

FDA  
approved

Approved NDA 21-586  
September 29, 2006

# PREP SCHOOL LESSON BOOK



3M Medical  
from the 3M Health Care family



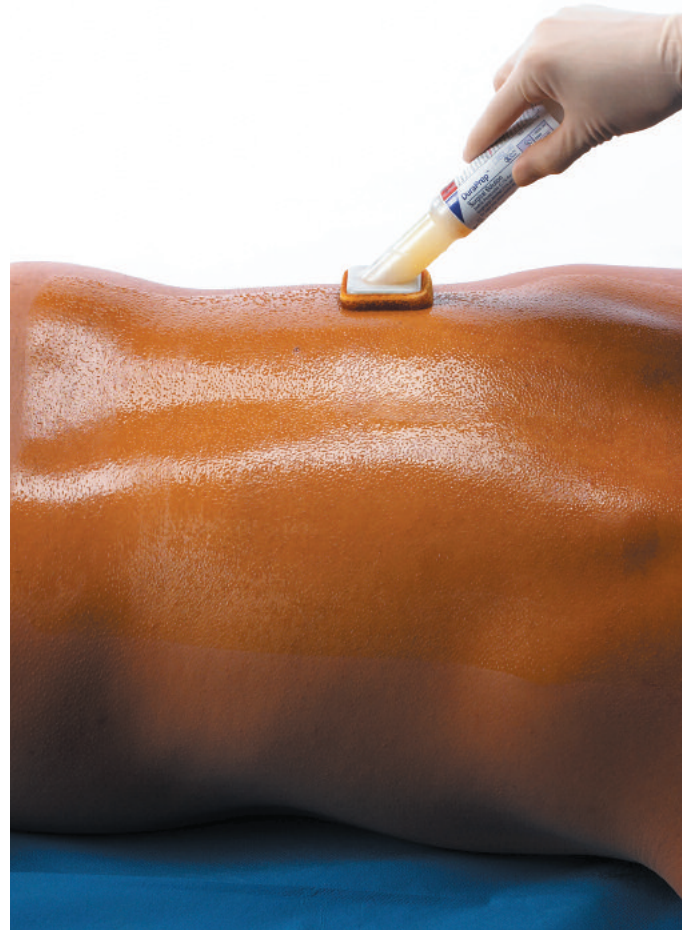
A large, white, calligraphic letter 'B' with elegant flourishes, serving as a decorative element for the start of the text.

Because all of the most commonly used patient skin preps meet the FDA criteria for immediate microbial kill and persistent antimicrobial activity, it's important to look at other factors that may affect prep performance when choosing a prep for surgical patients. In this lesson book, you will find several ways to compare patient skin preps based on factors that affect their application, performance and cost-effectiveness. These lessons will help you clarify what's important in selecting a prep for your facility. To learn more, contact your 3M representative or call the 3M Health Care Helpline at 1-800-228-3957.

## Facts speak loudest.

**Clinical results beat claims any day. And no surgical prepping solution has as much clinical documentation to support its efficacy story as 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation.**

For a complete package of safety and efficacy data, study information and other facts, talk to your 3M representative or call the 3M Health Care Helpline at 1-800-228-3957.



## Some surgical prep applicators cover a lot more ground than others.

With a 26 mL applicator of 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation, you can cover more than twice the area of the 26 mL ChloroPrep® (Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v) Antiseptic Skin Prep applicator.

According to labeling, a 26 mL applicator of ChloroPrep Antiseptic Skin Prep will cover an area 13.2 inches by 13.2 inches, or 174 square inches. In comparison, a 26 mL applicator of DuraPrep solution (8630) will cover 15 inches by 30 inches, or 450 square inches (Fig. 1). This is more than twice the area, with a single applicator. For procedures that call for large coverage with a prep, this can be the difference between using one and using several applicators. A difference that, ultimately, can add to the cost of a procedure (Fig. 2).

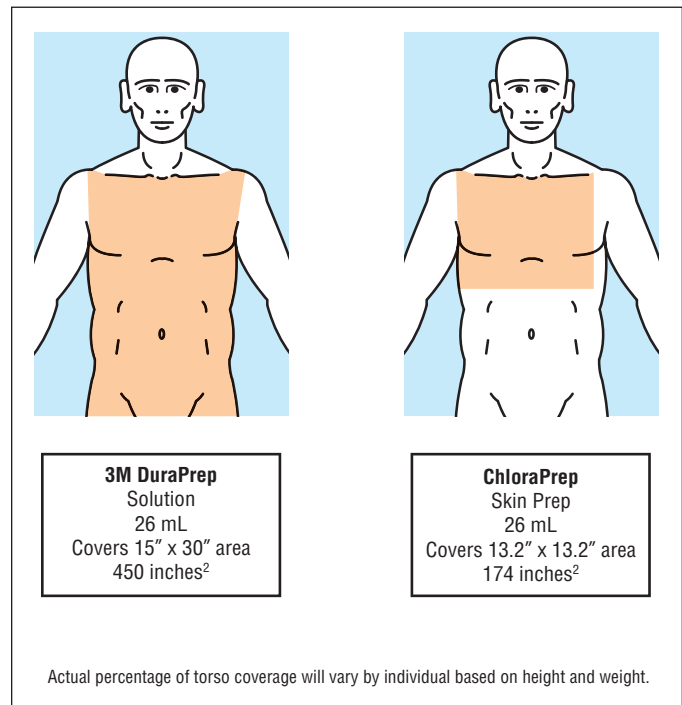


Fig. 1

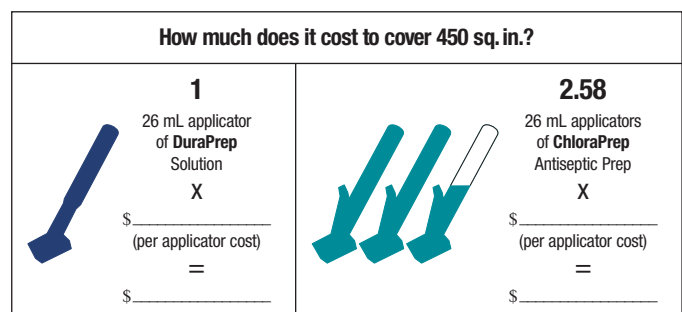


Fig. 2

## Unfortunately, when drape edges lift, microbes get a boost.

In clinical studies, 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation provided significantly greater drape adhesion than ChloroPrep® (Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v) Antiseptic Skin Prep and other water-soluble preps.

Incise drapes are used to create a sterile surface in procedures where the consequence of infection can have serious morbidity or mortality, such as cardio-thoracic, joint replacement and other implant surgeries, neurosurgery, and trauma. But when a drape lifts at the wound edge, the exposed skin allows for the potential of bacteria being transferred into the wound. In one study, drape lift was associated with a 6-fold increase in surgical site infections.<sup>1</sup> Therefore, it is important to consider the effect of different preps on drape adhesion. In clinical studies, DuraPrep solution provided significantly greater drape adhesion than ChloroPrep Antiseptic Skin Prep<sup>2</sup> and other water-soluble preps (Fig. 3, 4, 5).

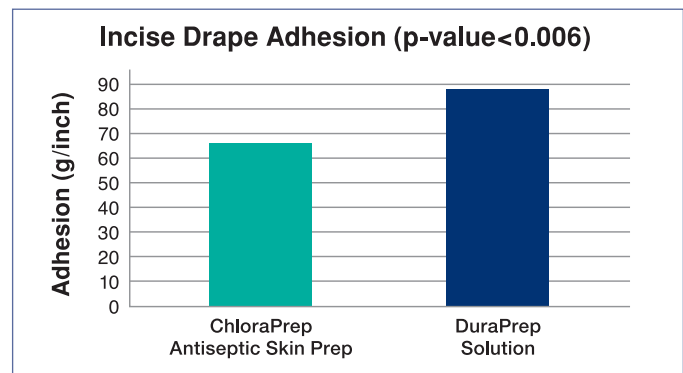


Fig. 3

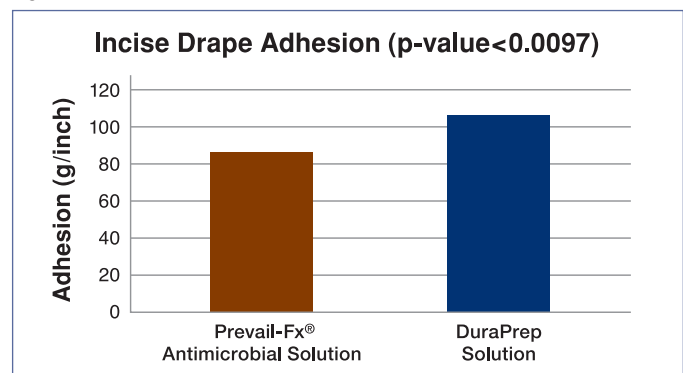


Fig. 4

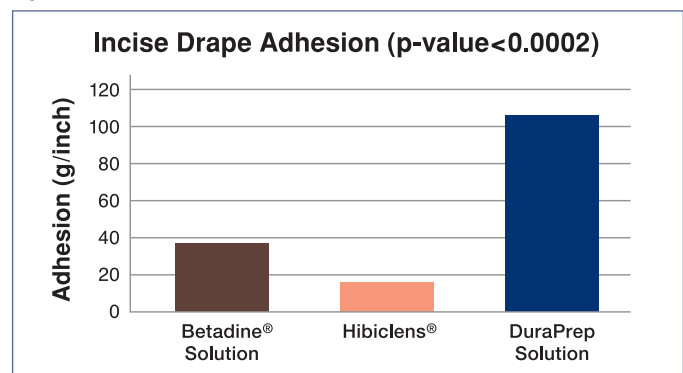


Fig. 5

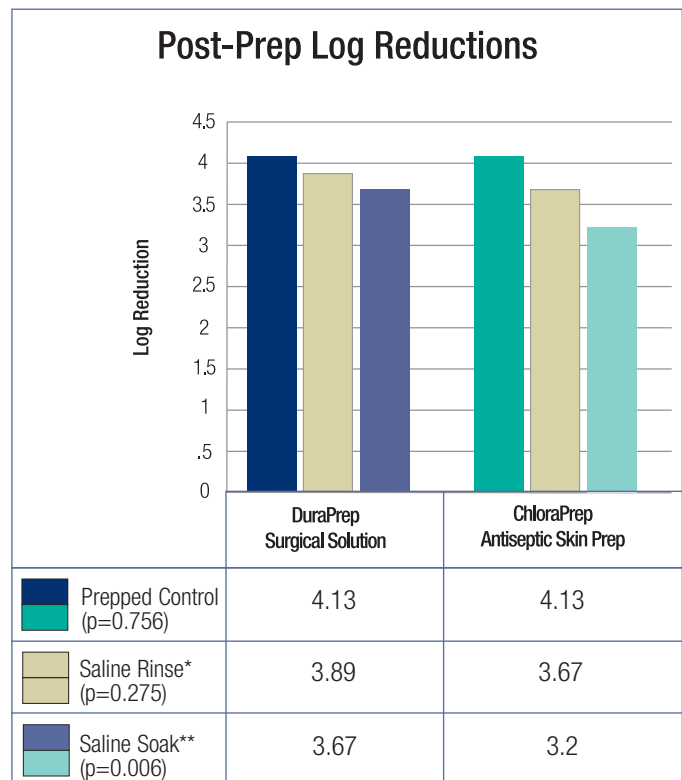
<sup>1</sup> Alexander, J.W., Aerni, S., and Plettner, J.P. 1985. Development of a Safe and Effective One-Minute Preoperative Skin Preparation. *Arch Surg.* 120: 1357-1361.

<sup>2</sup> Data on file (Study-05-010262, Study-05-010210, LIMS 9567), 3M Health Care.

## When blood and saline enter the scene, a good surgical prep doesn't run away.

**3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation contains a polymer that dries to a water-insoluble film and resists wash-off by blood and saline challenges.**

Studies show that blood and saline irrigation can significantly reduce the microbial effectiveness of some surgical patient preps. In fact, a recent study<sup>1</sup> showed that DuraPrep solution had greater log reduction than Chloraprep antiseptic skin prep when challenged by saline irrigation or soak - and that difference was statistically significant with the saline soak (Fig. 6).



\* 250 mL of sterile saline, slowly poured over a 2" x 2" area on the forearm.

\*\* Single sterile gauze saturated with 20-30 mL sterile saline before placement on the 2" x 2" forearm area for 5 minutes.

Fig. 6

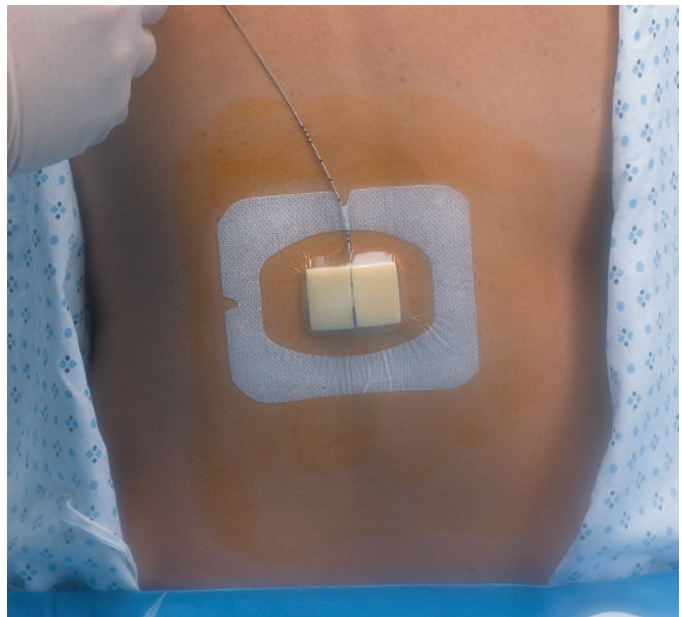
<sup>1</sup> *American Journal of Infection Control*, Volume 35, Issue 6, August 2007, 367-373.

## The right surgical prep won't create problems for the meninges.

Unlike ChloraPrep® (Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v) Antiseptic Skin Prep, 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation is indicated for use on intact skin procedures including lumbar puncture, epidural access and procedures where a patient prep might come in contact with the meninges.

Standardization of practice is a goal for healthcare facilities because it helps prevent error and assists in providing the same level of care for all patients. When you select DuraPrep solution as your prep for intact skin procedures, sensitivity to iodophors and children under 2 months of age are the only contraindications you need to worry about. DuraPrep solution helps you standardize your practice: one solution for intact skin.\*

\*See DuraPrep solution drug facts at the end of this brochure.



## You shouldn't need more than one set of instructions for one surgical prep.

ChloraPrep® (Chlorhexidine Gluconate 2% w/v and Isopropyl Alcohol 70% v/v) Antiseptic Skin Prep has different instructions for “wet” and “dry” sites (Fig. 7). 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation keeps it simple. The same instructions apply wherever you work.

### Instructions for Use

	DuraPrep Solution	ChloraPrep Antiseptic Skin Prep	
Application	Paint a single, uniform application and do not go back over areas already prepped.	<b>Dry Site</b> (such as abdomen or arm) Use repeated back-and-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic.	<b>Moist Site</b> (such as the inguinal fold) Use repeated back-and-forth strokes of the sponge for approximately 2 minutes. Completely wet the treatment area with antiseptic.
Dry Time — Mid-size applicator	Minimum of 3 minutes on hairless skin	Approximately 30 seconds	Approximately 1 minute
Dry Time — 26 mL applicator		Approximately 3 minutes	

Fig. 7

## A good surgical prep puts key labeling information right at your fingertips.

**When 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation is in your hands, so is the product's key safety information.**

Compare how easy it is to see important safety information with four different prepping solutions when they're in sterile packaging. Then, compare again, when each is being activated. Which makes it easiest for your staff to see and comprehend that information?

### In packaging

From left, Prevail-Fx® Antimicrobial Solution, DuraPrep solution, Chloraprep® Antiseptic Skin Prep, Merlin™ One Step Prep.



### During activation

From left, Prevail-Fx® Antimicrobial Solution, DuraPrep solution, Chloraprep® Antiseptic Skin Prep, Merlin™ One Step Prep.



**PREP SCHOOL**  
LESSON NO. 8

## Peace of mind is available in two convenient sizes.

With a long track record and millions of procedures behind it, you can count on 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation. And with two applicator sizes, it's right for most intact skin procedures.

No other one-step prepping solution has been proving its value in the operating room as long as DuraPrep solution. It is truly peace of mind where peace of mind is critical.

In addition, DuraPrep solution is available in two sizes, so you can choose the product that matches your needs — and avoid excess waste — in a wide variety of applications.



## When an operation is finished, a good surgical prep has only just begun.

**The iodine povacrylex in 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation provides long-lasting antimicrobial kill. Studies show persistent activity for at least 6 hours after simulated surgical conditions.**

Persistence for patient pre-operative skin preps is the product's ability to maintain low bacterial counts on the skin after a single application for an extended period of time, generally 6 hours (FDA criteria). While the FDA doesn't require a fluid challenge like you would find during a surgical procedure, we test DuraPrep solution's ability to kill bacteria after exposure to blood and saline. Figure 8 shows DuraPrep solution's ability to kill when inoculated with bacteria 15 minutes or 6 hours after being applied, challenged with blood and removed by saline solution. You want to choose a prep that continues to kill bacteria after exposure to blood and irrigating fluids. That's why 3M has tested the bactericidal activity of DuraPrep solution after fluid challenge.<sup>1</sup>

Aren't your patients worth it?

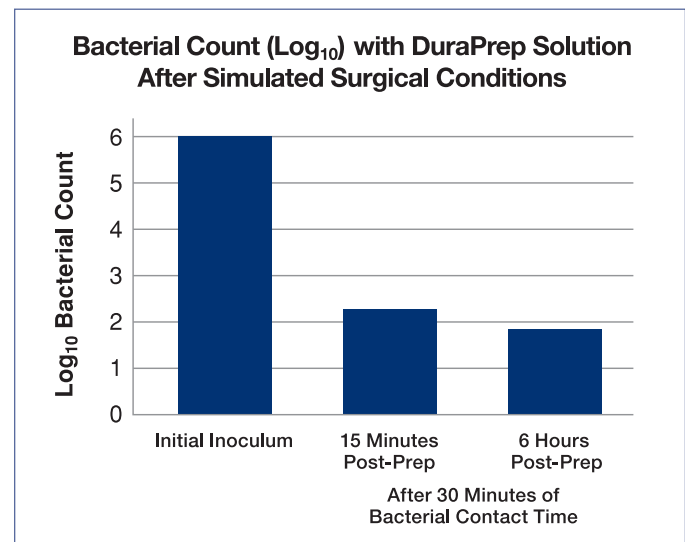


Fig. 8

## Not all surgical preps are created equal: Separating fact from fiction.

Fiction	Fact
All surgical preps have similar clinical documentation.	Based on clinical documentation, no other surgical prep stacks up to 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation.
A blood or saline challenge has the same effect on drape adhesion, regardless of prep used.	No other surgical prep maintains drape adhesion like DuraPrep solution.
All surgical preps delivered in an applicator are applied the same.	DuraPrep solution flows into the sponge and is applied in a single, painted coat while other prep solutions require scrub times of 30 seconds to 2 minutes.*
The larger the applicator, the better the value.	The best value is the appropriate amount of solution.
Iodophors are inactivated by blood and organic matter.	DuraPrep solution continues to kill bacteria contacting the film for at least 6 hours after exposure to blood and saline.
All surgical prep product labeling offers the user a clear view of safety information.	With other surgical prepping solutions, product safety information is not always so easy to see.
Peace of mind is difficult to come by with prepping solutions.	Peace of mind comes with experience.

Fig. 9

<sup>1</sup> Roberts AJ, Wilcox K, Devineni R, et al: Skin preparations in CABG surgery: A prospective randomized trial. *Complications in Surgery* Nov/Dec, pp 724-747 1995.

<sup>2</sup> Jacobson C, Osmon DR, Hanssen A, et al: Prevention of wound contamination using DuraPrep™ solution plus loban™ 2 drapes. *Clinical Orthopaedics and Related Research* Oct, pp 32-37 2005.

<sup>3</sup> Data on file (SRFE 1246), 3M Health Care.

## Explanation

No surgical prepping solution has as much clinical documentation to support its efficacy story as DuraPrep solution. Including:

- 5 human safety studies
- 7 *in vitro* studies
- 5 *in vivo* studies
- 5 clinical in-use studies

Conversely, a bare minimum of clinical studies is presented by most other prepping solutions in their sales literature.

DuraPrep solution offers significantly better drape adhesion than other major surgical preps. This advantage has been documented in clinical studies. Some other preps make claims with no documentation. With all the clinical data, you, your facility, and your patients can be assured that DuraPrep solution delivers the clinical benefits you need in a surgical prep.<sup>1,2,3</sup>

In addition to application time and technique differences, with some applicators you must squeeze solution into the applicator sponge to get flow. The 3M DuraPrep applicator provides consistent, easy solution flow without squeezing or scrubbing.

\*DuraPrep solution is flammable until completely dry (minimum of 3 minutes on hairless skin).

A 40 mL applicator can be wasteful with anything but the “largest” of procedures because it either gets thrown away or over-applied. Waste is not a good thing with an alcohol-based product. Proper disposal is an issue. That’s why we offer DuraPrep solution in two applicator sizes.

DuraPrep solution contains iodine povacrylex, an iodine acrylate co-polymer that dries to a water-insoluble film and resists wash-off by blood and saline challenges. 3M is the only company to provide clinical data showing efficacy after blood and saline challenge.

Important safety information is easy to see on the DuraPrep applicator and packaging. With other preps, it’s not always so easy to see.

DuraPrep solution has a history of success that has been proven for 18+ years and in more than 20,000,000 surgical procedures. You can count on it to perform according to plan.

## **CDC Guidelines: There's not just one.**

**Contrary to what some would have you believe, there are different CDC guidelines that address skin antisepsis.**

CDC guidelines can help drive best practice. But even when two guidelines address a shared segment, they are not interchangeable. For example, both the CRBSI and SSI guidelines address patient skin prep. But the rationale and recommendation in each are not the same. Bottomline: make sure you are using the appropriate CDC guideline before you make decisions on product use.

### **CDC Guideline for the Prevention of Intravascular Catheter-Related Bloodstream Infection (CRBSI)**

Focus: management of catheters in place for long-term monitoring or delivery of therapeutics.

Source: Guideline for the Prevention of Intravascular Catheter-Related Bloodstream Infection, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report. August 9, 2002; vol. 51.

### **CDC Guideline for the Prevention of Surgical Site Infection (SSI)**

Focus: multi-disciplinary category approach to reducing the risk of surgical site infection.

Source: Guideline for the Prevention of Surgical Site Infection, Centers for Disease Control and Prevention, Infection Control and Hospital Epidemiology. 1999; vol.20; 247-278.



## Iodine Povacrylex is not the same as Povidone Iodine.

It is a common misperception that all iodophors have the same properties. Not so. Iodine povacrylex, the active ingredient in 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation, has special attributes not found in povidone iodine scrub and paint skin preps. Compare for yourself.

Description	Iodine Povacrylex	Povidone Iodine Scrub and Paint
Effective in a single, painted coat <sup>1</sup>	Yes	No
Resists removal by irrigation <sup>2</sup>	Yes	No
<b>Persistent</b> - At least 48 hours against resident bacteria under a dressing after a blood and saline (fluid) challenge <sup>3</sup> - At least 12 hours against transient bacteria <sup>4</sup>	Yes	Unknown Unknown
Immobilizes bacteria remaining on the skin after prepping <sup>5</sup>	Yes	No
Promotes drape adhesion <sup>2,6,7</sup>	Yes	No

### References

1. Data on file (05-010214, LIMS 8304, LIMS 8918, LIMS 8058).
2. Roberts, A. *Skin Preparations in CABG Surgery: A Prospective Randomized Trial*: Complications in Surgery Nov-Dec 1995 pp. 740-747.
3. Data on file (05-010565).
4. Data on file (SRFE 1513).
5. Data on file (05-004891).
6. Jacobson CS, Osmondr, Hanssen A., et al: *Prevention of Wound Contamination Using DuraPrep Solution Plus Ioban 2 Drapes*. Clinical Orthopaedics No. 439. Oct 2005 pp. 32-37.
7. Data on file (LIMS 9567, 05-010210, 05-010262, 05-010212).

Fig. 10

# 3M™ DuraPrep™ Surgical Solution Drug Facts

## Active ingredients

Iodine povacrylex (0.7% available iodine) . . . . . Antiseptic  
Isopropyl alcohol, 74% w/w . . . . . Antiseptic

## Purpose

## Uses

Patient preoperative skin preparation:

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

## Warnings

**For external use only. Flammable, keep away from fire or flame.**

**To reduce the risk of fire:**

- do not use 26 mL applicator for head and neck surgery
- do not use on 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)
- avoid getting solution into hairy areas. Solution may take much longer to dry or may not dry completely.
- 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
- on infants less than 2 months old due to 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 other allergic reactions occur. These may be signs of a serious condition. On rare occasions, use of this product has been associated with skin blistering.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

## Directions (follow all directions for use)

- at the end of the prep, discard any portion of the solution which is not required to cover the the prep area. It is not necessary to use the entire amount available.

## Getting Patient Ready for Solution:

- use in well-ventilated area
- do not microwave or heat the solution applicator
- apply to clean, completely dry, residue-free, intact skin
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

## Activating the Applicator:

For 8635 (6 mL) applicator:

- grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever.
- with sponge parallel to floor, snap lever. Allow all fluid to flow into sponge.

For 8630 (26 mL) applicator:

- with sponge parallel to the 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.

## When Applying Solution:

- **DO NOT SCRUB.** Paint a single, uniform application and do not reprep area.
- **do not allow solution to pool.** Use 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.
- when using the 8630 (26 mL) applicator, clean umbilicus with enclosed swabs when applicable. (Moisten swabs by pressing against solution-soaked sponge applicator.)
- tuck prep towels as needed under both sides of the neck to absorb excess solution. Remove towels before draping.
- avoid getting solution into hairy areas. If this occurs, wipe hair with towel. Solution may take much longer to dry or may not dry completely.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself.



## After Applying Solution:

- to reduce the risk of fire, **wait until solution is completely dry (minimum of 3 minutes on hairless skin).** Solution will turn from a shiny to a dull appearance on skin alerting the user that the solution is completely dry and no longer flammable.

## While Waiting for Solution to Completely Dry:

- do not drape or use ignition source (e.g., cautery, laser)
- check for pooled solution. Use sterile gauze to soak up pooled solution. Do not blot because it may remove solution from skin.
- remove solution-stained materials. Replace if necessary.

## After Solution is Completely Dry:

- to reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry and all solution-stained materials are removed.
- if incise drapes are used, apply directly to dry prep. On completion of surgical procedure, removal of incise drape will remove film.
- apply dressing following standard practices



**Other Information** store between 20–25°C (68–77°F) • avoid excessive heat above 40°C (104°F) • solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

**Inactive Ingredients** ethyl alcohol, water

**Questions?** call 1-800-228-3957 (Monday through Friday, 7 a.m. to 6 p.m., CST) or visit [www.3M.com](http://www.3M.com).



## Medical Division 3M Health Care

3M Center, Building 275-4W-02  
St. Paul, MN 55144-1000  
U.S.A.  
1-800-228-3957  
[www.3m.com/healthcare](http://www.3m.com/healthcare)

## Medical Division 3M Canada

Post Office Box 5757  
London, Ontario N6A 4T1  
Canada  
1-800-563-2921

Please recycle. Printed in the U.S.A.  
© 3M 2007, 2008. All rights reserved.  
70-2009-7494-0

ChloraPrep is a registered trademark of Enturia.  
Betadine is a registered trademark of Perdue Pharma.  
Hibiclens is a registered trademark of Molnlycke RM Ltd.  
Prevail-Fx is a registered trademark of Cardinal Health, Inc.  
Merlin is a trademark of Tyco Healthcare Group LP or its affiliate.  
3M and DuraPrep are trademarks of 3M.