

LANCING DEVICE

OPTILET PRO

INSTRUCTIONS FOR USE

Read the instructions for using the lancing device before you collect a blood sample. If you have any questions on how to use the device, please contact the Helpdesk at the telephone number indicated in the manual.

1. INTENDED USE

The Optilet PRO lancing device is a safe and convenient medical device for obtaining a blood sample by puncturing the skin with disposable lancets. Thanks to the adjustable tip, the puncture depth can be adjusted to suit most skin types. The device is intended for multiple use by a single patient.

2. DESCRIPTION OF THE LANCING DEVICE AND TARGET USERS

The device has 9 puncture depth settings (from 1 to 9), designed for different skin types. The lower values are for shallower punctures, while the higher values are for deeper punctures (point 8.5). The shallower punctures are suitable for children and most adults. Deeper punctures work well for those with thicker or calloused skin. There is also the option of puncturing at alternative sites (other than the fingertip), for which a special attachment is available.

This lancing device is suitable for both children and adults. This device must not be used for blood collection by healthcare professionals in care facilities, clinics or health centres, nor must it be shared with others, including family members. Patients under 18 years of age should use the device under adult supervision.

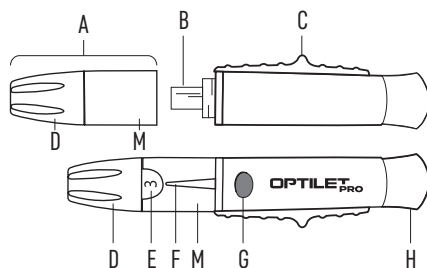
⚠ If the puncture is too deep, it may cause injury to children. Before using the lancing device on children for the first time, consult medical staff. Begin with the smallest possible puncture depth to see if this will produce an adequate blood sample.

3. SMOOTH STOP SYSTEM

A flexible vibration damper to reduce lancet vibration ensures a less painful puncture than lancing devices without this feature.

4. CONSTRUCTION OF THE LANCING DEVICE

- A. Lancing device attachment
- B. Lancet holder
- C. Lancet ejector for non-contact lancet removal
- D. Rotating tip for adjusting the puncture depth
- E. Numerical value of the puncture depth
- F. Puncture depth indicator
- G. Release button
- H. Pull button
- M. Attachment holder

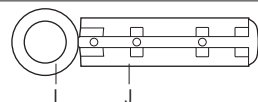


L. The transparent attachment (L) is used to collect blood samples from alternative sites (AST) other than the fingertip. Do not use the transparent attachment to collect a blood sample from the fingertip.

5. CONSTRUCTION OF THE LANCET

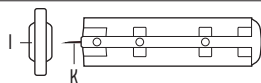
A new lancet after being removed from its packaging

- I. Protective cover
- J. Lancet body

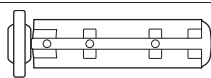


A lancet with the protective cover removed

- K. Lancet needle



A used lancet with the protective cover in place



6. ⚠ IMPORTANT SAFETY INSTRUCTIONS

6.1 When inserting the lancet into the lancet holder (B), ensure that the pull button (H) is not retracted.

6.2 Do not immerse the device in liquid.

6.3 The lancing device can only be used by a single patient.

The device may only be used for the purposes specified in these instructions within the specified target user group. The manufacturer is not liable for damages resulting from improper use of the product.

This device must not be used for blood collection on patients by healthcare professionals in care facilities, clinics or health centres, nor must it be shared with others, including family members. Patients under 18 years of age should use the device under adult supervision.

6.4 Do not reuse the lancet.

Lancets are for single use only. Re-use of the same lancet may blunt or bend the lancet tip, causing skin damage, scarring and more pain. The lancet and lancing device are for single patient use only. They should not be shared with another person. Re-use of the same lancet by another person is associated with an increased risk of microbiological hazards. Infection may occur with hepatitis B, hepatitis C and HIV, among others.

Collecting blood samples from alternative sites – avoid blood collecting from skin where blood vessels are visible or where moles are present to avoid excessive blood flow. Also, avoid collecting blood samples near tendons and bones, such as joints or ankle bones.

6.5 To reduce the risk of infection

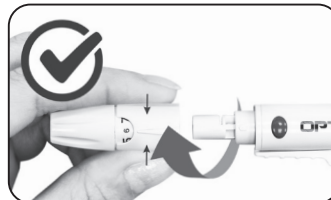
- Wash the puncture site with soap and water before taking the sample.
- Keep the device clean. Cosmetic products, oils, dirt, dust, etc. can cause malfunctions.

⚠ To avoid the risk of infection, always use a new, clean lancet. Lancets are for single use only.

7. STORAGE

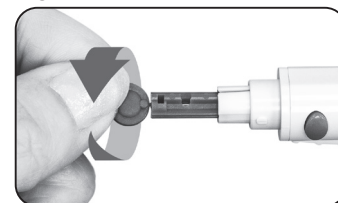
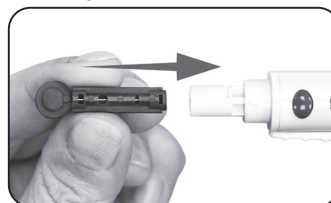
- Keep the device out of reach of small children, people with disabilities, pets and pests.
- The device should be stored in locations protected from adverse environmental influences, e.g. water and moisture, extreme temperatures, shock and falls, dirt and dust, sunlight, heat, cold and corrosive liquids.
- If the lancing device has fallen to the floor or been subjected to other mechanical stresses, check it for any damage or cracks. Do not use if the device is damaged.

8. PREPARING THE LANCING DEVICE



8.1 Unscrew the lancing device attachment (A) and the rotating tip for adjusting the puncture depth (D) together

Carefully unscrew the attachment (A) from the lancing device, grasping it by its holder (M) (indicated by the 2 small black arrows in the illustration above, on the left). **CAUTION:** When unscrewing the attachment, avoid holding the rotating tip (D) that is intended for regulating puncturing depth (in the illustration above, on the right).

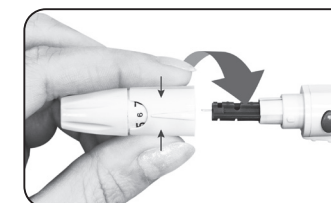


8.2 Place the lancet

Place the lancet in the holder (B) and push all the way in.

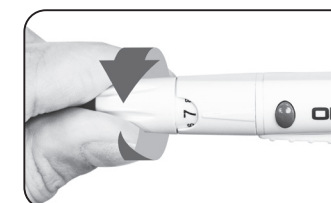
8.3 Carefully take off the lancet protective cover (I) – DO NOT THROW IT AWAY!

Twist and remove the lancet protective cover (I) to disconnect it from the lancet. Put the lancet protective cover (I) aside – it is required for the safe disposal of the lancet.



8.4 Put the lancing device attachment (A)

Screw the attachment (A) onto the device and tighten it fully. Be careful not to touch the exposed needle of the lancet (K).



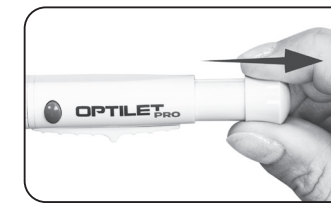
8.5 Depth adjustment setting (D)

By rotating the tip for adjusting the puncture depth (D), you can adjust the puncture depth, selecting numbers from 1 to 9 – smaller numbers indicate a shallower puncture, while larger numbers indicate a deeper puncture.

The selected value is shown by the puncture depth indicator (F). Choose the desired puncture depth to obtain an adequate blood sample with minimal discomfort.

Depth adjustment ranges:

- 1, 2 – for delicate skin
- 3, 4 – for normal skin
- 5, 6, 7, 8, 9 – for thick or calloused skin



8.6 Pull back the lancet button (H) until you hear a click



9.1 REMEMBER! Wash your hands!

Before taking a blood sample, wash your hands and the puncture site with warm water and soap. Rinse and dry your hands well.

9.2 Vigorously massage the intended puncture site

This will ensure you get enough blood for the sample.





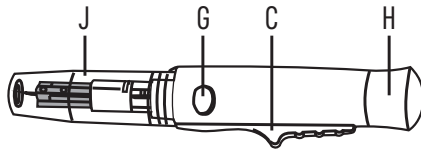
9.3 Collect the blood sample
Apply the lancing device to the side of the finger from which the blood sample is to be taken. Press the release button (G) to perform the puncture.

⚠ **Do not point the lancing device towards your face or towards other people.**

Apply a blood sample to the test strip.

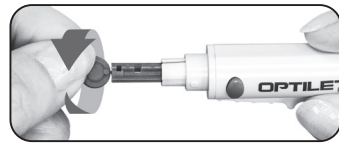
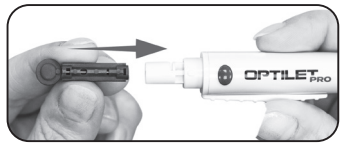
10. PUNCTURING AT AN ALTERNATIVE SITE

- J. Transparent attachment for alternative sites (AST).
- G. Release button
- C. Lancet ejector for non-contact lancet removal
- H. Pull button



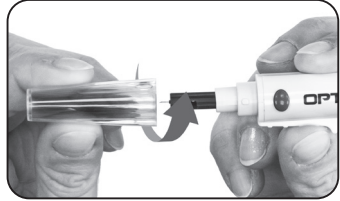
⚠ **IMPORTANT: If you are considering using a puncture site other than the fingertip, consult your doctor.** The transparent attachment for alternative sites (forearm or hand) is designed for use with the Optilet PRO lancing device to take a blood sample.

THIS DEVICE IS INTENDED FOR SINGLE PATIENT USE.



10.1 Insert the lancet into the lancet holder and remove the protective cover.

Insert the lancet into the lancet holder (B) and push firmly (see illustration above, on the left). Twist and remove the lancet protective cover (I) to disconnect it from the lancet (see illustration above, on the right). Put it aside- it is required for the safe disposal of the lancet.



10.2 Put on the transparent attachment for alternative sites.

Put on the transparent attachment for alternative sites instead of the lancing device attachment. When using the attachment, there is no need to adjust the puncture depth.

10.3 Pull back the lancet button (H) until you hear a click.



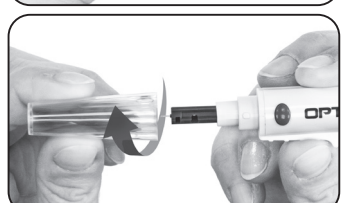
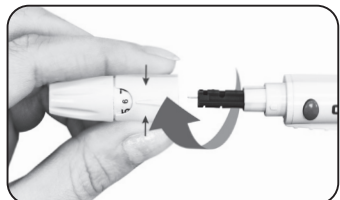
10.4 Hold the transparent attachment over the skin.

Press the lancing device firmly into place and press the release button (G). Wait until there is a sufficient volume of blood in the attachment.

10.5 Carefully lift the lancing device straight up.

Be careful not to smear the blood sample at the puncture site. Apply a blood sample to the test strip.

11. REMOVING THE USED LANCET

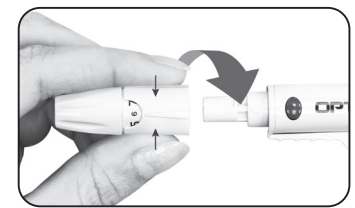


11.1 Remove the lancing device attachment (A) or the transparent attachment (AST)

Carefully remove the attachment (A) or the transparent attachment from the lancing device. Be careful not to touch the exposed lancet.

11.2 Put the cover (I) on the lancet

Before removing the lancet from the lancing device, place the lancet's protective cover (I) on a hard surface (such as a table) and then insert the lancet needle (K) into it. Properly placing the cover will protect you and others from potential exposure to needle sticks and infection.



11.3 Remove the lancet

Slide the lancet ejector (C) forward until the lancet slides out of the lancing device. Remove the used lancet.

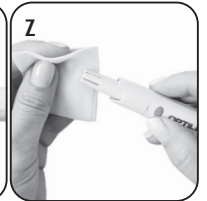
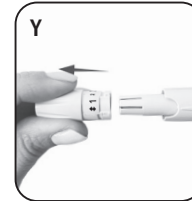
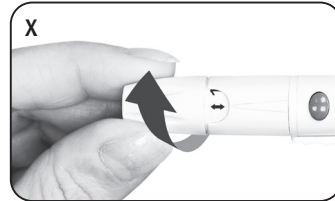
11.4 Put the attachment on

Place the lancing device attachment (A) back on the device. Tighten it until you hear a click.

12. CLEANING AND DISINFECTION OF THE LANCING DEVICE

We recommend that you clean and disinfect your device after each use. This ensures proper device function and reduces the user's risk of infection. Always wash your hands with warm soapy water and dry them thoroughly before cleaning and disinfecting. To clean, wipe the entire surface of the lancing device and attachment with a soft cloth moistened with clean water. To disinfect, wipe these same parts with a soft cloth moistened with 75% ethyl alcohol. Once both steps are complete, let the device dry completely.

12.1 Deep cleaning function



If blood enters the lancing device attachment, rotate the tip for adjusting the depth (D) to the setting: ↔ (Fig. X).

Remove the rotating tip for adjusting the puncture depth (D) from the attachment holder (Fig. Y) and wipe the newly exposed part of the attachment with a soft cloth moistened with the disinfectant solution (Fig. Z).

REMEMBER:

The rotating tip for adjusting the puncture depth (D) can only be reattached to the attachment holder (M) when the depth setting (E) is set to ↔ (Fig. X). After reattaching the rotating tip, set the puncture depth that's right for you.

13. DISPOSAL OF THE LANCING DEVICE

The used lancing device and lancet must be disposed of as infectious material in accordance with current regulations.

14. REPORTING SERIOUS INCIDENTS

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

Terms of use	Storage condition	Product lifetime
10-45°C (50-113°F)	Temperature: 4-30°C (39,2-86°F) Humidity: 15-90% relative humidity	5 years or 5,000 uses

EXPLANATION OF SYMBOLS USED

	Expiration date		Refer to user manual
	Manufacturer		For single use only
	Medical device		Date of the last revision
	Catalogue number		Do not re-sterilize
	Date of manufacture		Warning
	Batch number		Number of pcs. in the set
	Do not use if the packaging is damaged		Sterilised using irradiation
	Unique product type identification code		Single patient, multiple use

Marking for the OPTILET PRO lancing device: REF 5222

Marking for the OPTILETS lancets: 0197

Diagnosis S.A.
Gen. W. Andersa 38A
15-113 Białystok, Poland
www.diagnosis.pl
diagnosis@diagnosis.pl
tel. : + 48 85 732 22 34
fax : + 48 85 732 40 99

If you have any questions on how to use the device, please contact the Helpdesk (Polish language only)
+48 800 70 30 11
free telephone hotline for landlines,
8 a.m. to 4 p.m.; Monday to Friday
+48 85 874 69 28
for mobile phones, call costs are according to the operator's tariff