INSTRUCTIONS FOR USE

HENRY SCHEIN®



Surgical Skin Markers

NON STERILE Do Not Reuse RxONLY Not Made with Natural Rubber Latex

Henry Schein, Inc. 135 Duryea Road Melville, NY 11747 USA Made in USA

English

Indications for Use

Skin marker is used for surgical marking on intact skin

Intended User/ Patient Target Groups

Intended to be used by Healthcare Professionals on patients requiring medical procedures.

Instructions for Use:

- Mark desired areas on skin with the skin marker according to facility protocol.
- · Allow the markings to dry on the skin for approximately 1 minute before rubbing or applying prep solution.
- · Apply prep solution as instructed by prep solution manufacturer.
- · The skin marker ink must be applied to intact, dry skin before applying prep solution. The skin marker ink will not adhere to prep solution or wet skin.
- Prepping the skin with isopropyl alcohol before marking may increase the adherence of the ink to the skin.
- When prep solution is applied over the skin marker ink, some of the marking will smear, but the skin marker ink will still be visible.
- · Rulers packaged with skin markers are not measuring devices and should be used as an indicator only, and not for accurate measurements.
- · Device is intended to write for up to 24 feet.

Contraindication

Not for ocular use.

Sterilization Instructions

To ensure SAL of 10x-6, this product must be sterilized via gamma sterilization method in its original packaging configuration at a sterilization dose range of 22.2-40.0 kGy, using a validated process according to ISO 11137.

Warning

Reuse of device could result in infection/contamination and/or device failure which could lead to patient harm.

Disposal

Dispose or recycle general surgical devices per facility protocol and all applicable federal, state, regional, and/or local laws and regulations.

Notice to Users and/or Patients in EU

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.

WARNING: This product can expose you to chemicals including Gentian violet (Crystal violet), which is known to the State of California to cause cancer. For more information go to <u>www.P65Warnings.ca.gov</u>.

en Consult Electronic Instructions for Use