



SU010111 - SU010121 Skin Marker Pens

INSTRUCTION FOR USE

DESCRIPTION

m|devices Surgical Skin Marker Pens are a specific type of pen used to outline/mark the surgical incision site on the skin.

The pen is latex free, non cytotoxic and has been tested for biological safety in compliance with ISO10993 for skin irritation and sensitization.

The marking agent is based on gentian violet, a traditional marking agent which has wide tolerance within the population.

Surgical Skin Marker Pens are available in regular and fine tip with ruler and labels.

FOR USE BY A QUALIFIED CLINICIAN. THE BELOW IS ONLY A SUGGESTION AND FACILITY PROTOCOL MUST BE FOLLOWED FOR ALL CLINICAL PROCEDURES WHERE THIS PRODUCT IS USED.

CAUTION

- Single use.
- DO NOT re-sterilise.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight. Handle with care.
- STERILE (EO), DO NOT use if the package or product has been damaged or contaminated.
- EU Notice: any serious incident that has occurred in relation to the device should be reported to the manufacture and the competent authority of the Member State in which the user and /or patient is established.

STEPS


1. As per facility protocol, use approved surgical skin prep to disinfect skin area where marker pen will be used. Allow skin to dry before using surgical skin marker pen. Using the skin marker pen on wet skin could dry out the ink in the pen, or smudge the marking.
2. Remove cap and use as required.
3. Replace cap to prevent ink from drying out if the pen is being used intraoperatively and required again.
4. Use alcohol based solutions/wipes to remove ink from skin post operatively.

PRECAUTION

- Consider whether patient is sensitive to Gentian Violet.
- The pen should only be used on clean dry skin.
- Is for single patient use only.
- Not to be used on broken skin.

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