

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation

Commonly Asked Questions

Question:

I like the concept of a one-step prep procedure. I understand DuraPrep solution's alcohol content provides for fast kill of microbes and fast drying advantages. But, what happens to the alcohol and how long must I wait after use of this flammable product to safely begin the incision and electrocautery?

Answer:

As DuraPrep solution dries, the alcohol content is dissipated into the air. It's important to apply DuraPrep solution according to the Directions for Use and allow it to dry completely (minimum of 3 minutes on hairless skin; up to one hour in hair) prior to draping and/or electrocautery use.

When applying DuraPrep solution: **DO NOT SCRUB**. Paint a single, uniform application and do not reprep the area. Also, do not allow solution to pool. If pooling occurs during application, use the sponge applicator to absorb excess solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gauze. Avoid getting solution into hairy areas. **Wet hair is flammable**. If this occurs, wipe hair with towel. Solution in hair may take much longer to dry or may not dry completely. Do not allow the solution to pool under the patient or to be absorbed by towels or bed linens. If the solution drips or pools into an absorbent article, remove the article and replace it if required prior to draping and/or electrocautery use. The use of tucked towels before prepping followed by removal of the tucked towels immediately after prepping is a good practice.

The drug facts box on the package includes this warning and instructions on safe and proper product usage.

Each package and applicator is clearly labeled with warnings.

 ! WARNING
Flammable
<p>Keep away from fire or flame To reduce the risk of fire:</p> <ul style="list-style-type: none">• Do not use 26-mL applicator for head and neck surgery• Do not use on an area smaller than 8in. x 10in. 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 one 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 materials from prep area

Question:

The 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation warning states the dry time as a “minimum of 3 minutes on hairless skin.” What is considered hairless skin?

Answer:

Hairless skin is considered an area where hair is removed prior to the application of DuraPrep solution or where there is insufficient hair to require its removal.

Question:

Why did 3M file a New Drug Application (NDA) when DuraPrep solution has been on the market for so many years?

Answer:

When the Tentative Final Monograph for Healthcare Antiseptic Drug Products (TFM) was published in July 1994, the proposed form of iodophor allowed to be used as an active ingredient was limited to povidone iodine. After discussions with the FDA about the unique film-forming polymer in DuraPrep solution, 3M made the decision to file a new drug application (NDA).

Question:

Were changes made to the DuraPrep formulation when then new drug application was filed?

Answer:

No. The solution formulation has not changed. However, FDA requested that 3M submit a request and obtain approval for a new chemical name to clearly identify the novel iodine acrylate copolymer in DuraPrep solution, and to differentiate it from traditional iodophors such as povidone iodine. This new chemical name is iodine povacrylex.

Question:

What is iodine povacrylex?

Answer:

Iodine povacrylex is a proprietary iodine acrylate copolymer developed by 3M scientists, an example of 3M innovation. This copolymer provides several benefits: superior resistance to removal by blood and irrigating solutions compared to non-copolymer formulations (e.g. Betadine® scrub and/or paint), continued antimicrobial activity after blood and saline exposure, and excellent drape adhesion compared to non-copolymer formulations of either povidone iodine (PVP-I) or chlorhexidine gluconate (CHG).

Question:

What is the difference between Betadine® (povidone iodine [PolyVinylPyrrilidone-Iodine]) and iodine povacrylex?

Answer:

Betadine is the tradename for povidone iodine (PVP-I) manufactured by Purdue Pharma. There are many generic PVP-I formulations available today.

With reference to 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation and povidone iodine: There are many similar characteristics between the two Polymer-Iodine complexes. Both contain complex iodine and release free iodine which is the component that is bactericidal in all iodine-based skin antiseptics. Both have the same pyrrolidone ring (complexing vehicle), but unlike povidone-iodine which is water soluble, the addition of the acrylate copolymer in DuraPrep solution provides the ability for the iodine to remain on the skin during irrigation and other stresses during surgery rather than wash away. DuraPrep solution allows the continual release of free iodine which kills bacteria while the film is on the skin. This water-insoluble DuraPrep film also provides enhanced drape adhesion and immobilizes the bacteria remaining on the skin after prepping, helping to prevent migration of the skin flora where it may be carried into the incision through irrigation, instruments and gloves. These features enable DuraPrep solution to maintain skin flora counts below baseline for at least 48 hours* after exposure to blood and saline. DuraPrep solution's novel iodine povacrylex polymer provides many differentiating features compared to traditional PVP-I.

Question:

Why did DuraPrep solution not get a contraindication for electrosurgery/cautery?

Answer:

3M provided FDA with data on the DuraPrep applicator and its safe use. This information, along with DuraPrep solution's unique application instructions (i.e., paint, do not scrub) and enhanced product warnings, (e.g., minimum of 3 minute dry time on hairless skin; up to one hour in hair) allow for its continued use in surgery where electrocautery is contemplated.

* Following ASTM E1173

Question:

Can 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation be warmed for patient comfort reasons?

Answer:

No. DuraPrep solution contains alcohol and should not be warmed before use. Warmed DuraPrep solution will evaporate faster than room temperature product. Increased patient comfort will not be realized with warmed solution.

Question:

Can we use DuraPrep solution on open wounds? Lacerations? Gun shot wounds?

Answer:

No. DuraPrep solution is indicated for use on intact skin only. It is not appropriate for use on any open wounds, e.g. lacerations, decubitus ulcers, gun shot wounds.

Question:

Can DuraPrep solution be left under casting material?

Answer:

3M has not studied DuraPrep film under casting material. The DuraPrep dry film flakes off with patient's skin and may itch.

Question:

Do I need to do a Betadine® scrub and/or paint or Hibiclens® (CHG) scrub prior to DuraPrep solution application?

Answer:

No. All clinical studies were conducted with only one coating of DuraPrep solution without pre-prepping the skin with Betadine scrub and/or paint or Hibiclens scrub. Results demonstrate fast, broad-spectrum bactericidal activity. Pre-prepping the patient with Betadine or Hibiclens may leave a soapy residue on skin which, if not removed or allowed to completely dry, could compromise adhesion and result in the DuraPrep film peeling/flaking off during surgery.

Question:

Can DuraPrep solution be used on donor site skin prior to skin graft?

Answer:

DuraPrep solution is not recommended to prep the donor site prior to skin graft. The dermatome, an instrument for skin harvest, requires defatted, clean, and dry skin for proper contact. Therefore, alcohol is most commonly used to prepare the skin prior to its harvest. DuraPrep solution, like other iodophors, could hamper the dermatome's efficiency and the dermatoming of the DuraPrep film rather than of skin is a possibility.

Question:

Is it necessary to wear gloves while prepping with 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation?

Answer:

Each facility must develop its own policy regarding the use of gloves while applying DuraPrep solution. The most recent AORN guideline (patient prep updated in 2010, page 360) states: "Sterile gloves should be worn unless the antiseptic prep applicator is of sufficient length to prevent the antiseptic and patient's skin from contact with the non sterile glove."

Question:

Can DuraPrep solution be used as a skin prep before epidural and spinal catheter insertions?

Answer:

DuraPrep solution is appropriate for use as a skin prep on intact skin prior to invasive procedures such as: surgery, angiographies, epidural or spinal catheter insertion, and IV and central line insertion. DuraPrep solution should be applied in a single uniform coat and then allowed to dry completely before draping and catheter or needle insertion. Once dry, DuraPrep solution adheres to the skin and should not be carried into the injection site unless a piece of skin is cored with the needle. Typical needles used for these procedures are designed to cut through the skin and not core.

During the development phase of DuraPrep solution 3M specifically looked at tissue reaction to the DuraPrep film. The study performed was a USP Muscle Implantation Study using a standardized test protocol designed for determining tissue reaction to implant materials. The results of the study showed that both macroscopically and microscopically DuraPrep film was nonirritating. DuraPrep film can be left on after the catheter is placed and will keep resident bacterial counts low for at least 24 hours.

Question:

What is the process for re-prepping a patient with DuraPrep solution if the case is finished and the surgeon needs to re-open the patient and there is still Prep left on the skin?

Answer:

Open a new DuraPrep applicator and reapply the solution to the area. You do **not** need to remove the first coat of DuraPrep film. The second application of DuraPrep solution will partially dissolve the initial film and will reform the film as it dries. **Because you are applying a second coat of solution in this situation, it may take longer than the minimum 3 minutes on hairless skin; up to one hour in hair to dry.**

DuraPrep solution combines the benefits of alcohol with an iodophor in a film-forming polymer. This combination provides the fast effective kill of alcohol with the persistence

of the iodophor film. The DuraPrep film also provides the best adherence of incise drape to establish and maintain the sterile surface. The warning clearly states: Do not drape or use ignition source (e.g., cautery, laser) until dry (minimum 3 minutes on hairless skin; up to one hour in hair). As it dries, 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation turns from a shiny to a dull appearance alerting the user that the solution is no longer flammable.

Question:

Can one DuraPrep applicator be used for more than one incision site?

Answer:

There are many variables that go into the decision to prep more than one incision site. It would not be acceptable technique to go from a contaminated area such as the groin or axilla back to a clean incision site. Currently it is common practice for ORs to use one DuraPrep applicator to prep multiple incisions on a leg for cardiovascular surgery. Therefore if you are prepping two clean areas or two similar areas (i.e. both feet, both groins, both breasts, etc.), it is acceptable to prep multiple sites on the same patient with one applicator. In the same respect, it would also be acceptable to touch up a missed spot. The fact that DuraPrep solution combines the known efficacy of alcohol with that of an iodophor is an advantage over an aqueous iodophor solution. Alcohol is extremely fast acting, providing rapid initial bacterial kill. This rapid kill occurs throughout the entire application of the solution. The iodophor provides continued long lasting activity.

Question:

In the Drug Facts box for 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation it states: Do not use in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism. What prep can I use?

Answer:

Because infants less than 2 months of age have skin that is more permeable, there is a greater potential of absorption and irritation of any skin prep. For DuraPrep solution the warning is: “Do not use in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism.” Many of the preps marketed under the TFM also include a warning regarding use on infants. Given this information, the physician must then make a risk assessment and determine the course of action.

Question:

In the Drug Facts box for DuraPrep solution it states: “When using this product, use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn.” What preps can I use?

Answer:

This caution was added because there is no safety data regarding the absorption of skin prep and transfer through the mother’s milk to the nursing infant. Given this information, the physician must then make a risk assessment and determine the course of action.

Betadine is a registered trademark of Purdue Pharma L.P.
Hibiclens is a registered trademark of Regent Medical Limited.
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For More Information
Contact your 3M Health Care Sales Representative, or call the 3M Health Care Customer Helpline at **1-800-228-3957**. These products can be ordered from your local distributor. Outside the United States, contact the local 3M subsidiary.



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