PRODUCT

SHARD® Disposable Scalpel (Sterile) GMDN Code: 47569

(Available Sizes: 10, 11, 12, 15, 15C,)

(Stainless Steel, ABS Plastic, LDPE) Sterilized by Gamma radiation of minimum 25 kGy

DEVICE DESCRIPTION

Disposable Scalpel is made of stainless-steel blade fitted on the ABS handle and guarded with LDPE cap. The scalpel is packed in soft blister pouch. 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. The device is under the category of surgically invasive device and for transient use. The device is contact with intact skin and mucosal membrane.

MODE OF ACTION:

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

INDICATIONS

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

CONTRAINDICATIONS/ RESIDUAL RISK

- Re-use of blades can work as carrier for communicable disease to patient and/or user.
- Adverse events may happen 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, ophthalmic surgery & neurovascular surgeries.

PATIENT TARGET GROUP

The device can be used on all groups of patients.

INTENDED USERS

The device shall be used by qualified surgeons, doctors, or paramedical staff.

PREPARATION FOR DECONTAMINATION:

No requirement

APPLICATION ON THE BODY:

Intact Skin & Mucosal membrane.

CLEANING AUTOMATED:

No cleaning is required before use of the device.

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CLEANING MANUAL:
No cleaning is required before use of the device.

DISINFECTION
No disinfection required.

MAINTENANCE
No requirement

INSPECTION & FUNCTION TESTING:
Check for smooth functioning of medical device. Visually inspect for damage.

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 is any damage.

INSTRUCTIONS FOR USE

- Select proper type and size of scalpel as per the sight, always use bigger size for thick tissue and smaller for fine soft tissue.
- After selection clean the sight with proper disinfectant
- Inspect package for its intactness & expiring and then remove scalpel from package.
- With grip on handle choose the sight for incision.
- Incision must be placed as per the desired length preferably measured and marked.

WARNING

- Read instructions 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 dieses, undue diseases to patient and/or user
- Use product immediately after opening the pack.
- Do not use excessive force or use inappropriate equipment.
- Factory and distributor are not responsible for any possible consequences resulting from improper use.
- Factory and distributor 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.
- 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

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PRECAUTIONS:

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 sunlight.
- Keep away from rain.
- Storage temperature should be 50°F to 104°F / 10°C to 40°C.
- The humidity of storage area should be 35% RH to 65 % RH.
- Keep away from children.
- Store in a cool and dry place.

DISPOSAL SYSTEM

Discard the Device in proper waste container & dispose of the Product in accordance with accepted medical practice and applicable local, state and country laws and regulations or handling of bio-medical waste.

PACKAGING

The device is supplied in boxes of 10. The box contains soft blister pouches with external identification on the box.

RETURN OF DEVICE

The return of defective devices should be done as soon as possible. Damaged products should not be used under any circumstances, at any condition.

ADVERSE EVENT:

The improper use / misuse of device may cause 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 www.AD-Surgical.com

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