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## **INSTRUCTIONS FOR USE NON STERILE DISPOSABLE SCALPEL & THUMB SCALPEL**

### **DESCRIPTION:**

**Scalpels** consists of a Stainless Steel surgical blade mounted permanently on a plastic handle. Plastic Cover is provided to prevent the edge from getting damaged during transit. They are packed in bulk packing. 50 pcs to a poly bag. 2 Poly bags to an inner case.

Labelling and Marking of blades is fully compliant with the requirements of MDD/93/42/EEC, EN 1041, BS 2982:1992 & EN ISO 15223:2021.

### **INTENDED USE:**

- These are used for General Surgery & Surgical Incision
- Device is non Sterile for single use and for all age patient groups.
- It should be sterilized prior to use. The product is compatible for sterilisation by ETO.

### **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 surgeons who are trained and qualified in the appropriate surgical techniques.

### **CONTRAINDICATIONS:**

- Re-use of blade can work as carrier for communicable disease to patient and/or user
- Product should not be used without sterilization at user end
- The Selection of blade size other than the required may affect the intended Application of the device

### **STORAGE CONDITION:**

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

### **PRECAUTIONS:**

- Always remove scalpel from poly bag carefully to avoid injury.
- This device must only be used by surgeons who are trained & qualified in the appropriate skills.
- For single patient use only. Sterilise before use
- During use avoid twisting, bending or putting excessive force or strain on the blade in order to prevent breakage.
- Devices are extremely sharp, use care while handling.
- Care must be taken during disposal of device to avoid any contact or injury due to the sharp nature of the device.
- Blade is intended to cut cleanly without tearing the skin of patient.
- In case of changes in the performance of device for intended use replace the defective device with a new one to full fill the required application

### **USE**

- Remove plastic safety shield taking care not to damage blade
- Select proper type and size of Blade as per the site, always use bigger size for thick tissue and smaller for fine soft tissue. After selection clean the surgery site with proper disinfectant
- Incision must place as per the desired length preferably measured and marked.



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## INSTRUCTIONS FOR USE NON STERILE DISPOSABLE SCALPEL & THUMB SCALPEL

### DISPOSAL:

Discard the Scalpels in proper sharps disposal 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.
- Keep out of reach of children.
- 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
- 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.
- After use the scalpel 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 IN CASE OF RE-USE

- Difficult to cut at incision site during reuse.
- Any infectious disease can transfer.

### 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 as soon as possible after 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 separated with proper identification of damaged goods.

### SYMBOLS

	Batch code		Catalogue number		Do not re-use
	Caution, consult instruction for use		Keep dry		Don't Resterilize
	Keep away from heat		Consult instruction for use		Don't use if package is damaged
	Temperature Limitation		Non Sterile		Manufacturer



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### Sterilization Instructions

1. Place device into a kit or sterilization tray.
2. Using Ethylene Oxide sterilization method, sterilize according to the following parameters

Chamber Cycle Parameter	Specification
Concentration of Ethylene oxide	750 gm/m <sup>3</sup>
Exposure time	6 hours
Humidity Minimum	50% Rh
Temperature	45-50°C

### RECOMMENDED PROCEDURES FOR DISPOSABLE SCALPEL & THUMB SCALPEL

#### Product Image

Disposable Scalpel

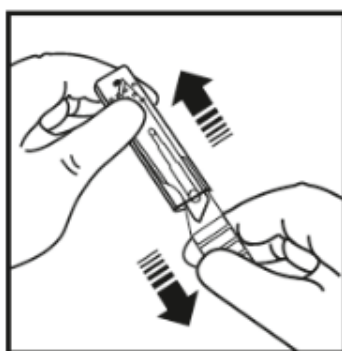


Thumb Scalpel



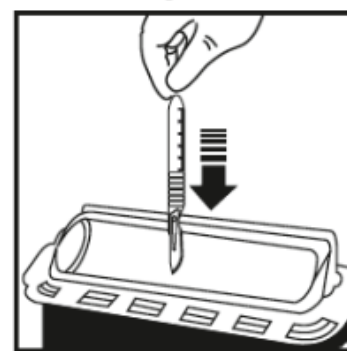
#### Use

##### To Use



Remove plastic safety shield taking care not to damage blade.

##### Disposal



Dispose scalpel in an approved sharps container.

#### DISPOSAL:

Discard the Scalpels in a proper sharps disposal 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