

 **INSTRUCTION FOR USE**

PRODUCT

Safety Scalpel (Sterile)

(Sizes: 10, 10A, 11, 11K,13, 15 ,15B, 15C, 15D, 17, 18, 19, 20, 21, 22, 23, 24, 24D, 25, 36,)

(Carbon Steel and Stainless Steel, ABS Plastic)

Sterilized by Gamma radiation of minimum 25 kGy and not more than 32 kGy (2.5 M Rads to 3.2 M.Rads)

INSTRUCTION FOR USE (IFU)

INTENDED USE

The device is used for incision/ cuts during surgery. The device is under category of surgically invasive device and for transient use. It is covering under surface device (nature of body contact) and contact with intact skin and mucosal membrane. Scalpel blade is retracted inside the inbuilt protection body and does not need to remove any protection cap before used by Surgeon reduce the risk of blood borne and sharp edge injury. The device is invasive device and for transient use.

MODE OF ACTION:

The grip of handle and angled cut blade facilitates a clean cut during the incision. It can directly use for incision after opening from the primary pack

INDICATIONS

- Dissection Incision.
- Different size for different thickness of tissue & sight.
- Removal of extra tissue from operating area
- Do not use in cardiac/ ophthalmic surgery.

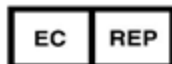
CONTRAINDICATIONS

- 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.

INSTRUCTIONS

- Inspect package for its intactness, expiration date.
- Peel off the device from the soft blister individual packing from pouch peel open side.
- To open for use, place thumb on button of sheath and retract backward until blade is exposed and shield is secured with click sound.
- To close, but not permanently lock, place thumb on button of sheath and push forward to the first catch. At this position, Scalpel may be reopened and closed again.
- Incision must place as per the desired length preferably measured and marked.
- After Use to dispose off the scalpel, press the sheath button with thumb and fully retract forward and then push the button. It will give a click sound and will permanently locked. At this position, Safety scalpel is safely covered and permanently locked for disposal.

	Keep away from sunlight
	Moisture limitation
	Temperature limitation
	Do not use if package is damaged
	Consult for IFU
	Non-Pyrogenic
	Caution/ Warning (Read IFU before use)
	Product reference/Art. No.
	Do Not Reuse
	Lot Number/Batch Number
	Date of Manufacturing
	Use By / Expiry Date
	Single sterile barrier sterilized by gamma radiation
	European Authorized Representative
	Manufactured by
	Do not resterilize
	Keep dry



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Medical Device symbol

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 **INSTRUCTION FOR USE**

 **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
- PARAMOUNT is not responsible for any possible consequences resulting from improper use.
- PARAMOUNT 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 device cause to change in mechanical properties and material used
- Re-sterilization and re-use of device may not meet the intended use as blade may be blunt
- Keep out of reach of children.
- After use, 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, use care while handling.
- Care must be taken so that the pouch must not open in an unsterile area otherwise the device 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 use of the device 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

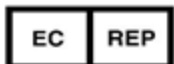
KNOWN CHARACTERISTICS OF DEVICE IN CASE OF RE-USE

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

STORAGE CONDITION:

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

DISPOSAL SYSTEM



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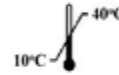
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Keep away from sunlight



Moisture limitation



Temperature limitation



Do not use if package is damaged



Consult for IFU



Non-Pyrogenic



Caution/ Warning (Read IFU before use)



Product reference/Art. No.



Do Not Reuse



Lot Number/Batch Number



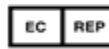
Date of Manufacturing



Use By / Expiry Date



Single sterile barrier sterilized by gamma radiation



European Authorized Representative



Manufactured by



Do not resterilize



Keep dry



Medical Device symbol

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 **INSTRUCTION FOR USE**

Discard the Device in proper sharp 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

RETURN OF DEVICE

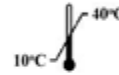
The return of defective device should be carried out within a week of receipt of the product along with the evidence or damaged product and the product should not have been used under any circumstances, at any condition.



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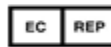
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