not** touch the blue start button until the on-body Infusor is on the skin and you are ready to begin the infusion.

**Do not** touch or fully open the cartridge holder until you are ready to load the cartridge.

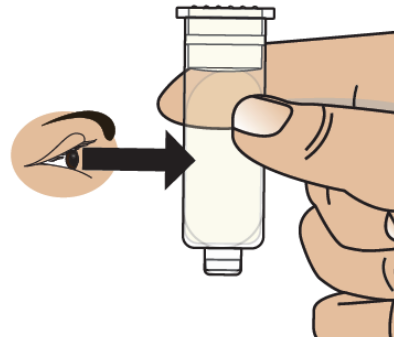


**Figure G**

**2.2** Check the liquid medicine in the prefilled cartridge (see Figure H). The liquid in the prefilled cartridge should be clear to slightly yellow.

**Do not** use the prefilled cartridge if the liquid is discolored or cloudy.

Call scPharmaceuticals at: 1-855-SCPHARMA (1-855-727-4276) or call your healthcare provider.



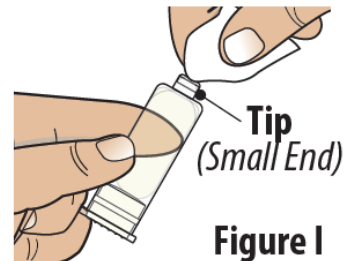
**Figure H**

## STEP 3

### Load Prefilled Cartridge into the On-Body Infusor

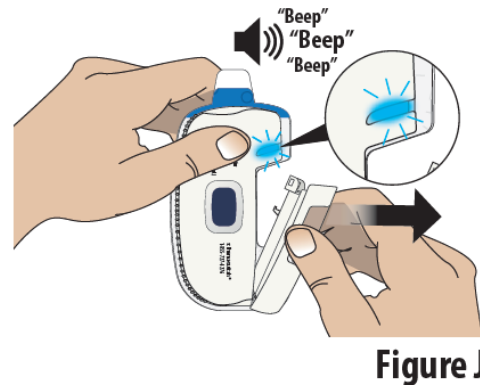
- 3.1** Clean the tip (small end) of the prefilled cartridge with an alcohol wipe (see Figure I).

**Do not** continue with the process of opening the cartridge holder all the way or loading the prefilled cartridge until you are ready to begin the infusion.



- 3.2** Open the cartridge holder all the way to turn on the on-body Infusor. The on-body Infusor "beeps" and the indicator light will begin blinking blue (see Figure J).

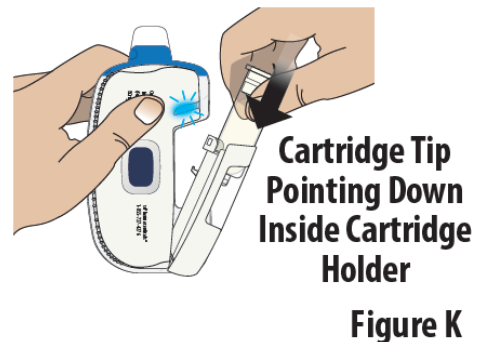
**Note:** Complete steps 3.3 through 6.1 within 30 minutes of fully opening the cartridge holder or the Infusor will alarm and cannot restart.



- 3.3** Insert the prefilled cartridge into the cartridge holder with the tip pointed down (see Figure K).

**Note:** The prefilled cartridge should slide into the cartridge holder easily. If it does not slide in easily, check the prefilled cartridge to make sure the tip is pointed down and try again.

**Do not** press the blue start button until on-body Infusor is applied to skin and you are ready to begin the infusion.



- 3.4** Close the cartridge holder all the way until it is even with the rest of the on-body Infusor (see Figure L). You may hear a "click" sound when it is closed.

**Note:** If the indicator light blinks red and the on-body Infusor "beeps", the on-body Infusor has experienced an internal error. **Do not** use the on-body Infusor (see On-Body Infusor Alarm section).



## Apply the On-Body Infusor

### STEP

4

### Select and Prepare Application Site

**4.1** Select one site on the stomach on either side of the belly button (navel). The site should be a **flat area** below the rib cage and above the belt line (see Figure M).

**Do not** select a site where the skin is irritated or broken.

**Do not** apply lotions, oils or ointments to the adhesion area of the abdomen.

**Do not** select a site where belts, waistbands or other types of clothing may rub against, disturb, or dislodge the on-body Infusor.

**Note:** Rotate application site (side of the stomach) each time if told by your healthcare provider to repeat dose.

**4.2** The site should be hairless or nearly hairless. If needed, remove excess hair by clipping or shaving the hair before applying the on-body Infusor (see Figure N).

**4.3** Wipe the skin where the on-body Infusor will be applied with an alcohol wipe and allow area to dry (see Figure O).

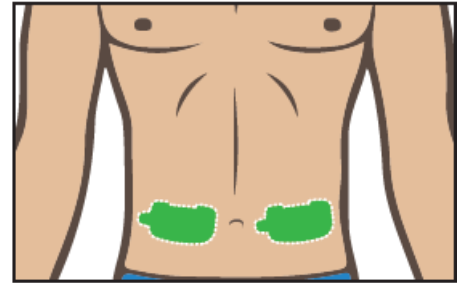


Figure M



Figure N

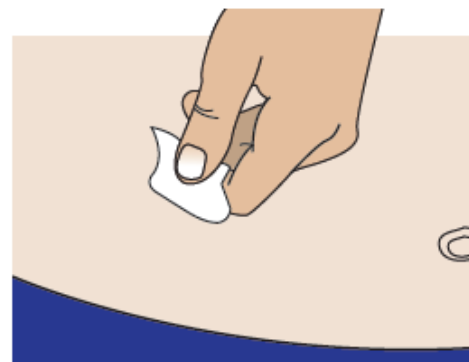


Figure O



## STEP 5 Apply the On-Body Infusor

**5.1** Pick up the on-body Infusor. Peel away the adhesive liner by grasping the white tab and pulling it away from the blue tab/adhesive backing (see Figure P).

**Do not** touch the sticky (adhesive) part of the on-body Infusor with your fingers or let it touch any objects or surfaces before the Infusor is placed on the skin.



Figure P

**5.2** Apply the on-body Infusor to the chosen skin site while standing or sitting up straight.

Position the on-body Infusor so that the cartridge window and the indicator light can be seen during the infusion (see Figure Q).

**Do not** bend over when applying the on-body Infusor.

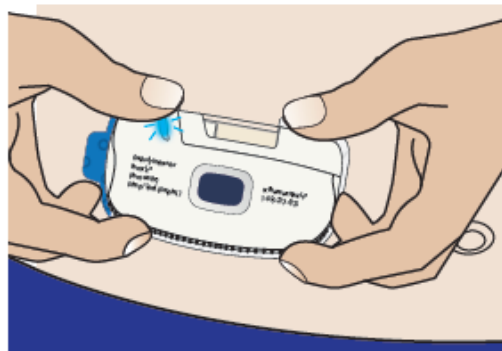


Figure Q

**5.3** Press the on-body Infusor firmly onto the skin and hold it for several seconds (see Figure R). Then rub your finger over the edges of the adhesive to get it to stick well.

**Do not** touch the blue start button until you are ready to start the infusion (see Step 6).

**Do not** remove and reapply on-body Infusor. The on-body Infusor adhesive might not work as well.



Figure R

## Start the Infusion

### STEP 6 Start the Infusion

**6.1** Firmly **press and release** the blue start button to begin the infusion (see Figure S).

The on-body Infusor will stick a very small needle just under the skin and begin delivering the medicine. The indicator light will start blinking green and the on-body Infusor "beeps", signifying that the infusion has begun.

**Note:** At the start of the infusion, you may also hear the on-body Infusor motor running for several seconds.

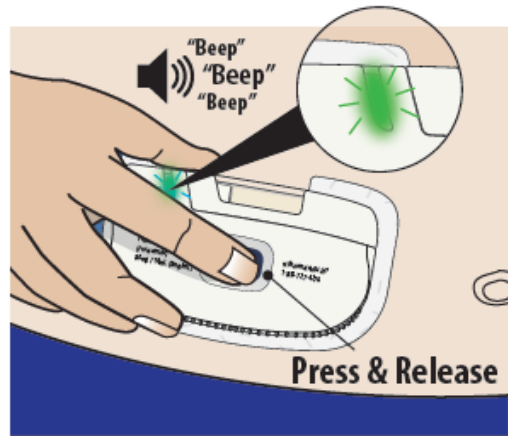


Figure S

## STEP 7 Allow Medicine to Deliver for 5 Hours

**7.1** Relax during the delivery period. The on-body Infusor should remain on the skin until the delivery is complete.

**Do not** exercise or take part in activities that might result in the on-body Infusor falling off. Take care not to bump the on-body Infusor while wearing it. It takes about 5 hours for the on-body Infusor to deliver all of the medicine. During the infusion, the indicator light will continue to blink green periodically, signifying that the infusion is running (see Figure T).

**Note:** If the on-body Infusor falls off or if the indicator light begins blinking red, call your healthcare provider right away (see On-Body Infusor Alarm section). **Do not** reapply or reuse the on-body Infusor. **Do not** apply a new on-body Infusor unless instructed to do so by your healthcare provider.

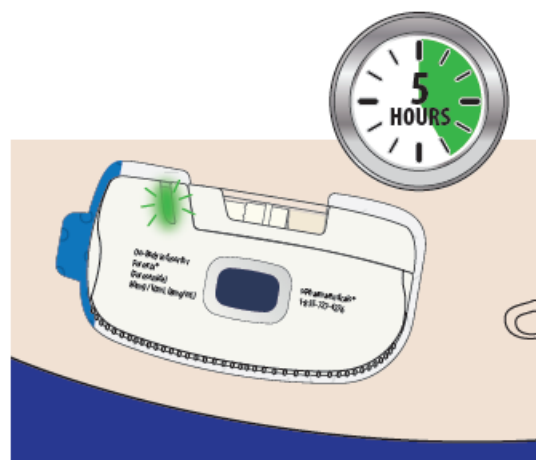


Figure T

### If You Have to Stop the Infusion Due to An Emergency, Do the Following:

- Remove the on-body Infusor from the skin (see Step 8). It will immediately stop infusing and the on-body Infusor will deactivate. **Do not** reuse the on-body Infusor. After the on-body Infusor is removed, it can no longer be used.
- Call your healthcare provider for further instructions.

## Remove and Dispose of the On-Body Infusor

### STEP

### 8

#### When Infusion is Complete, Remove the On-Body Infusor from the Skin

**8.1** The infusion is complete and the on-body Infusor is ready to be removed when (see Figure U):

- The indicator light turns solid green.
- The on-body Infusor "beeps".
- The white plunger rod fills the cartridge window all the way.

**Note:** If indicator light begins blinking red instead of green and the on-body Infusor "beeps", call your healthcare provider (see On-Body Infusor Alarm section).

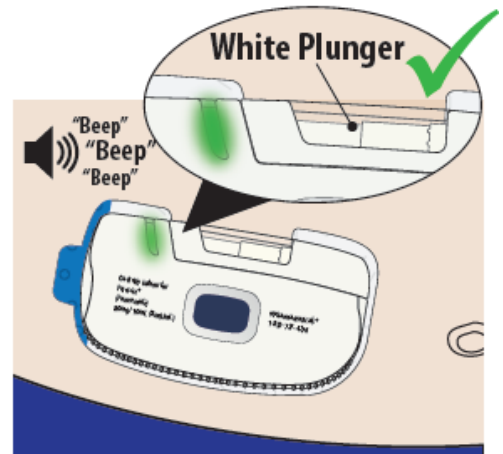


Figure U

**8.2** Peel the on-body Infusor off the skin by holding the skin down and pulling on the blue tab (see Figure V). When the on-body Infusor is removed, the indicator light will turn off, the needle cover will extend over the needle to protect against accidental needle sticks, and the on-body Infusor will turn off.

**Note:** You might have some discomfort after you remove the adhesive. This discomfort should quickly go away. However, some redness of the skin may remain.

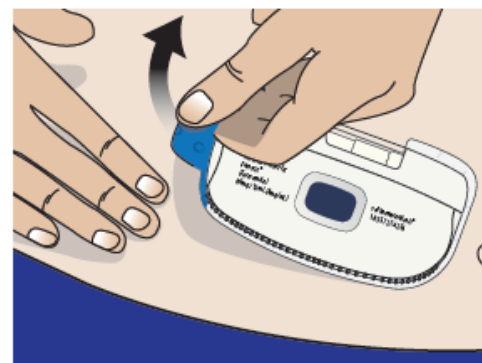


Figure V

**8.3** Check the infusion site. If there is any bleeding use a cotton ball or apply a small adhesive bandage.

## STEP 9

### Throw Away (Dispose) of Used On-Body Infusor

**9.1** Dispose of the used FUROSCIX On-Body Infusor and prefilled cartridge together into an FDA-cleared sharps container (see Figure W).

**Do not** attempt to remove the cartridge from the on-body Infusor; it cannot be removed.

**Do not** throw away the used on-body Infusor into household trash.



**Figure W**

If you do not have a FDA-cleared 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 your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used Needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

**Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

**Do not** recycle the on-body Infusor or sharps disposal container or throw them into household trash.

**Important:** Always keep the sharps disposal container out of the reach of children.

For more information refer to: <http://www.safeneedledisposal.org>

## Infusor Alarm

### What happened?

The Indicator light blinks red and the on-body Infusor "beeps" (see Figure X).

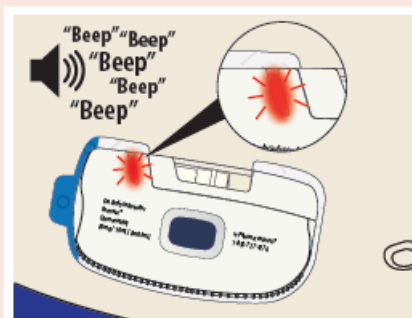


Figure X

### What does it mean?

There has been an internal error or the on-body Infusor came off the skin during the infusion.

### What to do?

Stop using the on-body Infusor. If the on-body Infusor is on the skin, carefully remove it. Call your healthcare provider for further instructions.

**Do not** reapply or reuse the on-body Infusor. It can no longer be used.












**Do not** apply a new on-body Infusor unless instructed to do so by your healthcare provider.

scPharmaceuticals, Inc.  
25 Mall Road, Suite 203, Burlington, MA 01803  
1-855-SCPHARMA (1-855-727-4276)

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

Issued: 10/2023

## Symbols Legend

Symbol	Meaning	Symbol	Meaning
	Read Instructions for Use before using		For single use only
<b>EXP</b>	Expiration Date		Non-pyrogenic
	Temperature Limitation		Manufactured for
<b>R<sub>x</sub>only</b>	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner		Type BF Equipment
<b>REF</b>	Catalog Number		Do not use if the package has been opened or damaged
<b>SN</b>	Serial Number		Humidity limitation
<b>LOT</b>	Lot Number		Atmospheric pressure limitation
<b>STERILE</b>   <b>EO</b>	Sterilized by Ethylene Oxide		MRI unsafe. Do not use the product during an MRI procedure.
	Keep dry		

**Supplemental Table 1. Demographics and Baseline Disease Characteristics**

	<b>Patients with HF (n=30)</b>	<b>Caregivers (n=15)</b>	<b>HCPs (n=15)</b>
Median (SD) age, years	57 (39–80)	49 (34–75)	37 (33–64)
Sex, n (%)			
Male	24 (80)	7 (47)	3 (20)
Female	6 (20)	8 (53)	12 (80)
English as a second language, n (%)	4 (13)	4 (27)	4 (27)
Race, n (%)			
White	13 (43)	3 (20)	3 (20)
Asian	3 (10)	4 (27)	7 (45)
Hispanic or Latino	7 (24)	3 (20)	0
Black	4 (14)	1 (7)	1 (7)
Other	3 (10)	4 (27)	4 (27)
Impairments, n (%)			
Hand <sup>a</sup>	8 (27)	1 (7)	0
Hearing <sup>b</sup>	4 (13)	0	0
Visual <sup>a</sup>	1 (3)	1 (7)	0
Mean (SD) duration of CHF, years	4.6 (5.2)	–	–
Training status, n (%)			
Trained <sup>c</sup>	15 (50)	0	0
Untrained	15 (50)	15 (100)	15 (100)
Highest level of education, n (%)			
GED	1 (3)	0	–
High school diploma	13 (44)	3 (20)	–



Associate's degree	6 (20)	2 (13)	2 (13)
Bachelor's degree	6 (20)	8 (54)	11 (74)
Master's degree	3 (10)	2 (13)	2 (13)
PhD	1 (3)	0	0

**Abbreviations:** GED, general educational development; HCP, healthcare practitioner;

HF, heart failure; IFU, instructions for use; PhD, doctor of philosophy; SD, standard deviation.

<sup>a</sup>Excluded if the level of impairment would prohibit unassisted injection.

<sup>b</sup>Excluded if unable to hear.

<sup>c</sup>15–30 minutes of training from an HCP who works with patients with CHF, with a review of IFU and a demonstration of the infusion process, followed by a 24-hour washout.