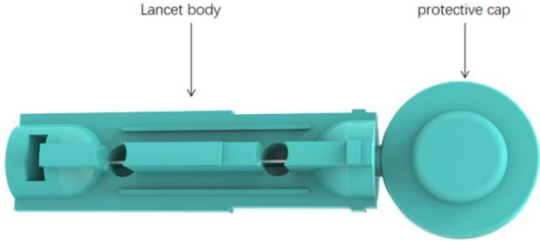
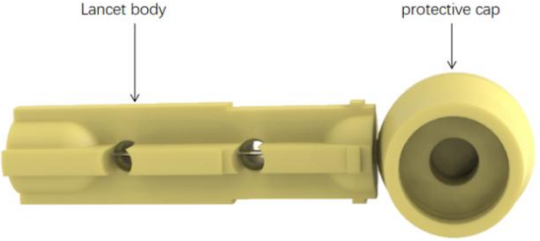
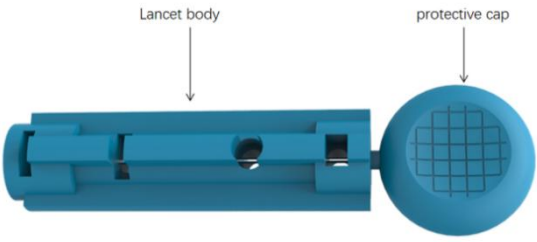
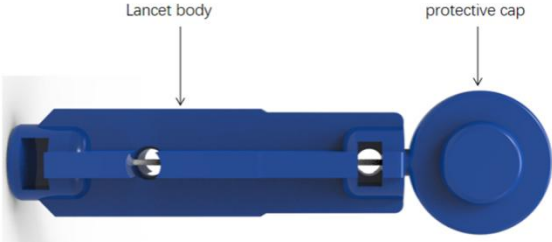
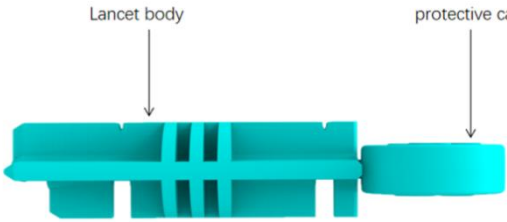
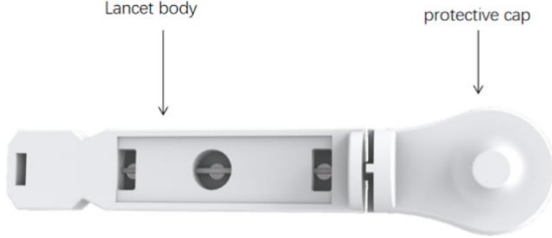


# Instructions for Use

**Product name:** Blood Lancet for Single Use

**Product model:** Model BY

Version	Product Picture
<input type="checkbox"/> BYY	
<input type="checkbox"/> BYY1	
<input type="checkbox"/> BYY2	
<input type="checkbox"/> BYY3	

<input type="checkbox"/> BYY4	
<input type="checkbox"/> BYB	

**Specifications:**

<b>Needle specifications</b>	<input type="checkbox"/> 18G; <input type="checkbox"/> 19G; <input type="checkbox"/> 20G; <input type="checkbox"/> 21G; <input type="checkbox"/> 22G; <input type="checkbox"/> 23G; <input type="checkbox"/> 24G; <input type="checkbox"/> 25G; <input type="checkbox"/> 26G; <input type="checkbox"/> 27G; <input type="checkbox"/> 28G; <input type="checkbox"/> 29G; <input type="checkbox"/> 30G; <input type="checkbox"/> 31G; <input type="checkbox"/> 32G; <input type="checkbox"/> 33G
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**Manufacturer:**

Ningbo Medsun Medical Co., Ltd.  
 No.55 Jinxi Road, Zhenhai, 315221 Ningbo,  
 P. R.China

**European Representative:**

Name: Shanghai International Holding Corp. GmbH (Europe)  
 Address: Eiffestrasse 80, 20537 Hamburg, Germany  
 Tel: 0049-40-2513175  
 Fax: 0049-40-255726  
 Email:shholding@hotmail.com





**Device description:**

The Blood Lancet for Single Use Model BY is a sterile, single-use medical device intended to be used with a lancing device for capillary blood sampling, designed for lay users to obtain capillary blood sample for self-monitoring of blood glucose.

Blood Lancet for Single Use Model BY is composed of a lancet body, a needle and a protective cap. The needle is fully enclosed by the protective cap.

Blood Lancet for Single Use Model BY is compatible with the following lancing devices:

Model	Compatible lancing devices		
	Manufacturer	Lancing devices	Product picture

BYY/ BYY1/ BYY2/ BYY3/ BYY4	Medsun	MEDSUN® CX11A / CX11B1 / CX11C1	
	LIFESCAN Johnson & Johnson	Penlet™ Plus	
	Genteel	Genteel Plus	
BYB	Medsun	MEDSUN® CX11B2 / CX11C2	

**Intended purpose:** The Blood Lancet for Single Use Model BY is a sterile, single-use medical device intended to be used with a lancing device for capillary blood sampling.

**Intended users:** lay users.

**Target patient populations:** adults and children over one year old.

**Indications:** The Blood Lancet for Single Use Model BY is intended to be used to obtain capillary blood sample for self-monitoring of blood glucose. 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 BY.

**Instructions for use:**

1. Select the puncture site for finger-prick: 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. Disinfect the puncture site with alcohol. Allow the site to air dry.
2. Insert a new Blood Lancet for Single Use Model BY into the lancing device.
3. Twist off the protective cap of the lancet.
4. Proceed with capillary blood sampling as described in the Instructions for Use of the corresponding lancing device.
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.
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 and penetration depth setting of the lancing device 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 not 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 setting of the lancing device shall not exceed **1.5 mm** for a finger-prick.
- 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).

**Sterilisation method:** Radiation sterilisation (Gamma or Electron beam)

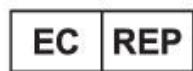
**Shelf life:** 5 years

**Storage:** The Blood Lancet for Single Use Model BY 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.