



DermaPrep[™]

PRODUCT INFORMATION AND INSTRUCTIONS FOR USE

BACKGROUND

The *DermaPrep*[™] is made of a sterile bi-layer (soft and abrasive) sponge with an imbedded irrigation system. After opening the sterile wrapping the *DermaPrep*[™] is connected by the mean of an infusion set or a similar regulated connecting tubing to a sterile saline (or water) container (bag or bottle). After opening and regulating the flow valve the sponge is used to clean the affected tissues providing the desired quantity of fluids. The soft foam is used for a gentle cleaning whereas the abrasive side is used for a thorough cleaning of foreign materials. The sponge is squeezed after each use into the bin and thereafter refilled with new, clean and sterile cleansing liquid. The amount and nature of the cleaning liquids is easily controlled. The amount of necessary liquid is minimal and the entire volume is used effectively to clean the skin surface without any loss and dripping on the sides.

PACKAGING AND STERILIZATION

- § The *DermaPrep*[™] is packaged in a pouch and is sterilized by Ethylene Oxide.
- § The pouch contents are sterile unless the package is opened or damaged.
- § The *DermaPrep*[™] is a single use device. Do not re-sterilize.

INDICATION

The *DermaPrep*[™] is intended for use for cleaning and of skin and wounds.

INSTRUCTIONS FOR USE

1. Open the package and take out the *DermaPrep*[™]
2. Remove the cap from the female luer lock.
3. Connect the female luer lock to I.V. line
4. Connect I.V. line to a source of sterile water or saline.
5. Open the clamp and allow the fluid to flow into the *DermaPrep*[™].
6. The wet *DermaPrep*[™] is used to rub and clean the skin. Use the soft side first. For more vigorously cleaning use the abrasive side.
7. Control the flow rate of the fluid using the roller clamp.
8. Squeeze the *DermaPrep*[™] into a bin in order to remove the dirt from the surface

PRECAUTIONS AND WARNINGS

Federal (US) law restricts this device to sale by or on the order of a physician.

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