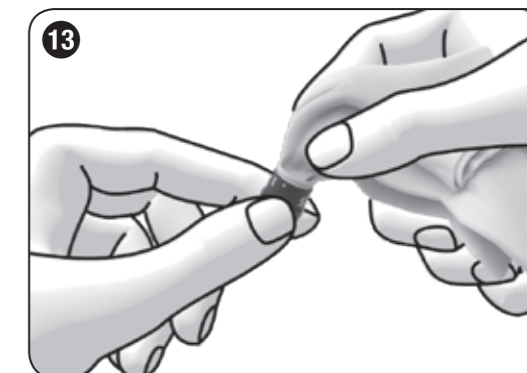
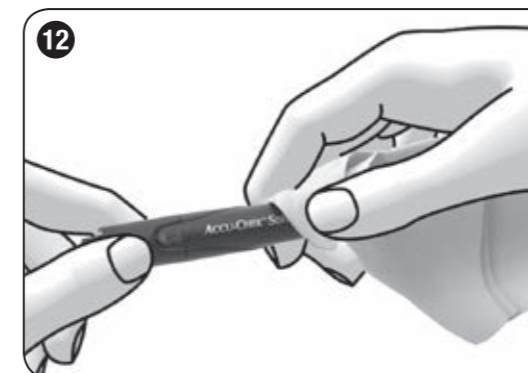
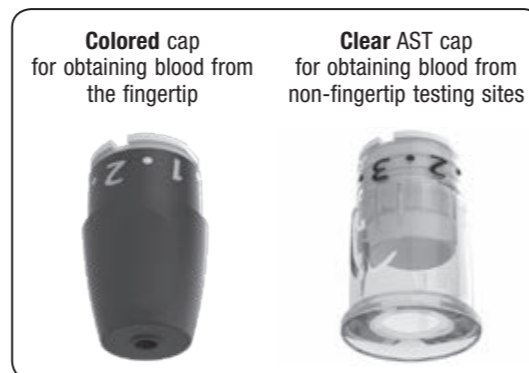
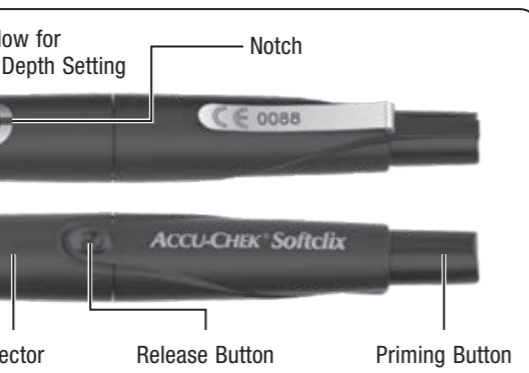
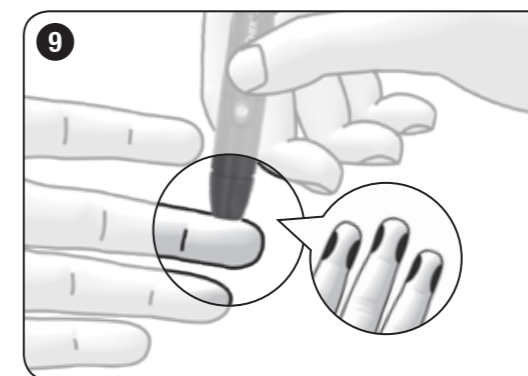
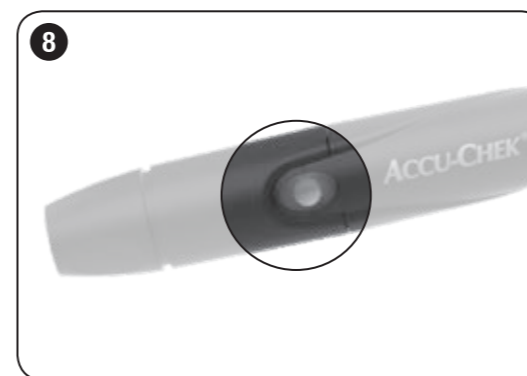
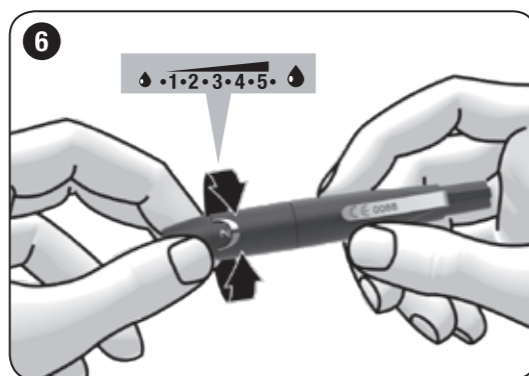
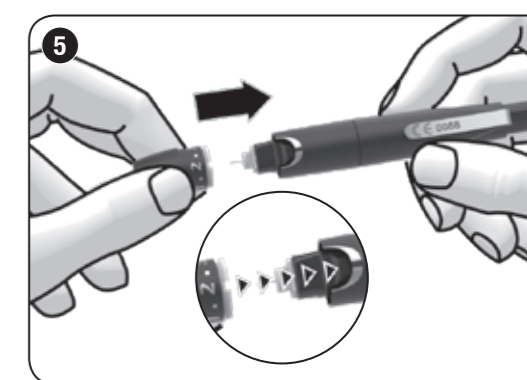
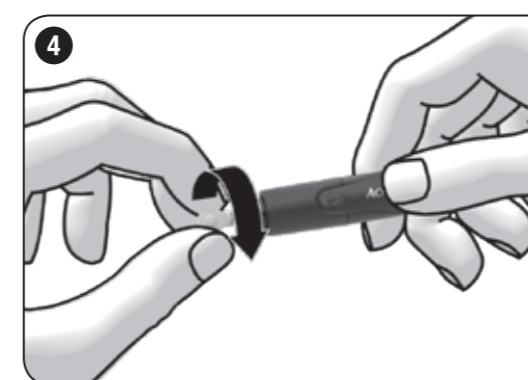
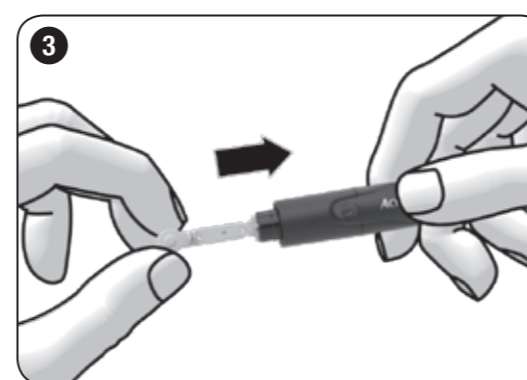
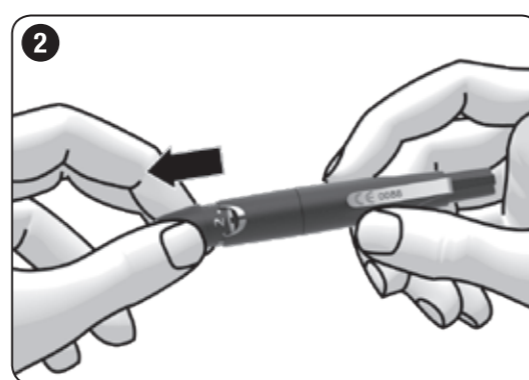


ACCU-CHEK® Softclix

Lancing device



0757505003



Instructions for Use

Intended Use

The lancing device is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from other sites, such as the palm, the upper arm, and the forearm, which is referred to as non-fingertip testing or alternate site testing. The lancing device is for use only on a single patient.

For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use.

Each lancet may only be used once to obtain blood. Used lancets must be safely discarded after a single use.

WARNING

Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient.

WARNING

If the lancing device is being operated by a second person who is providing testing assistance to the user, the lancing device should be cleaned and disinfected prior to use by the second person. The second person must wear protective gloves for all the steps when providing testing assistance.

Keep the lancing device with all its components away from children under the age of 3 years. There is a risk of suffocation if small parts (e.g. caps or similar objects) are swallowed.

Only insert Accu-Chek Softclix lancets into the Accu-Chek Softclix lancing device. Other lancets may impair the operation of the lancing device or damage it permanently.

If the lancing device falls with a lancet inserted, the lancet may become loose in the lancet holder. You cannot use it anymore to obtain blood. In rare cases, the lancet could protrude from the opening in the cap and you could injure yourself on it. Therefore, do not touch the front of the cap. If the lancing device falls, pick it up with care. Remove the cap from the lancing device. Pay

attention to the lancet so that you do not injure yourself on it. Always eject the lancet and discard it.

Features

The Accu-Chek Softclix lancing device is a device for virtually pain-free collection of capillary blood from the fingertips. The lancing device has 11 different penetration depths so that you can adjust the penetration depth to the texture of your skin. You insert a lancet into the lancing device. With the priming button, you prime the lancing device. With the release button, you trigger a lancet. When a lancet is triggered, it penetrates the skin. Afterwards, the lancet retracts automatically into the lancing device. This helps prevent accidental fingersticks.

Before Using the Lancing Device

▶ Wash your hands with warm water and soap (see 1).

Inserting a Lancet

You have to insert a lancet to be able to obtain blood with the lancing device.

- ▶ Remove the cap from the lancing device (see 2).
- ▶ Insert a new lancet into the lancet holder as far as it will go (see 3). The lancet must audibly click into place.
- ▶ Twist the protective cap off of the lancet (see 4).
- ▶ Place the cap back on again, lining up the notch on the cap with the notch on the lancing device (see 5). The cap must audibly click into place.

Setting the Penetration Depth

You can set 11 penetration depths (0.5 to 5.5). The penetration depth set is shown in the window. The larger the number, the greater the penetration depth.

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

▶ Rotate the comfort dial until the desired penetration depth is set (see 6).

Priming the Lancing Device

In order to be able to obtain blood, you must prime the lancing device.

▶ Press the priming button all the way down (see 7). Do not press the release button simultaneously.

The lancing device is primed when the center of the release button is yellow (see 8).

WARNING

Only prime the lancing device just before obtaining blood.

Obtaining a Blood Drop

In general, blood can be obtained from any finger. Certain fingers can be unsuitable if, for example, a skin or fingernail infection is present. We recommend obtaining capillary blood from the sides of the fingertips as these areas are the least sensitive to pain.

WARNING

- **Always use a new lancet when you obtain blood. In doing this, you reduce the risk of infection, and obtaining blood remains less painful.**
- **Only use the lancing device when the cap is attached. Without the cap, the lancet penetrates too deeply and may cause discomfort.**

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

▶ Disinfect the selected puncture site. The puncture site must dry completely afterwards.

▶ Press the lancing device firmly against the selected puncture site (see 9).

▶ Press the release button (see 10).

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 lancing device against the skin.

If not enough blood emerges, apply more pressure on the lancing device 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 your blood glucose meter.

We recommend protecting the puncture site from contamination afterwards.

Ejecting the Used Lancet

▶ Remove the cap from the lancing device (see 2).

▶ Slide the ejector forward (see 11).

The used lancet is ejected.

▶ Place the cap back on again.

▶ Dispose of used lancets according to local regulations.

WARNING

Dispose of used lancets in such a way as to prevent injury from the needles.

After Using the Lancing Device

▶ Wash your hands with warm water and soap (see 1).

Storing and Using the Lancing Device

Protect the lancing device from excessive humidity, sunlight and heat. Store and use at room temperature.

WARNING

Store the lancing device only without a lancet inserted.

Cleaning and Disinfecting the Lancing Device and Cap

The lancing device can spread infection if it becomes soiled with blood.^{1,2} During normal testing any lancing device may come in contact with blood. For this reason, it is important to keep the lancing device clean and disinfected.

To clean and disinfect without damaging the lancing device, follow these procedures carefully.

What is the difference between cleaning and disinfecting?

- Cleaning is the removal of dirt from the lancing device.³
- Disinfecting is the removal of most, but not all, disease-causing and other types of microorganisms (bloodborne pathogens) from the lancing device.³

Approved Cleaning and Disinfecting Product

The following product has been approved for cleaning and disinfecting the lancing device:

Super Sani-Cloth (EPA* reg. no. 9480-4)

* Environmental Protection Agency

Super Sani-Cloth can be purchased from Amazon.com, OfficeDepot.com, and Walmart.com.

• Do not use any other cleaning or disinfecting solutions. Using solutions other than the Super Sani-Cloth could result in damage to the lancing device.

• The effect of using more than one product interchangeably to clean and disinfect the lancing device has not been tested. Always use Super Sani-Cloth to clean and disinfect the lancing device.

• Roche has demonstrated that the product is good for 5-year use, after testing in a total of 260 disinfection cycles (equal to cleaning and disinfecting once per week for 5 years).

NOTE

For technical assistance or questions on cleaning and disinfecting, visit our website at www.accu-chek.com/support or call the Accu-Chek Customer Care Service Center at 1-800-858-8072.

When to Clean and Disinfect the Lancing Device

- Clean the lancing device to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the lancing device at least once per week to remove visible dirt or other material for safe handling.
- Clean and disinfect the lancing device before allowing anyone else to handle the lancing device, for instance, if you have someone assisting you. Do not allow anyone else to use the lancing device.

NOTE

• Do not throw away the cap after each use.

• Always remove the lancet before cleaning and disinfecting the lancing device.

• Using cleaning and disinfecting products could result in damage to the lancing device. If you notice any of the following signs of deterioration after cleaning and disinfecting your lancing device, stop using your lancing device and visit our website at www.accu-chek.com/support or call the Accu-Chek Customer Care Service Center at 1-800-858-8072: residue around buttons, difficulty in priming the lancing device, difficulty in inserting the lancet.

• You might observe a slight discoloration of the lancing device after multiple cleaning and disinfecting cycles. This does not affect the functionality of the device.

What to Clean and Disinfect

The following parts of the lancing device should be cleaned and disinfected:

- The entire lancing device surface
- The cap

How to Clean and Disinfect the Lancing Device

WARNING

Failure to follow these instructions may damage the lancing device and stop it from working properly.

- **Do not get any moisture into openings.**
- **Always use the same product for both cleaning and disinfecting.**

A separate Super Sani-Cloth should be used for cleaning and disinfection.

1. Wash hands thoroughly with soap and water.

2. Wipe the entire lancing device surface and the inside of the cap with a Super Sani-Cloth (see 2 and 5).

3. For disinfecting the lancing device, use a new cloth. Repeat step 2 making sure that the surface stays wet for 2 minutes.

4. Wash hands thoroughly with soap and water.

Discarding the Lancet and Lancing Device

Any product coming in contact with blood is considered contaminated (potentially infectious).^{*} During obtaining a blood drop, any lancet and lancing device may come in contact with blood. Lancets and lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.

Roche is committed to recycling and sustainability. Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used lancets and used lancing devices.

Remove the lancet before discarding the lancing device.

*29 CFR 1910.1030 – Bloodborne pathogens

We Are Here to Help

If you have any questions about your lancing device or any procedure in these instructions, visit our website at www.accu-chek.com/support or call the Accu-Chek Customer Care Service Center.

1-800-858-8072 phone

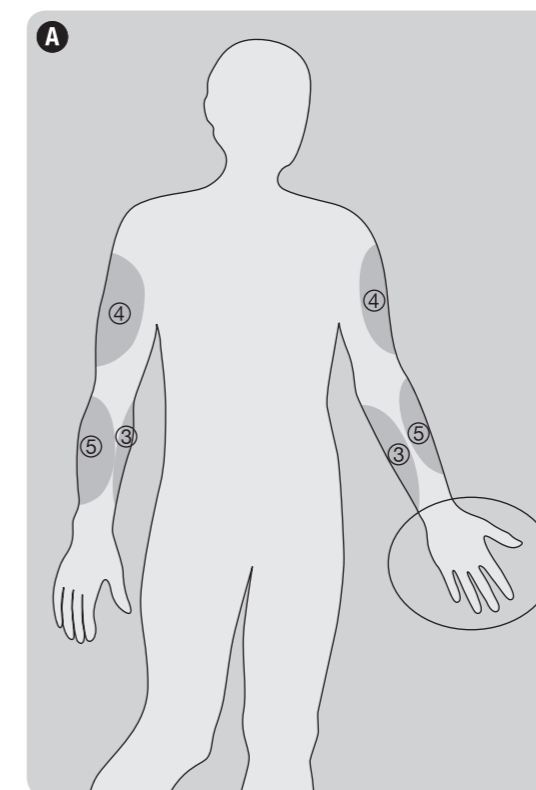
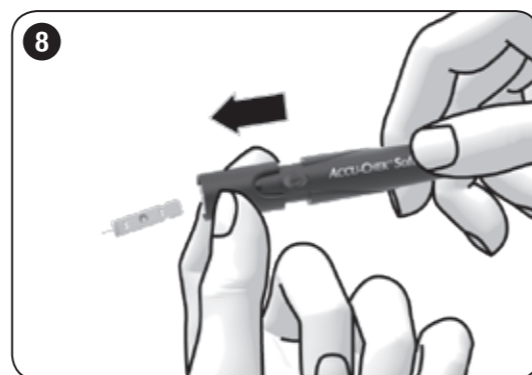
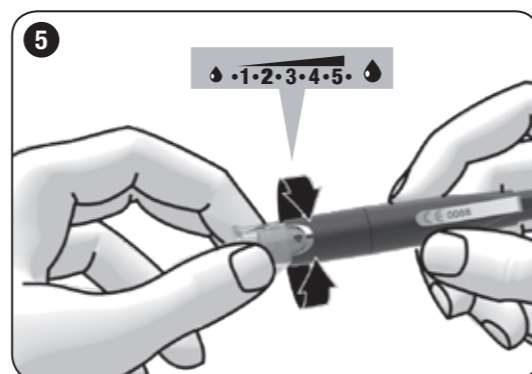
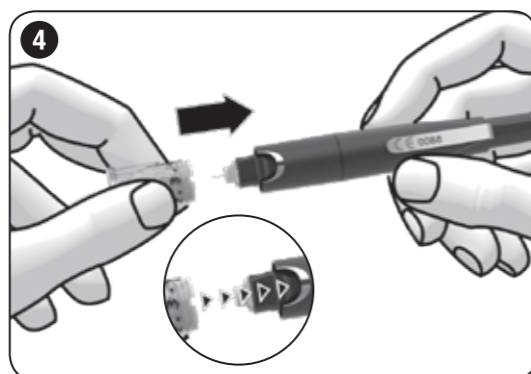
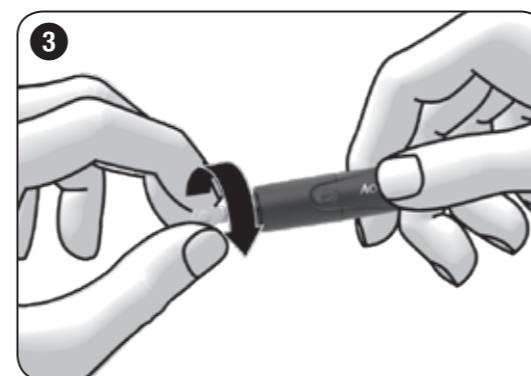
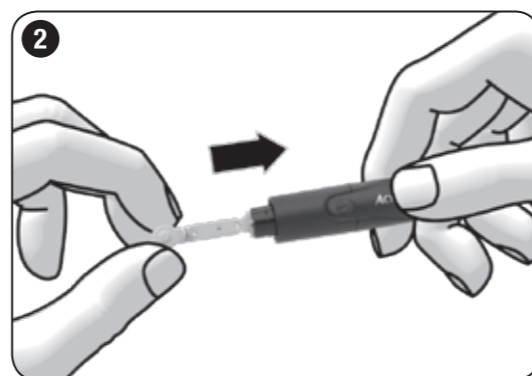
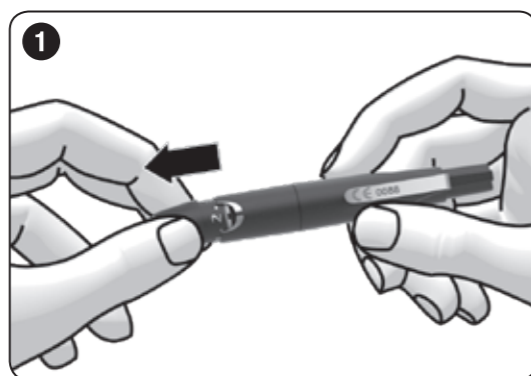
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ACCU-CHEK® Softclix

AST Cap

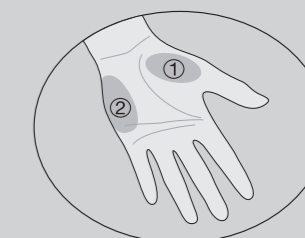
Alternate Site Testing (AST) cap for obtaining blood from a non-fingertip testing site



Non-fingertip testing sites

Not all sites are compatible with all meters. Consult your meter instructions for the non-fingertip testing sites suitable for your meter.

- ① Ball of the thumb
 - ② Ball of the little finger
- } Preferred sites



- ③ Inside of the forearm
- ④ Upper arm
- ⑤ Outside of the forearm

Instructions for Use

Intended Use

The lancet device is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from other sites, such as the palm, the upper arm, and the forearm, which is referred to as non-fingertip testing or alternate site testing. The lancet device is for use only on a single patient.

For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use. Each lancet may only be used once to obtain blood. Used lancets must be safely discarded after a single use.

WARNING

Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient.

WARNING

- Read these instructions and the instructions for use of the Accu-Chek Softclix lancet device on the other side of this package insert before using blood from non-fingertip testing sites for testing blood glucose.
- Before you decide to use blood from non-fingertip testing sites, consult your healthcare professional.
- Check the instructions for use for your blood glucose meter or contact customer support to determine whether you are allowed to test blood from non-fingertip testing sites with your meter and which testing sites are suitable.
- Blood obtained from the forearm or the upper arm is not always suitable for blood glucose testing (see section "Testing at the Right Time"). Under certain conditions, the test results for blood obtained from the forearm or the upper arm can differ from test results for blood obtained from the fingertip or the palm. These differences can cause the wrong therapy recommendation to be made and thus produce serious adverse health effects.

- If the test result for blood obtained from the forearm or the upper arm does not match how you feel, you should perform a test with blood obtained from the fingertip or the palm. If this test result also does not match how you feel, contact your healthcare professional.
- Use the AST cap only to obtain blood from non-fingertip testing sites. If you use the AST cap to obtain blood from the fingertip, the lancet penetrates too deeply and may cause discomfort.
- Keep the lancet device and all its components away from children under the age of 3 years. There is a risk of suffocation if small parts (e.g. caps or similar objects) are swallowed.
- Use the Accu-Chek Softclix AST cap only together with the Accu-Chek Softclix lancet device.

Testing at the Right Time

Do not test blood obtained from the forearm or the upper arm

- up to two hours following a meal, when blood glucose values can rise quickly
- after injection of bolus insulin, when blood glucose values can decrease quickly
- after exercise
- if you are ill
- if you think that your blood glucose is very low (hypoglycemia)
- if you know that you sometimes do not notice when you are hypoglycemic

Do not use alternate site testing to calibrate a continuous glucose monitoring system or to make insulin dosing calculations.

Placing the AST Cap on the Lancet Device

- ▶ Remove the colored cap from the lancet device (see 1).
- ▶ Insert a new lancet (see 2).
- ▶ Twist the protective cap off of the lancet (see 3).
- ▶ Place the AST cap on the lancet device, lining up the notch on the cap with the notch on the lancet device (see 4). The cap must audibly click into place.

Setting the Penetration Depth

- ▶ Rotate the comfort dial on the cap until the desired penetration depth is set (see 5).

NOTE

To obtain a sufficiently large blood drop, the puncture at non-fingertip testing sites must be deeper than at

the fingertip. However, these sites are usually less sensitive to pain.

Obtaining a Blood Drop

WARNING

Only use the lancet device when the AST cap is attached. Without the cap, the lancet penetrates too deeply and may cause discomfort.

- ▶ Choose a fleshy area of the non-fingertip testing site. Wash it with warm water and soap and dry it well.
- ▶ Disinfect the selected puncture site. The puncture site must dry completely afterwards.
- ▶ Press the priming button all the way down to prime the device (see 6).
- ▶ Press the lancet device firmly against the selected puncture site.
- ▶ Press the release button (see 7).

The lancet is released and it penetrates the skin.

- ▶ Press the lancet device firmly against the puncture site for a few seconds.

You can watch the blood drop form through the AST cap. The blood drop should be approximately this size: •

If the blood drop is smaller, release the pressure on the puncture site for a few seconds without removing the AST cap from the puncture site. Then reapply pressure to the AST cap until the blood drop is big enough.

- ▶ Test your blood glucose immediately after you obtain blood, according to the instructions for use for your blood glucose meter.

Ejecting the Used Lancet

- ▶ Remove the cap from the lancet device (see 1).
 - ▶ Slide the ejector forward (see 8).
- The used lancet is ejected.
- ▶ Replace one of the two caps on the lancet device.
 - ▶ Dispose of used lancets according to local regulations.

WARNING

Dispose of used lancets in such a way as to prevent injury from the needles.

Cleaning and Disinfecting the Lancet Device and AST Cap

Follow the instructions in the section "Cleaning and Disinfecting the Lancet Device and Cap" on the other side of this package insert in order to clean and disinfect the lancet device and AST cap appropriately.

One (1) Year Warranty

Roche warrants the Accu-Chek Softclix lancet device against defects in materials and workmanship for a period of one (1) year from the date of purchase. The liability of Roche under this warranty is limited to the repair or replacement, at Roche's option, of all parts or materials proven to be defective. This warranty does not cover repair or replacement of Accu-Chek Softclix lancet devices which have been subjected to alteration, misuse, tampering, or abuse.

THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED, OR STATUTORY. ROCHE DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Roche's entire liability with respect to the Accu-Chek Softclix lancet device shall be the repair or replacement of nonconforming devices, at Roche's option. In no case shall Roche be liable for incidental, indirect, special, or consequential damages. This warranty gives you specific legal rights, and you may have other rights which vary from state to state so the above limitation and exclusion may not apply to you. All inquiries about the Accu-Chek Softclix lancet device under the above warranty or service policy must be directed to the Accu-Chek Customer Care Service Center by calling 1-800-858-8072. You will be informed of the procedure necessary for replacement. Please DO NOT return any device to Roche without authorization.

IMPORTANT – Read carefully before use. Caution: A restricted license limits use of the Accu-Chek Softclix lancet device in the United States. The Accu-Chek Softclix system (device and lancets) and its use are protected by U.S. Patent Nos. 6,419,661 (expires 3-March-2020); 7,077,828 (expires 3-March-2020); and 7,322,998 (expires 3-March-2020). A license to use the Accu-Chek Softclix system is required until the last-to-expire patent listed above and is only granted when Accu-Chek Softclix lancets are used with the Accu-Chek Softclix lancet device. Accu-Chek Softclix lancets are high precision components that are produced to the close tolerances required for satisfactory operation with the Accu-Chek Softclix lancet device. Use of other lancets with the Accu-Chek Softclix lancet device may prevent or impair proper function of the Accu-Chek Softclix lancet device.

Using the Accu-Chek Softclix lancet device indicates your acceptance of the restricted license to use the Accu-Chek Softclix lancet device only with Accu-Chek Softclix lancets. Further, if you have purchased an

Accu-Chek Softclix lancet device that includes this restricted license, then this restricted license applies regardless of any additional offers found in Accu-Chek Softclix lancet device packages. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused Accu-Chek Softclix lancet device for a full refund. If you have any questions, please contact the Accu-Chek Customer Care Service Center at 1-800-858-8072. Except where prohibited by statute, all warranties covering the Accu-Chek Softclix lancet device are voided by use of the Accu-Chek Softclix lancet device with any lancets other than Accu-Chek Softclix lancets.

Patent Information

U.S. Pat.: <http://www.roche-diagnostics.us/patents>

References

- 1 FDA Public Health Notification: "Use of Fingertip Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). Update 11/29/2010." <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>. Accessed June 1, 2016.
- 2 CDC Clinical Reminder: "Use of Fingertip Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010)." <http://www.cdc.gov/injectionsafety/Fingertip-DevicesBGM.html>. Accessed June 1, 2016.
- 3 Healthcare Infection Control Practices Advisory Committee (HICPAC), William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2008. "Guideline for Disinfection and Sterilization in Healthcare Facilities." Atlanta. http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf. Accessed June 1, 2016.

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GTIN Global Trade Item Number

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

Manufactured in Germany for:
Roche Diabetes Care, Inc.
Indianapolis, IN 46256, USA

