



**Infusion Set
Instructions for use**





en Manufacturer



en Date of Manufacture YYYY-MM-DD



en Use-by (Expiry date) YYYY-MM-DD



en LOT number



en Reference / model number



en Sterilized using ethylene oxide



en Global Trade Item Number



en Do not use if package is damaged



en Keep away from sunlight



en Keep Dry



en Consult instructions for use



en Caution: see instructions for use



en Prescription required, does not apply in all geographies



en Do not re-use



en Non-pyrogenic



en Medical Device



en Single sterile barrier system



en Open here



en Distributed by



See page 4

Indications for use:

The inset™ infusion set is indicated for the subcutaneous infusion of insulin administered by an external pump. The infusion set is indicated for single use.

INTENDED USE

The infusion set is indicated for subcutaneous infusion of insulin in the treatment of diabetes. The infusion set has been tested to be compatible with insulins approved for subcutaneous infusion.

DESCRIPTION

inset™ is a medical device which combines an infusion set with an aid for infusion (serter). As the infusion set is an integrated part of the serter, inset™ is delivered assembled and ready for use as a single, sterile unit.

CONTRAINDICATIONS

inset™ is neither intended nor indicated for use in intravenous infusion of blood or blood products.

WARNINGS

- Carefully examine the instructions for use before inserting inset™. Failure to follow instructions may result in pain or injury.
- inset™ is only sterile and non-pyrogenic if the packaging is undamaged and unopened. Do not use if inset™ is already open or has been damaged. Ensure sterility by checking if the sterile paper and tamper-proof seal are undamaged.
- When using inset™ for the first time, do so in the presence of a healthcare provider. Since different individuals have varying amounts of subcutaneous layer, ensure that an appropriate cannula length is chosen to fit your needs.
- Inaccurate medication delivery, site irritation or infection may result from improper insertion or maintenance of your infusion site.
- Do not re-insert the introducer needle into the infusion set. This could cause a tearing or damage of the soft cannula and may lead to unpredictable medication flow.
- Reuse of the infusion set may cause site

irritation or infection and may lead to inaccurate medication delivery.

- Be sure that the needle guard is removed before insertion is made.
- If the soft cannula bends during insertion, apply a new inset™ immediately at a new site.

PRECAUTIONS

- Never try to fill or free a clogged tubing while the infusion set is inserted. This may result in unpredictable medication flow.
- When unwinding, release the tubing with caution as a hard pull of the tubing can result in damage to the serter. Ensure that the infusion set is properly in place in the serter when the tubing is fully released – see picture 8.
- Do not leave air in the infusion set. Make sure to fill the tubing completely. Consult pump manufacturer's instructions for use.
- inset™ is a single use device and should be disposed of immediately after use. Do not clean or re-sterilize.
- Do not in any way put disinfectants, perfumes, deodorants, cosmetics or other products

containing alcohol or disinfectants in contact with the connector or the tubing. These may impact the integrity of the infusion set.

- Replace the infusion set if the adhesive tape becomes loose or is displaced from its original site. Since the cannula is soft, it will not cause any pain if it becomes dislodged, and this may take place without notice. The soft cannula must always be completely inserted to receive the full amount of medication.
- Replace the infusion set every two to three days, or per your healthcare provider's instructions.
- If your insertion site becomes irritated or infected, replace infusion set and use new site until the first site has healed.
- Wash your hands before disconnecting and reconnecting the infusion set. Consult your healthcare provider on how to compensate for missed medication when disconnected.
- Never point a loaded serter towards any body part, where insertion is not desired.

RECOMMENDATIONS

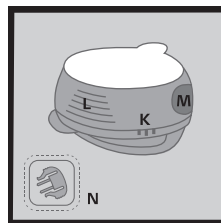
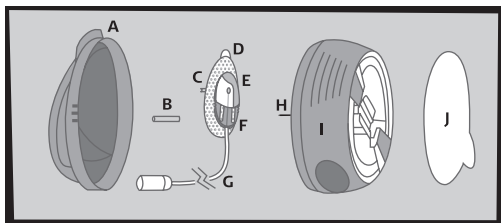
- Check your blood glucose level one to three hours after insertion of the infusion set. Measure your blood glucose on a regular basis. Discuss this with your healthcare provider.
- Do not change your infusion set just prior to bedtime, unless blood glucose can be checked one to three hours after insertion.
- If your blood glucose level becomes unexplainably high or an occlusion alarm occurs, check for clogs and leaks. If in doubt, change your infusion set since the soft cannula could be dislodged or partially clogged. Discuss plan to bring down your blood glucose level with your healthcare provider should any of these problems arise. Test your blood glucose level to ensure problem is corrected.
- Carefully monitor your blood glucose levels when disconnected and after reconnecting.
- If, during the use of this device or as a result of its use a serious incident has occurred, please report it to the manufacturer and to your national authority.

STORAGE & DISPOSAL

- Store inset™ in a cool, dry location at room temperature. Do not store inset™ in direct sunlight, or in high humidity.
- Store and handle insulin according to the manufacturer's instructions.
- Put the lid back on the serter and dispose in a proper sharps container according to local laws, to avoid the risk of needle stick.
- Dispose the used infusion set according to local regulations for biohazardous waste.

inset™ - Preparation and insertion

Read all instructions carefully before using the inset™. For information about pump therapy, possible errors, and potential risks and their causes, consult your pump manufacturer's instructions for use before connecting the infusion set. When using inset™, follow proper hygiene procedures. Please see the corresponding illustrations on page 8-10.



- 1 Wash your hands before inserting the infusion set.
- 2 Suggested insertion sites. Choose an insertion site as recommended by your healthcare provider. Do not use an area right next to your previous infusion site.
- 3 Clean the area for insertion with a disinfectant as directed by your healthcare provider. Be sure the area is air dry before inserting the infusion set.
- 4 Pull the red tape to remove the seal.
- 5 Remove the sterile paper.
- 6 Press the three raised dots on each side of the lid firmly with one hand and lift up the lid with the other hand.

CONTENTS

- | | |
|---------------------|-----------------------|
| [A] Lid | [F] Connector needle |
| [B] Needle guard | [G] Tubing |
| [C] Soft cannula | [H] Introducer needle |
| [D] Adhesive tape | [I] Serter |
| [E] Cannula housing | [J] Sterile paper |

IMPORTANT NOTE!

- [K] Three raised dots – press here when lifting the lid off (see Figure 6)
- [L] Lined indentations – press here when loading inset™ (see Figure 10)
- [M] Round Indentations – press here simultaneously when releasing inset™ (see Figure 12)
- [N] Disconnect cover (see Figure B)

CAUTION: Be careful not to bend or touch the introducer needle when preparing the serter and infusion set.

IMPORTANT NOTE! If the infusion set is not securely placed in the serter with the needle pointing straight ahead prior to insertion, pain or minor injury may occur. To avoid this, please ensure that the following steps are taken gently so

the infusion set is not loosened / removed by accident.

- 7 Unwinding the tubing:** Carefully twist the beginning of the tubing out of the slot. Now unwind the tubing from the serter by pulling it carefully upwards.

CAUTION: Do not touch the introducer needle when unwinding the tubing. Be careful not to pull too hard when the tubing is fully released. You could accidentally remove the infusion set from the serter.

- 8** Connect the infusion set to a pump reservoir and the pump. Prime infusion set. Ensure there are no air bubbles in the tubing. Consult pump manufacturer's instructions for use.

CAUTION: When priming the infusion set, hold the infusion set with the needle pointing down to ensure that medication does not come in contact with the adhesive backing paper.

- 9** Pull up gently to remove the adhesive backing paper.

- 10 Prepare the serter:** Place fingers on lined indentations. Press lined indentations on each side. Pull spring until you hear a "click".

- 11** Carefully remove the needle guard by gently twisting and then pulling it. Check that the soft cannula does not exceed the introducer needle.

CAUTION: Before positioning inset™ over a clean insertion site, place the tubing in the slot to ensure that the tubing is not caught underneath the infusion set during insertion.

- 12 Insert inset™:** Position inset™ over the insertion site. Simultaneously press the round indentations on either side of the serter to insert the infusion set.

- 13** Push gently on the center of the serter to secure the adhesive on the skin.

- 14** Remove the serter/introducer needle by grasping the center and pulling it gently back. Gently massage the adhesive tape onto the skin. Fill the empty space in the cannula with the following amount of insulin:

U-100 insulin:

6 mm : 0.1 units (0.001 ml)

9 mm : 0.2 units (0.002 ml)

- 15** Push the lid back in place until you hear a "click."

DISCONNECTING

- A** inset™ allows you to temporarily disconnect your pump without having to change the infusion set. Hold the adhesive tape in place by placing a finger just in front of the cannula housing, and gently squeeze the sides of the connector. Pull the connector needle straight out from the cannula housing.

- B** Insert the disconnect cover into the cannula housing until you hear a "click".

RECONNECTING

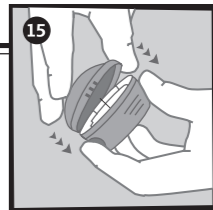
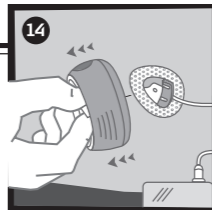
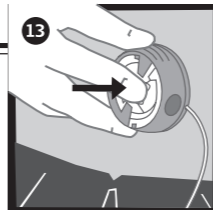
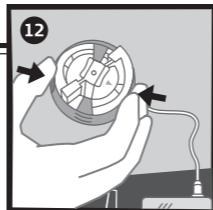
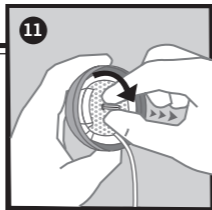
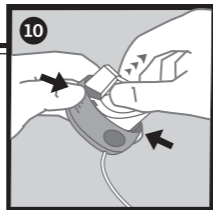
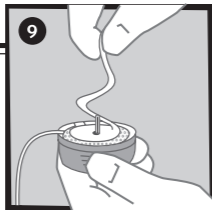
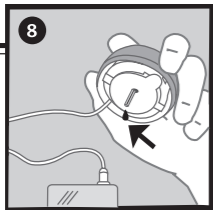
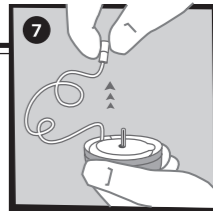
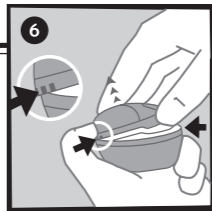
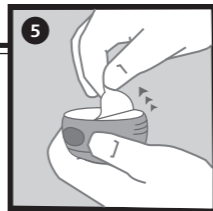
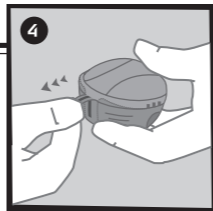
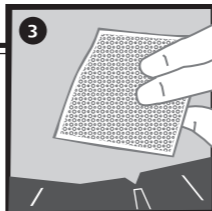
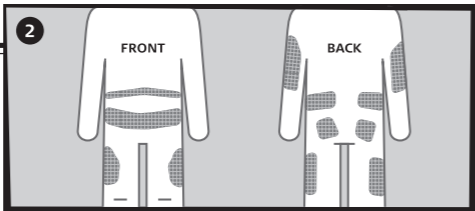
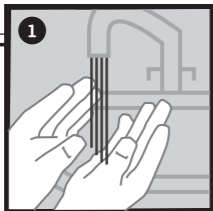
- C** If necessary, prime the infusion set until medication dispenses from the needle.

CAUTION: When priming the infusion set, hold the infusion set with the needle pointing down.

- D** Place a finger on the adhesive tape just in front of the cannula housing.

- E** Push the connector needle straight in until you hear a "click".

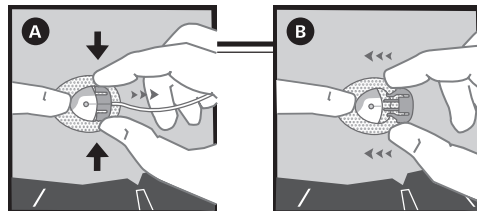
inset™



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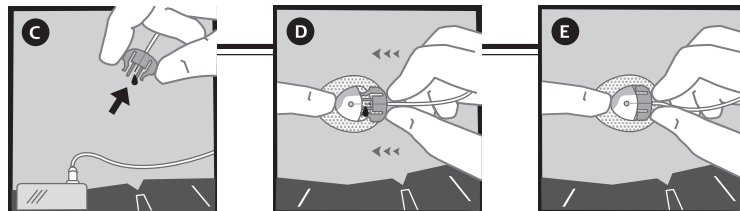
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DISCONNECTING



Click

RECONNECTING



Click





11 Hughes
Irvine, CA 92618, USA
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