

ENGLISH

INDICATIONS FOR USE

- The AccuSert Needle Inserter is intended for use at home or in a hospital environment to assist in inserting EMED subcutaneous administration needle sets into the subcutaneous tissue at 90 degrees.
- Single patient use only.

CONTRAINDICATIONS

Do not use the AccuSert Needle Inserter with non-compatible needle sets.

PRECAUTIONS

- Perform the first setup of the AccuSert Needle Inserter with guidance of your healthcare professional.
- Clean the AccuSert Needle Inserter as needed using only the recommended materials and instructions. Do not submerge.
- Do not sterilize. Heat and humidity may damage the device.
- Store the AccuSert in the released position in a dry area at room temperature.

WARNINGS

- Follow pharmacy/physician instructions.
- Failure to follow instructions may result in improper insertion, pain, or injury.
- Use aseptic technique during needle insertion to maintain sterility of the needle and the insertion area.
- Do not use AccuSert on broken skin to prevent contamination of the inserter and to reduce the potential for infection at the site of use.
- Do not use AccuSert if the needle set is damaged or bent.
- Do not use if AccuSert is broken or damaged.
- Adult operation of the device is recommended for child use.
- Never point AccuSert loaded with the administration set towards any body part where insertion is not desired to avoid accidental needle stick.

FEATURES

(A) AccuSert Needle Inserter reorder REF number: **FP-0010033** is intended to be used only with EMED OPTFlow Subcutaneous administration needle sets.

(B) Release button (C) Inserter Body (D) Tubing Slot

(E) Needle Carrier Handle (Shown at the released position)

(F) Curved Profile (G) Clamping mechanism (H) Needle carrier

INSERTION

1. Prepare infusion supplies (administration needle set, infusion pump) and site of infusion as recommended by your healthcare professional.
2. Verify you are using the AccuSert Needle Inserter with the correct type of EMED administration set, (see FEATURES section for information).
3. Remove the AccuSert Needle Inserter from packaging if necessary, then place on a tabletop facing upward.
4. Remove the wing guard from the administration set.

NOTE: Do not remove the needle protector until step 15.

5. Orient the administration set with the needle upright and tubing aligned with the tubing slot (D).
6. Fold the needle set wings down.
7. Carefully insert the needle set wings into the inserter clamping mechanism (G) and seat the needle set on to the needle carrier (H).
8. Hold the AccuSert Needle Inserter as shown.
9. Align the administration set on the needle carrier (H) and push down.

NOTE: Do not hold the tubing against the AccuSert body (C) during loading and needle insertion.

10. Continue to push down on the Needle Carrier Handle (E) all the way until it clicks and locks in place as shown in step 6.
11. Verify the needle set is properly located and clamped by the inserter. The needle should be oriented straight at 90 degrees.

CAUTION: If the infusion set is not properly loaded on the AccuSert, improper insertion, pain or minor injury may occur.

12. If the needle set is not properly located, use caution and hold the needle carrier handle (E) while slowly pressing down the release button (B) to allow the needle carrier to return to the released position.
13. Remove the administration set and repeat steps 5-12 or use a new set if damaged.
14. Hold the AccuSert Needle Inserter with one hand and orient away from the body.
15. Carefully remove the needle guard/protector with the other hand.
16. Use thumb and index fingers to pinch the skin as instructed by your healthcare professional.
17. While still holding the skin, position the AccuSert Needle Inserter on the desired site aligning the curved profile (F) against the skin keeping it perpendicular.
18. Continue pushing the AccuSert Needle Inserter against the skin and press the release button (B) down until it stops and you hear a click.
19. The needle set is released and inserted into the skin.
20. Continue holding the inserter against the skin.
21. Use one finger to push and hold down the tubing near the inserter.
22. Use the other hand to pull the inserter straight and away from the skin using caution not to lift the administration needle set.
23. Continue holding the set on the skin and apply the dressing per the administration needle set instructions to secure it on the skin.
24. Repeat steps 3-23 for multiple needles.
25. Perform the rest of the infusion as instructed by your healthcare professional and the instructions for use.

MAINTENANCE and STORAGE

- Calibration is not required when used as intended.
- The AccuSert Needle inserter should be disposed of and replaced after one year of use or after 500 uses.
- Cleaning is the only recommended maintenance for the AccuSert Needle Inserter as needed.
- Store the AccuSert in the released position in a dry area at room temperature.

CLEANING

1. To clean the AccuSert Needle Inserter, the following materials are required: Mild liquid soap (for example Ivory® liquid soap), clean, soft cloths, and a clean container.
2. Prepare a mild liquid soap solution using 1:7 ratio of mild liquid soap to room temperature water in the clean container.
3. Submerge the clean cloth into the mild soap solution.

NOTE: Do not submerge the device in soap solution or water.

4. Ensure AccuSert Needle Inserter in the released position. Thoroughly wipe all accessible surfaces using the wet cloth. Ensure that all areas are wiped until visibly clean.
5. Use a second clean and dry cloth and submerge the cloth in room temperature tap water.
6. Wipe all exposed surfaces until all visible liquid soap is removed.
7. Place the AccuSert Needle Inserter on a clean and dry surface until dry.
8. After cleaning, store the AccuSert Needle Inserter in the released position.

DISPOSAL

- Dispose the device in general waste collection according to local regulations.
- Do not attempt to disassemble device prior to disposal.

WARRANTY

The AccuSert Needle Inserter is warranted to be free from defects in materials and workmanship when used as intended for the expected use life of the product of one (1) year after purchase and first use.



EMED Technologies Corporation
1262 Hawks Flight Court, Suite 200
El Dorado Hills, CA 95762, U.S.A.
+1.916.932.0071
info@emedtc.com
www.emedtc.com

<p>RxOnly</p> <p>Caution: U.S. federal law restricts this device to sale by or on the order of a physician.</p>	<p>FEATURES:</p>			<p>3</p>	<p>4</p>
<p>7</p>	<p>9</p>	<p>10</p>	<p>11</p>	<p>15</p>	<p>16</p>
<p>17</p>	<p>18</p>	<p>21-22</p>	<p>23</p>	<p>24</p>	<p>25</p>

ENGLISH (EN)	
Symbol Glossary can be found at: www.emedtc.com/support	
	Warning
	Refer to instruction manual/booklet
	Read the instructions
	Don't use if package is damaged
	Single patient-multiple use
	This product is not made with latex
	Reference number
	Manufacturer
	Manufactured date
	Country of manufacture
	Medical Device
	Lot
	Quantity
	To sale by or on the order of a physician.
	Storage temperature limits
	EC Representative
	CE Mark