

insuJet™

Insulin - Jet Administration System

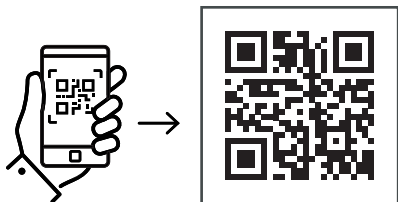
Instructions for use





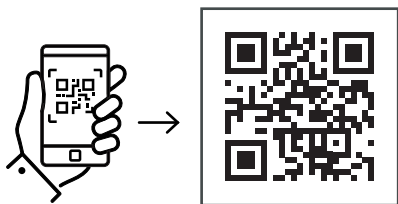
Please read this entire booklet before first use

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



www.insujet.com

For video-instructions for this InsuJet™ device, please visit the 'users' section on our website:



<https://insujet.com/users/>

Table of contents

Introduction	5
Clarification of intended use	5
Product overview	8
Warnings and precautions	10
Good hygiene and injection practices	12
Contraindications	13
Preparing the consumables	14
» Installing your InsuJet™ Adaptor	15
» Installing the Nozzle	18
How to charge	19
How to prime the InsuJet™	20
How to dose	23
Removing air bubbles	26
Where to inject	28
How to inject	29
» Injection quality	32
» Preventing contamination	32
Replacing the InsuJet™ Nozzle	33
Additional information	36
Using a InsuJet™ Comfort Ring	37
Administration site selection guide	38
Safety information	40
Side effects	41
Frequently asked questions & answers	44
Troubleshooting	47
Storage	51
Maintenance	52
Disposal and replacement	52
» Date of manufacture	52
» Use-by date	52
Product specifications	54
Symbol legend	55
Unique Device Identifier &	58
Contact details InsuJet™ dealer	58

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™ insulin-jet administration system is intended for the subcutaneous jet injection of insulin in adults and children with Diabetes Mellitus who require insulin therapy.

Insulin therapy may be used with the following patients:

- Patients with type I diabetes mellitus
- Patients with type II diabetes mellitus in whom control cannot be adequately achieved with oral hypoglycemics or diet.
- Patients with diabetes in pregnancy in whom control is inadequate with diet

The InsuJet™ insulin-jet administration system is for single patient use only.

The InsuJet™ insulin-jet administration system is suitable for **U100** (100 IU/ml), more information can be found under product specification.

The InsuJet™ can be used to inject 4 to 50 Insulin Units per administration. Insulin is not provided with the system.

For practice purpose, saline solution and/or sterile water for injection may be injected with the device.

Intended patient populations:

- Adults
- Children may only use the InsuJet under strong supervision from a diabetes specialist.
 - School age children of the age 6-12 who can be injected by a caregiver
 - Adolescents of the age 12-18 who can be trained to self-inject

The InsuJet may be used by healthcare providers who routinely administer injections. The InsuJet may also be used by patients to self-inject, or have other individuals administer injections of prescribed medication.

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.

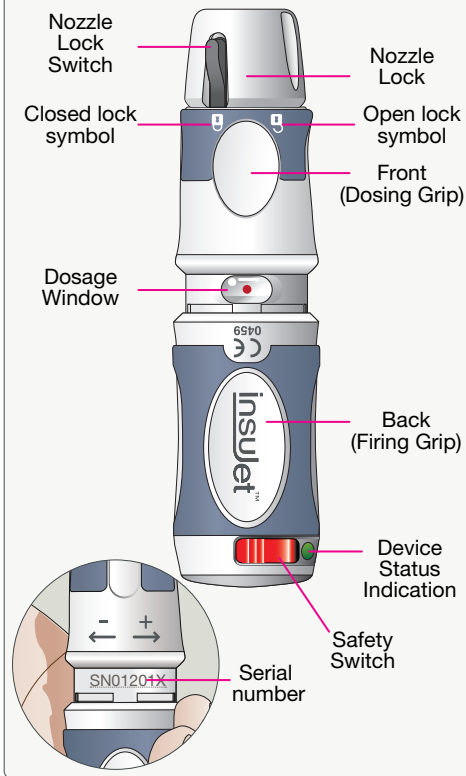
Refer to contraindications for reason for a person to not use the device

Product overview

The InsuJet™ package contains the following items:

- InsuJet™ Injector V5
- InsuJet™ Comfort Ring
- Carry Case
- Instruction For Use booklet
- Warranty Card
- Colour Labels

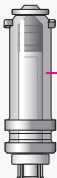
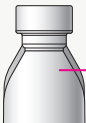
InsuJet™ Injector V5



Consumables and accessories

InsuJet™ consumables

(not included in the InsuJet™ package)

InsuJet™ Nozzle (0.5mL) P/N: 01075  Nozzle Cap  Nozzle	InsuJet™ 3mL Adaptor P/N: 01055  Adaptor Cap  3mL Adaptor  3mL Cartridge Holder (not sterile)
InsuJet™ 10mL Adaptor REF 01065  Adaptor Cap  10mL Adaptor	

InsuJet™ accessories:

InsuJet™ Comfort Ring  (not sterile)	Colour Labels P/N: 05601 
--	--

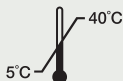
Warnings



- Do not drop the InsuJet™ injector or the consumables.
- The InsuJet™ should only be used for the administration of (U-100) 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™ and its consumables on the outer packaging. Do not use past its expiration date or past the indicated lifetime.
- 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.
- Do not store insulin inside the Nozzle. The Nozzle is only intended to be filled immediately before injection.
- 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. Using the same device for multiple patients may result in the direct transfer of bacteria, viruses or other germs from one person to another.
- 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.
- In case provided hygiene practices and warnings are not followed, the

consumables may be contaminated during use, possibly resulting in infections.

- The device delivers insulin using high pressure injection. The device has various safety features to ensure safe use. If any safety feature fails, stop using the device to avoid injury.
- In case a serious incident has occurred in relation to the device, this should be reported to EPG BV and the Competent Authority in your country.
- Temperature limits for use:



Max **5000 injections**,
or **4 years** use.
(whichever comes first)

Replace the InsuJet™ injector V5 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.



Max **56 injections**, or
14 days after its blister
packaging is breached.
(whichever comes first)

Replace the InsuJet™ Nozzle regularly. The same Nozzle should never be used for more than **56 injections**, or longer than **14 days** after its blister packaging is breached. 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, may cause bacterial contamination and may result in device malfunction, with loss of warranty.

Precautions

- Do not use the InsuJet™ other than described in this instruction for use. Failure to follow instructions may result in injury. Do not use the device when you are unable to follow the instructions. 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 hygiene and 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. Always keep the nozzle cover and adaptor caps on between use. This will 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.

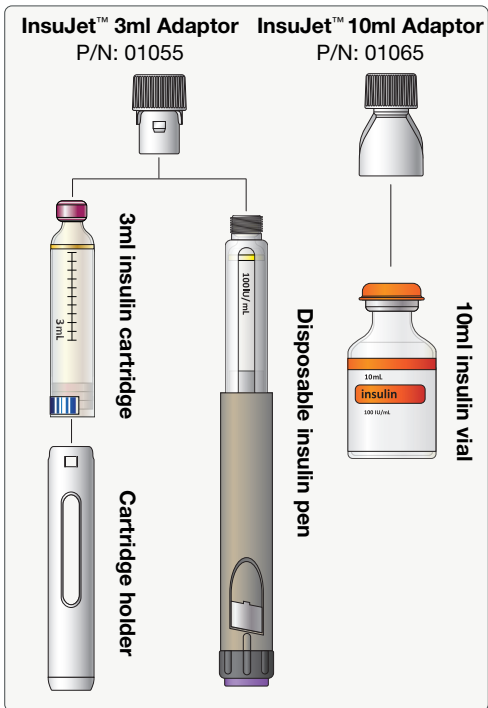
If you experience any prolonged or severe bruising or bleeding, it is recommended to stop using the system.

Preparing the consumables

Choose your InsuJet™ adaptor

There are two 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 if you want to use insulin from a 3mL insulin cartridge or from a disposable insulin pen.
- If you want to use insulin from a 10ml vial, use the 10ml Vial Adaptor.

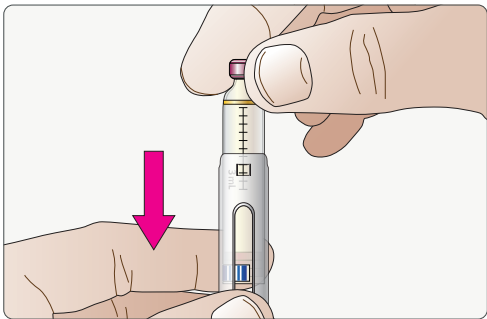


Example of the use of InsuJet adaptors for 3ml insulin cartridge, disposable penfil or 10ml insulin vials.

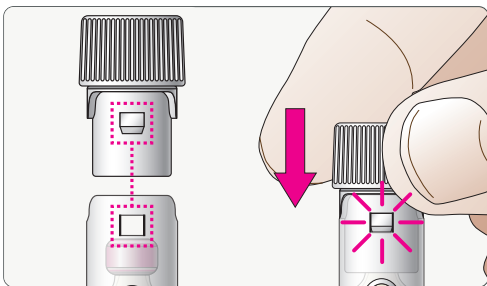
Installing your InsuJet™ Adaptor

Choose your adaptor type and check the expiration date. Remove a single blister from its strip, and open the blister seal by tearing the lid from one of the corners. Remove the adaptor without touching the needle.

3ml adaptor with 3ml cartridge

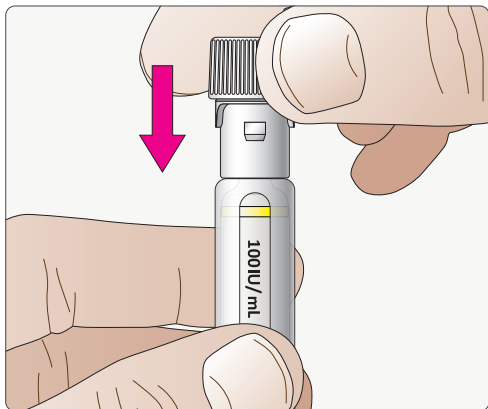


Slide the 3mL cartridge into the Holder, with the bottom of the cartridge downward.



Take the Adaptor and align the protrusions with the corresponding holes in the Holder. Push firmly until the Adaptor snaps in place. The Adaptor remains on the Holder.

InsuJet™ 3ml Adaptor with a disposable insulin pen



Take the 3ml Adaptor and place it on top of the disposable insulin pen. Push the Adaptor firmly onto the disposable insulin pen until it is fixed.

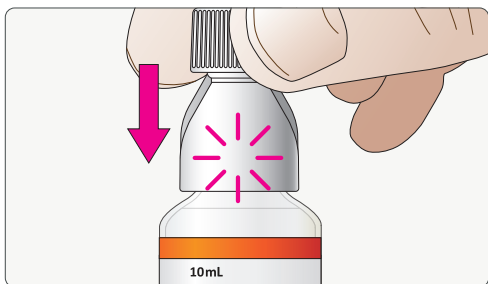


Align the Adaptor with the Nozzle and firmly rotate the Adaptor clockwise onto the Nozzle.

NOTICE:

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

InsuJet™ 10mL Adaptor with an insulin vial



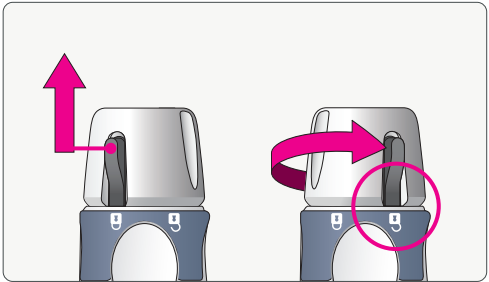
Remove the protective cap from the insulin vial.

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

The Adaptor remains on the vial.

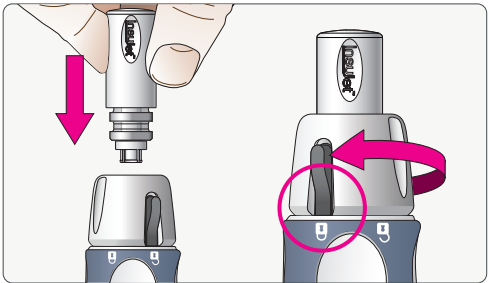
Note: Some patients may wish to perform a trial/practice injection using saline solution or sterile water. If provided in a 10ml glass vial (14mm cap), the 10ml adaptor may be used to connect with such a vial.

Installing the InsuJet™ Nozzle



Push the Nozzle Lock Switch upward. Turn the Nozzle Lock until the Switch points to the 'unlocked' position.

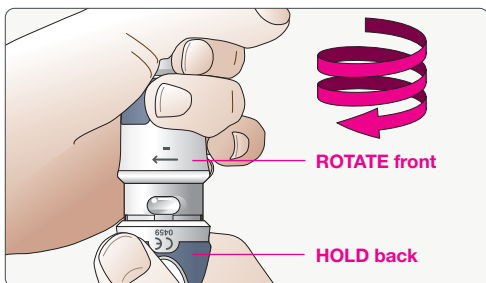
Remove a single blister from its strip, and open the blister seal by tearing the lid from one of the corners. Remove the nozzle from the blister.



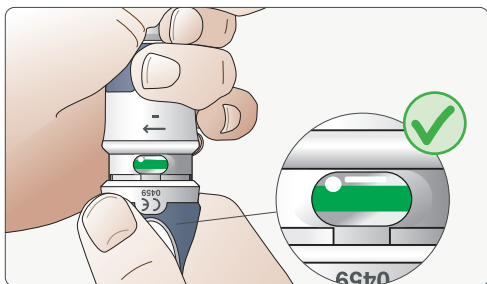
Firmly push the Nozzle into the Nozzle Lock. Once you have fully inserted the Nozzle, turn the Nozzle Lock until the Switch points to the 'locked' position.

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.

How to charge



Before each injection, the device needs to be charged. Rotate the dosing grip (front) in the direction of the minus “-” arrow, while holding the firing grip (back). The amount of units in the Dosage Window should decrease.

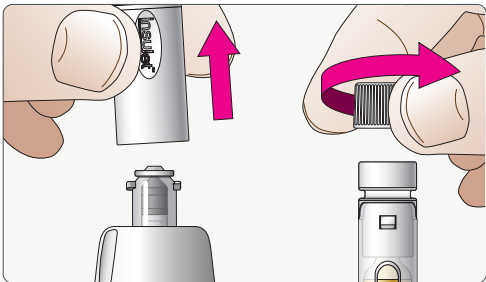


Continue to rotate the front, until it will go no further. Note that a green mark will become visible in the Dosage Window and next to the safety release switch.

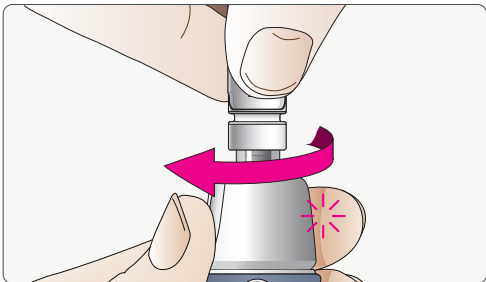
The InsuJet™ is now charged.

How to prime the InsuJet™

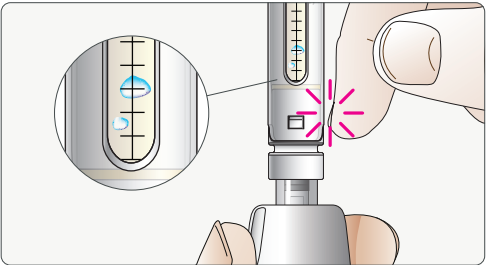
Prime your InsuJet™ every time you use a new Nozzle or new Adaptor. Priming reduces air bubbles inside the Nozzle.



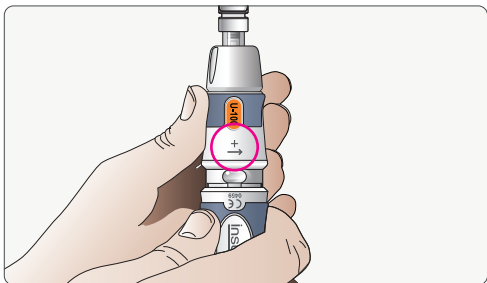
Remove the Nozzle Cap from the Nozzle and the Adaptor Cap from the Adaptor.



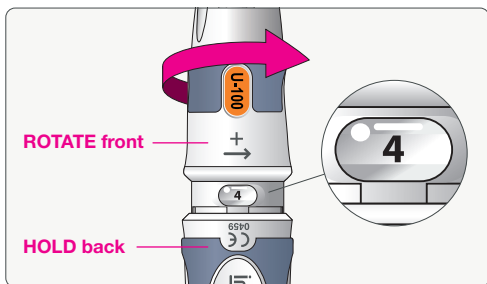
Align the Adaptor with the Nozzle and firmly rotate the Adaptor clockwise onto the Nozzle.



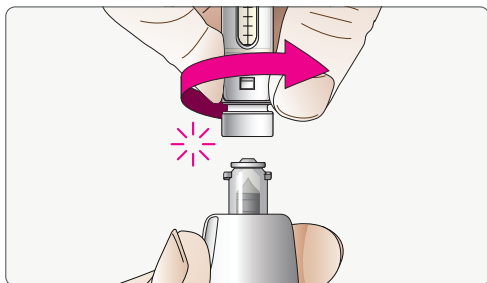
Tap the insulin cartridge or -vial firmly, to remove possible air bubbles from the needle opening inside the cartridge or vial.



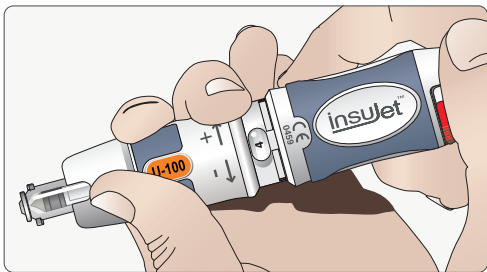
Hold the device with the insulin cartridge/ vial upwards and the Dosage Window facing you. On the Dosing Grip (front) of the InsuJet™, you will notice the plus “+” marking with a directional arrow.



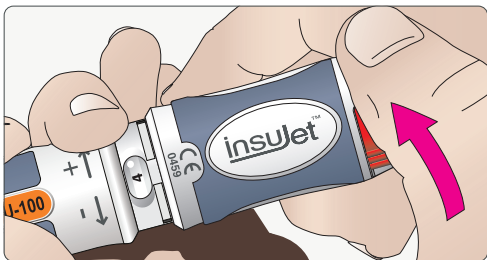
Hold the back of the device and turn the Dosing Grip (front) in the direction of the plus “+” arrow until the number ‘4’ appears in the dosage window.



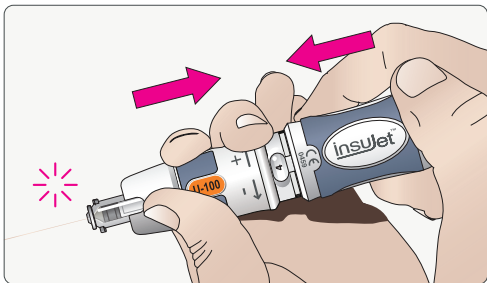
Disconnect the Adaptor with the insulin cartridge/vial from the Nozzle.



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 Dosing Grip (front) towards the back side, to expel the insulin from the Nozzle. You should hear a sound indicating that the device has fired. Your device is now primed and ready to be filled.

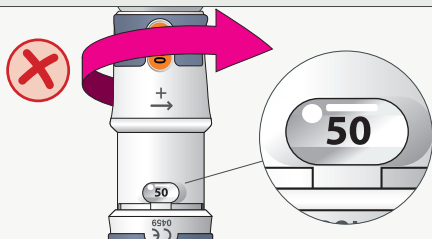
How to dose



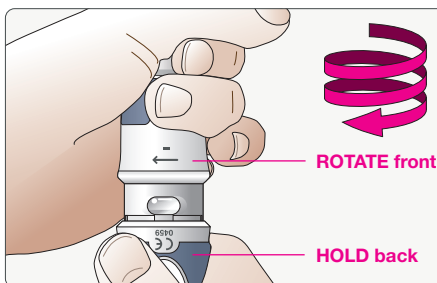
Warnings

Dosing should be done directly before injection. Do not store insulin inside the Nozzle for longer periods.

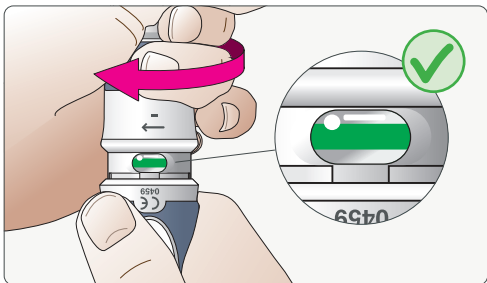
When dosing, always make sure to take up additional insulin, to compensate for possible air bubbles. The amount of additional insulin may vary per injection. 2 units is advised.



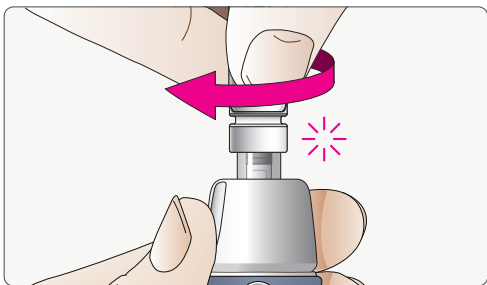
Do not attempt to force the InsuJet™ beyond the mechanical stop past the 50 IU indication. It may damage the device and potentially cause injury.



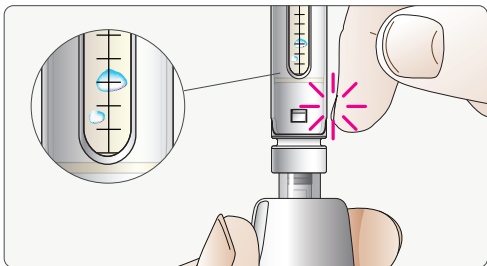
First, the device needs to be (re-) charged. While firmly holding the back of the device, rotate the front in the direction of the minus “-” arrow. The amount of units in the Dosage Window should decrease.



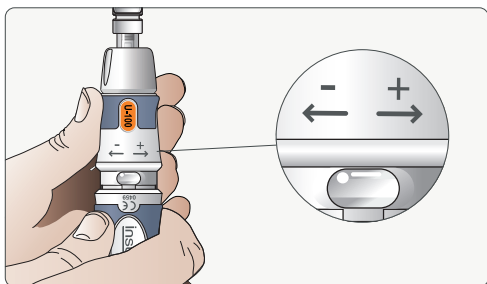
Continue to rotate the front, until it will go no further. Note that a green mark will become visible in the Dosage Window and next to the safety release switch.



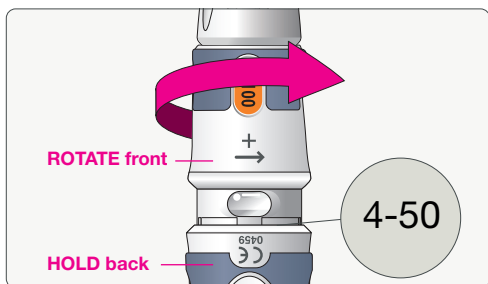
Align the Adaptor with the Nozzle and firmly rotate the Adaptor clockwise onto the Nozzle.



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



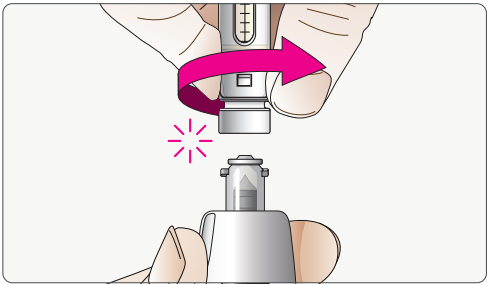
Hold the device with the insulin cartridge/ vial upwards and the Dosage Window facing you. On the Dosing Grip (front) of the InsuJet™, you will notice the plus “+” and minus “-” symbol, with a directional arrow.



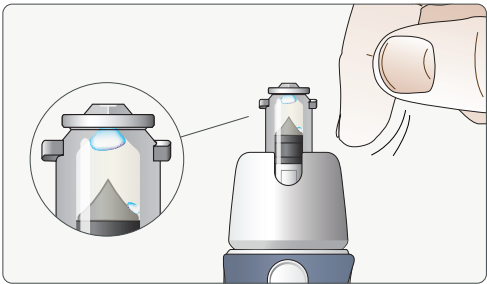
Turn the front of the device in the direction of the plus “+” arrow, until the target dose is visible in the Dosage Window.

Removing air bubbles

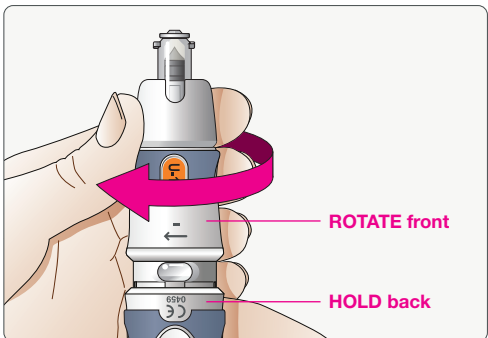
Take the following steps to remove possible air bubbles:



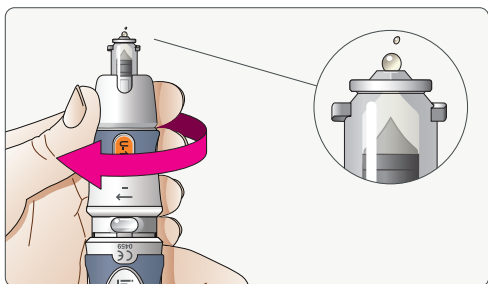
Disconnect the Adaptor with the insulin cartridge/vial from the Nozzle by turning it.



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



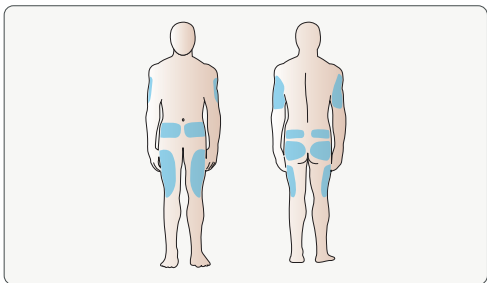
While holding the back of the device, gently rotate the front in the direction of the minus “-” arrow. The air bubble and the excess of insulin will flow through the hole in the Nozzle.



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

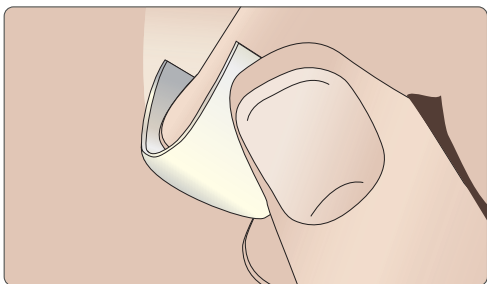
If no drop appears, re-connect the Adaptor with the cartridge/vial to the Nozzle, and take up additional insulin. Repeat the steps mentioned in this section.

Where to inject



To administer your insulin, follow the steps below:

Select your administration site. See page 38 for administration sites and administration techniques.



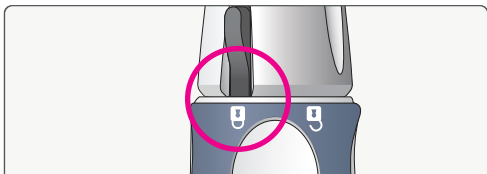
Wipe the chosen administration site with an alcohol swab. Let the skin dry before injection.

How to inject

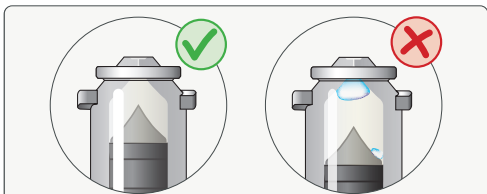


Warnings

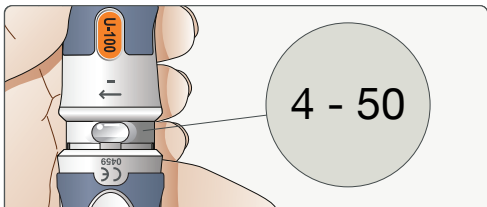
Before each injection:



Ensure that the Nozzle Lock Switch points to the locked position. This indicates that the Nozzle is secured.

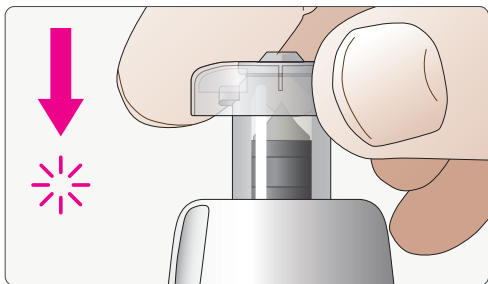


Ensure that the Nozzle is completely filled and free of air bubbles. If not, you will inject less insulin than shown in the Dosage Window, which will affect your anticipated blood glucose level. If there is air inside the Nozzle, repeat the air bubble removal steps on page 26 - 27.



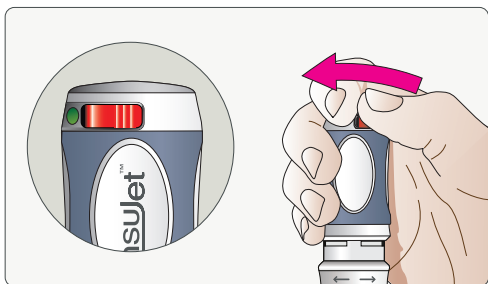
Ensure that you have set the correct dose.

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



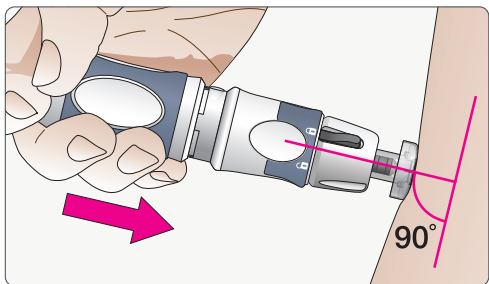
To install a Comfort Ring, hold the device by its front side and place the Comfort Ring on top of the Nozzle. Make sure that the round side of the part is facing outward. Push the Comfort Ring on the Nozzle until it snaps in place.

See page 37 for more information about the Comfort Ring.

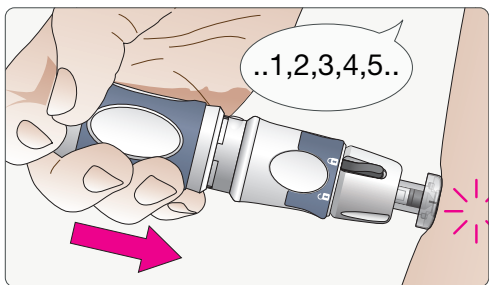


Hold the device only by its back side, slide away the red Safety Catch as far as it will go and hold in place.

While holding the red Safety Catch in place, position the InsuJet™ perpendicular (90°) to the skin. Make sure to only hold the back side of the device. Do not hold the middle or top part.



Push the back of the device directly towards your chosen administration site. Increase the force until the device automatically injects.



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

Injection quality

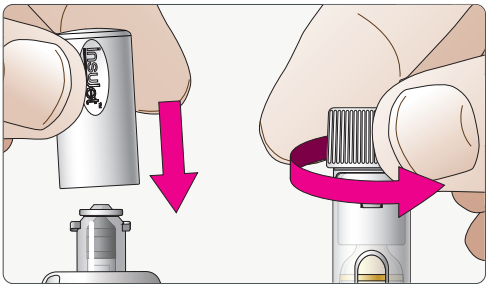
Evaluate the quality of your injection by the following guidelines:

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.

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

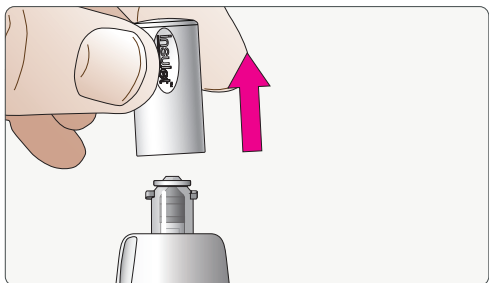
Preventing contamination



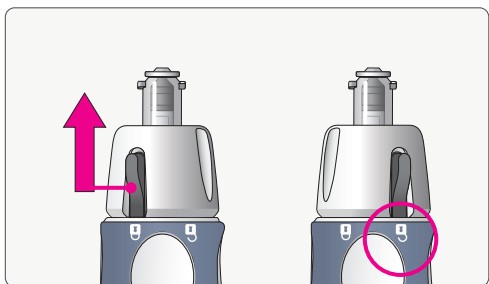
To keep the accessories clean between use, always put back the covers after use.

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

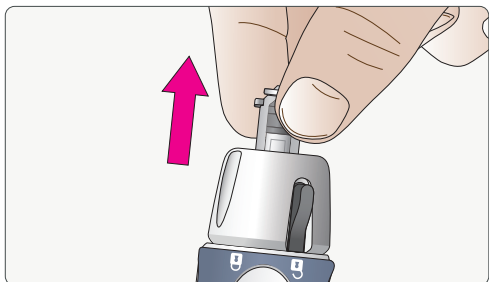
Replacing the InsuJet™ Nozzle



Remove the Nozzle Cover from the Nozzle.

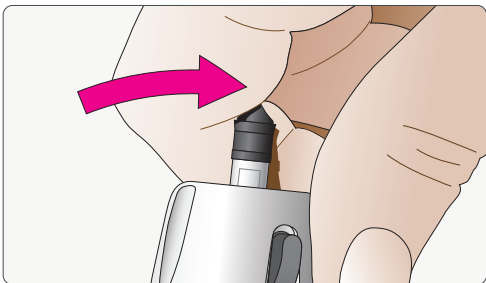


Push the Nozzle Lock Switch upward and turn the Nozzle Lock until the Switch points to the 'unlocked' position.

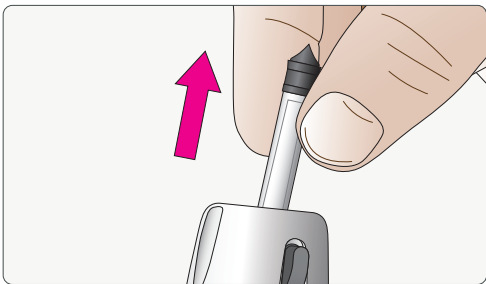


Pull the Nozzle out of the InsuJet™ with a firm straight pull.

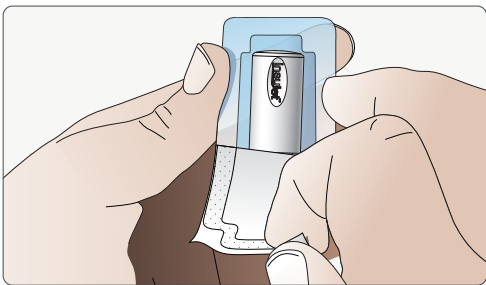
TIP: For additional grip during pulling, please connect an Adaptor to the Nozzle first.



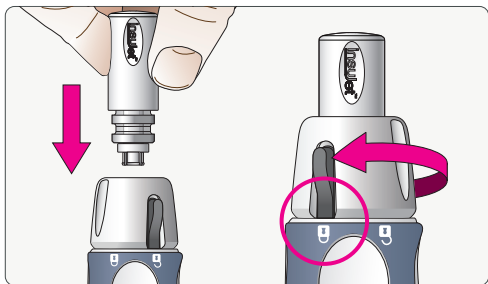
Loosen the internal part of the Nozzle by pushing it firmly to one side.



Remove the internal part of the Nozzle and discard.



Remove a new Nozzle from its packaging by separating one blister and tearing the sealing lid from one of the corners.



Firmly push the Nozzle into the Nozzle Lock.

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

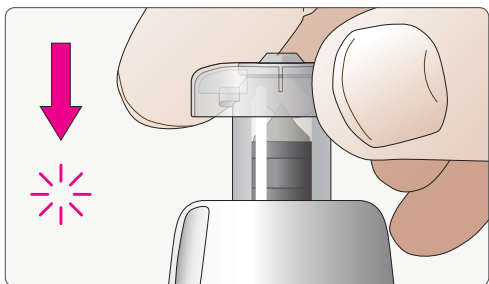
additional
information

Using a InsuJet™ Comfort Ring

InsuJet™ 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.



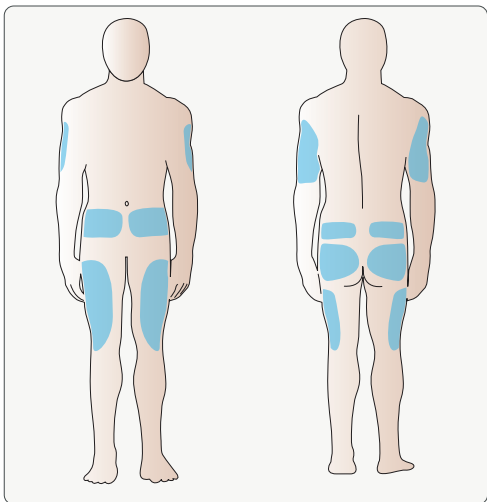
To install the Comfort Ring, hold the device by its front and place the Comfort Ring on top of the Nozzle. Make sure that the round side of the part is facing outward. Push the Comfort Ring onto the Nozzle until it snaps in place.

Replace the Comfort Ring together with the Nozzle.

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

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 belly button, 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 37 for instructions to install a Comfort Ring on the Nozzle.

Safety information

Clinical performance

For diabetes management, the application of insulin by the InsuJet™ results in a complete administration of medicinal product in the subcutaneous layer. Tolerability, total insulin absorption, total insulin action and total blood glucose lowering effect are equivalent to conventional needle injections.

Clinical benefits

- Greater patient acceptance among patients with needle-phobia, or patients who wish to administer insulin without needle
- Administration of insulin by jet injection enhances insulin absorption and reduces the duration of glucose-lowering action. This profile resembles more closely the pattern of endogenous insulin secretion and may help to achieve better meal insulin coverage and correction of postprandial glucose excursions
- The removal of needle sharps helps reduce the occurrence of needle stick injuries and cross contamination, making the InsuJet™ suitable for the treatment of patients from high-risk categories.
- The InsuJet™ targets the subcutaneous tissue just below the dermis reducing the chance of intramuscular injection.

Side effects

Always read the patient information leaflet of your prescribed insulin. The possible side effects are listed in this leaflet. Side effects which you may experience with the use of the InsuJet are listed in this section:

Bleeding - Common

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 - Common

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 25 units each instead of 50 units at once.

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

Infection - Very rare

Although very rare, infections potentially can be caused by microbial contamination being introduced into the body at the injection site.

Using an alcohol swab on the site you're going to inject, and timely replacement of the consumables will help to prevent infections.

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

Irritation - Rare

Individuals may develop a slightly red swelling and irritation at the site of an injection. This most commonly occurs when someone first begins insulin therapy and usually resolves over time. If the itching is troublesome, notify your health care provider.

Raised white bump - Common

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 25 units each instead of 50 units at once.

Intramuscular (IM) injection - Uncommon

The InsuJet is intended for the delivery of insulin to the subcutaneous layer of the skin.

Accidental intramuscular injection, may occur at injection sites without fat, causing the insulin to be injected in the muscle instead. Intramuscular injections may considerably increase the variability of insulin absorption and may impair glycemic control in insulin-dependent diabetic patient.

Uncomfortable administration - Common

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.

Scar-tissue / skin hardening - Common

Rotating your injection sites is crucial in preventing the build-up of scar tissue. If you inject into the same area of your body over and over every day, your body will build-up a harder fibrous tissue every time it heals from the injury of that injection.

Over time that build-up of scar tissue may interfere with your body's ability to properly absorb the insulin you injected.

By making an effort to inject in different areas of the body (thigh, belly, back of the arm, buttocks, etc.) and different parts of each area (upper thigh vs. lower thigh, etc.) you can prevent the rapid build-up of scar tissue.

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.

Hyperglycemia / Hypoglycemia - Common

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.

Too much insulin can lead to Hypoglycemia. Too little insulin may result in Hyperglycemia. Refer to the drug safety information or consult your diabetes care specialist for more information on how to recognize symptoms of hyperglycemia and hypoglycemia.

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.

Frequently asked questions & answers

How does the InsuJet™ administer insulin?

The front of the InsuJet™ is rotated to compress a spring that is used to power the InsuJet™. When the spring is released, it forces 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.

I am interested in using the InsuJet™ system. How do I know if the system is suitable for me?

The InsuJet™ is suitable for most people who require insulin therapy. Refer to the contra-indications for information about known conditions for whom the use of the InsuJet™ is not advised.

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. The Diabetes Care Specialist who is involved in your care, should be consulted as well.

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

- 10mL Vial
- Disposable insulin pen

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.

If you are severely visually impaired or legally blind, it is not recommended to use the InsuJet™ by yourself. 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

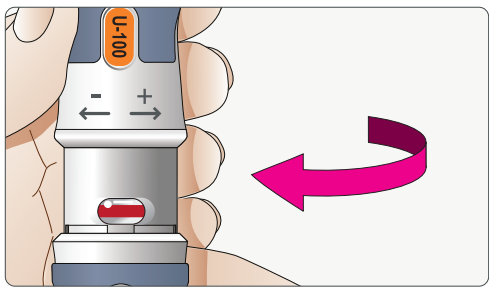
might lead to unexpected results.

For your convenience, we recommend using a separate InsuJet™ device for each type of insulin. Labels with different colours are included in the package. You can use these labels to easily identify the separate devices, as well as their Carry Cases.

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.



Red marking in the Dosage Window

A red marking will appear in the Dosage Window in case the device is accidentally winded beyond 50 units.

To return to 50 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 minus “-” arrow, to reduce the dose level.

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.

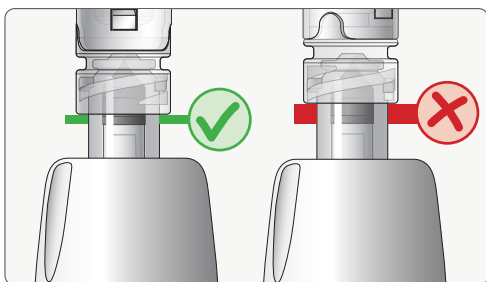
- Keep the InsuJet™ steady throughout the administration.
- After the injection, keep pressing the InsuJet™ onto the administration site for at least 5 seconds.
- Always ensure that there are no air bubbles in the Nozzle.

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.

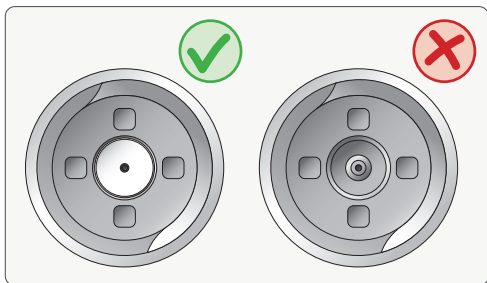
Unable to aspirate insulin from insulin vial or cartridge

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

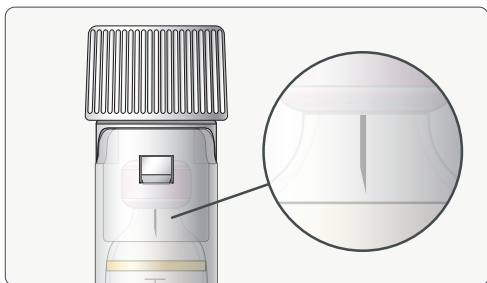


Check if the Adaptor is correctly installed on the Nozzle. Look from the side and inspect the position of the black Plunger tip (inside the Nozzle), relative to the Adaptor.

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.

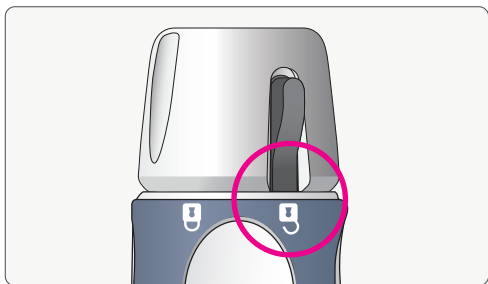


Check if a white, round part is visible when viewing into the Adaptor from the top. If not, replace the Adaptor.



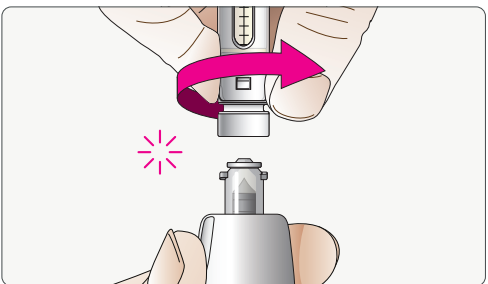
Check if the needle of the Adaptor pierced the septum of the cartridge or vial completely. The needle should be visible on the inside of the cartridge or vial. Please note that you can also smell the insulin once the needle fully pierced the septum.

Unable to install the Nozzle into the InsuJet™



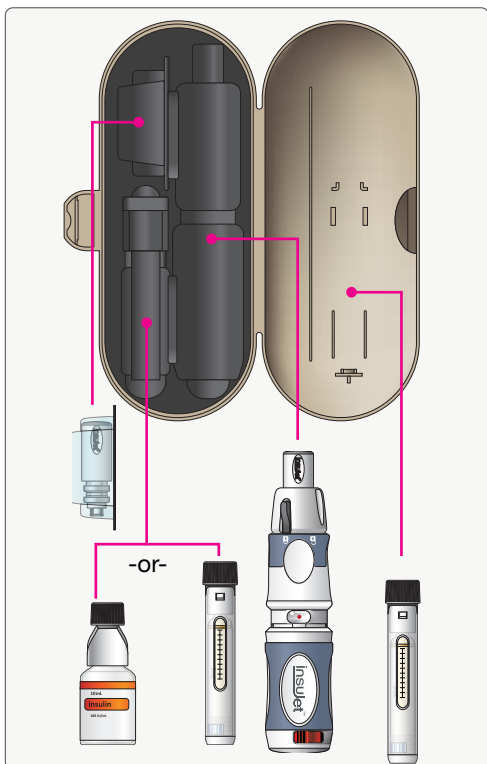
If you can't push the Nozzle into the Nozzle Lock, it may still be in the locked position. Before inserting the Nozzle, please ensure that the Nozzle Lock Switch points to the unlocked position.

Air inside the 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 the minus “-” arrow until the green marking is visible in the Dosage Window. Follow the steps described in the section ‘How to dose’ on page 23 to draw insulin into the Nozzle.

Storage



- Store the device inside the Carry Case.
- Store the InsuJet™ in dry conditions between 5°C and 40°C.
- Store your insulin according to the guidelines of the insulin manufacturer.
- 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.

Maintenance

- Handle the InsuJet™ with care. Do not drop the device or the consumables.
- 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.
- Never try to repair a broken InsuJet™.

Disposal and replacement

- All products can be discarded in regular household waste
- Discard the cartridge/vial Adaptor along with each empty insulin cartridge/vial.
- 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

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. 115g
Size:	length 140mm - 160mm
Dose Range:	4-50 international units of U100 insulin per administration (0.04 - 0.5mL)
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
Insulin types:	• Human and animal • Fast acting insulins (bolus): – Rapid Acting Insulin Analogs – Regular Human Insulin • Basal insulins: – Intermediate-acting, commonly: NPH/ Isophane – Long-acting, commonly: Glargine, detemir, degludec • Premixtures (e.g. 30/70)
Storage:	between 5°C and 40°C

Symbol legend

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 and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the Instructions for Use for additional information.	ISO 15223-1:2020	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 of conformity	A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in Medical Device Regulation 745 / 2017 and other applicable Union harmonization legislation.	765/2008/EC 768/2008/EC MDR 2017/745	N/A
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic	ISO 15223-1:2016	5.6.3
	Do not re-use more than 5000 times	Indicates a medical device that can not be re-used more than 5000 times	N/A	N/A
	Single person - Multiple use	Indicates a medical device that can be used multiple times by a single user.	ISO 15223-1:2020	5.4.12
	Do not re-use more than 56 times	Indicates a medical device that can not be re-used more than 56 times	N/A	N/A
	Do not re-use more than 14 days	Indicates a medical device that can not be re-used more than 14 days	N/A	N/A
	Medical Device	Indicates the item is a Medical Device	ISO 15223-1:2020	5.7.7
	Single Sterile Barrier System	Indicates that the device is packed in a sterile barrier system	ISO 15223-1:2020	5.2.11
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information	ISO 15223-1:2020	5.7.10
	U-100	Indicates that the device is calibrated for use of U-100 insulin	N/A	N/A

Unique Device Identifier & Contact details InsuJet™ dealer



Euro Offices Building 3rd Floor
Beechavenue 127, 1119 RB Schiphol-Rijk
The Netherlands

www.insujet.com | info@insujet.com



012100-EN-2.0

2 Nov 2021