

	 <p>Aditya Dispomed Products Pvt. Ltd. Plot No 19, Sector 6, IMT Manesar, Gurgaon-122050, Haryana, India T: +91 124 4764900 <a href="http://www.adityadispomed.com">www.adityadispomed.com</a></p>	<p><b>Document</b> IFU 08 <b>Revision</b> 06 <b>Date</b> 18-03-2025</p>
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## INSTRUCTIONS FOR USE

### STERILE DISPOSABLE SAFETY SCALPEL

**DESCRIPTION:**

**Disposable Safety Scalpel** is a advanced version of disposable scalpels consisting of a Stainless Steel surgical blade mounted permanently on a plastic handle and movable sheath having in built safety features during pass, use and dispose. Scalpels are packed in Peel Apart foil pouches. Device is intended for single use and is sterilized by/through Gamma Irradiation/ ETO.

Labelling and Marking of blades is fully compliant with the requirements of MDD/93/42/EEC, EU MDR 2017/745, EN ISO 20417:2021, BS 2982:1992. & EN ISO 15223-1:2021.

**INTENDED USE:**

- These are used for surgery & surgical incision.

**INDICATION:**

- Dissection incision
- Different size for different thickness of tissue and skin.
- Removal of extra tissues from operating area.

**INTENDED USER**

This device must be used by surgeon, doctor or paramedic staff who are trained and qualified in the appropriate surgical techniques.

**PATIENT TARGET GROUP**

Device can be used for all age patients group based on decision by surgeon, doctor or paramedic staff.

**CONTRAINDICATIONS:**

- Re-use of Scalpel can work as carrier for communicable disease to patient and/or user
- Adverse event may happen if Scalpel are used after expiry date of product sterility

**STORAGE CONDITION:**

- Keep away from direct sun light.
- Keep away from rain
- Storage temperature should be 5°C to 45°C
- Keep away from children
- Store in cool and dry place.

**SHELF-LIFE:**

5 Years (60 months) from the date of manufacturing

**PRECAUTIONS:**

- This device must only be used by surgeons who are trained & qualified in the appropriate skills.
- Care must be taken so that the pouch is not opened in an unsterile area otherwise the blade which has already been sterilized may become unsterile.
- Don't use if product or pouch appear to be damaged
- For single patient use only content supplied sterile
- During use avoid twisting, bending or putting excessive force or strain on the blade in order to prevent breakage.
- Always open the pouch from peel apart direction to avoid injury.
- Devices are extremely sharp, use care while handling.
- Proper procedures must be used as applicable for handling any sterile product.
- Care must be taken during disposal of device to avoid any contact or injury due to the sharp nature of the device.
- In case of changes in the performance of device for intended use replace the defective device by new to full fill the required application



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## USE

- Inspect the packaging to confirm its integrity before opening
- Use as per instruction in the attached sheet
- Dispose protected scalpel in an approved sharps container

## DISPOSAL:

Discard the Scalpels in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste



## WARNING

- Read instruction for use
- The product should be used only by a qualified surgeon, Doctor or paramedic.
- Before use always check integrity of product and packing along with expiry date.
- For single use only, If re-used this can work as carrier for communicable disease, HIV, Hepatitis, contagious diseases, undue diseases to patient and/or user
- Use product immediately after opening the pack
- ADPPL is not responsible for any possible consequences resulting from improper use.
- ADPPL do not hold any responsibility if device re-used or re-sterile.
- Sterility of product is not guaranteed if packet is broken/torn.
- Keep out of reach of children.
- After use of products must be disposed off as per country law of bio-waste handling rule
- The device does not include any measuring function. The scale provided on the handle of the device is only for indicative purpose and device is not measuring function

## KNOWN CHARACTERISTICS OF DEVICE & TECHNICAL FACTOR FOR THE RISK IN CASE OF RE-USE

- Difficult to cut at incision site during reuse.
- Any infectious disease can transfer.
- In case of reuse of device may cause communicable and transferable disease from the device.

## RETURN OF DEVICE

The documents & papers required for return of defective device and in compliance of law of the land for origin and destination shall be provided to ADPPL within a week (subject to any natural calamity) of receipt of the product along with the photograph & inspection report as an evidence of damaged product and the product shall not be used under any circumstances & it should be separately with proper identification of damaged goods.

## NOTICE TO THE USER




















**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 and/or patient is established. The details for the notice to the manufacturer of any serious incident can be reported through our web site**

**[www.adityadispomed.com](http://www.adityadispomed.com) and customer complaint contact T: +91 124 4764900.**

**In case of reporting to regulatory authority/competent authority of the member state as per law of the land for reporting of such incidents as per the regulation where the user is established.**



**SYMBOLS**

	Batch code		Catalogue number		Use by date
	Do not re-use		Caution, consult instruction for use		Do not use if package is damaged and consult instructions for use
	Keep dry		Keep away from heat		Do not re-sterilize
	Temperature Limitation		Consult instruction for use		Non-pyrogenic
	Sterilized using Irradiation		Sterilized using ethylene oxide		Medical Device
	Manufacturer		Authorized representative in the European Community		CE Mark with NB Number
	Country of Manufacturer				

The same IFU is available on our web site

## PROCEDURES FOR USE OF STERILE DISPOSABLE SAFETY SCALPEL

### 1. Ship/Pass position:

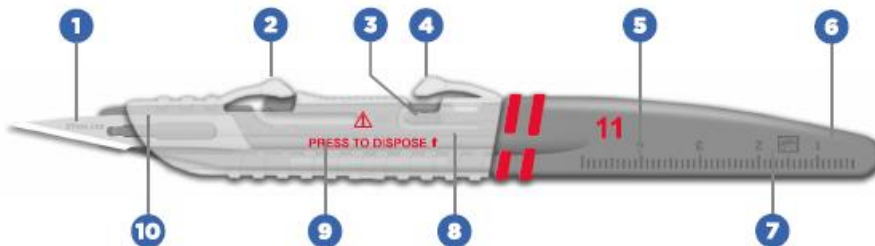
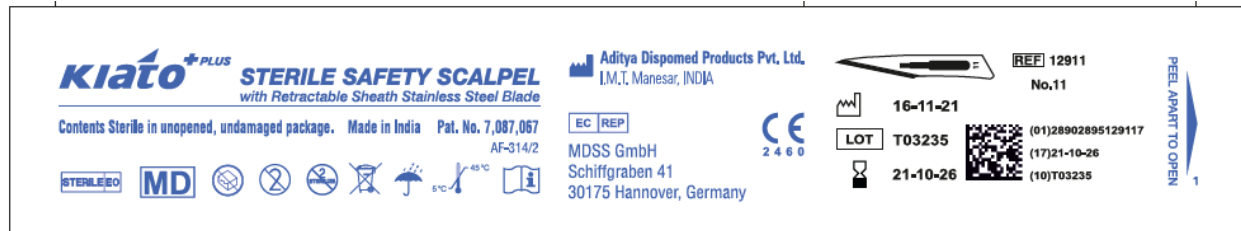


The retractable sheath securely covers the blade fully. The release button (latch) must be released to retract the sheath backwards to the Use Position. The sheath does not retract backwards without activation.

### 2. Use position:



The Surgical Blade is exposed and ready for use. Audible click confirms sheath is fully retracted.

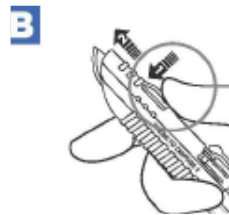


1. Firmly mounted stainless steel blade
2. Release button marked OFF
3. Dispose button
4. Release button marked ON
5. Graduated Scale
6. Ergonomically designed rigid handle
7. Fitment no
8. Rails on both sides
9. Usage instruction
10. Safety sheath cover



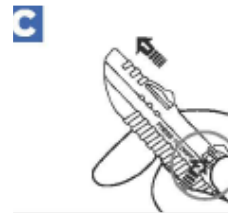
#### A. To Use

Press release button marked "ON" to depress latch on handle and retract sheath fully until it clicks. The blade is now exposed, and the sheath is locked in the "USE" position



#### B. To Pass

Press release button marked "OFF" and slide sheath forward in initial position until it locks in the "PASS" position



#### C. To Dispose

Slide sheath to "pass position" Push dispose button inward in the handle until it clicks and locks Dispose in an approved sharps container



### DISPOSAL:

Discard the Scalpels in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.