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(English)

PRODUCT

Surgical Blade (Sterile), GMDN Code: 37445

(Sizes: 9,10,10A,11,11P,12,12B,12D,13,14,15,15A,15B,15C,15T,16,17,18,19,20,21,22,22A,23,24,24D,25A,26,27,34,36,36D,60,PM40,PM40B,PM60,PM60B)

(Carbon Steel and Stainless Steel) Sterilized by Gamma radiation of minimum 25 kGy

Device Description: Surgical Blade is made of Stainless steel (Grade F) and Carbon steel (As per BS 2982). The Blade is packed in peel apart Aluminum Pouch with VCI liner to protect the blade from corrosion. The device is sterilized by Gamma Radiation & Expiry is 5 years from the date of manufacturing.

Intended Use : The device is used for incision/ cuts during surgery for all blade sizes. The device is under category of surgically invasive device and for transient use. The device is contact with intact skin and mucosal membrane.

Mode of action: Surgical blade is made of Stainless-steel / Carbon steel strip. Consistently sharp, angled cut blade facilitates a clean cut. It can directly use after mounting on metal B.P. handle compiling to ISO 7740 /EN27740 with specific shaft of fitment 3 & 4 according to the blade size.

Indications

- ❖ Dissection Incision.
- ❖ Different size for different thickness of tissue & sight.
- ❖ Removal of extra tissue from operating area.

Contraindications/Residual Risk

- ❖ Re-used of blades can work as carrier for communicable disease to patient and/or user.
- ❖ Adverse event may be happened if blades are used after expiry date as expiry date of product is expiry date of sterility.
- ❖ The Selection and size other than required may affect the intended application of device
- ❖ Do not use other than Surgical surgery
- ❖ Do not use if patient is allergic with metal.
- ❖ Do not use in cardiovascular and neurovascular surgeries.

Patient Target Group: The device can be used on all group of patients.

Intended Users: The device shall be used by qualified surgeon, doctor, or paramedical staff.

Preparation for decontamination: No requirement

Application of the body: Intact Skin & Mucosal membrane.

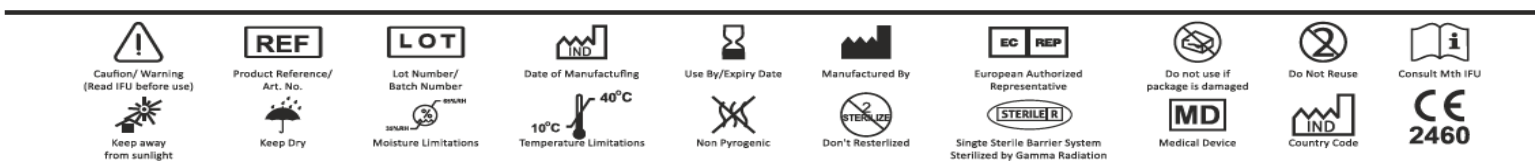
Cleaning automated: No cleaning is required before use of the device.


Cleaning manual: No cleaning is required before use of device.

Disinfection: No disinfection required

Maintenance: No requirement

Inspection & function testing: Check for smooth functioning of medical device. Visually inspect for damage.



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Additional information: NA

Description of component parts: None

System Preparation: Check the label for manufacturing and expiry dates (do not use the medical device after expiry). Make sure the package is not damaged. Visually examine the pouch to see if there are any damages.

INSTRUCTIONS FOR USE

- ❖ Select proper type and size of Blade as per the requirement.
- ❖ Inspect package of Blade for its intactness & expiration date.
- Attaching the Surgical Blade**
- ❖ Peel open pouch as in figure 1. Grip blade with forceps or needle clamp and remove from pouch, taking special care not to grip across the cutting edge of the blade itself.
- ❖ Holding on to the thickest part of blade with forceps or needle clamp, insert the handle into blade track. Slide blade back onto handle until it clicks into position as in figure 2.
- Removing the Surgical Blade**
- ❖ Grip bottom of blade with forceps/needle clamp and pull up to loosen blade from handle.
- ❖ Push blade forward from handle to remove blade, being careful not to jerk the blade off the track as in Figure 3.
- ❖ Dispose in approved puncture-resistant sharps container according to facility protocol and all applicable state, regional, and/or local laws and regulations.
- ❖ During the surgical procedure, use a containment method of choice, to protect Surgical team from any sharp's injuries, such as a plastic kidney dish.

Figure 1

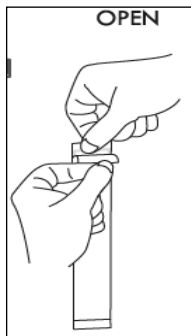


Figure 2

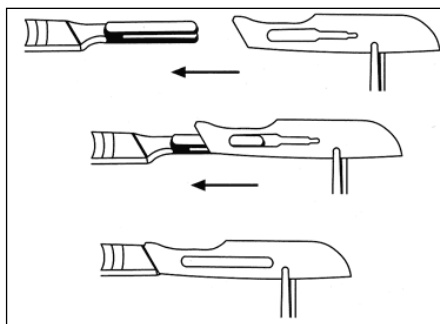
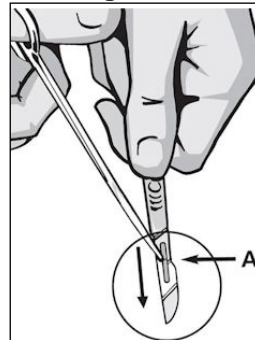



Figure 3



WARNING

- ❖ Read instruction for use.
- ❖ The product should be used only by a qualified surgeon, Doctor or paramedical staff.
- ❖ 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.
- ❖ Do not use excessive force or use with inappropriate equipment
- ❖ KSPL is not responsible for any consequences resulting from improper use.
- ❖ KSPL do not hold any responsibility if device re-used or re-sterile.
- ❖ Sterility of product is not guaranteed if packet is broken/torn.
- ❖ Re-sterilization and re-use of blade cause to change in mechanical properties and material used.

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- ❖ Re-sterilization and re-use of blade may not meet the intended use as blade may be blunt.
- ❖ Keep out of reach of children.
- ❖ After use of products must be disposed of as per country law of bio-waste handling rule.

PRECAUTIONS:

- ❖ Always open the pouch from peel apart direction to avoid injury.
- ❖ Devices are extremely sharp, take care while handling.
- ❖ Care must be taken so that the pouch is not opened in an unsterile area, otherwise, the Blade which has already been sterilized by Gamma radiation will become unsterile. 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.
- ❖ Proper care must be taken while getting Blade from the tray to avoid any injury or Accident.
- ❖ In case of changes in the performance of device for intended use replace the defective device by new to full fill the required application.

KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

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

STORAGE CONDITION:

- ❖ Keep away from direct sun light.
- ❖ Keep away from rain
- ❖ Storage temperature should be 10°C to 40°C
- ❖ Humidity of storage area should be 35% RH to 65 % RH.
- ❖ Keep away from children.
- ❖ Store in cool and dry place.

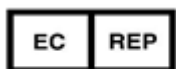
DISPOSAL SYSTEM: Discard the Surgical Blade in proper waste container & dispose of the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.

PACKAGING: The device is supplied in box of 10, box of 20 & box of 100. The box contained heat-sealed Aluminum peel pouches with external identification on the box.

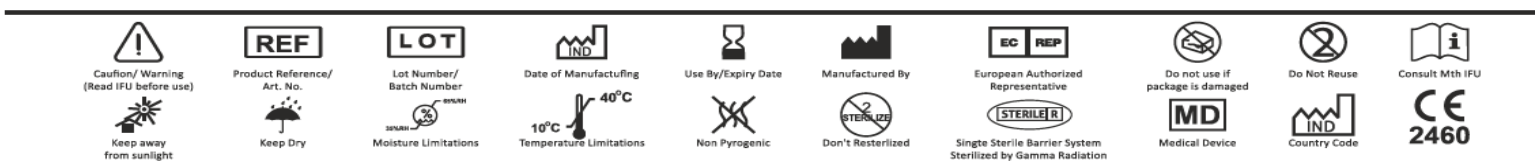
RETURN OF DEVICE : The return of defective device it should be carried out within a week of receipt of the product along with the evidence or damaged product and the product should not have been used under any circumstances, at any condition.


ADVERSE EVENT: The improper use / misuse of device may occur adverse event to patient or user e.g. deep cut, injury to user during fitment of blade. Any serious incident that has occurred 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.

ELECTRONIC VERSION OF IFU: Available on the website



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