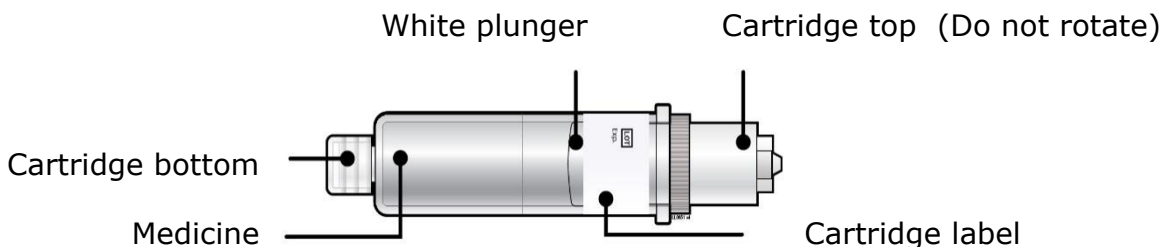


**Instructions for use:
Pushtronex® System for
Repatha® (ri-PAth-a)
(evolocumab)**

Single-Use On-Body Infusor and Prefilled Cartridge

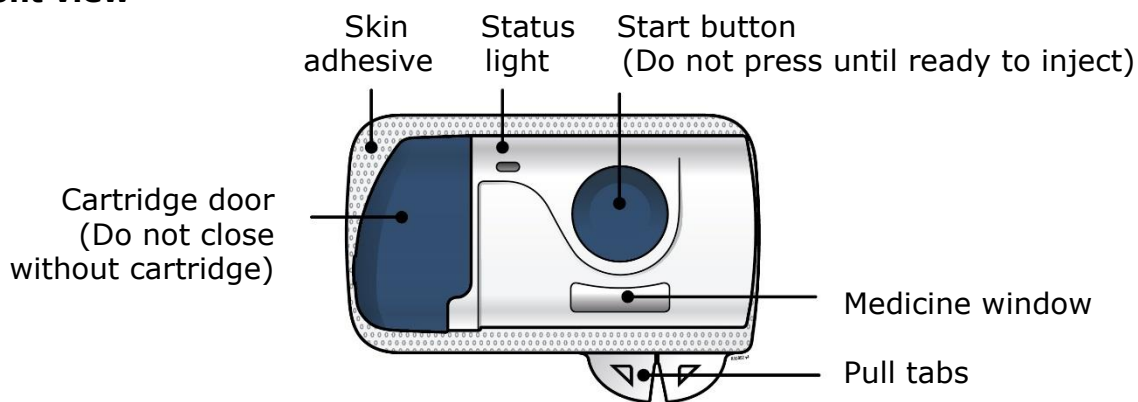
Guide to parts

Prefilled Cartridge

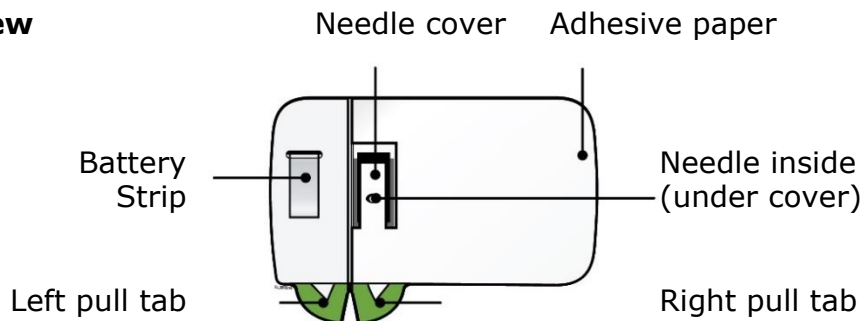


On-Body Infusor

Front view



Back view



Important: Needle is inside.

Important

Before you use the on-body infusor and prefilled cartridge for use with Repatha (evolocumab), read this important information:

- It is important that you do not try to give yourself the injection unless you have received training from your healthcare provider.
- Children who are 13 to 17 years of age should use the on-body infusor and prefilled cartridge under adult supervision, as instructed by the healthcare provider.

Storing your on-body infusor and prefilled cartridge

- Keep the on-body infusor and prefilled cartridge in the original carton to protect from light or physical damage.
- The on-body infusor and prefilled cartridge must be kept in the refrigerator 36°F to 46°F (2°C to 8°C).
- If removed from the refrigerator, the on-body infusor should be kept at room temperature at 68°F to 77°F (20°C to 25°C) in the original carton and must be used within 30 days.
- **Do not** store the on-body infusor and prefilled cartridge in temperatures above 77°F (25°C) such as in your vehicle's glove box or trunk. **Do not** freeze.

Using your on-body infusor and prefilled cartridge

- **Do not** shake the on-body infusor or prefilled cartridge.
- **Do not** remove the on-body infusor and prefilled cartridge from the box or clear tray until you are ready to inject.
- **Do not** touch the start button until you place the loaded on-body infusor and prefilled cartridge onto your skin and are ready to inject.
- You can only press the start button 1 time. If an error occurs, the on-body infusor cannot be used.
- **Do not** use the on-body infusor and prefilled cartridge if either has been dropped onto a hard surface. Part of the on-body infusor and prefilled cartridge may be broken even if you cannot see the break. Use a new on-body infusor and prefilled cartridge.
- **Do not** reuse the on-body infusor and prefilled cartridge. The on-body infusor and prefilled cartridge are for single use only.
- **Do not** let the on-body infusor get wet from water or any other liquids. It contains electronics that should not get wet.
- The single use on-body infusor for subcutaneous injection is made to only be used with the prefilled cartridge.
- Moderate physical activities can be done during the injection process, such as walking, reaching and bending.

- **Do not** use the on-body infusor and prefilled cartridge after the expiration date on the carton.
- The on-body infusor and prefilled cartridge are not made with natural rubber latex.

A healthcare provider who knows how to use the on-body infusor should be able to answer your questions. For more information, call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

Keep the on-body infusor and prefilled cartridge out of the reach of children.

Step 1: Prepare

- 1A** Remove the on-body infusor and prefilled cartridge carton from the refrigerator. Wait 45 minutes.

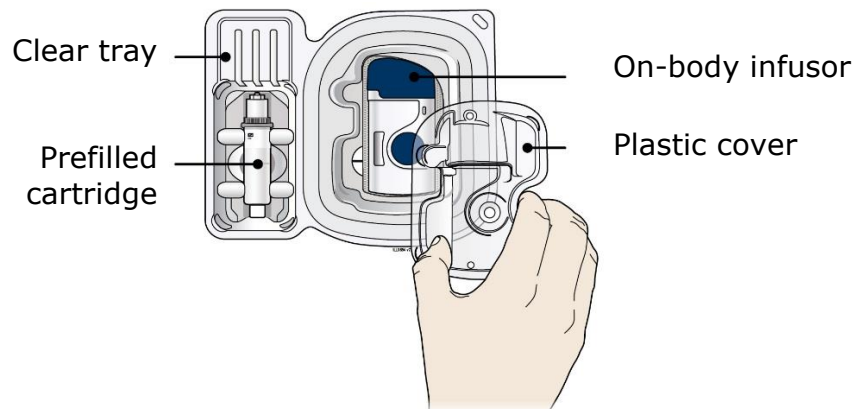


Important: Wait at least 45 minutes for the on-body infusor and prefilled cartridge to naturally reach room temperature in the carton.

- **Do not** try to warm the prefilled cartridge by using a heat source such as hot water or a microwave.

In any above cases, use a new on-body infusor and prefilled cartridge and call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

- 1B** Open the carton and peel away the white paper cover. Remove the plastic cover from the clear tray.



Leave the on-body infusor and prefilled cartridge in the clear tray until you are ready to inject.

- **Do not** touch the start button until the on-body infusor is on skin and you are ready to inject.
- **Do not** use if the white paper cover is missing or damaged.

1C Gather all materials needed for your injection and then wash your hands well with soap and water.

On a clean, well-lit work surface, place the:

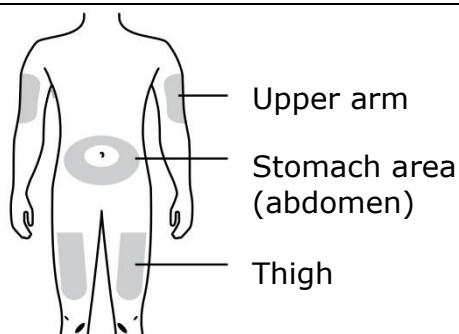
- Clear tray containing the on-body infusor and prefilled cartridge
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



1D To securely attach the on-body infusor, prepare and clean an injection site that is less likely to have body hair, or you can trim the area. Use a firm and flat skin surface.

You can use:

- Your thigh
- Stomach area (abdomen), except for a **two**-inch area right around your navel
- Outer area of upper arm (only if someone else is giving the injection)



Clean your injection site with an alcohol wipe. Let your skin dry.

- **Do not** touch this area again before injecting.
- **Do not** inject into areas where the skin is tender, bruised, red or hard. Avoid injecting into areas with wrinkles, skin folds, scars, stretch marks, moles and excessive hair.

Important: To attach the on-body infusor securely, it is important to use a firm and flat skin surface.

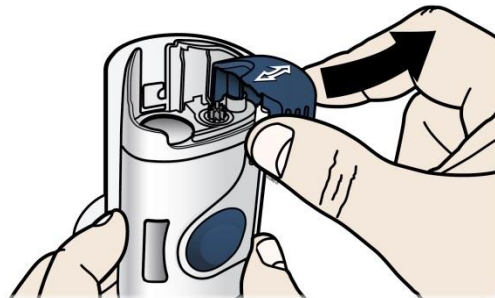
Step 2: Get ready

2A Open the on-body infusor by swinging the cartridge door to the right. Then, **leave the door open**. **Do not** close the cartridge door before the cartridge is loaded.

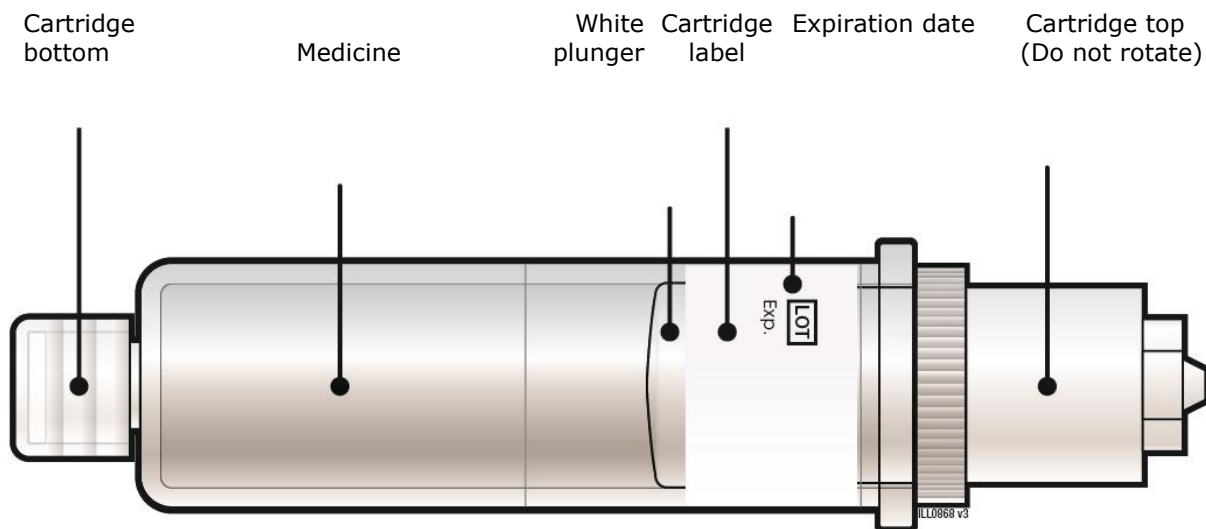
If you accidentally close the cartridge door, press on the left side of the door to release the door latch.

If you are still unable to open the door, call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

Do not press the start button until you are ready to inject.



2B Inspect the cartridge.



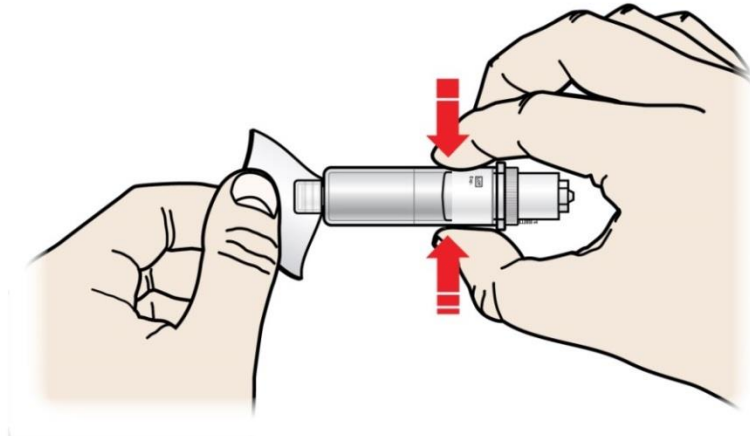
Check the expiration date: **do not** use if this date has passed.

Make sure the medicine in the cartridge is clear and colorless to slightly yellow.

- **Do not** use if the medicine is cloudy or discolored or contains flakes or particles.
- **Do not** use if any part of the cartridge looks cracked or broken.
- **Do not** use if pieces of the cartridge are missing or not securely attached.

In any above cases, use a new on-body infusor and prefilled cartridge and call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

2C Clean the cartridge bottom.

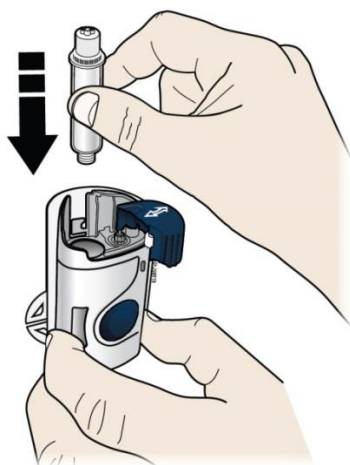


Grab Here

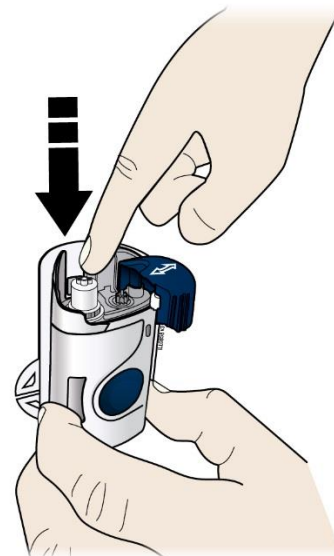
With 1 hand, hold the cartridge barrel and clean the cartridge bottom with an alcohol wipe.

- **Do not** remove or rotate the cartridge top or bottom.
- **Do not** touch the bottom of the cartridge after cleaning with alcohol wipe.

2D Load the cleaned cartridge into the on-body infusor and firmly press on the top until it is secured in place.



Load cartridge **straight**



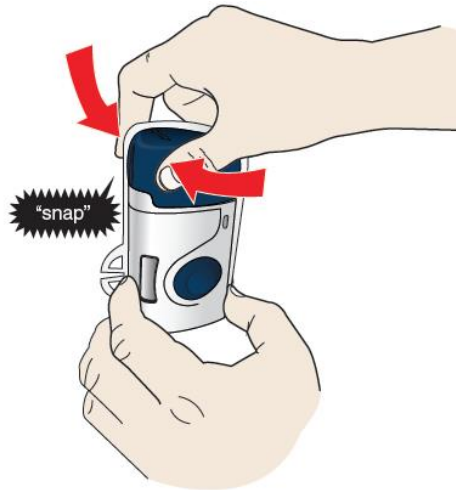
Press down **firmly**

Insert the cartridge bottom first.

- **Do not** touch the start button until you have placed the loaded on-body infusor on your skin.

2E Swing the door to the left. Then, squeeze firmly until it snaps shut. Apply enough pressure when closing the door and make sure there is a “snap” before going to the next step.

Squeeze Tight



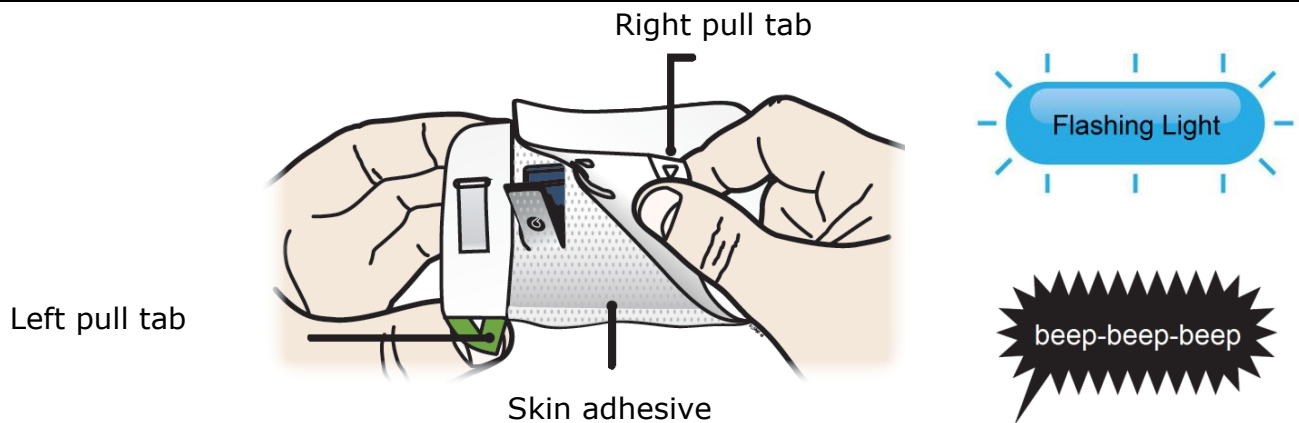
Make sure the cartridge fits securely in the on-body infusor before you close the door.

- **Do not** close the door if the cartridge is missing or not fully inserted.
- **Do not** touch the start button until you have placed the loaded on-body infusor on your skin.

Important: After you load the on-body infusor, go to the next step right away.

Step 3: Inject

3A Peel away **both** green pull tabs to show the adhesive. The on-body infusor is on when the blue status light flashes.

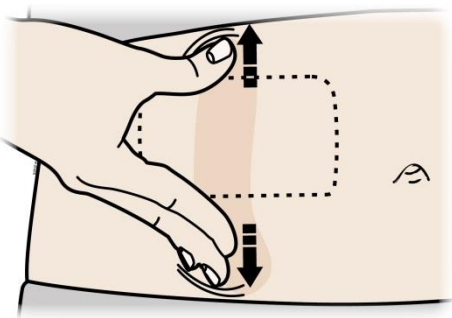


You must remove **both** green pull tabs to turn the loaded on-body infusor on. You will hear beeping and see a flashing blue status light.

- **Do not** pull the skin adhesive backing off of the on-body infusor.
- **Do not** touch the skin adhesive.
- **Do not** touch the start button until you have placed the loaded on-body infusor on your skin.
- **Do not** touch the needle cover area.
- **Do not** place the loaded on-body infusor on your body if the red status light flashes continuously.
- **Do not** fold the skin adhesive over onto itself.

3B Choose your on-body infusor injection site. Only use the outer arm if someone else is giving the injection.

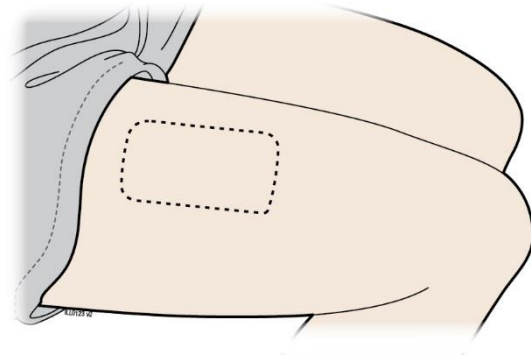
Stomach area placement



Stretch method for stomach

Thigh placement

or

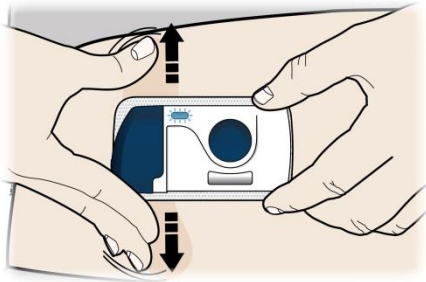


Do not stretch for thigh

Important: Adjust your body posture to avoid skin folds and bulges.

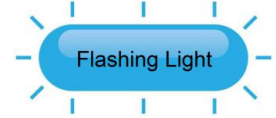
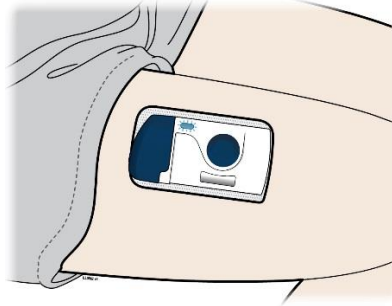
3C When the blue light flashes, the on-body infusor is ready. Keep the stretch (stomach area method only). Hold the loaded on-body infusor with the blue light visible, and place it on your skin. You may hear beeps.

Stomach area placement



or

Thigh placement

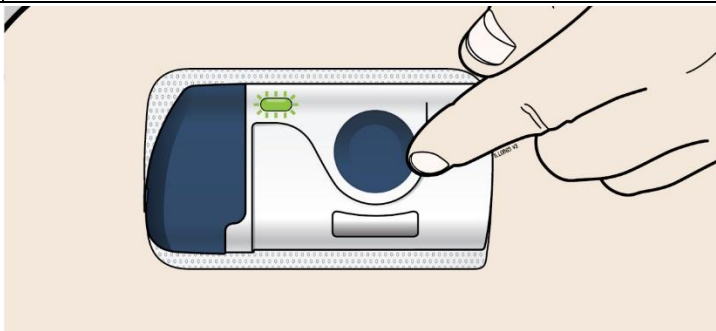


The loaded on-body infusor will lay flat on your body. Make sure all of the adhesive is attached to your skin. Run a finger around the adhesive edges to secure it.

Make sure clothing does not get in the way of the loaded on-body infusor, and you can see the blue light at all times.

- **Do not** move the loaded on-body infusor after it has been placed onto your skin.

3D Firmly **press and release** the start button. A flashing green light and a click signals the injection has started.



- You may hear a pumping sound.
- You may feel a pinch.
- Make sure you see a green, flashing status light.
- You may hear beeps that mean your injection has started.

Important: If medication leaks from the on-body infusor, call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

3E The injection takes about **nine** minutes to finish. The status light turns **solid green**, and the device beeps, when done.



It is okay to hear a pumping sound start and stop during injection.



Injection is finished when:

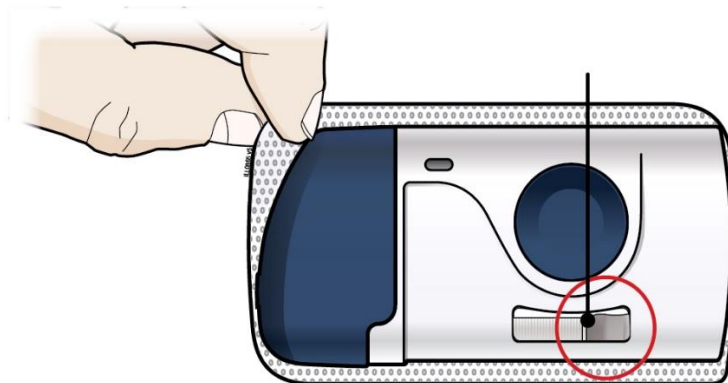
- The status light changes to **solid green**.
- You hear several beeps.
- The plunger fills medicine window all the way.



Step 4: Finish

4A When the injection is done, grab the skin adhesive to carefully peel the on-body infusor off skin. After removal, check the medicine window. The green light should now be off.

Used plunger filling medicine window



Check to see that the used plunger fills the medicine window all the way, and the green solid light turns off, letting you know all medicine has been injected. If the plunger did not fill the window, call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

- The used on-body infusor will beep when removed from your skin.
- It is normal to see a few drops of fluid on your skin after you remove the used on-body infusor.

4B Throw away the used on-body infusor in a sharps container.

- The on-body infusor contains batteries, electronics, and a needle.
- Put the used on-body infusor in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the on-body infusor in your household trash.
- 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 your used sharps disposal container.
- **Do not** recycle the on-body infusor or sharps disposal container or throw them into household trash.



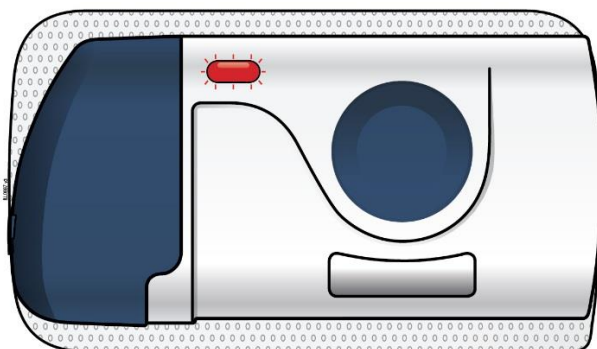
Important: Always keep the sharps disposal container out of the reach of children.

4C Check the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site. Apply an adhesive bandage if needed.

Troubleshooting

What do I do if the loaded on-body infusor status light continuously flashes red and I hear beeps?



Stop using the loaded on-body infusor. If the on-body infusor is attached to your body, carefully remove it. Call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

Commonly Asked Questions

What if I hear the on-body infusor beep and see a red blinking light when it is on my body?

This means that an error has happened. When this happens, the injection will stop by itself. Remove the on-body infusor from your body by slowly and carefully peeling it off of your skin, call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

What should I do if the on-body infusor comes off my body during the injection?

Though unlikely, if the on-body infusor comes off during the injection, the on-body infusor will make a beeping sound, you will see the blinking red light, and the on-body infusor will stop. The loaded on-body infusor can no longer be used, and do not reapply to your body. Call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

What if I push the start button before I place the on-body infusor on my skin?

If you have removed the adhesive backing and pressed the start button, the on-body infusor will make a beeping sound and you will see the blinking red light. The on-body infusor will stop. Stop using the on-body infusor, call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

What if the on-body infusor does not beep and the blue status light does not blink when I remove the pull tabs?

Check to see if both green pull tabs have been fully removed from the on-body infusor, including the adhesive paper over the battery strip and needle cover. If both green pull tabs have been fully removed and the on-body infusor still does not turn on, use a new on-body infusor and prefilled cartridge. Call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

What if I push the start button and nothing happens?

Remove the on-body infusor by slowly and carefully peeling it away from your skin. Do not reapply the same on-body infusor that you have already placed on your skin. Call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

What if I cannot open the cartridge door to insert the cartridge?

To open the on-body infusor door, press on the left side of the door to release the door latch. If you are still unable to open the door, call 1-844-REPATHA (1-844-737-2842) or visit www.REPATHA.com.

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



Manufactured by:
Amgen Inc.
Thousand Oaks, CA 91320-1799
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<part number> Revised: 12/2017 v4

U.S. License Number 1080

Additional environmental conditions

Relative humidity range is 15% to 85%.

Altitude range is -984 feet to 11483 feet (-300 meters to 3500 meters).











During injection, keep the on-body infusor a minimum of 4 inches (10 cm) away from other electronics such as cellular phones.

Warning: Do not modify the device.

On-body infusor operating temperature range is 59°F to 104°F (15°C to 40°C).

www.devicepatents.com.

SYMBOL TABLE

				
Do not re-use	Serial number	Type BF Applied Part	Do not use if packaging is damaged	On-Body Infusor containing 420 mg/3.5 mL (120 mg/mL)
				
Sterilized using ethylene oxide	Refer to Instructions for Use	Lot number	Keep dry	Open here