Universal

Dermark (Skin Marker)

REF **GS-6028, UN65-B**

INSTRUCTIONS FOR USE

⚠ **Caution:** Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions. Failure to do so may result in complications. To be administered by a professionally competent, qualified / a trained paramedic person. This device is Sterile & Ready for Use. Sterility is guaranteed -if pack is undamaged. The device is for Single Use Only.

Device Description: Surgical Skin Marker Pen with Ruler is a specific type of pen used to outline/mark the surgical incision site on the skin for surgery preparation. Marking ink is Gentian Violet colour ensures easy visibility. The marking ink gentian violet is a traditional marking agent for use as Surgical Skin marker. Ruler is packaged with skin marker is not measuring device and should be used as an indicator only, Individually packed in a peel open pack.

Population of Use: Adult & Paediatrics.

Intended User: To be administered by an expert qualified medical professional.

Intended Use: Skin marker is used for surgical marking on intact skin.

Preferred Route of Administration: Surgical incision site on intact skin.

Contents: One unit Skin marker with ruler.

Size: Standard.

Material of Construction: Polyester, PET, Gentian Violet, Polypropylene, Master Batch.

Storage: Store in a cool & dry place. 5°C - 40°C.

Indications : Preoperative marking , Surgical incision site on the skin.

Contraindications : Not to be used in patients with known hypersensitivity to any of the materials used or allergy to Gentian Violet (crystal violet) dye, Skin Allergy, Burns & Wounds, Not to be used on broken skin.

Potential Complications/Risks : Inadequate Marking due to inadequate dryness of ink, due to excessive oily skin.

Warnings: This device is intended for Single use only.

DO NOT reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factor, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing. Do not put the Device to use after the Use by Date or after the Date of Expiry.

Re-use of single use device creates a potential risk for patient or use. It may lead to contamination and/or impairment of functional capability. Contamination and / or limited functionality of the device may lead to injury, illness of the patient.

Precautions :

(i) Determine patient's condition and vitals status during device application / Operation.
(ii) Discard the device after single patient use.
(iii) Check the integrity of the Device before use.
(iv) Dispose the device & its accessories after single use as bio-medical waste as per applicable laws.
(v) Rulers packaged with skin markers are not measuring device and should be used as an indicator only and not for accurate measurements.

Adverse Events : Hypersensitivity to device material , Skin Allergy , Inadequate Marking.

General Instructions : To be administered by a professionally competent, qualified / a trained paramedic person.

Use Instructions :

1. Check the packing carefully, Do not use if packing is found damaged, torn or pierced Discard the piece.
2. Wash up and scrub hands and preferably use pre-sterile protective Gloves.
3. Peel-open the sealed packed paper pouch of the Surgical Skin Marker. Remove the Surgical Skin Marker Cap.
4. Mark gently on skin at required location.
5. Cap the Surgical marker & keep the marker in horizontal position.

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GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELLING

- STERILE EO — Sterilized Using Ethylene Oxide
- Country Of Manufacture
- Single Use Only
- Do Not Re-sterilize
- REF — Catalogue Number
- Manufacturer
- Non-pyrogenic
- Temperature Limit
- Single Sterile barrier system
- Do Not Use if Packing is Damaged and Consult Instruction for use
- Keep Dry
- Keep away from sunlight
- Instructions For Use
- Use by date
- Date of Manufacture
- LOT — Batch Code
- Caution
- MD — Medical Device