

3M™ DuraPrep™ Surgical Solution

(Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w)
Patient Preoperative Skin Preparation

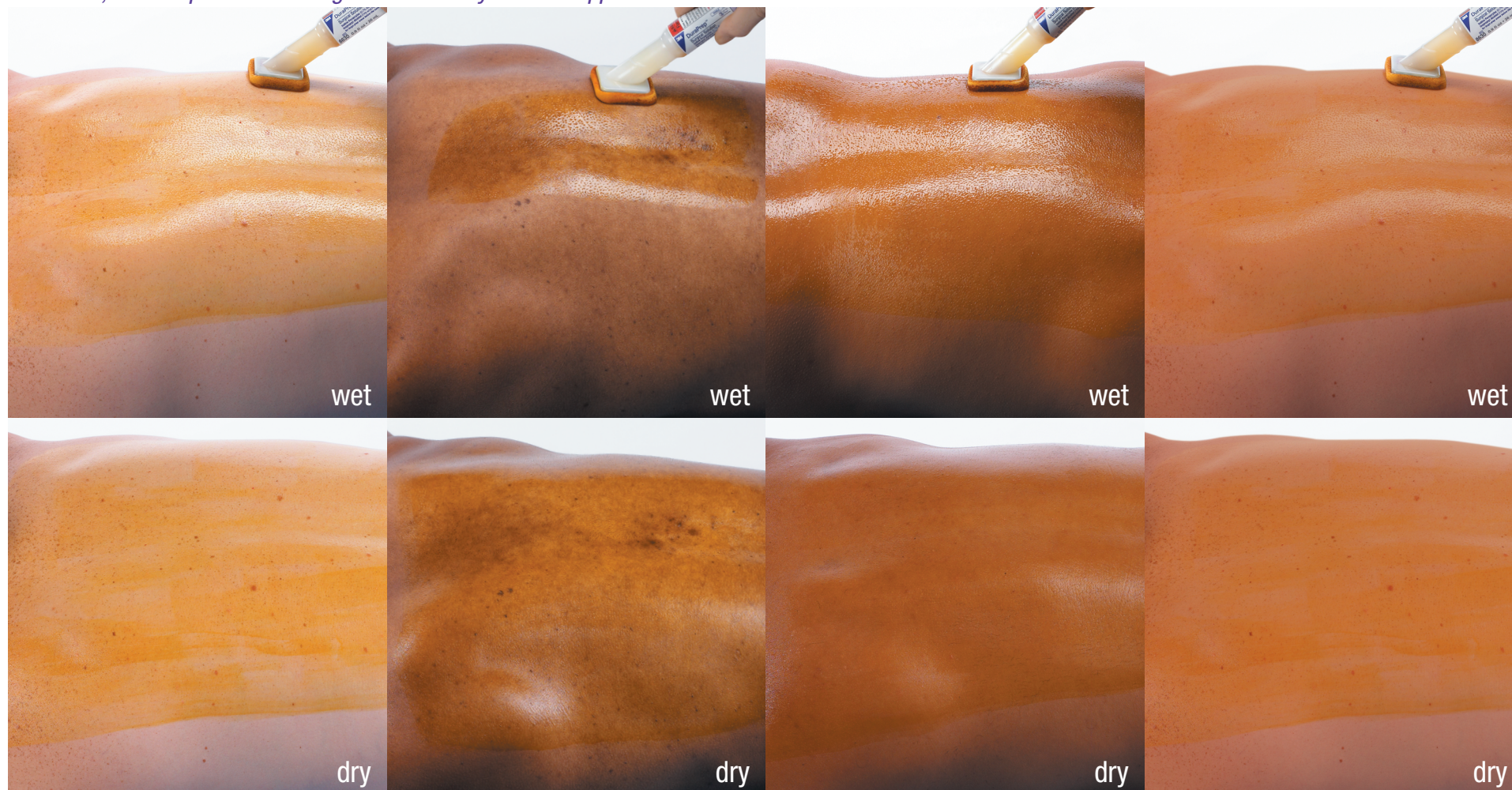
FDA
approved

Approved NDA 21-586
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Application Appearance

As it dries, DuraPrep solution changes from a shiny to a dull appearance.



For more information about DuraPrep solution, contact your local 3M distributor or sales representative, or contact the 3M Health Care Customer Helpline at **1-800-228-3957**. In other countries, contact the local 3M subsidiary.



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Application Instructions



1 Snap or Press

8635 (6 mL) With sponge parallel to floor, snap lever. Allow all fluid to flow into the sponge.

8630 (26 mL) With sponge parallel to floor, press the cap end of the applicator. Solution will begin to flow into the sponge. Wait for fluid level to reach indicator line of applicator barrel.



2 Paint

Beginning at the incision line and working your way out toward the periphery, paint a single uniform coat of solution on the skin. Use only light pressure. Do not scrub or go back over areas already prepped. If pooling occurs, immediately blot with the sponge applicator and continue.



3 Dry

Allow solution to dry thoroughly on skin (3 minutes on hairless skin; up to 1 hour in hair). As it dries, it turns from a shiny to a dull appearance, at which point it is no longer flammable. Do not use towel to blot dry. Use gauze to wick away any pooling. Once dry, proceed with draping.



4 Remove, if desired

DuraPrep solution continues to kill bacteria for at least 48 hours* after exposure to blood and saline. When removal is desired, apply 3M™ Remover Lotion and wipe away lotion and residue with a disposable towel.

Note: Prior to prepping

- When hair removal is necessary, the preferred procedure is to use a surgical clipper outside the OR room, close to the time of surgery. If a wet shave is used, be sure to thoroughly remove all soap residue.
- DuraPrep solution should be applied to clean, dry, residue-free, intact skin.
- Tuck prep towels as needed to absorb excess solution. Remove towels before draping.

Warning:

For external use only. Flammable, keep away from fire or flame. To reduce the risk of fire, PREP CAREFULLY:

- Do not use 26 mL applicator for head and neck surgery.
- Do not use 26 mL applicator or an area smaller than 8 in. x 10 in. Use a small applicator instead.
- Solution contains alcohol and gives off flammable vapors.
- Do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).
- Avoid getting solution into hairy areas. Wet hair is flammable. Hair may take up to 1 hour to dry.
- Do not allow solution to pool.
- Remove solution-stained material from prep area.

Do not use:

- On patients with known allergies to iodine or any other ingredients in this product.
- On open wounds, on mucous membranes, or as a general skin cleanser.
- In infants less than 2 months of age due to the risk of excessive skin irritation and transient hypothyroidism.

When using this product:

- Keep out of eyes, ears, and mouth. May cause serious injury if permitted to enter and remain. If contact occurs, flush with cold water right away and contact a doctor.
- To avoid skin injury, care should be taken when removing drapes, tapes, etc. applied over film.
- Use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn.

Stop use and ask a doctor if:

Irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition. On rare occasions, use of this product has been associated with skin blistering.

*Following ASTM E1173
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