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INS-830-1

Infusion Set

comfort™

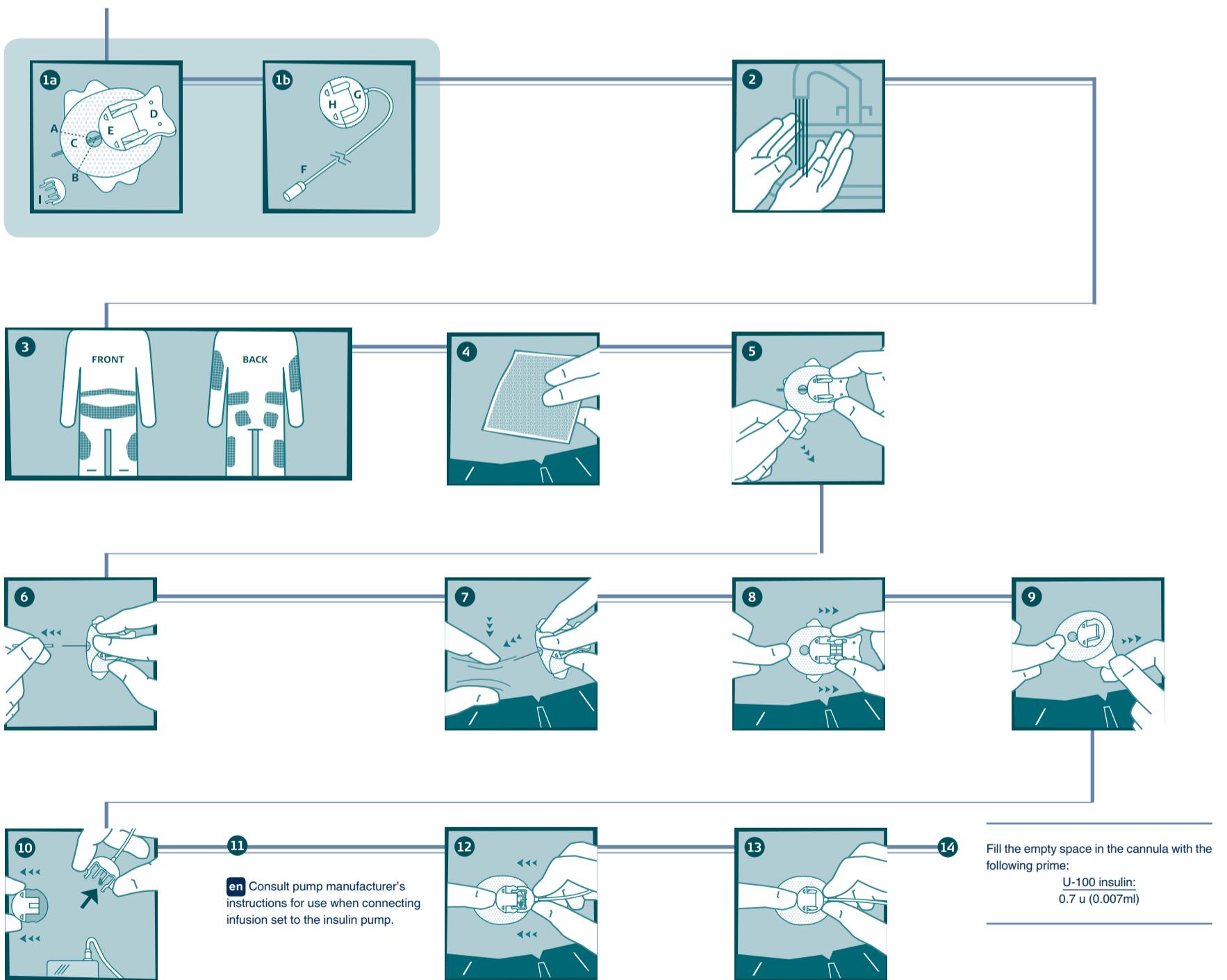
Instructions for use



Unomedical a/s · Aaholmvej 1-3 · Østed · 4320 Lejre · Denmark · www.infusion-set.com

Contents

- [A] Needle guard • [B] Soft cannula • [C] Adhesive tape • [D] Introducer needle • [E] Cannula housing • [F] Tubing • [G] Connector needle • [H] Circular protective cap
- [I] Disconnect cover



**Indications for use:**

The comfort™ infusion set is indicated for subcutaneous infusion of medication, including insulin, administered by an external pump.

**CONTRAINDICATIONS** comfort™ is neither intended nor indicated for use with blood or blood products (i.v. infusion).

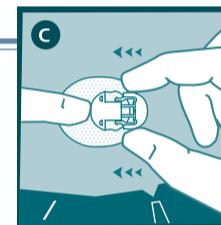
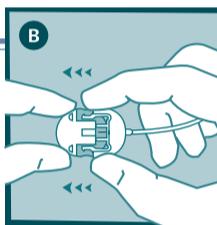
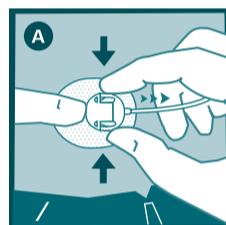
**WARNINGS**

- The comfort™ infusion set is only sterile and non-pyrogenic if the packaging is unopened and undamaged. Do not use it if the packaging is already open or is damaged.
- Go through instructions for use carefully before inserting comfort™, as failure to follow instructions may result in pain or injury.
- Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of infusion site.
- When using comfort™ for the first time, do so in the presence of a healthcare provider.
- comfort™ is a single use item, which must be disposed of after usage. Do not clean or re-sterilise.

- Be sure that the needle guard is removed before insertion.
- People with small or large amounts of subcutaneous fat should choose the insertion angle carefully, as the cannula could be placed in underlying muscle of dermal layer and hereby cause reduced or blocked medication delivery. Normal insertion angle between 20-45°. Consult your healthcare provider concerning this matter.
- Do not leave air in the infusion set. Make sure to fill comfort™ completely.
- Do not in any way put disinfectants, perfumes, deodorants or other products containing alcohol or disinfectants in contact with the luer-lock connector and the tubing, as these may affect the integrity of the infusion set.
- Replace the infusion set if the adhesive tape becomes loose.
- Check the infusion set frequently to ensure that the soft cannula remains firmly in place, and replace if it is not in place. Since the cannula is soft, it will not cause any pain if the soft cannula becomes fully or partially dislodged from the skin, and this may therefore take place without notice. The soft cannula must always be completely inserted to receive full amount of medication.
- Replace infusion set every 48-72 hours according to Centers for Disease Control guidelines, or per healthcare provider's instructions.
- If infusion site becomes inflamed, replace set and use new site until the first site has healed.
- Do not re-insert introducer needle into infusion set. Re-insertion could cause tearing of soft cannula which would result in unpredictable medication flow.
- Never prime the infusion set or attempt to free a clogged tubing while set is inserted. You may accidentally inject too much medication.
- Use aseptic techniques when temporarily disconnecting comfort™, and seal the cannula housing with the cover provided. Consult with healthcare provider on how to compensate for missed medication when disconnected.
- Protect comfort™ from direct sunlight. Store at room temperature.
- 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
- If infusing insulin, carefully monitor blood glucose levels when disconnected and after reconnecting.
- If infusing insulin, and blood glucose level becomes unexplainably high, or occlusion alarm occurs, check for clogs and leaks. If in doubt, change infusion set since soft cannula could be dislodged, crimped or partially clogged. Discuss plan for rapid replacement of insulin with health care provider should any of these problems arise. Test

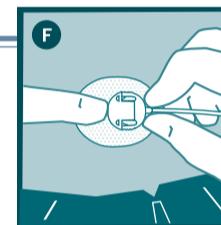
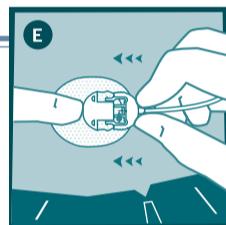
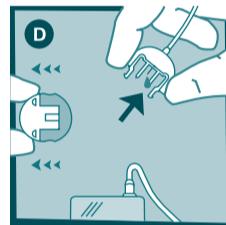
- blood glucose level to make sure problem is corrected.
- Check the blood glucose level 1-2 hours after introducing comfort™ and check the place of infusion several times a day, and measure your blood glucose regularly.
- If infusing insulin, do not change infusion set just prior to bedtime, unless blood glucose can be checked 1-2 hours after insertion.

**DISCONNECTING**



Click

**RECONNECTING**



Click



en Use by (year / month)



en Do not re-use



en Lot number



en Sterilized using ethylene oxide



en Reference / model number



en Attention: see accompanying documents



en Manufacturer

Rx ONLY

