

insuJetTM

Insulin - Jet Administration System

Instructions for use



Please read this entire
booklet before first use

If you have any questions, contact your local
distributor or visit the InsuJet™ website:

www.insujet.com

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Introduction

Thank you for choosing the InsuJet™ insulin-jet administration system. Be sure to read this entire manual and become familiar with the system before using it for any injections.

Clarification of intended use

The InsuJet™ system is intended for the subcutaneous jet injection of U-100 insulin in adults and children. The injector is designed for the administration of U-100 insulin, or saline solution for practice purposes. The InsuJet™ can be used to inject 4 to 40 units per administration, and is for single patient use only. Insulin is not provided with the injector.

Product description



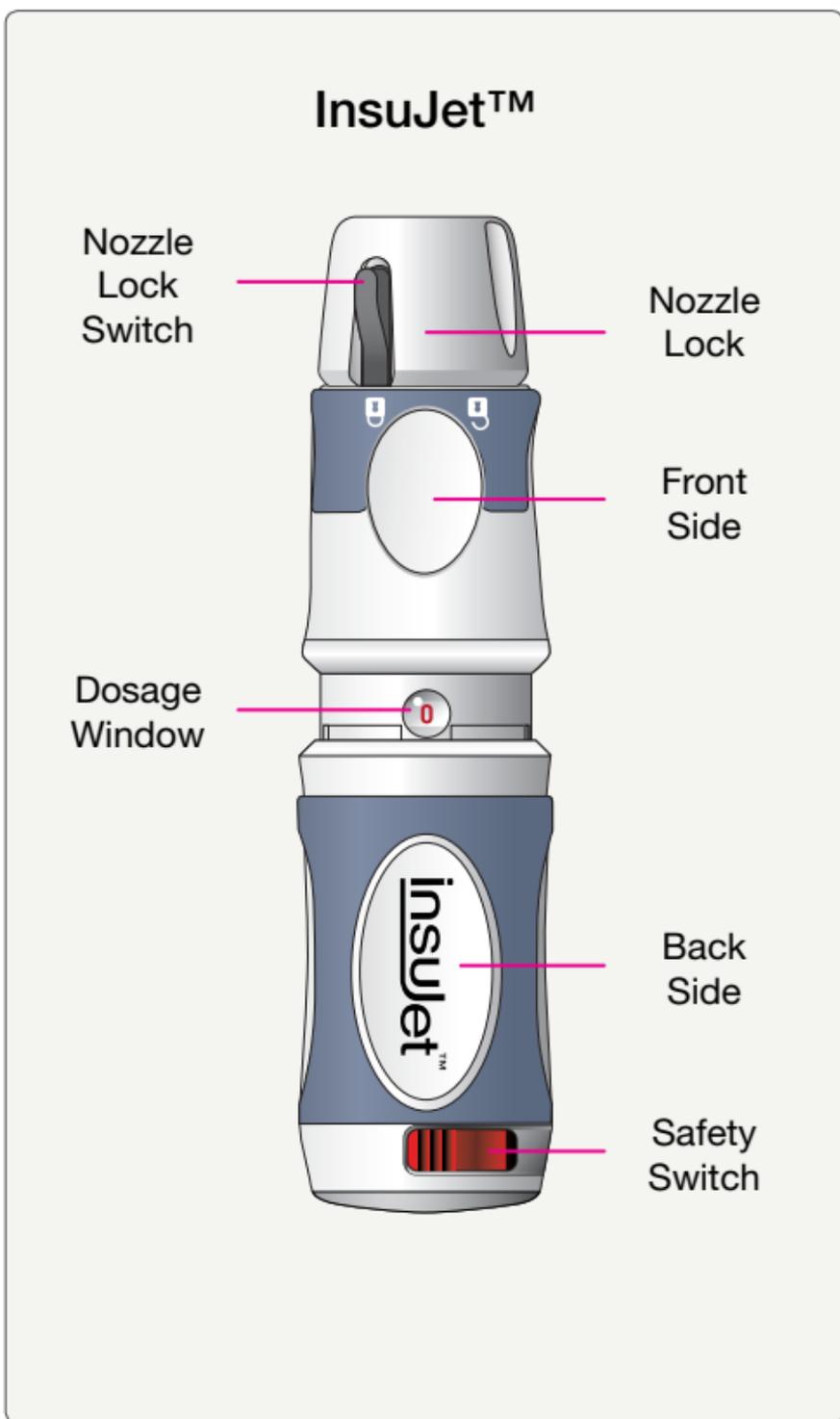
The InsuJet™ system is for people with diabetes and is used to administer insulin. The system works by positive displacement, i.e. by forcing insulin through a small orifice of a special Nozzle. This creates a thin, high pressure stream of insulin that penetrates the skin. In this manner the insulin is deposited into the subcutaneous tissue.

All pictures in this manual are shown for right-handed operation. From experience, it is known that left handed people can handle the InsuJet™ safely and comfortable as well.

Product overview

The InsuJet™ package contains the following items:

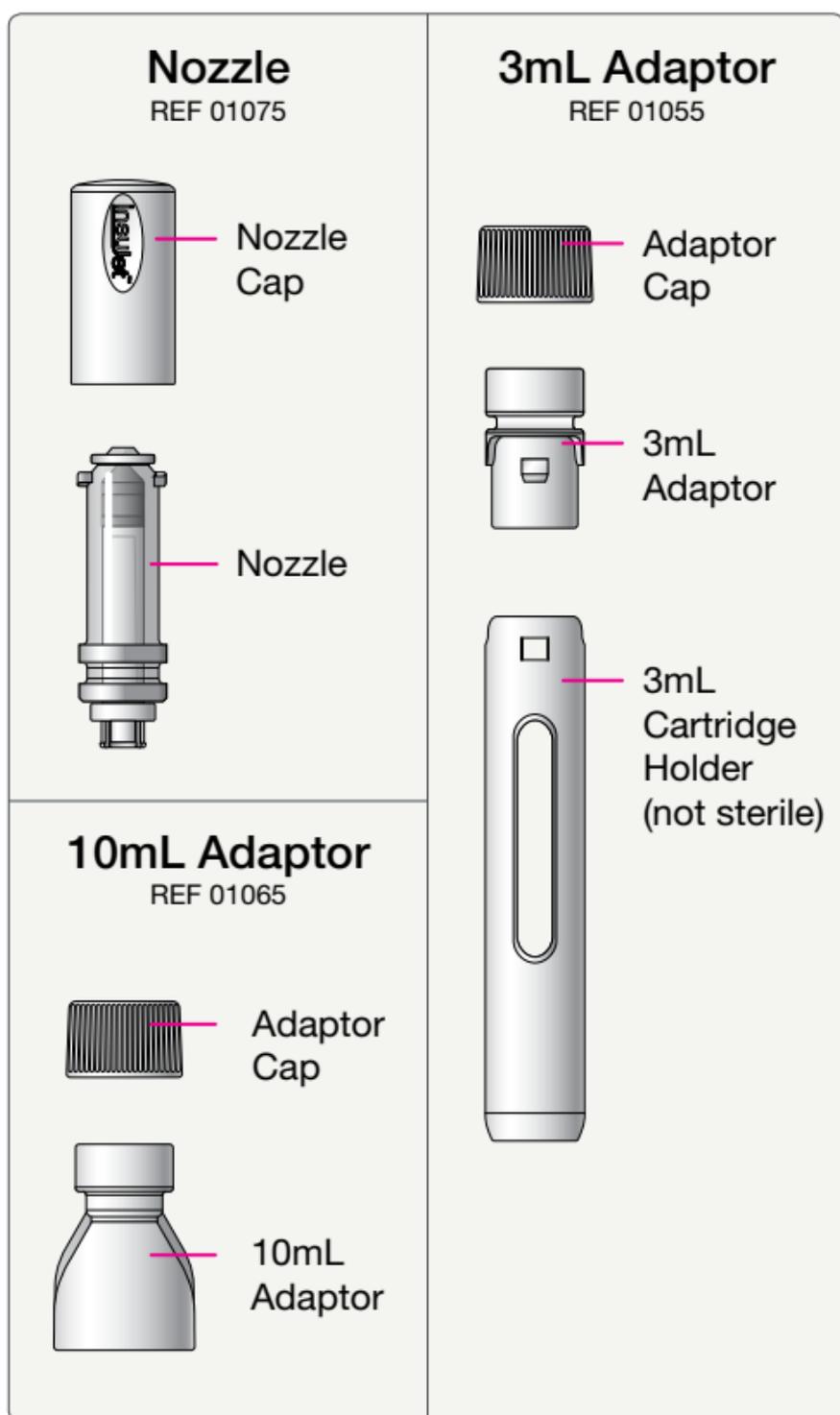
- InsuJet™ device
- Comfort Ring
- Carry Case
- Instruction For Use booklet
- Warranty Card



Consumables and accessories

InsuJet™ consumables:

NOTE: not included in the InsuJet™ package



InsuJet™ accessories:

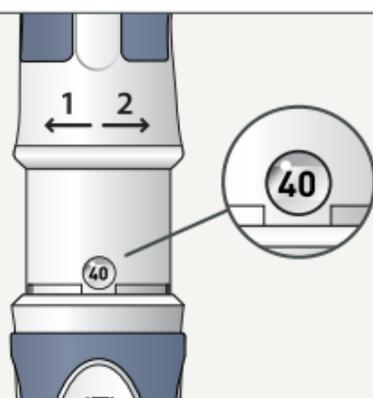


Warnings

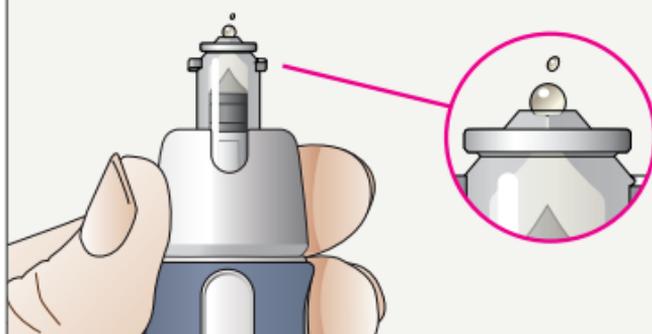
- The InsuJet™ should only be used for the administration of U100 insulins
- The InsuJet™ should only be used with InsuJet™ Nozzles and Adaptors.
- Check the expiration dates of your insulin. Do not use insulin past its expiration date.
- Check the expiration dates of the InsuJet™ consumables on the outer packaging. Do not use consumables past its expiration date.
- Check the integrity of the InsuJet™ consumables packaging. Do not use if the package is breached.
- Never use the same Nozzle for different types of insulin.
- Never use the same cartridge- or vial Adaptor for different insulin cartridges or vials. Discard the Adaptor with the empty insulin cartridge or vial.
- Be careful not to touch the needle inside the Adaptor.
- Never discharge the InsuJet™ without a Nozzle attached, or air inside the Nozzle. This is called DRY-FIRING and may damage the device beyond repair.
- Replace the Nozzle whenever the InsuJet™ has not been used for more than 3 days.
- Never use the same Nozzle or cartridge or vial Adaptor for different patients.
- Adult supervision is highly recommended when a child uses the

InsuJet™. Make sure that children are told that the InsuJet™ is not a toy.

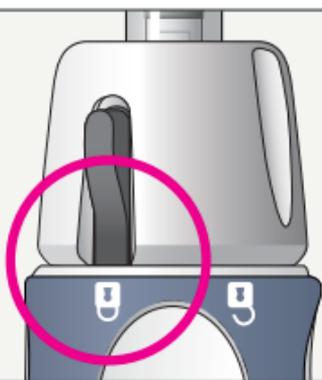
- Keep all medications and injection devices out of the reach of children.
- Never use, or attempt to repair a damaged or broken InsuJet™ or consumable.
- Temperature limits for use:



Do not attempt to force the InsuJet™ beyond the mechanical stop past the 40 IU indication. It may damage the device and potentially cause injury.



Ensure that the Nozzle is completely filled, and free of air bubbles before each administration. If not, you will administer less insulin than shown on the dosage window, which will affect your anticipated blood glucose level.



Before administration, ensure that the Nozzle Lock Switch points to the locked position. This indicates that the Nozzle is secured.



Replace the InsuJet™ in time. The same device should never be used for more than **5000 injections**. Do not use the device past the indicated expiry date. Device performance and safety may be affected when using the device beyond the indicated lifetime.



Replace the Nozzle regularly. The same Nozzle should never be used for more than **56 injections**, or longer than **14 days**. It is advised to replace the Nozzle every time a new cartridge or vial is used. Using the Nozzle beyond the indicated lifetime will cause insulin leakage and device malfunction, with loss of warranty.

Precautions

- Do not use the InsuJet™ other than described in this instruction for use. The manufacturer is not responsible for potential problems with products that are used in violation with this instruction for use.
- Please consult your Diabetes Care Specialist when you change your insulin administration system. Make sure to carefully monitor your blood glucose levels before using the InsuJet™, and for an appropriate amount of time thereafter.
- Always have a “BACK UP METHOD” available to take your insulin, in case your InsuJet™ gets lost or broken.

Good injection practices

- Wash your hands thoroughly before using the InsuJet™
- Clean the injection site as directed by your Diabetes Care Specialist.
- Avoid unnecessary contact with the Nozzle tip or the areas on the consumables that come into contact with the insulin, to prevent possible contamination.
- Monitor your blood glucose levels regularly as instructed by your Diabetes Care Specialist.

Contraindications

This product is not recommended for patients who are:

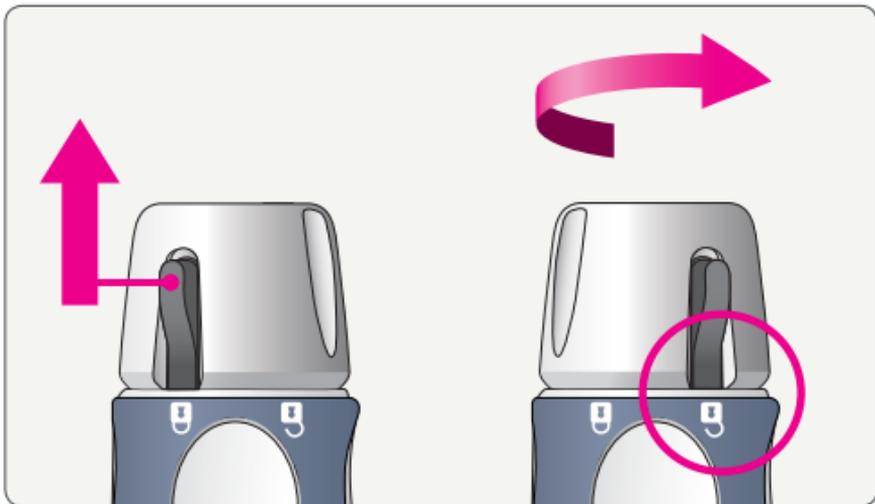
- Severely visually impaired;
- Physically unable to operate the system;
- Not able to understand or memorize the operating instructions for using the InsuJet™;
- Have a special skin type (e.g. psoriasis patients), which might impair a successful use of the InsuJet™. In case of doubt please consult your Diabetes Care Specialist.

Patients who bruise or bleed easily (e.g. people using antithrombotic drugs) may use the device with caution.

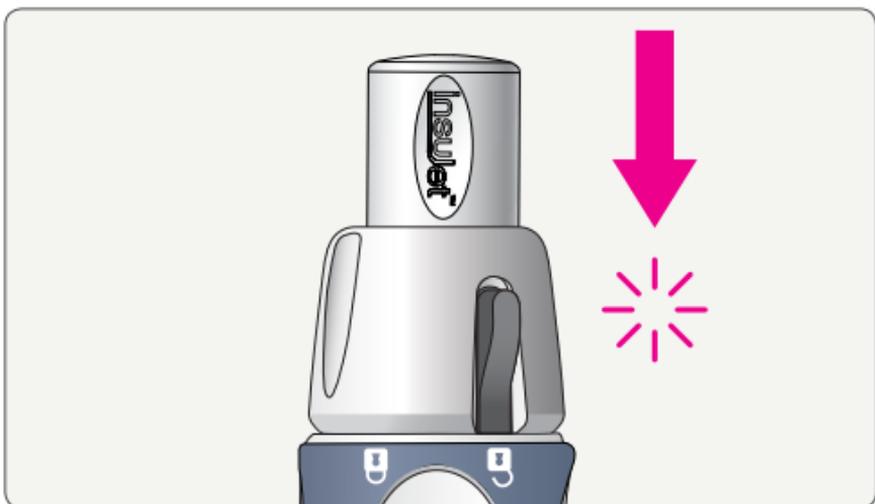
If you experience any prolonged or severe bruising or bleeding, it is recommended to stop using the system.

Operating instructions - Preparation

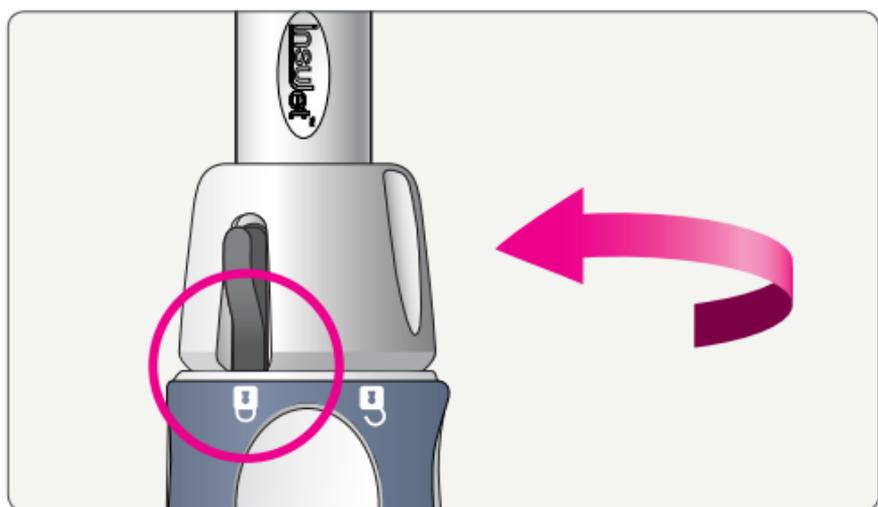
Installing the Nozzle



While pushing the Nozzle Lock Switch upward, rotate the Nozzle Lock counterclockwise until the Nozzle Lock Switch points to the 'padlock unlocked' icon.



Remove the Nozzle from its packaging. Push the back of the Nozzle firmly into the open end of the device, until it cannot go further.



Turn the Nozzle Lock clockwise. Make sure that the Nozzle Lock Switch points to the padlock locked position.

NOTICE:

If you cannot turn the Nozzle Lock to the locked position, please check if the Nozzle is installed correctly.

Ensure that the Nozzle is pushed firmly into the device until it cannot go further. Next, turn the Nozzle Lock clockwise until the Nozzle Lock Switch points to the padlock locked position.

Installing the Adaptor

There are different types of Adaptors available for the InsuJet™. These Adaptors are used to transport the insulin from an insulin cartridge or insulin vial into the Nozzle.

- Use a 3mL Adaptor and Cartridge Holder if you want to use insulin from a 3mL cartridge.
- Use a 3mL Adaptor if you want to use insulin from a disposable prefilled pen.
- If you want to use insulin from a 10mL vial, please use the 10mL Vial Adaptor.

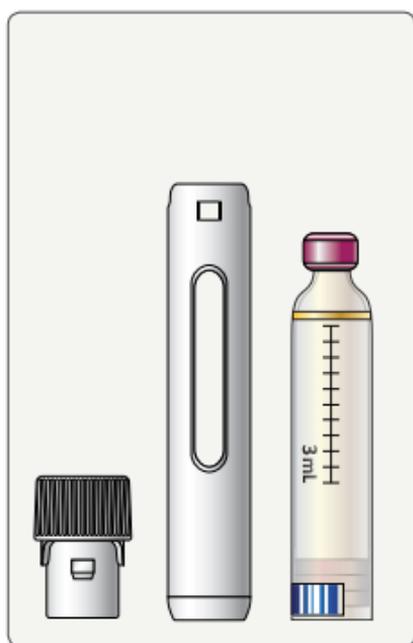
The Adaptors are sterile packed. Remove the Adaptor from the packaging after identifying the correct content.

3mL Adaptor
REF 01055

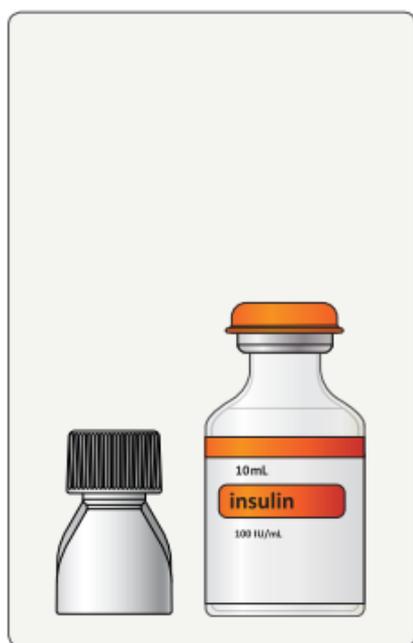


10mL Adaptor
REF 01065

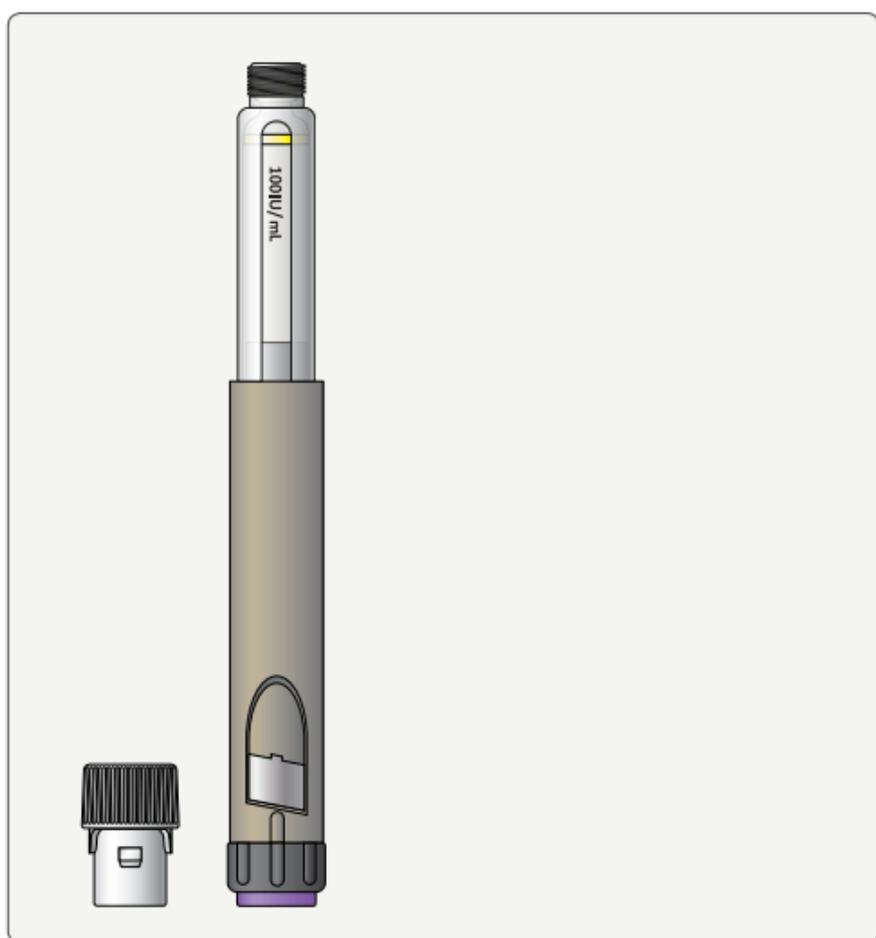




Example of a 3mL Adaptor with a 3mL cartridge



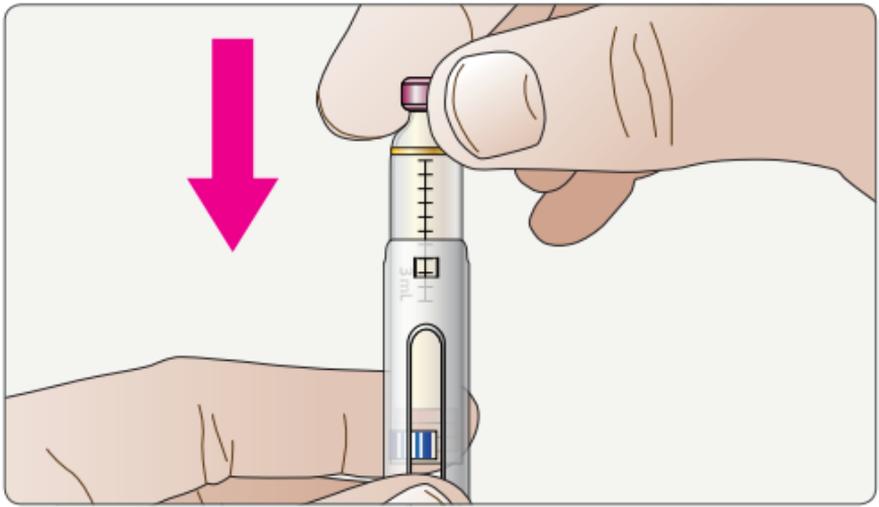
Example of a 10mL Adaptor with a 10mL Vial



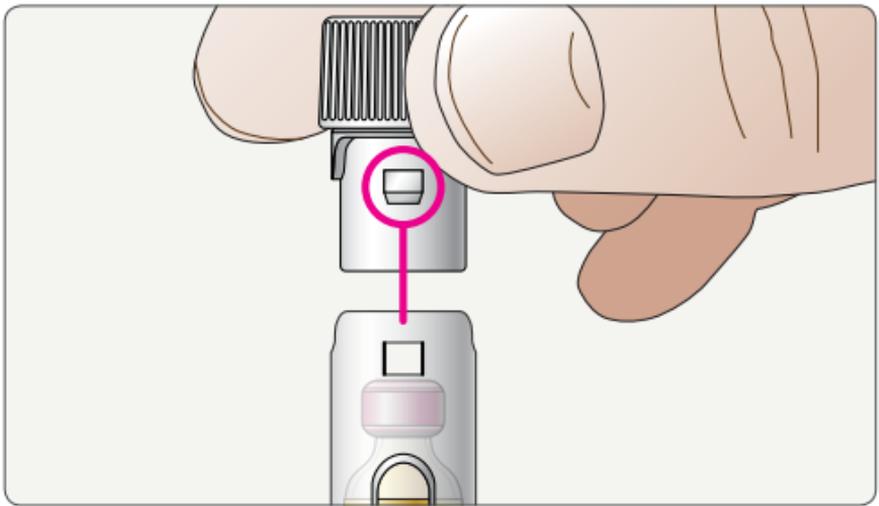
Example of a 3mL Adaptor with a Disposable penfill

NOTICE: For disposable penfill users, please refer to page 48 - 49 for instructions to install a 3mL Adaptor on a disposable penfill.

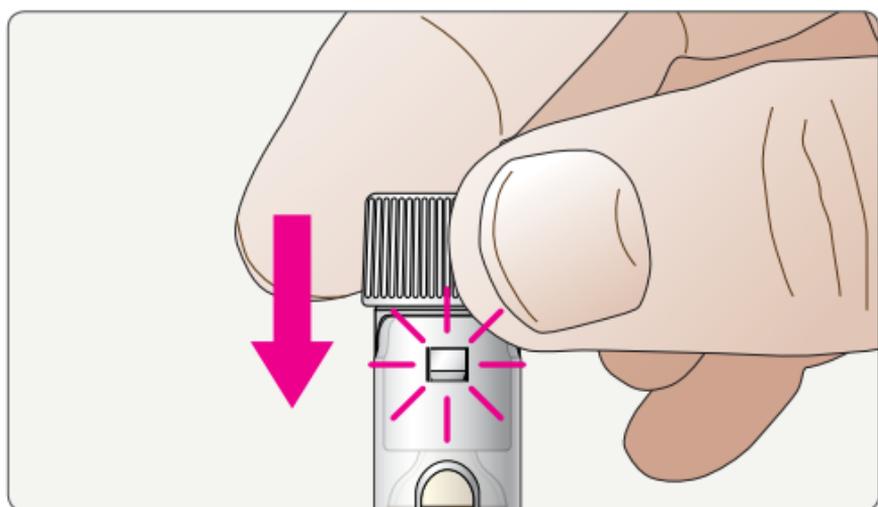
Installing a 3mL Adaptor



Slide the 3mL cartridge into the Holder, with the bottom of the cartridge downward.

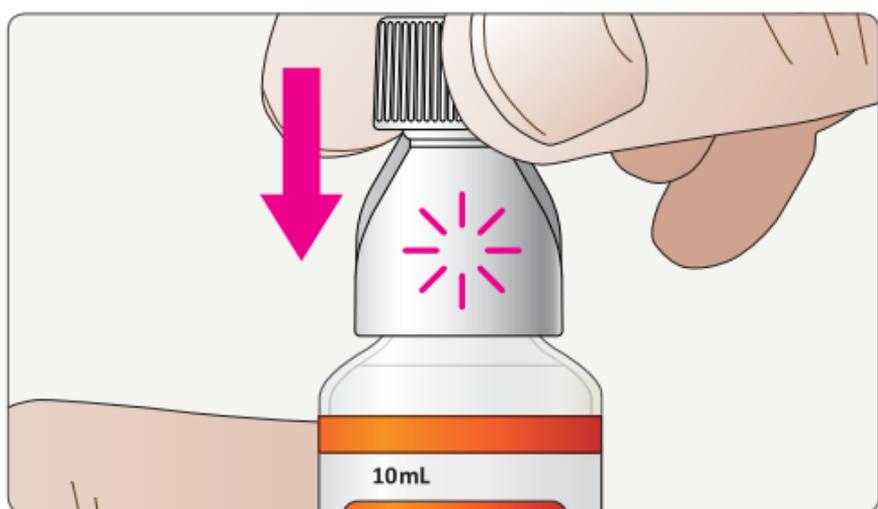


Take the Adaptor and place it into the Holder. Make sure that the protrusions on the Adaptor and corresponding holes in the Holder are properly aligned.



Push firmly until the Adaptor snaps in place.
The Adaptor remains on the Holder.

Installing a 10mL Adaptor



Remove the protective cap from the insulin vial.

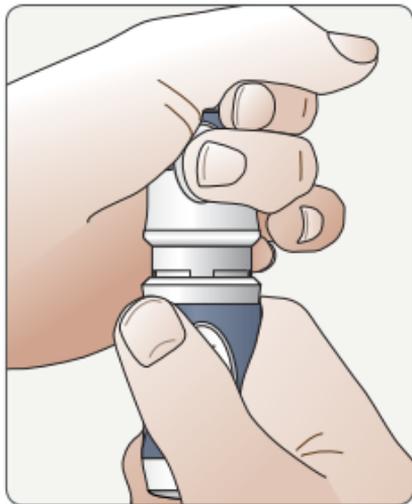
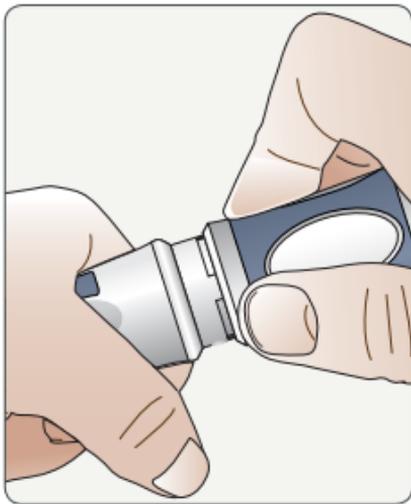
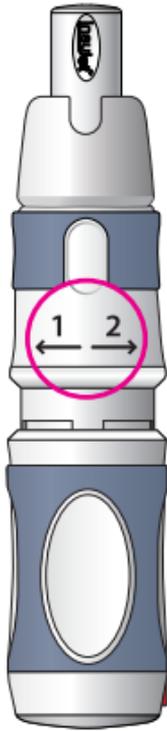
Push the 10mL Adaptor firmly onto the 10mL vial, until the Adaptor snaps in place.

The Adaptor remains on the vial.

Preparations for administration

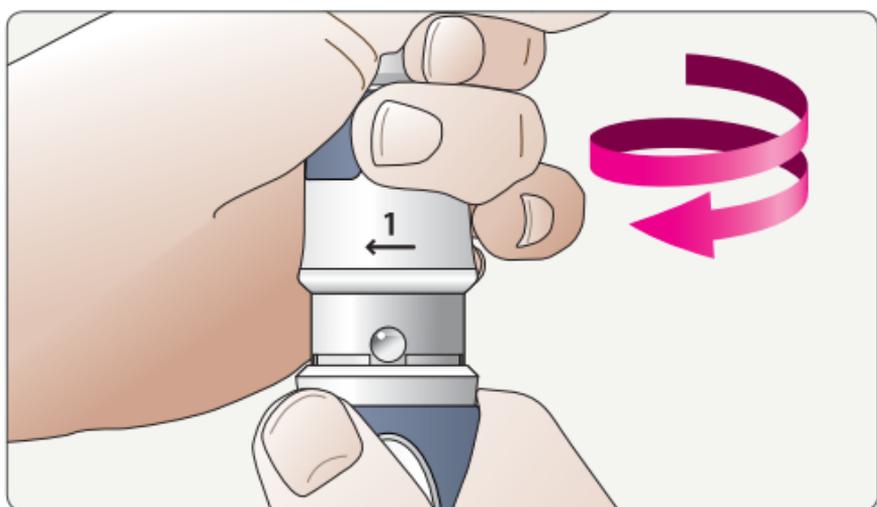
Charging the InsuJet™

Notice the Nr1 and Nr2 arrows on the front of the device.

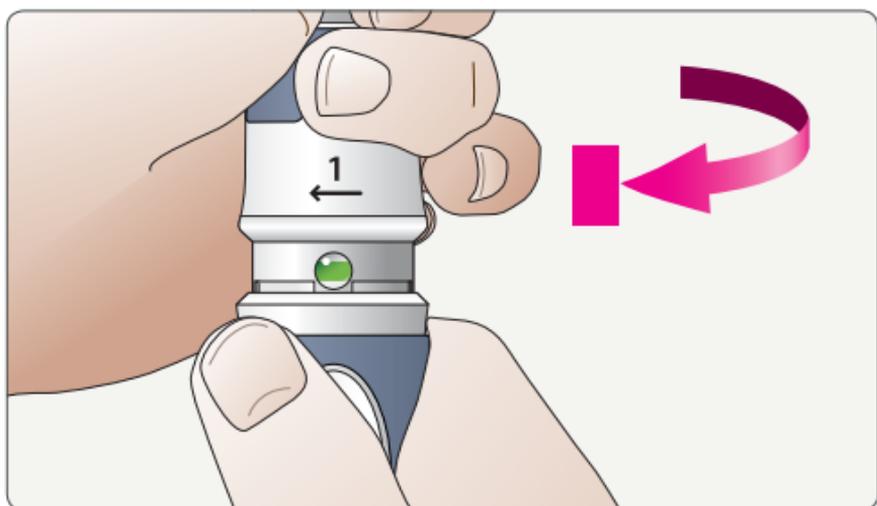


Hold the device in both hands, one hand holding the front of the device, the other holding the back.

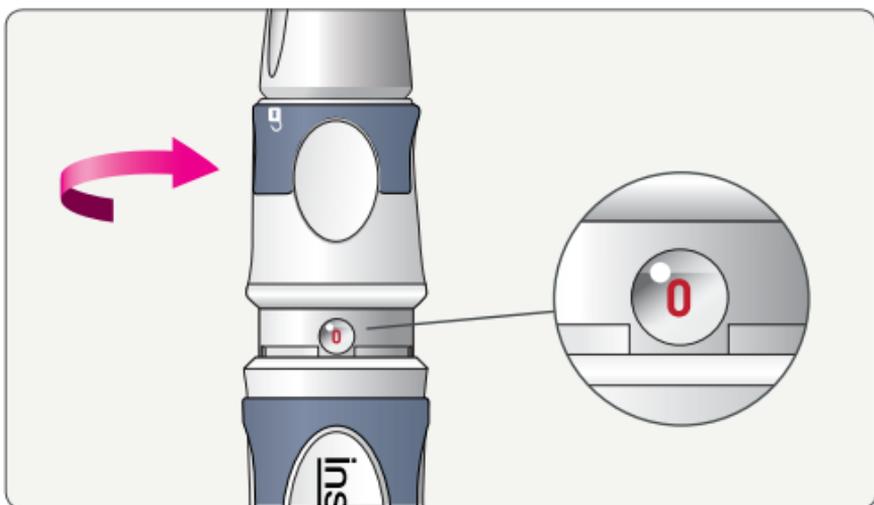
It is advised to hold the device in one of the two ways shown above.



While firmly holding the back of the device, start rotating the front in the direction of the Nr1 arrow. As the device is being charged, some force will be required. Note that the amount of units in the Dosage Window should decrease.



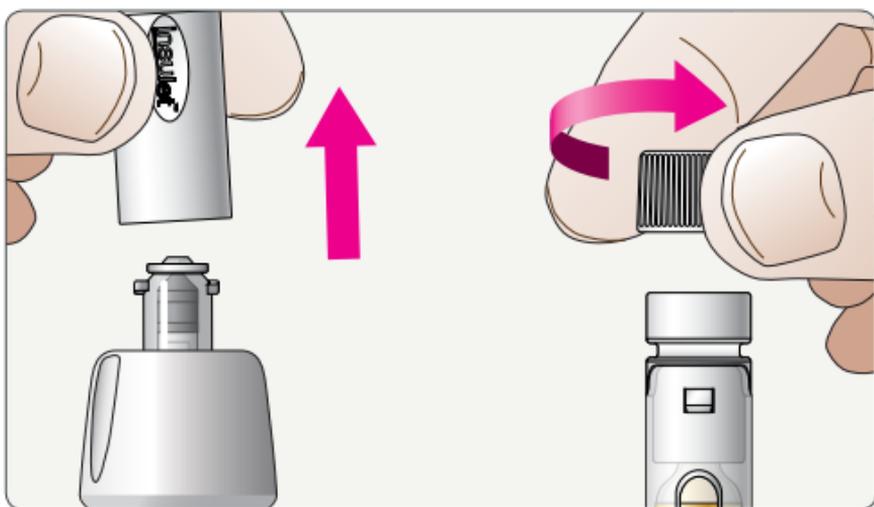
Continue to rotate the back until it will go no further. The InsuJet™ is charged when a green mark is visible in the Dosage Window.



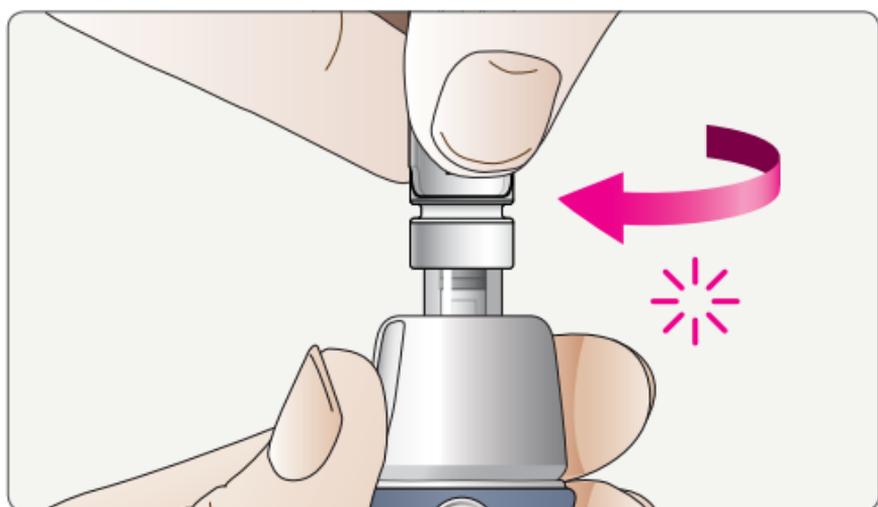
While holding the back of the device, rotate the front in the direction of the Nr2 arrow, until the number '0' re-appears in the Dosage Window. The front of the device should be easy to turn at this stage.

Priming the InsuJet™

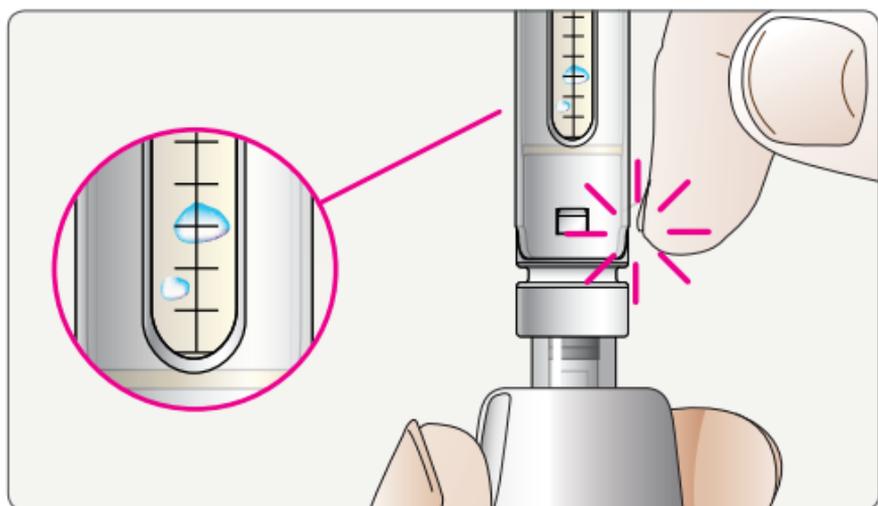
Prime your InsuJet™ every time you use a new Nozzle or new Adaptor. Priming reduces air bubbles inside the Nozzle.



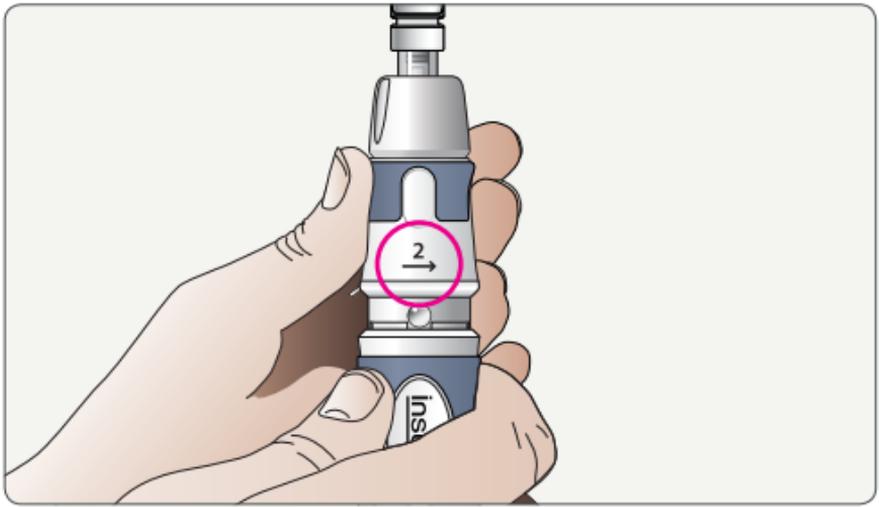
Remove the Nozzle Cap from the Nozzle and the Adaptor Cap from the Adaptor.



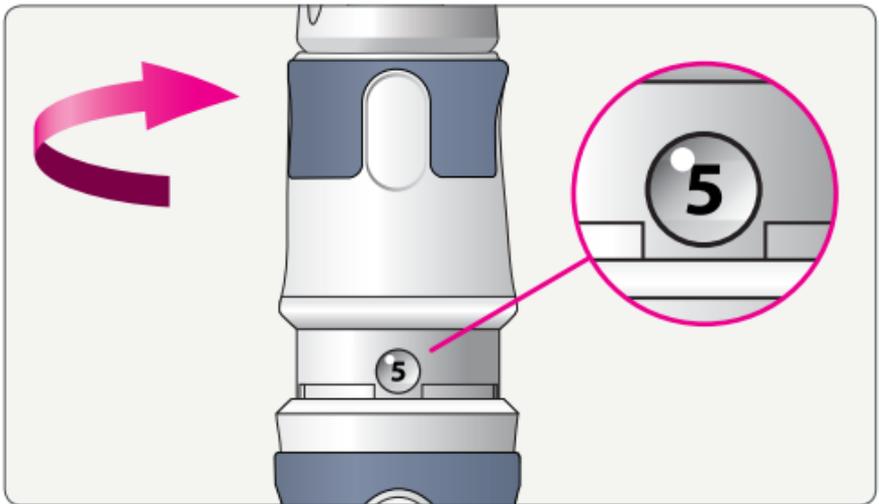
Align the Adaptor with the Nozzle and firmly rotate the Adaptor clockwise until the Adaptor snaps in place.



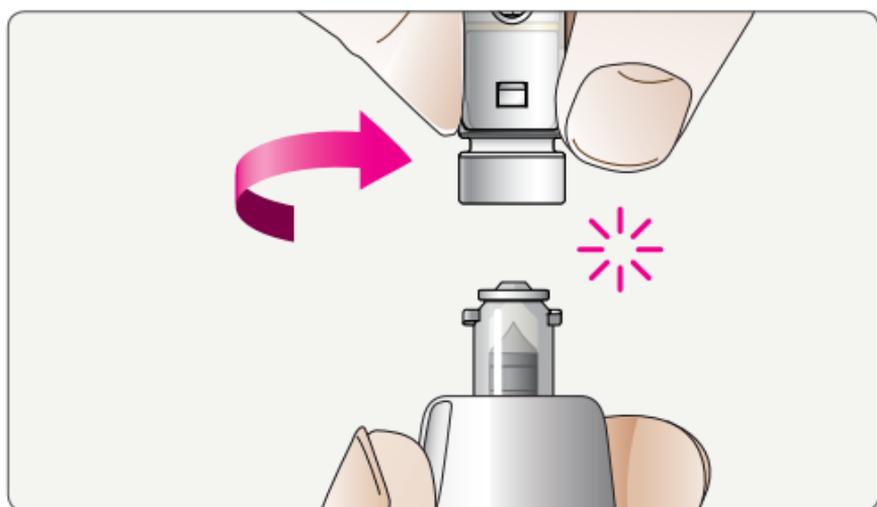
Tap the insulin cartridge or -vial firmly, to remove possible air bubbles from the needle opening inside the cartridge or vial.



Hold the InsuJet™ with the insulin cartridge/vial upwards and the Dosage Window facing you. On the front side of the InsuJet™ you will notice the number '2' with a directional arrow.



Hold the back of the device and turn the front in the direction of the Nr2 arrow until the number '5' appears in the dosage window. For each unit that is taken into the Nozzle, you will notice a 'notch'.



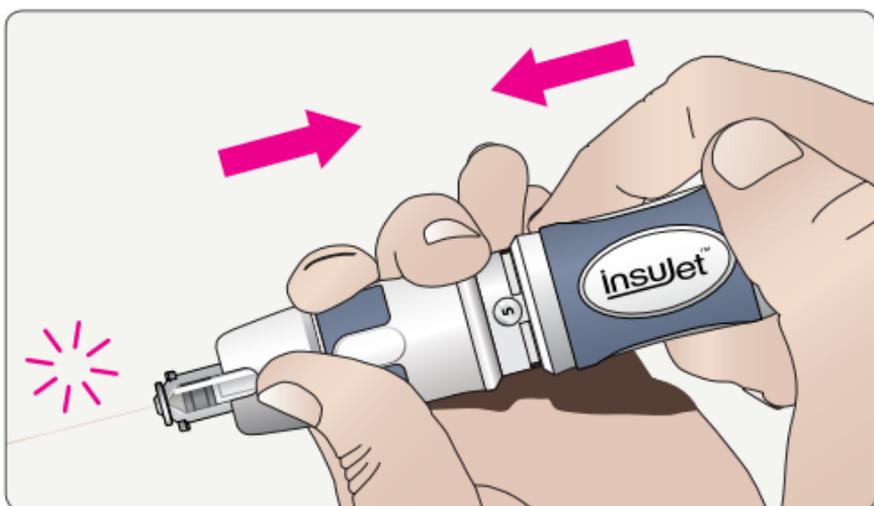
Disconnect the Adaptor with the insulin cartridge/vial from the Nozzle.



Hold the device as shown. Be careful to point your InsuJet™ in such way that the Nozzle is facing down and away from people.



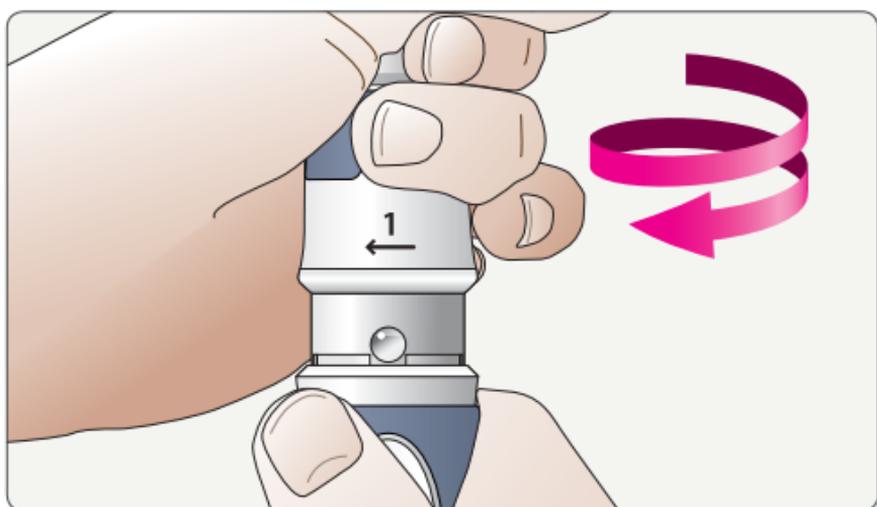
Slide away the red Safety Catch as far as it will go and hold in place.



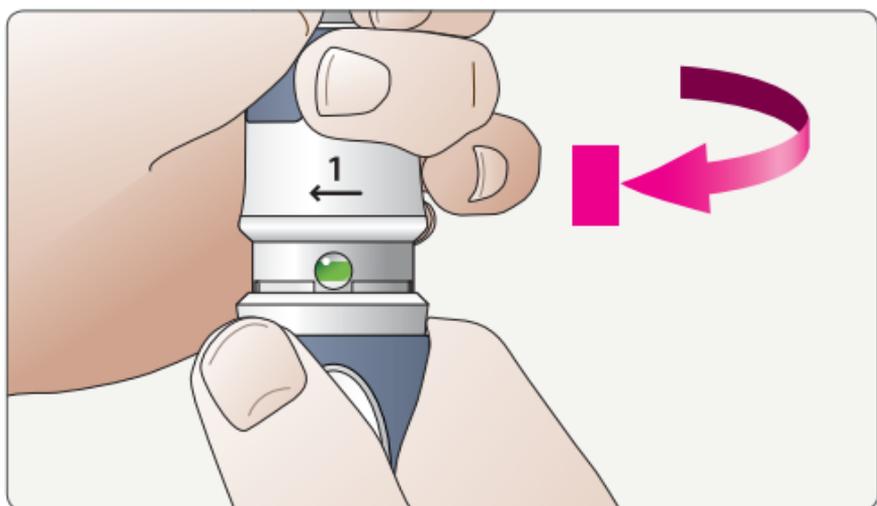
While holding the red Safety Catch in place, push the Front Body towards the Back Body to expel the insulin from the Nozzle.

Your device is now primed and ready to be filled.

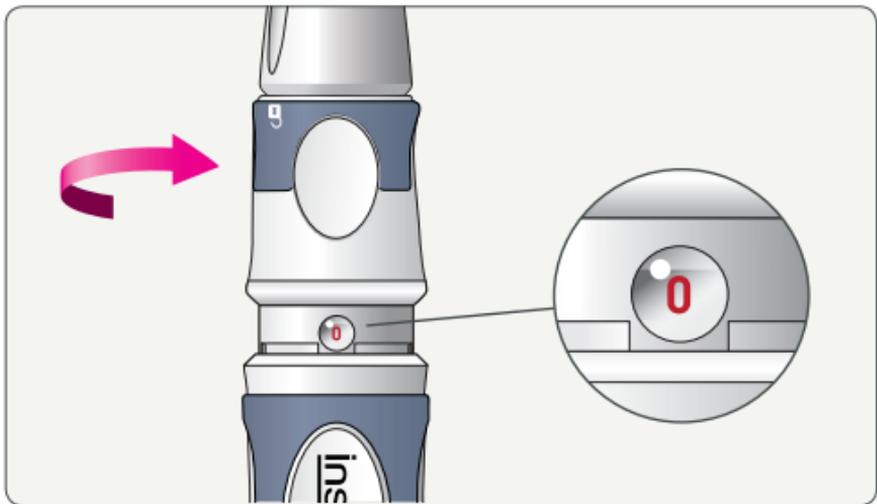
Re-charge the InsuJet™



While firmly holding the back of the device, start rotating the front in the direction of the Nr1 arrow. As the device is being charged, some force will be required. Note that the amount of units in the Dosage Window should decrease.

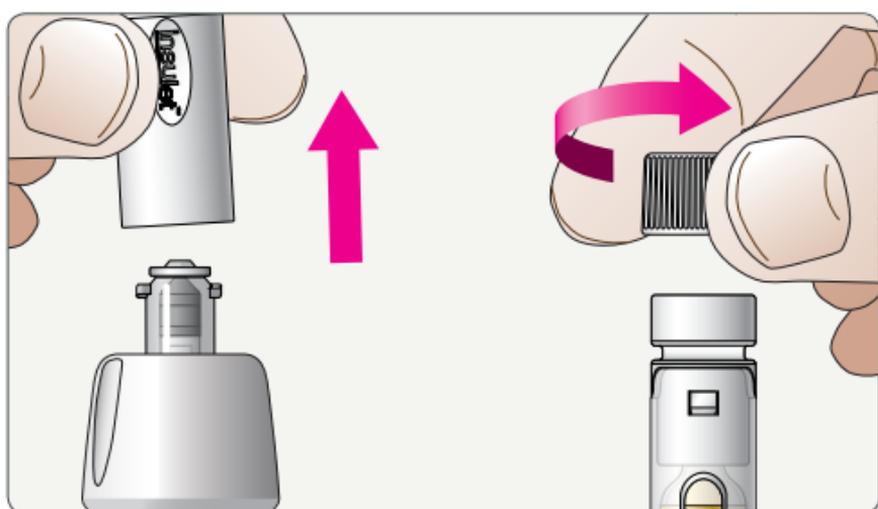


Continue to rotate the back until it will go no further. The InsuJet™ is now charged.

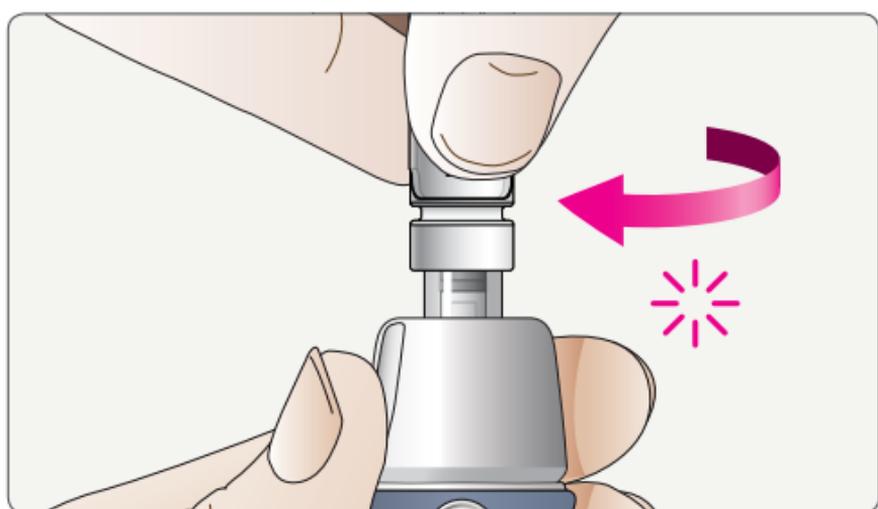


While holding the back of the device, rotate the front in the direction of the Nr2 arrow, until the number '0' re-appears in the Dosage Window. The front of the device should be easy to turn at this stage.

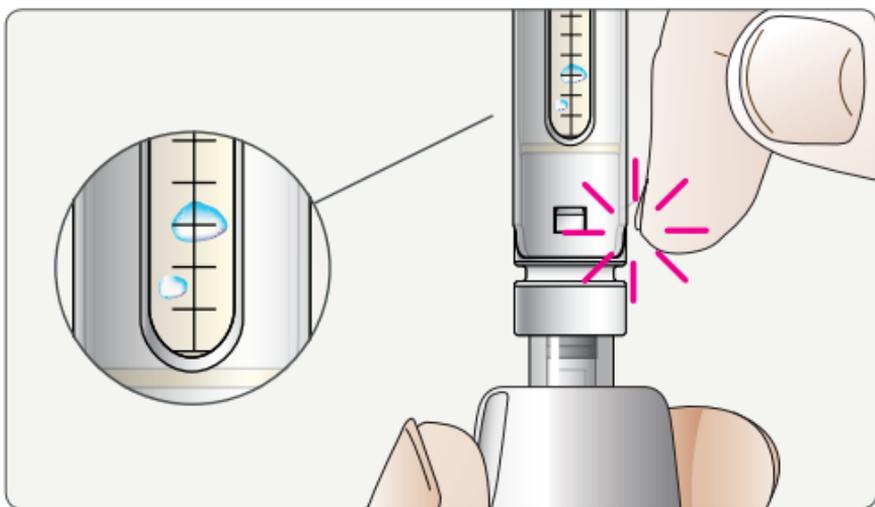
Connecting the Adaptor to the Nozzle



Remove the Nozzle Cap from the Nozzle and the Adaptor Cap from the Adaptor.

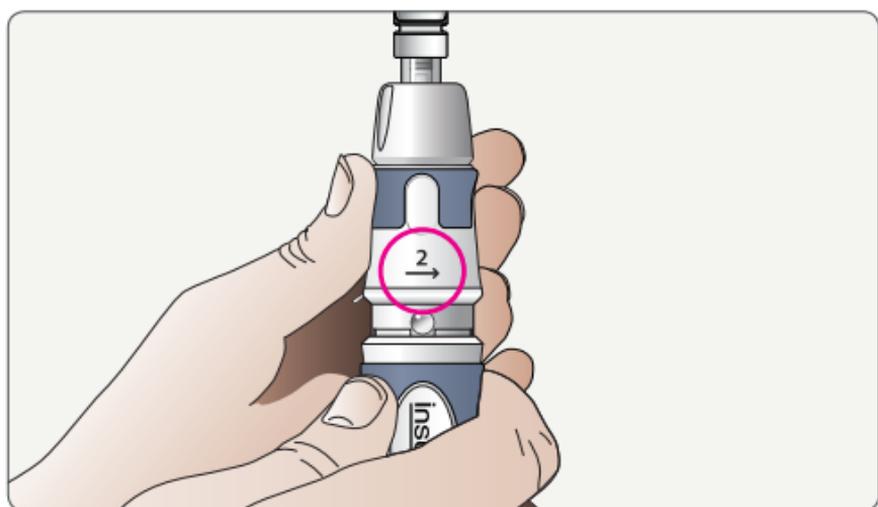


Align the Adaptor with the Nozzle and firmly rotate the Adaptor clockwise until the Adaptor snaps in place.

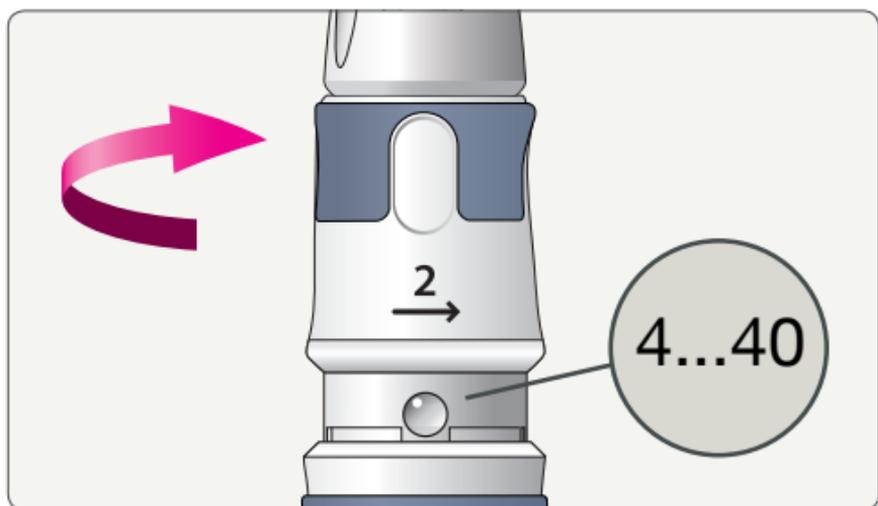


Tap the insulin cartridge or -vial firmly, to remove possible air bubbles from the needle opening inside the cartridge or vial.

Taking up insulin



Hold the InsuJet™ with the insulin cartridge/vial upwards and the Dosage Window facing you. On the front side of the InsuJet™ you will notice the number '2' with a directional arrow.

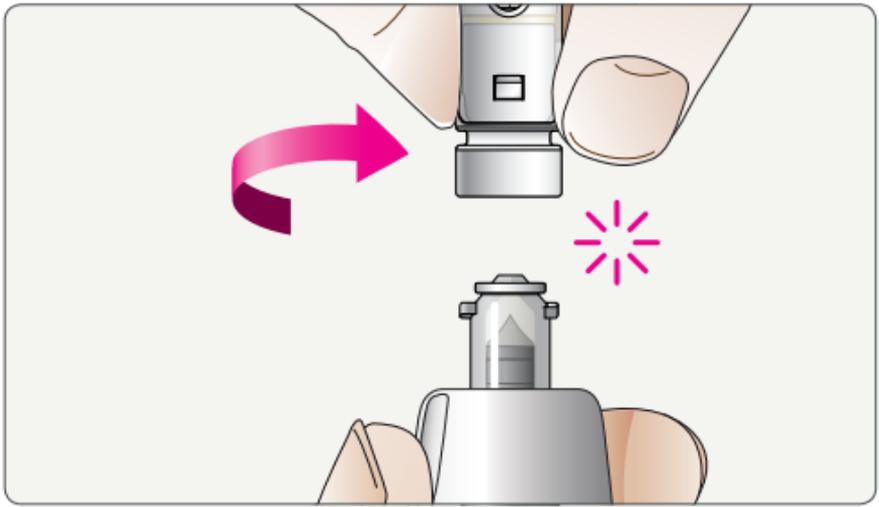


Hold the back of the device and turn the front in the direction of the Nr2 arrow to set the dosage.

Always take up additional insulin* to compensate for possible air bubbles.

For each unit that is taken into the Nozzle, you will notice a 'notch'.

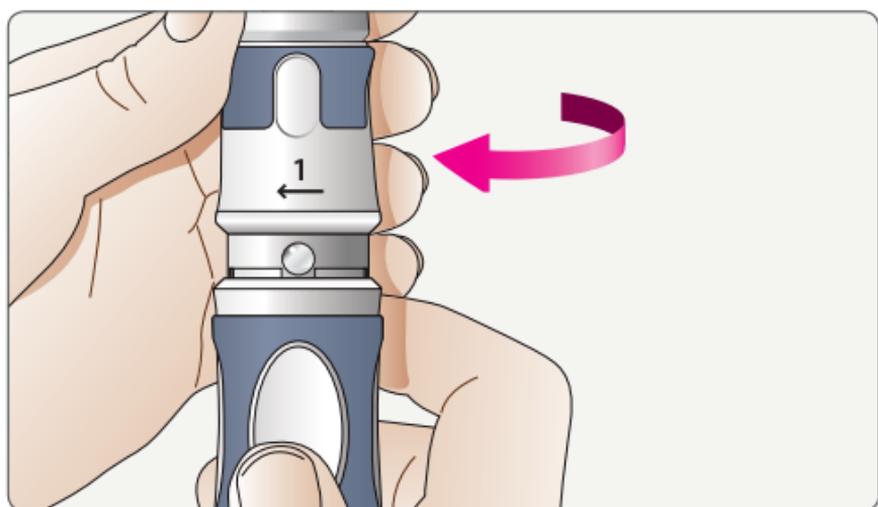
*The amount of additional insulin may vary per injection. 2 units is advised.



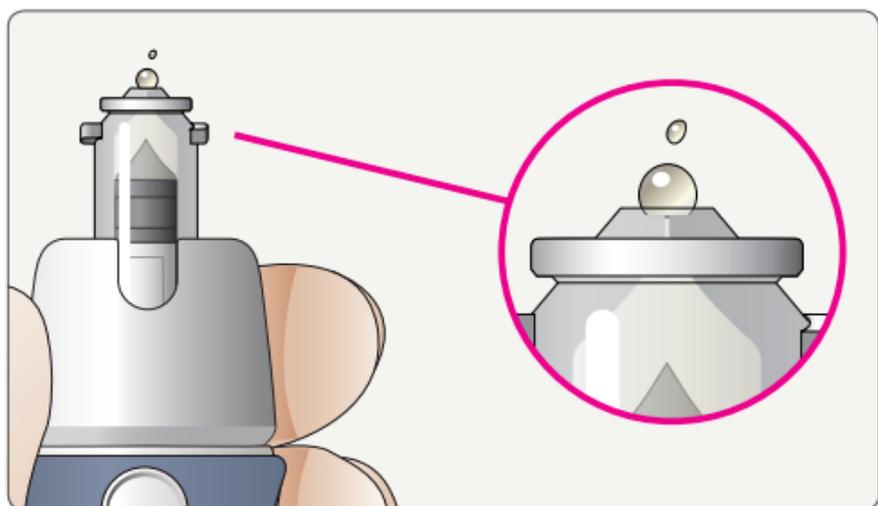
To remove possible air bubbles, start by disconnecting the Adaptor with the insulin cartridge/vial from the Nozzle.



Keep the InsuJet™ upright, and tap the Nozzle firmly with your fingertips, collecting all air bubbles close to the opening.

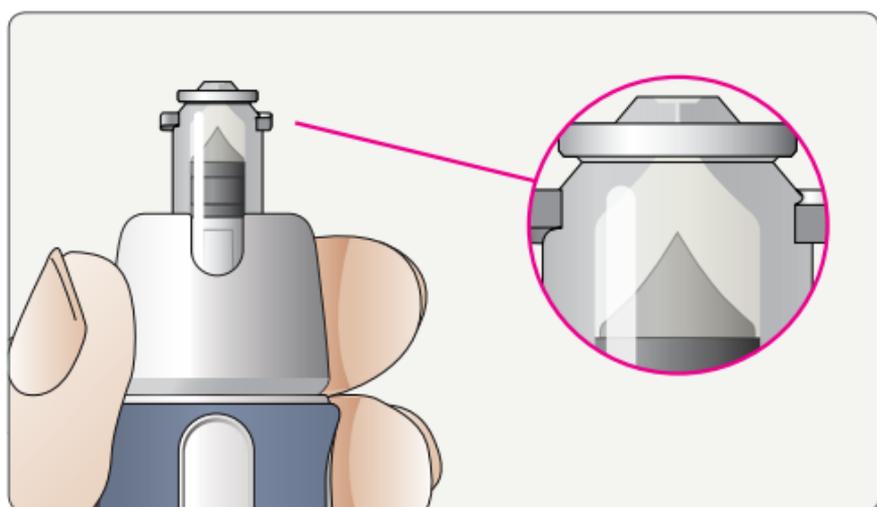


While holding the back of the device, gently rotate the front in the direction of arrow '1'. The air bubble and the excess of insulin will flow through the hole in the Nozzle.

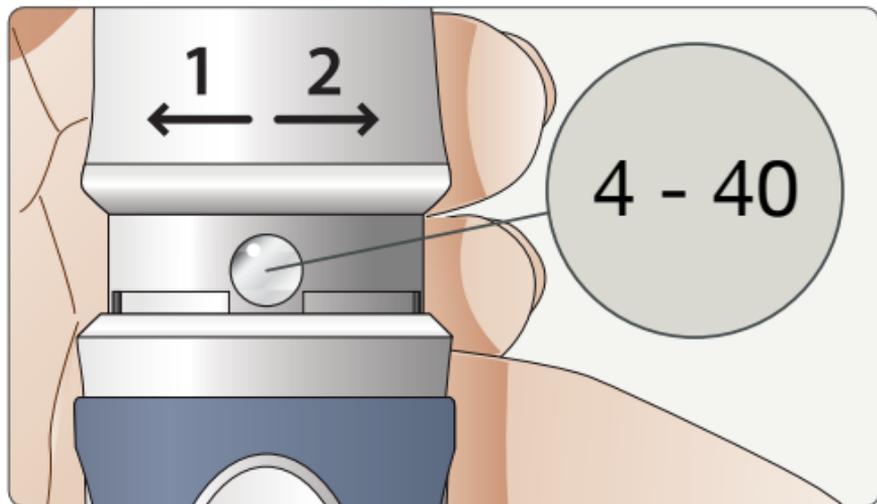


Continue to rotate until a drop of insulin becomes visible on top of the Nozzle.

If the drop doesn't appear, re-connect the Adaptor with the cartridge/vial to the Nozzle, aspirate some additional insulin from it and repeat the steps mentioned in this section.



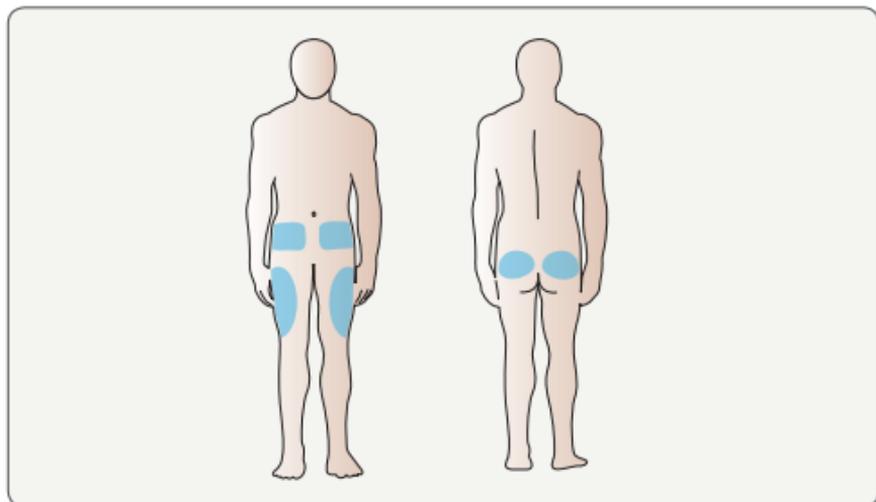
Check if the Nozzle is completely filled with insulin, before using the InsuJet™.



Before administration, always read the number of units in the dose window, to ensure you have set the correct dose.

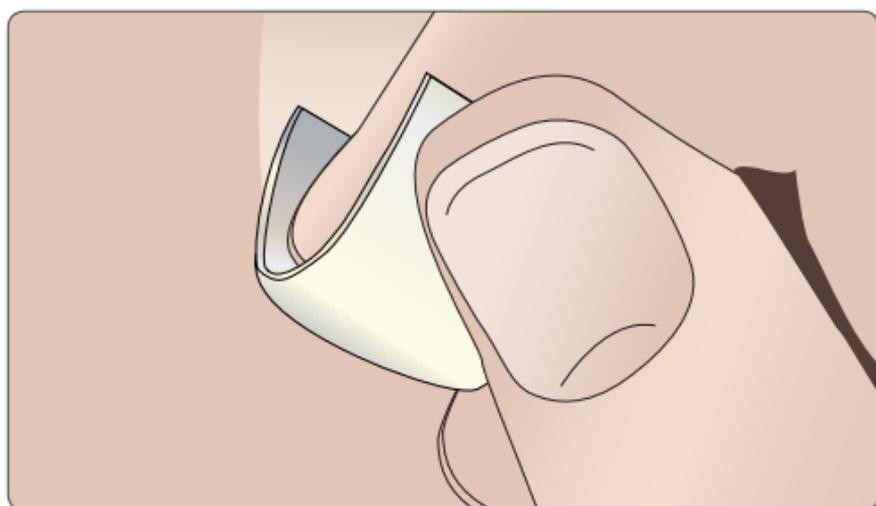
Administer insulin

To administer your insulin, follow steps 1 to 7 below:

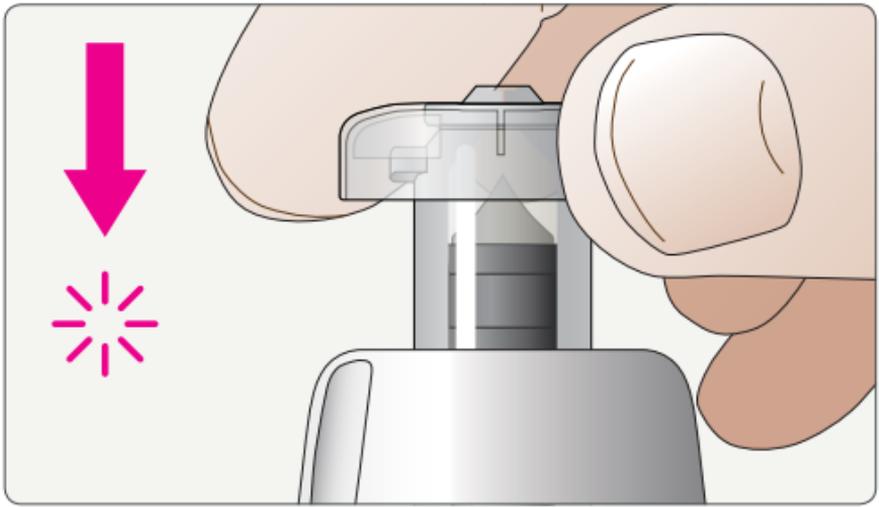


Step 1

Select your administration site. See page 53 - 54 for administration sites and administration techniques.



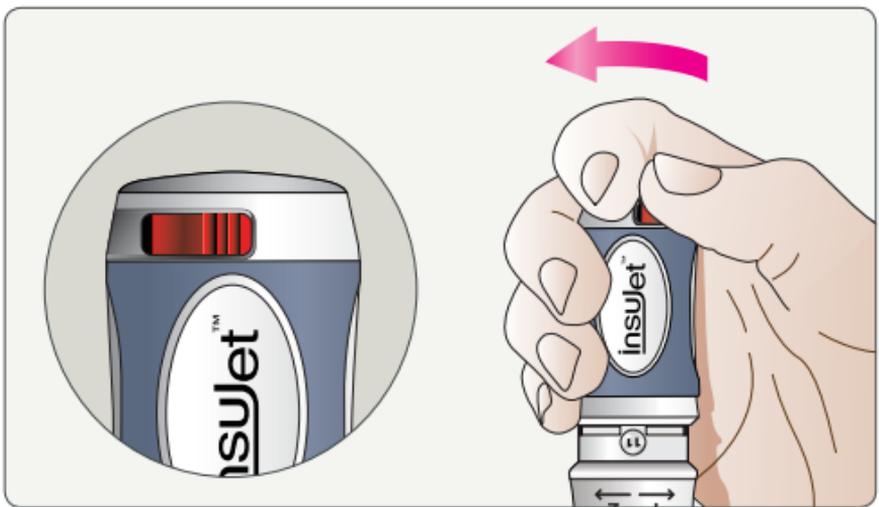
Wipe the chosen administration site with an alcohol swab. Let the skin dry before injection.



It is recommended to use a Comfort Ring, in case you feel discomfort when pushing the Nozzle against the skin.

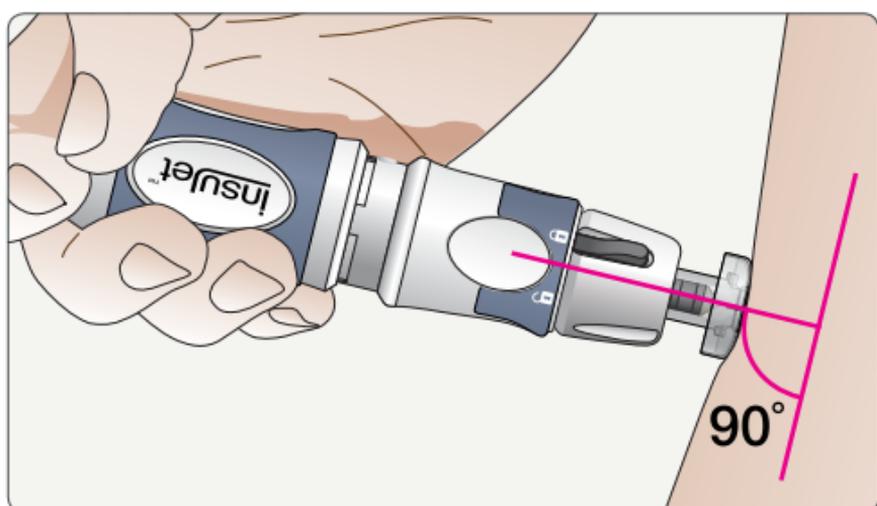
To install a Comfort Ring, hold the device by its Front and place the Comfort Ring on top of the Nozzle. Make sure that the round side of the part is facing outward. Push the Comfort Ring on the Nozzle until it snaps in place.

See page 47 for more information about the Comfort Ring.



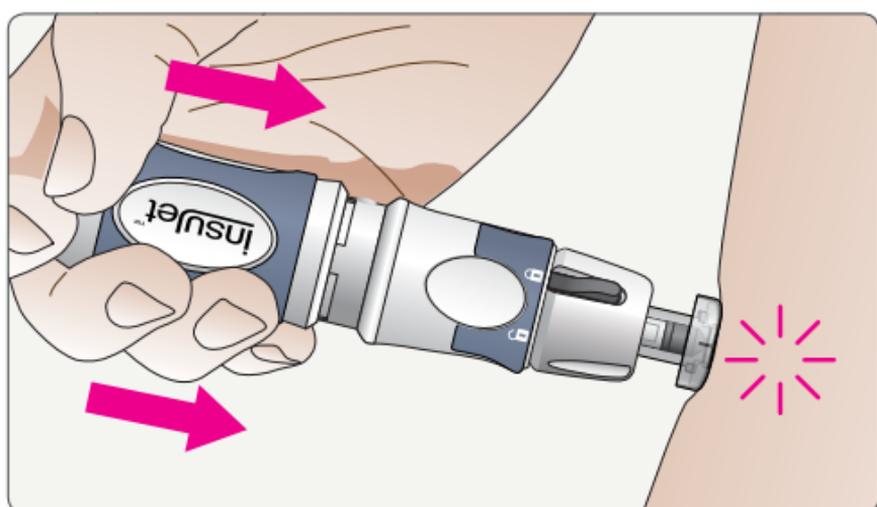
Step 2

Hold the device only by its back part, slide away the red Safety Catch as far as it will go and hold in place.

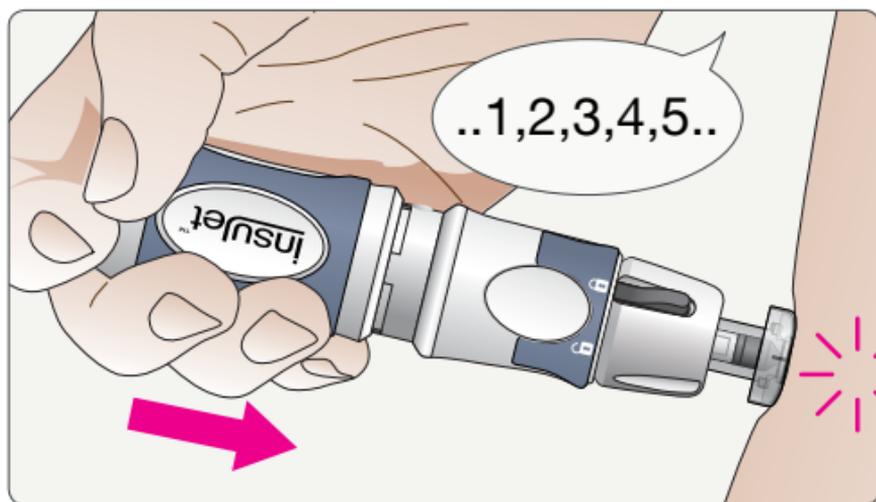


Step 3

While you are holding the red Safety Catch in place, position the InsuJet™ perpendicular (90°) to the skin.



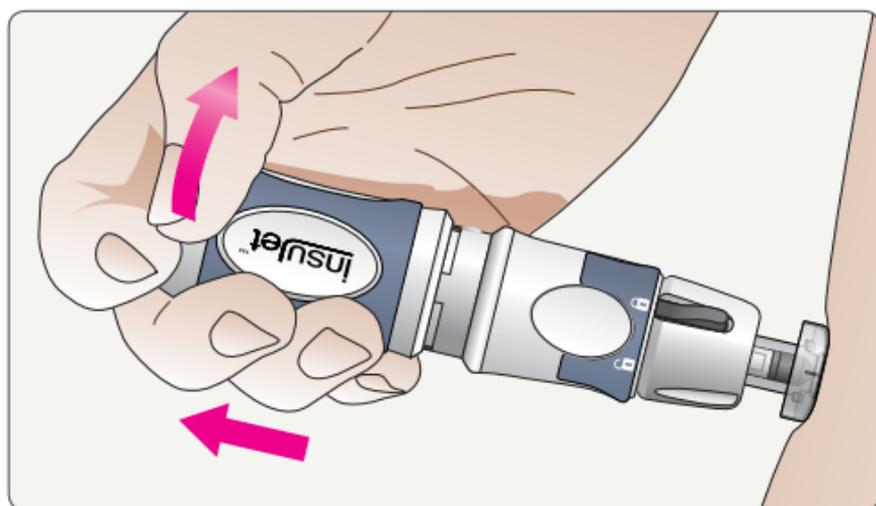
Push the back of the device directly towards your chosen administration site. When enough pressure is generated, the device will automatically activate the administration.



Step 4

After the administration, continue to push the Nozzle firmly against the skin for at least 5 seconds, to prevent insulin leakage.

NOTE: In case you experience pinprick bleeding after administration, please consider to continue pushing the Nozzle against the skin for up to 15 seconds.



Step 5

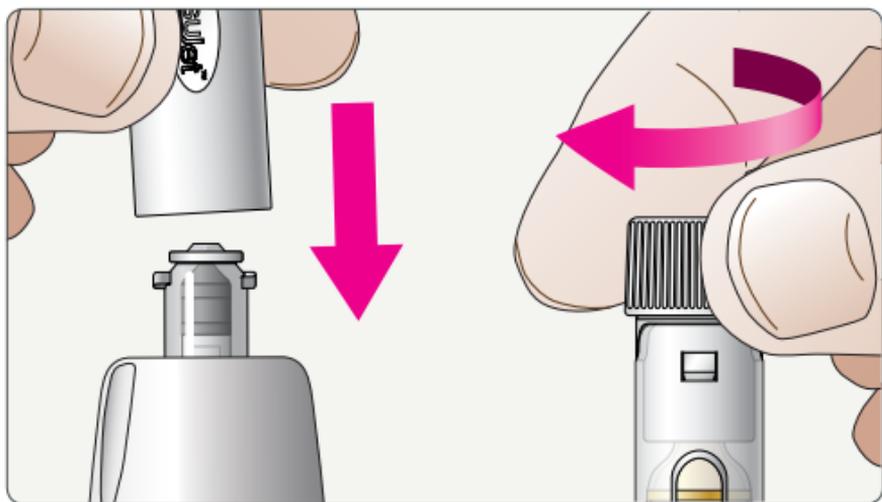
Remove the InsuJet™ from the skin and release the red safety catch.

Step 6

Evaluate the quality of your injection by the following guidelines:

Visual: Pinprick bleeding at the injection site is quite normal. Some dampness around the injection site is acceptable, but if you see insulin running from the injection site, you should consider the injection incomplete. Assume that some of your insulin is administered. Monitor your blood glucose level closely and contact your diabetes care specialist in case of doubt.

Sensation: It is quite normal to feel a slight sensation during and shortly after the injection. Contact your diabetes care specialist if you feel more than a slight sensation.

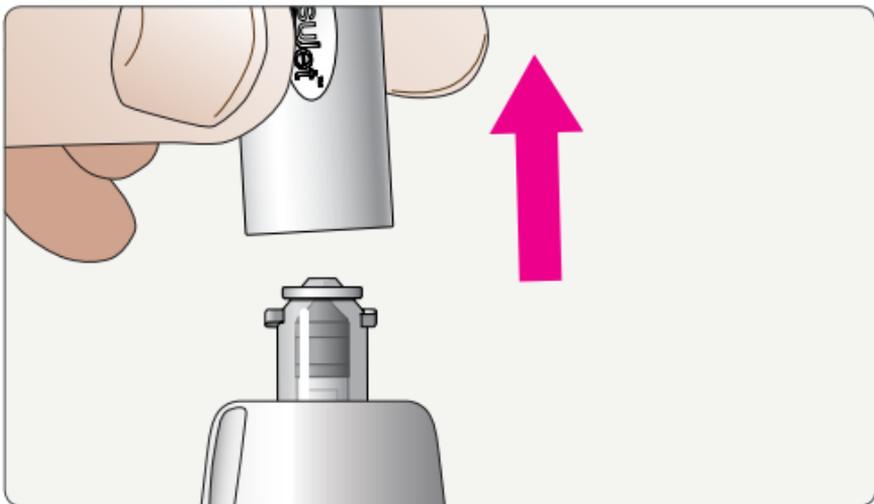


Step 7

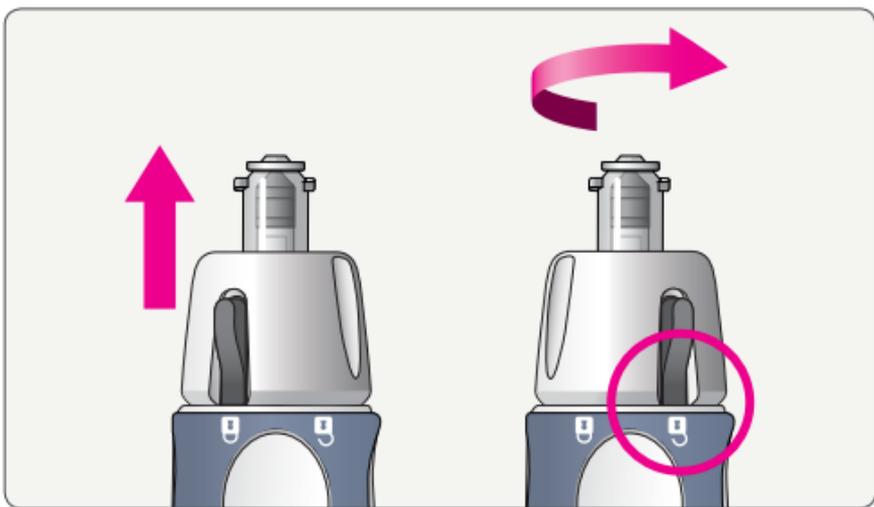
Remove the Comfort Ring and place the Nozzle Cover back on the Nozzle.

Place the Adaptor Cover back on the Adaptor. Store your insulin according the guidelines of the insulin manufacturer.

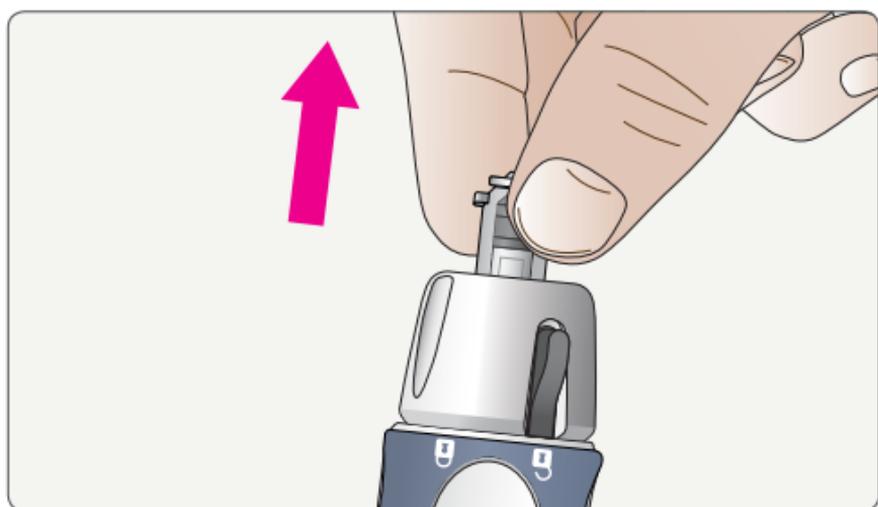
Replacing the Nozzle



Remove the Nozzle Cover from the Nozzle.

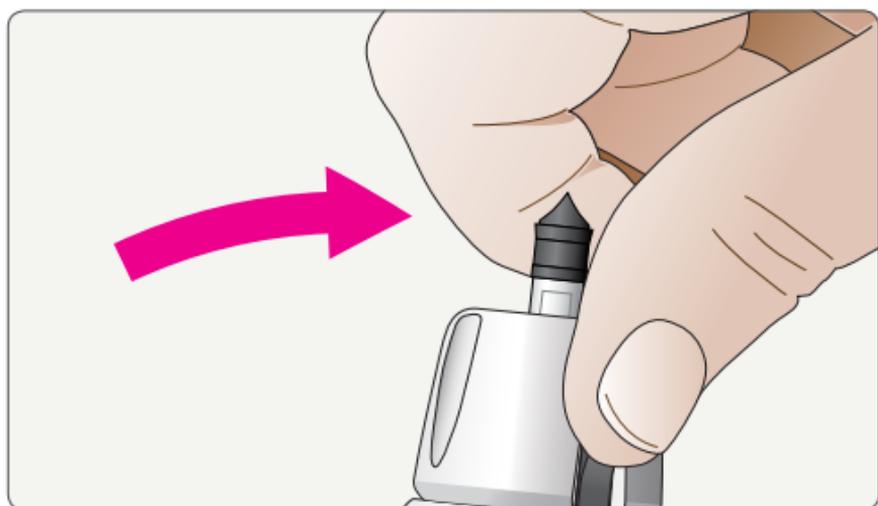


While pushing the Nozzle Lock Switch upwards, turn the Nozzle Lock until the Nozzle Lock Switch points to the unlocked position.



Pull the Nozzle out of the InsuJet™ with a firm straight pull.

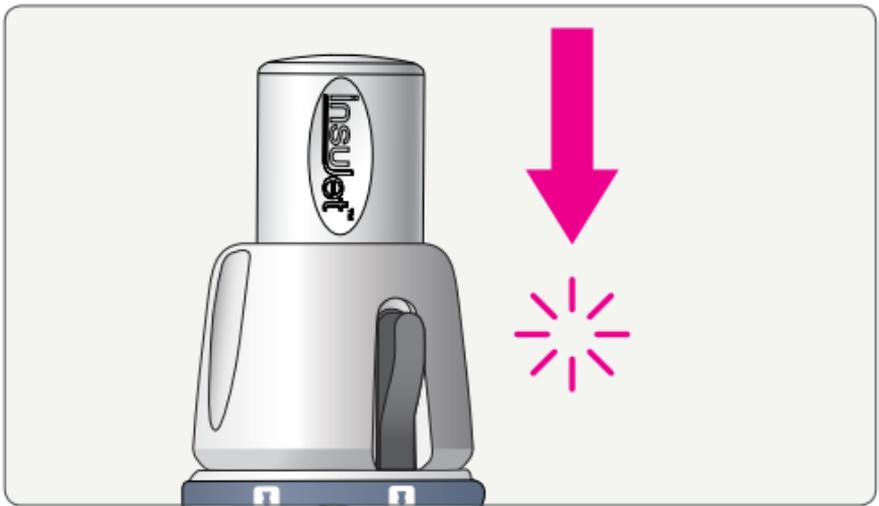
TIP: For additional grip during pulling, please connect an Adaptor to the Nozzle first.



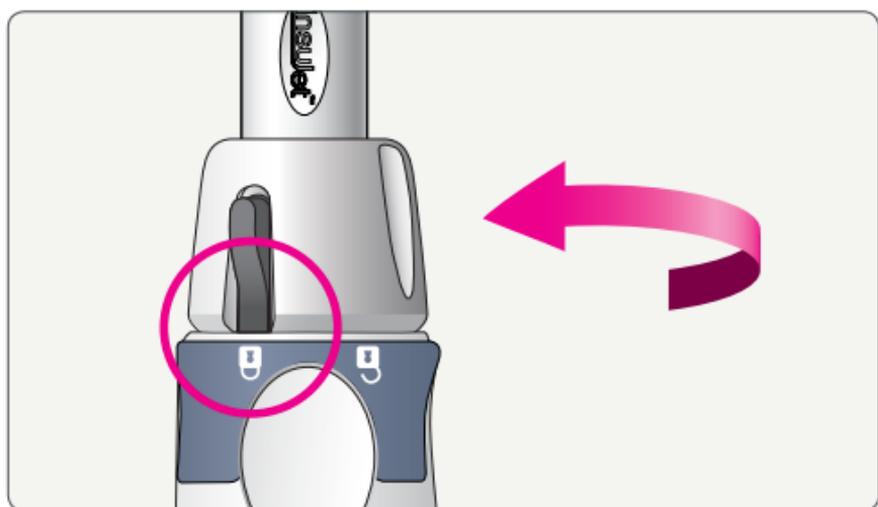
Loosen the internal part of the Nozzle by pushing it firmly to one side.



Remove the internal part of the Nozzle.
Discard the used Nozzle with your regular household waste.



Firmly push a new Nozzle into the Nozzle Lock of the InsuJet™. You should hear and feel a 'click' when the Nozzle snaps in place.



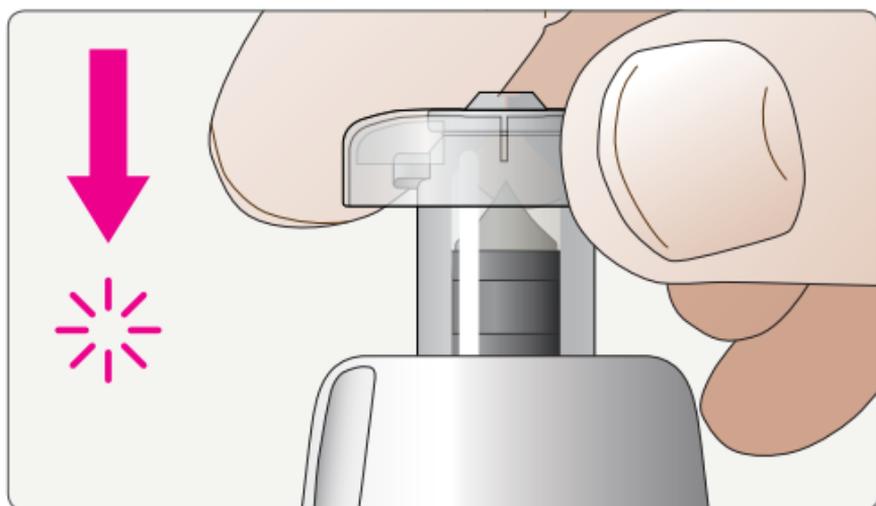
Once you have fully inserted the Nozzle, turn the Nozzle Lock until the Nozzle Lock Switch points to the locked position.

additional
information

Using a Comfort Ring



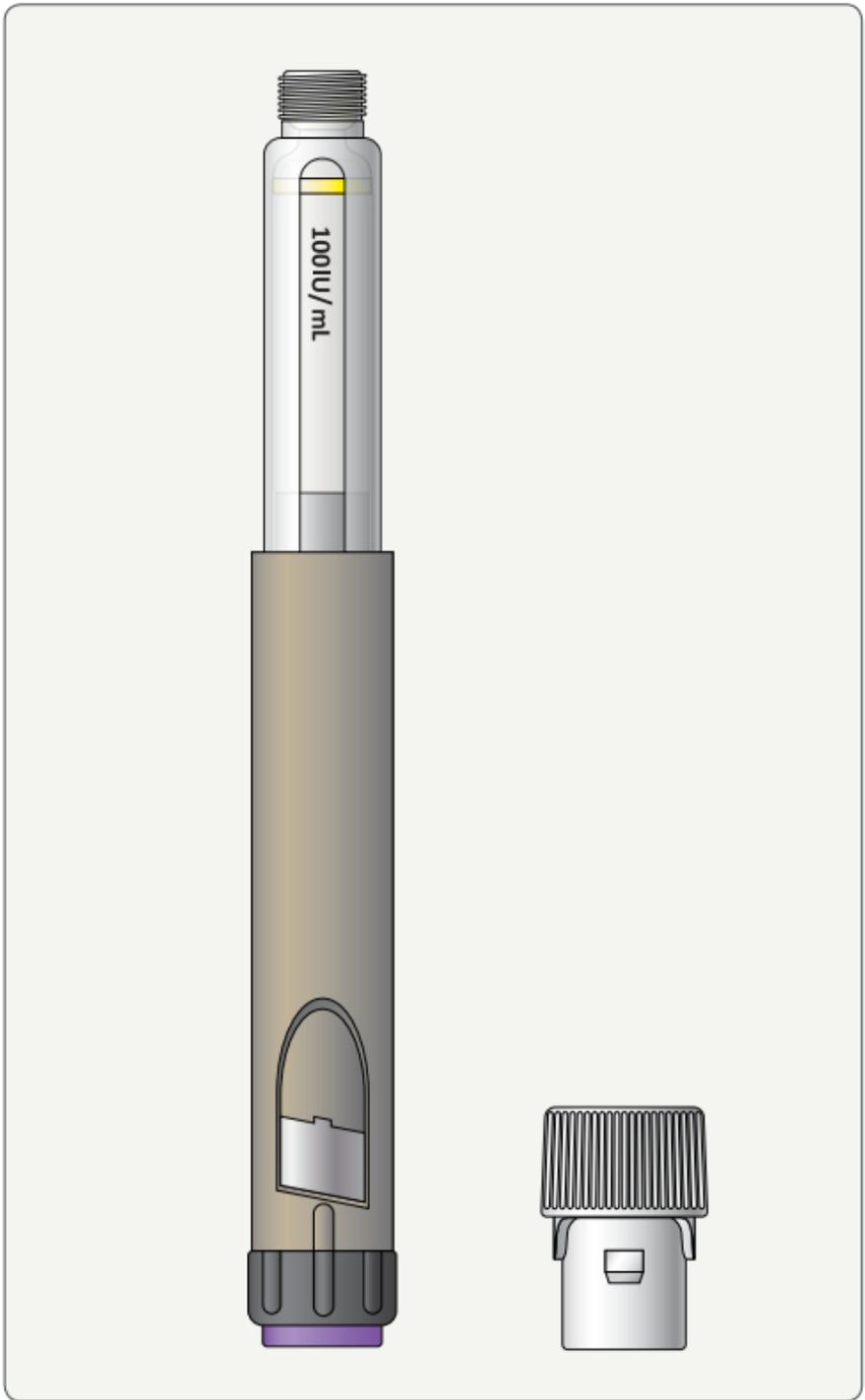
The Comfort Ring is a round, plastic disc that can optionally be used to reduce the pressure of the Nozzle on the skin, for relatively soft or sensitive administration areas. Place the Comfort Ring on top of the Nozzle, just before administration.



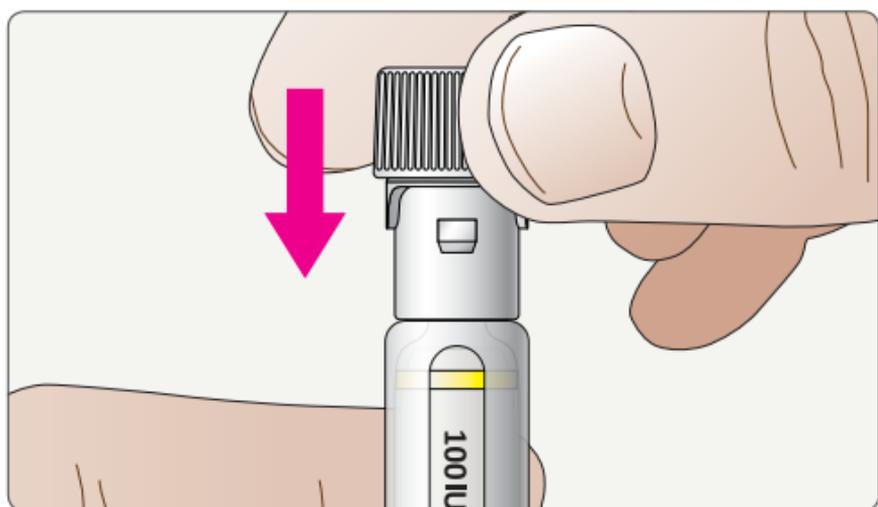
To install the Comfort Ring, hold the device by its Front and place the Comfort Ring on top of the Nozzle. Make sure that the round side of the part is facing outward. Push the Comfort Ring onto the Nozzle until it snaps in place.

NOTE: For hygienic reasons, be careful not to touch the Nozzle tip when installing the Comfort Ring.

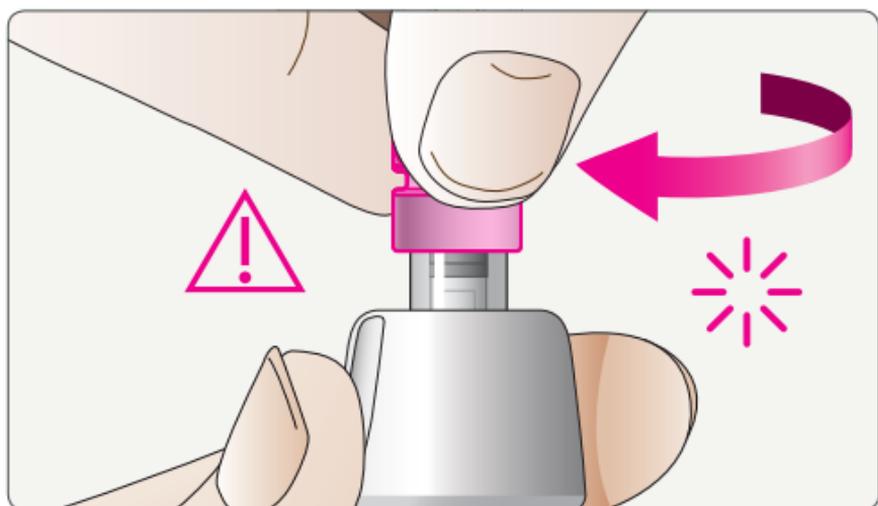
Using insulin from a disposable penfill



Example of a disposable penfill with a 3mL Adaptor



Take the 3mL Adaptor and place it on top of the disposable penfill. Push the Adaptor firmly onto the penfill until it is fixed.



NOTICE:

When attaching the Adaptor with a disposable penfill on the Nozzle, make sure to hold the Adaptor when rotating it onto the Nozzle.

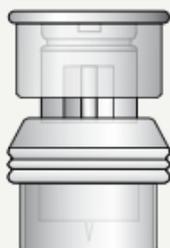
Rotate firmly and make sure that the Adaptor snaps in place.

Different types of Nozzles & Adaptors



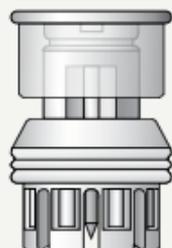
Nozzle

REF 01025



3mL Adaptor

REF 01035



10mL Adaptor

REF 01045



Nozzle

REF 01075



3mL Adaptor

REF 01055

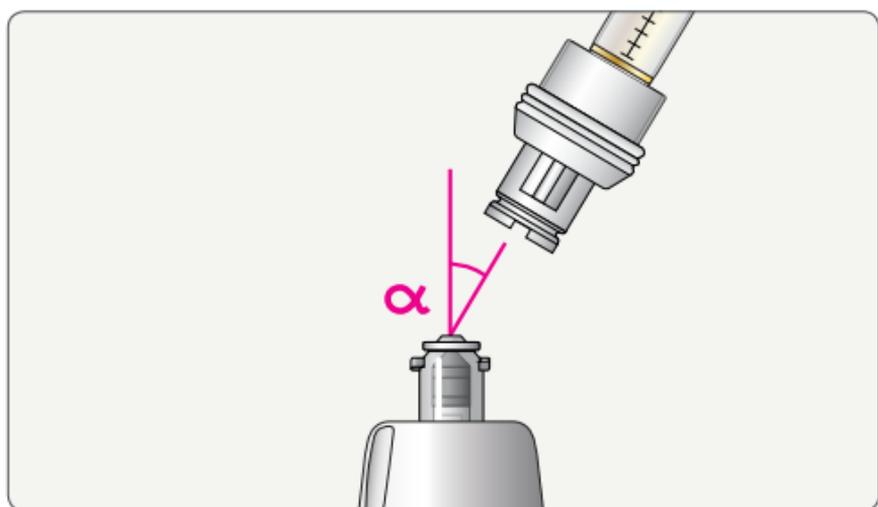


10mL Adaptor

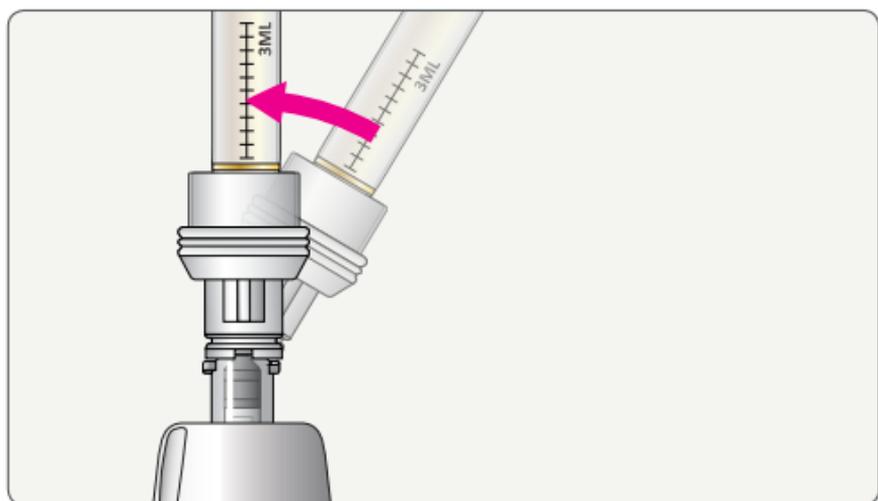
REF 01065

All types of InsuJet™ Nozzles and Adaptors are compatible with one another. There are six types available. Refer to the packaging label for part identification and REF numbers.

Using a 01035 or 01045 Adaptor with a 01075 Nozzle



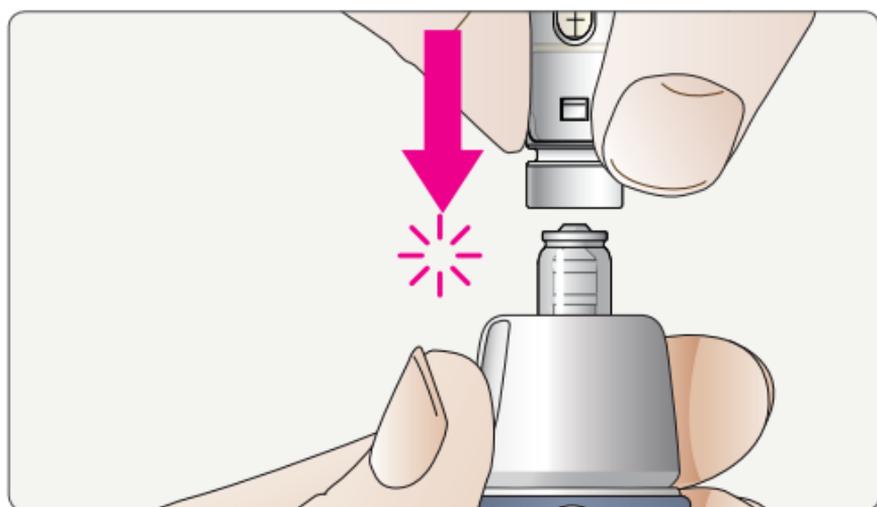
Push the Adaptor onto your insulin cartridge or vial until it snaps in place. Remove the Adaptor Cap and approach the Nozzle at an angle, connecting the clips of the Adaptor to the Nozzle at one side.



Tilt the Adaptor with the cartridge/vial upright. The Adaptor snaps to the Nozzle.

To remove the Adaptor, tilt the Adaptor to the opposite direction.

Using a 01055 or 01065 Adaptor with a 01025 Nozzle

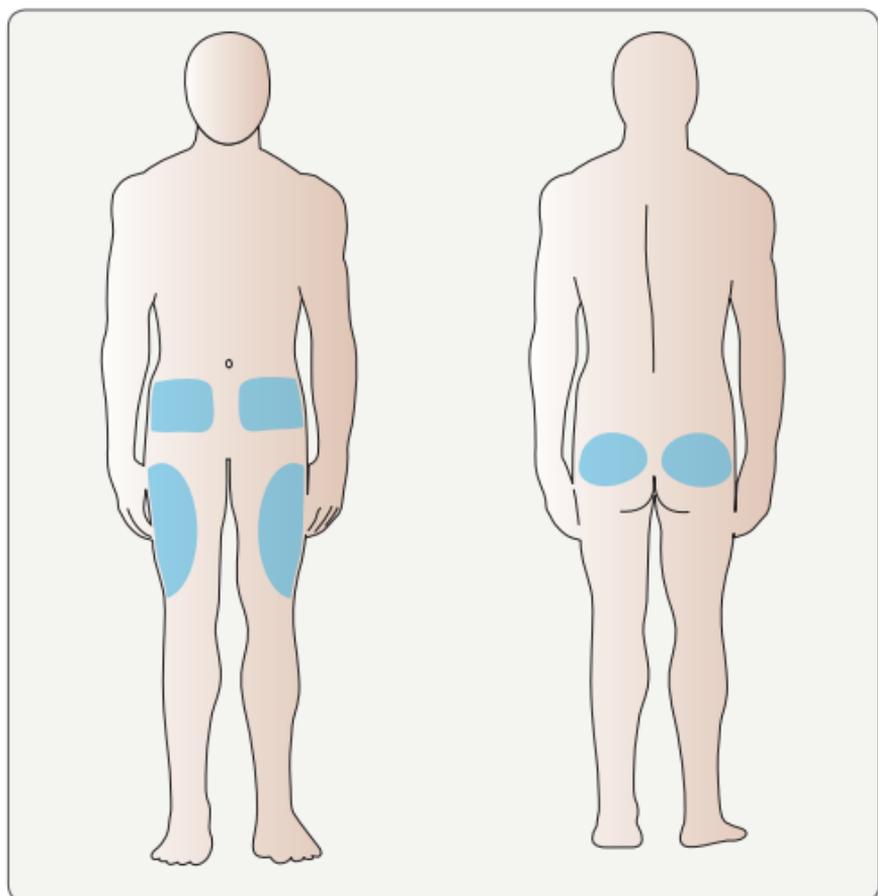


Align the Adaptor and Nozzle. Firmly push the Adaptor on the Nozzle. The Adaptor snaps in place.

To remove the Adaptor, pull the Adaptor from the Nozzle.

Administration site selection guide

NOTE: It is advised that your first InsuJet™ insulin administration takes place under the supervision of a Diabetes Care Specialist.



Any of the sites that are normally recommended for your insulin administration can be used with the InsuJet™. Choose an area with some fatty tissue. Avoid areas with low fat, or high muscle content.

Abdomen: Use the areas on the same level or slightly below your navel, as illustrated above. If you are unable to find a suitable administration site in the abdominal area, please consider another area.

Legs: Sit on a chair with the back of your legs supported and both feet flat on the floor. Relax your thigh muscle. The administration should take place on the front or outer portion of the thigh.

Buttocks: Find a sitting position that allows you to reach the buttocks. The administration should take place in the upper outer portion of your buttock.

NOTE: For relatively soft or sensitive administration areas, it is recommended to use a Comfort Ring during administration. See page 47 for instructions to install a Comfort Ring on the Nozzle.

Frequently asked questions & answers

How does the InsuJet™ administer insulin?

The back of the InsuJet™ is rotated to compress a spring that is used to power the InsuJet™. The release of the spring forces insulin through a small orifice of a special Nozzle, creating a thin, high pressure stream of insulin that penetrates the skin. In this manner the insulin is deposited into the subcutaneous tissue.

I am interested in using the InsuJet™. Should I discuss with my Diabetes Care Specialist about switching to the InsuJet™?

Yes. You should involve your Diabetes Care Specialist in any discussion and decision relating to switching to the InsuJet™.

I am currently using an alternative insulin administration device. Can I switch to the InsuJet™?

Yes. You can switch to the InsuJet™ but, like any changes in the management of your diabetes, the changeover period needs to be carefully monitored and the Diabetes Care Specialist who is involved in your care, should be consulted.

Will I have to change my type of insulin to use the InsuJet™?

Generally speaking, you will continue to use the insulin prescribed to you, so there should be no change in the types of insulin used.

Which insulin vial and cartridge sizes are suitable for use with the InsuJet™?

Insulin that is supplied in the following manners can be loaded into the InsuJet™, using the appropriate InsuJet™ Adaptors:

- 3mL cartridge
- Disposable penfill
- 10mL Vial

Is the InsuJet™ suitable for children and the elderly?

The InsuJet™ should only be used on the recommendation of a Diabetes Care Specialist. These specialists can assess the suitability of the InsuJet™ for a particular individual and his or her environment.

Is the InsuJet™ suitable for use by partially sighted?

The InsuJet™ should only be used on the recommendation of a Diabetes Care Specialist. These specialists can assess the suitability of the InsuJet™ for a particular individual and their environment. It is not recommended that anyone who is severely visually-impaired or legally blind administer insulin using the InsuJet™. A competent caregiver can assist using the InsuJet™.

Will the InsuJet™ cause skin blistering or any other complications?

The InsuJet™ may be used, but with caution, by anyone who bruises or bleeds easily. In the event of excessive bruising the usage of the InsuJet™ should be discontinued. The InsuJet™ will normally not cause blistering, but anyone who has a skin condition associated with the administration sites to be used, should consult his Diabetes Care Specialist before switching to the InsuJet™.

In case I use different types of insulin, why should I use a separate InsuJet™ device for each type?

The same Nozzle should never be used to administer different types of insulin. After each administration, a small insulin residue will remain inside the Nozzle. This residue affects the composition of the subsequent administration. Especially when long- and short acting insulins are alternated, this might lead to unexpected results. For your convenience, we recommend using different coloured InsuJet™ devices for each type of insulin.

Troubleshooting

The InsuJet™ is a mechanical instrument which is designed and manufactured with greatest care. However, it may eventually fail to operate properly. Always make sure you have easy access to an alternative insulin delivery system.

This section is designed to provide you with tips on solving minor problems which you may encounter when you use the InsuJet™ system.

Bleeding

A tiny pinprick bleed following administration is not unusual for some people and can simply be wiped off. If a larger amount of blood is present you may have hit a capillary, which is unlikely to happen next time. Apply pressure to the administration site. This will stop the bleeding in most cases.

If you experience any prolonged or severe bleeding, it is recommended to stop using the system.

Bruising

If you tend to bruise easily with a needle-based device, you may bruise with the InsuJet™ as well. Please consider using a Comfort Ring, to reduce the pressure of the Nozzle on your skin.

If you require a relatively large amount of insulin, it may be worth splitting your dose; E.g. 2 doses of 20 units each instead of 40 units at once.

If you experience any prolonged or severe bruising, it is recommended to stop using the system.

Raised white bump

This may indicate that, while successful, your administration did not penetrate sufficiently into your skin. If this happens, practice your administration technique.

If you require a relatively large amount of insulin, it may be worth splitting your dose; E.g. 2 doses of 20 units each instead of 40 units at once.

Red marking in the Dosage Window

A red marking will appear in the Dosage Window in case the device is accidentally winded beyond 40 units. To return to 40 units and below, first remove the Adaptor with the cartridge or vial from the Nozzle. Hold the back of the device and rotate the front in the direction of the Nr1 arrow, to reduce the dose level.

Uncomfortable administration

Similar to administration with a needle, an uncomfortable administration can occur if you administer insulin close to a nerve ending. This cannot be foreseen, although some people may find that particular areas are more sensitive and should be avoided.

Note: Administration of cold insulin can be painful. Remove the insulin from the refrigerator some time before administration.

Possible side effects of insulin injection

Insulin side effects amongst diabetics are rare, but when they occur, allergic reactions can be severe and pose a significant risk to health.

Always read the patient information leaflet of your prescribed insulin. The possible side effects are listed in this leaflet.

If you are in doubt, contact your Diabetes Care Specialist for medical advice about the side effects of insulin injection.

Infection

If you notice (signs of) an infection at the injection site, please consult your doctor.

Hyperglycemia / Hypoglycemia

Hyperglycemia, or high blood sugar is a condition in which an excessive amount of glucose circulates in the blood.

Hypoglycemia, also known as low blood sugar, is when blood sugar decreases to below normal levels.

Please refer to the patient information leaflet of your prescribed insulin or contact your Diabetes Care Specialist for more information about hyper- and hypoglycemia and how to maintain normal blood glucose levels.

Wet injection

Excessive moisture at the administration site following insulin administration indicates that an incomplete dose of insulin was given. The cause of a wet injection is, in most cases, related to the injection technique. The main points to consider when perfecting your administration technique are the following:

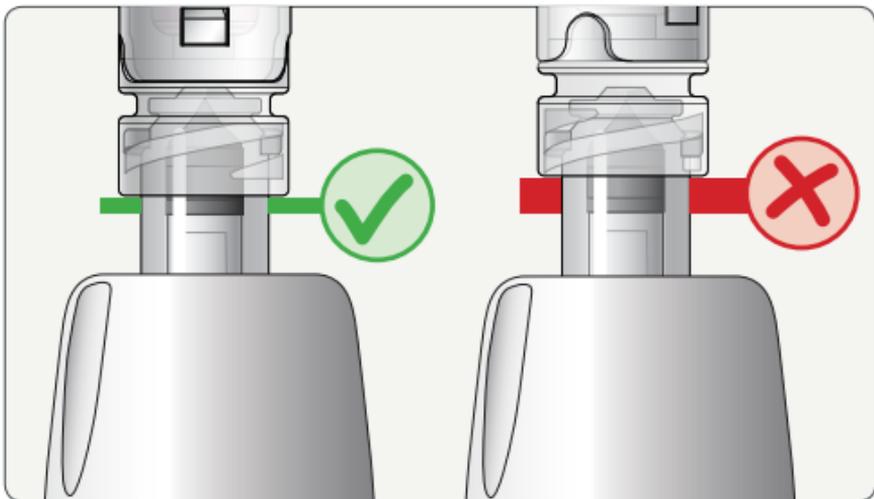
- Keep the top of the Nozzle perpendicular (at an angle of 90°) relative to the administration site.
- Keep the InsuJet™ steady throughout the administration.
- After the injection, keep pressing the InsuJet™ onto the administration site for at least 5 seconds.
- Always ensure that there are no air bubbles in the Nozzle.

In case of a wet injection, you should monitor your blood glucose levels carefully and adjust your next dose accordingly.

If you notice constant insulin leakage during administration, stop using the InsuJet™ immediately and revert to your alternative insulin administration method. Please contact your Diabetes Care Specialist.

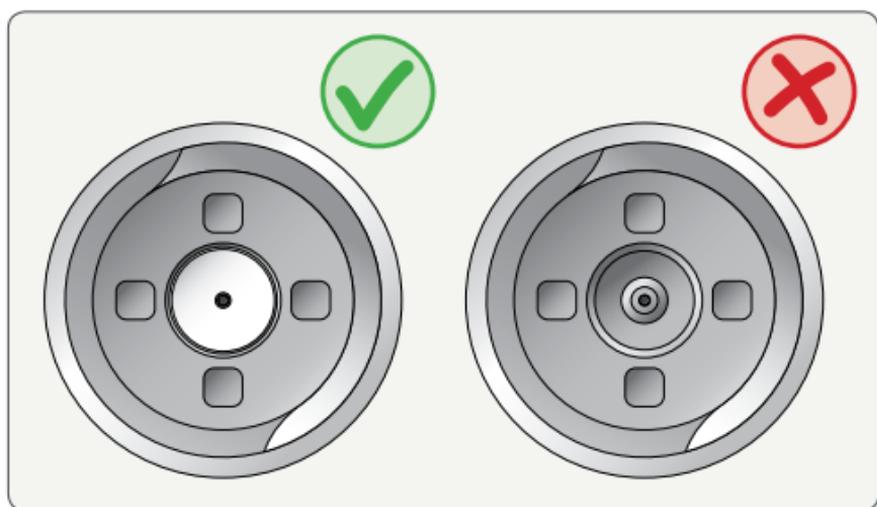
Unable to aspirate insulin from insulin vial or cartridge

If you experience problems aspirating insulin from your cartridge or vial, please check the following three items:

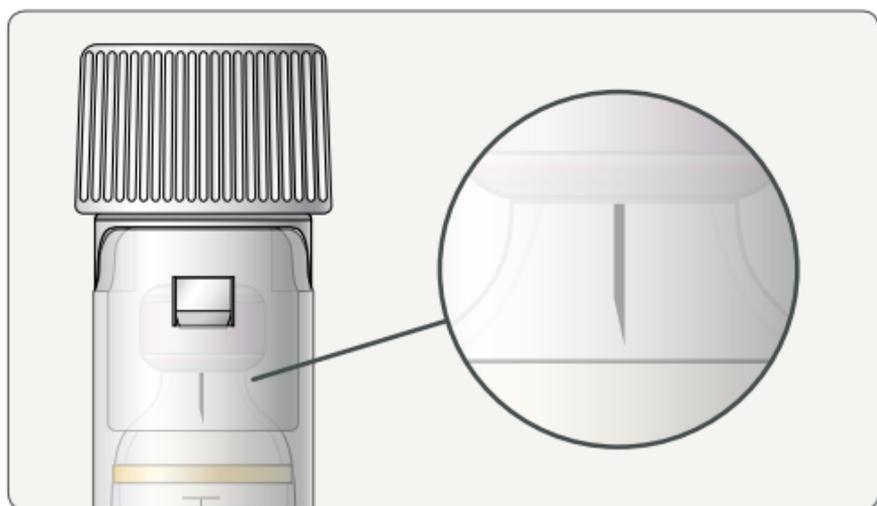


1. Check if the Adaptor is correctly installed on the Nozzle. Look from the side and inspect the position of the black Plunger tip (inside the Nozzle), relative to the Adaptor.

Only a small section of the Plunger tip should be visible, as illustrated on the left side of the image. If a larger area of the Plunger tip is visible, firmly rotate the Adaptor clockwise, until it snaps in place.



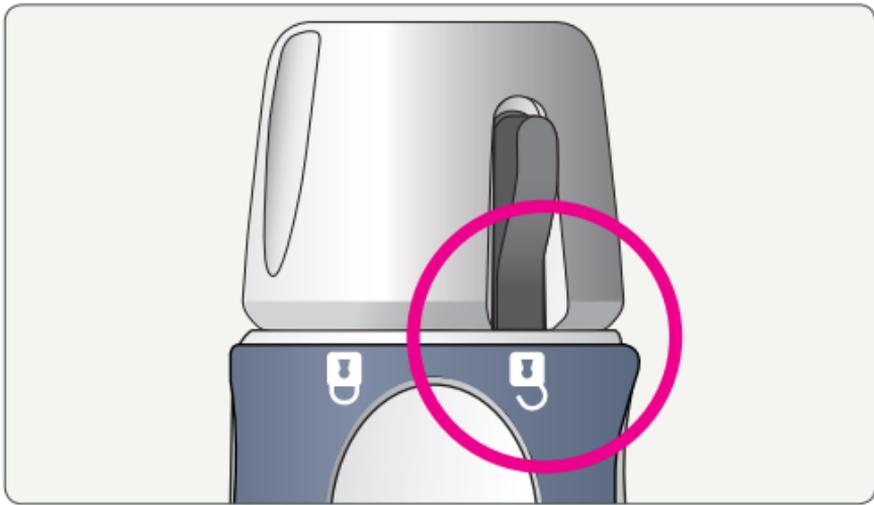
2. Check if a white, round part is visible when viewing into the Adaptor from the top. If not, replace the Adaptor.



3. Check if the needle of the Adaptor pierced the septum of the cartridge or vial completely. The needle should be visible on the inside of the cartridge or vial. Please note that you can also smell the insulin once the needle fully pierced the septum.

If the needle is not visible, rotate the cartridge inside the Holder. The needle will cut itself through the septum.

Unable to install the Nozzle into the InsuJet™

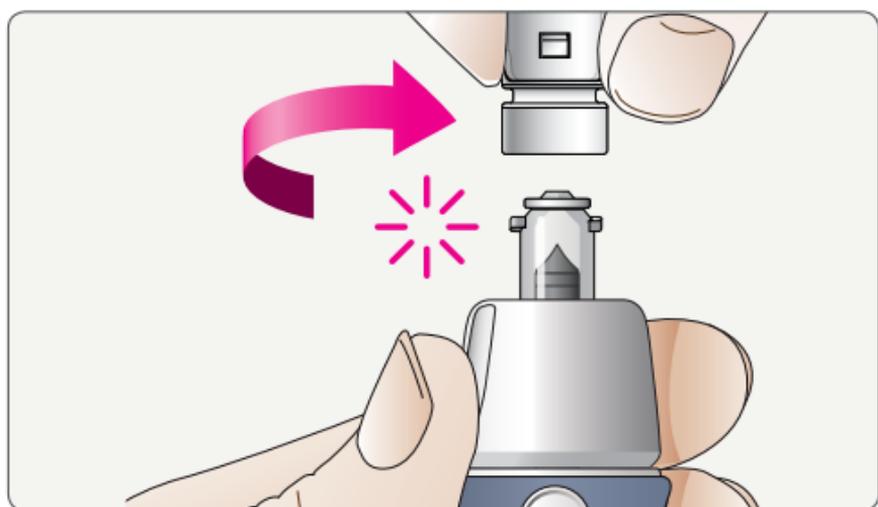


If you can't push the Nozzle into the Nozzle Lock, it may still be in the locked position. Before inserting the Nozzle, please ensure that the Nozzle Lock Switch points to the unlocked position.

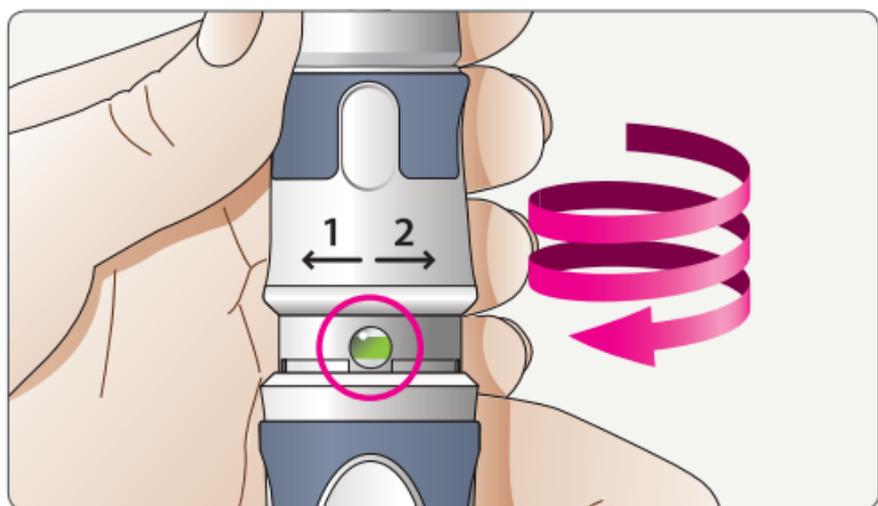


Besides the position of the Nozzle Lock Switch, you can also view into the device from the top. Two triangular parts will be visible. In unlocked position, the two parts are aligned, allowing the triangular shapes of the Nozzle into the Nozzle Lock. After the Nozzle is completely pushed into the mechanism, and the Nozzle Lock is rotated to its closed position, the second triangular part will lock the Nozzle.

Air inside Nozzle



If you experience problems drawing insulin from your cartridge or vial, it is likely that the Nozzle contains (an excessive amount of) air. To remove the air from the Nozzle, first remove the Adaptor with the cartridge or vial from the Nozzle.

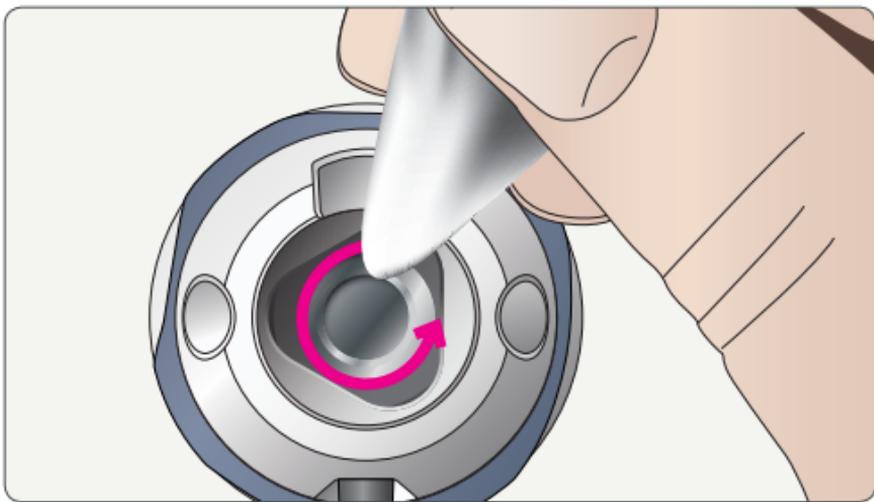


Keep the InsuJet™ upright. While holding the back of the device, rotate the front in the direction of arrow '1' until the green marking is visible in the Dosage Window.

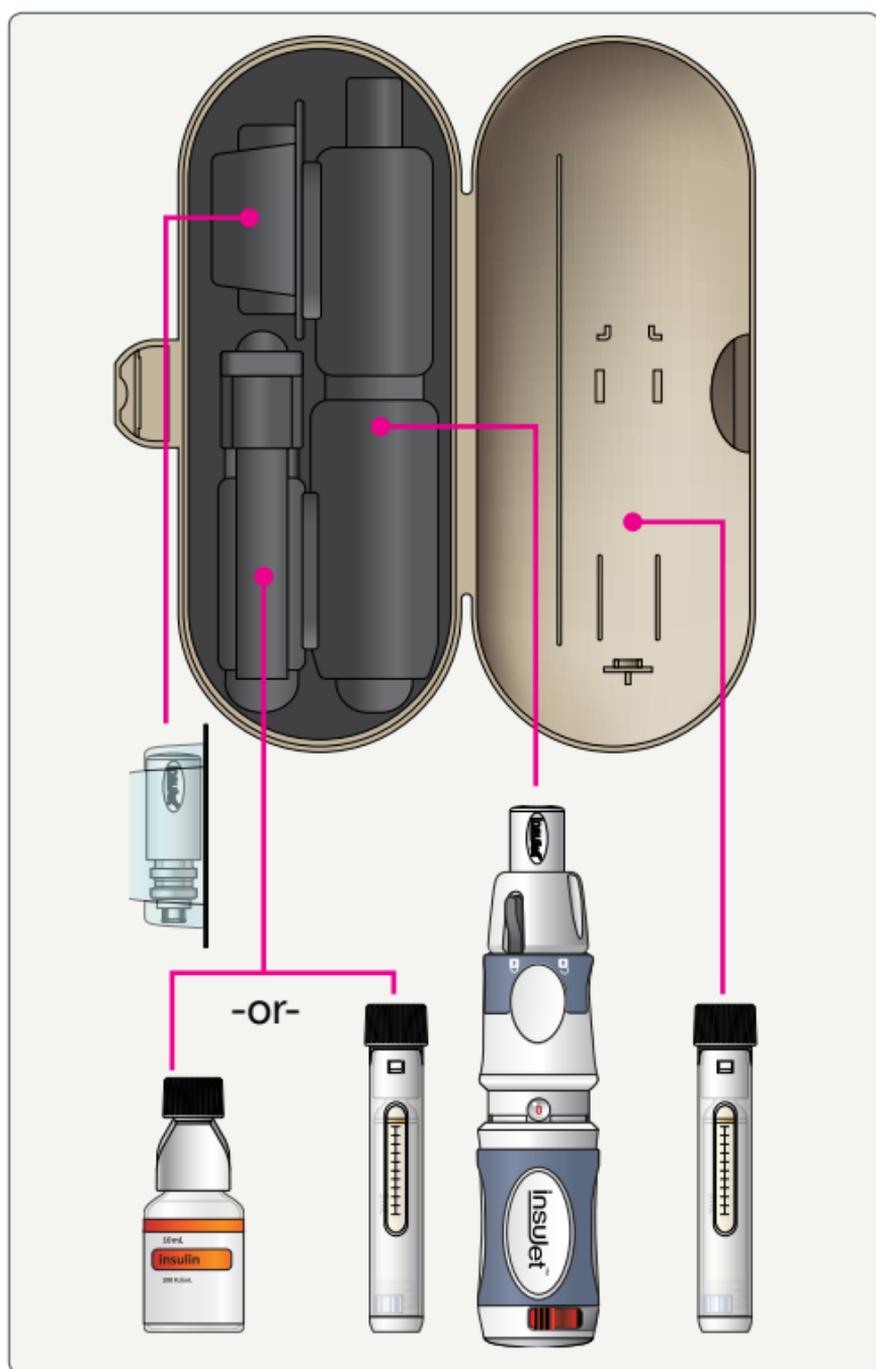
Follow the steps described in the section 'PREPARING THE INSUJET FOR ADMINISTRATION' to draw insulin into the Nozzle.

Maintenance

- Handle the InsuJet™ with care. Do not drop the device or the consumables.
- To clean the InsuJet™, wipe the exterior with a damp cloth.
- Do not immerse the InsuJet™ in liquid.
- Place the Nozzle Cap on the Nozzle, after each administration.
- Place the cartridge/vial Adaptor Cover back on the cartridge/vial Adaptor, after drawing insulin into the Nozzle.
- Discard the cartridge/vial Adaptor along with each empty insulin cartridge/vial.
- Never try to repair a broken InsuJet™.
- During Nozzle replacement, clean the metal colored surface that is visible when viewed into the top of the device. Use a dry tissue to gently wipe the surface clean, as shown below.



Storage



- Store the device inside the Carry Case.
- Store the InsuJet™ in dry conditions between 5°C and 40°C.
- Do not store the system in the refrigerator or in a damp area. Dampness may affect the device and cause corrosion.
- When you travel by plane or in the event of sudden pressure or temperature changes, keep the vial/cartridge adaptors in your hand luggage and upright, to prevent leakage of insulin from the vials.

Symbol glossary

Symbol	Title	Description / Explanatory Text	Standard	Ref. No. of Symbol
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2016	5.5.1
	Date of Manufacture	Indicates the date when medical device was manufactured	ISO 15223-1:2016	5.1.3
	Use by Date	Indicates the date after which device is not used	ISO 15223-1:2016	5.1.4
	Batch Code	Batch code so the lot or batch can be identified	ISO 15223-1:2016	5.1.5
	Serial Number	Serial number so the device can be identified	ISO 15223-1:2016	5.1.7
	Catalogue Number	Indicates catalogue number, part number of device	ISO 15223-1:2016	5.1.6
	Sterilized using Ethylene Oxide	A medical device sterilized by ethylene oxide	ISO 15223-1:2016	5.2.3
	Do not resterilize	Do not resterilize Indicates a medical device that is not to be resterilized.	EN 980	5.2.2
			ISO 15223-1:2016	5.2.6
			ISO 7000-2608	NA
	Temperature Limit	Indicates temperature the medical device can be exposed	ISO 15223-1:2016	5.3.7
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1:2016	5.2.8
	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.	ISO 15223-1:2016	5.4.4
	Consult Instructions for Use	Indicates the need for user to refer to instructions for use	ISO 15223-1:2012	5.4.3

Symbol	Title	Description / Explanatory Text	Standard	Ref. No. of Symbol
	CE Marking	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive. Signifies European technical conformity.	765/2008/EC 768/2008/EC MDD 93/42/EEC (Articles 4,11,12,17, Annex II)	NA
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic	ISO 15223-1:2016	5.6.3

Product specifications

The InsuJet™ is a spring-powered needle-free device, designed for subcutaneous administration of insulin. The InsuJet™ system is designed for single person usage only.

Weight:	InsuJet™ Approx. 140g
Size:	length 140mm - 160mm
Dose Range:	4-40 international units of U100 insulin per administration
Dose Accuracy:	± 1 unit for doses of 20 units or less ± 5% for doses above 20 units
Dose Scale Graduation:	1 unit increments
Administration Duration:	less than 0.3 seconds
Insulin Concentration:	the InsuJet™ is calibrated for U100 insulin
Storage:	between 5°C and 40°C

Replacement

The InsuJet™ is a so-called ‘active’ medical device, meaning that its mechanical function will eventually deteriorate to a point that safe and comfortable administration can no longer be performed with it.

Replace your InsuJet™ device in time. The same device should never be used for more than **5000 injections**, or past the **Use-by date** that is shown below.

Date of manufacture



Use-by date



For your convenience, please find below a table to determine when your device should be replaced.

Replacement guidance	
Nr. of injections per day	Replace your InsuJet™ device:
3 or less	before the Use-by date of the device
4	41 months after first use <u>or</u> before device Use-by date*
5	32 months after first use <u>or</u> before device Use-by date*
6	27 months after first use <u>or</u> before device Use-by date*
7	23 months after first use <u>or</u> before device Use-by date*
8	20 months after first use <u>or</u> before device Use-by date*

* Whichever comes first

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012000-EN-8.2

21 June 2018