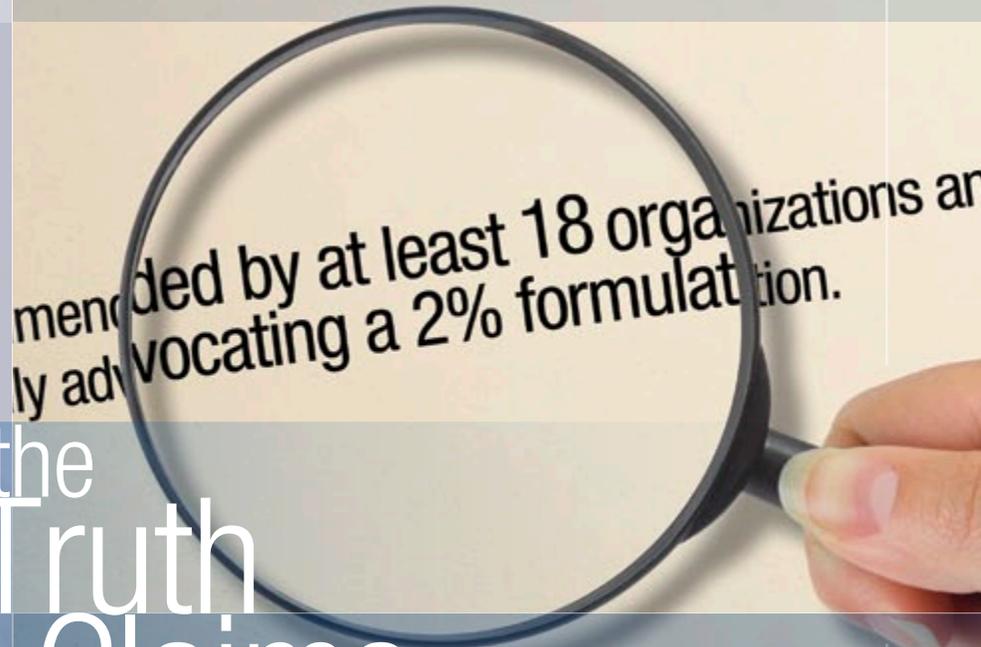


3M™ DuraPrep™ Surgical Solution

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

Patient Preoperative Skin Preparation



Applying the
Whole Truth
To The **Claims**



Everywhere you turn, there is misinformation being printed about patient preoperative preps. The whole truth, on the other hand, has not been easy to find. As you read this brochure, you will see both what is being claimed and the whole truth. We hope you find this information helpful as you consider which patient prep best fits your needs.

The Claim	The Whole Truth
<p>“(ChloroPrep* is) CDC Preferred.” (ChloroPrep presentation handout)</p>	<p>The CDC does not have an overall preference for preps. There are actually two different CDC guidelines that address skin antisepsis.</p> <ol style="list-style-type: none"> 1. Source: CDC Guideline for the Prevention of Intravascular Catheter Related Infections, <i>Morbidity and Mortality Weekly Report</i>. August 9, 2002; Vol. 51. “Although a 2% Chlorhexidine-based preparation is preferred, tincture of iodine, an iodophor, or 7% alcohol, can be used.” 2. Source: CDC Guideline for the Prevention of Surgical Site Infection, 1999 <i>Infection Control and Hospital Epidemiology</i>, April 1999 Vol. 20 No. 4 pp. 248-278. “Use an appropriate antiseptic agent for skin preparation (Table 6). Apply preoperative antiseptic skin preparation in concentric circles moving toward the periphery. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary.”
<p>“ChloroPrep is less irritating, non-allergenic and non-toxic.” (Skin bacteria: The #1 cause of surgical site infections. 2005, MRK-543-2) (A full line of ChloroPrep products for all your needs. 2006, MRK-06577)</p>	<p>The FDA’s Summary Basis of Approval for ChloroPrep stated: “The product is safe for its intended use, though it is one of the most irritating topical products which has been seen in this Division when evaluated by standard predictive patch tests.” Source: Medical Review, NDA 20-832, p. 18.</p>
<p>“Residual activity of ChloroPrep is 48 hours while traditional iodophor residual activity is only 2–3 hours.” (Skin bacteria: The #1 cause of surgical site infections. 2005, MRK-543-2)</p>	<p>The ChloroPrep Clinical Compendium, page 29, shows that in their studies PVP-I scrub and paint had residual activity comparable to ChloroPrep. The prepped area did not undergo a fluid challenge of any type. The 2–3 hour information for PVP-I is taken from hand hygiene studies. It is inappropriate to compare hand study data to prepping data (abdomen and groin) for several reasons: 1) hands include a load of bacteria (under the nails) that are not present in the abdomen or groin and 2) hands are exposed to more transient bacteria. The test methods for each indication (hand prep and patient preoperative skin preparation) are different.</p>
<p>“Traditional iodophors (PVP-I) require >2 minutes for the release of free iodine (onset of action).” (MRK-06573, 06753R) Source: Crosby CT, Mares AK. Skin antiseptics past, present, and future <i>J Vasc Access Devices</i> Spring 2001: 26–31.</p>	<p>An <i>in vitro</i>⁺ study on the mechanism and extent of release of iodine from various iodophors (U of TN, 1998) showed release of iodine for both PVP-I and PVP-I gel at 1 minute. Source: Fowler, Philip T., et al., <i>In Vitro Studies on the Mechanism and Extent of Release of Iodine From Various Iodophors</i>. <i>American Association of Pharmaceutical Sciences</i>, Nov. 1998. + The clinical significance of <i>in vitro</i> data is unknown.</p>
<p>“Traditional iodophors are neutralized in the presence of blood, serum, and other protein-rich biomatter.” (A full line of ChloroPrep products for all your needs. 2006, MRK-06577) (Think rapid, persistent, superior 2005-ADV-0150106)</p>	<p>This is not true for all iodophors. 3M has tested DuraPrep solution** post exposure to blood and can demonstrate that it remains bactericidal. Source: Data on file, Study-05-010565, 3M Health Care.</p>
<p>“Standardized protocol — helps promote aseptic technique.” (A fundamentally better system for preoperative skin preparation - 2007 MRK- 07001)</p>	<p>ChloroPrep labeling provides two protocols: one for dry skin sites and one for moist skin sites. This is not standardized because application varies by site. Source: ChloroPrep Instructions for use.</p>

*ChloroPrep® Patient Preoperative Skin Preparation 2% Chlorhexidine Gluconate (CHG) & 70% Isopropyl Alcohol (IPA)

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

The Claim	The Whole Truth
<p>“(ChloroPrep®) Kills more bacteria than traditional iodophors and alcohol.”</p> <p>(Skin bacteria: The #1 cause of surgical site infections. 2005, MRK-543-2) (Think rapid, persistent, superior 2005. ChloroPrep 10.5mL & 26mL-2005-ADV-0650306)</p>	<p>When comparing activity, it’s inaccurate to compare data from unrelated studies. FDA sets criteria for bacterial log reduction which manufacturers must meet to receive NDA approval. Bacterial kill is dependent on several factors including patient bioburden, patient susceptibility to active agents on environmental conditions and product application methods.</p> <p>Source: Federal Register. June 17, 1994.</p>
<p>“In a prospective randomized trial of three selected surgical preparatory solutions, ChloroPrep was the most effective solution for eliminating potential wound contaminants from the forefoot prior to surgery.”</p> <p>(Think rapid, persistent, superior 2005. ChloroPrep 10.5mL & 26mL-2005-ADV-0650306)</p>	<p>3M disagreed with the conclusions of the study and submitted a Letter to the Editor stating namely that 1) no neutralization of the preps was undertaken, so water-soluble preps had the ability to continue to kill bacteria collected, 2) the sampling for DuraPrep solution** was taken from the top of the film, not the skin, so true bacterial reduction was not determined.</p> <p>Source: <i>J. Bone Joint Surg. Am.</i>, May 2006; 88: 1160–1161.</p>
<p>“Chlorhexidine gluconate is highly recommended by at least 18 organizations and initiatives, with 11 specifically advocating a 2% formulation.”</p> <p>(www.chloraprep.com/evidencebasedguidelines.html)</p>	<p>The list of organizations and initiatives following this claim includes websites, but does NOT indicate that some are only accessible to members, nor does it mention that most of these sites are recommending CHG for intravascular or dialysis site maintenance.</p>
<p>“Chlorhexidine gluconate has been used for years as a surgical scrub, hand wash and skin cleanser, and can be used anywhere that a patient’s skin is prepared prior to a procedure.”</p> <p>(Skin bacteria: The #1 cause of surgical site infections. 2005, MRK-543-2)</p>	<p>CHG should not be used everywhere.</p> <p>Hibiclens cleanser*** (aqueous Chlorhexidine gluconate) has the following warnings: For external use only. Keep out of eyes, ears and mouth. Hibiclens should not be used as a preoperative skin preparation of the face or head. Misuse of Hibiclens has been reported to cause serious and permanent eye injury when it has been permitted to enter and remain in the eye during surgical procedures. If Hibiclens should contact these areas, rinse out promptly and thoroughly with water. Avoid contact with meninges. Chlorhexidine gluconate has been reported to cause deafness when instilled in the middle ear through perforated eardrums. Irritation, sensitization and generalized allergic reactions have been reported with chlorhexidine-containing products, especially in the genital areas.</p> <p>Source: Hibiclens package insert</p> <p>ChloroPrep labeling contains the following warnings: For external use only. Flammable: Keep away from fire or flame. Do not use in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption...for lumbar puncture or in contact with the meninges, on open skin wounds or as a general skin cleanser... Keep out of eyes, ears and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.</p> <p>Source: ChloroPrep package insert</p> <p style="text-align: right;"><i>Continued on back</i></p>

*ChloroPrep® Patient Preoperative Skin Preparation 2% Chlorhexidine Gluconate (CHG) & 70% Isopropyl Alcohol (IPA)

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

***Hibiclens® Antiseptic/Antimicrobial Skin Cleanser (4% chlorhexidine gluconate)

The Claim	The Whole Truth
<p>“Review more than 37 clinical studies that support the efficacy of 2% chlorhexidine and chlorhexidine based solutions, as superior patient preoperative skin preparation antiseptics.” (www.chloraprep.com/whatischloraprep.html)</p>	<p>These studies primarily involve venous access. Only three studies are done in a surgical setting. Of these, one study (pacemaker insertion) changed several practices at the same time. The second study (foot and ankle surgery) showed zero infections with DuraPrep solution and one infection with Chloraprep. The third study (shoulder study) did not include a protocol where neutralization of the preps was undertaken. Water-soluble preps had the ability to continue to kill bacteria collected. The shoulder study did not evaluate surgical site infection.</p> <p>Source: www.chloraprep.com/publishedstudies.html</p>

Ordering Information

3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation is indicated for topical use as a persistent, film-forming preoperative skin preparation with fast, broad-spectrum antimicrobial activity.

Cat. No.	Description	Coverage	Size	Items/Box	Boxes/Case
8630	DuraPrep solution	Applicator covers 450 sq. in. (15 in. x 30 in.); ideal for large procedures—Thoracic and CV, spine, total hip and knee, C-section, major abdominal.	26 mL	20	1
8635	DuraPrep solution	Applicator covers 80 sq. in. (8 in. x 10 in.); ideal for mid-size procedures—biopsies, foot and hand, angiography, head and neck procedures.	6 mL	50	1

Warnings

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 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; 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
- 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.

To learn more about DuraPrep solution, contact your 3M representative, call the 3M Health Care Helpline at 1-800-228-3957 or visit 3M.com/infectionprevention.



3M Health Care Infection Prevention Division

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