

Lancing Device Package Insert

English

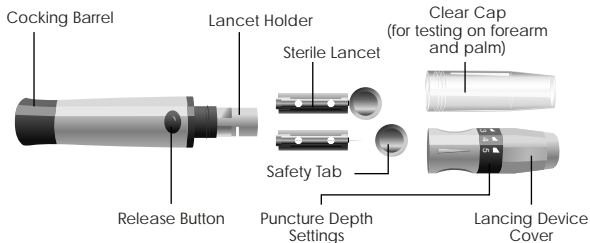
PRINCIPLE AND INTENDED USE

The *Clarity Plus* Lancing Device is used with compatible disposable sterile lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for blood glucose testing or other testing utilizing small amounts of blood.

INSTRUCTION FOR USE

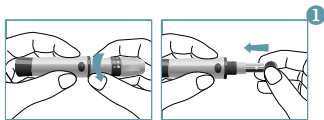
Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

IMPORTANT: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.

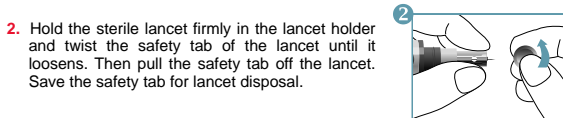


Sampling from the fingertip

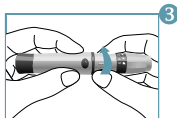
For fingertip sampling, adjust the depth penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.



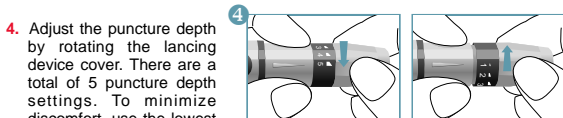
1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.



2. Hold the sterile lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens. Then pull the safety tab off the lancet. Save the safety tab for lancet disposal.



3. Carefully screw the lancing device cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the lancing device cover is fully sealed on the lancing device.

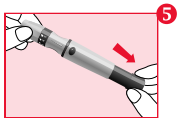


4. Adjust the puncture depth by rotating the lancing device cover. There are a total of 5 puncture depth settings. To minimize discomfort, use the lowest setting that still produces an adequate drop of blood.

Puncture Depth Settings:

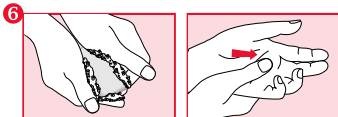
1 and 2 for delicate skin • 3 for normal skin • 4 and 5 for calloused or thick skin

Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

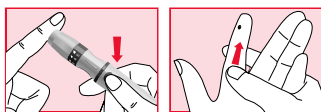


5. Pull the cocking barrel back to set the lancing device. You may hear a click. The lancing device is now loaded and ready for obtaining a drop of blood.

6. Prior to testing, wipe your hand with an alcohol swab or wash your hands with soap. Use warm water to increase blood flow in your fingers if necessary.



Then dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

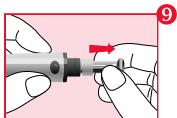
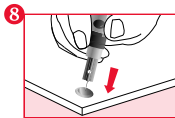


7. Hold the lancing device against the side of the finger to be lanced with the lancing device cover resting on the finger. Push the release button

to prick your fingertip. You should hear a click as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood.

For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make your fingers sore and callused.

8. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.

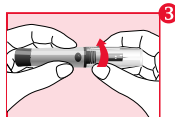


9. Press the release button to make sure that the lancet is in the extended position. Pull the lancet straight out of the lancet holder and discard it in an appropriate container. Place the lancing device cover back on the lancing device.

Sampling from forearm or palm (at the base of the thumb)

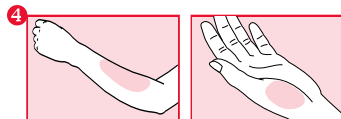
The forearm and palm areas have fewer nerve endings than the fingertip so you may find that obtaining blood from these sites is less painful than from the fingertip. The technique for forearm and palm sampling is different. You need the clear cap to draw blood from these sites. The clear cap is not adjustable for puncture depth.

Follow Steps 1 and 2 above to insert a sterile lancet into the lancet holder and



3. Screw the clear cap onto the lancing device.

4. Choose a puncture site on the forearm or palm. Select a soft, fleshy area that is clean and dry, away from bone, and free of visible veins and hair.



Wipe the puncture site with an alcohol swab or wash with soap. Use warm water to increase blood flow. Then dry the skin thoroughly.

To bring fresh blood to the surface of the puncture site, massage the puncture site vigorously for a few seconds until you feel it getting warm.



5. Place the lancing device against the puncture site. Press and hold the clear cap against the puncture site for a few seconds. Press the release button

of the lancing device, but **do not immediately lift the lancing device** from the puncture site. Continue to hold the lancing device against the puncture site until you can confirm a sufficient blood sample has formed.

CARE OF THE LANCING DEVICE

Clean the lancing device using a soft cloth with mild soap and warm water as required. Use 70% Isopropyl Alcohol to disinfect the lancing device. Carefully dry the lancing device. Do not immerse the lancing device in liquid.

PRECAUTIONS

Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.

Do not use the lancet if the needle is bent.

Use caution whenever the lancet needle is exposed.

Never share lancets or the lancing device with other people.

In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.

Avoid getting the lancet device or lancets dirty with hand lotion, oils, dirt or debris.

LIMITED WARRANTY

If the lancing device does not work for any reason other than obvious abuse in the first 5 years after purchase, we will replace it with a new or equivalent lancing device free of charge. Please contact Clarity Diagnostics for replacement.