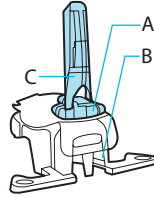
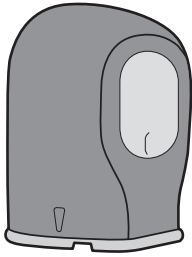




ENLITE™

Serter
User Guide

CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use.



Enlite sensor system

Serter

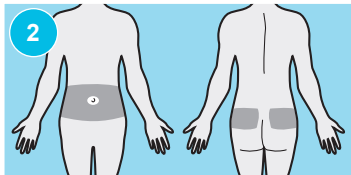
A. Sensor
B. Pedestal
C. Needle housing

Recorder or transmitter
(device)

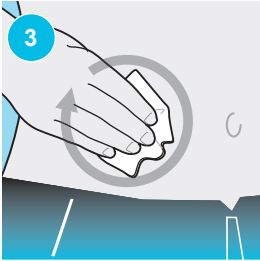


1. Wash your hands.

CAUTION: Healthcare professionals and caregivers should wear gloves when handling the sensor.



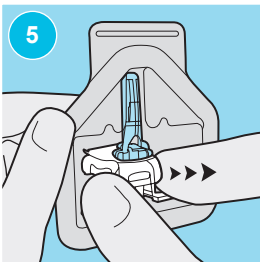
2. Select an insertion site.



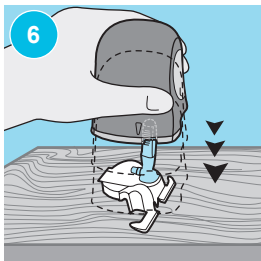
3. Clean the insertion site with alcohol. Let the area air dry.



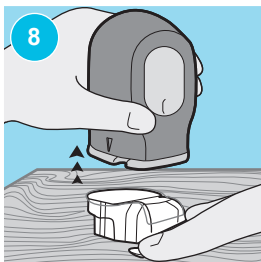
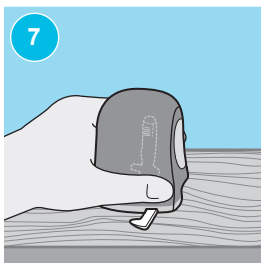
4. Open the sensor package.



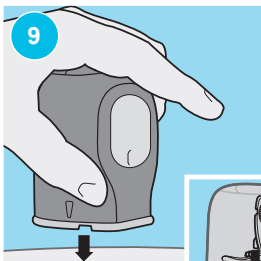
5. Remove the pedestal from the package. Place the pedestal on a flat surface.



6-7. Push the Serter down onto the pedestal until the base of the Serter sits flat on the table.



8. To detach the Serter from the pedestal, place two fingers on the pedestal arms and slowly pull the Serter straight up. Do not detach the pedestal from the Serter in mid-air, as this might damage the sensor.



WARNING: Never point a loaded Serter toward any body part where insertion is not desired.

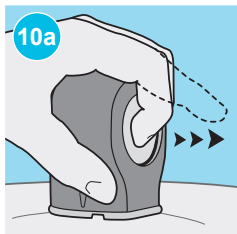
9. Place the base of the Serter flat against your insertion site.



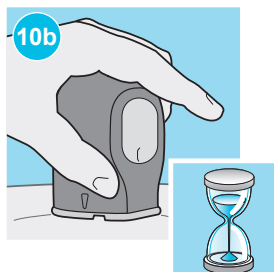
WARNING: The Sertter injects sensor upon button release.

NOTE: A second button push is required to remove the Sertter from the sensor.

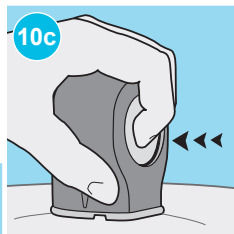
To insert the sensor, complete the following four steps:



10a. Press the button in and then release.



10b. Wait 5 seconds to allow the adhesive time to stick to skin.



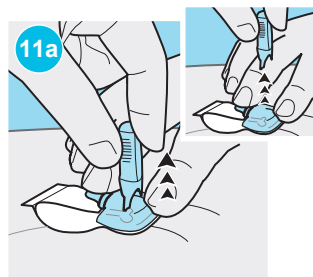
10c. Press and hold in the button.



10d. While holding the button in, slowly lift the Sertter away from the skin.

If you inserted the sensor into yourself, complete step 11a. If you are a healthcare professional or caregiver who inserted the sensor into a Patient, complete step 11b

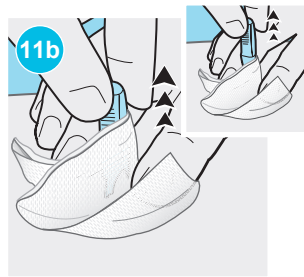
Patient:



11a. Gently hold the base of the sensor against the skin. Hold the needle housing at the top and slowly pull straight up, away from the sensor.

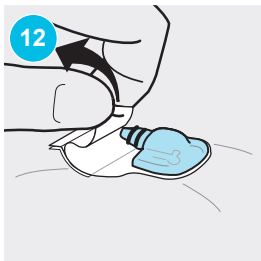
OR

Healthcare professional or caregiver:

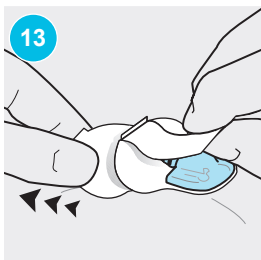


11b. Wrap sterile gauze around the sensor (as shown in image 11b). Gently hold the base of the sensor against skin. Hold the needle housing at the top and slowly pull straight up, away from the sensor.

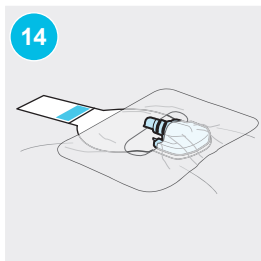
WARNING: If bleeding occurs, apply steady pressure using sterile gauze or clean cloth for up to three minutes.



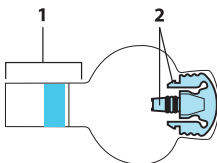
12. Straighten the sensor adhesive tab so that it lies flat against the skin.



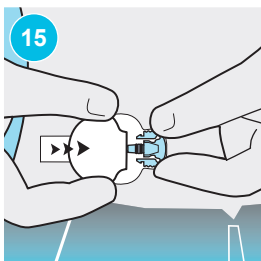
13. While holding the sensor in place, gently lift the adhesive tab. Carefully remove the bottom piece of white paper from under the adhesive pad. Press the adhesive against the skin.



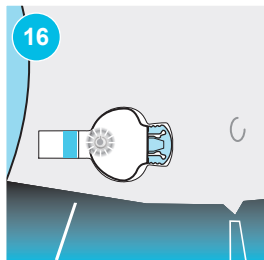
14. Before connecting the device, apply overtape. Do not cover the adhesive tab (1) or sensor connectors (2) with overtape.



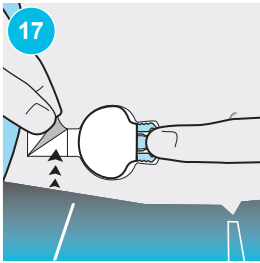
NOTE: For details on starting the sensor, consult the device user guide.



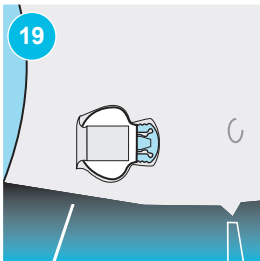
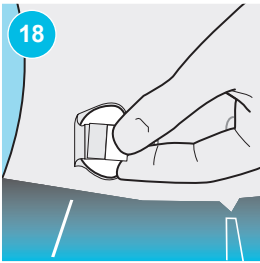
15-16. Connect the device to the sensor.



NOTE: Overtape is not shown in steps 15-19.



17-19. Cover the device with the sensor adhesive tab.



Indications for use

The Enlite™ insertion device (Serter) is indicated as a single-patient use device and it is not intended for multiple-patient use. The Serter is used as an aid for inserting the Enlite™ glucose sensor (sensor).

Contraindications

Do not use the Enlite Serter on products other than the Enlite sensor. Medtronic cannot guarantee this product's safety or efficacy if used on other products.

Warnings

Be sure to read this entire user guide before attempting to insert the sensor. Failure to follow directions may result in pain or injury. The Enlite Serter does not work the same as other Medtronic insertion devices. **The Serter injects the sensor into the insertion site when the button is released**, not when the button is pressed.

Bleeding, swelling, irritation or infection at the insertion site are possible risks associated with inserting the sensor and sometimes result from improper insertion and maintenance of insertion site. Check the insertion site often for these conditions and to ensure that the sensor is still in place. Consult your healthcare professional if these conditions persist.

A retractable needle is attached to the sensor. Minimal blood splatter may occur when the needle is removed from the sensor. When removing the needle from someone other than yourself, do so at arms length and pointed away from self and others. Keep the needle housing within sight at all times to avoid accidental needle stick injury.

Watch for bleeding at the insertion site. If bleeding occurs, do not attach the device to the sensor.

Apply steady pressure using a sterile gauze or clean cloth for up to three minutes.

If bleeding stops, attach the device to the sensor.

If bleeding does not stop, DO NOT attach the device to the sensor.

1. Remove the sensor and discard.

2. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation and treat accordingly.

3. Insert a new sensor in a different location.

If the sensor is not securely placed in the Serter, pain or minor injury may occur.

This product contains small parts and may pose a choking hazard for young children.

Refer to the Enlite Glucose Sensor User Guide for additional sensor related warnings.

Precautions

Always wash your hands with soap and water before inserting the sensor. Healthcare professionals and caregivers should wear gloves when handling the sensor and Serter.

Do not insert the sensor through tape and only use alcohol to clean the insertion site. Do not use any other type of skin preps prior to insertion.

Establish a rotation schedule for choosing each new sensor site.

Dispose of used sensors and needle housings in a sharps container after each single use. Do not clean or resterilize, and do not try to extract the needle from the needle housing.

Where to insert the sensor

CAUTION: Make sure the sensor site is at least 3 inches (7.5 cm) away from the insulin pump infusion site or manual injection site. When replacing the sensor, select a new site that is at least 2 inches (5 cm) from the previous site.

Choose an insertion site that has an adequate amount of subcutaneous fat. The Enlite sensor has been approved for use on the abdomen and buttock areas. See step 2 for a diagram of these areas.

Do not insert the sensor in muscle or areas constrained by clothing or accessories; areas with tough skin or scar tissue; sites subjected to rigorous movement during exercise; in sites on the belt or waistline; or within 2 inches (5 cm) of the navel.




Storage and handling

Store the Serter in the released position to maintain optimum product performance and life.

Serter maintenance

The Serter is intended for single-patient use. Follow this procedure to clean the Serter after each use:

- 1. Dampen a clean cloth with mild liquid soap and warm water. Wipe the Serter.
- 2. Rinse the Serter with warm tap water.
- 3. Wipe the Serter with 70% isopropyl alcohol.
- 4. Place the Serter on a clean, dry cloth and let it air dry.

	Follow instructions for use.	REF	Catalogue number
	Batch code		Manufacturer

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