

contact™ detach

INDICATIONS FOR USE

The contact™ detach is indicated for subcutaneous infusion of insulin administered by an external pump. The infusion set is indicated for single use.

INTENDED USE

The infusion set is indicated for subcutaneous infusion of insulin in the treatment of diabetes. The infusion set has been tested to be compatible with insulins approved for subcutaneous infusion.

PRODUCT DESCRIPTION

contact™ detach is a 90-degree, stainless steel needle infusion set with a standard luer lock connection. The contact™ detach needle (drawing 1a) and tubing (drawing 1b) make up the infusion set.

CONTRAINDICATIONS

contact™ detach is neither intended nor indicated for intravenous infusion (I.V.) of medication, including blood and blood products.

WARNINGS

- Carefully examine the instructions for use before inserting

contact™ detach. Failure to follow instructions may result in pain or injury.

- The infusion set is only sterile and non-pyrogenic if the packaging is undamaged and unopened. Do not use it if the packaging is already opened or is damaged.
- When using contact™ detach for the first time, do so in the presence of a healthcare provider.
- Inaccurate medication delivery, site irritation or infection may result from improper insertion or maintenance of your infusion site.
- Do not reuse the infusion set. Reuse of the infusion set may cause site irritation or infection and may lead to inaccurate medication delivery.
- Carefully remove the needle guard before inserting the infusion set.
- Do not bend the needle prior to insertion, and do not use the infusion set if the needle is bent or has been damaged.

PRECAUTIONS

- Never prime the infusion set or attempt to free a clogged tubing while the infusion set is inserted. You may accidentally inject too much medication.
- Check the infusion site frequently to ensure that the steel needle remains firmly in place. Replace with a new infusion set at a new site, if the infusion set is not in place.

- contact™ detach is a single-use item which must be disposed of after usage. Do not clean or re-sterilize.
- Do not in any way put disinfectants, perfumes, deodorants, cosmetics or other products containing alcohol or disinfectants in contact with the connector or the tubing. These may impact the integrity of the infusion set.
- Replace with a new infusion set if the adhesive tape becomes loose.
- Change the infusion set every one to two days, or as recommended by your healthcare provider.
- Upon removal, carefully loosen the edges of the adhesive tape, and remove the infusion set slowly by pulling straight out. Make sure that the needle is still attached to the adhesive and pulled completely out of the skin. If the needle is missing, immediately contact your healthcare provider for assistance.
- If the infusion site becomes irritated or infected, replace with a new infusion set and use a new site until the first site has healed.
- Use aseptic techniques when temporarily disconnecting contact™ detach, and seal the coupling housing with the cover provided. Consult with healthcare provider on how to compensate for missed medication when disconnected.

RECOMMENDATIONS

- Check the blood glucose level one to three hours after

introducing contact™ detach and check the infusion site several times a day. Measure your blood glucose regularly.

- If blood glucose level becomes unexplainably high, or an occlusion alarm occurs, check for clogs and leaks. If in doubt, change the infusion set. Discuss plan for rapid replacement of insulin with your healthcare provider should any of these problems arise. Test blood glucose level to make sure problem is corrected.
- Do not change the infusion set just prior to bedtime, unless blood glucose can be checked one to three hours after insertion.
- Carefully monitor blood glucose levels while disconnected and after reconnecting.
- 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 to your national authority.

STORAGE & DISPOSAL

- Store contact™ detach in a cool, dry location at room temperature. Do not store contact™ detach in direct sunlight, or in high humidity.
- Store and handle insulin according to the manufacturer's instructions.
- Dispose of the infusion set in a proper sharps container according to local laws, to avoid the risk of needle stick.

INS 0625-1
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Infusion Set
Instructions for use

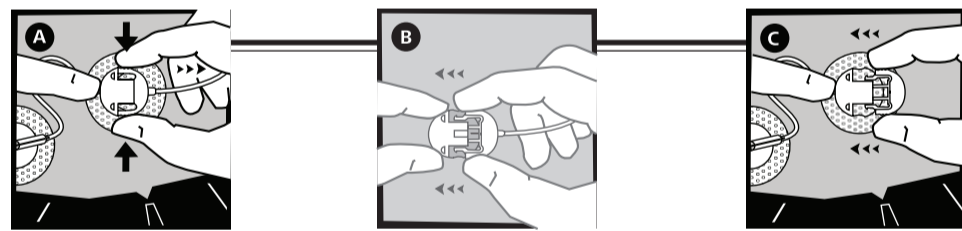


Unomedical a/s - A ConvaTec Company · Aaholmvej 1-3 · Østed · 4320 Lejre · Denmark
www.infusion-set.com · Made in Mexico



Manufacturer	Date of Manufacture YYYY-MM-DD	Use-by (Expiry date) YYYY-MM-DD	LOT number
Reference / model number	Sterilized using ethylene oxide	Single sterile barrier system	Do not use if package is damaged
Keep away from sunlight	Keep Dry	Consult instructions for use	Caution: see instructions for use
Prescription required, does not apply in all geographies	Do not re-use	Non-pyrogenic	Medical Device
Global Trade Item Number	Open here	Distributor	

DISCONNECTING

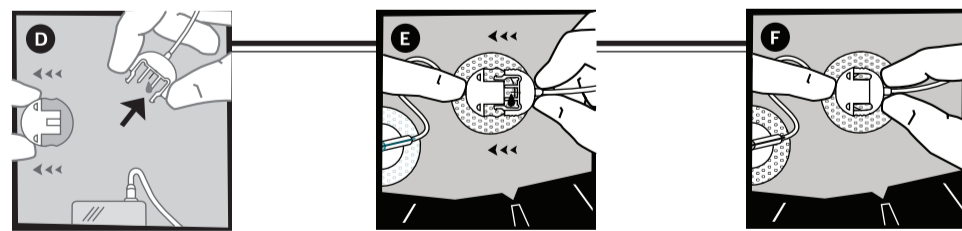


Disconnect the connector needle from the coupling housing by pressing the grips and pulling straight out.

Connect the circular protective cap to the connector needle.

Connect the disconnect cover to the coupling housing

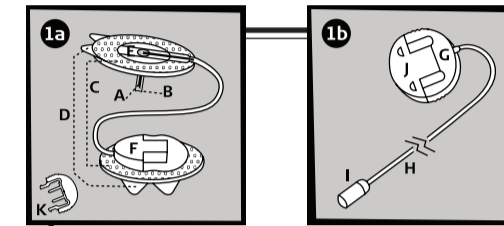
RECONNECTING



Remove the circular protective cap from the connector needle and if necessary prime the tubing.

Remove the disconnect cover from the coupling housing. Place a finger in front of the coupling housing and push the connector needle straight in.

Click.



Preparation and insertion

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|----------------------------|-----------------------------|
| Content | [F] Coupling housing |
| [A] 90-degree steel needle | [G] Connector needle |
| [B] Needle guard | [H] Tubing |
| [C] Adhesive tape | [I] Connector |
| [D] Backing paper | [J] Circular protective cap |
| [E] Retaining wings | [K] Disconnect cover |
