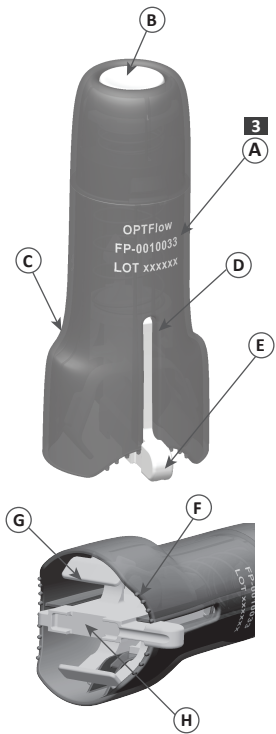


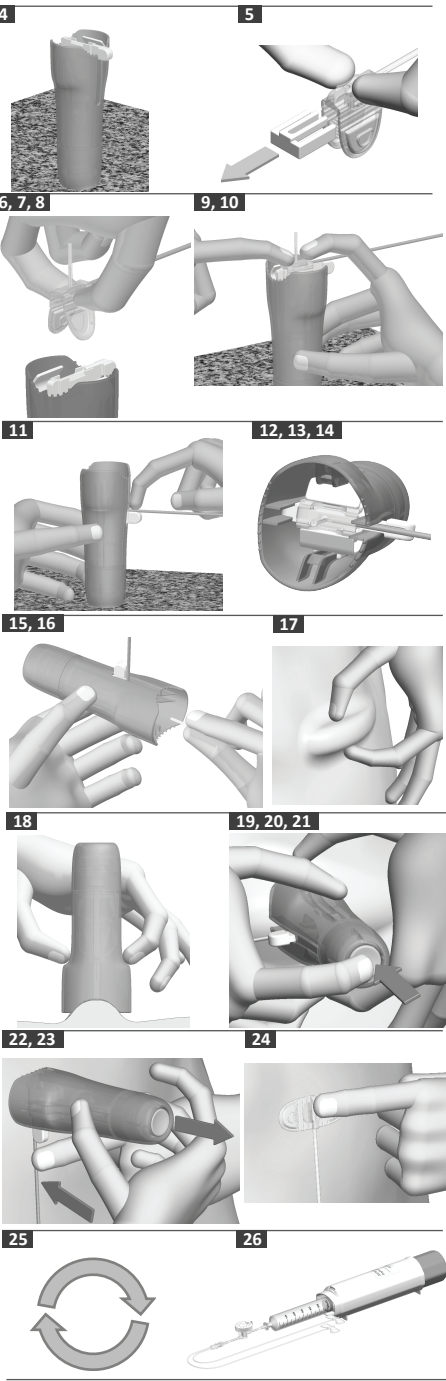
AccuSert® FEATURES



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



Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



AccuSert® Needle Inserter Instructions for Use

EN

INDICATIONS FOR USE

- The AccuSert Needle Inserter is intended for use at home or in a hospital environment to assist in inserting EMED Subcutaneous 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. Re-use by multiple patients may result in infection and/or cross-contamination.
- Use aseptic technique during needle insertion to maintain sterility of the needle and the insertion area. Failure to use aseptic technique may result in infection and/or cross-contamination.
- 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.
- Carefully remove the needle guard before inserting the needle set into your skin. 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 the AccuSert loaded with the Subcutaneous set towards any body part where insertion is not desired to avoid accidental needle stick.
- U.S. federal law restricts this device to sale by or on the order of a physician.

FEATURES (see corresponding product images)

(A) AccuSert Needle Inserter reorder REF number: FP-0010033 is intended to be used only with EMED OPTFlow Subcutaneous Infusion 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 (Subcutaneous needle set, infusion pump) and site of infusion as recommended by your healthcare professional.
2. Inspect the AccuSert Needle Inserter for contamination before each use and promptly clean the device if there are signs of soilage, follow instructions provided in the "Cleaning" section of this IFU.
3. Verify you are using the AccuSert Needle Inserter with the correct type of EMED Subcutaneous set, (see FEATURES section for information).
4. Remove the AccuSert Needle Inserter from packaging if necessary, then place on a tabletop facing upward.
5. Remove the wing guard from the Subcutaneous set.
NOTE: Do not remove the needle protector until step 16.
6. Orient the Subcutaneous set with the needle upright and tubing aligned with the tubing slot (D).
7. Fold the needle set wings down.
8. Carefully insert the needle set wings into the inserter clamping mechanism (G) and seat the needle set on to the needle carrier (H).
9. Hold the Accusert Needle Inserter as shown.
10. Align the Subcutaneous 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.
11. Continue to push down on the Needle Carrier Handle (E) all the way until it clicks and locks in place as shown in step 11.
12. 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.
13. 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.
14. Remove the Subcutaneous set and repeat steps 6-13 or use a new set if damaged.
15. Hold the AccuSert Needle Inserter with one hand and orient away from the body.
16. Carefully remove the needle guard/protector with the other hand.
17. Use thumb and index fingers to pinch the skin as instructed by your healthcare professional.
18. 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. Ensure not to block the free movement of the Needle carrier handle (E).
19. Continue pushing the AccuSert Needle Inserter against the skin and press the release button (B) down until it stops and you hear a click.
20. The needle set is released and inserted into the skin.
21. Continue holding the inserter against the skin.
22. Use one finger to push and hold down the tubing near the inserter.
23. Use the other hand to pull the inserter straight and away from the skin using caution not to lift the Subcutaneous needle set.
24. Continue holding the set on the skin and apply the dressing per the Subcutaneous needle set instructions to secure it on the skin.
25. Repeat steps 5-24 for multiple needles.
26. Perform the rest of the infusion as instructed by your healthcare professional and the infusion pump 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 as needed is the only recommended maintenance for the AccuSert Needle Inserter.
- Store the AccuSert in the released position in a dry area at room temperature.

CLEANING

1. Clean the AccuSert Needle Inserter on as needed basis.
2. 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.
3. Prepare a mild liquid soap solution using 1:7 ratio of mild liquid soap to room temperature water in the clean container.
4. Submerge the clean cloth into the mild soap solution.
NOTE: Do not submerge the device in soap solution or water.
5. 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.
6. Use a second clean and dry cloth and submerge the cloth in room temperature tap water.
7. Wipe all exposed surfaces until all visible liquid soap is removed.
8. Thoroughly inspect the AccuSert Needle Inserter. If there are still signs of soilage, then repeat steps 4 to 8.
NOTE: Do not use AccuSert Needle Inserter that remains dirty after performing the cleaning steps.
9. Place the AccuSert Needle Inserter on a clean and dry surface until dry.
10. 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 warrantied 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. Please contact EMED Technologies if you have any questions or concerns regarding the Accusert Needle Inserter or its use.

NOTE: In the event any serious incident occurs due to the use of this product, the healthcare provider, user or patient shall report the incident to EMED Technologies at +1-916-932-0071 and the competent authority in your region.

English (EN) Symbols	Symbol Glossary can be found at: www.emedtc.com/support
	Caution
	Non-sterile
	Refer to instruction manual/booklet
	Unique device identifier
	Don't use if package is damaged
	Single patient multiple use
	Does not contain or has presence of natural rubber
	Catalogue number
	Manufacturer
	Importer
	Country of manufacture and Manufacturing date
	Medical Device
	Batch number
	Packaging unit
	To sale by or on the order of a physician.
	Storage temperature limit
	Authorized Representative in the European Community / European Union
	CE Mark
	Repeat