

# ACCU-CHEK® Safe-T-Pro Uno

## Sterile, single-use lancening device Sterile Einmalstechhilfe

### Autopiqueur stérile à usage unique

0588662\_0635971

## Instructions for Use

Read these instructions for use before you obtain blood with this sterile, single-use lancening device.

**Intended Use**  
The Accu-Chek Safe-T-Pro Uno lancening device is intended to be used for obtaining capillary blood.  
The lancening device is an aid for the determination of diagnostic parameters in blood, for example, blood glucose.  
The intended users are healthcare professionals.  
The lancening device can be used to obtain capillary blood from adults, adolescents, children, and neonates.

**Contraindications**  
The lancening device must only be used for obtaining capillary blood. In case of children up to 1 year, adolescents, and adults, blood must be taken from the fingertip. In case of children under 1 year of age and neonates, blood must be taken from the heel.  
In general, blood can be obtained from any finger. Certain fingers can be unusable, for example, a skin or fungal infection is present.

**General Safety Information**  
Read the instructions for use contain warnings and precautions:  
**WARNING** indicates a foreseeable serious hazard.  
A **PRECAUTION** describes a measure you should take to use the product safely and effectively or to prevent damage to the product.

**WARNING**  
**Risk of suffocation**  
This product contains small parts that can be swallowed. Keep the small parts away from small children and people who might swallow small parts.  
If the lancening device was dropped or exposed to other mechanical stress, check it for damages, for example, cracks. If the lancening device is damaged, do not use it.

**Device Description**  
See illustration **1**.  
① Release button  
② Housing  
③ Sterility cap of the needle  
Due to a pre-set depth of 1.5 mm blood volumes for diagnostic purposes can be obtained.

Due to the siliconized needle, the specially beveled needle cut, and the thin needle diameter (0.36 mm, 28 G), blood sampling is nearly pain free.  
The lancening device is designed for single use only.

**Preparing to Obtain Blood**  
**PRECAUTION**  
**Risk of infection**  
A puncture site that has not cleaned can lead to infection.  
Before obtaining blood clean the puncture site.

**Children younger than 1 year and neonates**  
**WARNING**  
**Risk of injury**  
If the lancening device is used at the fingertip of children younger than 1 year of age and of neonates, it can injure the finger.  
Only use the lancening device at the feet of children younger than 1 year of age and of neonates.

With children younger than 1 year of age and neonates, the capillary blood must be obtained from the heel. Obtaining blood must occur from the lateral areas of the sole (see black areas in illustration **2**). The puncture must occur vertically to the sole (see arrows in the enlargement). While obtaining blood, the child should be held with its foot vertically facing the floor. A site, which has already been punctured, must not be punctured a second time.  
To improve blood flow at the heel before obtaining blood, you can carefully warm the heel, for example, by wrapping it in a warm, moist cloth at a maximum 42 °C. Wash the child's heel with warm water and soap, rinse it thoroughly and let it dry completely. Disinfect the heel with an alcohol wipe. Afterwards, let the heel dry completely.

**Children as of 1 year, adolescents, and adults**  
Obtain capillary blood from the side of the fingertip, as these sites register the least amount of pain (see black areas in illustration **3**). Any finger can be used for the puncture.  
Wash the patient's hands with warm water and soap, rinse them thoroughly and let them dry completely. This ensures that the puncture site is clean and it increases the blood flow. If you are using alcohol wipes in addition, the finger must also be allowed to dry completely.

**Obtaining Blood**  
**WARNING**  
**Risk of infection**  
A lancening device with missing sterility cap is not sterile anymore.  
If the sterility cap is missing, do not use the lancening device.

**PRECAUTION**  
**Risk of infection**  
If the use by date of the lancening device has expired, there is a risk of infection.  
Use only lancening devices that are within the use by date. The use by date is printed next to the **w** symbol on the packaging.

- Twist the sterility cap one quarter turn and pull it off (see illustration **1**).
- Hold the lancening device between the index finger, middle finger, and thumb (see illustration **2**).
- Press the lancening device firmly against the chosen puncture site.
- Using your thumb, press the release button down completely (see illustration **3**).
- Remove the lancening device from the puncture site.
- Wait for a blood drop to emerge from the puncture site.
- Gently massage the finger towards the fingertip or exert slight pressure on the heel to encourage a sufficiently large blood drop to form.
- For some diagnostic tests, the fingertip or heel must not be vigorously massaged or compressed, as doing so can produce incorrect test results.

**WARNING**  
**Risk of infection**  
In rare cases, the needle is not pulled back into the lancening device after you obtained blood.  
Check that the needle does not protrude after you obtained blood. Discard the used lancening device with the needle protruding as infectious material in accordance with your facility's disposal regulations.

**Operating Conditions**  
Use the lancening device under the following operating conditions:  
Temperature range: +5 to +45 °C  
Relative humidity range: 5 to 90 %

**Storing the Lancening Device**  
Do not store the lancening device at extreme temperatures, for example, in a hot car. This can damage the lancening device.

**Discarding the Lancening Device**  
During obtaining a blood drop, the lancening device can come into contact with blood.  
**PRECAUTION**  
**Risk of infection**  
The lancening device has come into contact with blood, it can transmit infections.  
Discard the used lancening device as infectious material in accordance with your facility's disposal procedures.

**Reporting of Serious Incidents**  
For a patient/user/third party in the European Union and in countries with identical regulatory regime, 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**  
2021-01

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**Blutentnahme vorbereiten**  
**VORSICHTSMASSNAHME**  
**Infektionsgefahr**  
Eine nicht gesäuberte Einstichstelle kann zu einer Infektion führen.  
Säubern Sie die Einstichstelle vor der Blutentnahme.

**Kinder unter 1 Jahr und Neugeborene**  
**WARNING**  
**Verletzungsgefahr**  
Verletzungsgefahr bei Kindern unter 1 Jahr und Neugeborenen an der Fingerbeere verwendet wird, kann dies zur Verletzung des Fingers führen.  
Verwenden Sie die Stechhilfe bei Kindern unter 1 Jahr und Neugeborenen nur an der Ferse.

Bei Kindern unter 1 Jahr und Neugeborenen muss das Kapillärblut aus der Ferse entnommen werden. Das Blut darf nur aus den seitlichen Bereichen der Ferse entnommen werden. Die Ferse muss trocken sein.  
Check that the needle does not protrude after you obtained blood. Discard the used lancening device with the needle protruding as infectious material in accordance with your facility's disposal regulations.

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## Instructions d'utilisation

Veillez lire attentivement ces instructions d'utilisation avant de procéder à un prélèvement de sang à l'aide de cet autopiqueur stérile à usage unique.

**Utilisation prévue**  
L'autopiqueur Accu-Chek Safe-T-Pro Uno est destiné à prélever du sang capillaire.  
Ce produit peut être utilisé par des professionnels de santé.  
L'autopiqueur peut être utilisé pour obtenir du sang capillaire d'adultes, d'adolescents, d'enfants et de nouveau-nés.

**Contre-indications**  
L'autopiqueur ne doit servir qu'à l'obtention de sang capillaire. Chez les enfants âgés de 1 an, les adolescents et les adultes, le sang doit être prélevé à l'aide du doigt. Chez les enfants de moins de 1 an et les nouveau-nés, le sang doit être prélevé à partir du talon.  
En général, tous les doigts conviennent au prélèvement. Certains doigts peuvent ne pas convenir au prélèvement s'ils présentent, par exemple, une infection de la peau ou de l'ongle.

**Informations générales relatives à la sécurité**  
Les instructions d'utilisation contiennent des avertissements et des précautions : Un **PRÉCAUTION** indique un risque grave prévisible.  
Un **PRÉCAUTION** écarte une mesure que vous devez prendre pour utiliser le produit de manière sûre et efficace ou pour prévenir toute dégradation du produit.

**AVERTISSEMENT**  
**Risque de suffocation**  
Ce produit contient de petites pièces pouvant être avalées. Tenez les petites pièces hors de portée des enfants en bas âge et des personnes susceptibles d'avaler de petites pièces.

En cas de chute à terre de l'autopiqueur ou d'exposition à d'autres contraintes (tel que le lavage des mains ou de l'alcool), le produit peut être contaminé. Si l'autopiqueur est contaminé, ne l'utilisez pas.

**Description du dispositif**  
Voir figure **1**.  
① Bouton de déclenchement  
② Corps de l'autopiqueur  
③ Manch

