

t:90™ infusion set



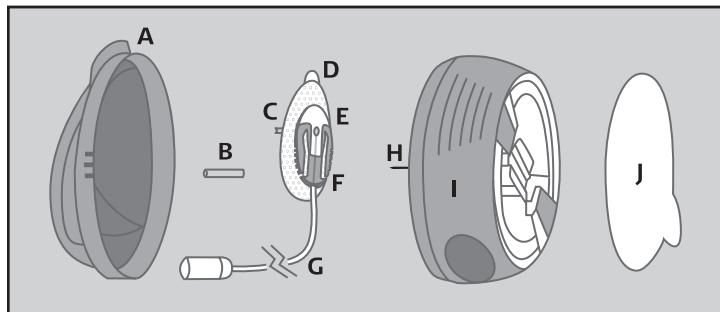
TANDEM®
DIABETES CARE

Instructions for Use



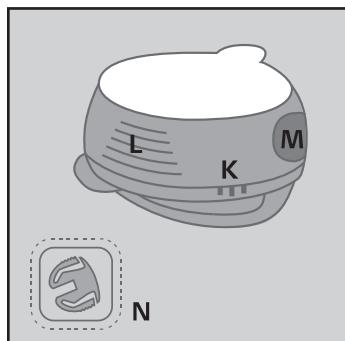
t:90™ Infusion Set – Preparation and insertion

Read all instructions carefully before using the t:90™ Infusion Set. 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. Follow proper hygiene procedures.



CONTENTS

- | | | | |
|-----------------|---------------------|----------------------|------------------|
| A. Lid | D. Adhesive | G. Tubing | J. Sterile paper |
| B. Needle guard | E. Cannula housing | H. Introducer needle | |
| C. Soft cannula | F. Connector needle | I. Insertion device | |



IMPORTANT NOTE!

- K. Three raised dots – press here when lifting the lid off (see figure 6)
- L. Lined indentations – press here when loading (see figure 10)
- M. Round Indentations – press here when releasing (see figure 12)
- N. Disconnect cover (see figure B)

INDICATIONS FOR USE

The t:90™ Infusion Set is indicated for the subcutaneous infusion of insulin administered by an external pump.

DESCRIPTION

This product is an infusion device which combines an infusion set (catheter) with an aid for infusion (inserter). As the infusion set is an integrated part of the inserter, this product is delivered assembled and ready for use as a single, sterile unit.

CONTRAINdications

This product is neither intended nor indicated for use in intravenous infusion of blood or blood products.

WARNINGS

- This product is only sterile and non-pyrogenic if the insertion device is unopened and undamaged. Do not use if the insertion device is already open or has been damaged. Ensure sterility by checking if the sterile paper and tamper-proof seal are undamaged.
- Carefully examine the instructions for use before inserting product. Failure to follow instructions may result in pain or injury.
- When using product 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.
- 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 affect the integrity of the infusion set.
- Product is a single use device and should be disposed of immediately after use. Do not clean or re-sterilize.
- Product can be disposed of safely after insertion if the lid has been placed back on. Please consult your local pharmacy for sharp containers.
- Be sure that the needle guard is removed before insertion is made.
- Release the tubing with caution as a hard pull of the tubing can result in damage to the infusion set/introducer needle. Ensure that the infusion set is properly in place when the tubing is fully released – see picture 8.
- Do not leave air in the infusion set. Make sure to fill tubing and cannula completely.
- Inaccurate medication delivery, infection and/or site irritation may result from improper insertion or maintenance of your infusion site.

- Replace the infusion set every 48-72 hours, or per your healthcare provider's instructions.
- If the soft cannula bends during insertion, discard and apply a new product immediately.
- 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 slips out, and this may take place without notice. The soft cannula must always be completely inserted to receive the full amount of medication.
- If your infusion site becomes inflamed, replace infusion set and use new site until the first site has healed.
- Do not re-insert the introducer needle into the infusion set. This could cause a tearing of the soft cannula and unpredictable medication flow.
- Never try to fill or free clogged tubing while the infusion set is inserted. This may result in unpredictable medication flow.
- Always clean the insertion site when temporarily disconnecting the infusion set. Consult your healthcare provider on how to compensate for missed medication when disconnected and after reconnecting.
- Protect the product from direct sunlight and atmospheric humidity. Store in a dry place at room temperature.
- Never point a loaded insertion device towards any body part, where insertion is not desired.
- Reuse of the infusion set may cause infection, site irritation, or damage to the cannula/needle. A damaged cannula/needle may lead to inaccurate medication delivery.

RECOMMENDATIONS

- Check your blood glucose level 1-2 hours after inserting product. Measure your blood glucose on a regular basis. Discuss this with your healthcare provider.
- When using insulin, do not change your infusion set just prior to bedtime, unless blood glucose can be checked 1-2 hours after insertion.
- When you are infusing insulin and 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, crimped or partially clogged. Discuss a plan for rapid replacement of insulin with your healthcare provider should any of these problems arise. Test your blood glucose level to make sure the problem is corrected.

	Use by (year/month)
	Do not re-use
	Sterilized using ethylene oxide
	Attention: See accompanying documents
	See Instructions for Use
	Reference / model number
	Lot number
	Manufacturer

Distributed by:

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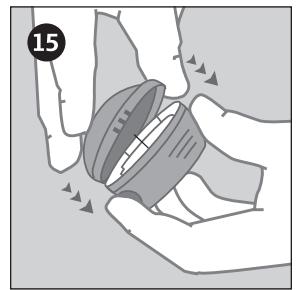
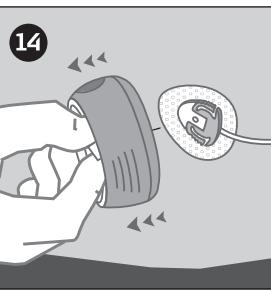
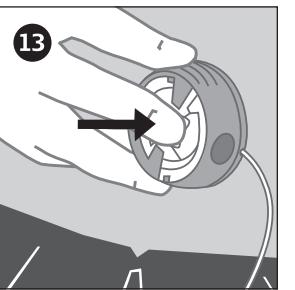
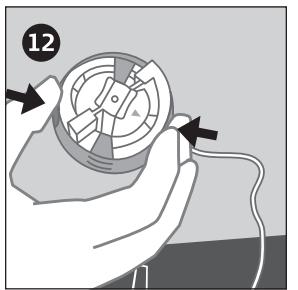
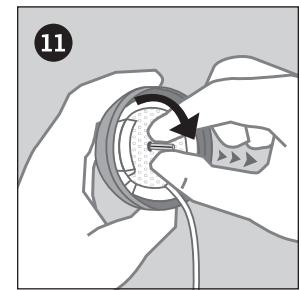
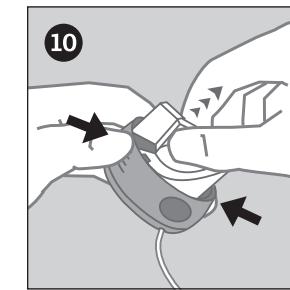
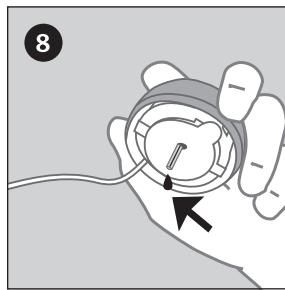
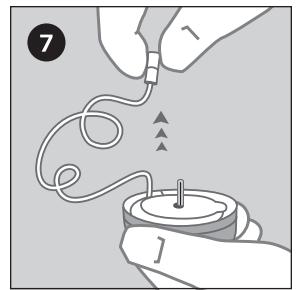
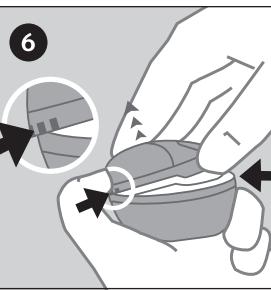
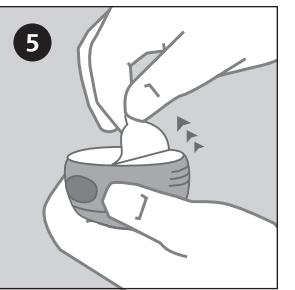
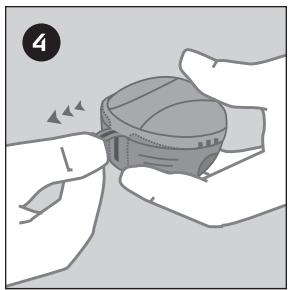
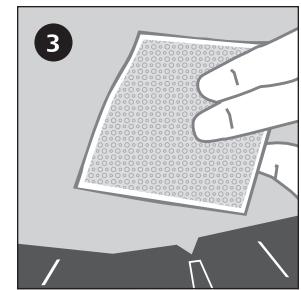
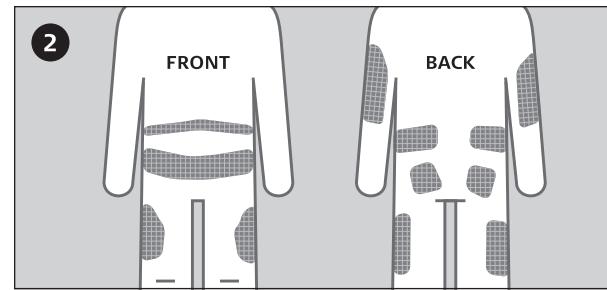
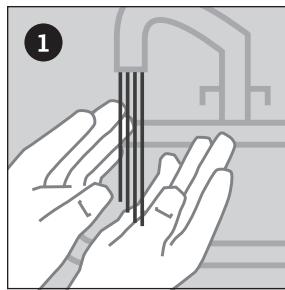
Legal Manufacturer:

Unomedical
A Convatec Company

Unomedical a/s
Aaholmvej 1-3, Østed | 4320 Lejre, Denmark
Made in Mexico

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RX Only



1. Wash your hands before inserting infusion set.
2. Recommended injection areas. Do not use an area right next to your previous place of insertion.
3. Clean the area for insertion with a disinfectant as directed by your healthcare team. Be sure the area is dry before inserting product.
4. Pull the red tape and 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 with the other hand.

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

IMPORTANT NOTE! If the infusion set is not securely placed in the insertion device 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. Pull up gently. Now unwind the tubing from the insertion device 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 introducer needle.

8. Connect product to a pump cartridge. Prime infusion set. Ensure there are no air bubbles in the tubing or cannula.

CAUTION: When priming the infusion set, hold product 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 inserter:** Place fingers on lined indentations. Press lined indentations on each side. Pull spring up until you hear a "click".

11. Carefully remove the needle guard by gently twisting and then pulling it.

CAUTION: Before positioning product over clean insertion site, place the tubing in the slot to ensure that the tubing is not caught underneath the device during insertion.

12. **Insert infusion set:** Position product over the insertion site. Simultaneously press the round indentations on both sides of the insertion device to insert.

13. Push gently on the center of the inserter to secure the adhesive on the skin.

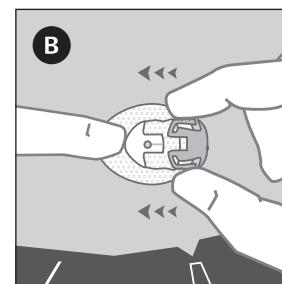
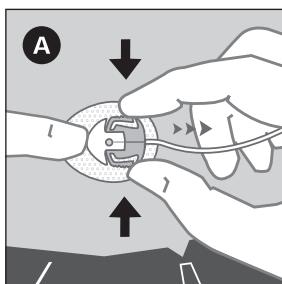
14. Remove the inserter/introducer needle by grasping the center and pulling it back gently. Massage the tape thoroughly onto the skin. Fill the empty space in the cannula with the following amount of insulin:

U-100 insulin:
6 mm : 0.3 units
9 mm : 0.5 units

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

TO DISCONNECT

- A. Product allows you to temporarily disconnect your pump without having to change the infusion set. Hold the adhesive in place by placing a finger just in front of the cannula housing, and gently squeeze the sides. Pull the connector needle straight out from the cannula housing.
- B. Insert the disconnect cover into the cannula housing until you hear a "click".



TO RECONNECT

- C. Prime the infusion set until medication dispenses from the needle.
- CAUTION:** When priming the infusion set, hold 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".

