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INSTRUCTIONS FOR USE

NON STERILE BULK DISPOSABLE SAFETY SCALPEL

DESCRIPTION:

Disposable Safety Scalpel is an advanced version of the disposable scalpel having inbuilt safety features to facilitate Pass, Use and Dispose. The safety features enable the product to meet OSHA guidelines and to minimise the risk of sharp injuries. The product consists of a handle with a permanently mounted stainless steel surgical blade and retractable safety cap that can be permanently locked for safe disposal. Usage instructions are clearly marked or printed on the product itself. It is offered in 2 different sizes. A smaller one for fitment 3 blades and a slightly larger one for fitment 4 blades.

It is sold in bulk packing. 50 pcs to a poly bag. 2 Poly bags to an inner case.

Labelling and Marking of the safety scalpel 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 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.
- In case of changes in the performance of device for intended use replace the defective device with a new one to fulfill the required application

USE

- Use as per instruction in the attached sheet
- Dispose protected scalpel in an approved sharps container.



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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 |



NON STERILE BULK DISPOSABLE SAFETY SCALPEL

RECOMMENDED STERILIZATION INSTRUCTIONS

- Place device into a kit or sterilization tray with brightly coloured Spacer piece fitted as can be seen from the image.

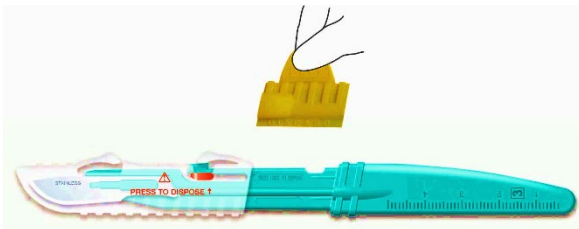


- Using Ethylene Oxide sterilization method, sterilize according to the following parameters

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

RECOMMENDED USAGE INSTRUCTIONS

- Remove Spacer



- Ship/Pass position:

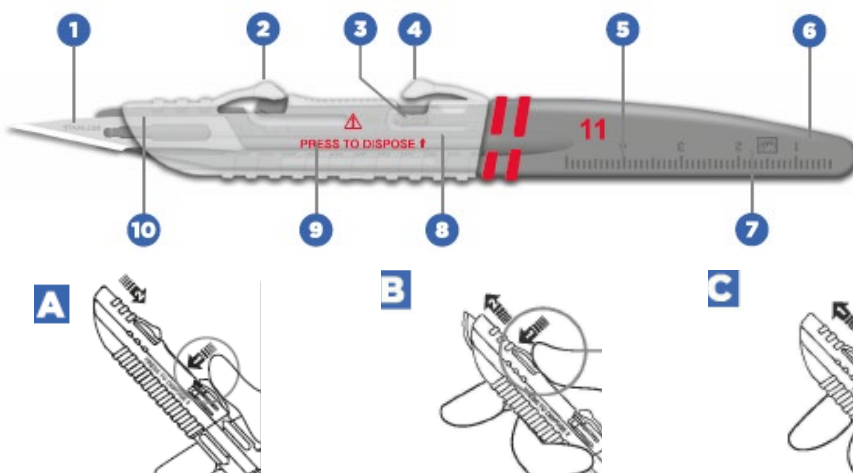


The retractable sheath securely covers the blade fully. The release button (latch) must be released to retract the sheath backwards to the Use Position. The sheath does not retract backwards without activation.

- Use position:



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



- Firmly mounted stainless steel blade
- Release button marked OFF
- Dispose button
- Release button marked ON
- Graduated Scale
- Ergonomically designed rigid handle
- Fitment no
- Rails on both sides
- Usage instruction
- 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 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.