

REF

GIMA 23840	I23204
GIMA 23841	I23105
GIMA 23842	I23106
GIMA 23843	I23108

CE 0123



Berpu Medical Technology Co., Ltd.
No.14 Xingji Road, Yongxing Street, Longwan District,
325000 Wenzhou, Zhejiang Province,
PEOPLE'S REPUBLIC OF CHINA
Made in China



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



Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com



M23840-M-Rev.1.04.25

INSTRUCTIONS FOR USE

Product Name:
Sterile Insulin pen needles for Single Use

Specification:

- OD of Needle : 0.18mm (34G), 0.20mm (33G), 0.23mm (32G), 0.25mm (31G), 0.3mm (30G), 0.33mm (29G), 0.36mm (28G);
- Needle length : 3.5 mm ~ 13 mm;
- Example: The OD of Sterile insulin pen needle for single use is 0.18 mm, Needle length is 4 mm, will be marked as 0.18 x 4 mm;
- The structure and components are shown in Figure 1.

Product Structure:

Schematic representation of Sterile Insulin pen needles for Single Use:

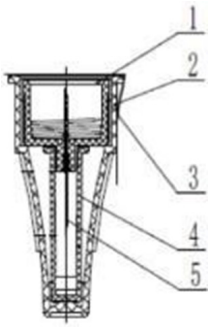


Figure 1. Sterile Insulin pen needles for Single Use
1. Needle hub
2. Hub sheath
3. Sealed paper
4. Needle protective cover
5. Needle tube

Intended purpose:

The Sterile Insulin pen needles for Single Use is intended for medical purpose to use with pen injector devices for the subcutaneous injection of insulin. It can only be used once and shall be disposed as medical waste after use.

Intended users:

In home or medical institution, used by the doctor or patient to inject insulin.

Contraindications:

1. Patients who are told by a doctor that they are not suitable for taking drugs by injection.
2. Inflammation, tumors, and traumatic ulceration were found in the injection site.
3. Severe bleeding, coagulation tendency, platelet, or coagulation factor is significantly reduced or anticoagulant therapy with heparin, dicoumarin.
4. Injection during tetanus attack and rabies spasm may induce paroxysmal spasm.
5. Epilepsy convulsions, psychiatric patients, and uncooperative patients need to be injected under guardianship.

Cautions and Warning:

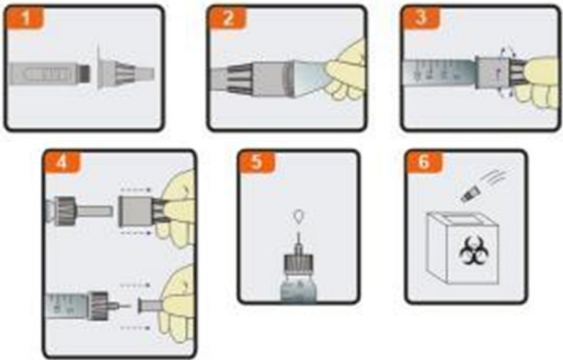
1. Please check the package of this product before use; Do not use if package is damaged.
2. Pay attention to check any foreign substances and impurities in the primary package, and whether the Needle cap dropped off, if any, don't use the product.
3. This product is only for single use and should not be reused. Reuse the product maybe lead to infection.
4. Use it immediately after opening the primary package and disposed as medical waste after use.
5. Use the product before the expiry date marked on the label. The shelf life of the product is 5 years. Don't use the product if the shelf life has expired.
6. This product is strictly prohibited from secondary sterilization.
7. The injection site should not be kneaded by hand.
8. During operation, the user should be careful not to be needlestick.
9. Make sure that the Needle tip is not damaged or any burrs before use. If so, do not use it.
10. This product should be stored in a cool, dry, clean, well-ventilated environment without corrosive gas.

Potential complications:

1. Pain;
2. Injection site bleeding;
3. Redness;

How to use:

1. Prepare the insulin pen syringe per its instructions;
2. Tear out sealed paper on hub sheath of the insulin pen needle;
3. Connect the insulin pen syringe to the insulin pen needle, and tighten in a clockwise direction;
4. Take out the needle from its hub sheath and needle protective cover vertically;
5. Exclude the air inside the syringe, and inject the fluid;
6. After injection, discard the insulin pen needle in the nearest sharps collector or per your site policy.



Sterilization:

EO Sterilization.

Shelf life:

5 years.

Signs and Symbols Used on Labels:

Symbol	Description	Symbol	Description	Symbol	Description
	Imported by		Lot number		Country of manufacture and date of manufacture
	Use-by date		Sterilized using ethylene oxide		Caution: read instructions (warnings) carefully
	Disposable device, do not re-use		Don't use if package is damaged		Medical Device
	Do not re-sterilize		Authorized representative in the European community		Manufacturer
	Medical Device compliant with Regulation (EU) 2017/745		Consult instructions for use		Unique device identifier
	Keep away from sunlight		Keep in a cool, dry place		Single sterile barrier system
	Fragile, handle with care		Product code		Not made with natural rubber latex

Storage conditions:

The product should be stored in a dry room with excellent ventilation and without caustic gases.

Transportation conditions:

The product shall be protected from hook, heavy pressure and rain during normal transportation.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies