

ACCU-CHEK® FastClix

Finger pricker and lancet

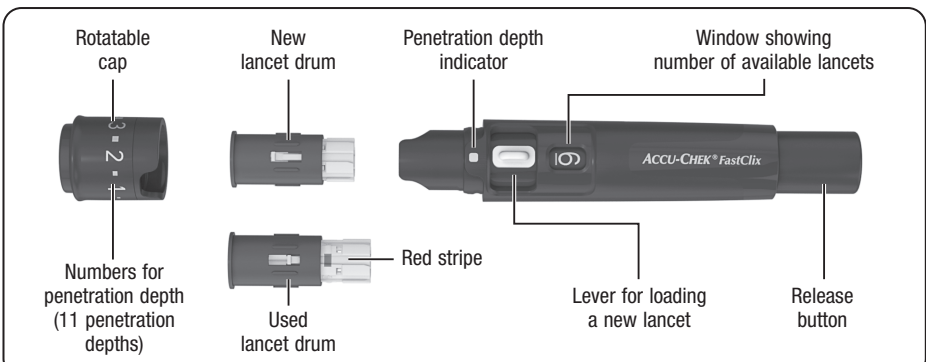
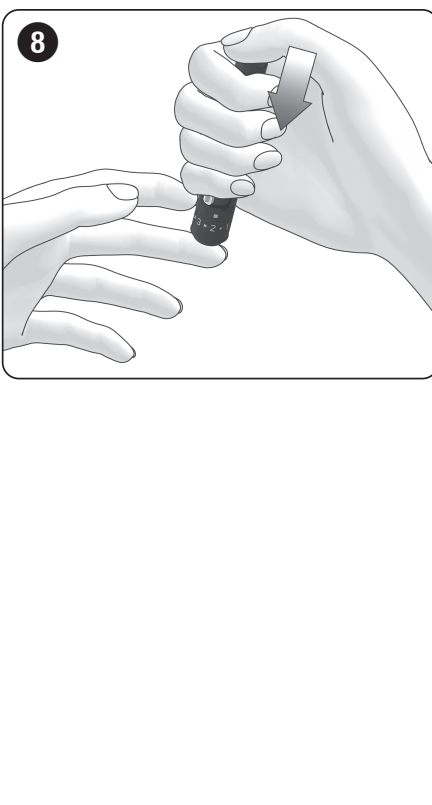
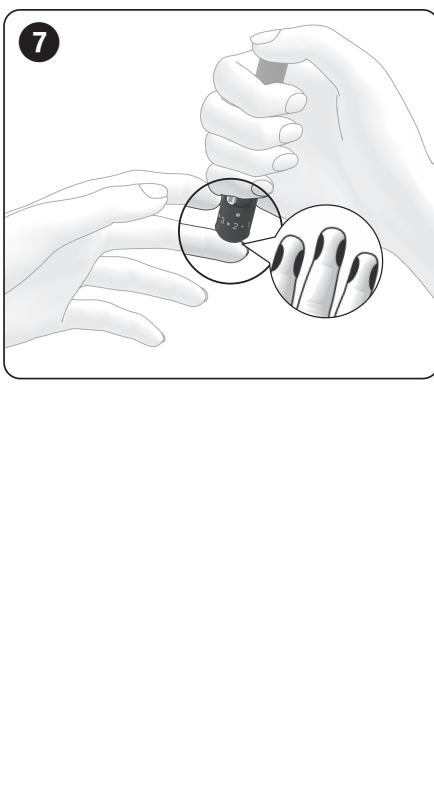
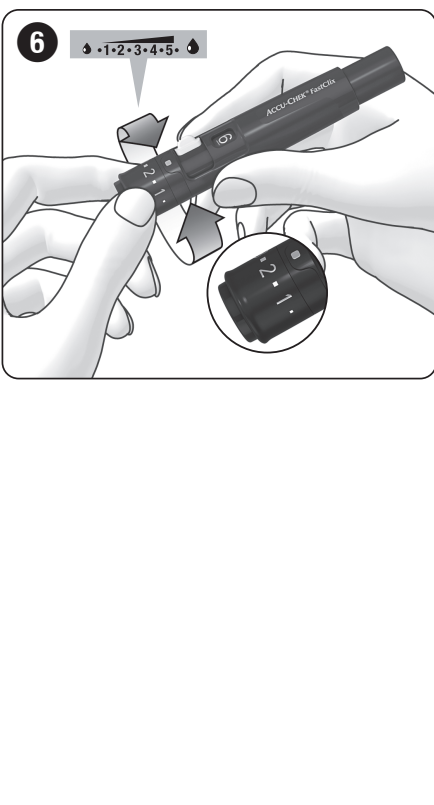
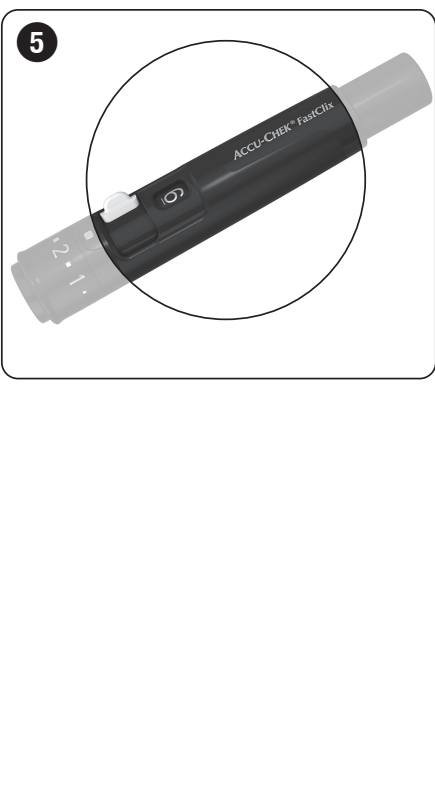
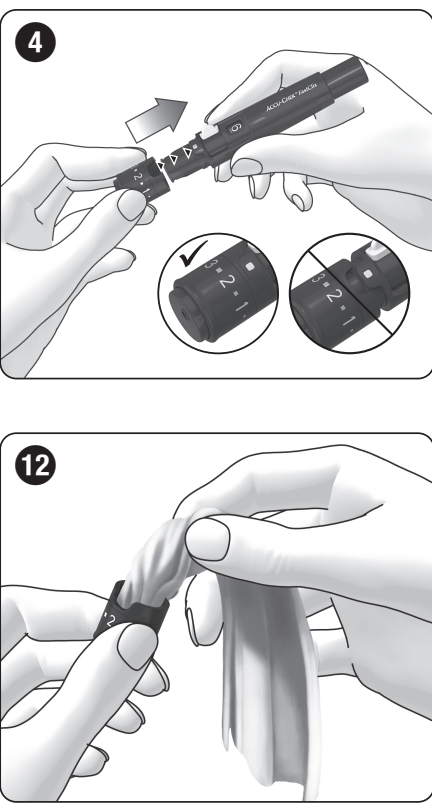
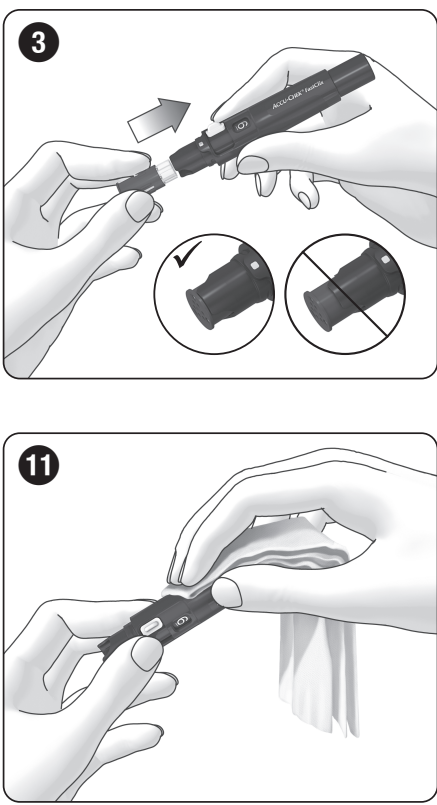
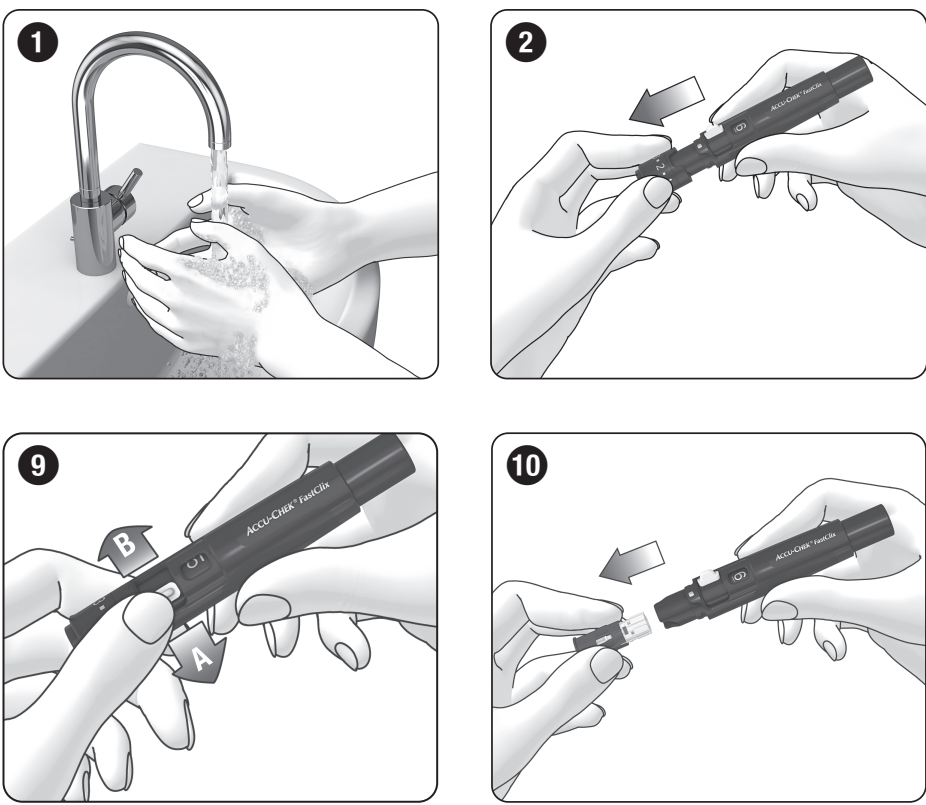
Fingerprikker og lancet

Blodprovetaket og lansett

Blodprovstagare och lansetti

Lansettikynä ja lansetti

DE 0924569300 (02) – US 09245693002



Instructions for Use

Intended Use

Finger pricker
The Accu-Chek FastClix finger pricker is a device for simple, virtually pain-free collection of capillary blood from the fingertips. The Accu-Chek FastClix finger pricker is intended for single patient use only. It is only allowed to be used to obtain blood from one person. There is a risk of infections being transmitted if the finger pricker is used by other people, even by family members, or if healthcare professionals use this finger pricker to obtain blood from different people. This finger pricker is therefore not suitable for professional use in healthcare facilities and institutions. It is not a sterile product.

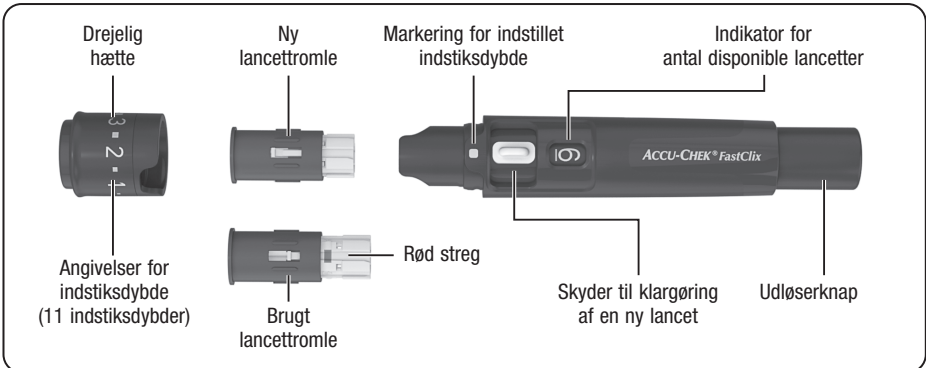
Lancet
Six Accu-Chek FastClix lancets are in a drum. The lancet drum is intended to be used with the Accu-Chek FastClix finger pricker. The lancet drum is a disposable part. Each lancet in it is intended to be used only once. The Accu-Chek FastClix lancet drum includes 6 lancets and is intended to be used with the Accu-Chek FastClix finger pricker for simple, virtually pain-free collection of capillary blood. The lancet drum is a disposable article with 6 lancets each intended to be used only once. Each lancet has a protective cap that guarantees sterile condition until its first use. The lancets are sterilized using irradiation. The used lancet drum is protected against re-use.

Features of the Finger Pricker

The finger pricker has 11 different penetration depths so that you can adjust the penetration depth to the texture of your skin. With the release button, you can prime the finger pricker and trigger a lancet in a single step. When a lancet is triggered, it penetrates the skin. You insert a lancet drum with 6 lancets into the finger pricker. You can obtain blood using a new, sterile lancet 6 times before the lancet drum needs changing.

Before You Get Started

Read these instructions for use before you obtain a blood drop from your fingertip.



Brugsanvisning

Tilslået anvendelse

Fingerprikker
Accu-Chek FastClix fingerprikkeren er et udstyr til let og næsten smertefri udtagning af kapillærblod fra fingerspidser. Accu-Chek FastClix fingerprikkeren er udelukkende beregnet til brug på én patient. Med denne må du kun udtage blod fra én og samme person. Der er risiko for overførsel af infektioner, hvis fingerprikkeren bruges af andre personer, også af familiemedlemmer, eller hvis sundhedspersonale bruger denne fingerprikker til blodudtagning på forskellige personer. Denne fingerprikker er derfor ikke egnet til professionel anvendelse i sundhedsvæsenets institutioner. Den er ikke et sterilt produkt. Målguppen er personer som gennemfører egenkontrol af diabetes.

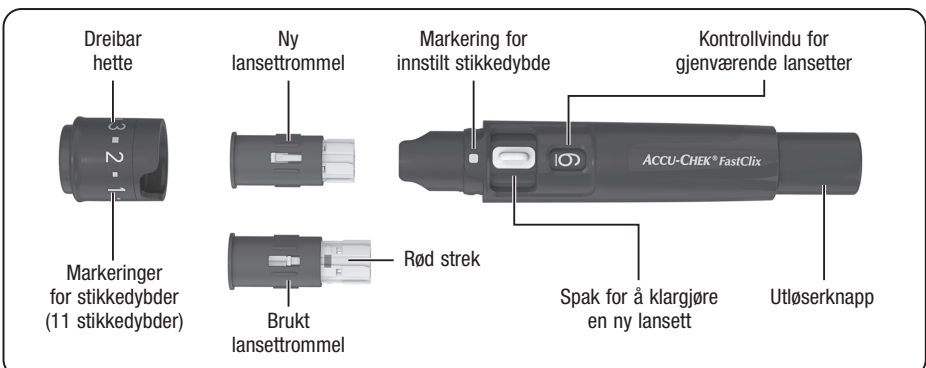
Lancet
En tromle indeholder seks Accu-Chek FastClix lancetter. Lancettromlen er beregnet til brug med Accu-Chek FastClix fingerprikkeren. Lancettromlen er en engangsdel. Hver lancet i tromlen er beregnet til engangsbrug. Accu-Chek FastClix lancettromlen indeholder 6 lancetter og er beregnet til brug med Accu-Chek FastClix fingerprikkeren til let og næsten smertefri udtagning af kapillærblod. Lancettromlen er en engangsdel med 6 lancetter som hver er beregnet til engangsbrug. Hver lancet har en beskyttelsesdæksel, der garanterer sterilitet frem til første brug. Lancetterne er steriliseret med stråling. Den brugte lancetromle er beskyttet mod genbrug.

Funktioner i fingerprikkeren

Fingerprikkeren har 11 forskellige indstikdybde, således at indstikdybden kan tilpasses din hudtype. Med udløserknappen kan du på én gang side fingerprikkeren og udløse lancetten. Når lancetten udløses, trænger den ind i huden. En lancetromle med 6 lancetter sættes ind i fingerprikkeren. Det vil sige, at man kan udtage blod 6 gange med en steril lancet inden lancettromlen skal skiftes.

For du går i gang

Læs denne brugsanvisning, før du udtager en bloddråbe fra din fingerspids.



Brugsanvisning

Brugsanvisning

Brugsanvisning
Accu-Chek FastClix-blodprøvetakeren er et redskab for å å kapillærblod fra fingerpungen på en enkel og næsten smertefri måde. Accu-Chek FastClix-blodprøvetakeren er kun beregnet til bruk på én pasient. Med den er det kun tillatt å å blodprøve fra den samme personen. Det oppstår infeksjonsrisiko hvis blodprøvetakeren også brukes av andre personer, også av familiemedlemmer, eller hvis helsepersonell bruker den samme blodprøvetakeren til å å blodprøve av mer enn én person. Denne blodprøvetakeren er derfor ikke egnet til profesjonell bruk innen helsevesenets institusjoner. Den er ikke et sterilt produkt. Målguppen er personer som utfører egenkontroll av diabetes.

Lansett
En trommel inneholder seks Accu-Chek FastClix-lansetter. Lansettrommelen er beregnet til bruk med Accu-Chek FastClix-blodprøvetakeren. Lansettrommelen er en engangsdel. Hver lansett er beregnet til engangsbruk. Accu-Chek FastClix-lansettrommelen inneholder 6 lansetter og er beregnet til bruk med Accu-Chek FastClix-blodprøvetakeren for å å kapillærblod på en enkel og næsten smertefri måte. Lansettrommelen er en engangsdel med 6 lansetter som hver er beregnet til engangsbruk. Hver lansett har en beskyttelsesdette som garanterer sterile betingelser fra første gangs bruk. Lansettene er sterilisert med stråling. Lansettrommelen er siket mot genbruk.

Blodprøvetakerens egenskaper
Blodprøvetakeren har 11 ulike stikkedybder, slik at du kan tilpasse stikkedybden til din individuelle hudtype. Med utløserknappen kan du klargjøre blodprøvetakeren og utløse en lansett i ett trinn. Når en lansett utløses, stikker den gjennom huden. Du setter en lansettrommel med 6 lansetter inn i blodprøvetakeren. Du kan å blodprøve ved å bruke en ny, steril lansett 6 ganger før du må skifte lansettrommel.

For du begynner

Læs denne brugsanvisningen før du tar en blodprøve fra fingerpungen.

Risk of injury
Parts of the finger pricker, for example, the release button, may shoot away during use. Do not point the finger pricker at your face or other people.

If the finger pricker or lancet drum was dropped or exposed to other mechanical stress, check them for damages, for example, cracks. Do not use them if they are damaged.

Preparation

Wash your hands with warm water and soap before you obtain blood (see 1). Dry your hands thoroughly. This reduces contamination of the puncture site and stimulates blood flow.

Inserting the Lancet Drum
You have to insert a lancet drum to be able to obtain blood with the finger pricker.

WARNING

Risk of infection

Lancets in a damaged lancet drum may not be sterile any longer.

If the lancet drum is damaged or shows cracks do not use it to obtain blood.

Remove the cap from the finger pricker (see 2).

Insert a new lancet drum – white end first – into the finger pricker (see 3).

Do not insert a lancet drum and press the release button at the same time. Do not insert a lancet drum with the release button resting on a surface, for example, a table top. This could release a lancet which could inadvertently prick you.

The lancet drum is properly inserted when it is completely inside the finger pricker, and only the projecting edge protrudes from the finger pricker at the front (see 4).

Place the cap back on again. The cut-out section at the edge of the cap must fit around the correspondingly shaped curvature with the penetration depth indicator (silver square) (see 5).

The cap is on correctly when it is pushed back so far it will go, and you hear and feel it click into place.

The cap can only be correctly placed on up to the stop position when the lancet drum is completely inside the finger pricker. Do not use any force to place the cap on as this might damage the cap and the finger pricker.

Correct the position of the lancet drum if needed. Each lancet drum contains 6 lancets. The first lancet is now ready to be used. The window showing the number of available lancets shows 6; there are now 6 lancets available (see 6).

Tip

Do not remove the lancet drum before all 6 lancets have been used. The lancet drum cannot be re-inserted once it has been removed from the finger pricker.

Setting the Penetration Depth

You can set 11 penetration depths (0.5 to 5.5). The silver square (penetration depth indicator) on the finger pricker indicates the current penetration depth setting. The larger the number, the greater the penetration depth.

If you have no experience with this finger pricker, we recommend setting a low penetration depth, such as penetration depth 2.

WARNING

Risk of injury
If the penetration depth is too large, the puncture can injure children.

Before using the finger pricker for the first time on children, ask your healthcare professional. Start with the lowest penetration depth.

Rotate the cap until the desired penetration depth lines up with the indicator (see 7).

Obtaining a Blood Drop

WARNING

Risk of infection
The lancet was used several times to obtain blood. To prevent infections from being transmitted, use the lancet only once to obtain blood.

Risk of infection
In rare cases, the lancet is not pulled back into the finger pricker after you obtained blood.

To prevent infections from being transmitted, check that the lancet does not protrude from the cap after you obtained blood. If the lancet protrudes from the cap, carefully set the finger pricker aside. Keep the finger pricker out of reach and contact customer support.

PRECAUTION

Risk of infection
The puncture site was not cleaned. Before obtaining blood clean the puncture site.

Risk of infection
The use by date of the lancet has expired. Use only lancets that are within the use by date. The use by date is printed next to the symbol on the packaging.

In general, blood can be obtained from any finger. Certain fingers can be unsuitable if, for example, a skin or fungal infection is present. We recommend obtaining capillary blood from the sides of the fingertips as these areas are the least sensitive to pain. Use a new lancet each time you obtain blood so that obtaining blood remains virtually pain free.

Only use the finger pricker when the cap is attached. Without the cap, the lancet penetrates too deeply and the puncture can become painful.

Press the finger pricker firmly against the selected puncture site (see 8).

Press the release button all the way down (see 9).

The lancet is released and it penetrates the skin.

Massage the finger in the direction of the fingertip to encourage a blood drop to form.

The amount of blood that emerges depends on the penetration depth and the pressure used to hold the finger pricker against the skin.

If not enough blood emerges, apply more pressure on the finger pricker when you next obtain blood. If that is not sufficient, increase the penetration depth progressively in addition.

If too much blood emerges, decrease the penetration depth.

Test your blood glucose immediately after you obtained blood, according to the instructions for use for blood glucose control.

We recommend protecting the puncture site from contamination afterwards.

Loading a New Lancet

If you have already used the finger pricker to obtain blood, you will need a new lancet the next time you obtain blood.

Push the lever at the side of the finger pricker as far as it will go in direction A and then back in direction B (see 10).

The next lancet is now ready to be used. The window next to the lever shows the new number of available lancets, which has decreased by one, for example, 5 instead of 6.

Proceed as in the previous step each time you need to change the lancet.

Each time a new lancet is loaded, the number of available lancets shown in the window decreases by one, for example, from 4 to 3. When you have loaded the sixth and last lancet, the window shows 1.

Replacing a Used Lancet Drum

When you have used the sixth and last lancet, you need to replace the used lancet drum with a new one.

Remove the cap from the finger pricker (see 2).

Remove the lancet drum from the finger pricker (see 3).

When a lancet drum has been used, a red stripe is visible on the white cylinder. A used lancet drum has a built-in lock that stops you from using it again. Used lancet drums can be disposed of in household waste if no other regulations apply in your country.

Insert a new lancet drum (see section Inserting the Lancet Drum).

Operating Conditions

Use the finger pricker including accessories under the following operating conditions:

- Temperature range: +5 to +45 °C
- Relative humidity range: 5 to 90 %

Storing the Finger Pricker and Lancet Drums

Do not store the finger pricker and lancet drums at extreme temperatures, for example, in a hot car. This can impair the operation of the finger pricker and lancet drums.

Cleaning and Disinfecting the Finger Pricker and Cap

PRECAUTION

Risk of infection
The finger pricker and cap may have come into contact with blood.

To prevent infections from being transmitted, clean and disinfect the finger pricker and cap always before and after use. Handle them, for example, to assist you.

To prevent infections from being transmitted, you must clean and disinfect the finger pricker and cap regularly:

- At least once a week
- Wipe the finger pricker and the cap with 70 % isopropanol
- Always before someone else handles the finger pricker, for example, to assist you.

You need lint-free cloths in which you can wrap the whole finger pricker, water and 70 % isopropanol.

Before you disinfect with finger pricker and the cap, you first have to clean them to remove blood and other dirt.

To avoid damaging the finger pricker and the cap:

- Do not dip the finger pricker and the cap in the fluids.
- Use only water for cleaning and only 70 % isopropanol for disinfecting.

Remove the cap from the finger pricker (see 2).

Remove the lancet drum from the finger pricker (see 3).

Cleaning

Moisten a cloth with water.

Wipe the finger pricker and the cap thoroughly. Wipe the finger pricker from the outside only (see 11) and the cap from the outside and the inside (see 12).

Dry the finger pricker and the cap with a dry cloth.

Disinfecting

Dampen a cloth with 70 % isopropanol.

Wipe the finger pricker and the cap thoroughly for 2 minutes each. Wipe the finger pricker from the outside only and the cap from the outside and the inside.

Place the cap back on again.

Wrap the whole finger pricker in the cloth.

Leave the finger pricker wrapped for 8 minutes.

Unwrap the finger pricker and let it dry in the air.

Disposing of the Finger Pricker

PRECAUTION

Risk of infection
The finger pricker has come into contact with blood and is disposed of improperly.

To prevent infections from being transmitted, dispose of the used finger pricker as infectious material according to the regulations applicable in your country.

During obtaining a blood drop, the finger pricker may come into contact with blood. A used finger pricker therefore carries a risk of infection.

Dispose of an unused finger pricker as plastic waste. For information about correct disposal, contact your local council or authority.

Alternative Sites for Obtaining Blood

You can obtain capillary blood for blood glucose testing not only from the fingertips, but also from other sites (palm, forearm, upper arm, calf or thigh), so-called alternative site testing (abbreviated as AST). To be able to obtain capillary blood from other sites, you have to replace the regular cap by a special cap, the Accu-Chek FastClix AST cap.

Ordering Information

If you want to order an Accu-Chek FastClix finger pricker, Accu-Chek FastClix lancet drums or an Accu-Chek FastClix AST cap, contact the Accu-Chek Customer Careline (see section Customer Support).

Reporting of Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regimes; 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.

Last Update

2021-03

Customer Support

United Kingdom
Roche Diabetes Care Limited
Charles Avenue, Burgess
West Sussex, RH15 9RY, United Kingdom
Accu-Chek Customer Careline[®]

UK Freephone number: 0800 701 000
RO Freephone number: 1 800 709 000
*calls may be recorded for training purposes
Some mobile operators may charge for calls to these numbers

www.accu-check.co.uk

Malta
Dampen Corporation
23, Santitas Building
Tower Street
Milsa MSD1824
Freephone: 80073102

Consult instructions for use or consult electronic instructions for use

Caution, refer to safety-related notes in the instructions for use accompanying this product.

Use by

Sterilized using irradiation

Use only once

Single patient multiple use

Medical device

Manufacturer

Unique device identifier

Catalogue number

Batch code

Complies with the provisions of the applicable EU Legislation

CE

0123

ACCU-CHEK and FASTCLIX are trademarks of Roche.

© 2021 Roche Diabetes Care

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
www.accu-check.com

Roche

Risiko for personskade

Del af fingerprikkeren, f.eks. udløserknappen, kan hoppe bort under brug.

Du må ikke vende fingerprikkeren mod dit ansigt eller mod andre personer.

Hvis fingerprikkeren eller lancettromlen er blevet kastet eller udsat for anden mekanisk belastning, skal de kontrolleres for skader, f.eks. revner. De må ikke bruges, hvis de er beskadiget.

Sæt udløskende Accu-Chek FastClix lancetromler i Accu-Chek FastClix fingerprikkeren. Andre lancetter eller lancetromler kan hæmme fingerprikkerens funktion eller ødelægge fingerprikkeren.

Forbudelse

Vask dine hænder med varmt vand og sæbe, før du udtager blod (se 1). Tør hænderne omhyggeligt. Det reducerer forurensning af indstikstedet og stimulerer blodgennemstrømningen.

Indsættelse af lancettromlen

Du skal sætte en lancetromle for at udtage blod med fingerprikkeren.

ADVARSEL

Risiko for infektion
Lancetter i en beskadiget lancetromle er måske ikke længere sterile.

Hvis lancetromlen er beskadiget eller viser revner, må du ikke bruge den til at udtage blod.

Træk hæften af fingerprikkeren (se 2).

Skyd en ny lancetromle – med den hvide ende foran – ind i fingerprikkeren (se 3).

Du må ikke isætte en lancetrommel ind i fingerprikkeren, da du trykker på udløserknappen. Du må ikke sætte en lancetromle samtidig med, at udløserknappen hviler på en overflade, f.eks. en bordplade. Dette kan eventuelt have til følge, at lancetten bliver udløst, og du risikerer at blive stukket.

Lancetromlen er sat på korrekt i, hvis den sidder fuldstændigt i fingerprikkeren, så kun kanten fortløber ud af fingerprikkeren (se 4).

Sæt hæften på igen. Bughningen i hæftens kant skal grube ind i hvidenden (se 5).

Hæften er sat rigtigt på, når den er skubbet på til slutposition. Hver lancet har et følbart indbrud. Hæften er nem at sætte på til anlæget, kun hvis lancetromlen sidder fuldstændigt i fingerprikkeren.

Du skal bryde kræfter på at sætte hæften på, da dette kan beskadige hæften og fingerprikkeren. Korrekt i stedet for pålægningen af lancetromlen.

Hver lancetromle indeholder 6 lancetter. Den første lancet er nu klar til brug. Indikatoren for antal disponible lancetter viser 6-tal, dvs. at der er 6 disponible lancetter (se 6).

Tip
Lancetromlen må ikke fjernes, før alle 6 lancetter er brugt op. Du kan ikke sætte lancetromlen ind igen, når du først har fjernet den fra fingerprikkeren.

Indstilling af indstikdybden

Du kan indstille 11 indstikdybder (0,5 til 5,5). Den sølvfarvede kvadrant (markering for indstikdybde) på fingerprikkeren viser den indstillede indstikdybde.

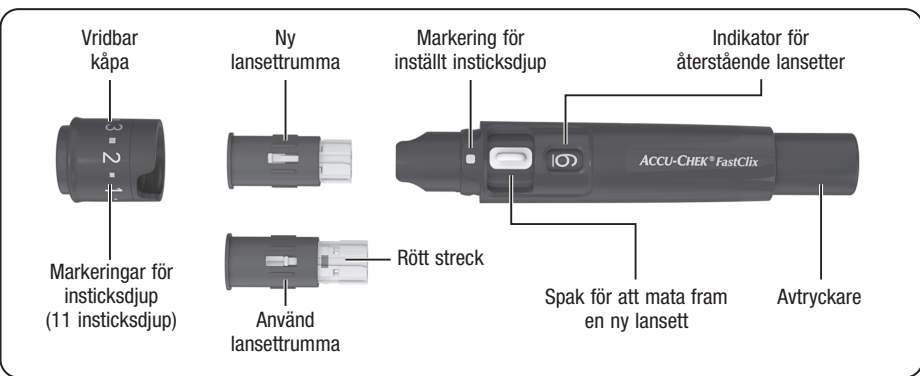
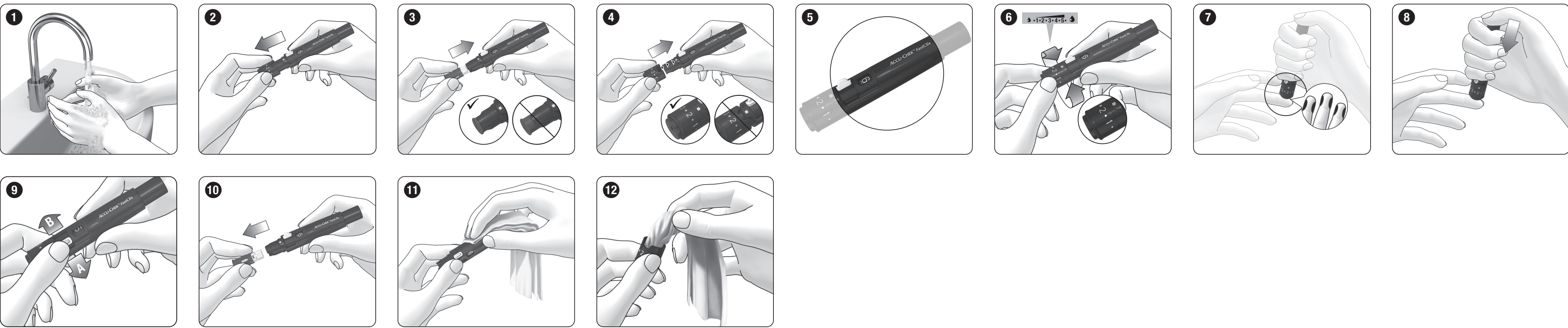
Fare for personskade

Del af blodprøvetakeren, for eksempel udløserknappen, kan hoppe bort under brug. Ikke pek blodprøvetakeren mod ansigtet ditt eller mot andre personer.

Hvis blodprø

ACCU-CHEK® FastClix

Blodprovstagare och lansett Lansettikynä ja lansetti



Bruksanvisning

Avsedd användning

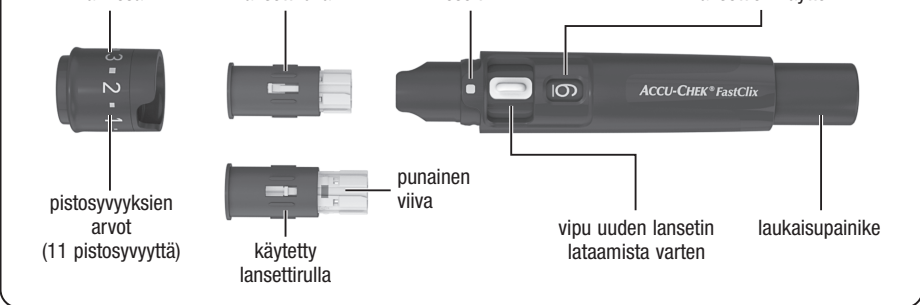
Blodprovstagare
Accu-Chek FastClix-blodprovstagaren är en enhet för enkel och så gott som smärtfri provtagning av kapillärblood från fingertoppen. Accu-Chek FastClix-blodprovstagaren är endast avsedd för engångsbruk! Den får alltså endast användas för att ta blod från en och samma person. Det finns risk för infektionsspridning om blodprovstagaren används av andra personer, även av familjemedlemmar, eller om sjukvårdspersonal använder den här blodprovstagaren för att ta blod från fler än en person. Den här blodprovstagaren är därför inte avsedd för professionell användning inom offentliga sjukvårdsanläggningar. Blodprovstagaren är inte en steril produkt.
Personer inom området självövervakning av diabetes betraktas som målgrupp.

Lansett
Det finns sex Accu-Chek FastClix-lansetter i varje lansetttrumma. Lansetttrumman är avsedd att användas tillsammans med Accu-Chek FastClix-blodprovstagaren. Lansetttrumman är en engångsödel. Varje lansett i lansetttrumman är avsedd att användas endast en gång. Accu-Chek FastClix-lansetttrumman innehåller 6 lansetter och är avsedd att användas tillsammans med Accu-Chek FastClix-blodprovstagaren för enkel och så gott som smärtfri provtagning av kapillärblood. Lansetttrumman är en engångsartikel med 6 lansetter och var och en av lansetterna är avsedd att användas endast en gång. Varje lansett har en skyddsskåpa som garanterar att lansetten förblir steril fram till den används för första gången. Lansetterna steriliserar med bestrålning. En använd lansetttrumma är skyddad mot återanvändning.

Blodprovstagarens egenskaper

Blodprovstagaren har 11 olika insticksdjup så att du kan anpassa insticksdjupet till just din hud. Med avtryckaren kan du i ett enda steg ladda blodprovstagaren och utlösa en lansett. När lansetten utlöses stöcks den in i huden. Du sätter in en lansetttrumma med 6 lansetter i blodprovstagaren. Du kan ta blod med en ny, steril lansett 6 gånger, innan du behöver byta lansetttrumma.

Käyttöohje



Käyttöohje

Käyttötarkoitus
Lansettikynä
Accu-Chek FastClix -lansettikynä on tarkoitettu kapillaariverinäytteen ottamiseen sormenpäästä helposti ja ilman kivutonta. Accu-Chek FastClix -lansettikynä on tarkoitettu vain potilaan henkilökohtaiseen käyttöön. Sitä saa käyttää vain yhden henkilön verinäytteen ottoon. Jos toinen henkilö, perheenjäsenet mukaan luettuna, käyttää lansettikynää tai jos terveydenhuollon ammattilainen käyttää samaa lansettikynää verinäytteen ottoon useammalla henkilöllä, on demassa infektion leviämisen riski. Tämä lansettikynä ei siksi sovellu ammattikäyttöön terveydenhuollon laitoksissa. Se ei ole steriili tuote.
Käyttökäytännön kuuluvat diabeteksen onseurainta tunnettuihin häiriöihin.
Lansetti
Lansettitruuna sisältää kuusi Accu-Chek FastClix -lansettitruuna on tarkoitettu käytettäväksi yhdessä Accu-Chek FastClix -lansettikynän kanssa. Lansettitruuna on kertakäyttöinen. Jokainen sen sisältämä lansetti on tarkoitettu käytettäväksi vain kerran. Accu-Chek FastClix -lansettitruuna sisältää 6 lansetta ja se on tarkoitettu käytettäväksi yhdessä Accu-Chek FastClix -lansettikynän kanssa kapillaariverinäytteen ottamiseen sormenpäästä helposti ja ilman kivutonta. Lansettitruuna on joutunut kosketuksiin veren kanssa ja siinä on ulkoneva teräsväsi kohta. Tärkeistä lansettikynä ja lansettitruuna vaurioiden varalta infektion leviämisen välttämiseksi. Hävittä vaurioitunut lansettikynä ja lansettitruuna tartuntavaarallisen maassasi voimassa olevien määräysten mukaisesti.

Lansettikynän ominaisuudet
Lansettikynässä on 11 pistosvyöryä, joten voit valita pistosvyöryiden osan ihtopyysi mukaan. Laukaisupainikkeen avulla voit viritellä lansettikynän ja laukaisua lanetin yhdellä kertaa. Kun lansetti laukaase, se työntyy ihoon. Lansettikynän asetetaan lansettitruuna, joka sisältää 6 lansetta. Verinäyte voidaan siis ottaa 6 kertaa steriilillä lansetilla, jonka jälkeen lansettitruuna vaihdetaan.