



ACCU-CHEK LinkAssist Insertion Device Instruction Manual

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ACCU-CHEK®

ACCU-CHEK LinkAssist Insertion Device



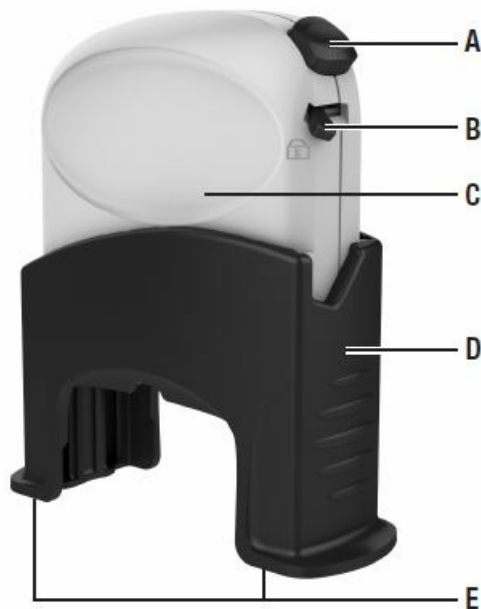
Product Information

- **Brand:** Accu-Chek
- **Model:** LinkAssist Insertion Device
- **Manufacturer:** Roche Diabetes Care GmbH
- **Country of Origin:** Switzerland
- **Intended Use:** Insertion of the headset of the Accu-Chek
- **FlexLink infusion set (USA: Accu-Chek Ultraflex infusion set)** into the skin
- **Reusable:** Yes
- **Guarantee:** 18 months from the date of purchase of materials and workmanship

Product Usage Instructions

1. Read the instructions for the use of the Accu-Chek FlexLink infusion set (USA: Accu-Chek Ultraflex infusion set) and the Accu-Chek LinkAssist insertion device before using the device.
2. Check the insertion device for damages, e.g. cracks, if it was dropped or exposed to other mechanical stress. Do not use the insertion device if it is damaged.
3. Insert the headset of the Accu-Chek FlexLink infusion set (USA: Accu-Chek Ultraflex infusion set) into the insertion device until you feel it click into place.
4. Press the release button to release the safety catch and slide it towards the base to lock it in place.
5. Place the insertion device on your skin and slide the safety catch toward the contact areas until it clicks into place.
6. Press the pre-tensioning element to insert the cannula into your skin.
7. Wait a few seconds before removing the insertion device from your skin.
8. Press the release button to release the safety catch and slide it towards the base to unlock it.
9. Remove the headset from the insertion device and dispose of it properly.
10. Clean the insertion device with a soft cloth and store it in a clean and dry place.

Overview



- **A** Release button
- **B** Safety catch
- **C** pretensioning element
- **D** Base
- **E** Contact areas

Intended Use

The Accu-Chek LinkAssist insertion device is intended for the insertion of the head set of the Accu-Chek FlexLink infusion set (USA: Accu-Chek Ultraflex infusion set) into the skin. The insertion device can be reused multiple times. The insertion device is intended to be used by one person only and must not be used by other people.

Before You Get Started

Read these instructions for use and the instructions for use of the Accu-Chek FlexLink infusion set (USA: Accu-Chek Ultraflex infusion set) before using the insertion device. If the insertion device was dropped or exposed to other mechanical stress, check it for damages, e.g. cracks. Do not use the insertion device if it is damaged.

Information describing a situation for which there is a foreseeable serious hazard with the use of the device is preceded by the following heading:

WARNING

Information regarding any special care you should exercise for the safe and effective use of the device, or to avoid damage to the device that could occur as a result of use, including misuse, is preceded by the following heading:

PRECAUTION

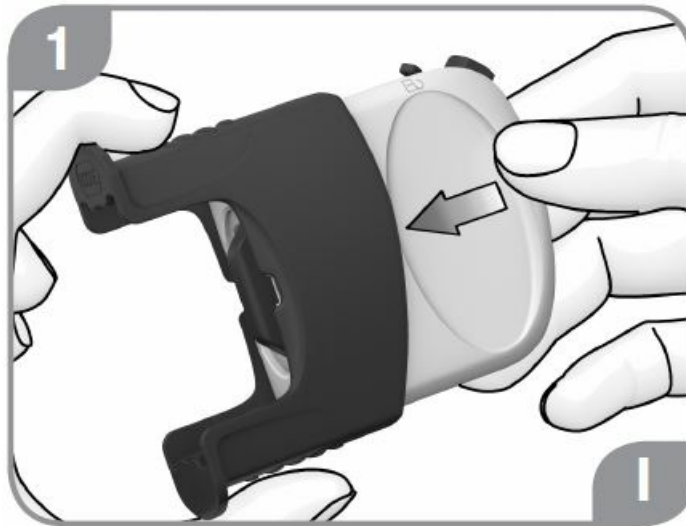
Inserting the Cannula into the Skin

PRECAUTION

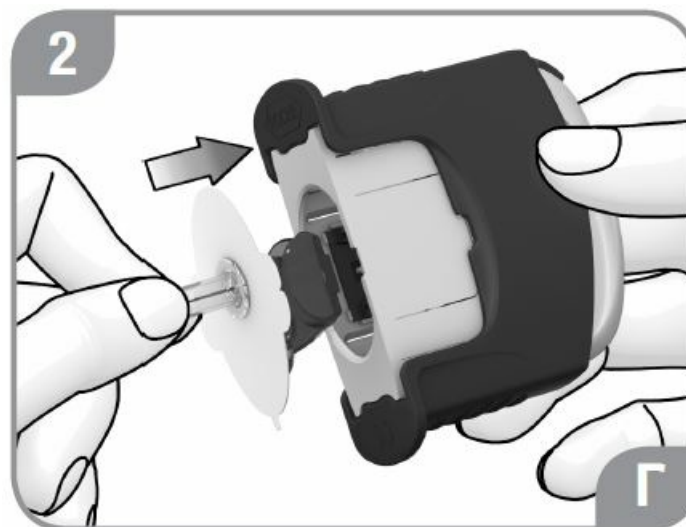
Risk of injury

If a headset is inserted into the insertion device, the headset could be released accidentally. Do not point the inserted headset at your face or other people's.

- Push the pre tensioning element of the insertion device into the base.



- Remove the headset of the infusion set from the packaging.
- Hold the headset by the needle cover.
- Insert the headset, with the blue handling aid pointing upwards, into the insertion device, until you feel the headset click into place.

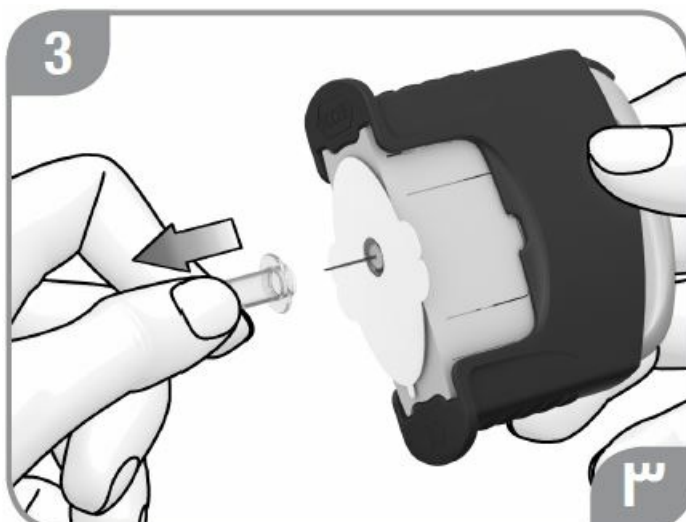


WARNING

Risk of infection or injury

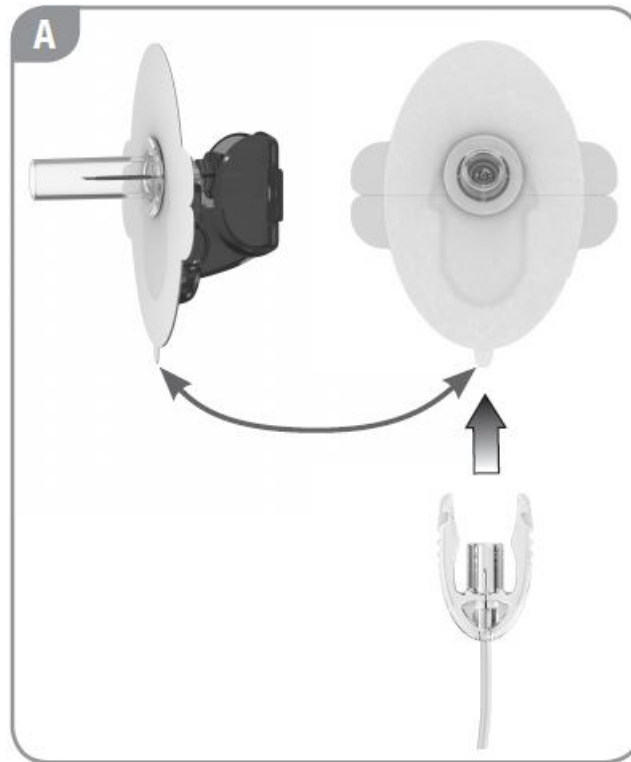
If you remove the needle cover, the introducer needle of headset is not protected anymore. Take care and do not touch the introducer needle.

- Remove the needle cover.

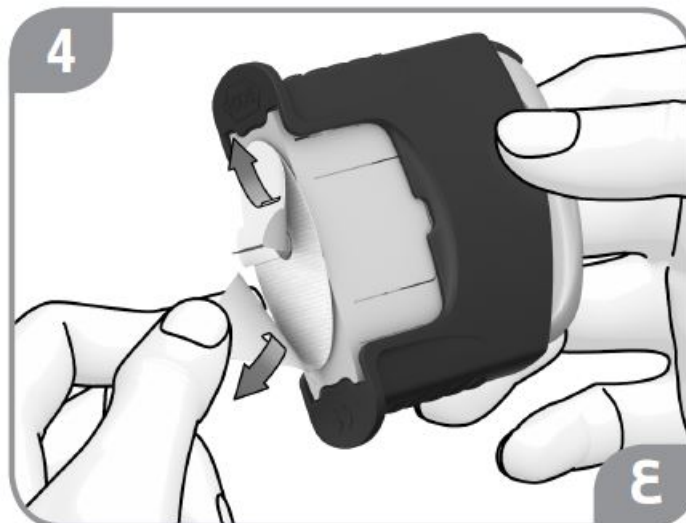


Tip:

The small tab on the protective film of the adhesive pad indicates the side of the headset to which you will later connect the transfer set. See illustration **A**.



- Remove both parts of the protective film from the adhesive pad.





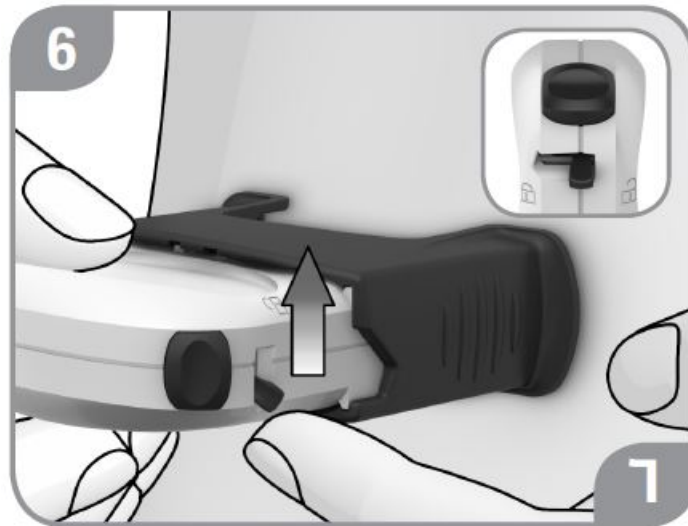
- Pull the pre-tensioning element upwards, away from the base, as far as it will go.



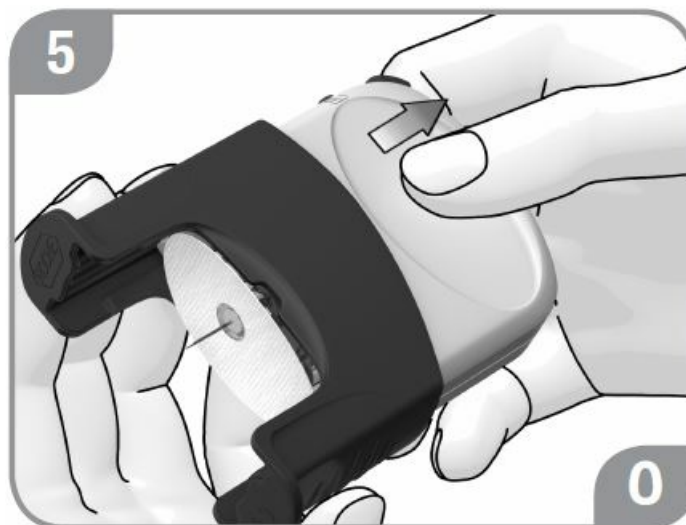
PRECAUTION

Risk of injury

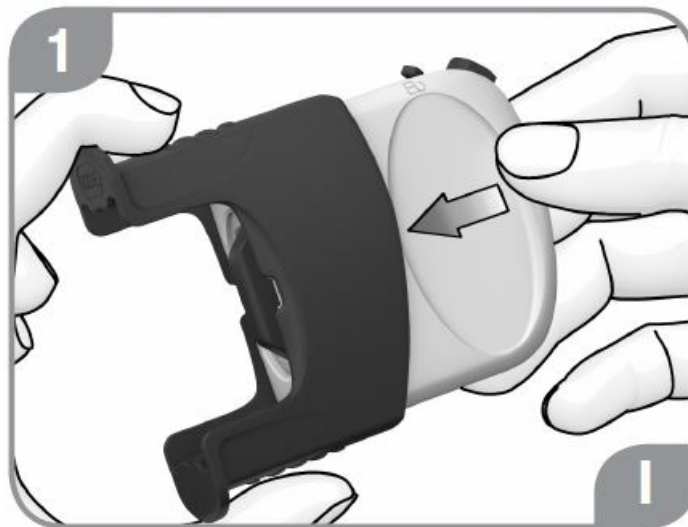
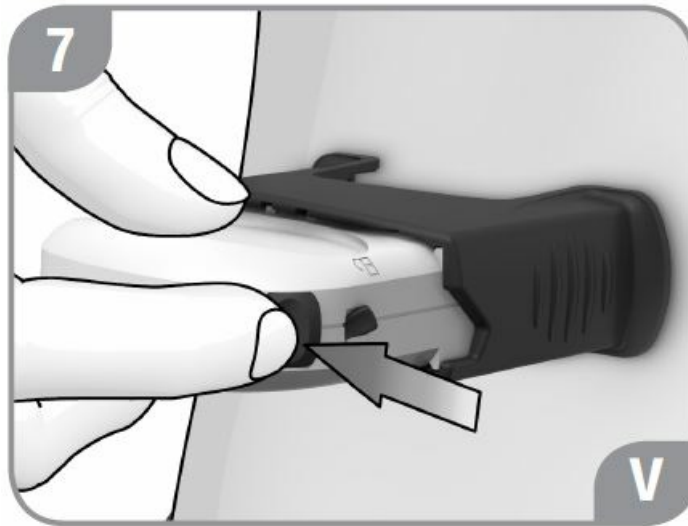
- If the safety catch is in the  position, the insertion device is no longer locked. The headset could be released accidentally.
- Do not slide the safety catch to the  position, until you have the insertion device placed on your skin.
- Place the insertion device onto the chosen infusion site, holding it horizontally. It must be positioned in such a way that the whole surface of each contact area on the base of the insertion device is resting on the skin.
Tip: You should be able to comfortably reach the side of the headset which had the small tab on the protective film. That is where you will later connect the transfer set.
- Slide the safety catch to the position. The insertion device is now unlocked.
- Press the release button. The cannula is inserted under the skin.
- Remove the insertion device.



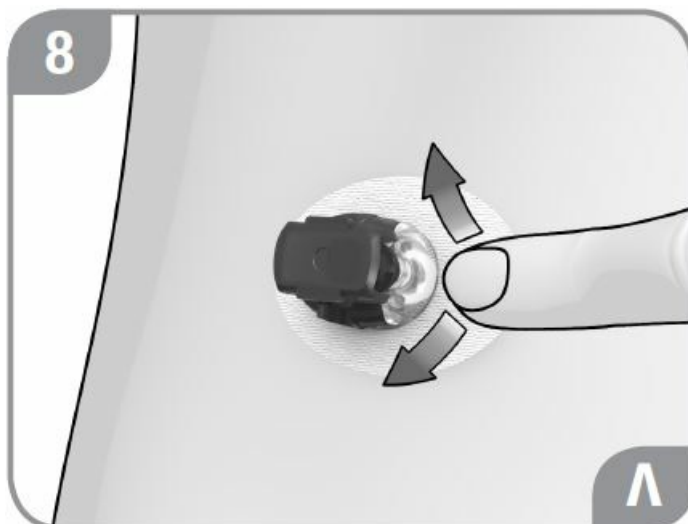
If the headset of the infusion set is still in the insertion device, push the pre-tensioning element back into the base. Continue with step 5.



If the cannula is not properly positioned under the skin, remove the adhesive pad from the skin and pull out the cannula. Start at step 1 with a new headset.



- Press the adhesive pad onto the skin.
- Continue with removing the handling aid of the headset. Follow the instructions for use of the infusion set.



Cleaning the Insertion Device

- Moisten a cloth with water, with a mild hand soap, or with a standard disinfectant (for example, 70 % ethanol).
- Wipe the outside of the insertion device. Do not dip the insertion device into the cleaning fluids.
- Allow the insertion device to dry completely.

Storing the Insertion Device


Keep the product dry and away from sunlight.

Store the insertion device with the pretensioning element retracted and without tension. See illustration **B**.



- Pull the pre-tensioning element upwards, away from the base, as far as it will go.



- Slide the safety catch to the  position.
- Press the release button.

Disposing of the Insertion Device

- Dispose of the insertion device as plastic waste.

For information about correct disposal, contact your local council or authority.

Reporting of Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regimes (Regulation 2017/745/EU on medical devices); 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.

Guarantee

There is a guarantee of 18 months on the Accu-Chek LinkAssist insertion device for materials and workmanship, from the date of purchase.

For detailed warranty and service information please refer to the Warranty section at the end of this manual.

Warranty

Accu-Chek LinkAssist Limited 18-Month Warranty

Roche Diabetes Care, Inc. ("Roche") warrants to the original purchaser of the Accu-Chek LinkAssist insertion device that your Accu-Chek LinkAssist insertion device will be free from defects in materials and workmanship for 18 months from the date of purchase. If, during this 18-month period, the insertion device does not work properly because of a defect in materials or workmanship, Roche will replace it with a new Accu-Chek LinkAssist insertion device or equivalent product free of charge. The warranty on the replacement insertion device will expire on the

date of the original warranty expiration or 90 days after the shipment of a new insertion device, whichever period is longer. The purchaser's exclusive remedy with respect to the Accu-Chek LinkAssist insertion device shall be a replacement.

This warranty does not apply to the performance of an insertion device that has been damaged by accident or has been altered, misused, tampered with, or abused in any way.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR OPERATION OF THE ACCU-CHEK LINKASSIST INSERTION DEVICE OR ITS PARTS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FROM THE SALE OF THE INSERTION DEVICE, AND SHALL EXTEND FOR A LONGER DURATION THAN EIGHTEEN MONTHS FROM THE DATE OF PURCHASE.

Some states do not allow limitations on how long an implied warranty will last or the exclusion of incidental or consequential damages, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, which vary from state to state.

Warranty and Service Instructions

All requests for the return of the Accu-Chek LinkAssist insertion device under the above warranty must be made to Roche Diabetes Care, Inc. Indianapolis, IN 46256, USA. You will be mailed a return authorization label, which must be affixed to your carton for shipping the system to Roche. Cartons received without this label will be returned to you at your expense.

Consult instructions for use

Caution

Refer to safety-related notes in the instructions for use accompanying this product.

- Keep away from sunlight
- Keep dry
- Single patient – multiple uses
- Date of manufacture
- Medical device
- Manufacturer
- Unique Device Identifier
- Catalogue number
- Batch code

Rx only

Federal law (USA) restricts this device to sale by or on the order of a physician.

- This product fulfills the requirements of the European Regulation 2017/745 on medical devices.

Customer Support

In the US, distributed by:

Roche Diabetes Care, Inc. Indianapolis, IN 46256, USA

Toll-Free: 1-800-280-7801

Accu-Chek Customer Care Service Center: 1-800-688-4578

www.accu-chek.com.

Australia

Roche Diabetes Care Australia Pty. Limited Pump Support: 1800 633 457

www.accu-chek.com.au.

Singapore

Accu-Chek ExtraCare line: 6272 9200 www.accu-chek.com.sg.

Roche Diabetes Care South Africa (Pty) Ltd.
Hertford Office Park, 90 Bekker Road Vorna Valley, Midrand
South Africa

1686

Email: info@accu-chek.co.za

Call Toll Free: 080-34-22-38-37 (SA only);

+ 254 20 523 0560 (Kenya only);

+ 27 (11) 504 4677 (Other countries)

Distributed in the United Kingdom by:

Roche Diabetes Care Limited

Charles Avenue, Burgess Hill West Sussex, RH15 9RY, United Kingdom Accu-Chek Pump Careline 1):

UK Freephone number: 0800 731 22 91 ROI Freephone number: 1 800 88 23 51

Calls may be recorded for training purposes Some mobile operators may charge for calls to these numbers.

burgesshill.insulinpumps@roche.com.

www.accu-chek.co.uk.

www.accu-chek.ie.

Made in Switzerland

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In the US, distributed by:

Roche Diabetes Care, Inc.

Indianapolis, IN 46256, USA


Toll-Free 1-800-280-7801

Roche Diabetes Care GmbH

Sandhofer Strasse 116 68305 Mannheim, Germany

www.accu-chek.com.

Documents / Resources

	ACCU-CHEK LinkAssist Insertion Device [pdf] Instruction Manual LinkAssist Insertion Device, LinkAssist, Insertion Device
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References

- chek.ru
- [Willkommen bei Accu-Chek](#)
- [Accu-Chek® |](#)
- [Willkommen bei Accu-Chek | Switzerland](#)
- [Bienvenido a Accu-Chek | Chile](#)
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