

medbar®

Skin Marking Set Fine and Ultra Fine Tip



REF 241



CE 2292

STERILE EO



Skin Marking Set

Intended Use

- Site marking is essential to prevent wrong site surgery and promote patient safety.
- The surgical site mark should not be easily removed with skin preparation but should not be so permanent as to last weeks or months after the surgical procedure.
- Included in the protocol is marking the surgical site for procedures involving incisions, percutaneous punctures or insertions with respect to laterality.
- One of the main issues associated with use of skin markers is the permanence of the mark (i.e., whether the mark will be visible after skin preparation to identify the appropriate surgical site).

Product Features

- Fine tip is considered the traditional surgical tip.
- Ultra fine tip is widely used for plastic and facial surgery application.
- Biocompatible ink.
- Flexible ruler in cms and inches.
- Insoluble.
- Non-toxic and non-tattooing.

Biocompatibility

- Biological evaluation of Skin Marking Set done according to ISO 10993-1.
- Tests for in vitro cytotoxicity done according to ISO 10993-5.
- Tests for irritation and skin sensitization done according to ISO 10993-10.

Skin marking set do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves.

Sterilization

Phototherapy Eye Bands sterilized with Ethylene oxide.
Validated for ISO 11135 standard.

Quality

- Manufactured under ISO 13485 Quality Management System standard.
- CE marked according to 93/42/EEC Medical Device Directive and classified as Class II a medical device.
- Notified Body: UDEM Ltd. Şti. (2292)
EC Certification No: M.2016.106.7000
GMDN Code: 37465

Shelf Life

5 years.

Packaging

- 50 pcs/inner bag.
- 1200 pcs outer box.
- Box dimensions: 42*38*57 cm.
- Box weight: 12 KG.

Skin Marking Set Versions

241 01 Skin Marking Set (Fine Tip)

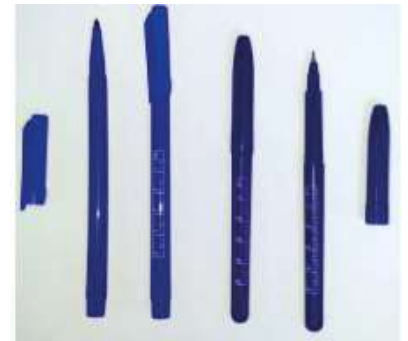


(1 mm tip)

241 03 Skin Marking Set (Ultra Fine Tip)



(0.5 mm tip)



| REF NO | PRODUCT NAME | STERILIZATION | PACKAGING UNIT |
|--------|-----------------------------------|---------------|--------------------|
| 241 01 | Skin Marking Set (Fine Tip) | EO | 50 pcs inner box |
| 241 03 | Skin Marking Set (Ultra Fine Tip) | EO | 1200 pcs outer box |



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