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Revision 03

Instructions for Use

Product name: Blood Lancet for Single Use

Product model: Model XH

Specifications:

	Needle	**Blade**
Version	☐ XH1 ☐ XH2 ☐ XH3 ☐ XH4 ☐ XH5 ☐ XH6	☐ XH1 Blade ☐ XH2 Blade ☐ XH3 Blade ☐ XH4 Blade ☐ XH5 Blade ☐ XH6 Blade
Penetration depth	☐ 1.2 mm ☐ 1.5 mm ☐ 1.6 mm ☐ 1.8 mm ☐ 2.0 mm ☐ 2.4 mm ☐ 2.8 mm	☐ 1.6 mm ☐ 1.8 mm ☐ 2.0 mm
Needle or blade (width) specifications	☐ 18G; ☐ 19G; ☐ 20G; ☐ 21G; ☐ 22G; ☐ 23G; ☐ 24G; ☐ 25G; ☐ 26G; ☐ 27G; ☐ 28G; ☐ 29G; ☐ 30G; ☐ 31G; ☐ 32G; ☐ 33G	☐ 1.5 mm ☐ 1.2 mm ☐ 1.1 mm ☐ 0.9 mm ☐ 0.8 mm

Manufacturer:

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Device description:

The Blood Lancet for Single Use Model XH is a sterile, single-use medical device intended for capillary blood sampling, designed for healthcare professional and lay users to obtain capillary blood sample for medical testing.

Blood Lancet for Single Use Model XH (Figure 1) is composed of a protective cap, a front spring, housing, needle body with tri-bevel edge needle or blade, a rear spring and a back cover (push button). The needle body with needle or blade is hidden inside the housing/protective cap.

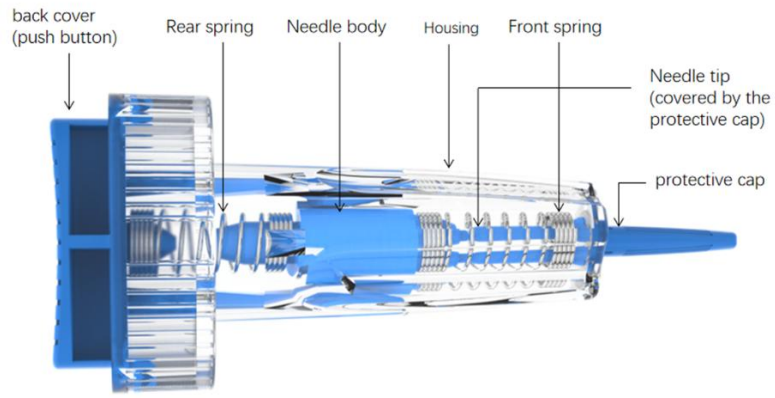

Figure 1. Schematic view of Blood Lancet for Single Use Model XH

Intended purpose: The Blood Lancet for Single Use Model XH is a sterile, single-use medical device intended for capillary blood sampling.

Intended users: healthcare professionals and lay users.

Target patient populations: all populations.

Indications: The Blood Lancet for Single Use Model XH is intended to be used to obtain capillary blood sample to perform medical testing, including blood glucose monitoring and other testing where capillary blood is required. The Blood Lancet for Single Use has no specific indications.

Contra-indications: There are no noted contra-indications for the Blood Lancet for Single Use Model XH.

Instructions for use:

1. Select the puncture site:
   For finger-prick (adults and children over one year old): the middle or ring finger is preferred. Avoid the thumb and index finger because of callus and avoid the little finger because the tissue is thin. The palmar surface of the fingertip shall be used. The puncture should occur across the fingerprints.
   For heel-prick (infants less than one year old): obtaining blood must occur on the medial or lateral plantar surface of the heel.
2. Disinfect the puncture site with alcohol. Allow the site to air dry.
3. Twist off the protective cap and pull it straight out.
4. Position the lancet firmly against the puncture site and push the button to activate the lancet. An audible click indicates the activation.

5. Dispose the used lancet into an approved sharps disposal container in accordance with facility guidelines and local regulations.
6. Wipe away the first drop of blood with a sterile gauze pad. Wait a few seconds to allow the blood drop to form. If the blood drop is too small, gently apply intermittent pressure along finger capillaries up to the puncture site to obtain the required blood volume.
7. Continue with blood glucose testing or other testing. Or, proceed with capillary blood collection according to your facility's established procedures.
8. After the blood collection procedure is complete, apply firm pressure to the site to stop the bleeding.

Warnings and precautions:

- Please read the Instructions for Use carefully before using the product.
- Consult healthcare professionals for the appropriate lancet specification (penetration depth and needle diameter/blade width) if this is not already known.
- The product is for single use only. Do not reuse. Do not resterilise.
- Do not use the product if the protective cap is damaged or unintentionally opened before use.
- If the product is damaged or contaminated, do no use the product.
- Do not use the product if the shelf life has expired.
- Select a puncture site that is warm, pink and free of any calluses, burns, cuts, scars, bruises, or rashes. The site should not be cyanotic (bluish from lack of oxygen), edematous (swollen), or infected. Avoid skin areas that have evidence of previous punctures or are otherwise compromised.
- For finger-prick, avoid the thumb and index finger because of callus, and avoid the little finger because the tissue is thin.
- When collecting capillary blood samples from children, the product shall be operated by their parent or guardian or healthcare professionals.
- For children over 1 year and below 8 years, the penetration depth shall not exceed **1.5** mm for a finger-prick.
- When collecting capillary blood samples for neonate screening, the product shall be operated by healthcare professionals.
- In infants less than one year old, the capillary blood must be obtained from the heel. Obtaining blood must occur on the medial or lateral plantar surface of the heel.
- To collect capillary blood from the heel of infant under one year of age, the penetration depth shall not exceed **2.0** mm, otherwise the calcaneus (heel bone) is at risk of being injured.
- For infants, punctures must not be performed on:
    - The posterior curvature of the heel.
    - The central area of an infant's foot (area of the arch).
    - The fingers of a new-born or infant less than one year old, to avoid injuring the bone.
    - A swollen site.
    - Previous puncture sites.
    - Earlobes.
- To obtain the required blood volume, avoid strong repetitive pressure (milking); it may cause hemolysis or tissue-fluid contamination of the blood specimen.

- This product contains small parts. Keep out of reach of children. Discard the product immediately after use.
- Handle the product carefully to avoid needlestick injuries.
- Dispose the used lancet into an approved sharps disposal container in accordance with facility guidelines and local regulations.

Residual risks and undesirable side-effects:

The product is single use only. Re-using lancets increase the risks of infections and cause wound healing issues (e.g., residual pain, after bleeding, bruising, scarring).

The product is safety lancet designed to prevent needlestick injuries. In very rare cases, needlestick injuries can happen with defective products.

Sterilisation method: Radiation sterilisation (Gamma or Electron beam)

Shelf life: 5 years

Storage: The Blood Lancet for Single Use Model XH shall be stored in dry and clean place. Avoid exposure to strong light. Recommend to store in room temperature.

Symbols:

 Manufacturer 

Authorized representative in the European Community

 Date of manufacture  Use-by date 

Batch code

 Do not use if package is damaged  Do not re-use

Sterilized using irradiation 

Do not resterilize

 Consult instructions for use 

Medical device

 Caution

Incident reporting:

The user and/or patient shall report any serious incident that has occurred in relation to the device to Ningbo Medsun Medical Co., Ltd and the competent authority of the EU Member State in which the user and/or patient is established.