

Ningbo Medsun Medical Co., Ltd.		
Title: IFU of Blood Lancet for Single Use		NO.: IFU-001
Page: 1/4	Edition/Revision: 01/01	Issue Date: 2020.06.10

[Product Name]: Blood Lancet for Single Use



产品名称：一次性使用采血针

[Product Type]:型号:

- BYY BYY1 BYY2 BYY3 BYY4 BYB
XY1 XY2 XY3 XY4 XY1 Blade XY2 Blade XY3 Blade XY4 Blade
XH1 XH2 XH3 XH4 XH5 XH6 XH1 Blade XH2 Blade XH3 Blade
XH4 Blade XH5 Blade XH6 Blade

[Specification]:规格:

17G、18G、19G、20G、21G、22G、23G、24G、24G、25G、26G、27G、28G、29G、30G、31G、32G、33G

[Intended Use]: 预期用途

The lancet is used for peripheral blood collection when clinical examination. 用于临床检查时的末梢血采集。

[The Combination of the Device with Product]: 设备与产品的结合

Model BYY、BYY1、BYY2、BYY3、BYY4、BYB used with lancing device.

Model XY1、XY2、XY3、XY4、XY1 Blade、XY2 Blade、XY3 Blade、XY4 Blade、XH1、XH2、XH3、XH4、XH5、XH6、XH1 Blade、XH2 Blade、XH3 Blade、XH4 Blade、XH5 Blade、XH6 Blade used independently.

BYY、BYY1、BYY2、BYY3、BYY4、BYB 与采血笔配合使用

XY1、XY2、XY3、XY4、XY1 Blade、XY2 Blade、XY3 Blade、XY4 Blade、XH1、XH2、XH3、XH4、XH5、XH6、XH1 Blade、XH2 Blade、XH3 Blade、XH4 Blade、XH5 Blade、XH6 Blade 型采血针单独使用

[Product Brief Introduction]: 产品简介

Model BYY、BYY1、BYY2、BYY3、BYY4、BYB blood lancet is composed with protective cap, solid needle and handle, a silicone coating is applied to the needle tip;

Model XY1、XY2、XY3、XY4、XY1 Blade、XY2 Blade、XY3 Blade、XY4 Blade blood lancet is composed with Protective cap、Slider、Needle、Short spring、Housing、Needle holder、Long spring、Back cover, a silicone coating is applied to the needle tip, except model XY3、XY4、XY3 Blade、XY4 Blade.

Model XH1、XH2、XH3、XH4、XH5、XH6、XH1 Blade、XH2 Blade、XH3 Blade、XH4 Blade、XH5 Blade、XH6 Blade blood lancet is composed with Springs、Back cover、Housing and Needle holder; Silicone coating is applied to the needle tip, except models XH3、XH4、XH6、XH3 Blade、XH4 Blade、XH6 Blade.

BYY、BYY1、BYY2、BYY3、BYY4、BYB型采血针由保护帽、实心针和连接柄组成，针尖增加硅油层。

XY1、XY2、XY3、XY4、XY1 Blade、XY2 Blade、XY3 Blade、XY4 Blade型采血针由弹簧、后盖、外壳、滑块、保护帽和针体组成。针尖增加硅油层，除XY3型、XY4型、XY3 Blade型、XY4 Blade型。

XH1、XH2、XH3、XH4、XH5、XH6、XH1 Blade、XH2 Blade、XH3 Blade、XH4 Blade、XH5 Blade、XH6 Blade型采血针由弹簧、后盖、外壳和针体组成，针尖增加硅油层，除XH3、XH4、XH6、XH3 Blade、XH4 Blade、XH6 Blade型。

[Instructions for use]: 使用说明

Model BYY、BYY1、BYY2、BYY3、BYY4、BYB

1.Preparation before use

- a) Select proper specification of the lancet per request;
- b) Scrub and disinfect the test site with iodine or alcohol.

Ningbo Medsun Medical Co., Ltd.		
Title: IFU of Blood Lancet for Single Use		NO.: IFU-001
Page: 2/4	Edition/Revision: 01/01	Issue Date: 2020.06.10

2、Instructions

a) When collecting blood, install the lancet in the lancet holder, remove the protective cap of the lancet, and then cover the cap of lancing device. Then align the lancet with the sterilized area and press the button to complete. (See the lancing device manual for the operation method)

c) Once used, simply discard lancet into a sharps container or dispose per the local regulations.

1、使用前准备

- a) 根据使用要求，选取不同规格采血针；
- b) 对采血部位皮肤表面进行擦洗消毒。

2、使用方法

- a) 自动采血时，将采血针安装于采血笔针座中，拧掉采血针的保护帽，然后将采血笔帽盖上。然后让采血笔对准已消毒的部位，按动发射键即可完成。（采血笔操作方法详见采血笔说明书）
- b) 采血完毕后，采血针在使用后收集在仅放置尖锐物的的生物危害容器中。

Model XY1、XY2、XY3、XY4、XY1 Blade、XY2 Blade、XY3 Blade、XY4 Blade

1.Preparation before use

- a) Select proper specification of the lancet per request;
- b) Scrub and disinfect the test site with iodine or alcohol.

2. Instructions

- 1) Remove the protective cap from the lancet;
- 2) Place end of lancet on the test site;
- 3) Push the lancet down against test site to activate the lancet mechanism;
- 4) Once used, simply discard lancet into a sharps container.

1、使用前准备

- a) 根据使用要求，选取不同规格采血针；
- b) 对采血部位皮肤表面进行擦洗消毒。

2、使用方法

取（拧）下保护帽，将采血针对准采血部位，直接向下按动即可弹出针尖，并刺入采血部位实施采血，采血针在使用后收集在仅放置尖锐物的的生物危害容器中。

Model XH1、XH2、XH3、XH4、XH5、XH6 、XH1 Blade、XH2 Blade、XH3 Blade、XH4 Blade、XH5 Blade、XH6 Blade

1.Preparation before use

- a) Select proper specification of the lancet per request;
- b) Scrub and disinfect the test site with iodine or alcohol.

2. Instructions

- 1) Twist and remove the protective cap from the lancet;
- 2) Place end of lancet on the test site;
- 3) Push the lancet button down against test site to activate the lancet mechanism;
- 4) Once used, simply discard lancet into a sharps container.

1、使用前准备

- a) 根据使用要求，选取适用规格的采血针；
- b) 对采血部位皮肤表面进行消毒。

Ningbo Medsun Medical Co., Ltd.		
Title: IFU of Blood Lancet for Single Use		NO.: IFU-001
Page: 3/4	Edition/Revision: 01/01	Issue Date: 2020.06.10

2、使用方法

采血时拧动保护杆，然后拔出保护杆，将采血针对准采血部位，向下按动后盖，即可对采血部位实施采血，采血针在使用后收集在仅放置尖锐物的生物危害容器中。



[Cautions]: 注意事项

1. The lancet is used for the patients need to do blood inspection;
 2. Please read instructions before use;
 3. Select proper specification and depth of the lancet per request. Don't press too much when use.
 4. Improper protection measures, improper handling after use may cause infection, in order to prevent infection, the operator needs to wear gloves, masks and hats;
 5. Please refer to the local regulations when the operator is stabbed or contaminated by blood during proper use.
 6. The lancet is a sterile product and single use. Check the packaging before use. Prohibited to use the lancet with the following conditions:
 - 1) Expired;
 - 2) Damaged package.
 7. Once used, simply discard lancet into a sharps container or dispose per the local regulations.
 8. When a child does the blood sampling, the blood collection should be carried out by the guardian or professional medical staff.
 9. This product contains small parts and there is a risk of suffocation. Please place it in a place that is difficult for children to reach.
- 1、采血针使用对象为需要采血检验的患者；
 - 2、使用前请阅读使用说明书；
 - 3、根据使用要求，选取不同规格采血针和选定刺入深度。采血时，不要用力过猛；
 - 4、防护措施不当、使用后处理不当可能造成感染，为防止感染，操作者需戴手套、口罩、帽子操作；
 - 5、采血针在正确使用过程中操作者被刺伤或被血液溅污时的处理请参照当地法规；
 - 6、采血针为无菌产品，一次性使用。采血针使用前应检查包装，发现下列情况应禁止使用：
 - ① 质保期已过；
 - ② 包装损坏。
 - 7、已用过的采血针放入符合要求的医疗废弃物收集袋中，贴上符合要求的警示标识及标签（标签上注明：产生单位、产生日期、类别和备注），按当地法规处理。
 - 8、采血对象为儿童时，应由监护人或专业医护人员实施采血。
 - 9、本产品含有细小零件，会有窒息风险，请放置于儿童不易触及的地方

[Contraindications]: None **禁忌症: 无**
















[Storage and transportation]: **存储和运输**

1. The lancets should be protected against collision and extrusion to avoid damage to the sealed package and the deformation of the needle body.
2. The products shall be stored in a dry, clean, and well ventilated environment.

Ningbo Medsun Medical Co., Ltd.		
Title: IFU of Blood Lancet for Single Use		NO.: IFU-001
Page: 4/4	Edition/Revision: 01/01	Issue Date: 2020.06.10

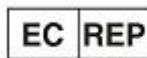
- 1、采血针应谨防碰撞、挤压，以免破坏密封包装和针体变形损坏。
- 2、采血针应储存在干燥，干净，通风良好的环境中。

[Symbols]:符号

	Name and address of the Manufacturer 生产商名称、地址		CE mark and Identification number of Notified Body CE 标志和认证机构的识别号码
	Authorized Representative in the European community 欧盟授权代表		Batch number 批号
	Caution 警告		Date of manufacture 生产日期
	Single use 一次性使用		Expiry date 失效日期
	Read instructions before use 使用前请阅读使用说明书		Keep dry 保持干燥
	Do not use if package is damaged 包装破损请勿使用		Keep out of the sun 怕晒
	Radiation sterilization 辐照灭菌		Handle with care 小心轻放
	Keep upright 向上	---	---



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



Shanghai International Holding Corp. GmbH
(Europe)
Eiffestrasse 80, 20537 Hamburg, Germany