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A ConvaTec Company

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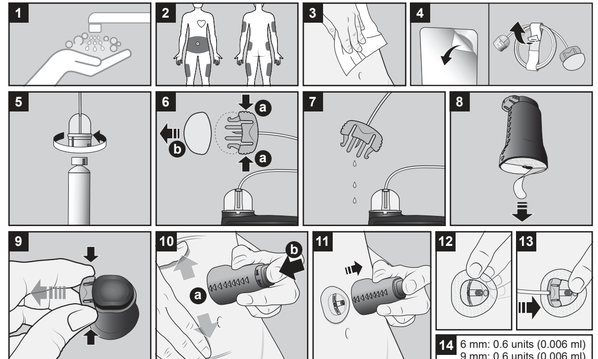
Medtronic Extended

Infusion Set •

PLACEHOLDER FOR GTIN

PLACEHOLDER FOR PART BARCODE

M995121A022_1 2021-07



EN	Disconnecting from Site	JA	
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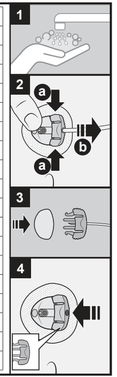

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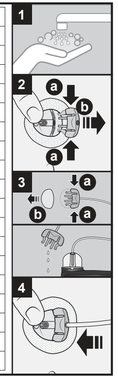

EN	Reservoir Change without Set Change	JA	
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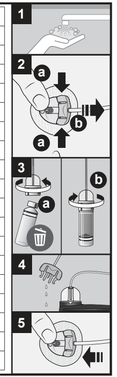

EN	Removing Infusion Set from Body	JA	
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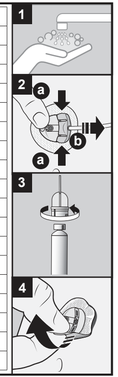

Medtronic Extended

EN	See page 2	HU		ET	
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Indications for use

The Medtronic Extended infusion set is indicated for subcutaneous infusion of medication administered by an external pump. The infusion set is indicated for single use.

Description

The Medtronic Extended infusion set has a 90–degree soft cannula. It is delivered ready to use in a pre–loaded insertion device with automatic needle retraction. It is provided sterile and nonpyrogenic.

Intended use

The infusion set is indicated for subcutaneous infusion of insulin in the treatment of diabetes mellitus. Refer to the Medtronic insulin pump user guide for a list of compatible insulins and infusion sets.

Contraindications

This infusion set is indicated for subcutaneous use only. Do not use the infusion set for intravenous infusion. Do not use the infusion set with blood or blood products.

General instructions

- The infusion set may be worn for a maximum of seven days, or according to the insulin labeling, whichever duration is shorter.
- If the infusion set is being used for the first time, do the first set–up in the presence of a healthcare professional.

Warnings

- Do not use the infusion set if the package is opened or damaged. An opened or damaged package may be contaminated. This can cause an infection.
- Do not use the infusion set beyond seven days as this may cause inaccurate insulin delivery, infection, or site irritation.
- Do not use the infusion set beyond the Use-by date, or if the package is opened or damaged, as sterility may be compromised.
- Do not use the infusion set if the disconnect cover is removed. Use a new infusion set instead. One purpose of the disconnect cover is as a safety feature against accidental firing of the insertion device which could cause injury.
- Do not change the infusion set just before bedtime unless blood glucose can be checked one to three hours afterwards.
- Do not put alcohol, disinfectants, perfumes, deodorants, cosmetics, or other substances with solvents on the infusion set. These substances may damage the integrity of the infusion set.
- Never point the insertion device toward any body part where insertion is not desired.
- Always rotate the insertion site when changing the infusion set. Reusing an insertion site too often may cause scarring and unpredictable insulin delivery. Review the pump user guide on how to rotate insertion sites.
- Check the insertion site often through the clear window. Improper insertion and maintenance of the insertion site can cause inaccurate insulin delivery, infection, or site irritation. Replace the infusion set at a new site if the soft cannula is not properly inserted.
- Check the cannula housing and tubing for blood. Blood may cause insufficient insulin delivery. This may result in high blood glucose. Replace the infusion set at a new site if there is blood.
- Fill the tubing completely with insulin before insertion. Do not leave air in the tubing. An uncontrolled amount of insulin may be delivered if air is present.
- Check the tubing for clogs or leaks if a blood glucose reading is high. Clogs or leaks may restrict insulin delivery and result in high blood glucose. Replace the infusion set even if a clog or leak is suspected, but not found.
- Do not attempt to clear air or an occlusion in the tubing while it is connected to the body. An uncontrolled amount of insulin may be delivered. This can cause high or low blood glucose. Disconnect the tubing before adjusting it.
- Do not reuse the infusion set. Reuse of the infusion set may cause damage to the cannula or needle and may lead to infection, site irritation, or unpredictable insulin delivery.
- If insulin or any other liquid gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. **This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.** If this occurs, start over with a new reservoir and infusion set.
- For no delivery or Insulin Flow Blocked alarms, refer to the pump user guide.
- Do not use the reservoir or infusion set if either is damaged while connecting. A damaged reservoir or infusion set may cause too little delivery of insulin due to leakage, which may cause hyperglycemia.

Precautions

- Do not use another type of infusion set without consulting a healthcare professional for correct

handling. A healthcare professional should always be consulted when choosing an infusion set.

- Choose insertion sites as recommended by a healthcare professional. The choice of site depends on treatment and patient-specific factors such as body composition and physical activity level.
- Check that the insertion site is free of skin irritation, such as redness, scar tissue, or bleeding. Do not insert the infusion set into muscle or over bone. Doing so can cause pain or may damage the infusion set. If the infusion set is improperly inserted, replace the infusion set and insert at a new site.
- If needed, remove body hair around the insertion site to ensure that the adhesive sticks to the skin.
- Do not use an insertion site located under a belt or waistband, or where the site is constrained by clothing or accessories. Insertion at these locations can cause disconnection of the infusion set and interruption of insulin delivery, and lead to hyperglycemia.
- Do not reposition the infusion set on the body after the adhesive is placed on the skin. Repositioning the infusion set may damage the adhesive. Replace the infusion set if the adhesive is damaged.
- Always check blood glucose one to three hours after inserting a new infusion set, or after changing the reservoir while using the same infusion set. This will confirm that the amount of insulin being infused is having the intended effect on blood glucose levels.
- Check blood glucose several times throughout the day or as recommended by a healthcare professional.
- Consult a healthcare professional for how to correct for missed insulin and for how much time the pump can remain disconnected.

Storage and disposal

- Store infusion sets in a cool, dry location at room temperature. Do not store infusion sets in direct sunlight, or in high humidity.
- Store and handle insulin according to the manufacturer's instructions.
- Dispose of the insertion device in a proper sharps container according to local laws.
- Dispose of a used infusion set according to local regulations for biohazardous waste.

Serious incident

- 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 a national authority.

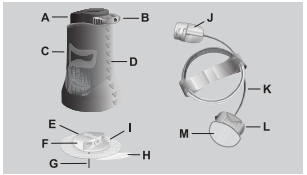
Warranty

- For product warranty information, please contact a local Medtronic support representative, or visit: www.medtronicdiabetes.com/warranty

Additional information for the healthcare professional

- Consider treatment and patient–specific factors when choosing an insertion site.
- The length of the soft cannula should be based on treatment and patient factors such as physiology and activity level. If the soft cannula is too long, insertion pain or insertion into the bone or muscle may occur. If the soft cannula is too short, leakage or irritation at the insertion site may occur. In both cases, the infusion must be stopped and a new soft cannula with a different length must be inserted at a new insertion site.
- Inform the patient that the selection of an insertion site is dependent on cannula length.

Components



A. Top button
B. Disconnect cover
C. Insertion device
D. Raised arrows indicating tubing direction
E. Clear window
F. Cannula housing
G. Soft cannula
H. Paper backing
I. Adhesive
J. Tubing connector
K. Tubing
L. Site connector
M. White cap for site connector

Instructions for use

- Read all instructions carefully before using the Medtronic Extended infusion set.
- Consult the pump user guide for important information about pump therapy prior to connecting the infusion set. This information includes connection and filling procedures, possible errors, and potential risks related to pump therapy.
- Follow good hygienic procedures. If this infusion set is being used for the first time, perform the first set-up in the presence of a healthcare professional.

Inserting infusion set into body

Unfold the front cover of this booklet to view images that are keyed to the steps below.

1. Wash hands with soap and water.
2. Select a recommended insertion site (shown in gray) and as indicated by a healthcare professional.
3. Clean the insertion site with a disinfectant as directed by a healthcare professional. Allow to air dry before inserting the infusion set. Remove hair around the insertion site to ensure the adhesive sticks to the skin if needed.
4. Open the package and remove the paper from the tubing.
5. Place the tubing connector on the top of a newly filled reservoir. If a MiniMed tubing connector is in use, twist the tubing connector clockwise until it locks in place.

   For the MiniMed tubing connector: If insulin or any other liquid gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. **This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.** If this occurs, start over with a new reservoir and infusion set.
6. Remove the white cap from the site connector by (a) squeezing the sides of the site connector then (b) pulling the white cap off. Keep the white cap for later use.
7. Put the reservoir into the pump, then completely fill the tubing with insulin as instructed by the pump user guide. Do not leave any air in the tubing. The tubing is completely filled when drops of insulin are seen coming out of the site connector.
8. Remove the paper backing from the adhesive. Be careful not to touch the adhesive.
9. Remove the disconnect cover from the insertion device by gently squeezing the sides of the disconnect cover then pulling it away from the insertion device. Keep the disconnect cover for later use. The raised arrows indicate the tubing direction.

10a. Stretch the skin until smooth. Then press the insertion device against the skin.

10b. Press the top button down completely to insert the infusion set.

11. Gently and carefully remove the insertion device.
12. Gently press the adhesive onto the skin with one finger. Replace the infusion set if the adhesive does not stick to the skin.
13. Gently hold the cannula housing steady with one finger. Then push the site connector straight into the cannula housing until it clicks.
14. Fill the soft cannula with insulin:

    6 mm: 0.6 units (0.006 ml)
    9 mm: 0.6 units (0.006 ml)

Dispose of the insertion device in an appropriate sharps container according to local laws.
Keep the disconnect cover and the white cap for use when the infusion set is disconnected.

Disconnecting from site

1. Wash hands with soap and water.
2. Gently hold the cannula housing steady with one finger. Then (a) squeeze the sides of the site connector and (b) pull the site connector out of the cannula housing.
3. Put the white cap on the site connector.
4. Put the disconnect cover on the cannula housing. Then push the cover into the cannula housing until it clicks.

Reconnecting to site

1. Wash hands with soap and water.
2. Use one finger to gently hold the cannula housing steady. Then (a) squeeze the sides of the disconnect cover and (b) pull the disconnect cover out from the cannula housing.
3. Remove the white cap from the site connector by (a) squeezing the sides of the site connector then (b) pulling the white cap off. Ensure that there is no air in the tubing. **If there are air bubbles in the tubing:** Fill the tubing with insulin as instructed in the pump user guide. Do not leave any air in the tubing.
4. Use one finger to gently hold the cannula housing steady. Then, push the site connector into the cannula housing until it clicks.

Reservoir change without set change

1. Wash hands with soap and water.
2. Use one finger to gently hold the cannula housing steady. Then (a) squeeze the sides of the site connector and (b) pull it out from the cannula housing.
3. Remove the reservoir from the pump then (a) remove the tubing connector from the reservoir by turning the connector counter-clockwise. Dispose of the used reservoir in an appropriate container according to local laws. Do not throw away the tubing. Set it aside on a clean surface. For specific instructions on removing reservoir from the pump, refer to the pump user guide. (b) Place the tubing connector on the top of a newly filled reservoir. Twist the tubing connector clockwise until it locks in place.
   For the tubing connector, make sure there is no liquid inside the tubing connector or on top of the reservoir. Liquid can block vents and cause inaccurate insulin flow. This can result in high or low blood glucose. If there is liquid, use a new infusion set and a new reservoir.
4. Put the reservoir into the pump. Ensure that there is no air in the tubing. **If there are air bubbles in the tubing:** Fill the tubing with insulin as instructed in the pump user guide. Do not leave any air in the tubing.
5. Use one finger to gently hold the cannula housing steady. Then, push the site connector into the cannula housing until you hear a click. **Do not fill the cannula. When reconnecting the infusion set following a reservoir-only change, filling the cannula may result in the delivery of too much insulin, which could cause hypoglycemia.**

Removing infusion set from body

1. Wash hands with soap and water.
2. Use one finger to gently hold the cannula housing steady. Then (a) squeeze the sides of the site connector and (b) pull the site connector out of the cannula housing.
3. Remove the reservoir from the pump. Remove the tubing connector from the reservoir by turning the connector counter-clockwise. For specific instructions on removing the reservoir from the pump, refer to the pump user guide.
4. Carefully lift the adhesive around the cannula housing. Then, pull the soft cannula out of the skin.

EN	Caution	JA	
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EN	Do not re-use	JA	
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LOT			
EN	Batch code	JA	
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EN	Keep dry	JA	
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EN	Open here	JA	
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MD

EN	Medical device	JA	
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EN	Non-pyrogenic	JA	
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EN	Consult instructions for use	JA	
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EN	Single sterile barrier system	JA	
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EN	Replace every X days	JA	
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REF			
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EN	Use-by-date (YYYY-MM-DD)	JA	
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GTIN			
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EN	Keep away from sunlight	JA	
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EN	Do not use if package is damaged	JA	
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	R_x *Only*		
EN	Requires a prescription in the USA	JA	
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STERILE EO			
EN	Sterilized using ethylene oxide	JA	
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EN	Date of manufacture (YYYY-MM-DD)	JA	
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	CE0459
EN	Conformité Européenne (European Conformity) This symbol means that the device fully complieswith applicable European Union Acts.
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